A Comparative Analysis of Pressure Sore Treatment Modalities in Community Settings

N. Small

A Comparative Analysis of Pressure Sore Treatment Modalities in Community Settings

by

Nico Small

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Study Leader: Prof. M. Mulder
Co-study Leader: Mrs. M.J. Mackenzie

I hereby certify that this dissertation, which is submitted by me for the degree Magister Societatis Scientiae in Nursing at the University of the Orange Free State, has not been submitted previously for any degree to any other university.

I certify that this is my own work.

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N. Small

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CHAPTER ONE

Introduction, problem statement and methodology

1.1 INTRODUCTION

The management of chronic wounds - particularly pressure sores - in community settings, poses a clinical problem which challenges the patient's tolerance and the clinician's diligence and ingenuity (Wood, Griffiths & Stoner, 1997:256). Pressure sores can be painful, lead to infection and are associated with considerable morbidity and increased mortality (Patterson & Bennett, 1995:919; Bale, Banks, Hagelstein & Harding, 1998:65). Treatment costs of these wounds are high in terms of resources (Colin, 1995:65; Wood *et al.,* 1997). However, since there is untold cost in terms of pain and suffering to the patient, it is impossible to calculate the *true* cost of pressure sores (Dealey, 1994:87).

1.2 PROBLEM STATEMENT

The literature is virtually flooded with research articles on countless techniques of pressure sore prevention, nevertheless the occurrence of pressure sores remains a costly and frustrating health problem (Torrance & Maylor, 1999:27). In fact, the frustration and desperation which clinicians often feel is illustrated by a five year study in one locality which showed 72 different topical treatments applied to pressure sores (Frantz cited in Anthony, 1996:313).

According to James (1997b:12), patients in a community setting are as vulnerable to sustaining pressure sores as those in hospital. The same author identified several *community risk factors* that are likely to present problems to skin integrity, namely immobility and unrelieved pressure, malnutrition, age, incontinence and chronic illness.

Due to the increase in the ageing population and the associated higher degree of morbidity, along with the emphasis on provision of care shifting towards the earlier discharge of acutely ill patients, it is expected that the number of patients at risk of developing pressure sores in the community will increase (Inman & Firth, 1998:515; Glover, 2000:161). This phenomenon will add to the at-risk-population in the community thereby placing a greater demand on community resources as a result of an increase in the incidence of pressure sores.

From the aforementioned, it is clear that the most cost-effective and acceptable method of wound management is needed to address the problem of large numbers of pressure sores in the community. A cost-effective method of wound management implies a method that will result in rapid wound healing. Research done by Winter (1962:294) has shown that a moist wound environment promotes re-epithelialisation and healing, thereby supporting cost-effective wound care management. Even though this landmark study was published more than 30 years ago, forming the foundation of the researched base of *moist wound healing*, many clinicians still use alternative treatment methods that cause desiccation of the wound-bed and thereby impede the healing process.

Since wound healing is an intricate and dynamic process, it has been suggested that no single dressing is suitable for the management of all wounds, particularly at all stages of the healing process (Bux, 1996:305). However, the majority of modern dressings are now designed to maintain a moist environment at the wound interface, providing conditions for rapid epithelialisation and thereby improved wound healing (Frantz & Gardner, 1994:39; Bux, 1996:305; Dale, 1997:12).

Though many of these modern dressings are more expensive than traditional cellulose-based products, very often wounds dressed with newer products heal more rapidly than those dressed with conventional materials resulting in cost savings (Thomas, 1997c[1]).

The choice of dressing or treatment method may be influenced by several factors - a major one being the ***cost***. Another influence on the choice of dressing or treatment method is its ***acceptability*** to patients and caregivers. Often patients with chronic wounds and their caregivers have firm views on the dressings that they will accept based upon prior experience with these or similar materials (Thomas, 1997c). From the aforementioned, the following questions arise:

How does the cost-effectiveness of current wound care management compare with more advanced wound care management and how acceptable are these treatment modalities to patients with pressure sores and their caregivers in the community?

1.3 PURPOSE OF THE RESEARCH

The purpose of this study is to: compare current wound care management methods with a more advanced wound care management method in the treatment of patients with pressure sores in the community.

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[1] All articles retrieved from electronic media such as the Internet and CD-ROMs will not have page numbers included in the references due to the fact that the printed page numbers have no relation to the original articles' page numbers. However, hard copies of the articles are available from the researcher on request.

1.3.1 Research objectives

The objectives of this study are to:

- Compare the **cost-effectiveness,** with regard to treatment cost and rate of healing, of current wound care management with advanced wound care management in the treatment of pressure sores in the Bloemfontein community of the Free State Province, over a six week period.

- Assess the **acceptability** of these treatment modalities - to patients with pressure sores and their caregivers in the community over a six week period – in terms of (i) *ease of application,* (ii) *comfort of the dressing,* (iii) *durability of the dressing over the period of application* and (iv) *ease of removal.*

1.4 RESEARCH METHODOLOGY

1.4.1 Research design

This study will be conducted as a prospective, randomized clinical trial. As such, an experimental research design will be applied.

1.4.2 Population and sampling

The sample population will be individuals with uninfected pressure sores living in the Bloemfontein community. Patients will be recruited via referrals from primary health care clinics, community health care workers, social workers and other health care professionals practising in the community.

Several patient recruitment strategies, as described by Spilker (1991:87), will be used to *increase* patient recruitment. They include the following:

- Communicating with colleagues directly, via e-mail and telephone, requesting referrals.
- Speaking at formal and informal professional meetings requesting referrals.
- Placing notices in places where colleagues and/or patients will notice.
- Placing advertisements in local newspapers (see Appendix 1).

Once recruited, *inclusion* and *exclusion* criteria will be used to enroll patients into the study.

The following *inclusion* criteria are to be used:

- Patients in the community aged 18 years or older with a clinically uninfected Stage[2] 2, 3 or 4 pressure sore.
- Patients, or their guardians, who give informed consent.
- Patients who are willing and able to comply with the treatment.

The following *exclusion* criteria are to be used:

- Patients aged younger than 18 years.
- Patients or their guardians, who decline to participate in the study.
- Patients with clinically infected wounds.
- Patients with a Stage 1 pressure sore.

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[2] All pressure sores referred to in this study were classified according to the Sterling Pressure Sore Severity Scale (SPSSS) (see Figure 4.2, p.72).

Once enrolled, a patient can *withdraw* or be *withdrawn* from the study for the following reasons:

- at the patient's own request;
- if the patient moves from the geographical area;
- develops a concurrent illness and is unable or unwilling to continue in the trial;
- develops a wound infection;
- death.

A detailed discussion of the *inclusion* and *exclusion* criteria as well as the *withdrawal procedure* is provided in Chapter 7.

Sampling will be done by randomly allocating 40 patients with stage 2, 3 or 4 clinically uninfected pressure sores, respectively, into a control and an experimental group. The Stirling Pressure Sore Severity Scale as described by Waterlow, (1996:54), will be used as classification system to stage the pressure sores.

1.4.3 Treatment modality

Two wound care treatment modalities will be used, namely an *advanced* wound care management method for patients allocated to the experimental group, and the *currently used* management method for patients allocated to the control group.

1.4.3.1 Advanced wound care management

The wounds will be aseptically cleansed with warm (approximately 37^0C) sterile, physiological saline.

Following this, they will be covered with Smith & Nephew™ wound care products (see Appendix 2 for a list of the Smith & Nephew™ products to be used in the study as well as instructions for use and contra-indications). The particular Smith & Nephew™ product (s) used will be dictated by the nature of each wound. Selection and application of subsequent dressings will also be adapted to best meet the needs of each wound and its phase of healing.

1.4.3.2 Currently used wound care management

The wounds will be aseptically cleansed and covered with the available and currently used wound care materials and/or methods as encountered by the researcher in the community. These materials and/or methods will be listed in Appendix 3 along with references to the relevant sections in the literature review where they will be discussed.

1.4.4 Period of treatment

Each wound will be managed by either the advanced wound care management method or the currently used wound care management method for a period of **six weeks** or until one of the following end points has been reached:

- the wound has healed;
- patient withdraws (see Section 6.4.4);
- an adverse event occurs by which treatment benefit is unacceptably inferior to treatment risk (see Chapter 6 for a detailed discussion of the action to be taken in the case of an adverse event).

1.4.5 Data collection

Patients will be clinically assessed at entry week (week 0) and at weekly intervals thereafter for six consecutive weeks. Data will be collected using four data collection forms namely:

- An initial patient information chart.
- A weekly wound assessment chart that includes the Braden Risk Assessment Scale (see Table 4.1).
- A record of dressing changes and products to be used.
- An assessment of dressing acceptability (see Appendix 4 for copies of the data collection instruments).

Data related to the following will be collected: the cost-effectiveness (rate of wound healing related to cost) and acceptability of treatment method. In addition to the four data collection forms all wounds will be evaluated by means of *photography, wound tracing* and *measuring of the wound dimensions* (see Sections 6.7.1.2, 6.7.1.3 and 6.7.1.4).

1.4.6 Cost-effectiveness

The cost-effectiveness of the wound management method will be determined by assessing the *rate of wound healing* and the associated *cost* of the particular management method.

The **rate of wound healing** will be determined by comparing the initial and thereafter weekly clinical assessment and evaluation of the wound size and appearance.

Additionally the following will be used to determine the **cost** of the advanced wound care management method in relation to that of the currently used wound care management method:

- The duration of the dressing changes, viz. the number of days the dressing remains in place.
- The amount and cost of dressing material used over the six-week period.
- The time taken to perform each dressing change.

Cost will be calculated from the perspective of a private wound care practitioner.

1.4.7 Acceptability of treatment method

The patient's and the caregiver's acceptance of the management method will be assessed in terms of the following:

- ease of application;
- comfort of the dressing;
- durability of the dressing over the period of application and
- ease of removal of the dressing.

1.4.8 Data analysis

Data will be analysed by statisticians of the Department of Biostatistics of the University of the Orange Free State, using S.A.S. software. Demographic and baseline information will be summarized by group of patients.

Numeric variables will be summarized by means and standard deviations, or percentiles if the distributions are skew. Categorical variables will be summarized by frequencies and percentages. The percentage of withdrawals and adverse events will be compared between the two groups using 95% confidence intervals for differences in percentages.

This phase of the study will be elaborated on in Chapter 6.

1.4.9 Validity and reliability

The following measures will be taken to increase the validity and reliability of the study.

Random assignment to experimental and control groups will be used as design strategies to control extraneous variables. The same strategy will address lack of equivalence between the experimental and control groups.

Multiple evaluation methods will be used in the weekly assessment of wound healing to address mono-operation bias as described by Burns and Grove (1993:269) (see Section 6.7.1).

User errors related to the wound photography will be addressed by the consistent use of the same camera and operated by the same individual.

The data collection forms will be forwarded to domain experts for comment. This will be followed by a pilot study to test and improve the data collection forms and evaluation methods mentioned in Section 1.4.5 thereby assuring validity of the instrument. Reliability will be supported by the consistent use of the instrument and evaluation methods.

1.5 ETHICAL CONSIDERATIONS

1.5.1 The right to self determination

Participation in this study will be voluntary. Patients will be enrolled into the study only with *written, informed* consent, provided by themselves or their legal guardians, and where possible in collaboration with their attending physician(s). Consent forms will be made available in Afrikaans, English and South-Sotho (see Appendix 5). Patients will also have the right to withdraw from the study at any time without penalty.

1.5.2 Confidentiality

All patient names will be kept confidential. Similarly all study findings will be stored and handled in the strictest confidence.

1.5.3 Protection from harm

All patients will be carefully monitored and in case of any adverse event these patients will be discontinued and managed appropriately (see Chapter 6, Section 6.6.4).

1.5.4 Declaration of Helsinki

The study will be performed in accordance with the guidelines of the Declaration of Helsinki (1964) as revised in Somerset West, South Africa in 1996 (see Appendix 6).

1.5.5 Approval of protocol

Before commencing the study, the researcher will submit the study protocol to the Ethics Committee, Faculty of Health Sciences, University of the Orange Free State, Bloemfontein.

The study will not be initiated until the protocol has been approved and a copy of the ethics approval has been received in which the protocol is mentioned by name and number.

1.6 TIMING

The study will commence as soon as the Ethics Committee approval has been obtained. It is expected that the study will commence in May 1999 and continue uninterruptedly until the required sample size, as specified in Section 1.4.2, has been obtained. The anticipated completion date of the study is June 2000.

1.7 CONCEPTUALISATION

The following are operational definitions of concepts used in this study.

- **Acceptability of treatment method** – refers to the following elements:
    - *comfort* of application and removal of the dressing as perceived by the patient;
    - *pain* associated with the dressing changes as perceived by the patient;
    - *ease* of application and removal of the dressing as reported by the researcher;
    - *durability* of the dressing as reported by the researcher.

- **Advanced wound care management method** – in this study refers to the aseptic cleansing of the wound with warm (approximately 37°C) sterile, physiological saline and subsequently the covering or dressing of the wound with an appropriate Smith & Nephew™ product (see Appendix 2 for a list of the Smith & Nephew™ products used in this study as well as instructions for use and contra-indications).

- **Adverse event** - refers to any undesirable clinical occurrence in a patient whether it is thought to be related to the investigational product(s) or not (Spilker, 1991:197; European Committee for Standardization, 1993:4 & Human Subject Protection Committee, 1997).

- **Device related adverse incidents** - refer to any undesirable clinical occurrence in a patient which is thought to be directly related to the investigational product(s) (Spilker, 1991:197; European Committee for Standardization, 1993:4; Human Subject Protection Committee, 1997).

- **Community settings** – refer to all areas of residence, excluding hospitals, within the *Bloemfontein community* which include the following:

  - all areas within the old municipal boundaries of Bloemfontein;
  - Bainsvlei- and Bloemspruit smallholdings; and
  - Mangaung (Van Heerden, 1999).

- **Cost-effectiveness** – in this study refers to the simultaneous measurement of costs and effectiveness of treatment.

The ***cost of treatment*** (cost of wound treatment method, number of dressing changes and time taken to perform each dressing change measured in terms of money) in relation to the ***effectiveness*** (measured in terms *of rate of healing* or *reduction in wound size,* expressed as a percentage) (Spilker, 1991:302; Robinson, 1993a:672; Robinson, 1993c:793; Brooks, 1997:136; Brooks & Semlyen, 1997:492).

- **Currently used wound care management method** – refers to the aseptic cleansing and covering or dressing of the wound with the available and currently used wound care materials and/or methods as encountered by the researcher in the community (See Appendix 3). These materials might include some advanced or modern dressings, however any Smith & Nephew™ products will be excluded.

- **Extrinsic factors** – refer to external factors that contribute to the development, maintenance and deterioration of a pressure sore. These factors include *pressure, friction, shear* and *excessive moisture* (Dealey, 1994:84; James, 1997a:8-9).

- **Intrinsic factors** – refer to the internal factors that contribute to the development, maintenance and deterioration of a pressure sore. These factors include: *old age, immobility, sensory deficits, body weight, nutrition, medication, and incontinence* (Dealey, 1994:85-86; James, 1997a:8).

- **Local factors** – refer to the factors in and around the wound that influence the rate of healing. They include *impaired blood supply; temperature fluctuations; wound site; infection; foreign bodies, eschar, slough, necrotic tissue; desiccation; pressure, friction and shear; changes in oxygen tension and skin maceration* (Baxter & Mertz, 1992:16; Flanagan, 1997b:30; Brychta, Germann, Gericke, Rietzsch & Tautenhahn, 1999: 41-42).

- **Pressure sore** – is defined as a lesion primarily caused by external factors namely: unrelieved pressure against soft tissue (usually over bony prominences), shear, friction or moisture or a combination of any of these and predisposed by certain intrinsic factors (Bridel, 1993:231; Agency for Health Care Policy and Research [AHCPR], 1994:1; Brychta *et al.*, 1999: 81) (see Section 2.2.1 and 2.2.2).

- **Pressure sore management** – is the holistic management of the patient with a pressure sore which includes all aspects namely: intrinsic and extrinsic factors which contributed to the development, maintenance and deterioration of the pressure sore; local and systemic factors which may impede the wound healing process and the method of pressure sore (wound) treatment.

- **Systemic factors** – are factors within or inherent to the body systems that influence the rate wound healing. They include *nutrition, infection, medication, radiotherapy, old age and underlying conditions* such as diabetes, malignancy, immuno-deficiency and vascular disease (Dealey, 1994:28-29; Brychta *et al.*, 1999:38-41).

- **The Stirling Pressure Sore Severity Scale (SPSSS)** – is a wound classification system whereby pressure sores are staged to classify the degree of tissue damage observed thus providing a more accurate and detailed wound description. Stages one to four are described as follows:

  Stage 1:
  Discoloration of intact skin (light finger pressure applied to the site does not alter the discoloration).

Stage 2:

Partial-thickness skin loss involving damage to epidermis and/or dermis.

Stage 3:

Full-thickness skin loss involving damage or necrosis of subcutaneous tissue but not extending to underlying bone, tendon or joint capsule.

Stage 4:

Full-thickness skin loss with extensive destruction and tissue necrosis extending to underlying bone, tendon or joint capsule (Waterlow, 1996:56).

- **Withdrawals** – refers to patients that are withdrawn from the study due to the following reasons: at the patient's own request; if the patient moves from the geographical area; developed a concurrent illness and is unable or unwilling to continue in the trial; developed a wound infection; death.

- **Wound treatment method** – is the method used to treat the pressure sore or wound. This includes the choice of wound cleanser, method of cleansing, choice of topical treatment and choice of wound dressing(s). In this study reference is made to two treatment methods, namely an advanced wound care management method and the currently used wound care management method.

1.8 CONCEPTUAL FRAMEWORK

In figure 1.1 below, the conceptual framework used in this study is delineated.

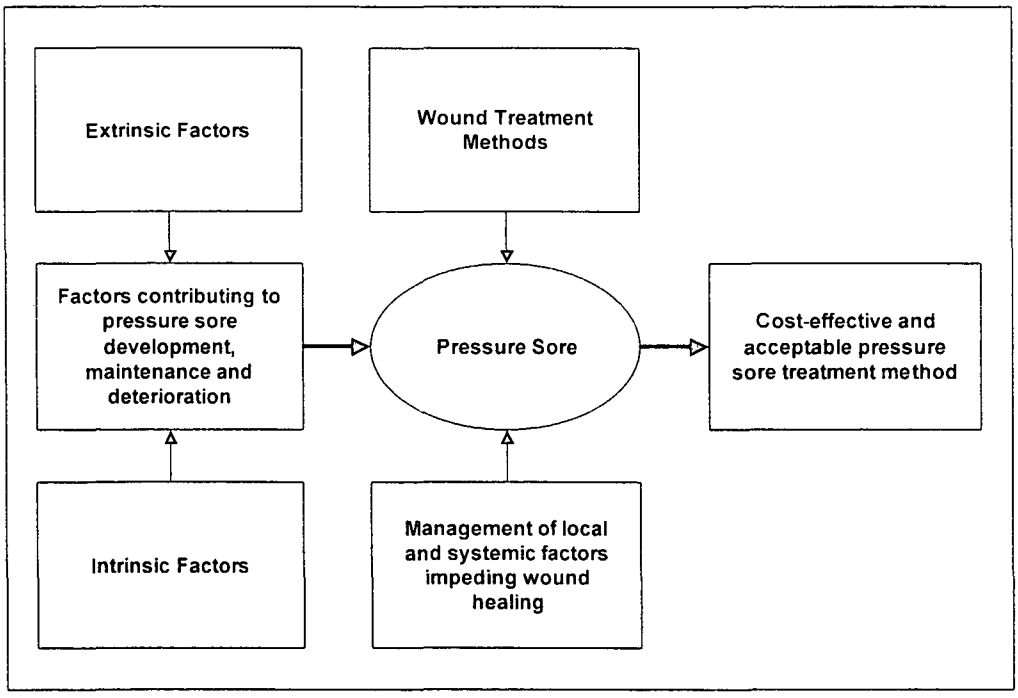


Figure 1.1: Conceptual Framework

1.8.1 Exposition of the conceptual framework

The conceptual framework may be seen as a process initiated with the presence of factors that contribute to the development of a pressure sore. These factors are categorized as intrinsic and extrinsic. **Intrinsic factors** include: old age, immobility, sensory deficits, body weight, nutrition, medication, and incontinence. **Extrinsic factors** include pressure, friction, shear and excessive moisture. If these factors are not adequately addressed they will not only contribute to the development of more pressure sores but will maintain and exacerbate existing pressure sores.

Once a pressure sore develops, several factors influence the (wound) healing process. These are referred to as local and systemic factors that *impede* wound healing. **Local factors** include: impaired blood supply; temperature fluctuations; wound site; infection; foreign bodies; eschar; slough; necrotic tissue; desiccation; pressure, friction and shear; changes in oxygen tension and skin maceration. **Systemic factors** include nutrition, infection, medication, radiotherapy, old age and underlying conditions such as diabetes, malignancy, immuno-deficiency and vascular disease. In order to achieve the maximum wound healing potential these factors should, where possible, be counterbalanced.

An additional factor which influences wound healing, either positively or negatively, is the **wound treatment method.** The two wound treatment methods that are compared in this study are the advanced and the currently used wound care management methods.

The conceptual framework illustrates all the above factors and their interrelationships as a dynamic process. The anticipated outcome of this process is a **cost-effective and acceptable pressure sore treatment method**.

However, this outcome can only be achieved through a holistic approach, cognisant of all factors described above.

1.9 DELINEATION OF CHAPTERS

Chapter One	Introduction, problem statement and methodology
Chapter Two	Literature review: Pressure sores: definition and aetiology
Chapter Three	Literature review: Healing of pressure sores
Chapter Four	Literature review: Principles of pressure sore management
Chapter Five	Literature review: Economic evaluation of pressure sore management
Chapter Six	Research methodology
Chapter Seven	Results and discussion
Chapter Eight	Conclusions, limitations and recommendations

1.10 CONCLUSION

This study will compare two treatment modalities in the management of pressure sores in the community and aims to aid wound care practitioners in selecting a more cost-effective and acceptable method of pressure sore management.

CHAPTER TWO

Pressure sores: definition and aetiology

2.1 INTRODUCTION

In this chapter pressure sores are defined and the aetiology discussed.

2.2 DEFINITION

Pressure sores are defined as lesions primarily caused by external factors, namely unrelieved pressure against soft tissue (usually over bony prominences), shear, friction or moisture or a combination of any of these and predisposed by certain intrinsic factors (Bridel, 1993:231; Agency for Health Care Policy and Research [AHCPR], 1994:1; Brychta *et al.*, 1999:81) (see Section 2.3.1 and 2.3.2).

For many years pressure sores were incorrectly termed decubitus ulcers – the Latin definition of the term decubitus implies lying flat. The term decubitus was therefore changed to pressure since one can develop a pressure sore while assuming any body position (Phipps, Cassmeyer, Sands & Lehman, 1995:2348). Thus, the term pressure sore most accurately reflects the aetiology of the damage.

2.3 AETIOLOGY

Pressure sores are caused by a combination of contributing external (extrinsic) and internal (intrinsic) risk factors (Dealey, 1994:84; Patterson & Bennett, 1995:919-920; Lueckenotte, 1996:791; Langemo, 1999). An overview of these factors will be provided in the following paragraphs.

2.3.1 Extrinsic factors

Pressure, shear, friction, and moisture are external risk factors that lead to the development of pressure sores. However, pressure on soft tissue over bony prominences or other hard surfaces is considered the most important causative factor (Cullum, Deeks, Fletcher, Sheldon & Song, 1995:289; Perdue, 1995: 66; Lueckenotte, 1996:791).

2.3.1.1 Pressure

It is widely quoted in the literature that when the pressure applied to soft tissue between a bony prominence and a hard surface (known as interface pressure) exceeds the normal capillary filling pressure of 32 mmHg, capillary flow can be obstructed, resulting in hypoperfusion and localized ischaemia (Torrance, 1983:11; Dealey, 1994:84). However, Kemp and Krouskop (1994:27) challenge this hypothesis stating that a value of 32 mmHg would not be a safe estimate of tissue viability since arteriolar capillary pressures as low as 12 mmHg have been recorded in persons with peripheral vascular disease. Bridel (1993:233) adds a further argument against this hypothesis stating that the collagen content of the dermis, which alters with disease and/or age, will affect the capacity of the dermis to buffer external pressure, thus the threshold pressure will vary from individual to individual. Furthermore, when external pressure is applied to the skin, an autoregulation process allows internal capillary pressures to rise correspondingly.

This autoregulation process breaks down only in those with normal circulation when external pressure exceeds diastolic pressure, indicating that the use of 32 mmHg is conservative.

Conversely, in patients with increased susceptibility (the elderly or severely ill) where the autoregulatory mechanism is compromised, occlusion has been reported when pressures of less than 20 mmHg are applied again indicating that the use of 32 mmHg is inappropriate.

From these arguments it is apparent that there are wide variations in individual capacity to resist pressure and the use of 32 mmHg as a universal threshold for estimating tissue viability for *all* patients, may be inappropriate.

Pressure causing prolonged hypoperfusion can result in a cascade of hypoxia, acidosis, haemorrhage into the interstitium (non-blanchable erythema), and accumulation of toxic cellular wastes leading to cell death and tissue necrosis. With prolonged hypoperfusion, fibrinolytic activity decreases and leads to fibrin deposition and clotting within blood vessels, which may further compromise blood flow (Patterson & Bennett, 1995:920; Collier, 1999:63).

Several studies have established an inverse relationship between the amount of time and the amount of pressure necessary to produce pathologic tissue changes (Maklebust, 1987:363-364).

However, Bridel (1993:235) points out that due to the individual nature of response to pressure of skin and underlying tissues, pressures of *any* value and time periods of *any* duration need to be considered. Pressure applied to the epidermis results in the highest pressure in tissues nearest to the bone. The pressure is dissipated in such a way that a cone-shaped gradient of pressure exists with the base of the cone on the underlying bony surface (Baxter & Mertz, 1992:19).

The damage produced by the cone-shaped pressure gradient results in a pattern of tissue damage described as the **iceberg effect** (see Figure 2.1, p.25).

Thus, the visible sore at the skin surface fails to reveal the true extent of tissue damage (Dealey, 1994:84; Miller & Collier, 1997:6; Banks, 1997:506).

Maklebust (1987:365) proposes that although clinical awareness of impending necrosis occurs only when the skin becomes inflamed, it is most likely that necrosis of the subcutaneous tissue, fat, and muscle has already occurred over a surface wider than the apparent area of skin loss.

Common bony prominences susceptible to pressure sore development are the sacrum, ischial tuberosity, lateral malleolus, trochanter, and heels (Inman & Firth, 1998:516). Yet, Lueckenotte (1996:791) cautions that *any* pressure point is a vulnerable area when pressure is intense and prolonged. Another important force that acts directly on the epidermis is friction.

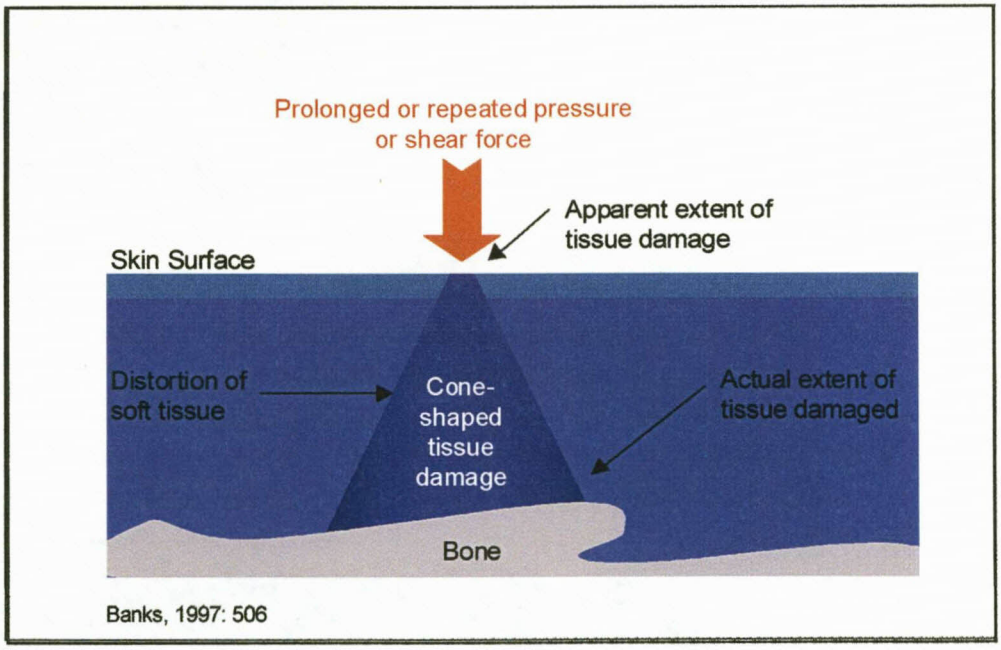


Figure 2.1: The Iceberg effect

2.3.1.2 Friction

Friction between the skin and an external surface such as bedclothes, linen, footwear or a prosthetic device results in a loss of the upper layer of the skin – the *stratum corneum*. Loss of this protective layer leads to further breakdown, as more delicate layers of tissue are exposed, thus accelerating the development of pressure sores (Patterson & Bennett, 1995:920).

In some cases restless patients and patients with uncontrollable spasms develop skin damage from friction. However, according to Dealey (1994:84), the most common cause of friction is dragging rather than lifting the patient across the bed.

2.3.1.3 Shear

Shear force results when friction between the skin and a supporting surface holds the soft tissues in place while gravity pulls the axial skeleton down. An example of this is when the head or backrest of the bed is raised and the patient's torso slides down. Tension generated by this motion stretches and perforates arterioles, which are perpendicular to and supply the dermal layers, thereby compromising micro-circulation (Crow, 1988:68; Dealey, 1994:84; Patterson & Bennett, 1995: 920). According to Banks (1997:506) a combination of friction and shear force is potentially damaging especially to elderly skin because of the shrinkage of collagen and elastic fibres in the dermal layer and weakening of the dermal-epidermal junction.

Figures 2.2, 2.3, 2.4 and 2.5, on the following two pages, illustrate some of the *most common* at risk pressure point sites in various positions, as well as the mechanical forces of friction and shear.

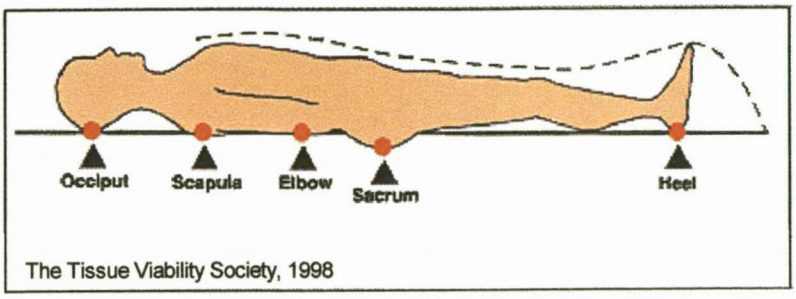


Figure 2.2: At risk pressure points in the supine position

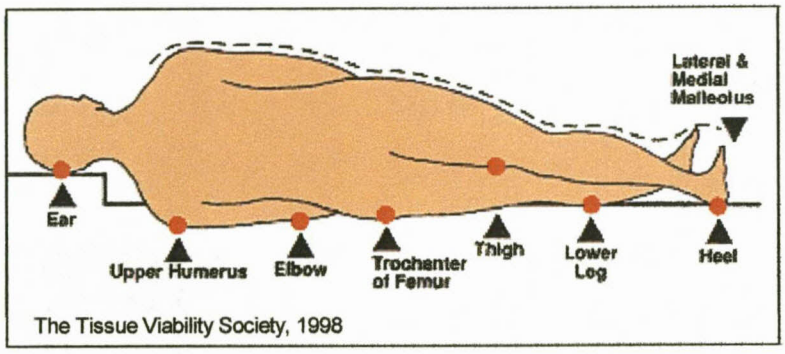


Figure 2.3: At risk pressure points in the lateral position

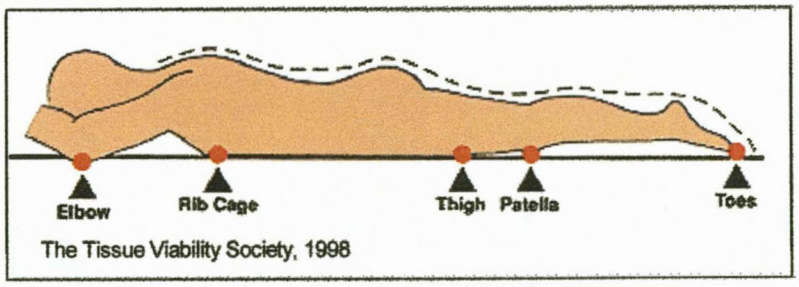


Figure 2.4: At risk pressure points in the prone position

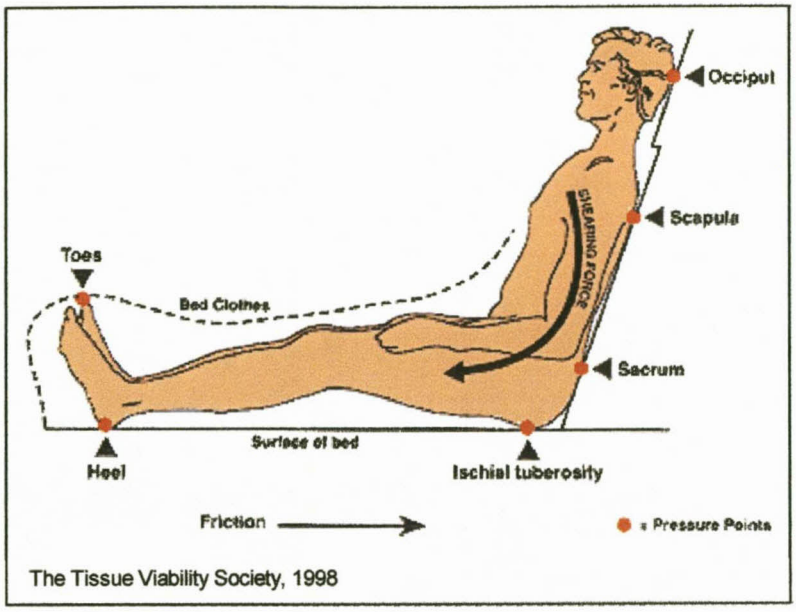


Figure 2.5: At risk pressure points in the sitting position

2.3.1.4 Excessive moisture

Moisture in itself does not cause pressure sores (Bridel, 1993:235). However, prolonged exposure to moisture as contained in urine, diarrhoea, perspiration, and wound drainage, softens the *stratum corneum* and leads to skin maceration. Macerated skin loses its integrity, has decreased tensile strength, is easily damaged, exacerbates the effects of friction, and therefore greatly increases the risk of pressure sore development. Moist skin will also stick to bed linen and thus increase the risk of shear damage (Maklebust, 1987:369; Dealey, 1994:85; Patterson & Bennett, 1995:920).

2.3.2 Intrinsic factors

Although the body is subjected to extrinsic factors on a daily basis, pressure sores do not necessarily develop unless certain *intrinsic factors* are present.

The following intrinsic risk factors have been identified from the literature and will be discussed: age, immobility, sensory deficits, body weight, nutrition, medication, and incontinence.

2.3.2.1 Age

Although pressure sores can occur at any age, there is a correlation between the ageing process and the incidence of pressure sores (Banks, 1997:507; Scott, 1998:78). Ageing is associated with thinning of the epidermis, decreased numbers of dermal blood vessels, loss of dermal elastin (both in quantity and quality), increased skin permeability, and some muscle atrophy. The decreasing amounts of collagen fibres stiffen and the immune response becomes sluggish.

All these age-related changes impair the early warning signs of erythema, delay crucial early immunologic responses, and thereby increase the susceptibility of older people to pressure sore development (Torrance, 1983:25; Staas & Cioschi, 1991:539; Dealey, 1994:85; Patterson & Bennett, 1995:920; Bennett & Moody, 1995:31; Lueckenotte, 1996:793; Lewis, 1997:41).

2.3.2.2 Immobility and sensory deficits

Reduced mobility and sensory deficits can affect the ability to relieve pressure effectively if at all, and have been found to be significant contributory factors for many patients with pressure sores (Dealey, 1994:86; Maklebust, 1995:47; Banks, 1997:507; James,1997b:8).

Many conditions such as stroke, arthritis, multiple sclerosis, spinal cord trauma, head injury, over-sedation, depression and confusion contribute to immobility (Maklebust, 1987:371).

Immobility predisposes to shearing and friction and Bergman-Evans, Cuddigan and Bergstrom (1994:22) state that immobility and inactivity are also associated with the development of *larger* ulcers.

2.3.2.3 Body weight

Patients of low body weight with little subcutaneous fat and poor muscle bulk, have less protection from pressure at bony prominences. Obese patients have more fatty padding to cushion underlying tissues and give a more even distribution of pressure. However, the overweight patient presents more handling difficulties and shearing force and friction may be special problems when moving such patients.

Obese patients may also perspire excessively, causing maceration of the skin which further increases the risk of tissue damage due to shear and friction (Torrance, 1983:21-22; Dealey, 1994:86; Banks, 1997:507). In addition to these problems, Armstrong (1998:221) reports that obese patients have reduced tissue oxygenation and collagen production, which in turn will slow healing in existing pressure sores.

2.3.2.4 Nutrition

Prospective studies demonstrate that nutritional risk factors for developing pressure sores are consuming inadequate calories and protein and having a low serum albumin level of less than 30-35g/l (Colburn, 1990:63; Phipps *et al.*, 1995:2351; Lueckenotte, 1996:793). According to James (1997a:8) protein deficiency may be further exacerbated if a pressure sore forms, as protein is lost via the wound exudate. Factors affecting nutritional intake are dental problems, underlying disease, depression, isolation or grief.

Additional risk factors which may affect the nutritional intake of patients, particularly in a community setting, are lack of money, impaired physical ability leading to a reduced ability to prepare food, lack of carer support and confusion.

In a retrospective community-based study Bergquist and Frantz (1999) found anaemia, as a measure of nutrition, predictive of pressure sore development.

Breslow & Bergstrom (1994) and Lewis (1996:484) state that although there is some evidence that vitamin C, provided at levels exceeding the RDA, may *improve healing* of pressure sores, there is no strong evidence that biochemical or dietary deficiencies of zinc or vitamins A, C or E are major risk factors for the *development* of pressure sores.

2.3.2.5 Medication

Steroids, anti-inflammatory medication, strong analgesia, sedatives, beta-blockers and cytotoxic drugs can increase the risk of pressure damage by reducing skin integrity, mobility, sensation or appetite. Some drugs may cause diarrhea or urinary incontinence, such as diuretics, antibiotics and laxatives and thereby add to the risk of pressure sore development (Dealey, 1994:87; Bennett & Moody, 1995:71; Banks, 1997:507).

2.3.2.6 Incontinence

Studies have found a strong correlation between incontinence and pressure sore development. Prolonged contact with urine and/or faeces results in maceration of the *stratum corneum* and may destroy the protective acid-base mantle. Normal, healthy skin maintains an acid pH of 4,5 to 5,5, which protects it from microbial colonization. Freshly voided urine has a pH of 6.

However, when exposed to air it becomes more alkaline often rising to 13 thereby increasing the risk of damage to the epidermis (Cassell, 1986:36; Patterson & Bennett, 1995:920).

It has been suggested that faecal incontinence may be a more important risk factor than urinary incontinence (Allman, Laprade, Noel, Walker, Moorer, Dear & Smith, 1986:340). In addition to skin maceration associated with faecal incontinence, the bacterial ureases from faecal soiling can split urea to ammonia, also causing the pH of the skin to rise and become increasingly permeable, thus making the skin more susceptible to injury. Additionally, chemical irritants contained in faeces, such as proteolytic enzymes, may irritate the skin and directly injure epithelial cells in a relatively short period of time. Furthermore, the same authors propose that once its protective barrier is destroyed, the compromised skin places an individual at risk of developing a local infection that could ultimately lead to a systemic infection.

2.3.2.7 Smoking

Smoking causes vasoconstriction, which in turn reduces tissue perfusion. Additionally, carbon monoxide inhaled during smoking binds to haemoglobin with an affinity greater than 200 times that of oxygen. The presence of carboxyhaemoglobin shifts the oxygen dissociation curve to the left thereby exacerbating poor tissue oxygenation as less oxygen can be used. This results in impaired metabolism and slower healing (Towler, 2000:101).

Dealey (1994:39) cited a 1992 report by Siana, Frankild and Gottrup that nicotine affected macrophage activity and reduced epithelialization and wound contraction. Smoking may result in loss of appetite and smokers have been found to be deficient in vitamins B_1, B_6, B_{12} and C. These vitamin deficiencies has been shown to interfere with wound healing (Dealey, 1994:44; Banks, 1997:507). From the above it may be concluded that the deleterious effects of smoking contribute significantly to the risk of pressure sore development.

2.3.2.8 Infection

Systemic infection may cause pyrexia, increased metabolism, excessive perspiration and tissue breakdown thereby increasing the risk for pressure sore development significantly (Maklebust, 1987:370; Phillips, 1997:36).

2.3.2.9 Underlying diseases

Many underlying conditions or diseases can cause immobility, loss of sensation, muscle spasms, excessive perspiration and incontinence and therefore predispose patients to develop pressure sores.

Disorders which may predispose patients include diabetes, arthritis, Alzheimer's disease, Parkinson's disease, multiple sclerosis, carcinoma and gastrointestinal, pancreatic, liver and renal problems (Allman *et al.*, 1986:337; Dealey, 1994:85-87; Patterson & Bennett, 1995:920; James, 1997b:14; Banks, 1997:507).

2.3.2.10 Skin condition

Ageing or the use of long-term high-dose steroids may result in "tissue paper" skin that is particularly susceptible to breakdown. Oedematous skin is also at risk of over-stretching due to excessive fluid in the tissues, resulting in damage to the micro-circulation, reduced oxygen supply and impaired removal of metabolic by-products which predispose to tissue damage (Banks, 1997:507; Arao, Obata, Shimada & Hagisawa, 1999:1). In addition research has linked dry, flaky or scaling skin to an increased incidence of pressure sores (Skewes, 1996:33).

2.3.2.11 Other factors

Banks (1997:507) reported that state of consciousness, pain, psychological and socio-economic factors may also be contributory factors. Emotional stress leads to release of cortisol from the adrenal glands. The effects of cortisol are believed to alter the skin's ability to absorb mechanical loads, such as pressure. Cortisone may also affect cellular metabolism between capillary beds and cells, making the skin vulnerable to breakdown and poor healing (Maklebust, 1987:370; Lueckenotte, 1996:793). According to Song (1999:8) radiation therapy may similarly compromise the skin and thereby increase its susceptibility to tissue damage.

Research by Bergquist and Frantz (1999) to identify risk factors related to the development of pressure sores, revealed that when an adult child was the primary caregiver, subjects were 5,8 times more likely to develop a pressure sore. Yet, the mechanism by which the adult child as primary caregiver was associated with pressure sore development was unclear.

The same researchers reported that being male increased the risk of developing a pressure sore by 86%. Again, the mechanism by which the male gender was associated with pressure sore development was unclear. However, the findings of this study were consistent with two studies that used large data sets to explore the risk factors associated with pressure sore development (Specter, Kapp, Tucker & Sternberg; Specter cited in Bergquist & Frantz, 1999).

2.4 CONCLUSION

From the preceding paragraphs it is clear that apart from the primary external mechanical forces, there are multiple additional external and internal factors that contribute and/or predispose to the development of pressure sores.

CHAPTER THREE

Healing of pressure sores

3.1 INTRODUCTION

In this chapter the healing of pressure sores will be discussed with reference to the physiology of wound healing and the factors that influence the healing process.

3.2 PHYSIOLOGY OF WOUND HEALING

Wound healing is a dynamic and highly complex process, which would require a lengthy detailed explanation in order to cover *all* known physiological aspects. Scholars have written many *in-depth* analyses of this intricate process and it is not the intention of this researcher to describe it to the extent found elsewhere. However, it is important and necessary that the wound care practitioner has a good understanding of the *basic* physiological processes involved in wound healing for several reasons namely:

- Recognition of the different stages or phases of wound healing allow the practitioner to select appropriate dressings.

- Knowledge and understanding of the normal physiology enables the practitioner to recognize the abnormal.

- Knowledge and understanding of the requirements of the healing process means that appropriate nutrition can, where possible, be given to the patient (Dealey, 1994:1).

Therefore, in the light of the above, a brief overview of the *basic* physiological processes of wound healing will be explicated in the following paragraphs.

In the management of wound healing, wounds are often described as healing by first and second intention. Healing by first or primary intention occurs when there is no tissue loss and the skin edges are held in apposition to each other, such as sutured traumatic or surgical wounds. Granulation tissue is not visible, scar formation is minimal and healing is usually rapid.

Healing by secondary intention occurs in large wounds - such as chronic wounds, for example pressure sores and leg ulcers - with considerable tissue loss. Natural healing occurs by the formation of granulation tissue, which fills the cavity. The healing process takes longer and results in more scarring. Healing by first and second intention was first described as early as 350 B.C. by Hippocrates. In addition wounds labelled as open and closed are the same as healing by second and first intention respectively (Tudor & Gupta, 1992:70; Dealey, 1994:2; Miller & Collier, 1997:3; Banks, 1998e:265).

For the sake of discussion the *healing process* must be divided into phases. Some authors, such as Sieggreen (1987:439), Cooper (1990:170), Tudor and Gupta (1992:70), Konstantinides and Lehmann (1993:25) and Frantz and Gardner (1994:35), separate the healing trajectory into three phases. Others separate the healing process into four or more phases depending on their perspective (Dealey, 1994:1; Banks, 1998e:265). Similarly the terms used to describe the phases also differ from author to author. However, the events described within each phase allow one to identify the phase being addressed.

Using the four-phase approach, as described by Banks (1998e:265), the healing trajectory may be divided into the ***inflammatory phase***, the ***reconstruction phase***, the ***epithelialization phase*** and the ***maturation phase***. Although the phases will be discussed separately, different steps of each phase may occur simultaneously.

3.2.1 The inflammatory phase

Inflammation is an important part of the body's defence mechanism. It is a non-specific response to tissue damage and/or infection and is an essential part of the healing process. The onset of inflammation occurs immediately after injury, normally lasting three to five days (Sieggreen, 1987:440; Cooper, 1990:170 –171; Tudor & Gupta, 1992:72; Konstantinides & Lehman, 1993:25; Dealey, 1994:2).

Vascular and cellular responses occur *immediately* after injury in an attempt to wall the wound off from the external environment. Platelets activated as a result of vessel wall injury, aggregate and blood coagulation is initiated.

Damage to the micro-circulation at the area of injury causes vasoconstriction of vessels in an attempt to control bleeding and to protect against increased exposure to bacterial contamination. During the initial period of vasoconstriction, leukocytes, erythrocytes and platelets line the vessel wall. This initial reaction is brief and lasts from 5 to 10 minutes (Sieggreen, 1987:440; Cooper, 1990:170). The complement system consisting of proteins that normally lie dormant in the blood, the interstitial fluid and on the mucosal surfaces, is also activated. Activation of this system by microbes or antigen-antibody complexes, causes three activities: *vasodilatation* of capillaries; *chemotaxis* (unidirectional migration) of phagocytic leukocytes into the injured region; and *opsonization* (coating) of the microbes for effective phagocytosis (Cooper, 1990:170). Bradykinin and histamine are also released from injured tissues, causing vasodilation so that 10 to 30 minutes after injury the vessels in and around the wound dilate and capillary permeability is increased (Sieggreen, 1987:440; Tilbury, 1991a:30).

Fluid, protein, enzymes and cells normally found in the intravascular compartment, move through gaps in the capillary walls (*diapedesis*) into the extracellular space causing oedema and erythema - hence manifesting the typical *redness, heat, swelling, pain and loss of function* associated with the inflammatory response (Cooper, 1990:171; Tudor & Gupta, 1992:72; Dealey, 1994:2; Harding, Bale & Assenheimer, 1997).

Two types of leukocytes, polymorphonuclear (PMNs) granulocytes and mononuclear agranulocytes, enter the wound initially, thereby providing it with resistance to infection (Sieggreen, 1987:440, Cooper, 1990:171; Tudor & Gupta, 1992:72). The PMNs begin to digest bacteria that are present. However, their life span is very short and after two to three days they become part of the wound exudate. Mononuclear agranulocytes, with a longer life span, having entered the wound bed with the PMNs, begin their function. Once in the tissues they give rise to macrophages. These macrophages are larger than neutrophils and are therefore able to phagocytose larger particles, such as necrotic debris, dead neutrophils as well as bacteria (Konstantinides & Lehmann, 1993:25). Macrophages also produce a variety of substances that stimulate healing, including:

- Transforming growth factors (TGF-α, TGF-β) promote the formation of new tissue and influence angiogenesis and neovascularisation.
- Tumor necrosing factor facilitates the breakdown of necrotic tissue and tumors, stimulates angiogenesis and growth of new tissues.
- Fibroblast growth factor (FGF-1 and FGF-2) stimulates angiogenesis and the production of fibroblasts.
- Prostaglandins promote the inflammatory response.
- Complement factors mark invading foreign bodies.
- Platelet-derived growth factor (PDGF) is involved in initiating the inflammatory phase of healing (Flanagan, 1997b:24, Gill, 1998:411, 412; Graham, 1998:465).

Considerable resources of energy and nutrients are required during this phase. If this phase is prolonged by irritation of the wound - such as infection, foreign bodies or damage caused by the dressing – it can delay healing and cause the patient to become debilitated (Dealey, 1994:3; Banks, 1998e:265).

3.2.2 The reconstruction phase

Macrophages play an important role in bridging the inflammation and reconstruction phases. They provide growth factors, which attract fibroblasts to the wound, stimulate fibroblast division and collagen production (Tudor & Gupta, 1992:72). Fibroblast activity is dependent on local oxygen supply. Poorly vascularized tissues will therefore not heal well. Thus, macrophages assist in enhancing fibroblast activity by stimulating *angiogenesis* (formation of a new capillary network) capable of supplying oxygen to the wound (Sieggreen, 1987:442; Ehrlich, 1998). Relatively low levels of oxygen at the wound surface encourage the macrophages to produce angiogenesis factor, which in turn instigates the process of neo-angiogenesis (Dealey, 1994:4; Banks, 1998e:265).

Undamaged capillaries beneath the wound grow towards the wound surface, loop back and give a granular appearance to the wound surface. The loops form a network within the wound supplying oxygen and nutrients. In wounds healing by secondary intention, such as pressure sores, this *granulation tissue* is clearly visible. It consists of a dense array of macrophages, fibroblasts, capillary buds and loops in a matrix of fibronectin, collagen and hyaluronic acid. Certain specialized fibroblasts – myofibroblasts – have a contractile apparatus, which causes contraction of the wound around the fifth or sixth day. This *contraction* reduces the surface area of open wounds. However, according to Flanagan (1997b:25) the amount of contraction possible in a particular wound depends on its anatomical location and the degree of mobility of the surrounding tissue.

The number of macrophages and fibroblasts gradually reduces as the wound fills with new tissue and a capillary network is established (Cooper, 1990:172; Tilbury, 1991a:30; Dealey, 1994:5; Harding, Bale & Assenheimer, 1997; Banks, 1998e:265).

3.2.3 The epithelialization phase

In open wounds, such as pressure sores, this phase cannot commence until the wound cavity is sufficiently filled with granulation tissue. However, in closed wounds this phase may commence as early as the second day post-injury (Dealey, 1994:5). Moisture is required to allow cells to advance over the wound bed, viz. *epithelialization* (Winter, 1962:293; Harding, 1996a:46). The squamous cells at the wound margins and around hair follicle remnants proliferate and migrate over the wound surface in a "leap-frog" fashion. This leap-frogging process involves a cell moving two or three cell lengths before stopping, while other cells are coming up from behind to continue the process (Garrett, 1998:358). When advancing epithelial cells from opposing wound borders meet, either at the centre of the wound or at the margin, the process of cellular movement appears to cease. Garret (1997:177) refers to this process as *contact inhibition* as it prevents further cell movement. According to Sieggreen (1987:440) and Banks (1998e:265) epithelialization also provides a waterproof protective covering against loss of fluids and entry of bacteria to the newly repaired wound.

3.2.4 Maturation phase

During this phase, also known as the *remodelling phase*, which begins on about day 21 after injury and may extend to a year or two post-injury, the wound matures and tensile strength increases (Sieggreen, 1987:442; Cooper, 1990:173; Dealey, 1994:5; Banks, 1998e:265). The wound becomes less vascularized as there is a reduced need to bring cells to the wound site.

Injury alters the symmetry of healthy tissue and when new collagen is initially laid down, the pattern is random and disordered (Tudor & Gupta, 1992:72).

During this phase of healing these randomly arranged collagen fibres are re-organized or remodelled to lie at right angles to the wound margins thereby providing greater overall strength (Tilbury, 1991a:31; Frantz & Gardner, 1994:36). Cooper (1990:174) points out that if alterations occur in the remodelling and cross linking of collagen during this phase, complications such as contractures, adhesions and even obstruction of tube-like organs (for example the bowel and ureters) may occur. The scar tissue gradually grows smoother and its colour fades. This may take a considerable period of time and regardless of how well collagen realigns itself, the full tensile strength of normal uninjured tissue, may not be achieved (Konstantinides & Lehmann, 1993:27; Dealey, 1994:5; Banks, 1998e:265).

3.3 FACTORS INFLUENCING WOUND HEALING

The healing process, as described above, is greatly influenced by multiple factors. The successful management of any wound requires the identification of any and all factors that may impede healing and where possible, interventions to address or rectify these factors. The following systemic and local factors have been identified from the literature and will be discussed.

3.3.1 Systemic factors

The systemic factors, which may affect wound healing, include *nutrition, infection, medication, radiotherapy, old age and underlying conditions* such as diabetes, malignancy, immuno-deficiency and vascular disease.

3.3.1.1 Nutrition

In the following paragraphs several important macro- and micro-nutrients, their role in the wound healing process and the results of their deficiency, will be discussed.

3.3.1.1.1 Macro-nutrients

Relevant macro-nutrients include protein, carbohydrates, fats and water.

3.3.1.1.1 (a) Protein

Protein, as a fundamental requirement in the healing process, assists in neo-vascularization, fibroblast proliferation, collagen synthesis, lymph formation and wound remodeling. It is also associated with collagen and proteoglycan synthesis (Silane, 1992:42; Dealey, 1994:40; Partridge, 1998:351).

Protein deficiency decreases the body's resistance to infection as it alters antibody response time and limits leukocyte phagocytic capabilities. The inflammatory process is prolonged and fibroplasia impaired. Additionally, collagen synthesis is impaired and macrophage production decreased. An indicator of visceral protein status is serum albumin levels. Hypo-albuminia (<32 g/l) promotes generalized oedema, which in turn slows oxygen diffusion and metabolic transport mechanisms from the capillaries and cell membrane (Bobel, 1987:380; Konstantinides & Lehmann, 1993:26-29; Lewis, 1998:31; Banks, 1998f:319).

3.3.1.1.1 (b) Carbohydrates

Carbohydrates aid in cell proliferation and the phagocytic activity of leukocytes to prepare wounds for fibroplasia. They are needed for cellular energy and associated with collagen and proteoglycan synthesis. Carbohydrate deficiency decreases resistance to infection and impairs collagen synthesis (Maklebust, 1987:369; Silane, 1992:42; Konstantinides & Lehmann, 1993:26; Dealey, 1994:40; Banks, 1998f:319).

3.3.1.1.1 (c) Fats

Fat (fatty acids) as a source of cellular energy, is required for the normal functioning of cell membranes and promotes cell synthesis. A deficiency of this nutrient may inhibit tissue repair (McLaren, 1992:139; Dealey, 1994:40; Flanagan, 1997b:33; Banks, 1998f:319).

3.3.1.1.1 (d) Water

Water constitutes 65-70% of the total body weight and is the medium in which almost all metabolic processes occur. Water is therefore considered to be the most important nutrient of all and essential to life. Loss of water or dehydration results in electrolyte imbalance, impaired cellular function and subsequently delayed wound healing (Barker, 1991:26; Flanagan, 1997b:31).

3.3.1.1.2 Micro-nutrients

Relevant micro-nutrients include vitamins A, B, C, E and K as well as the minerals copper, iron and zinc.

3.3.1.1.2 (a) Vitamin A

According to Konstantinides and Lehmann (1993:26), vitamin A is a co-factor in collagen synthesis and cross-linkage. It is essential for the stimulation of fibroplasia and epithelialization (Frantz & Gardner, 1994:41). Furthermore, it counteracts the anti-inflammatory effects of steroids on cell membranes. A shortage leads to altered collagen synthesis and cross-linking between fibers. This results in a decreased rate of epithelialization in wound closure (Dumas, 1994:3; Dealey, 1994:40).

3.3.1.1.2 (b) Vitamin B complex

Vitamin B complex - including pyridoxine, riboflavin and thiamin - contribute to antibody and white blood cell formation; are co-factors in cellular development and promote enzyme activity necessary for the metabolism of proteins, fats and carbohydrates. Deficiency results in decreased resistance to infection (McLaren, 1992:142; Konstantinides & Lehmann, 1993:26; Dealey, 1994:40; Banks 1998f:319).

3.3.1.1.2 (c) Vitamin C

Lewis (1998:32) describes Vitamin C as a co-factor for the enzyme collagen prolyl hydroxylase, which hydroxylates peptide-bound proline on proto-collagen to hydroxyproline. This is used in the formation of the triple helix of collagen. Konstantinides and Lehmann (1993:26) state that vitamin C is essential for neutrophil superoxide production and bacterial killing. It also improves capillary formation and decreases capillary fragility.

Vitamin C deficiency decreases the chemotaxis of neutrophils and monocytes; alters tensile strength; increases capillary fragility; impairs local antibacterial defences and increases the tendency for dehiscence of newly formed tissue (Konstantinides & Lehmann, 1993:26; Dumas, 1994:3; Dealey, 1994:40; Frantz & Gardner, 1994:41; Banks, 1998f:319). According to Lewis (1998:32) the emerging role of vitamin C as a scavenger of oxygen free radicals may further enhance its importance in wound healing, as this appears to be a process that stimulates healing.

3.3.1.1.2 (d) Vitamin E

Vitamin E prevents lipid peroxidation of poly-unsaturated fatty acids in cell membranes by oxygen free radicals and hence has an important protective role in anti-oxidant defence and wound healing (Barker, 1991:31; McLaren, 1992:142).

3.3.1.1.2 (e) Vitamin K

Vitamin K plays an essential role in coagulation. Deficiency of this vitamin results in an increased risk of haemorrhage and haematoma formation (Silane, 1992:41; Konstantinides & Lehmann, 1993:27; Banks, 1998f:319).

3.3.1.1.2 (f) Copper

Copper is an intrinsic part in the oxidase system that aids in collagen cross-linkage and indirectly influences wound healing via the stimulation of erythropoiesis. Even though deficiency is rare, it may result in decreased collagen synthesis, anaemia and skeletal demineralisation (Barker, 1991:24; McLaren, 1992:141; Dumas, 1994:5).

3.3.1.1.2 (g) Iron

Iron is vital to red blood cell function because it enables the transport of oxygen. Iron deficiency reduces the oxygen carrying capacity of blood, results in anaemia increasing the risk of local tissue ischaemia; impairs tensile strength and collagen cross-linkage (Bobel, 1987:382; Silane, 1992:42; Dumas, 1994:4; Dealey, 1994:46; Banks, 1998f:319).

3.3.1.1.2 (h) Zinc

Zinc is considered to be a critical element in protein synthesis and tissue repair (Silane, 1992:42 and Hampton, 1997:5). Konstantinides and Lehmann (1993:27) describe zinc as a co-factor in numerous enzyme systems involved in cellular proliferation and cell membrane stabilization. Zinc deficiency therefore exerts a considerable impact on all stages of healing resulting in a reduced epithelialization rate; decreased collagen synthesis; reduced rate of gain in wound strength and decreased synthesis of retinal binding protein (McLaren, 1992:141; Dumas, 1994:4).

Lewis (1998:483) points out that, like vitamin C, zinc is a scavenger of free radicals, a process that may aid healing. However, the same author states that even though zinc therapy has been shown to be beneficial in patients with poorly healing surgical wounds, most studies have not proved consistent and it is now known that there is no beneficial effect to supplementing zinc in patients where serum zinc concentrations are *normal.*

Optimum wound healing depends not only upon the adequate *intake* of the above-mentioned nutrients, but also upon their adequate *absorption.*

3.3.1.2 Infection

Systemic infection has a detrimental effect on healing, as the wound has to compete with any infection for leukocytes, oxygen and essential nutrients. Wound healing may not take place until after the body has dealt with the infection (Dealey, 1994:28). Furthermore, systemic infection can cause increased body temperature, excessive perspiration, increased metabolism and tissue breakdown, all of which may prolong the inflammatory stage of wound healing (Banks, 1997:507). A recent study carried out by Kramer and Kearney (2000) confirmed that increased body temperature due to local or systemic infection processes is associated with poorer wound healing.

3.3.1.3 Medication

Dumas (1994:5) state that almost all medication has an influence on healing, either directly or indirectly. However, according to the literature the categories of medication that have the most deleterious effect on wound healing are steroid and non-steroid anti-inflammatory drugs, chemotherapeutic agents and immunosuppressive drugs.

3.3.1.3.1 Steroid and non-steroid anti-inflammatory drugs

The administration of steroids mimics and exacerbates the ageing process and leads to a reduction in the collagen content of the skin. It slows the rate of epithelialization and new vessel growth, thereby decreasing the tensile strength of newly closed wounds and inhibiting wound contraction (Zederfeldt, Jacobsson & Ahonen, 1986:14; Hastings, 1993:70; Bridel, 1993:236; Dealey, 1994:47; Bennett & Moody, 1995:28; Banks, 1997:507).

However, Silane (1992:44) and Dealey (1994:47) state that vitamin A supplementation may help offset these adverse effects. Anstead (1998) adds that even though vitamin A restores the inflammatory response and promotes epithelialization and the synthesis of collagen, it does not reverse the detrimental effects of glucocorticoids on wound contraction and infection.

Non-steroid anti-inflammatory drugs such as aspirin may decrease the tensile strength at the wound margin and delay the healing process (Dumas, 1994:6; Bennett & Moody, 1995:28; Johnson, 1995:279).

3.3.1.3.2 Chemotherapeutic agents

These drugs inhibit DNA/RNA synthesis, suppress protein synthesis, inhibit mitosis and delay fibroblast proliferation, all of which contribute to decreased collagen synthesis (Zederfeldt, Jacobsson & Ahonen, 1986:14; Dumas, 1994:6). These effects result in an increased risk of infection, and in granulating wounds, less exudate, granulation tissue and slower rates of contraction (Hastings, 1993:70; Song, 1999:8).

3.3.1.3.3 Immunosuppressive drugs

These agents significantly interfere with the ability of the immune system to respond to antigenic stimulation by inhibiting cellular and humoral immunity. Immunologic deficiency impairs many aspects of the inflammatory phase of healing such as macrophage functioning. It also predisposes to infection and therefore negatively affects wound healing (Anderson & Anderson, 1990:455; Silane, 1992:44; Bennett & Moody, 1995:72).

3.3.1.3.4 Other

Other medications that may delay healing include drugs such as beta-blockers due to their effect in increasing peripheral vascular resistance (Hastings, 1993:70; Hofman, 1997:53). Anticoagulants and phenotoin may act on the healing process in ways similar to glucocorticoid action (Silane, 1992:44).

3.3.1.4 Radiotherapy/Irradiation

Local irradiation impairs wound healing by depleting dermal fibroblasts and decreasing the proliferative potential of endothelium, whereas total body irradiation depresses bone marrow-derived elements, virtually eliminating wound macrophages. Furthermore the tissue changes associated with irradiation are related to the cumulative dose of treatment. High doses may lead to vessel narrowing and reduced blood flow, causing a delay in wound healing (Hastings, 1993:70; Dealey, 1994:54; Cherry, Hughes, Kingsnorth & Arnold, 1995:20; Bennett & Moody, 1995:131; Song, 1999:8).

3.3.1.5 Old age

Studies carried out on animals and humans suggest that ageing is associated with decreased inflammatory and proliferative responses, delayed angiogenesis, delayed remodelling and slower re-epithelialization. A significantly higher incidence of wound infection has also been found in patients over the age of 55 years (Dealey, 1994:29; Desai, 1997:237).

3.3.1.6 Underlying systemic conditions

The presence of specific medical disorders has a significant influence on healing. These conditions include diabetes mellitus, cardiovascular and respiratory diseases, renal failure as well as disorders of the digestive, nervous and immune systems (Sieggreen, 1987:443; Cooper, 1990:175; Silane, 1992:41; Hastings 1993:72; Dealey, 1994:42-43; Banks, 1997: 507).

A detailed discussion of these conditions and how they adversely affect the healing process falls beyond the purpose of this review. However, since successful wound management requires a holistic approach to, and comprehensive assessment of the patient, which includes consideration of *all* factors that may impede wound healing, a brief summary of how malfunctioning body systems impact on healing is provided in Table 3.1 (see p.53).

3.3.2 Local factors

Local factors that influence the rate of healing include impaired blood supply; temperature fluctuations; wound site; infection; foreign bodies, eschar, slough, necrotic tissue; desiccation; pressure, friction and shear; changes in oxygen tension and skin maceration (Baxter & Mertz, 1992:16; Flanagan, 1997b: 30).

3.3.2.1 Impaired blood supply

Disturbances to the peripheral blood supply will reduce tissue perfusion limiting the local supply of oxygen and other nutrients required for tissue repair (Flanagan, 1997b:30).

TABLE 3.1: Malfunctioning of body systems: impact on healing

Body System	Impact on healing
Respiratory system	◈ Impairs oxygenation resulting in decreased blood oxygen.
Circulatory system	◈ Arterial and venous insufficiency results in poor circulation to the wound site, causing inadequate tissue oxygenation and nutrition as well as impaired clearance of cellular waste. ◈ Anaemia causes a reduction in the oxygen-carrying capacity of the blood, resulting in inadequate tissue oxygenation.
Digestive system	◈ Malnutrition and/or malabsorption may lead to protein, calorie, vitamin and mineral deficiencies.
Excretory system	◈ Incontinence and/or renal failure may cause skin irritating moisture/chemicals, increased susceptibility to infection, faulty collagen deposition, and increased levels of nitrogenous breakdown products.
Nervous system	◈ Impaired sensation results in no pain signals to warn of damage. ◈ Impaired movement may result in excessive pressure from remaining too long in one position, resulting in pressure sores. ◈ Impaired central nervous system due to drug therapy, narcotics and sedatives may decrease awareness.
Immune system	◈ Immune deficiency increases susceptibility to infection and may result in lack of elements necessary for the inflammatory phase.
Endocrine system	◈ Diabetes results in the inability to metabolize glucose which leads to basement membrane thickening and increased levels of sorbitol, causing micro-circulatory impairment, peripheral neuropathy, increased susceptibility to infection and impairment of the inflammatory response.

Table 3.1 continues...

TABLE 3.1 Continued...

Body System	Impact on healing
Psychological system	◈ Anxiety may be related to dermatological conditions. ◈ Stress causes the release of adrenaline and an increased secretion of adrenocorticotrophic hormone (ACTH), which stimulates the production of adrenal cortex hormones. ACTH regulates the production of glucocorticoids, which cause a reduction in the mobility of granulocytes and macrophages, impeding their migration to the wound. This effectively suppresses the immune system and reduces the inflammatory response. ◈ Drug, as well as alcohol and nicotine abuse cause vascular injury (arteriosclerosis and perfusion abnormalities). This group of patients is often malnourished with reduced immune responses. ◈ Patients with dementia or self-harming tendencies can be uncooperative and non-compliant.

(Cooper, 1990:175; Silane, 1992:41-46; Flanagan, 1997b:31-32; Silhi, 1998:5; Partridge, 1998:350; Brychta *et al.*,1999:41)

3.3.2.2 Temperature fluctuations

A fall of two degrees Celsius at the wound interface is enough to reduce the rate of oxy-haemoglobin dissociation and oxygen availability thereby inhibiting cell division significantly and thus slowing the formation of new tissue (Harding, Bale & Assenheimer, 1997). Research has found that a constant temperature of 37^0C promotes both macrophage and mitotic activity during granulation and epithelialization (Glide, 1992:74; Dealey, 1994:18; Hampton, 1997:6; Miller & Collier, 1997:19; Kloth, Berman, Dumit-Minkel, Sutton, Papanek & Wurzel, 2000). Extremes of temperature also cause tissue damage (Flanagan: 1997b:30).

3.3.2.3 Wound site

The position of a wound affects its vascularity and determines the mobility of the wound site. Wounds on or close to joints tend to heal slower as the constant movement (flexion and extension of the joint) may disrupt the delicate newly formed tissues (Brychta *et al.*, 1999:41).

3.3.2.4 Local infection

Several researchers suggest that microbial populations greater than 10^5 colony-forming units per gram of tissue are indicative of infection and contribute to delayed healing. However, much smaller numbers of certain bacterial species, for example *pyogenic streptococci,* may cause infection (Baxter & Mertz, 1992 and Cooper & Lawrence, 1996b:294). Recent research debates the relevance of this quantitative measurement as a diagnosis of infection (Miller & Gilchrist, 1997:7). These authors propose that the diagnosis of wound infection is not dependent on numbers or state of replication of bacteria but rather on the response of the individual - the host reaction - to those bacteria.

Chronic wounds such as pressure sores, are typically seen in the elderly and the immune response (host reaction) may be absent or diminished. Gilchrist (1997:150) points out that there is no evidence that bacteria need to be removed from chronic wounds for healing to occur. The most obvious sign though, of wound infection is that it will either not start healing, or that it will stop healing. This is because wound infection prolongs the inflammatory phase, causes further tissue damage, delays collagen synthesis and epithelialization (Flanagan, 1997b:30).

3.3.2.5 Foreign bodies, necrotic tissue, slough and eschar

It is well documented that the presence of necrotic tissue, slough and eschar impair the healing of a wound by impeding epithelial migration and impairing the supply of nutrients to the wound bed.

It may act as a medium for bacterial growth and subsequent infection (Tilbury, 1991d:25; Glide, 1992:78; Baxter & Mertz, 1992:18; Bennett & Moody, 1995:43; Gilchrist, 1997:150; Harding, Bale & Assenheimer, 1997; Hampton, 1997:5; Hofman, 1997:53). Additionally foreign bodies, such as cotton wool fibres, can cause tissue irritation, prolong the inflammatory response and act as foci for infection (Flanagan, 1997b: 30).

3.3.2.6 Desiccation

Winter (1962:293) compared healing in dry (desiccated) and moist superficial wounds and found that the moist wounds formed new epidermal covering 40% faster than the dry wounds. The same author concluded that this was because new epidermal cells could migrate easily across the moist wounds whereas in the desiccated wounds, the cells had to negotiate the scab, which took longer. Subsequent research suggests that the inflammatory process is greatly accelerated in a moist environment, leading to faster healing (Harding, Bale & Assenheimer, 1997).

Conversely, a dry environment will lead to dehydration and cell death (Tilbury, 1991c:18; Baxter & Mertz, 1992:18; Krasner, 1992:39; Moore, 1996:46 and Miller & Collier, 1997:17).

3.3.2.7 Pressure, friction and shear

Mechanical forces such as pressure, friction and shear significantly impair wound healing by prolonging tissue damage (Flanagan, 1997b:30). These forces are discussed in Sections 2.3.1.1, 2.3.1.2 and 2.3.1.3.

3.3.2.8 Oxygen tension

The role of oxygen in wound healing can appear contradictory. It has been shown that macrophages, which instigate the healing process, require hypoxia in order to stimulate angiogenesis (and thereby the formation of new granulation tissue) and there is evidence that high oxygen concentrations, for example hyperbaric oxygen therapy, can stimulate wound repair. However, it has also been shown that hypoperfusion, ischaemia and tissue hypoxia can inhibit healing (Miller & Collier, 1997:19).

Inadequate oxygen perfusion results in the formation of unstable collagen with low tensile strength and lower tissue resistance to infection by lessening the phagocytic activity of leukocytes (Baxter & Mertz, 1992:22; Hampton, 1997:5; Flanagan, 1997b:30). It can therefore be concluded that the role of oxygen in wound healing is still being elucidated.

3.3.2.9 Skin maceration

If the peri-wound area is exposed to excess moisture from exudate, perspiration or incontinence, maceration and damage to the surrounding skin may occur which may predispose to infection, skin sensitivities, irritation, further skin breakdown and impede wound healing (Dealey, 1994:72).

3.4 CONCLUSION

Optimal wound healing is attained when the systemic and local factors, as discussed in the preceding paragraphs, are corrected or offset.

CHAPTER FOUR

The principles of pressure sore management

4.1 INTRODUCTION

The truism, prevention is better than cure, is particularly relevant as far as pressure sores are concerned. However, despite attempts at prevention, pressure sores remain a common occurrence. Effective pressure sore management is best achieved through a team approach involving patients, their family or caregivers and health care providers. In this chapter the principles of pressure sore management will be discussed with particular reference to *pressure sore risk assessment; assessment* of the patient and the pressure sore(s); *relieving pressure* and *pressure sore (wound) care* (Laverty, Mallet & Mulholland, 1997:79; Langemo, 1999).

4.2 PRESSURE SORE RISK ASSESSMENT

Pressure sore risk assessment scales attempt to identify the presence of extrinsic and intrinsic factors that are known to increase an individual's susceptibility to pressure damage, and to quantify the risk with a numerical score (Flanagan, 1997a:3; Banks, 1998b:91; Langemo, 1999). Even though pressure sore risk assessment is part of patient assessment, it should be used as a *guide* to pressure sore risk and not as an indicator of *pressure sore development* (Banks, 1998b:91). Phillips (1997:44) and Scott (2000:70) support this view and add that risk assessment tools can only be effective if used in conjunction with expert clinical judgement.

Norton first researched pressure sore risk assessment in 1962. Numerous risk assessment tools have since been developed (Birchall, 1993:35; Waterlow, 1996:54; Healey, 1996:80; Flanagan, 1997a:6; Banks, 1998b:91). The reported sensitivity and specificity of these tools vary considerably because of variations in patient groups and/or clinical settings.

Specificity is defined as the percentage of patients who do not develop pressure sores and were predicted not to, and sensitivity is the percentage of patients who develop pressure sores and were predicted to do so. An ideal pressure sore risk calculator would have to demonstrate good predictive value and be both 100% specific and 100% sensitive. However, in reality this is not possible as sensitivity and specificity have an inverse relationship (Flanagan, 1997b:158; Phillips, 1997:44).

Risk assessment tools have been criticized because little research has been carried out to test their reliability, and there is concern that some may over-predict risk, resulting in the ineffective use of scarce resources. However, Banks (1998b:91) points out that the use of a recognized risk assessment tool can facilitate clinical decision-making and support requests for pressure relieving equipment. In the following paragraphs a few of the more widely known risk assessment scales will be described, indicating the patient group for whom each one was developed, and the variables used in the scoring system (see Appendix 7 for examples of each scale discussed in 4.2.1, 4.2.2, 4.2.3, 4.2.4 and 4.2.5).

4.2.1 Norton risk assessment scale

The Norton scale was developed in 1962 and is one of the most common and popular risk calculators because it is quick and easy to use. Variables taken into account are physical health, mental health, activity, mobility and incontinence, each giving a numerical score. The lower the score the higher the risk. Maximum score 20; a score of 14 or below indicates patient at risk (Torrance, 1983:32; Bassett, 1993:146; Dealey, 1994:91; Walding & Andrews, 1995:33; Banks, 1998b:91; Flanagan, 1998a:484). The Norton scale was, however, developed in a unit for the care of elderly people and according to Birchall (1993:35) its application to general nursing must be questioned.

4.2.2 Douglas risk assessment scale

The Douglas pressure sore calculator was developed in a male medical ward, mainly caring for patients following myocardial infarction. It is based on the Norton scale, and addresses the following variables: nutritional state, activity, incontinence, pain, skin state, mental state, special risk factors (diabetes, steroid therapy, cytotoxic therapy and dyspnoea). The lower the score the higher the risk. A score of less than 18 suggests the patient is at risk of developing pressure sores (Dealey, 1997:32). Birchall (1993:35) cautions that although this scale appears to be comprehensive and relatively easy to use, there is little evidence to support its effectiveness, as the initial research involved only 28 patients over a one-month period.

4.2.3 Waterlow risk assessment card

This risk assessment card was developed as a more comprehensive guide to pressure sore prevention and treatment. The risk assessment is more complex than the Norton scale as it covers many more predisposing factors that put patients at risk. The Waterlow was developed for use among general adult populations, the initial research being carried out in a general hospital caring for medical, surgical, orthopaedic and elderly patients. Variables include: Build/weight for height, continence, skin type, mobility, sex, age, appetite, tissue malnutrition, neurological deficit, major surgery/trauma and medication. The higher the score the higher the risk. Scores are divided into categories: 10-14 = at risk; 15-19 = high risk; 20+ = very high risk (Waterlow, 1985:49; Healey, 1996:80; Waterlow, 1996:58; Flanagan, 1997b:159; Banks, 1998b:91; Flanagan, 1998a:484; Pang & Wong, 1998:148).

4.2.4 The Pressure Sore Prediction scale

The Pressure Sore Prediction Scale (PSPS) was initially developed in 1975 and published in 1987 by Lowthian (Dealey, 1997:32). It was first used in an orthopaedic setting and has since been implemented in a variety of clinical areas. The score constitutes the use of a simple six-point questionnaire and the variables used are: sitting up, unconscious, poor general condition, incontinence and mobility. The higher the score the higher the risk. Highest score is 16; scores above six indicate a patient at risk (Dealey, 1997:32-33).

4.2.5 The Gosnell scale

This scale was developed in 1973 by Gosnell in the USA and was based upon the earlier work of Norton. Nutritional status was added as an assessment criterion and data concerning admission, discharge, medical diagnosis and demographic details were also included. Further additions to this scale were the inclusion of skin appearance, height, weight, vital signs and medications. The original Gosnell scale was revised in 1987 and again in 1988. The initial scoring of five risk factors - mental status, continence, mobility, activity and nutrition were reversed so that the higher the score, the greater the risk of pressure sore development. The category describing skin appearance was also expanded to include moisture, temperature, colour and texture. These changes resulted in a possible risk factor score of between five and 20: the higher the score, the higher the patient's risk status (Flanagan, 1997b:159; Flanagan, 1998a:484).

4.2.6 The Braden scale

Braden and Bergstrom, who were reviewing nursing practices in nursing homes, developed the Braden risk assessment score in the USA. The Braden scale consists of six predisposing factors or variables: sensory perception, moisture, activity, mobility, nutrition and friction/shear. Included in this scoring system are specific assessment criteria for each of the risk factors described. In both categories describing sensory perception and nutritional status, there is a second range of potential responses, which improves reliability by reducing user ambiguity.

The nutrition section is specific without being too complicated. Practitioners are able to identify patients who are receiving tube feeds, parental nutrition or simple intravenous support.

The sections describing friction/shear and moisture recognize the importance of these factors in contributing to tissue breakdown and remind the practitioner of relevant practical considerations.

Most of the identified risk factors are awarded a rating of between one (least favorable) to four (most favorable) except friction/shear which can be given a maximum rating of three. The maximum score possible is 23, indicating low risk status, whilst the minimum score is six, indicating a high-risk patient. Patients with a score of 16 or less were originally considered to be at risk of developing pressure sores. However, it has since been recommended that the cut off point be moved up to 18 (Bergstrom, Demuth & Braden, 1987:417; Dealey, 1994:91; Dealey, 1997:32; Banks, 1998b: 91; Flanagan, 1998a:484; Pang & Wong, 1998:148; Langemo, 1999).

A recent study carried out by Pang and Wong (1998:147) in a Hong Kong rehabilitation hospital compared the predictive power of the Norton, Braden and Waterlow scales. Both the Waterlow and Norton scales had relatively high sensitivity (81% and 95%, respectively), whereas the Braden Scale had both high sensitivity (91%) and specificity (62%) – highest of the three scales. All three scales had relatively high negative predictive values (>90%). However, for the positive predictive value, the Braden Scale scored the highest percentage of the three scales. Thus, in terms of sensitivity, specificity, positive predictive value and percentage of correct classification, the Braden Scale has an advantage over the other two scales. These results confirm the findings of similar previous studies (Flanagan, 1997a: 6; Hopkins, Gooch & Danks, 1998:37; Olson, Tkachuk & Hanson, 1998:209).

In the light of the above and the fact that the Braden Scale is used extensively in various care settings in the USA, this risk assessment tool will be utilized in this study. Table 4.1 illustrates the Braden Scale.

TABLE 4.1: Braden risk assessment scale

Patient's Number:				Date of Assessment:			
Sensory perception Ability to respond meaningfully to pressure-related discomfort	**1. Completely limited:** 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.	**2. Very limited:** Responds only to painful stimuli. Cannot communicate discomfort except by moaning or restlessness, OR Has a sensory impairment which limits the ability to feel pain or discomfort over half of body.	**3. Slightly limited:** 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 one or two extremities.	**4. No impairment:** Responds to verbal commands. Has no sensory deficit which would limit ability to feel or voice pain or discomfort.			
Moisture Degree to which skin is exposed to moisture	**1. Constantly moist:** Skin is kept moist almost constantly by perspiration, urine, etc. Dampness is detected every time patient is moved or turned.	**2. Moist:** Skin is often but not always moist. Linen must be changed at least once a shift.	**3. Occasionally moist:** Skin is occasionally moist, requiring an extra linen change approximately once a day.	**4. Rarely moist:** Skin is usually dry; linen requires changing only at routine intervals.			
Activity Degree of physical activity	**1. Bedfast:** Confined to bed.	**2. Chairfast:** Ability to walk severely limited or nonexistent. Cannot bear own weight and/or must be assisted into chair or wheel chair.	**3. Walks occasionally:** Walks occasionally during day but for very short distances, with or without assistance. Spends majority of each shift in bed or chair.	**4. Walks frequently:** Walks outside the room at least once every two hours during waking hours.			

Table 4.1 continues...

TABLE 4.1: Braden risk assessment scale continued...

Patient's Number:				Date of Assessment:			
Mobility Ability to change and control body position	**1. Completely immobile:** Does not make even slight changes to body or extremity position without assistance.	**2. Very limited:** Makes occasional slight changes to body or extremity position but unable to make frequent or significant changes independently.	**3. Slightly limited:** Makes frequent though slight changes in body or extremity position independently.	**4. No limitations:** Makes major and frequent changes in position without assistance.			
Nutrition Usual food intake pattern	**1. Very poor:** Never eats a complete meal. Rarely eats more than a third of any food offered. Eats two servings or less of protein (meat or dairy products) per day. Takes fluids poorly. Does not take a liquid dietary supplement, OR is nil per mouth and/or maintained on clear liquids or IV for more than five days.	**2. Probably inadequate:** Rarely eats a complete meal and generally eats only about half of any food offered. Protein intake includes only three servings of meat or dairy products per day. Occasionally will take a dietary supplement, OR Receives less than optimum amount of liquid diet or tube feeding.	**3. Adequate:** Eats over half of most meals. Eats a total of four servings of protein (meat, dairy products) each day. Occasionally will refuse supplement if offered, OR Is on tube feeding or total parenteral nutrition regimen, which probably meets most of nutritional needs.	**4. Excellent:** Eats most of every meal. Never refuses a meal. Usually eats a total of four or more servings of meat and dairy products. Occasionally eats between meals. Does not require supplementation.			

Table 4.1 continues...

TABLE 4.1: Braden risk assessment scale

Patient's Number: Date of Assessment:

Friction and shear	**1. 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 repositioning with maximum assistance. Spasticity, contractures, or agitation leads to almost constant friction.	**2. Potential problem:** 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.	**3. No apparent problem:** Moves independently in bed and in chair and has sufficient muscle strength to lift up completely during move. Maintains good position in bed or chair at all times.			
A total score of 18 and lower indicates a risk of developing pressure sores				Total score:		

(Bergstrom, Demuth & Braden, 1987:417; Dealey, 1994:91; Dealey, 1997:32; Banks, 1998b: 91; Flanagan, 1998a:484; Pang & Wong, 1998:148)

4.3 ASSESSMENT

Assessment is the starting point in preparing to treat or manage a patient with a pressure sore. Holistic assessment involves the entire person, not just the pressure sore, and is the basis for planning treatment and evaluating its effects (Broekkamp, 1994:1; Briggs, 1996:229; Hampton, 1997:5). Assessment of the pressure sore and the patient will be discussed in the following paragraphs.

4.3.1 Assessment of the pressure sore

A thorough assessment is the starting point in preparing to treat an individual with a pressure sore. Assessment forms the basis for planning treatment and evaluating its effects. It is also essential for communication among caregivers.

Initial assessment of the pressure sore will include the *site; stage* (including the absence or presence of sinus tracts, undermining or tunneling); *dimensions* (length, width, and depth); *appearance of the wound bed* (including colour as well as the presence or absence of necrotic tissue, slough, granulation tissue, and epithelialization); *exudate; odour; the surrounding skin, clinical signs of wound infection* and *pain at the wound site.* Pressure sores should be reassessed at least weekly. The Agency for Health Care Policy and Research (1994:4) proposes that if the condition of the patient or the wound deteriorates, the treatment plan should be reevaluated as soon as any evidence of deterioration is noted.

4.3.1.1 Site

Pressure sores usually occur over bony prominences, but some areas are more prone to pressure sores than others. Figure 4.1 (p.71) illustrates common sites for pressure sores and frequency of ulceration per site. These findings allow for specific aspects of care that need to be considered such as adequate pressure relief, reduction of friction and selection of appropriate dressings. The position of a wound may also be an indication of potential problems, such as the risk of contamination of wounds in the sacral region, or immobility caused by wounds on the foot (Dealey, 1994:67).

4.3.1.2 Staging of pressure sores

Classification or staging of pressure sores is just one aspect of assessment. Its purpose is to clarify and describe objectively the depth and extent of tissue damage (Dealey, 1994:99; Phillips, 1997:19; Banks, 1998a:23). In practice a pressure sore grading system has the potential to:

- Promote the accurate transfer of information between different groups caring for a patient, allowing assessment of progress and deterioration;
- Encourage precise documentation and
- Provide guidance to staff using protocols in decision-making, for example when making a choice about which pressure-relieving equipment or dressing to use (Phillips, 1997:21; James, 1998:669).

A grading system can reflect the severity of the sore in a number of ways, either by measuring the depth of skin affected or, alternatively, by assessing the stage of tissue breakdown. There are numerous pressure sore staging or classification systems available. In 1992 a National Consensus Conference was held in Stirling in the United Kingdom in an attempt to provide a standard classification system.

The outcome of this conference was the publication of the Stirling Pressure Sore Severity Scale (SPSSS). In arriving at this system the panel considered 12 systems (Waterlow, 1996:54).

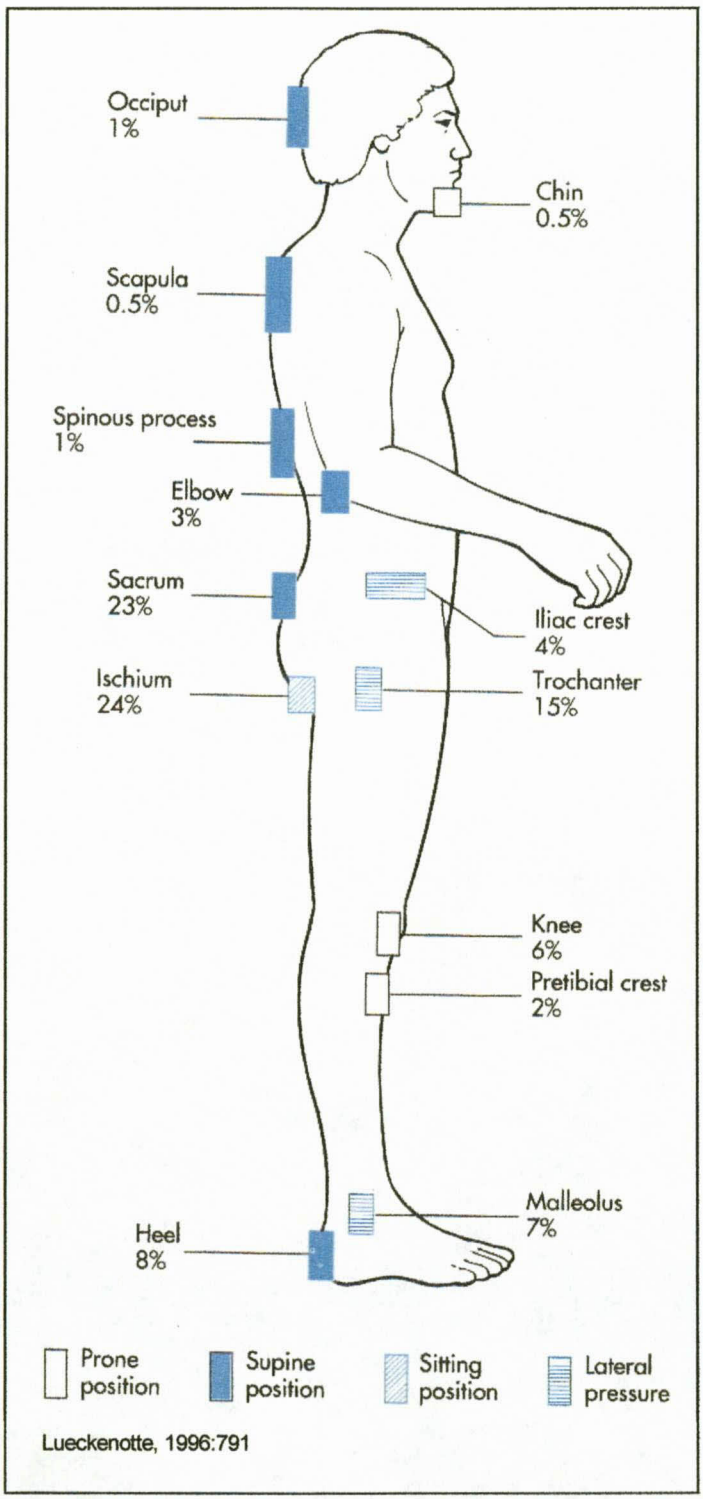


Figure 4.1: Common sites for pressure sores and frequency per site

The same author points out that even though it is impossible to accurately assess whether any system is better than another, the SPSSS is a consensus of acknowledged experts in the field. In addition to a standard scoring system numbering one to four, the Stirling grading system has a third and fourth digit classification further to describe the wound bed and any infective complications. James (1998:670) and Waterlow (1996:54) recommend that it be used for research purposes as it provides a more detailed and sophisticated wound description (Bennett & Moody, 1995:83; Walding & Andrews, 1995:34; James, 1998:670). The SPSSS will therefore be utilized as classification system in this research study. Figure 4.2 illustrates the Stirling Pressure Sore Severity Scale.

Figure 4.2: The Stirling pressure sore severity scale

Stage 0	***No clinical evidence of a pressure sore***
0.0	Normal appearance, intact skin
0.1	Healed with scarring
0.2	Tissue damage but not assessed as a pressure sore

Stage 1	***Discolouration of intact skin (light finger pressure applied to site does not alter the discolouration)***
1.1	Non-blanchable erythema with increased local heat
1.2	Blue/purple/black discolouration. The sore is at least Stage 1.

Stage 2	***Partial-thickness skin loss or damage involving epidermis and/or dermis***
2.1	Blister
2.2	Abrasion
2.3	Shallow ulcer without undermining of adjacent tissue
2.4	Any of these underlying blue/purple/black discolouration or induration. The sore is at least Stage 2.

Stage 3	***Full-thickness skin loss involving damage or necrosis of subcutaneous tissue but not extending to underlying bone, tendon or joint capsule***
3.1	Crater without undermining of adjacent tissue
3.2	Crater with undermining of adjacent tissue
3.3	Sinus, the full extent of which is uncertain
3.4	Full-thickness skin loss but wound bed covered with necrotic tissue (hard or leathery black/brown tissue or softer yellow/cream/gray slough) which masks the true extent if tissue damage. The sore is at least a Stage 3. Until debrided it is not possible to observe whether damage extends into muscle or involves damage to bone or supporting structures.

Stage 4	***Full-thickness skin loss with extensive destruction of tissue. Necrosis extending to underlying bone, tendon or joint capsule***
4.1	Visible exposure of bone, tendon or capsule
4.2	Sinus assessed as extending to bone, tendon or capsule

Third digit classification – for the nature of the wound bed	
X.X.0	Not applicable; intact skin
X.X.1	Clean, with partial epithelialization
X.X.2	Clean, with or without granulation but no obvious epithelialization
X.X.3	Soft slough, cream/yellow/green in colour
X.X.4	Hard or leathery black/brown (dead/avascular) tissue

Fourth digit classification – for infective complications	
X.X.X.0	No inflammation surrounding the wound bed
X.X.X.1	Inflammation surrounding the wound bed
X.X.X.2	Cellulitis bacteriologically confirmed

Waterlow, 1996:56

4.3.1.3 Dimensions

The measurement of a wound has an important place in wound care. Without baseline and ongoing wound measurements it is impossible to achieve an objective approach to managing and treating a wound (Dealey, 1994:76; Hampton, 1997:7). Plassmann (1995:269) adds to this by emphasizing that the accurate measurement of wound size is vital for assessing the progress of healing. However, due to the three-dimensional and dynamic structure of wounds, accurate measurement is difficult. This difficulty stems from three particular problems, which directly affect the accuracy of any and all measurement techniques. Dealey (1994:78), Plassmann (1995:269) and Banks (1998d:212) describe these problems as the following:

(i) The definition of a wound's margin

The wound margin is usually determined by the subjective assessment of the human observer who performs the measurements and decides if a particular part of the area in question belongs to the wound.

(ii) Wound flexibility

Wounds that are undermined, large or deep are capable of changing their appearance significantly, thus jeopardising the reproducibility of measurements.

(iii) The natural curvature of the human body

Measurement techniques that do not account for the natural curvatures of the body will also produce inaccurate results.

Despite these problems, various attempts have been made to measure the area and volume of wounds. In the following paragraphs several area and volume measuring techniques, as described in the literature, will be reviewed namely: ruler-based measurements, transparency tracings, photographic methods, ultrasonic surface scanning, casts, saline, computerized stereo-photogrammetry, structured light technique, laser triangulation, video image analysis and magnetic resonance imaging.

4.3.1.3 (a) Ruler-based measurements

This is the simplest measurement technique and is accomplished by measuring the wound at its greatest length and breadth and the depth if appropriate. In wounds that are fairly regular in shape this can be a fairly successful method. In a wound care study to compare healing rates and costs of two different dressings for pressure sores Sebern (1986:727) calculated the surface area by assuming an elliptical shape, which provides a more accurate wound area of a pressure sore. The area is calculated as follows:

$$Area = \pi \times r_1 \times r_2, \text{ where } \pi = 3.14$$

However, the accuracy may be questionable if many different individuals use it. Dealey (1994:77) points out that if necrotic tissue or slough is present, the true wound size will only become apparent as debridement occurs. Wound measurement will indicate that the wound has increased in size and can give a misleading picture of wound progress. This technique is inexpensive, readily available, easily accomplished by most clinicians and causes little patient discomfort. The technique can become three-dimensional when a depth measurement is added, for example by gently inserting a sterile swab to the maximum depth (Langemo, Melland, Hanson, Olson, Hunter & Henly, 1998:337).

4.3.1.3 (b) Transparency tracings

This technique involves tracing the outline of the wound on a flexible two-layer transparency with an imprinted metric grid. The tracing is made on the upper sheet, and the lower sheet, which is in contact with the wound, is disposed of after use (Griffin, Tolley, Tooms, Reyes & Clifft, 1993:64; Dealey, 1994:77). After the tracing is taken, several methods may be used to determine its area. One method is to place the transparency on metric graph paper and count the number of 5 mm^2 squares. A less time-consuming method is to cut the tracings out and weigh them on a precision scale (Bohannon & Pfaller, 1983:1624). Schubert (1997:154) describes transparency tracings as an effective method of measuring wound area as it is inexpensive, rapid, requires minimal training and provides instant results. This technique may further be improved by transferring the wound tracings to a computer and having the measurements taken by hand-held scanners or electronic cameras. The boundaries of the tracing are automatically identified by the computer software making this a faster and more accurate technique (Plassmann, 1995:269).

4.3.1.3 (c) Photographic methods

The simplest *non-contact* technique according to Melhuish, Plassmann and Harding (1994:41), is that of photography and the study of and measurement of photographs known as photogrammetry. However, in order to monitor the progress of healing by taking photographs, it is essential to ensure that each photograph is comparable to the others. To achieve such consistency it is necessary to exercise as much control as possible over the variables, which may influence the results (Dealey, 1994:78). Bellamy (1995:313-316) and Flanagan (1997b:42) suggest that special consideration should be given to the following:

(i) Choice of equipment

As no two makes of camera are exactly alike, it is recommended that the same model be used on each occasion. Whether the camera is manual, semi-automatic or fully automatic is a matter of personal preference, provided that the photographer has complete control over focusing, magnification and exposure functions. Additionally a tripod, while not essential, may be useful to ensure accurate camera positioning and framing of the subject.

(ii) Choice of materials

As the colour of a wound is an important indicator of its condition, only colour film should be used. Whichever format (prints or slides) is chosen it is essential to be consistent with the manufacturer, the type and speed of the film used.

(iii) Choice of processing

Processing and printing should be carried out in the same place on every occasion to ensure consistent results.

(iv) Control of subject

The patient's position in relation to the camera is the most difficult variable to control. It is therefore advisable to make comprehensive notes on each occasion and have previous photographs available for reference at subsequent sessions. If measurements are to be taken from photographs, then a scale such as a ruler should be placed in the plane of focus and, for aesthetic reasons, towards the edge of the frame.

(v) Control of lighting

In order to achieve consistent results, the amount, angle and direction of light falling on the subject must be controlled which will ensure that the subject is evenly illuminated and that any shadows cast are small. Careful notes should therefore be made about the angle and direction of light so that repeat photographs may be taken.

(vi) Control of background

The background of a clinical photograph should be plain and unobtrusive. Any bright colour will introduce some measure of unwanted colour cast into the subject. Additionally the background should be even, right to the edge of the frame.

(vii) Maintaining the same distance

In order to achieve consistent results and to ensure that each photograph is comparable to the others, the same distance between the camera lens and the wound surface should be maintained on each occasion.

(viii) Consent and storage

Other considerations include obtaining written informed consent from the patient before taking photographs and ensuring that the images are stored in a secure place and are not published without prior consent of the patient.

4.3.1.3 (d) Ultrasonic surface scanning

This method has been successfully used but compared with an optical camera, the resolution is always poor since it is difficult to focus the ultrasonic waves to a sufficiently narrow beam. According to Plassmann (1995:272) ultrasonic depth scanners have been useful in the measurement of small wounds and scars.

4.3.1.3 (e) Casts

Wound volume may be measured with impression materials such as high-viscosity vinyl poly-siloxane but cheaper and faster measurements may be obtained by using dental alginate hydrocolloid materials. Usually casts can be extracted from a lesion without difficulty. However if the shape of a wound makes it impossible to verify that no material is left in the cavity, this method should not be used (Dealey, 1994:80; Flanagan, 1997b:41; Plassmann, 1995:272).

4.3.1.3 (f) Saline

Volume measurements may be made by covering the wound with transparent adhesive film and filling the lesion with sterile saline by injecting it through the film (Flanagan, 1997b:41).

However, experiments have shown that on wound models a precision of more than 10% is rarely achievable (Plassmann, 1995:272). In some cases it is impossible to position the patient in a way which allows the wound to be filled with saline.

4.3.1.3 (g) Computerized stereo-photogrammetry

Stereo-photogrammetry is a system that was developed to obtain a measurement of the volume of a wound. It accomplishes this by providing a three-dimensional picture from two photographs taken simultaneously from different angles. The image thus obtained is measured and analyzed by computer. Although this has been found to be suitable for clinical trials, it is a costly procedure requiring trained personnel (Dealey, 1994:79).

4.3.1.3 (h) Structured light technique

Using this technique the wound area is illuminated by a projector with a set of parallel strips of light. A camera is connected to an image-processing computer and from the known positions of the camera and projector the observed intersection points of the strips of light with the wound's surface, a three-dimensional representation of the observed area can be produced by triangulation (Dealey, 1994:79; Plassmann, 1995:272; Flanagan, 1997b:41). This technique has formed the basis of the development of the MAVIS project (Measurement of Area and Volume Instrument) initiated by Jones & Plassmann (1996) and continued by an interdisciplinary team in the medical laboratories at the University of Glamorgan. The aims of the MAVIS project are to measure wound dimensions without physical contact to achieve a precision of about 5%, to make a portable and easy-to-use instrument and to make measurements rapidly (Berris & Sangwine, 1997).

4.3.1.3 (i) Laser triangulation

A new technique that uses light from lasers in the same way as ultrasound is currently used is under investigation. By scanning the wound with low powered lasers it is possible to obtain a three dimensional image. However, the special equipment requires both specialized rooms and precise settings which restricts its use (Melhuish, Plassmann & Harding, 1994:41).

4.3.1.3. (j) Video image analysis

Video image analysis of wounds using video cameras and image processing software is becoming very popular and can be used to look at many different parameters of a wound such as size, shape and colour. One such system is the Verge Videometer Measurement and Documentation (VeVMD). Using this system the wound can be seen on a computer screen with a target plate to help coordinate consistent measurement of the wound, regardless of distance from the camera, angle or position of the patient (Melhuish, Plassmann & Harding, 1994:41; Beaumont & Anderson-Dam, 1998:20; Salcido, 2000). However, the cost of these systems is still prohibitively expensive.

4.3.1.3 (k) Magnetic resonance imaging

Magnetic resonance imaging of wounds allows a detailed analysis of wound size, shape and dimensions; however, the equipment is very expensive and must have a purpose-built environment for use (Melhuish, Plassmann & Harding, 1994:41).

Finally, most authors agree that regardless of the technique used, what is of the greatest importance is *consistency* in the use of the measurement technique to determine actual changes (Dealey, 1994:78; Bellamy, 1995:316; Flanagan, 1997b:42; Langemo *et al.*, 1998:339; Beaumont & Anderson-Dam, 1998:16).

In this study four wound measurement techniques, namely ruler-based measurements, transparency tracings, saline volume measurements (where possible) and standardized digital wound photography were be utilized. The results of each method were triangulated to achieve a final measurement. Additionally the researcher performed each of these techniques personally thereby increasing the reliability and validity of the measurements.

The measurement of a wound has an important place in wound care. Without baseline and ongoing wound measurements it is impossible to achieve an objective approach to managing and treating a wound (Dealey, 1994:67; Hampton, 1997:7). Plassmann (1995:269) emphasizes that the *accurate* measurement of wound size is vital for assessing the progress of healing.

4.3.1.4 Appearance of the wound bed

The appearance of the wound bed provides an indication of the phase it has reached on the continuum of healing, as well as any complication that may be present (Krasner, 1992:37; Dealey, 1994:67; Krasner, 1995:44).

A ***black*** wound indicates a necrotic wound, often with hard eschar present. This dehydrated and dead tissue will delay healing and requires removal to provide a healing environment. Krasner (1995:45) describes two types of ***yellow*** wounds, namely those that are infected and those that contain fibrous slough. Infected wounds are characterized by yellow, light green or cream-coloured exudate (pus), comprised of bacteria, cellular debris, and leukocytes (Hampton, 1997:7).

Fibrous slough is usually yellow, cream-coloured, or white. It often appears soft and stringy and may stick to the wound bed. As slough provides an excellent medium for bacterial proliferation, it needs to be removed to optimize the healing process.

A ***red*** wound indicates the presence of granulation tissue. Healthy granulation tissue may appear deep pink or red in colour and is moist with raised "granules". These are delicate loops of capillaries, which are easily damaged. A granulating wound represents a healthy, healing wound and the maintenance of an optimum healing environment is therefore essential (Dealey, 1994:70; Krasner, 1995:44; Hampton, 1997:7; Flanagan, 1998b:508-510). An overabundance of granulation tissue or hypergranulation will inhibit the migration of epithelial cells and thus delay the healing process.

It appears that the cause of hypergranulation is an excessive inflammatory response that results in an increase in growth factors and stimulation of ground substance formation and fibroblast proliferation. However, the reason this occurs is unclear (Dunford, 1999:506).

Treatment methods used in the community for hypergranulation include the following:

- change from an occlusive to a vapour permeable dressing such as a polyurethane dressing;
- application of light pressure to the wound bed by the addition of supplementary padding;
- short-term application of a low dose of corticosteroids;
- removal using a caustic substance such as silver nitrate;.
- allowing the hypergranulation to resolve itself without treatment

According to Dunford (1999:507) there is no consensus as to the correct treatment for this condition.

A ***pink*** wound represents an epithelialising wound. Epithelial tissue migrates from the wound margins and from undamaged hair follicles and moves over the wound surface once granulation is level with the surrounding skin (Harding, Bale & Assenheimer, 1997; Hampton, 1997:7; Banks, 1998d:211).

Another method that can be used to assess and document the appearance of the wound bed is to place a metric grid (as discussed in section 4.3.1.3 [b]) over a photographic image of the wound. The black, yellow, red and pink areas are then demarked and the number of squares in each area counted and expressed as a percentage of the total area (total number of squares) of the wound surface (Andriessen, 2000). In the absence of advanced technology this method, even though tedious and time consuming, does provide a more accurate and objective assessment of the wound appearance. Therefore this method will be used to assess the appearance of the wound bed in this study.

4.3.1.5 Exudate

The amount of wound exudate varies during the different phases of the healing process. In general, exudate production decreases as the wound progresses towards healing (Dealey, 1994:67; Thomas, 1997a:327). Although chronic wounds such as pressure sores are associated with the presence of some exudate, normal granulation tissue is relatively dry. Therefore, the sudden appearance of increased amounts of exudate in a wound may be an indicator of an infection. According to Miller and Gilchrist (1997:10) this is due to the underlying capillaries dilating as part of the inflammatory response, in order to allow leukocytes in particular to migrate to the source of an infection. The increased permeability of the capillaries also allows for the leakage of greater quantities of plasma. In addition to assessing the amount of exudate, the appearance of the exudate needs to be determined. Exudate may appear bloody, serous, serosanguinous or purulent and may be clear, pink, light red, dark red, pinky yellow or green in colour (Bennett & Moody, 1995:44).

However, in a healthy healing wound the exudate normally appears pale yellow in colour (Thomas, 1997a:327). Terms used to describe exudate volume include heavy, moderate and light but these are imprecise, subjective assessments.

Colour, consistency, purulence and odour of exudate are other characteristics widely used to define wound status for which there are no objective measurements (Nelson, 1997:11). Attempts to provide more objective descriptions of exudate volume include weighing of dressings, measuring the diameter of drainage area on the dressing and, in the case of gauze dressings, the number of dressings through which exudate strike-through occurred. However, none of these attempts have been proven to be very successful and/or practical especially in community settings. Therefore, for the purposes of this study, the researcher described **exudate level** as: *high, medium* or *low* and indicated amount of **exudate change** as: *unknown (on initial assessment), same as last assessment, increasing* or *decreasing.* Even though these are subjective descriptions, the reliability of this assessment method was improved by the fact that the researcher performed all the dressing changes personally and was able to compare each assessment with the preceding one.

4.3.1.6 Odour

All wounds have some smell associated with them. However, Miller and Gilchrist (1997:12) point out that the presence of an offensive odour may indicate the possibility of infection. The smell from malodourous wounds is caused by a cocktail of volatile agents that includes short chain organic acids, (n-butyric, n-valeric, n-caproic, n-haptanoic and n-caprylic) produced by anaerobic bacteria, together with a mixture of amines and diamines such as cadavarine and putrescine that are produced by the metabolic processes of other proteolytic bacteria (Thomas, Fisher, Fram & Waring, 1998).

Infection caused by anaerobic bacteria such as *Bacteriodes* or, less commonly, *Clostridium welchii,* often produce an acrid or putrid smell due to the presence of necrotic tissue. Aerobes such as *Klebsiella*, *Proteus* and *Pseudomonas* tend to produce strong "fishy" odours (Bennett & Moody, 1995:63; Thomas *et al.*, 1998).

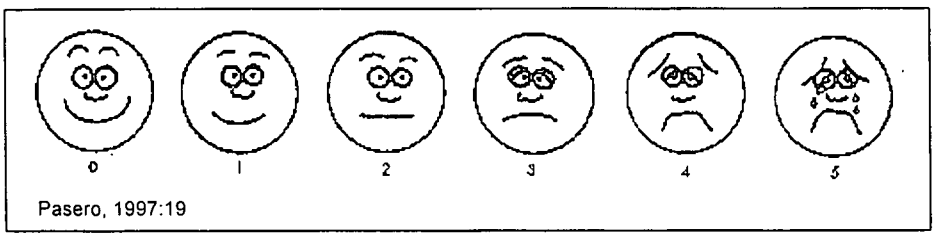
4.3.1.7 Surrounding skin

From the literature it is evident that little attention has been given to the need to care for the skin around the wound. The skin surrounding the wound may be intact, erythematous, indurated, edematous, fragile, dry-scaling or macerated. Intact, healthy skin is vulnerable to maceration, erosion and insults from wound exudate, repeated dressing changes or other trauma and therefore needs to be protected (Krasner, 1992:40). Nelson (1997:11) adds that wound exudate may *exacerbate* peri-wound skin damage either directly or by inducing excoriation and delay healing by provoking a local irritant or allergenic contact dermatitis.

4.3.1.8 Pain at the wound site

The impact of pain on the patient has been well documented in the literature and a discussion thereof falls beyond the scope of this review (Bennett & Moody, 1995:41). It is imperative however, that all patients should be assessed for pain related to the pressure sore or its treatment. Lindholm (1998:1) stresses the importance of pain assessment and that caregivers should not assume that because the patient is unable to express or respond to pain, that it does not exist.

Research has shown that a patient's own report is the single best indicator of pain and an appropriate pain assessment instrument is therefore required (Pasero, 1997:19). Many patients are unable to understand or relate to the often-used zero-to-10 numerical pain rating scale. The same author reports that the Wong-Baker Faces Pain Rating Scale, as seen in Figure 4.3, has been found to be easier to use and friendlier.



Pasero, 1997:19

Figure 4.3: Wong-Baker faces pain rating scale

Several studies done by Wong (1993), Stein (1995) and Keck (1996), as cited by Pasero (1997:19), have confirmed the validity and reliability of the Faces scale and it was therefore used in this research study.

4.3.1.9 Clinical signs and symptoms of wound infection

The very nature of wounds, a discontinuity of the epidermis resulting in the presence of serous exudate, makes them prone to acquiring and frequently becoming colonized with a variety of bacteria. However, it is important for the clinician to distinguish between *contamination,* which is the presence of non-multiplying bacteria and *colonization,* which is the presence and multiplication of bacteria with no host reaction. *Infection* occurs when colonizing microorganisms in tissue result in the appearance of distinctive signs also referred to as an associated *host reaction* (Cooper & Lawrence, 1996a:235; Miller & Gilchrist, 1997:8). The response of individual patients to the presence of bacteria within their wounds varies from person to person. The term host reaction describes the variety of different signs and symptoms that may occur once bacteria overwhelm the body's normal healing process.

Wound infection may therefore be indicated if one or more of the following are present:

- Inflammation and increased temperature around the wound.
- Redness (erythema).
- Swelling (oedema) or cellulitis.
- New or increased pain in or around the wound.
- An increase or change in wound exudate.
- Granulation tissue which is friable and bleeds easily.
- Granulation tissue of an unusual darker colour.
- Odour which has changed or become unpleasant.
- Unusual staining on the wound dressing when removed.
- General malaise in the patient.
- A non-healing wound or a wound that is not healing at the expected rate.
- Tissue, sometimes at the base of the wound, which does not progress to healing.
- Wound breakdown or dehiscence.
- Presence of pus (purulent discharge).
- Superficial bridging / pocketing at the base of the wound.
- Fever.
- Lymphangitis (AHCPR, 1994:19; Cutting & Harding, 1994:198; Dealey, 1994:68-69; Mackenzie & Ziady, 1995:27; Harding, 1996b:391; Gilchrist, 1996:386; Hollingworth, 1997:8-9; Miller & Gilchrist, 1997:9; Andriessen, 1999a:2).

Flanagan (1997b:35) emphasizes that any factors causing immuno-suppression will influence a patient's ability to respond classically to the presence of infective organisms.

Immuno-suppressed patients may present with generalized septicaemia without any localized evidence of wound infection as described above. The same author cautions that failure to discriminate between the normal inflammatory response and the presence of infection may further complicate accurate assessment of clinical wound infection. For the purposes of this study the researcher assessed patients for any of the above signs and symptoms whilst considering risk factors, listed in Table 4.2, which may predispose patients to infection.

TABLE 4.2: Risk factors which may predispose to wound infections

Risk Factors	Rationale
Age	Patients over 65 years have a significantly higher incidence of wound infection.
Build/height for weight	Obesity increases wound infection rate to 13.5%.
Nutritional status	Poor nutrition increases the infection risk.
Diabetes	Hyperglycaemia affects the body's defence mechanism by impairing the response of white blood cells – neutrophils in particular.
Special risks	Irradiation, steroids and immunosuppressive drugs cause greatly increased infection rates.
Underlying disease	Some underlying diseases may directly affect the healing process, whilst others may cause a level of disability which may affect the patient's ability to maintain safe standards of hygiene, thus increasing the risk of infection.

(Dealey, 1994:29,30 and Silhi, 1998:51)

4.3.2 Assessment of the patient

Assessment of the patient should address the *physical health and complications*, *nutritional assessment and management* and the *psychosocial assessment and management.*

4.3.2.1 Physical health and complications

Since a pressure sore should be assessed in the context of the patient's overall physical and psychosocial health, a complete history and physical examination should be performed. Additionally, wound care practitioners should be alert to complications associated with pressure sores. These include amyloidosis, endocarditis, osteomyelitis, bacteraemia, advancing cellulitis, heterotopic bone formation, maggot infestation, meningitis, perineal-urethral fistula, pseudo-aneurysm, septic arthritis, sinus tract or abscess, squamous cell carcinoma in the pressure sore and systemic complications of topical treatment such as iodine toxicity and hearing loss after topical neomycin and systemic gentamycin (AHCPR. 1994:4).

4.3.2.2 Nutritional assessment and management

Numerous studies have linked malnutrition with pressure sores (Bridel, 1993:236; Dealey, 1994:86; Lewis, 1996:483; James,1997a:8; Lewis, 1997:41; Banks, 1998f:318).

Nutritional screening is therefore an essential part of the initial assessment. The goal of nutritional assessment and management is to ensure that the diet of the patient contains nutrients adequate to support healing. In this study the patients' nutritional status was assessed by means of the Braden risk assessment scale.

4.3.2.3 Psychosocial assessment and management

The presence of a wound, especially a chronic wound, may cause stress, anxiety and depression in a patient. In some cases anxiety may even evoke dermatological conditions (Dealey, 1994:32). Therefore, a psychosocial assessment that provides the information necessary to formulate a plan of care consistent with individual and family preferences, goals and abilities, is necessary. According to the Agency for Health Care Policy and Research (1994:7) the goal of psychosocial management is to create an environment conducive to patient adherence to the pressure sore treatment plan.

Thus far two of the four basic principles of pressure sore management have been discussed, namely: *pressure sore risk assessment* and *assessment* of the pressure sore(s) as well as the patient. In the following sections *relieving pressure* and *pressure sore (wound) care* will be reviewed.

4.4 RELIEVING PRESSURE

The most important prevention practice that must be achieved on a consistent basis is minimization of pressure over bony prominences and existing pressure sores (Patterson & Bennett, 1995:920). In the following paragraphs positioning techniques and support surfaces for both *bed-* and *chair-bound* patients will be discussed.

4.4.1 Bed-bound patients

Positioning devices may be used to raise a pressure sore off the support surface. Where the patient is no longer at risk for developing pressure sores, these devices may reduce the need for pressure–reducing overlays, mattresses and beds. According to the AHCPR (1994:9) a written repositioning schedule should be established based on the patient's risk for additional sores and on the response of the tissue to pressure. The same authors propose that patients at higher risk of additional sores and those with a longer duration of reactive hyperaemia should be turned more frequently.

Bed-bound patients judged unable to reposition themselves should be turned gently and without causing additional mechanical trauma, sequentially from back to left to right side every two to three hours. However, care should be taken to avoid placing direct pressure on the greater trochanter and lateral malleolus by using the so-called *30^0 tilt technique*. This technique involves placing the patient in a laterally inclined position, supported by pillows, with their back making a 30^0 angle with the support surface. Positioning devices such as pillows should be placed between the knees and lower legs to relieve pressure, as well as along the back and arms to maintain optimal positioning (Dealey, 1994:93; Patterson & Bennett, 1995:920).

When supine, heels must be elevated off the support surface to prevent pressure sores from developing. This, according to Patterson and Bennett (1995:920), is a common and potentially devastating complication in patients recovering from hip fractures and strokes. In addition the head of the bed should be maintained at the lowest degree of elevation consistent with medical conditions and other restrictions. Maklebust and Sieggreen (1996) recommend that the head of the bed should not be raised more than 30 degrees. They also suggest that patients who must have the head of the bed elevated during meals or tube feedings should have the head lowered again about one hour after eating.

The most commonly used devices *thought* to relieve pressure and prevent pressure sore formation, include sheepskin fleeces and foam or air rings (doughnut-shaped devices). Sheepskin fleeces can absorb moisture thereby reducing the risk of friction. However they do not reduce pressure. Sheepskins can also increase the risk of infection and should therefore be laundered frequently. However, this causes them to become matted and they may form ridges under the patient, causing localised pressure damage. Foam or air rings do not prevent pressure sores either. In fact they increase pressure around the ring, causing congestion in the centre. This may result in oedema and blister formation (Banks, 1998c:159). The tissue in the ring can also become ischaemic from lack of blood flow as a result of the pressure. Consequently sheepskins and rings are not considered to be pressure relieving equipment (AHCPR, 1994:12-13; Patterson & Bennett, 1995:921).

The use of *proven* pressure relieving equipment is a useful adjunct to the main preventive measure of regular positioning. The different types of pressure relieving equipment include the following:

- Overlays
- Mattresses
- Beds
- Chairs
- Cushions
- Padding
- Pillows

The literature refers to various terms when discussing pressure relieving equipment. Therefore the following terms will be defined.

- ***Interface pressure***

The pressure at the interface between the surface on which an individual is sitting or lying and a bony prominence. It is usually described in terms of the pressure exerted by the surface upon the individual.

- ***Support system***

A general term used to describe all pressure relieving equipment.

- ***Pressure relieving equipment***

Equipment that moulds or contours itself around the body. This reduces the pressure over the bony prominences by distributing the pressure.

- ***Overlays***

These are also called toppers and are laid on top of a mattress.

- ***Mattresses***

These are intended to replace the ordinary mattress. If they are laid on top of an ordinary mattress, they may be too high and unstable for safe patient care.

- ***Beds***

Total systems comprising a bedframe and mattress

- ***Dynamic systems***

Support systems that actively provide pressure relief or pressure reduction.

- ***Static systems***

Support systems that remain stable.

Young (cited in Dealey, 1997: 58) proposed a number of criteria by which support systems may be assessed or selected for use. Young's criteria are as follows: effectiveness, ease of use, maintenance, ease of nursing procedures and patient acceptability.

Using these criteria Table 4.3 summarises information about the different types of overlays, mattresses and beds.

TABLE 4.3: Assessing overlays, mattresses and beds

Effectiveness	Ease of use	Maintenance	Ease of nursing procedures	Patient acceptability
Hollow core fibre overlays				
Suitable for low risk patients	Good	Laundering can result in matting of fibres	Not so easy moving patient in bed	Generally good
Foam overlays				
Good pressure reduction – for low to medium risk patients	Good	No problems	Generally good – raises height of bed – consideration with transfers	Generally good
Gel overlays				
Only demonstrated for operating table use	Heavy to move	None required	No problems	May find it cold to touch

Table 4.3 continues...

TABLE 4.3: Assessing overlays, mattresses and beds continued...

Effectiveness	Ease of use	Maintenance	Ease of nursing procedures	Patient acceptability
Static air overlays				
Suitable for medium to high risk patients	Must be correctly inflated	Vulnerable to punctures	Generally no problems	Generally good
Alternating pressure overlays				
Suitable for medium to high risk patients	Some training needed, but fairly simple to use	Annual maintenance check	Generally no problems – raises height of bed	Mostly good – some find movement unpleasant
Low air loss overlays				
Suitable for medium to high risk patients	Some training needed, but fairly simple to use	Equipment most often rented	Generally no problems	Some find the pump noisy
Foam replacement mattresses				
Performs better than a standard mattress – for medium risk patients	None required	Annual check for grounding	No problems	Generally good
Gel mattresses				
Suitable for medium to high risk patients	Heavy and difficult to move from one bed to another	None	May be difficult to move patients on it	Some patients may find the mattress unstable
Alternating air pressure mattress				
Suitable for high risk patients	Some training needed; fairly simple to use	Annual maintenance check	Generally no problems	Mostly good; some find movement unpleasant
Airwave mattress				
Suitable for high risk patients and those with pressure sores	Some training needed; fairly simple to use	Annual maintenance check	Generally no problems	Mostly good; some find it a little hard

Table 4.3 continues...

TABLE 4.3: Assessing overlays, mattresses and beds continued...

Effectiveness	Ease of use	Maintenance	Ease of nursing procedures	Patient acceptability
Dynamic air flotation mattresses				
Suitable for high risk patients and those with pressure sores	Some training needed; fairly simple to use	Annual maintenance check	Generally no problems	Mostly good; some find movement unpleasant
Low air loss mattresses				
Suitable for high risk patients	Some training needed; fairly simple to use	Equipment most often rented	Generally no problems	Some find the pump noisy
Low air loss beds				
Suitable for high risk patients and those with pressure sores	Complex equipment training needed	Usually rented	Generally no problems – some may find the bed high	Generally good
Air-fluidised beds				
Suitable for high risk patients and those with pressure sores	Training needed	Usually rented	Generally no problems	Generally good

(Banks, 1998c:159-160; Pring, 1998:173-174; Groen & Groenier, 1999:335; Scott, Baker, Kelly, Stoddard & Leaper, 1999:437-439; Russel, Reynolds, Carr, Evans, & Holmes, 2000:52-55; Gaymar Industries Inc., 2000)

As can be seen in Table 4.3 a variety of support surfaces have been shown to provide an environment in which pressure sores improve. According to the AHCPR (1994:11) however there is no compelling evidence that *one support surface consistently performs better than all others, under all circumstances.* Therefore, the caregiver should consider several factors when selecting a support surface including the clinical condition of the patient, the nature of the care setting and the characteristics of the support surface. Another obvious and important factor to consider is the cost.

Many of the pressure support systems discussed in Table 4.3 are costly and beyond the reach of the majority of patients in community settings. It is therefore imperative that caregivers in community settings emphasize the importance of frequent repositioning, the *30^0 tilt technique* and the correct use of pillows. It should also be noted however, that support surfaces are only *one* part of a comprehensive treatment plan. Should a pressure sore fail to heal, the entire plan should be re-evaluated before the support surface is changed.

4.4.2 Chair-bound patients

According to Collins and Shipperley (1999:123) seated individuals are at risk from developing pressure damage for the following reasons:

- A small body surface area has to support a disproportional amount of body weight;
- The anatomy of the pelvis makes it difficult to maintain stability, leading to individuals adopting a poor position;
- The properties of the seating cushion may be inadequate for the patient or;
- The chair itself may be of a poor design or in poor condition.

A patient who has a pressure sore on a sitting surface should avoid sitting. However, if the pressure on the sore can be relieved, limited sitting may be allowed. Proper positioning is important whilst sitting and the caregiver should consider postural alignment, distribution of weight, balance, stability and pressure relief when positioning sitting individuals. For immobile patients in chairs, repositioning should occur every hour given the greater pressure at the sacrum with sitting. Individuals who are able should be taught to shift their weight every 15 minutes while seated (Dealey, 1994:97; AHCPR, 1994:12; Patterson & Bennett, 1995:921; Dealey, 1997:70).

Many chairs have a reclining back of between 15^0 and 40^0 which puts the patient in a semi reclining posture. This may make it more difficult for the patient to get up. Dealey (1994:97) recommends that a chair should have a recline of not more than 10^0 enabling the patient to move more freely. Cushions may be added to chairs to improve pressure relief, but the same author states that the cushion should not make the chair so high that the patient's feet do not touch the floor.

Wheelchairs have a canvas base which exerts pressures up to 226 mmHg (Rithalia cited in Dealey, 1994:97). It is therefore essential that a cushion should always be used in a wheelchair. A wide range of cushions is available and wheelchair–bound patients need to have a specialist assessment to identify the cushion most suited to the specific needs of each one.

Since pressure is considered to be the most important causative factor in the aetiology of pressure sores, the *pressure relieving* principle of pressure sore management is vital. In the following section the final principle in pressure sore management namely *pressure sore (wound) care,* will be discussed.

4.5 PRESSURE SORE (WOUND) CARE

Initial care of the pressure sore involves protection of the surrounding skin, wound cleansing, debridement, the application of appropriate dressings and possibly adjunctive therapy.

4.5.1 Protection of the surrounding skin

The surrounding or peri-wound skin is vulnerable and needs to be both *cleansed* and *protected* (Krasner, 1992:40).

Hence the following measures may be implemented:

- Thoroughly, but gently without causing undue trauma, cleanse the surrounding skin with a mild non-irritating, hypo-allergenic soap and water and dry well.
- Apply a skin sealer such as Skin-prep® or affix transparent film to the surrounding skin.
- Use an appropriate absorbent dressing on wounds with a high level of exudate.
- Apply a hydrocolloid frame to the surrounding skin to which adhesive tape can be affixed.
- Clothing or tube gauze instead of adhesive tape may be used to keep dressings in place.
- A porous adhesive tape such as Micropore® may be used.
- Rotate skin areas to which adhesive tape is applied.
- Adhesive tape corsets and safety pins may be used to hold dressings in place thereby obviating the need to renew the tape at every dressing change (Krasner, 1992:40; Bradley & Pupiales, 1997:43 and Brychta *et al.*, 1999:110).

Dealey (1994:72) proposes that further research into this aspect of wound care is much needed.

4.5.2 Wound cleansing

Wound healing is optimized and potential for infection significantly decreased when all necrotic tissue, excess exudate, metabolic wastes, foreign debris or wound surface contaminants are removed from the surrounding skin and wound surface (Frantz & Gardner, 1994:38; Miller & Gilchrist, 1997:15-16).

According to Glide (1992:76) wound exudate appears to play an active role in wound cleansing and exudate should therefore be left undisturbed unless it is profuse and causing discomfort or hygiene problems to the patient or if it is obviously infected. The same author cautions that *repeated* cleaning of a wound that is clean, with very little exudate and signs of healthy granulation, may in fact do more harm than good. Unnecessary, excessive or inappropriate cleaning can traumatize newly formed, delicate tissues, reduce the surface temperature of the wound and remove exudate which itself may possess bactericidal properties, growth factors and proteases, thus delaying the wound healing process (Leaper, 1998:373). The Agency for Health Care Policy and Research (1994:15) supports this view and proposes that the benefits of obtaining a clean wound must be weighed against the potential trauma to the wound bed as a result of cleaning. Considering the above, wound cleansing may be defined as the removal of both organic and inorganic debris from the wound bed and surrounding skin, whilst maintaining the optimum local environment to facilitate wound healing.

4.5.2.1 Wound cleansers

Over the years many different cleansing solutions (medicated and non-medicated) have been in vogue for wound cleaning. The use of antiseptics has been one of the most controversial issues in wound care over the past decade.

Research has found that antiseptics have limited advantage over normal saline and some antiseptics can adversely affect blood flow in the healing wound. Therefore the gains made in killing bacteria are more than counterbalanced by the losses in interfering with the wound healing process (Glide, 1992:76). For the purposes of this study wound cleansers are defined as any agent used for cleansing a wound. A brief overview of some cleansing agents that have traditionally been used, is provided in the following paragraphs.

4.5.2.1 (a) Cetrimide

Cetrimide is effective against a wide range of Gram-positive and Gram-negative organisms. It is often used in combination with chlorhexidine – particularly in the initial cleansing of dirty wounds. An example of such a combination is Savlon®, which is a combination of 15% cetrimide and 1,5% chlorhexidine gluconate. Cetrimide however, has a toxic effect on fibroblast cells in culture and may cause irritation and sensitization. It is therefore not recommended as a *routine* cleanser of non-infected wounds (Frantz, 1991:48; Tilbury, 1991b:20; Dealey, 1994:12; Murphy, 1995:78; Bennett & Moody, 1995:65; Flanagan, 1997b:60).

4.5.2.1 (b) Chlorhexidine

Chlorhexidine 0,5% solutions are widely used and are effective against a wide range of Gram-positive and Gram-negative organisms and some fungi, but ineffective against acid-fast bacilli, spores and viruses. Examples of chlorhexidine solutions are Hibitane®, Hibidil® and Hibisol®. The efficacy of chlorhexidine is rapidly reduced by organic matter such as blood, pus and soap. Acquired resistance has been reported with *Proteus mirabilis* and *Pseudomonas aeruginosa* (Murray, 1988:75; Tilbury, 1991b:20; Dealey, 1994:12-13; Murphy, 1995:78; Lawrence, 1996:45).

4.5.2.1 (c) Chlorinated solutions

These include EUSOL (Edinburgh University Solution of Lime), Dakin's solution (surgical soda solution), Chloramine-T and Milton®. From a review of the literature several objections to the use of hypochlorites have been identified and include the following:

- Rapid deactivation in the presence of organic matter.
- Cytotoxic – particularly to fibroblasts, keratinocytes and leukocytes.

- Prolong the inflammatory response.
- Reduce capillary flow.
- May cause acute renal failure and hyponatraemia.
- Damage granulation and epithelial tissue.
- Reduce collagen synthesis and decrease wound tensile strength.
- Can act as an irritant to both the wound and the surrounding skin and cause oedema.
- Can cause some patients pain on contact.
- Have a short shelf life.
- Usage is both costly and time consuming as it requires frequent dressing changes (Tilbury, 1991b:17; AHCPR, 1994:15; Dealey, 1994:14; Frantz & Gardner, 1994:38; Patterson & Bennett, 1995:923; Whittington, 1995:33; Cooper & Lawrence, 1996c:379; Lawrence, 1996:44; Flanagan, 1997b:59-60; Miller & Gilchrist, 1997:13).

In view of this evidence several authors question the justification for their continued use and according to Murphy (1995:78) the British National Formulary no longer recommends them. There is however, still a body of medical opinion that questions this evidence and prescribes and supports the use of hypochlorites.

Critique against this evidence is the following:

- There appears to be a lack of consensual findings reported in the literature regarding the effects of hypochlorites on wound healing.
- Much of the research has methodological weakness.
- Some studies are anecdotal and descriptive.

- Studies reporting life threatening side-effects document single cases only.
- As many studies make use of animal wound models, the relevance of these findings remains uncertain and questionable.
- Very few studies have been conducted using humans.
- Nursing literature has had the tendency to refer to these studies without adopting a critical stance (Flanagan, 1997b:60).

It could be concluded that with the development and availability of alternative wound cleansers that are safe, effective and easy to use, the continued use of hypochlorites is risky.

4.5.2.1 (d) Hydrogen peroxide

Hydrogen peroxide has an oxidizing effect, which destroys bacteria. It reacts with catalase in wounds to cause frothing thereby helping to lift out foreign matter. Its effect lasts for the short period over which oxygen is released. It is also deactivated by the presence of organic matter. Hydrogen peroxide is cytotoxic to fibroblasts unless diluted to a strength of 0,003%.
However, this dilution is ineffective against bacteria (Dealey, 1994:13). Irrigation with hydrogen peroxide under pressure or into cavities may cause oxygen embolus and surgical emphysema. It may also cause an irritant skin response (Murray, 1988:75; Tilbury, 1991b:20; Frantz & Gardner, 1994:38; Bennett & Moody, 1995:65; Maklebust, 1995:48; Patterson & Bennett, 1995:65; Whittington, 1995:33).

4.5.2.1 (e) Iodine

Iodine is a broad spectrum antiseptic available in both an alcohol and an aqueous solution. The latter is used in wound care, usually as povidine iodine 10% which contains 1% available iodine. It is used as a skin disinfectant and to clean grossly infected wounds.

Studies have found it to be effective against MRSA (Methicillin Resistant *Staphylococcus aureus*). Lawrence (1998b:422) cautions that the findings of these studies may be attributable to methodological bias. According to Dealey (1994:13) research has found it to be cytotoxic to fibroblasts unless diluted to 0,001%, that it retards epithelialization and lowers the tensile strength of the wound. It has also been reported that povidine 5% damaged the micro-circulation of the healing wound, but that a 1% solution was innocuous (Ferguson, 1988:55; Tilbury, 1991b:21; Lawrence, 1996:44).

Its antimicrobial action is reduced by contact with organic matter such as pus and exudate, therefore the preparations must be applied at intervals sufficiently short for the brown colouration to persist (active iodine is brown, inactivated iodine converts to colourless iodides). Toxic effects that can be associated with iodine include mental depression, nervousness, insomnia, myxoedema, hypersensitivity and skin reactions (Lawrence, 1998b:422). The same author adds that the likelihood of encountering these adverse effects depends on the concentration and the particular use of povidone-iodine.

Due to reports of its adverse effects, as described above, some authors have questioned its use in open wounds. However, new, low-concentration, slow-release formulations that have been developed appear to be safe, have useful antimicrobial properties and may be effective for the treatment of a variety of wounds. In view of these new developments the European Tissue Repair Society unanimously agreed in 1997 that the use of iodine in wound care should be reconsidered (Gilchrist, 1997:150).

4.5.2.1 (f) Phenol solutions

Clear soluble phenol solutions include White phenol, Lysol® and Dettol®. These solutions are active against staphylococci, mycobacteria and Gram-negative bacteria such as pseudomonas.

As they are easily deactivated by organic matter and soap, they are used to disinfect *clean* environmental surfaces. Although effective as an environmental disinfectant, their use as routine wound cleansers is inappropriate (Ziady, Small & Louis. 1997:111).

4.5.2.1 (g) Ringer's lactate

Irrigation with Ringer's solution contributes to efficient wound cleansing (Brychta *et al.,* 1999:108). According to Andriessen (1999b:12) the use of Ringer's lactate as a wound cleanser is particularly beneficial for infected wounds and wounds with compromised micro-perfusion. It is suggested that the pH level of Ringer's solution inhibits the growth of certain organisms such as *Pseudomonas aeruginosa.* Additionally, Ringer's is free from side-effects and also provides the cells with essential electrolytes such as sodium, potassium and calcium which favour cell proliferation and thus healing (Brychta *et al.,* 1999:55; Andriessen, 2000). However, there is no known published scientific research to confirm these suggested benefits of Ringer's lactate as a wound cleanser.

4.5.2.1 (h) Sodium chloride

Saline solution (0,9%) is probably the least harmful cleansing agent. It is a physiological compatible (isotonic) solution, nontoxic and effective in removing contaminants from the wound surface. Manufacturers frequently recommend that it be used in conjunction with many of the modern wound management products (Ferguson, 1988:52; Murray, 1988:75; Tilbury, 1991b:20; Glide, 1992:76; Krasner, 1992:39; Frantz & Gardner, 1994:38; Dealey, 1994:16; AHCPR, 1994:15; Bux, 1996:307; Miller & Gilchrist, 1997:13; Flanagan, 1997b:61; Gilchrist, 1999).

Saline is readily available and relatively inexpensive since it can also be made at home. The AHCPR (1994:15) provides the following recipe:

- Use 1 gallon (4,5 litres) of distilled water or boil 1 gallon (4,5 litres) of tap water for 5 minutes. **Do not use well (borehole) water or seawater.**
- Add 8 teaspoons (40 ml) of table salt to the distilled or boiled water.
- Mix the solution well until the salt is completely dissolved. Be sure storage container and mixing utensil are clean (boiled).
- Cool to room temperature before using. This solution can be stored at room temperature in a tightly covered glass or plastic bottle for up to one week.

4.5.2.1 (i) Water

Tap water may be used to irrigate and cleanse non-infected wounds. Water has been used for centuries without any reported detrimental effects and has always been used in first aid situations to clean wounds (Dealey, 1994:16; Murphy, 1995:80). Fears concerning bacterial contamination from non-sterile water supplies and subsequent effects on wounds appear to be unfounded according to Flanagan (1997b:61). The same author suggests the running of tap water for a few minutes prior to wound cleansing to flush out any potentially high levels of bacteria. In fact a study done in Sweden found more bacterial growth – particularly *Pseudomonas aeruginosa* - in wounds cleansed with sterile saline than with tap water (Lindholm 1998:1; Lindholm, Bergsten & Berglund, 1999:10).

Notably all the research mentioned above has been done in first world or developed countries. It might therefore be inappropriate to generalize the findings of these studies to under-developed and/or developing countries such as South Africa.

4.5.2.2 Temperature of cleansing solutions

Research has demonstrated that phagocytic and mitotic cellular activity significantly decreases at temperatures below 28^0C. Lengthy dressing changes and the application of cool cleansing solutions may reduce the surface temperature by several degrees (Glide, 1992:74; Dealey, 1994:18).

It was found that during dressing changes surface temperature could drop so low that it would take at least four hours before mitotic activity reached a peak again (Ferguson, 1988:53 citing Johnson, 1986). The ideal wound temperature to promote healing, has been identified as 37^0C (Miller & Gilchrist, 1997:19). Cleansing solutions should therefore be stored at room temperature or may be warmed if cold (Flanagan, 1997b:62).

4.5.2.3 Cleansing techniques

Wounds may be cleansed using either a *vigorous* or a *gentle* technique.

4.5.2.3 (a) Vigorous cleansing techniques

Vigorous techniques include placing the wound in a whirlpool. This technique may be considered for cleansing pressure sores that contain thick exudate, slough, or necrotic tissue. The immersion of wounds in water with forceful agitation softens necrotic eschar/tissue and makes them more amenable to sharp debridement. However, care should be taken to avoid trauma that may result if the wound is positioned too close to the high-pressure water jets (Frantz & Gardner, 1994:38).

4.5.2.3 (b) Gentle cleansing techniques

Gentle techniques include gently wiping the wound surface with a soft, moist, gauze dressing or gentle irrigation.

When cleansing by gently wiping the wound surface, care should be taken not to disrupt granulation tissue. According to Frantz & Gardner (1994:38) when cleansing the wound in this manner, a "patting" technique is preferable to rubbing the wound.

Wound irrigation is recommended for wounds with granulation tissue, in which the goal is to remove surface contaminants and leave granulation tissue unharmed. Safe and effective pressure sore irrigation pressures range from four to 15 pounds per square inch (psi). Irrigation pressures below four psi may not cleanse the wound adequately, and pressures greater than 15 psi may cause trauma, wash away growth factors and proteases and drive bacteria into the wound tissue. Irrigation devices that deliver eight psi of pressure have been found to be more effective in removing bacteria and preventing infection than is a bulb syringe (Krasner, 1992:39; Frantz & Gardner, 1994:38; AHCPR, 1994:15, 16; Leaper, 1998:373). Table 4.3 indicates the irrigation pressures delivered by various clinically available devices (see Table 4.3, p.99).

TABLE 4.3: Irrigation pressures delivered by various clinical devices

Device	Irrigation Impact Pressure (PSI)
Spray Bottle-Ultra Klenz® [a] (Carrington Laboratories, Inc., Dallas TX)	1.2
Bulb Syringe[a] (Davol Inc., Cranston, RI)	2.0

Table 4.3 continues...

TABLE 4.3: Irrigation pressures delivered by various clinical devices continued...

Device	Irrigation Impact Pressure (PSI)
Piston Irrigation Syringe (60-MI) with catheter tip (Premium Plastics. Inc., Chicago, IL)	4.2
Saline Squeeze Bottle (250-mL) with irrigation cap (Baxter Health Care Corp., Deerfield, IL)	4.5
Water Pik® at lowest setting (#1) (Teledyne Waterpik, Fort Collins, CO)	6.0
Irrijet® DS Syringe with tip (Ackrad Laboratories, Inc., Cranford, NJ)	7.6
35-mL syringe with 19-gauge needle or angiocatheter	8.0
Water Pik® at middle setting (#3)[b] (Teledyne Waterpik, Fort Collins, CO)	42
Water Pik® at highest setting (#5)[b] (Teledyne Waterpik, Fort Collins, CO)	>50
Pressurized Cannister-Dey-Wash® [b] (Dey Laboratories, Inc., Napa, CA)	>50

(a) These devices may not deliver enough pressure to adequately cleanse wounds.

(b) These devices may cause trauma and drive bacteria into wounds. They are not recommended for cleansing soft-tissue wounds.

(AHCPR, 1994:17 citing Beltran, Thacker & Rodeheaver, 1994)

In this study the gentle-cleansing techniques were utilized.

4.5.3 Debridement

Debridement involves the removal of devitalized tissue. Moist, devitalized tissue supports the growth of pathological organisms. The presence of moist, devitalized tissue and foreign debris provide a culture medium for the growth of pathological organisms and the ultimate development of a wound infection. Therefore, the removal of devitalized tissue such as necrotic tissue and slough, favourably alters the healing environment of a wound (AHCPR, 1994:13; Frantz & Gardner, 1994:36-37; Vowden & Vowden, 1999a:237). There are several methods of wound debridement namely: sharp (surgical), mechanical, enzymatic, autolytic and biological.

4.5.3.1 Sharp (surgical) debridement

Sharp or surgical debridement involves the use of a scalpel, scissors, or other sharp instrument to remove devitalized tissue. This is the most rapid form of debridement and the most appropriate technique for removing adherent eschar and devitalized tissue in wounds. In patients with clotting disorders this technique is contra-indicated. However, it is essential that those performing sharp debridement possess the necessary clinical skills and meet professional licensing requirements (Krasner, 1992:40; Frantz & Gardner, 1994:37-38; AHCPR, 1994:13; Miller & Collier, 1997:18; Vowden & Vowden, 1999b:294). Dealey (1994:119) supports this view and proposes that surgical debridement should only be performed by a skilled surgeon because of the risk of capillary bleeding. Consequently this method might have considerable cost implications.

4.5.3.2 Mechanical debridement

This debridement method is accomplished by placing saline-soaked coarse-mesh dressings in the wound and allowing the dressings to dry. These dressings are often referred to as wet-to-dry dressings. According to Frantz and Gardner (1994:37) this method is controversial because granulation tissue also adheres to the dressing and is continually disrupted at dressing changes. The same authors suggest that wet-to–dry dressings should be discontinued once the wound begins to granulate. Flanagan (1997b:64) argues that this technique usually requires frequent dressing changes and in practice this may encourage the tight packing of wound cavities, which compromises capillary blood flow, causes discomfort to the patient and prolongs wound closure. Furthermore, mechanical dedridement can cause considerable pain to the patient despite the persistent belief that since the tissue is dead no pain should be experienced (Tong, 1999:338). In view of this argument, it is proposed that the continuation of this method of debridement should be reconsidered.

4.5.3.3 Enzymatic debridement

Enzymatic debridement is accomplished by applying topical debridement agents to devitalized tissue on the wound surface (AHCPR, 1994:13; Flanagan, 1997b:62). Despite the availability of numerous debriding agents on the market, Bradley, Cullum and Sheldon (1999) found insufficient evidence to promote the use of one debriding agent over another. The different types of enzymes in these agents react differently and require specific secondary dressings and changing schedules to avoid adverse reactions such as maceration, inflammation or pain in the wound and surrounding skin. This debridement method is contra-indicated in patients with clotting disorders and as with any other method, it should be used cautiously in patients with infection, cellulitis, cavity wounds, wounds with exposed nerves, or neoplasms (Krasner, 1992:40; Dealey, 1994:16).

4.5.3.4 Autolytic debridement

This debridement method involves the use of synthetic dressings to cover a wound and allow devitalized tissue to self-digest from enzymes normally present in wound fluids. Although this method is much more time consuming than sharp debridement, it is more selective and usually painless for the patient. Hydrogels, hydrocolloids and transparent film dressings are good choices to promote autolysis (Krasner, 1992:40). According to Krasner (1992:40) this method should be used with caution in immuno-suppressed patients and the Agency for Health Care Policy and Research (1994:15) adds that this technique should not be used if the wound is infected.

4.5.3.5 Biological debridement

This method of debridement – also known as biosurgery - involves the use of myiasis (maggots). The larvae used for the treatment are those of *Lucilia sericata* or the greenbottle fly. The maggots (or larvae) are specifically bred so that they do not carry any bacteria. They are introduced onto a wound from a transparent flask and contained with a net dressing covered with an absorbent pad. Originally it was suggested that the number of larvae applied should not exceed 10 per cm^2 as this is about the maximum number that can fit into this area when fully grown. However, according to Thomas, Andrews and Jones, (1998:524) the maximum number applied is not critical, provided that a vast excess is not used and the surrounding skin is well protected. Each treatment is left in place for two to three days. Proponents of the therapy claim that it is a fast, safe and effective method to treat wounds that need debriding, are infected or are non-healing (Thomas, Jones, Shutler & Andrews in Miller & Gilchrist, 1997:21; Courtenay, 1999:177; Vowden & Vowden, 1999a:240). The main action of the maggots is two-fold. First, they break down dead tissue via secretion of enzymes.

They then ingest this liquefied material along with wound bacteria. According to Miller and Gilchrist (1997:22) it appears that maggots may stimulate the production of granulation tissue. Disadvantages of maggot therapy include aesthetic reasons and local discomfort and itching sometimes caused by their use (Flanagan, 1997b:65).

The selection of any particular wound debridement method, as discussed above, should be carefully considered and is dependent on a combination of factors, namely clinical and practical considerations.

Clinical considerations include:

- Potential contamination
- Location of the wound
- The extent of tissue damage and type of tissue involvement
- The size of the wound and extent of devitalized tissue
- The amount of exudate production

Practical considerations include:

- Time available.
- Availability of resources.
- User skill, knowledge base and professional accountability.
- Cost-effectiveness.
- The care environment – hospital or community.
- The patient's wishes (Flanagan, 1997b:63; Vowden & Vowden, 1999a:240).

Finally, the debridement method selected should be appropriate to the patient's condition and treatment goals.

4.5.4 Topical treatment

Over the years, as with wound cleansers, many topical treatment methods have been used to treat wounds. Some of these methods include the use of vegetable shortening, egg whites, petroleum jelly and baby powder, urea of chloroform, antacids, and many more. Cobwebs, clay and wool or linen bandages sometimes soaked in gum or boiled in water or wine are all old documented treatment methods. A few of these treatment modalities have some beneficial properties, however there are no known research studies to support their use in wound healing (Whittington, 1995:32).

Despite much research and advances in modern wound care, a wide variety of topical treatments are still being applied to wounds without any recognition of the need for research-based care. In the following paragraphs some of these topical treatments, as encountered by the researcher in practice locally, will be discussed. These topical treatments include the use of antibiotics, dyes, sugar and essential oils.

4.5.4.1 Antibiotics

A wide range of antibiotics is available in topical form. They are potentially hazardous and are not always absorbed into the wound. Because of varied barriers to diffusion in the wound, such as necrosis and pus, antibiotics can only reach the actual infection deep in the wound with difficulty. Subsequently there is considerable risk to the patient of sensitization as well as the development of resistant organisms especially when used routinely over prolonged periods of time in uninfected wounds as is currently the practice of many health care professionals (Dealey, 1994:15; Hosein, 1996:389; Brychta *et al.*, 1999:55). This risk is compounded by the practice of concocting topical mixtures of different topical and in some cases, crushed or powdered systemic antibiotics.

Another serious disadvantage of prolonged topical antibiotic use is the occurrence of contact allergies. Furthermore, certain topical antibiotics impair proliferation and epithelialisation of wounds (Brychta *et al.*, 1999:55). Because of the reasons mentioned above the topical use of antibiotics has become controversial and is no longer recommended.

The AHCPR (1994:18) however, recommends the use of a *two week* trial of topical antibiotics for clean pressure sores that are not healing or are continuing to produce exudate after two to four weeks of optimal patient care. The antibiotic should be effective against Gram-negative, Gram-positive and anaerobic organisms, for example silver sulphadiazine. The agency further recommends the use of *appropriate* systemic antibiotic therapy for patients with bacteraemia, sepsis, advancing cellulitis or osteomyelitis. Systemic antibiotics are not required for pressure sores with *only* clinical signs of local infection (AHCPR, 1994:20).

4.5.4.2 Dyes

Dyes have traditionally been used as astringents to dry macerated skin around wounds and for their antiseptic properties. A study by Niedner and Scopf in 1986 (as cited in Dealey, 1994:15) found that *0,5% brilliant green* significantly retarded the formulation of granulation tissue.

Acriflavine is an antimicrobial dye structurally related to acridine. Acriflavine hydrochloride is a mixture of 3,6-diamino-10-methylacridium-chloride hydrochloride and 3,6-diaminoacridine dihydrochloride. The acridine derivatives are slow-acting antiseptics. They are bacteriostatic against Gram-positive bacteria, less effective against Gram-negative bacteria and ineffective against spores. Their activity is increased in alkaline solutions and is not reduced by tissue fluids.

Acriflavine has been used in the treatment of infected wounds, burns and for skin disinfection. However, prolonged treatment may delay wound healing. Additionally, hypersensitivity to acridine derivatives has been reported (Reynolds, 1993:782; Hift, 2000).

Crystal violet (Gentian violet) was once widely used as an astringent. Its use on broken skin and mucous membranes is now banned in the United Kingdom following reports that the dye was carcinogenic in animals (Murphy, 1995:78). Despite this, some local health care professionals still continue with its use on wounds.

Mercurchrome is a mercury compound widely used for its bacteriostatic and fungistatic properties. There have been several reports of mercury toxicity following its use as well as anaphylaxis and aplastic anaemia (Tillbury, 1991b:20-21; Dealey, 1994:15). According to Murphy (1995:78) mercury compounds may cause dermatitis, hypersensitivity and toxicity in epidermal cells. Considering the associated hazards descibed above, there can be no justification for its use on wounds.

4.5.4.3 Sugar

Sugar paste has been used in wounds, usually in the form of honey, for many centuries. More recently sugar pastes have been developed to clean dirty and malodorous wounds and no toxic effects have been reported (Tillbury, 1991b:21-38; Dealey, 1994:24). It is thought that sugar paste, which has a high osmotic pressure, exerts its antibacterial effect by competing for the water present in the bacterial cells (Murphy, 1995:80).

According to Lawrence (1999:155) concentrations of sugars, such as 70% glucose, are bactericidal to some species but not fungicidal.

The same author adds that honey can contain antiseptics such as hydrogen peroxide, which may further enhance its benefits. Research undertaken by Cooper and Molan (1999:161) found that honey with an average level of antibacterial activity can be effective in preventing the growth of *pseudomonas* on the surface of a wound even if the honey were diluted more than ten-fold by exudation from the wound. As *pseudomonas* is generally accepted to be an important pathogen in chronic wounds, it would seem that the use of honey on wounds in which the presence of *pseudomonas* causes a problem, might be a treatment option.

4.5.4.4 Essential oils

Essential oils are thought to interact with the body pharmacologically, physiologically and psychologically. In order to establish the role of essential oils in wound care, Baker (1998:355) carried out a literature search of controlled trials, randomised controlled trials and case studies reported since 1980. Table 4.4 presents examples of reports on the use of essential oils in wound care.

TABLE 4.4: Examples of the use of essential oils in wound care

Management of pain
◈ Ylang ylang *(Cananga odorata)* ◈ Wintergreen *Gaultheria procumbens)*
Management of odour
◈ Bergamot *(Citrus bergamia)* ◈ St John's Wort *(Hypericum perforatum)*
As an anti-inflammatory agent
◈ Lavender *(Lavandula officinalis)* ◈ Roman camomile *(Anthemis nobilis)*
Wound cleansing
◈ Myrrh *(Commiphora myrrha)* ◈ Tea tree *(Melaleuca alternifolia)*

(Heenan, 1997; Baker, 1998:355)

According to Heenan (1997) preliminary findings of trials comparing the effectiveness of tea tree oil and vancomycin against MRSA, suggest that tea tree oil may well have a role and that it is probably much safer than vancomycin.

Price and Price (as cited in Baker, 1998:355) suggest combining the oil with water and either spraying it on the wound or applying it to the wound on a non-adherent dressing and securing the dressing in place with cling film to prevent evaporation of the oil. However, the same authors identify the following possible adverse effects from the use of essential oils in wound care:

- dermal toxicity (some essential oils are skin irritants, usually those containing high levels of aldehydes or phenols); irritation is usually short-lived and localised;

- mucous membrane irritation (essential oils with a substantial phenol content);

- phototoxicity (this occurs when the essential oils react with the skin when exposed to ultraviolet radiation. It may result in erythema, hyperpigmentation and possibly vesiculation);

- contact sensitisation (a few oils may cause a reaction after repeat applications, appearing as redness, irritation and possibly vesiculation).

Despite obvious support for the use of essential oils in wound care from many health care professionals, it is difficult to find reliable scientific evidence from which guidelines for good practice could be developed.

It is clear from the preceding paragraphs that there is very little, if indeed any evidence, to support the use of routine topical applications or treatments to *uninfected pressure sores*. However, wounds certainly need to be covered and in the following section wound dressings will be discussed.

4.5.5 Wound dressings

Throughout the centuries humans have always covered their wounds. The primary function of dressings was for protection. However, in more recent times, due to the expanded knowledge of the physiology of the healing process and the recognised influence of dressings on the biochemical and morphological processes during healing, the function of wound dressings has gone beyond that of mere protection.

A review of the literature reveals current consensus that the attributes of an ideal dressing should be the following:

- To protect the wound.
- Not to contaminate the wound with particles and toxic substances.
- Allow gaseous exchange of oxygen, carbon dioxide and water vapour.
- Allow removal without causing trauma.
- Keep the wound warm and moist.
- Assist the removal of exudate and necrotic tissue.
- Be impermeable to micro-organisms.
- Allow monitoring of the wound.
- Be conformable and moldable.
- To be safe to use (non-toxic, non-sensitizing, non-allergenic)
- To be capable of absorbing exudate where necessary (Dealey, 1994:19; Bennett & Moody, 1995:50; Dale, 1997:12; Miller & Collier, 1997:16; Fox, 1998:87; Culley, 1998:884; Baranoski, 1999).

Advances in the development of wound dressings in the last 20 years have meant that a wide range of different dressing materials has become available to practitioners. The development of the more recent dressing products is all based on the fundamental principle of promoting moist wound healing. Despite the wide variety of dressing products currently available on the market, new products are constantly being developed. Consequently, the *selection* of dressing materials has become increasingly complex as the range of wound dressing products expands. In an attempt to simplify the selection of wound management products, dressings are usually classified according to generic name. However, the *classification* of wound dressings is also becoming more complicated since not all products sharing the same classification work in exactly the same way and manufacturers are beginning to develop products, referred to as composite dressings, that are a combination of one or more of the generic groups (Hess, 2000a:26). In the following paragraphs the major categories of primary dressings, examples, their indications, advantages and disadvantages will be reviewed.

4.5.5.1 Semi-permeable adhesive film dressings

These dressings are transparent, adhesive-coated, polyurethane, semi-permeable films (see Table 4.5, p.121).

4.5.5.2 Hydrocolloids (wafers and pastes)

Hydrocolloid dressings consist of a hydrocolloid base containing a variety of constituents including gelatine, pectin and sodium carboxymethylcellulose in an adhesive polymer matrix. The hydrocolloid base is hydrophilic in contrast to the adhesive matrix, which is hydrophobic. The outer layer of these dressings is a combination of waterproof polyurethane foams and films which prevents strike-through.

TABLE 4.5: Transparent adhesive film dressings

Examples	Indications	Advantages	Disadvantages
OpSite® (Smith & Nephew) *Bioclusive®* (Johnson & Johnson Medical) *Hydroflim®* (Hartmann) *Tegaderm®* (3M)	◦ Minor burns, lacerations and abrasions ◦ Skin donor sites ◦ Pressure sores: stage 1 and some stage 2 sores ◦ Secondary dressing in certain situations ◦ Post-operative wounds ◦ Entrance sites of peripheral and central intra-venous lines	◦ Impermeable to external fluids and bacteria ◦ Transparent/hypo-allergenic/vapour-permeable ◦ Conformable ◦ Can be left in place for up to seven days ◦ Does not require secondary dressing ◦ Reduces surface friction ◦ Reduces pain in superficial wounds ◦ Allows easy tracing of the wound	◦ Non-absorptive ◦ Application can be difficult ◦ Cannot be used on wounds with fragile surrounding skin or infected wounds

(Willey, 1992:44, 45; Dealey, 1994:225, 226; Erwin-Toth & Hocevar, 1995:48; Walker, 1996:36, 37; Dale, 1997:13; Thomas, 1997c; Baranoski, 1999; Brychta *et al.*, 1999:102,103)

Montero, Cedeno, Oreamuno and Valverde (1999:16) compared hydrocolloid dressings (Comfeel™) and traditional gauze dressings in the treatment of pressure sores. The two dressings were compared in terms of the rate of wound healing and cost over an eight-week period. Results of the study showed that the healing time for pressure sores treated with the hydrocolloid dressings were shorter than those treated according to the traditional method. Furthermore the cost of treatment with the hydrocolloid (Comfeel™) was significantly lower compared with the traditional treatment. The results of this study confirm the findings of a similar study by Krysiak, Wolowicka and Dyk (1998:20) (see Table 4.6, p.123).

4.5.5.3 Hydrogels

Most of these products share a common basic structure consisting of about 2-3% of a gel-forming polymer such as carboxymethylcellulose, modified starch or sodium alginate, together with 20% propylene glycol as a humectant and preservative. The balance, about 80%, consists of water. Most hydrogels are similar in appearance but laboratory tests have indicated that their fluid donating properties can vary considerably. In addition some products are also able to absorb a limited amount of fluid from exuding wounds (Thomas, 1997c). Currently three forms of hydrogels are available:

- Amorphous hydrogels - packaged in tubes, foil packets and spray bottles.
- An impregnated-gauze hydrogel – an amorphous hydrogel impregnated into a gauze pad.
- Sheet hydrogels – consisting of a gel supported by a thin fibre mesh (Hess, 2000b).

TABLE 4.6: Hydrocolloids

Examples	Indications	Advantages	Disadvantages
Comfeel® (Coloplast) *DuoDerm®* (Convatec) *Granuflex®* (Convatec) *Tegasorb®* (3M Health Care) *Hydrocoll®* (Hartmann)	∘ Partial-thickness wounds ∘ Pressure sores: superficial stage 3 and some approved clean stage 4 ∘ Wounds with necrosis or slough ∘ Wounds with mild to moderate exudate	∘ Waterproof and impermeable to external bacteria and contaminants ∘ Conformable and easy to apply ∘ Support autolytic debridement ∘ Minimally to moderately absorptive ∘ Protect granulation and newly formed epithelial tissue ∘ Colour change indicates when to change dressing ∘ Can be used with compression for the treatment of venous ulcers ∘ Create a moist environment which promotes healing and is helpful for pain relief in the treatment of arterial leg ulcers, thus reducing the need for analgesics ∘ No secondary dressing is needed ∘ Help contain wound odour ∘ Last long, thus saving money and nursing time	∘ Not recommended for wounds with heavy exudate, sinus tracts, infections; wounds that expose bone or tendon; or wounds with fragile surrounding skin ∘ May be difficult to remove and may leave residue on the skin ∘ Not transparent ∘ Can melt at the edges, soften and wrinkle with wear and movement ∘ May curl or "seep" under edge ∘ Unpleasant odour from gelled dressing at dressing change ∘ Can cause sensitivity to the adhesive

(Fowler, Cuzzell and Papen, 1991:63, 64; Willey, 1992:44, 45; Dealey, 1994:198, 210; Erwin-Toth & Hocevar, 1995:48; Maklebust, 1995:49; Hofman, 1996:68; Dale, 1997:13; Krysiak, Wolowicka & Dyk, 1998:21; Baranoski, 1999; Brychta *et al.*, 1999:102,103)

In 1996 Colin, Kurring, Quinlan and Yvon (1996:444) compared the performance of a hydrogel (Intrasite Gel™) and a dextranomer paste (Debrisan Paste™) in the management of sloughy pressure sores in the hospital environment. They reported that the hydrogel and the paste performed to a similar standard in terms of debridement of non-viable tissue. At day 21, however, the median reduction in wound area was 35% in the hydrogel group compared with 7% in the dextranomer paste group. Furthermore at each assessment the hydrogel was found to be easier to apply than the dextranomer paste. The hydrogel was also found to be associated with less pain.

A subsequent study by Bale, Banks, Hagelstein and Harding (1998:65) compared the efficacy of two hydrogel dressings (Intrasite Gel™ and Sterigel™) in the debridement of necrotic pressure sores. This randomised, controlled, assessor-blind, clinical trial involved 50 patients whose wounds were assessed weekly using computerised wound analysis for four weeks or until debrided. The researchers concluded that there were no statistically significant differences in comfort, wound odour, surrounding skin condition or time to debridement between the two groups (see Table 4.7, p.125).

4.5.5.4 Absorption or filler dressings

Four preparations in this category include:

- Copolymer starch dressings
- Dextranomers
- Calcium alginates
- Hydrofibre dressings

TABLE 4.7: Hydrogels

Examples	Indications	Advantages	Disadvantages
IntraSite Gel® (Smith & Nephew) *Granugel®* (Convatec) *NU-Gel®* (Johnson & Johnson Medical)	◦ Partial-and full-thickness wounds (stage 2, 3, and 4 pressure sores) ◦ Wounds with necrosis or slough ◦ Burns and tissue damaged by radiation ◦ For softening of eschar ◦ For debridement and at all stages of healing up to the formulation of granulation tissue ◦ For filling dead spaces within a wound	◦ Provide a moist environment ◦ Soothing and cooling ◦ Fill dead spaces ◦ Promote autolytic debridement ◦ Provide minimal to moderate absorption ◦ Conform to wound bed ◦ Transparent to translucent ◦ Many are non-adherent ◦ Can be used when infection is present ◦ Easy to apply ◦ Available in sheets and gels	◦ Most require secondary dressing ◦ Not used for heavily exuding wounds ◦ May dry out, then adhere to wound bed (Sheet form in particular) ◦ May macerate surrounding skin ◦ If the incorrect depth of dressing is used, the wound may dry out around the edges

(Willey, 1992:44, 45; Dealey, 1994:14; Erwin-Toth & Hocevar, 1995:49; Maklebust, 1995:49; Walker, 1996:38, 39; Thomas, 1997c; Heenan, 1999:72; Hess, 2000b)

The majority of these dressings are a non-woven composite of calcium alginate fibres, a cellulose-like polysaccharide. It is a highly absorptive dressing which is manufactured from brown seaweed and forms a soft gel in the presence of wound exudate.

Another dressing in this category is the hydrofibre dressing which consists of a soft non-woven fibre of sodium carboxymethylcellulose. The hydrofibre acts by direct absorption of fluid into the fibres themselves. Conventional dressings, including alginates, absorb liquids into the interstitial space between the fibres. Direct absorption into the fibres greatly increases the fluid-handling capacity of the dressing per unit weight of dressing material (Robinson, 2000:32). A study by Armstrong and Ruckley (1997:344) which compared a hydrofibre dressing (Aquacel™) with a widely used alginate, found that the hydrofibre dressing achieved significantly longer wear times than the alginate. This translated into significant savings in terms of nursing time and overall cost of wound care (see Table 4.8, p.128).

4.5.5.5 Semipermeable polyurethane foam dressings

Polyurethane foam dressings have a hydrophilic action that provides a low adherent wound contact layer. Some of these dressings have moisture-vapour-permeable backings which are hydrophobic, preventing vertical strike-through. The exudate is absorbed horizontally and once the dressing is saturated, exudate becomes visible at the dressing edges as lateral strike-through. Although the various polyurethane foam dressings are classified under one title, their construction varies considerably.

In 1995 Bowszyc, Silny, Bowszyc-Dmochowska, Kazmierowski, Ben-Amer, Garbowska and Harding (1995:110) conducted a clinical trial in Poland during which the efficacy of a polyurethane foam dressing (Lyofoam™) and a hydrocolloid dressing (Granuflex™) was compared.

They found that both dressings were comfortable, caused little pain on removal and were easy to apply. However the same researchers reported that the foam dressing was significantly easier to remove from the wound than the hydrocolloid dressing.

In a subsequent study by Bale, Squires, Varnon, Walker, Benbow and Harding (1997:463) in which a polyurethane dressing (Allevyn Adhesive™) and a hydrocolloid dressing (Granuflex™) were compared in the management of pressure sores, they confirmed the results of the Polish study.

TABLE 4.8: Absorption or filler dressings

Examples	Indications	Advantages	Disadvantages
*Ferris PolyMem®** (Ferris Mfg.Corp.) *Debrisan®*** (Johnson & Johnson Medical) *Algi DERM®**** (Convatec) *Kaltostat®**** (Convatec) *Sorbsan®**** (Maersk) *Tegagen®**** (3M Health Care) *Sorbalgon®**** (Hartmann) *Aquacel® Hydrofibre***** (Convatec)	◦ Wounds with moderate to large amounts of exudate (donor sites, leg ulcers, pressure sores and fungating wounds) ◦ Wounds with combination exudate and necrosis ◦ Wounds that require packing and absorption ◦ Infected, exuding wounds	◦ Easy to apply and remove ◦ Absorb up to 20 times their weight in drainage ◦ Fill dead space ◦ Support autolytic debridement in presence of exudate ◦ Alginate dressings have haemostatic properties ◦ They can be used on infected wounds ◦ They provide a moist environment which relieves pain ◦ They are ideal for use in cavity wounds ◦ They are bio-degradable	◦ Require secondary dressing ◦ Not recommended for dry or lightly exuding wounds ◦ Can dry wound bed ◦ Will adhere to wound bed if there is insufficient exudate ◦ Produce a greenish gel which can be misinterpreted as a sign of wound infection

(Willey, 1992:45; Dealey, 1994:217, 228, 229, 234, 235; Erwin-Toth & Hocevar, 1995:49, 50; Maklebust, 1995, 49; Walker, 1996:37, 38; Convatec, 1996; Dale, 1997:13; Thomas, 1997c; Heenan, 1998:37, 38; Heenan, 1999:72; Brychta *et al.*, 1999:97,98; Robinson, 2000:32; Thomas, 2000:58,59)

* Copolymer starch dressings
** Dextranomers
*** Calcium alginate
**** Hydrofibre dressings

However, an additional finding of Bale and co-workers was that the absorbancy of the poylurethane foam dressing (Allevyn Adhesive™) was significantly better than that of the hyrdocolloid dressing.

Another multi-centre study which also compared the performance of a polyurethane dressing (Allevyn Adhesive™) to a hydrocolloid dressing (Granuflex™) in the management of stage 2 and 3 pressure sores, confirmed the findings of the two studies mentioned above. Moreover, they reported that in contrast to the hydrocolloid dressings (Granuflex™), the polyurethane dressings (Allevyn Adhesive™) were not associated with damage to the wounds or the surrounding skin (Shutler, Stock, Harding, Squires, Wilson, Vernon, Walker, Ridley and Benbow, 1995) (see Table 4.9, p.130).

4.5.5.6 Odour absorbing dressings

These low adherent dressings are combined with either activated charcoal cloth or activated carbon in order to reduce wound odour. The deodorising agent is combined with various other materials including alginates, foams or low-adherent wound contact layers (see Table 4.10, p.131).

4.5.5.7 Gauze impregnated dressings (Tulle Gras)

Open mesh, cotton, rayon, viscose or gauze impregnated with white or yellow soft paraffin, antiseptics or antibacterial agent (see Table 4.11, p.132).

4.5.5.8 Iodine-containing dressings

These are knitted viscose dressings impregnated with 10% povidone-iodine in a water-soluble polyethylene glycol base (see Table 4.12, p.133).

TABLE 4.9: Semipermeable polyurethane foam dressings

Examples	Indications	Advantages	Disadvantages
Allevyn® (Smith & Nephew) *Allevyn Adhesive*® (Smith & Nephew) *Tielle*® (Johnson & Johnson Medical) *Lyofoam*® (Acme United Corporation) *Allevyn Cavity*® (Smith & Nephew)	◦ Partial- and full-thickness wounds with minimal to moderate exudate (pressure sores, venous leg ulcers and burn wounds) ◦ Secondary dressing for wounds with packing to provide additional absorption ◦ Around drainage tubes	◦ Non-adherent ◦ Conformable (not *Allevyn Cavity*®) ◦ Manage light to moderate amounts of exudate ◦ Easy to apply and remove ◦ May be used under compression ◦ Can be used on wounds that have surrounding body hair ◦ Can be used on infected wounds (not *Tielle*®) ◦ Can be cut to shape/size of wound (not *Allevyn Cavity*®) ◦ *Lyofoam*® is highly permeable to moisture vapour and is also used as low adherent dressing for minor injuries and other wounds in the final stages of healing	◦ Require secondary dressing, tape or net (except *Tielle*® and *Allevyn Adhesive*®) ◦ Not for use with dry eschar, wounds with no exudate, or wounds with sinus tract unless packed ◦ May adhere if exudate becomes reduced ◦ *Allevyn Cavity*® does not conform to cavity shape and the available sizes may be inappropriate for cavity size

(Doughty, 1991:49; Willey, 1992:44, 45; Dealey, 1994:190, 191, 192, 218, 219, 237, 238; Erwin-Toth & Hocevar, 1995:50; Maklebust, 1995:49; Bennett & Moody, 1995:55, 56; Walker, 1996:36, 39; Thomas, 1997c; Dale, 1997:13, 14; Thomas, 1997b:482; Smith & Nephew, 1997:4-7; Culley, 1998:884; Heenan, 1999:72; Baranoski, 1999)

TABLE 4.10: Odour absorbing dressings

Examples	Indications	Advantages	Disadvantages
Actisorb Plus® (Johnson & Johnson Medical) *Lyofoam C* ® (Seton Health Care)	◦ Malodorous wounds such as fungating carcinomas, leg ulcers or infected wounds with low to moderate exudate	◦ Effective method of controlling odour ◦ Simple to use ◦ An effective combination of dressing and charcoal (*Lyofoam C* ®)	◦ Cannot be cut to size (*Actisorb Plus*®) ◦ May adhere to wound if used as a primary dressing (*Actisorb Plus*®) ◦ Absorb less exudate than ordinary *Lyofoam*® (*Lyofoam C* ®) ◦ *Actisorb Plus*® is contra-indicated for patients sensitive to nylon ◦ *Lyofoam C* ® is contra-indicated for wounds with dry eschar ◦ Ineffective when moist

(Dealey, 1994:189, 190, 219, 220; Bennett & Moody, 1995:63, 63; Thomas, 1997c; Dale, 1997:13, 14; Thomas, 1997b:482; Thomas *et al.*, 1998; Heenan, 1999:72)

TABLE 4.11: Gauze impregnated dressings

Examples	Indications	Advantages	Disadvantages
Jelonet® (Smith & Nephew) non-medicated *Bactigras*® (Smith & Nephew) medicated *Grassolind*® (Hartmann) non-medicated	◦ Superficial wounds (abrasions, lacerations and leg ulcers) ◦ Wounds in the later stages of healing (lightly exuding wounds) ◦ Medicated tulle dressings may be effective to counter and/or treat infection	◦ Do not adhere to wound bed ◦ Medicated tulle may reduce the risk of infection (*Bactigras*® contains chlorhexidine which is active against a wide variety of bacteria) ◦ Maintain a moist wound surface	◦ Need frequent changing because threads may become incorporated into granulation tissue ◦ Require secondary dressing ◦ Antimicrobial agents in medicated tulle may be harmful to fibroblasts ◦ The sticky residue remaining on the skin and wound is often difficult to remove ◦ May adhere to the wound if dressing dries out

(Krasner, 1992:38; Krasner, 1995:47; Bennett & Moody, 1995:52; Thomas, 1997c)

TABLE 4.12: Iodine-containing dressings

Examples	Indications	Advantages	Disadvantages
Inadine® (Johnson & Johnson Medical)	◦ Shallow infected wounds, superficial burns, leg ulcers and on skin areas where orthopaedic pins protrude ◦ Contaminated traumatic injuries	◦ Has a broad spectrum antiseptic affect ◦ Can be used prohpylactically or to treat a wide range of bacterial, protozoal and fungal infections ◦ Easy to use	◦ Little absorptive capacity ◦ Some patients may develop a sensitivity or be allergic to povidone or povidone iodine ◦ As iodine can be absorbed through the tissues, these products should not be applied during pregnancy, lactation and to patients with thyroid disorders

(Dealey, 1994:210, 211; Bennett & Moody, 1995:52; Krasner, 1995:47; Dale, 1997:13, 14; Thomas, 1997b:482; Lawrence, 1998b:422; Lawrence, 1998a:332; Heenan, 1999:72)

4.5.5.9 Gauze dressings

These are dressings made from woven cellulose (cotton and rayon fibres) (see Table 4.13, p.135).

Although some practitioners still use cotton wool as a secondary dressing and to clean wounds with, its use is not recommended (See Section 3.3.2.5). As such it is not included in any category of wound dressing.

From the preceding paragraphs it is evident that no single dressing is suitable for the management of all types of wounds, and few are ideally suited to the treatment of a single wound during all the stages of the healing trajectory. Therefore, the product that best meets the needs identified after a thorough, holistic assessment of the **patient** and the **wound** should be selected. *Acceptability, availability* and *cost* are additional factors to be considered in the process of dressing selection.

The *cheapest acceptable* and *available* dressing that will be effective in meeting the identified needs should be selected, bearing in mind the extra costs of more frequent renewal and the need for secondary dressings. Nonetheless, if based on the evidence of sound economic evaluation, the selection process may be greatly enhanced thereby providing high quality wound care whilst achieving significant cost savings.

TABLE 4.13: Gauze dressings

Examples	Indications	Advantages	Disadvantages
Numerous products available	◦ Exudative wounds ◦ Wounds with dead spaces, tunneling or sinus tracts ◦ Wounds with combination exudate or necrotic debris	◦ Readily available and relatively inexpensive ◦ Can be used with appropriate solutions such as gels, normal saline or topical antimicrobials to keep wounds moist, provided the dressings are kept moist ◦ Can be used in conjunction with other dressings ◦ Can be used on infected wounds ◦ Wet-to-damp dressings support autolytic debridement and absorb exudate and contain bacteria in the gauze, which are removed when the dressing is changed ◦ Can be used for gentle cleansing of wounds	◦ Will disrupt wound healing if allowed to dry ◦ Require secondary dressing ◦ If tightly packed it may compromise blood flow and delay wound closure ◦ Moisture from gauze dressings may macerate the surrounding skin ◦ Require frequent dressing changes which is time consuming ◦ Cellulose dressings may disintegrate and particles can be introduced into the wound which may elicit an inflammatory response, the formation of fibrous tissue and hypertrophy

(Krasner, 1991:49; Willey, 1992:44,45; Krasner, 1992:38; Frantz & Gardner, 1994:39; Maklebust, 1995:49; Erwin-Toth & Hocevar, 1995:51; Krasner, 1995:47; Walker, 1996:38; Thomas, 1997b:479; Lawrence, 1997:46; Heenan, 1999:72)

4.6 ADJUNCTIVE THERAPY

Several adjunctive therapies claim to enhance pressure sore healing. These include the following: negative-pressure therapy; radiant heat therapy; electrotherapy; hyperbaric oxygen; infrared, ultraviolet and low energy laser irradiation; ultrasound; miscellaneous topical agents (such as vitamins, hormones and cytokine growth factors) and systemic drugs other than antibiotics such as vasodilators, serotonin inhibitors and fibrolytic agents (Undersea and Hyperbaric Medical Society (UHMS), 1992; AHCPR, 1994:18; Baxandall, 1996:49; Moon, 1998; Sussman, 1998; Banwell, 1999:79; Youn, 1999; Barry, 2000:52; Mcculloch, 2000; Kloth et al., 2000).

Most of these adjunctive therapies have additional cost implications and are not suited to routine use in community settings. Since none of them were used in this study a detailed discussion of these adjunctive therapies falls beyond the scope of this review.

4.7 CONCLUSION

This chapter provided an overview of the principles of pressure sore management. The following chapter will review economic evaluation approaches of pressure sore management.

CHAPTER FIVE

Economic evaluation of pressure sore management

5.1 INTRODUCTION

Robinson (1993a:671) describes *economic evaluation* (or economic appraisal as it is sometimes referred to) in health care, as a range of techniques that may be used to assemble evidence on the expected costs and consequences of different procedures or programs. Economic evaluation in the health sector has become increasingly significant. This fact is underscored by the high treatment cost of pressure sores (Colin, 1995:65; Torrance & Maylor, 1999:27).

A review of the relevant literature reveals four main economic evaluation approaches in health care: cost-minimization analysis, cost-benefit analysis, cost-utility analysis and cost-effective analysis (Spilker, 1991:307; Robinson, 1993a:671; Brooks & Semlyen, 1997:492-493 and Manheim, 1998:149). A brief discussion of these evaluation approaches is provided in the following paragraphs.

5.2 COST-MINIMIZATION ANALYSIS

Cost-minimization analysis is defined as the analysis and comparison of costs for two (or more) interventions shown (or believed) to be equivalent in outcomes or consequences. Therefore, the objective of this type of analysis is to identify the least expensive way to achieve the same therapeutic outcomes that need not be measured. An example of this would be alternative forms of delivery in maternity services such as at home or in hospital, but the outcome is the same, live births (Spilker, 1991:303; Robinson, 1993b:726; Brooks & Semlyen, 1997:492). Since the outcome of any pressure sore treatment method is debatable, this type of analysis is unlikely to be appropriate for this particular study.

5.3 COST-BENEFIT ANALYSIS

Spilker (1991:303) defines this economic evaluation approach as the simultaneous measurement of costs and consequences of treatment, where both are expressed in terms of money. The cost-benefit analysis approach has been criticized for its use of monetary measures, especially with value outcomes. For example, outcomes such as *improved patient well being* or *acceptability of a treatment method,* are difficult to translate into a monetary value (Robinson, 1993a:671-672; Brooks, 1997:136; Brooks & Semlyen, 1997:493).

In light of this limitation and the fact that no comprehensive cost-benefit studies of pressure sore management have been reported in the literature, a cost-benefit analysis approach is not suitable for this study.

5.4 COST-UTILITY ANALYSIS

Cost-utility analysis is defined as the simultaneous measurements of costs and consequences of treatment. Measurements of *quality of life* consequences are usually made in terms of preference for one intervention over another. Price (1996:139) describes *quality of life* as a multi-dimensional construct, which can be measured via physical, psychological and social aspects of well-being and/or function as perceived by patients and/or observers.

According to Spilker (1991:303), the objective of a cost-utility analysis is to choose the least expensive approach to achieve a set standard gain, expressed in terms of artificial units such as *quality adjusted life years* (QALYs).

A Quality-adjusted life-year (QALY) is constructed from a scale, usually normalised from zero to one, on which is placed a variety of health states. The endpoints are typically, 'full health' and 'dead'. If a patient's health state is 0.7 before treatment and the patient is restored to full health after treatment, a gain of 0.3 QALYs would accrue for each subsequent life-year (Pritchard, 1996:148). Brooks and Semlyen (1997:493) propose that the pressure sore field would appear to be a candidate for cost-utility analysis, since pressure sores can have serious implications for quality of life. However, some problematic issues are involved, for example, it would be necessary to distinguish between changes in the quality of life attributable to the treatment of the pressure sore, from changes due to treatment for medical conditions.

There is universal agreement amongst scholars that the most important source of information about the impact of a particular disease or disorder on the quality of life, is the patient (Spilker, 1990:16; Dazord & Gerin, 1994:4; Reid: 1996:142). Given this fact, the majority of questionnaires and scales used to assess quality of life, originate with the patient's perspective rather than that of the experts, as research has shown that the ratings of doctors and other health-care staff differ substantially from those of patients (Horton, 1995:2; Price, 1996:139). However, there are some circumstances in which patients are unable to rate the quality of their own lives such as those suffering from age-related dementia or Alzheimer's disease. In these cases, the debate continues about who should act as proxy rater, and about the validity, and indeed the meaningfulness, of such ratings (Downie, 1999:381; Harding, 2000:188).

In the light of the above it is evident that a formal assessment of quality of life, as an endpoint in this study, will be inappropriate. However, as one of the objectives of this study were to assess the acceptability of pressure sore treatment methods, the researcher implicitly assessed one of the dimensions of quality of life.

5.5 COST-EFFECTIVE ANALYSIS

This type of analysis is defined as the simultaneous measurement of costs and consequences of treatment. Costs are measured in terms of money, and effectiveness is measured in terms of obtaining a specified objective. Thus, the objective of a cost-effectiveness study is to choose the least expensive approach to achieve a set standard of gain, expressed in terms of a meaningful medical unit. Cost-effective results are expressed as a ratio of costs to benefits (Spilker, 1991:302; Robinson, 1993a:672; Robinson, 1993c:793; Brooks, 1997:136; Brooks & Semlyen, 1997:492).

5.6 CONCLUSION

In this study the *cost* of treatment method was measured in terms of money and the *effectiveness* of the treatment method was measured in terms of reduction in wound size, over a time period of six weeks.

CHAPTER SIX

Research Methodology

6.1 INTRODUCTION

In the following chapter the research methodology will be explicated in the light of the advantages it offers this study. Included will be a review of the instrument used in this study.

6.2 PURPOSE OF THE RESEARCH

The purpose of the study was to compare the current wound care management method with a more advanced wound care management method in the treatment of patients with pressure sores in the community.

6.2.1 Research objectives

The objectives of this study were to:

- Compare the **cost-effectiveness,** with regard to treatment cost and rate of healing, of current wound care management to advanced wound care management in the treatment of pressure sores in the Bloemfontein community of the Free State Province, over a six week period.

- Assess the **acceptability** of these treatment modalities - to patients with pressure sores and their caregivers in the community over a six week period – in terms of (i) *ease of application,* (ii) *comfort of the dressing,* (iii) *durability of the dressing over the period of application* and (iv) *ease of removal.*

6.3 RESEARCH DESIGN

Of the nine main experimental designs available to the nurse researcher, as identified by Burns and Grove (1993:317-323), a *prospective, randomised clinical trial* was best suited to the phenomenon under investigation.

This experimental design may be further classified as an *open-label* clinical trial since both the researcher and the patients knew the nature of the treatment. As patients were placed into two treatment groups and data obtained from each group compared, the design could additionally be classified as a *cross-sectional* clinical trial as described by Spilker (1991:28).

In support of the chosen design the following was noted. Experimental designs provide a significant amount of control in order to examine causality more closely. It has also been proposed that this technique should be used to examine areas of nursing practice, such as comparing traditional nursing care practices with newer techniques (Burns & Grove, 1993:323).

6.4 POPULATION

The population of this study consisted of patients with uninfected pressure sores, living in the Bloemfontein *community* which included the following areas:

All areas within *the old municipal* boundaries of Bloemfontein; Bainsvlei- and Bloemspruit smallholdings, and Mangaung (Van Heerden, 1999).

6.4.1 Patient recruitment

Patients were recruited via referrals from primary health care clinics, community health care workers, social workers and other health care professionals practising in the community. Several patient recruitment strategies, as described by Spilker (1991:87), were used to *increase* patient recruitment. They included the following:

- Communicating with colleagues directly, via e-mail and telephone, requesting referrals.
- Speaking at formal and informal professional meetings requesting referrals.
- Placing notices in places where colleagues and/or patients would see them.
- Placing advertisements in local newspapers (see Appendix 1).

Once recruited, *inclusion* and *exclusion* criteria were used to enroll patients into the study.

6.4.2 Inclusion criteria

The following criteria were used to enroll patients:

- Patients in the community aged 18 years or older with a clinically uninfected Stage 2, 3 or 4 pressure sore.
- Patients, or their guardians, who gave informed consent.
- Patients who were willing and able to comply with the treatment.

6.4.3 Exclusion criteria

The criteria used to exclude patients from the study were:

- Patients aged younger than 18 years.
- Patients or their guardians, who declined to participate in the study.

- Patients with clinically infected wounds (see Chapter 4, Section 4.3.1.9).
- Patients with a Stage 1 pressure sore.

In establishing the above criteria the following were considered.

- Most clinical trials are conducted on adults between 18 and 65 years of age (Spilker, 1991:658). Furthermore, according to the Child Care Act, number 74 of 1983, Section 39(4), persons of 18 years and older are considered competent to consent independently, without the assistance of a parent or guardian, to any medical treatment (South Africa, Act No. 74, 1983). Therefore, patients **below the age of 18 years were excluded**. However, since pressure sores are generally associated with the elderly, **no upper age limit** was specified in the inclusion criteria.

- In accordance with the worldwide accepted Good Clinical Practice Guidelines as described by Spilker (1991:450), only patients, or their legal guardians, who gave **informed consent** were included in the study.

- As **infected wounds** may require additional treatment such as systemic antibiotic therapy, and are therefore not comparable to uninfected wounds in terms of treatment cost and healing rate, these wounds were excluded from the study.

- According to the Sterling Pressure Sore Severity Scale, Stage 0 (described as no clinical evidence of a pressure sore) and **Stage 1** (described as discoloration of intact skin) sores, do not involve skin loss or damage to the dermis and/or epidermis (Waterlow, 1996:54). As such they do not allow for objective measurement of the rate of healing as in wounds classified as Stage 2, 3, or 4, and were therefore excluded from the study.

6.4.4 Withdrawal procedure

Any patient who interrupted the trial treatment for longer than one week, either consecutively or in total, was withdrawn from the study. Patients who did not respond to the management method were withdrawn from the study only at the point where it became necessary to change the treatment on clinical grounds. Furthermore, patients could withdraw or be withdrawn for the following reasons:

- At the patient's own request;
- If the patient moved from the geographical area;
- Developed a concurrent illness and was unable or unwilling to continue in the trial;
- Developed a wound infection;
- Death.

6.5 SAMPLING METHOD

Sampling was carried out by randomly allocating 58 eligible patients with a Stage 2, 3 or 4 clinically uninfected pressure sore(s), into an equally sized control- and experimental group. Randomisation was done by stage and according to a computer generated randomisation list provided by the Department Biostatistics at the University of the Orange Free State.

If a patient had more than one pressure sore, all sores were treated with the same treatment modality. However, only one sore was chosen at random for inclusion in the study and it was on the basis of this sore's SPSSS classification, that randomisation of treatment modality occurred. In order to select one sore at random, the sores were numbered from top (superior) to bottom (inferior), left to right and a random number selected from a random number table.

The sample size was derived from an extensive and exhaustive literature review of community-based wound care studies. Unlike institution-based studies, community-based studies do not allow for larger sample sizes without certain implications (Banks & Bale, 1994:304). These implications refer to several practical issues that arise from larger studies, such as variable control and the financial implications of extensive community-based studies that require additional skilled field workers.

In view of the above and the documented success of smaller comparable studies by Bale, Squires, Varnon, Walker, Benbow and Harding (1997: 463) and Bale, Banks, Hagelstein and Harding (1998:65), the researcher decided, in collabaration with the Department of Biostatistics at the University of the Orange Free Sate, that a sample size of at least 40 patients was a statistically adequate number.

6.6 TREATMENT MODALITY

Two pressure sore treatment modalities were used namely: an *advanced* wound care management method and the *currently* used management method (see conceptual definitions, Section 1.7). Patients allocated to the experimental group were treated with the advanced method and patients allocated to the control group were treated with the currently used method.

6.6.1 Advanced wound care management

This management method was based on the principle of the research-based concept of moist wound healing (see Sections 3.2.3 and 4.5.5). All patients in the experimental group were treated exclusively with Smith & Nephew™ wound care products. The procedure was conducted in the following manner:

The peri-wound area was cleansed with a gentle, hypoallergenic soap (Protex™ factor 1[3]) and water to remove any exudate and transient micro-organisms from the surrounding skin. The surrounding intact skin was dried with sterile gauze as contained in the Smith & Nephew Surgipak™.

The wounds were then aseptically cleansed with warm (approximately 37^0C), sterile, physiological saline as contained in Adcock Ingram's Sab-Saline™ plastic containers (see Sections 4.5.2.1 and 4.5.2.2).

The saline was warmed as recommended by Bux and Malhi (1996:307), by placing the individual single dose 30 ml plastic ampules of saline solution in a jug of water heated to 40 ^{0}C, as measured by a standard thermometer, for 30 minutes. Assurance was obtained from the manufacturer that this method of heating would not have a deleterious effect on the saline or the container (Healy, 2000). The heated saline ampules were then placed and transported in an insulated container to maintain a temperature of approximately 37^0C. A gentle cleansing technique was used by either irrigation, if the wound had delicate granulation tissue, or by gently patting the wound bed.

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[3] Protex™ factor 1 is hypoallergenic and tested by dermatologists. It provides mild antibacterial protection for delicate and sensitive skin, and is especially recommended for children and people with sensitive skin (Colgate-Palmolive, 1999).

Irrigation was accomplished by using a sterile 20-ml syringe and 18-gauge needle thereby delivering an irrigation pressure of approximately eight pounds per square inch (psi) – an irrigation pressure considered by the AHCPR (1994:15) to be safe and effective for wound cleansing (see Section 4.5.2.3 [b]). Where any non-viable tissue was present on the surface of the wound requiring debridement, a thin layer of IntraSite™ gel was applied on the wound bed and covered with either Allevyn™ Cavity, in the case of cavity wounds, or Allevyn™ non-adhesive, hydrocellular sheets or Allevyn™ Adhesive.

If the wound was granulating and no non-viable tissue was present at the surface, then Allevyn™ non-adhesive, hydrocellular sheets or Allevyn™ Adhesive were applied directly to the wound. Transparent OpSite Flexigrid™ dressings were applied to Stage 2 epithelialising wounds or blisters.

OpSite Flexigrid™ was also used as a secondary dressing to secure Allevyn™ non-adhesive dressings. All the selected dressings were applied to the wounds strictly according to the manufacturer's instructions (see Appendix 2 for a list of the Smith & Nephew™ products used in the study as well as instructions for use and contra-indications).

6.6.2 Currently used wound care management

The procedure was carried out in the following manner:

The peri-wound area was cleansed with gentle, hypoallergenic (Protex™ factor 1) soap and water to remove any exudate and transient micro-organisms from the surrounding skin. The wound was then aseptically cleansed and covered with the *available* wound care materials and/or methods as used on that particular patient at that time by the patient or primary caregiver.

These materials included some advanced or modern dressings, however any Smith & Nephew™ products were excluded. These materials and/or methods are listed in Appendix 3 along with references to the relevant sections in the literature review where they are discussed.

In order to avoid cross-contamination and subsequent wound infection, the researcher maintained strict adherence, in **both treatment modalities throughout the entire study**, to the basic principles of asepsis and infection control, as recommended by the Agency for Health Care Policy and Research (1994:20) (see Appendix 8).

Similarly, throughout the study, the researcher provided continuous education and encouraged all patients and caregivers to adhere to the measures for pressure reduction, daily skin examination and intermittent pressure relief techniques as described in the Clinical Practice Guidelines by the AHCPR (1994:1-10) (see Appendix 8). Additionally the researcher attempted to, where possible, to address those identified factors that could delay wound healing.

6.6.3 Period of treatment

Each patient was managed by either the advanced wound care management method or the currently used wound care management method for a period of **six weeks** or until one of the following end points were reached:

- the wound healed;
- the patient withdrew;
- an adverse event occurred in which treatment benefit was unacceptably inferior to treatment risk.

The decision for a six-week treatment period was based on the treatment period used in similar successful pressure sore studies undertaken by Kurring, Roberts and Quinlan (1994:1050), Colin, Kurring, Quinlan and Yvon (1996:444), Thomas, Banks, Bale, Fear-Price, Hagelstein, Harding, Orpin and Thomas (1997:384) and Bale, Banks, Hagelstein and Harding (1998:66) and Price, Bale, Crook and Harding (2000:202). The decision was also based on previous experience that pressure sores would either heal or make some progress towards healing in six weeks.

6.6.4 Adverse event

The researcher took the following action in cases of an *adverse event* (see conceptual definitions, Section 1.7): All patients experiencing an adverse event were monitored until symptoms subsided or until there was a satisfactory explanation for the changes observed. These observations were forwarded to a suitably qualified clinician (the patient's primary caregiver and/or attending physician) at the start of the event. Where the adverse event placed the patient's wellbeing at risk, all experimental treatment was discontinued, the patient withdrawn from the study and the case referred to the qualified clinician. All findings were recorded under "adverse event(s)" on page six (question 24) of the *Weekly Wound Assessment Chart* and page four (question 14) of the *Record of Dressing Changes and Products Used* (see Appendix 4) as well as in the study findings.

Additionally, if the adverse event occurred in the experimental group and was thought to be a *device-related adverse incident* (see conceptual definition, Section 1.7), Smith & Nephew™ were to be contacted immediately.

6.7 DATA COLLECTION

Data collection was facilitated by means of direct observation using four data collection forms namely: an *Initial Patient Information Chart*, a *Weekly Wound Assessment Chart*, a *Record of Dressing Changes* and an *Assessment of Dressing Acceptability*. Additionally four evaluation methods were used to assess the rate of wound healing namely:

- standardised digital wound photography;
- tracing of the wound edges;
- measurements of the wound and its appearance as well as
- descriptive field notes.

A digital camera (Sony Digital Mavica™ MVC-FD7) was used to photograph each wound weekly for six weeks. Direct observation and photography were chosen as data collection methods for the following advantages that they offered the study:

- Both methods allowed the researcher to collect data in the natural setting. This was of particular importance as the study was conducted in the community.

- Direct observation and photography facilitated analysis, validity checks, and triangulation (Burns & Grove, 1993: 412).

Besides the data collected by means of direct observation and photography, the presence of the researcher at the data collection phase of the study was useful in providing additional information regarding the phenomenon. This information was recorded on case record pages attached to each *Weekly Wound Assessment Chart* and *Record of Dressing Changes*.

These field notes provided valuable insights into the phenomenon that could not necessarily be obtained from the quantitative data collection methods.

6.7.1 The instruments

As mentioned, the data was collected using four data collection forms (see Appendix 4), photography, tracing and measuring the wounds.

6.7.1.1 Data collection forms

These forms were developed from an extensive and exhaustive literature review. In support of the review, domain experts were approached for comments on the contents of the data collection forms. The four domain experts included two wound care specialists form the School of Nursing of the University of the Orange Free State and two bio-statisticians from the Department of Biostatistics also at the University of the Orange Free State. The wound care specialists were chosen for their qualifications and more than 20 years clinical experience in the field of wound care and nursing research.

The bio-statisticians were chosen for their unique qualifications in statistical analysis as well as their vast experience in the field of clinical and health-related research. Together these domain experts provided invaluable input that contributed to the development and refinement of the data collection forms.

Related items were grouped together to facilitate an easy, logical and practical flow of data collection during the initial enrolment and at each subsequent dressing change. This also ensured the elimination of any undue discomfort to the patient during the data collection process.

The *Initial Patient Information Chart,* completed on initial enrolment, included relevant baseline data such as gender, age, allergies, weight, length and wound site. Content-related validity was supported by the assurance that the key concepts namely, **cost-effectiveness** and **acceptability** as well as the related constructs were included and adequately covered by questions on the remaining three data collection forms. (The *Weekly Wound Assessment Chart*, a *Record of Dressing Changes and Products Used* and an *Assessment of Dressing Acceptability*). Table 6.1 (p.156) provides coverage of the concepts in these data collection forms to assure that all the key areas of concern were addressed.

6.7.1.2 Standardised digital wound photography

Standardised photography was chosen as an assessment method using a Sony Mavica™ MVC-FD7 digital camera. Each wound was photographed on entry, and thereafter every week, for six weeks. The weekly photographs of each patient's wound can be viewed using the CD-ROM attached to the back cover of this document.

A digital camera was chosen for the following advantages that it offered the study:

This type of camera captures digital images that are directly transferred to a computer disk. Therefore the cost and variables associated with conventional film and film development processes were eliminated thus increasing the reliability of this assessment method (see Chapter 4, Section 4.3.1.3 [c]). The images taken were instantly visible to the researcher and the patient on the camera's visual display screen. This feature enhanced patient motivation and compliance with the treatment.

Furthermore, the images could instantaneously be transferred to a personal computer without the need of a scanning device. Once the images were transferred to a computer they could be stored, accessed at any time, analysed and duplicated at no extra cost.

TABLE 6.1: Coverage of questions in data collection forms

Concept	Constructs	Questions related to concepts		
		Form 1	Form 2	Form 3
Cost-effectiveness	• Cost of treatment	16, 17, 18, 20	9, 10, 11, 13	
	• Number of dressing changes	6, 7, 19	3, 4, 12	
	• Rate of healing: - *Factors that impede healing*	8, 9, 10, 10.1, 10.2, 11, 12, 14, 15, 16, 17, 18, 21, 22	5, 5.1, 5.2, 6, 7, 9, 10, 11	
Acceptability	• Pain	13, 13.1	8, 8.1	
	• Comfort of application and removal			3.1, 3.2
	• Ease of application and removal			4.1, 4.2
	• Durability	6, 7, 19	3, 4, 12	5

Form 1: Weekly Wound Assessment Chart (see Appendix 4)
Form 2: Record of Dressing Changes and Products Used (see Appendix 4)
Form 3: Assessment of Dressing Acceptability (see Appendix 4)

The photography was standardised by maintaining the same distance of 15 cm between the camera lens and the wound surface (see Section 4.3.1.3 [c] vii) Camera settings such as focus and exposure were standardised and maintained throughout the study (see Section 4.3.1.3 [c] i). The lighting was standardised by the use of a portable Reflecta® Flectalux GLX 1006 halogen lamp (see Section 4.3.1.3 [c] v). Additionally a disposable decimal ruler was placed in the plane of focus of each photograph to facilitate measurements made from the photographs. Comprehensive notes were made on each occasion with regard to the patient's position and angle to the camera. Previous photographs were kept available for reference at subsequent sessions (see Section 4.3.1.3 [c] iv).

6.7.1.3 Tracing of the wound margins

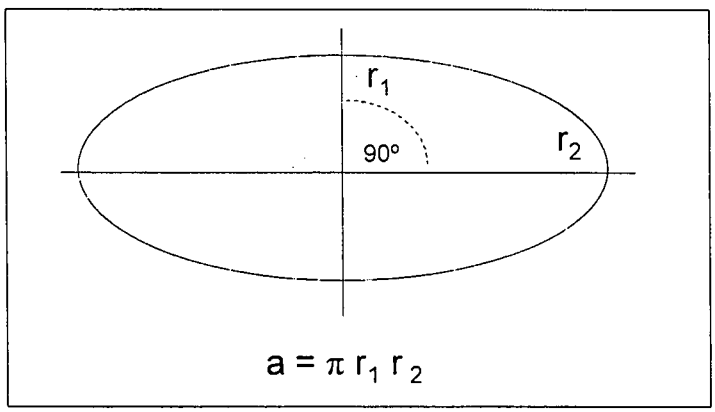
Upon entry and thereafter at weekly intervals, the wound margins were traced in the following manner. After the wound was cleansed, a Transparent OpSite Flexigrid™ dressing was placed over the wound. The wound edges were then carefully traced on the rigid flexigrid using a waterproof black felt-tipped pen. The rigid flexigrid was then removed and attached to the patient's data collection forms. The transparent Opsite™ film covering the wound, was left in place to facilitate the following evaluation method namely measurements of the wound.

6.7.1.4 Measurements of the wound

Immediately following the removal of the rigid flexigrid, a decimal ruler was placed over the transparent Opsite™ film covering the wound, and the maximum *length* and *width* of the wound measured in millimeters.

Leaving the wound bed covered with the Opsite™ film whilst measuring, eliminated direct contact of the ruler with the wound bed thereby avoiding the possibility of cross-infection and/or further undue trauma to the delicate wound surface area. As a further precautionary measure to avoid infection, the ruler was cleansed with soap and water and disinfected with an alcohol swab in between patients.

Surface area was calculated by assuming an elliptical shape:



a (area) = π x r_1 x r_2, where π = 3.14

Figure 6.1: Area of an Ellipse

In the case of cavity wounds where it was possible to measure wound *volume*, the following procedure as described by Flanagan (1997a:41), was followed. After measuring the length and width of the wound, a 10ml. sterile syringe with a 20 gauge needle was used to inject warm sterile physiologic saline through the Opsite™ transparent film. Saline was injected until the cavity was filled, whilst ensuring all air bubbles were removed. The wound volume (expressed in millilitres) was calculated by deducting the remaining volume in the syringe from 10 ml.

However, this method of determining wound volume could not be used in all cavity wounds due to several practical reasons (Ter Riet, Kessels & Knipschild, 1998:261).

These included wounds located on or near joints or natural anatomical curvatures where it was impossible to obtain a level surface area. Additionally, in some cases the patient's general condition did not allow for them to be positioned in an optimal position to perform this particular measurement method.

In addition the appearance of the wound bed was assessed each week by placing a metric grid with 5 mm^2 squares over the enlarged photographic image of the wound on the computer screen. The black (necrotic), yellow (slough), red (granulating) and pink (epithelializing) areas were then outlined with a thin black felt tipped pen and the number of squares within each area counted and expressed as a percentage of the total area (total number of squares) of the traced wound surface. Consequently the wound appearance could be measured with more accuracy and objectivity.

6.8 DATA ANALYSIS

The data analysis included a *cost* analysis and *statistical* analysis.

6.8.1 Cost analysis

The following was used to calculate the monetary cost[4] of wound treatment: cost of wound care products and wound care tariffs.

[4] All monetary costs referred to in this study were appropriate for the period August/September 2000.

6.8.1.1 Cost of wound care products

Data related to the type and amount of wound cleansers, topical applications and dressing material used for each patient were analysed and the cost of wound treatment per patient per group that completed the study, was calculated.

The prices of all the products used in the *experimental group* were obtained from suppliers of Smith & Nephew™ products in the Bloemfontein area. However, the prices used in the cost analysis reflect the retail prices that patients would have paid if they had bought the products through an independent wound care practitioner.

In order to arrive at a reasonable cost for products used in the *control group*, the researcher obtained the cost for each item from six different suppliers in the Bloemfontein area and calculated an average cost per item. Two independent wound care practitioners verified the prices and cost calculations (Smart, 2000; Blom, 2000). See Appendix 9 for price lists and cost analysis.

Saline as wound cleanser, was excluded from the cost analysis in both groups since saline can be made by patients and their caregivers in the community setting at a minimal cost (see Section 4.5.2.1[h]). However, for the sake of convenience and practicality pre-packed saline containers (Adcock Ingram's 30 ml Sab-Saline™ ampoules) were used in the experimental group. Similarly the cost of a gentle soap (see Section 6.6.1) to clean the peri-wound area in both groups was excluded in the cost calculations since most patients already used this or a similar item.

6.8.1.2 Wound care tariffs

The wound care tariffs as published by the Board of Health Care Funders (2000), were used in the calculation of the treatment cost. The severity (stage) of the pressure sore determined the treatment tariff. The tariffs list is included in Appendix 9.

6.8.2 Cost-effectiveness

Using the same methodology as proposed by Harding, Bale, Banks and Orpin (1994:9) of the Wound Healing Research Unit, Cardiff, cost-effectiveness was expressed by dividing the number of patients that healed into the total cost of treating that particular group. This indicated the cost of healing per patient healed.

6.8.3 Statistical analysis

Data was analysed by a statistician from the Department of Biostatistics of the University of the Orange Free State, using S.A.S. software. Demographic and baseline information was summarized by group. Numeric variables were summarized by means and standard deviations, or percentiles if the distributions were skew. Categorical variables were summarized by frequencies and percentages. Changes between baseline and consecutive treatment week information were summarized per group by means and standard deviations, percentiles or percentages, as appropriate for the difference between the groups, with 95% confidence intervals. The percentage of dropouts, withdrawals and adverse events were compared between the two groups using 95% confidence intervals for differences in percentages.

In support of the use of confidence intervals the following was considered. Since no single study determines the scientific opinion on a subject, it is incumbent upon the researcher to provide a more *complete* analysis of the study results.

Therefore methodologists in particular recommend that clinical researchers routinely report confidence intervals rather than probability (*P*) values (Bailar & Mosteller, 1992:186; Armitage & Berry, 1994: 98). Gardner and Altman (1989: 13) advocate the use of confidence intervals by stating the following: "The confidence interval thus provides a range of possibilities for the population value, rather than an arbitrary dichotomy based solely on statistical significance. There is a close link between the use of a confidence interval and a two-sided hypothesis test. If the confidence interval is calculated then the result of the hypothesis test can be inferred at an associated level of statistical significance."

6.9 VALIDITY AND RELIABILITY

To increase the validity and reliability of the study, several approaches and techniques were applied, namely: assuring content-related validity evidence; addressing mono-operation bias; consistent use of instrument; randomization; inclusion of homogenous patients, conducting of a pilot study and monitoring.

6.9.1 Assuring content-related validity evidence

The researcher assured the content-related validity evidence in the following manner. The preliminary data collection forms were forwarded to four domain experts for comment regarding the appropriateness, accuracy and representativeness of items on the forms (see Section 6.7.1.1). Once these comments were returned, appropriate changes to refine the forms were made.

They included grouping of items, coding block changes and refinement of item seven on the *Record of Dressing Changes* and item 12 on the *Weekly Wound Assessment Chart.* These refinements were important as they assisted in the early recognition of wound infection, which was an exclusion criterion.

6.9.2 Addressing mono-operation bias

Mono-operation bias, as described by Burns and Grove (1993:269), to assess wound healing, was addressed by the use of multiple evaluation methods (as described in Section 6.7), thereby improving the construct validity. The evaluation methods included the following:

- Standardised wound photography using the same automatic digital camera (Sony Digital Mavica™ MVC-FD7) and operated consistently by the *same* individual thereby limiting user errors (see Section 6.7.1.2);

- Tracing of the wound edges using a standard transparent grid (see Section 6.7.1.3);

- Accurate measurements of the length, width and where applicable the volume of the wound, by means of the consistent use of a decimal measurement tool (see Section 6.7.1.4);

- Objective assessment of the appearance of the wound bed (see Section 6.7.4.1);

- Narrative descriptive field notes of the wound appearance made by the researcher.

6.9.3 Consistent use of instrument

Reliability of the instrument was improved through consistent use of it throughout the data collection process. This was facilitated by the use of only one data collector, a practice known to bypass the bias and inconsistency caused by multiple data collectors as well as problems associated with interrater reliability.

6.9.4 Randomization

Random assignment to experimental and control groups was used as a design strategy to control extraneous variables such as unrelieved pressure, incontinence, age, level of health, nutritional and functional status. Lack of equivalence between the experimental and control groups was also controlled by random assignment of patients to groups.

6.9.5 Inclusion of homogeneous patients

Patients were homogeneous in terms of three extraneous variables namely the presence of a clinically uninfected Stage 2, 3 or 4 pressure sore, aged 18 years or older and living in the community within the boundaries of the Municipal area of Bloemfontein.

6.9.6 Pilot study

Two patients, who complied with the inclusion and exclusion criteria as described in Sections 6.4.2 and 6.4.3, were selected to constitute a **pilot study**.

One was allocated to the experimental group and the other to the control group as described in Sections 6.6.1 and 6.6.2. The patients were randomly allocated to the respective treatment methods. The pilot study commenced on 19 May 1999 and was concluded two weeks later on 2 June 1999. The pilot study provided the researcher with the opportunity to test and improve the data collection forms with regard to how long they took to complete, the order and grouping of items. It also provided the researcher with the opportunity to become familiar with the digital camera and standardising the photographic technique in terms of lighting, background, distance and angle, thereby facilitating and maintaining accuracy and consistency during data collection.

6.9.7 Monitoring

The study and treatment methods were continuously monitored by Smith & Nephew's official study monitor as well as the two study leaders who regularly accompanied the researcher on visits to patients, thereby improving the validity and reliability of the study.

6.10 ETHICAL CONSIDERATIONS

The three main ethical considerations in this study refer to the right to self-determination, confidentiality and protection from harm.

6.10.1 The right to self determination

Patients were asked to partake voluntarily in this study (see Appendix 1). Patients were only enrolled into the study with *written informed* consent, provided by themselves or their legal guardians, and where possible in collaboration with their attending physician(s).

All participants were asked to sign a consent form, which contained a detailed description of the trial procedures and methods. Consent forms were available in Afrikaans, English, and South-Sotho (see Appendix 5). In addition patients had the right to withdraw from the study at any time without penalty.

6.10.2 Confidentiality

All patient names were kept confidential. The study number allocated to them during the study identified patients throughout the evaluation and documentation. Where any photograph taken of a patient's wound in any way revealed the patient's face, this area was blacked out to protect the patient's identity. The patients were told that all study findings would be stored on computer and handled in the strictest confidence. The signed informed consent forms remained with the researcher. The researcher also agreed to keep the forms for 15 years and will allow them to be inspected on request.

6.10.3 Protection from harm

All patients were carefully monitored and where any adverse event occurred, which, in the opinion of the researcher, was a result of the trial management method, the patients concerned were discontinued and managed appropriately as discussed in Section 6.6.4).

6.10.4 Declaration of Helsinki

The study was performed in accordance with the guidelines of the Declaration of Helsinki (1964) as revised in Tokyo in 1975, Venice in 1983, Hong Kong in 1989 and Somerset West, South Africa in 1996 (see Appendix 6 for a copy of the declaration).

6.10.5 Approval of protocol

Before the start of the study, the researcher submitted the study protocol and advertisement to the Ethics Committee, Faculty of Health Sciences, University of the Orange Free State, Bloemfontein. The study was initiated after the protocol and format of the newspaper advertisement were approved and a copy of the ethics approval received in which the protocol was mentioned by name and number (see Appendix 10 for a copy of the Ethics Committee approval letter).

6.11 TIMING

The study commenced on 4 June 1999 after the Ethics Committee approval was obtained. It continued uninterruptedly for 12 months until 18 June 2000, when the required sample size, as mentioned in Section 6.5, was attained.

6.12 CONCLUSION

The design and methodology of this study were chosen through careful consideration of the phenomenon under investigation. The unique needs were then matched to the most appropriate research design and methodology.

CHAPTER SEVEN

Results and discussion

7.1 Introduction

The preceding chapter provided a detailed exposition of the research methodology followed in this study. In this chapter the results of the data analysis will be interpreted and discussed.

7.2 Base-line data

Sixty patients were screened for inclusion in the study, of whom 58 patients (N=58) were considered suitable for entry. Upon entrance 28 patients were randomly allocated to the experimental group (n_e=28), as discussed in Section 6.5, and 30 patients to the control group (n_c=30). On entry base-line data was acquired by means of two forms (See Appendix 4). The *Initial Patient Information Chart* was used to gather demographic data and all the relevant assessment data with regard to the pressure sore was recorded on the *Weekly Wound Assessment Chart.*

7.2.1 Initial Patient Information Chart

The base-line demographic data of both groups acquired on entry using the *Initial Patient Information Chart,* were the following: gender, age, allergies, weight, height (body mass index) and wound site. This data is provided in Table 7.1 and discussed below.

TABLE 7.1: Base-line demographic data

Demographic data	Experimental group (n_e=28)		Control group (n_c=30)	
Gender	Frequency	%	Frequency	%
Male Female	7 21	(25%) (75%)	16 14	(53%) (47%)
Age				
Minimum Median Maximum [5] C.I. [-10; 1]	19 yrs 76,5 yrs 89 yrs		24 yrs 78 yrs 97 yrs	
Allergies	Frequency	%	Frequency	%[6]
None Morphine Penicillin Bee sting	27 1 0 0	(96,4%) (3,6%)	28 0 1 1	(93,3%) (3,3%) (3,3%)
Body mass index (BMI)				
Minimum Median Maximum C.I. [-1,63; 2,07]	17 22 27		13 21 28	

Table 7.1 continues...

[5] C.I. indicates 95% confidence intervals for the *median* difference between the experimental and control groups. Values in brackets refer to those values of the respective groups: [control; experimental]. When the interval includes zero it is an indication that there may be no difference, in which case the probability (*P*) value will be larger than 0,05 and the null hypothesis will therefore not be rejected.

[6] The sum of individual percentages may at times not total 100% due to rounding off errors.

TABLE 7.1: Base-line demographic data continued...

Demographic data	Experimental group (n_e=28)		Control group (n_c=30)	
BMI Male Patients	Frequency	%	Frequency	%
	(n=7)		(n=16)	
underweight <20	2	(28,6%)	8	(50%)
normal weight ≥20 and ≤25	5	(71,4%)	7	(43,8%)
overweight >25	0	-	1	(6,2%)
BMI Female Patients	Frequency	%	Frequency	%
	(n=21)		(n=14)	
underweight <19	4	(19,1%)	2	(14,3%)
normal weight ≥19 and ≤24	9	(42,9%)	8	(57,1%)
overweight >24	8	(38%)	4	(28,6%)
Weight distribution	Frequency	%	Frequency	%
underweight	6	(21,4%)	10	(33,3%)
normal weight	14	(50%)	15	(50%)
overweight *(using the BMI as reference)*	8	(28,5%)	5	(16,6%)
Wound site	Frequency	%	Frequency	%
Sacrum	11	(39%)	15	(50%)
Trochanter	6	(21,4%)	6	(20%)
Malleolus	3	(10,7%)	0	-
Iliac crest	2	(7,1%)	2	(6,7%)
Ischium	2	(7,1%)	1	(3,3%)
Heel	2	(7,1%)	3	(10%)
Wrist	1	(3,6%)	0	-
Lat. side of foot	1	(3,6%)	0	-
Elbow	0	-	2	(6,7%)
Scapula	0	-	1	(3,3%)

7.2.1.1 Gender

From Table 7.1 it can be seen that the patients in the experimental group were predominantly females (75%) as opposed to the control group where gender distribution was more balanced. However, the disparate gender distribution between the two groups was of no clinical importance.

7.2.1.2 Age

The median age of patients in the experimental group was 76,5 years and that of the control group 78 years. This finding confirms the association of the aging process with the incidence of pressure sores as presented in the literature (Banks, 1997:507; Scott, 1998:78). The 95% confidence interval [-10; 1] suggests that patients in the control group tended to be older. Similarly this tendency was not significant and of no clinical importance.

7.2.1.3 Allergies

As far as allergies were concerned no patient in either group had an allergy that could have had any undue influence on the wound treatment and/or outcome.

7.2.1.4 Body mass index (weight distribution)

There was no significant difference [-1,63; 2,07] in weight distribution between the two groups.

7.2.1.5 Wound site

As Table 7.1 indicates, the majority of pressure sores in both the experimental group (70 %) and control group (60,4%) were located on the sacrum or trochanters, both common *at risk* sites for pressure sore development according to Lueckenotte (1996:791). However, the site with the highest frequency of ulceration was the sacrum.

7.2.2 Weekly wound assessment chart – week zero

The baseline data with regard to assessment of the pressure sores (wounds) for both groups were acquired during week zero (on entry) by means of the *Weekly Wound Assessment Chart*. The initial wound assessment data included the pressure sore risk assessment, wound duration since onset, dimensions, pressure sore stage, level of exudate, appearance of the wound bed, surrounding skin/wound margin, pain, factors that may delay wound healing and medications used. This data is compared in Table 7.2 and discussed below.

TABLE 7.2: Base-line pressure sore (wound) assessment data

Assessment data	**Experimental group (n_e=28)**	**Control group (n_c=30)**
Risk assessment	Frequency %	Frequency %
Number of patients with a Braden score of 18 or less	26 (92,9%)	26 (86,7%)
Duration in weeks		
Minimum Median Maximum C.I. [-1; 1]	1 week 2 weeks 72 weeks	1 week 2 weeks 520 weeks

Table 7.2 continues...

TABLE 7.2: Base-line pressure sore (wound) assessment data continued...

Assessment data	Experimental group (n_e=28)		Control group (n_c=30)	
Wound dimensions				
Length				
minimum	3 mm		5 mm	
median	22,5 mm		18,5 mm	
maximum	85 mm		145 mm	
C.I. [-7; 10]				
Width				
minimum	4 mm		4 mm	
median	14 mm		11 mm	
maximum	73 mm		70 mm	
C.I. [-4; 6]				
Area				
maximum	4873 mm^2		5694 mm^2	
median	196 mm^2		174 mm^2	
minimum	9 mm^2		23 mm^2	
C.I. [-87; 137]				
Pressure sore stage	**Frequency**	**%**	**Frequency**	**%**
Stage 2	21	(75%)	23	(76,6%)
Stage 3	5	(17,8%)	4	(13,3%)
Stage 4	2	(7,1%)	3	(10%)
Level of exudate	**Frequency**	**%**	**Frequency**	**%**
High	3	(10,7%)	2	(6,7%)
Medium	5	(17,9%)	4	(13,3%)
Low	20	(71,4%)	24	(80%)
Type of exudate	**Frequency**	**%**	**Frequency**	**%**
Bloody	0		0	
Serous	22	(78,6%)	25	(83,3%)
Serosanguineous	3	(10,7%)	3	(10%)
Combination/other	3	(10,7%)	2	(6,7%)

Table 7.2 continues...

TABLE 7.2: Base-line pressure sore (wound) assessment data continued...

Assessment data	Experimental group (n_e=28)		Control group (n_c=30)	
Appearance of the wound bed	Mean		Mean	
Necrotic/ black tissue	18%		7,6%	
C.I. [0; 10]				
Slough/ yellow tissue	16,9%		25,6%	
C.I. [-20; 5]				
Granulating/ red tissue	46,7%		48,9%	
C.I. [-20; 15]				
Epitheliating/ pink tissue	18,2%		18,8%	
C.I. [-10; 10]				
Surrounding skin/wound margins	Frequency	%	Frequency	%
Intact	24	(85,7%)	25	(83,3%)
Erythema	5	(17,9%)	8	(26,7%)
Indurated	0	-	0	-
Macerated	2	(7,1%)	2	(6,7%)
Oedematous	2	(7,1%)	1	(3,3%)
Localised heat	0	-	0	-
Fragile	14	(50%)	13	(43,3%)
Dry-scaling	0	-	0	-

Table 7.2 continues...

TABLE 7.2: Base-line pressure sore (wound) assessment data continued...

Assessment data	Experimental group (n_e=28)		Control group (n_c=30)	
Pain	Frequency	%	Frequency	%
No pain	24	(85,7%)	28	(93,3%)
At dressing change	3	(10,7%)	0	-
Intermittent	0	-	1	(3,3%)
Persistent	1	(3,6%)	1	(3,3%)
Degree pain	Frequency	%	Frequency	%
	24	(85,7%)	28	(93,3%)
	0	-	0	-
	2	(7,1%)	0	-
	2	(7,1%)	1	(3,3%)
	0	-	1	(3,3%)
	0	-	0	-
Factors that may delay wound healing	Frequency	%	Frequency	%
Poor nutrition	19	(67,9%)	20	(66,7%)
Impaired circulation	18	(64,3%)	23	(76,7%)
Impaired sensation	7	(25%)	8	(26,7%)
Foreign bodies	0	-	0	-
Dehydration	0	-	1	(3,3%)
Non-compliance	1	(3,6%)	2	(6,7%)
Smoking	2	(7,1%)	2	(6,7%)

Table 7.2 continues...

TABLE 7.2: Base-line pressure sore (wound) assessment data continued...

Assessment data	Experimental group (n_e=28)		Control group (n_c=30)	
Factors that may delay wound healing	Frequency	%	Frequency	%
Underlying disease	7	(25%)	14	(46,7%)
Pharmacological agents	11	(39,3%)	11	(36,7%)
Impaired mobility	25	(89,3%)	24	(80%)
Complementary medicines	0	-	0	-
Anaemia	0	-	2	(6,7%)
Mechanical forces	26	(92,9%)	30	(100%)
Systemic infection	0	-	2	(6,7%)
Medications	Frequency	%	Frequency	%
None	8	(28,6%)	8	(26,7%)
NSAIDS	5	(17,9%)	4	(13,3%)
Chemotherapy	0	-	1	(3,3%)
Beta-blockers	0	-	1	(3,3%)
Anticoagulants	3	(10,7%)	4	(13,3%)
Phenotoin	2	(7,1%)	1	(3,3%)
Radiation	0	-	0	-
Analgesia	3	(10,7%)	3	(10%)
Sedatives	4	(14,3%)	2	(6,7%)
Diuretics	3	(10,7%)	6	(20%)
Antibiotics	1	(3,6%)	2	(6,7%)
Laxatives	0	-	1	(3,3%)
Steroids	0	-	2	(6,7%)

7.2.2.1 Risk assessment score

A Braden Scale score of 18 or less, indicating a patient at risk for pressure sore development was given to 92,9% patients in the experimental group and 86,7% patients in the control group. Since all patients had pressure sores, these percentages reflect the high *sensitivity* of the Braden Scale in predicting pressure sore development. These results confirm the research findings of Pang and Wong (1998:148) and support the use of the Braden Scale in this study.

7.2.2.2 Wound duration

The median wound duration in both groups was two weeks, again indicating no significant difference between the two groups on entry as far as this particular variable was concerned.

7.2.2.3 Wound dimensions

The median surface area of wounds in the experimental group was 250 mm^2 and those in the control group 222 mm^2 with the 95% confidence interval [-111; 175] indicating no significant statistical difference with regard to wound dimensions of patients upon entry.

7.2.2.4 Pressure sore stage

Most patients, (21 [75%] in the experimental group and 23 [76,6%] in the control group) were assessed as having stage two pressure sores and the remainder classified as stages three and four. These results indicate an even distribution with regard to pressure sore staging.

7.2.2.5 Wound exudate, appearance and margins

Most patients in both groups had a low *level* of wound exudate. Similarly the majority of patients [22 (78,6%) in the experimental group and 25 (83,3%) in the control group] had the same *type* of wound exudate (serous). It is also evident from the confidence intervals listed in Table 7.2 above, that there was no significant difference between groups in the assessment of the *appearance of the wound bed.* Assessment of the *wound margins* on entry revealed that 24 (85,7%) patients in the experimental group and 25 (83,3%) patients in the control group had intact wound margins.

7.2.2.6 Pain

Three patients allocated to the experimental group (10,7%) experienced pain *at dressing change* on entry. It should be noted, however, that the reported pain was associated with the removal of the dressings that were in place on recruitment and not the experimental treatment that was initiated.

7.2.2.7 Factors that may delay wound healing

Multiple factors that could delay healing were identified in all patients. The two factors that occurred with the highest frequency in both groups were *mechanical forces* and *impaired mobility*. Additionally there was a high incidence of *impaired circulation* and *poor nutrition* in both groups. These results are consistent with those factors identified from the literature that not only impair the wound healing process, but contribute to the development and maintenance of pressure sores (Flanagan, 1997b:30).

7.2.2.8 Medications used

The two groups were also similar as far as medication use was concerned.

Statistical analysis (using 95% confidence intervals) of the base-line data presented in Tables 7.1 and 7.2, revealed no significant differences between the two groups on entry. This important fact confirms that the process of randomization by stage, as described in the methodology, succeeded in producing two equivalent groups of patients that were homogenous in terms of demographic and prognostic factors and thus comparable - a vital prerequisite for experimental research. See Section 6.5.

7.3 Progression of the study

In the section below results of the following will be presented: weekly comparison of groups; comparison of each week with baseline data; withdrawals; reasons for withdrawals; healers and non-healers.

7.3.1 Weekly comparison of groups

The following section will indicate how the patients in both groups that remained in the study compared with each other *per week* in terms of the following variables: Braden risk assessment score; wound dimensions (area) and wound appearance (percentage necrotic, slough, granulation and epithelial tissue).

7.3.1.1 Comparison of Braden scores

The 95% confidence intervals in the Table below indicate that there were no significant differences in the weekly Braden scores of patients that remained in the study. Therefore the patients remained comparable in terms of the risk factors assessed by the Braden scale (See Section 4.2.6).

TABLE 7.3: Comparison of Braden risk assessment scores

	Experimental group	95% Confidence interval	Control group
Week one	N=26		N=26
Minimum	7		7
Median	12		11.5
Maximum	22	[-2; 2]	20
Week two	N=20		N=22
Minimum	7		7
Median	11.5		11.5
Maximum	18	[-2; 2]	19
Week three	N=17		N=17
Minimum	8		7
Median	12		12
Maximum	22	[-2; 4]	19
Week four	N=14		N=11
Minimum	9		7
Median	12		11
Maximum	22	[-1; 5]	19
Week five	N=12		N=11
Minimum	9		7
Median	12.5		11
Maximum	22	[-1; 6]	19
Week six	N=11		N=10
Minimum	9		7
Median	14		10.5
Maximum	22	[0; 6]	19

7.3.1.2 Comparison of wound dimensions

There were no significant differences in the weekly measurements of wound area between the two groups as can be noted by the confidence intervals in Table 7.4.

TABLE 7.4: Comparison of wound dimensions (area)

	Experimental group	95% Confidence interval	Control group
Week one	N=26		N=26
Minimum	9 mm^2		23 mm^2
Median	164 mm^2		174 mm^2
Maximum	4873 mm^2	[-84; 126]	5694 mm^2
Week two	N=20		N=22
Minimum	9 mm^2		23 mm^2
Median	209 mm^2		191 mm^2
Maximum	4873 mm^2	[-119; 215]	5694 mm^2
Week three	N=17		N=17
Minimum	23 mm^2		37 mm^2
Median	214 mm^2		188 mm^2
Maximum	4873 mm^2	[-110; 283]	5694 mm^2
Week four	N=14		N=11
Minimum	24 mm^2		47 mm^2
Median	296 mm^2		242 mm^2
Maximum	4873 mm^2	[-230; 452]	5694 mm^2
Week five	N=12		N=11
Minimum	24 mm^2		47 mm^2
Median	209 mm^2		242 mm^2
Maximum	4873 mm^2	[-268; 371]	5694 mm^2
Week six	N=11		N=10
Minimum	24 mm^2		47 mm^2
Median	377 mm^2		225 mm^2
Maximum	4873 mm^2	[-605; 538]	5694 mm^2

7.3.1.3 Comparison of wound appearance

The weekly measurements of the wound appearance (measured in terms of the percentage of necrotic, slough, granulating and epithelialating tissue) of patients who remained in the study are compared in Table 7.5 below. Once again no significant differences were found between groups with regard to wound appearance as indicated by the 95% confidence intervals. Therefore the patients that remained in the study were comparable with regard to this variable.

TABLE 7.5: Comparison of wound appearance

	Experimental group	95% Confidence interval	Control group
Week one	N=26		N=26
% Necrotic tissue			
Minimum	0%		0%
Median	0%		0%
Maximum	100%	[0; 0]	100%
% Slough tissue			
Minimum	0%		0%
Median	7.5%		10%
Maximum	90%	[-25; 5]	95%
% Granulation issue			
Minimum	0%		0%
Median	45%		45%
Maximum	100%	[-20; 20]	100%
% Epithelialating tissue			
Minimum	0%		0%
Median	10%		15%
Maximum	60%	[-10; 5]	85%
Week two	N=20		N=22
% Necrotic tissue			
Minimum	0%		0%
Median	0%		0%
Maximum	100%	[0; 20]	100%

Table 7.5 continues...

TABLE 7.5: Comparison of wound appearance continued...

	Experimental group	95% Confidence interval	Control group
Week two continued..	N=20		N=22
% Slough tissue			
Minimum	0%		0%
Median	10%		10%
Maximum	70%	[-20; 5]	95%
% Granulation tissue			
Minimum	0%		0%
Median	40%		45%
Maximum	100%	[-25; 15]	100%
% Epithelialating tissue			
Minimum	0%		0%
Median	12.5%		17.5%
Maximum	60%	[-10; 10]	85%
Week three	N=17		N=17
% Necrotic tissue			
Minimum	0%		0%
Median	0%		0%
Maximum	100%	[0; 20]	100%
% Slough tissue			
Minimum	0%		0%
Median	10%		30%
Maximum	90%	[-25; 10]	80%
% Granulation tissue			
Minimum	0%		0%
Median	40%		45%
Maximum	90%	[-35; 10]	100%
% Epithelialating tissue			
Minimum	0%		0%
Median	15%		15%
Maximum	60%	[-10; 10]	50%
Week four	N=14		N=11
% Necrotic tissue			
Minimum	0%		0%
Median	5%		0%
Maximum	100%	[0; 20]	100%
% Slough tissue			
Minimum	0%		0%
Median	15%		10%
Maximum	90%	[-10; 20]	70%

Table 7.5 continues...

TABLE 7.5: Comparison of wound appearance continued...

	Experimental group	95% Confidence interval	Control group
Week four continued..	N=14		N=11
% Granulation tissue			
Minimum	0%		0%
Median	20%		50%
Maximum	90%	[-50; 5]	100%
% Epithelialating tissue			
Minimum	0%		0%
Median	10%		10%
Maximum	60%	[-15; 10]	50%
Week five	N=12		N=11
% Necrotic tissue			
Minimum	0%		0%
Median	5%		0%
Maximum	100%	[0; 20]	100%
% Slough tissue			
Minimum	0%		0%
Median	15%		10%
Maximum	90%	[-10; 30]	70%
% Granulation tissue			
Minimum	0%		0%
Median	17.5%		50%
Maximum	90%	[-60; 0]	100%
% Epithelialating tissue			
Minimum	0%		0%
Median	10%		10%
Maximum	60%	[-15; 10]	50%
Week six	N=11		N=10
% Necrotic tissue			
Minimum	0%		0%
Median	0%		0%
Maximum	100%	[0; 20]	100%
% Slough tissue			
Minimum	0%		0%
Median	20%		10%
Maximum	90%	[-10; 35]	70%
% Granulation tissue			
Minimum	0%		0%
Median	20%		47.5%
Maximum	90%	[-50; 20]	90%
% Epithelialating tissue			
Minimum	0%		0%
Median	10%		12.5%
Maximum	60%	[-20; 10]	50%

From the above it is evident that despite withdrawals the *groups remained comparable* throughout the study period

7.3.2 Comparison of each week with baseline data

This section will show the results (95% confidence intervals) of the *differences between each successive week and baseline* (i.e. week 1 minus week 0; week 2 minus week 0 etc.), as well as the *difference between groups* in terms of the following variables: Braden risk assessment score; wound dimensions (area) and wound appearance (percentage necrotic, slough, granulation and epithelial tissue).

TABLE 7.6: Differences in variables between groups per week

Variable/week	95% Confidence interval
Braden score	
Week 1-0	[0; 0]
Week 2-0	[0; 0]
Week 3-0	[-5; 2]
Week 4-0	[0; 0]
Week 5-0	[0; 0]
Week 6-0	[0; 0]
Wound area	
Week 1-0	[-89; 31]
Week 2-0	[-162; 60]
Week 3-0	[-210; 16]
Week 4-0	[-264; 148]
Week 5-0	[-185; 234]
Week 6-0	[-477; 234]
Wound appearance	
% Necrotic tissue	
Week 1-0	[0; 0]
Week 2-0	[0; 0]
Week 3-0	[-10; 0]
Week 4-0	[-20; 0]
Week 5-0	[-75; 0]
Week 6-0	[-75; 0]

Table 7.6 continues...

TABLE 7.6: Differences in variables between groups per week continued...

Variable/week	95% Confidence interval
Wound appearance continued..	
% Slough tissue	
Week 1-0	[0; 5]
Week 2-0	[-5; 10]
Week 3-0	[-10; 20]
Week 4-0	[-15; 5]
Week 5-0	[-15; 10]
Week 6-0	[-20; 10]
% Granulation tissue	
Week 1-0	[-5; 5]
Week 2-0	[-10; 5]
Week 3-0	[-15; 20]
Week 4-0	[-15; 25]
Week 5-0	[-15; 35]
Week 6-0	[-20; 35]
% Epithelialating tissue	
Week 1-0	[-5; 10]
Week 2-0	[-5; 20]
Week 3-0	[-15; 25]
Week 4-0	[-10; 40]
Week 5-0	[-10; 50]
Week 6-0	[-15; 80]

From the confidence intervals in the Table above it can be seen that although there were no *significant differences* between the groups with regard to the indicated variables there were discernable *trends* in the appearance of the wounds.

The difference in the percentage of necrotic tissue in the control group between week zero and week one, compared with the difference in the experimental group was similar [0; 0]. However, the difference between week zero and week six, compared with the difference in the experimental group was [-75; 0]. This confidence interval indicates a higher value for the control group thereby suggesting that the wounds in this group had more necrotic tissue than the experimental group when comparing week six with week zero. In addition, the confidence intervals indicating the differences in percentages of epithelialating tissue of wounds in the experimental group in relation to the control group, increased from week zero to week six [-15; 80]. This finding suggests that wounds in the experimental group progressed more rapidly towards healing than wounds in the control group.

The following section will provide an overview of the progression of the study during the six-week treatment period with regard to patients who withdrew, whose pressure sores were healed and those in whom healing was not achieved. For the sake of discussion these groups will be referred to as the *withdrawals, healers* and *non-healers.*

7.3.3 Withdrawals

Fifty-eight patients (N=58) were enrolled in the study in week zero. However, during the course of the six-week period a total of 17 (29,3%) patients were *withdrawn* as they died, moved from the geographical area, developed a wound infection or were hospitalized. Table 7.7 below indicates the frequency and cumulative frequency (Cf.) of withdrawals in both treatment groups by week. Patients whose pressure sores *healed* during the study period are also indicated.

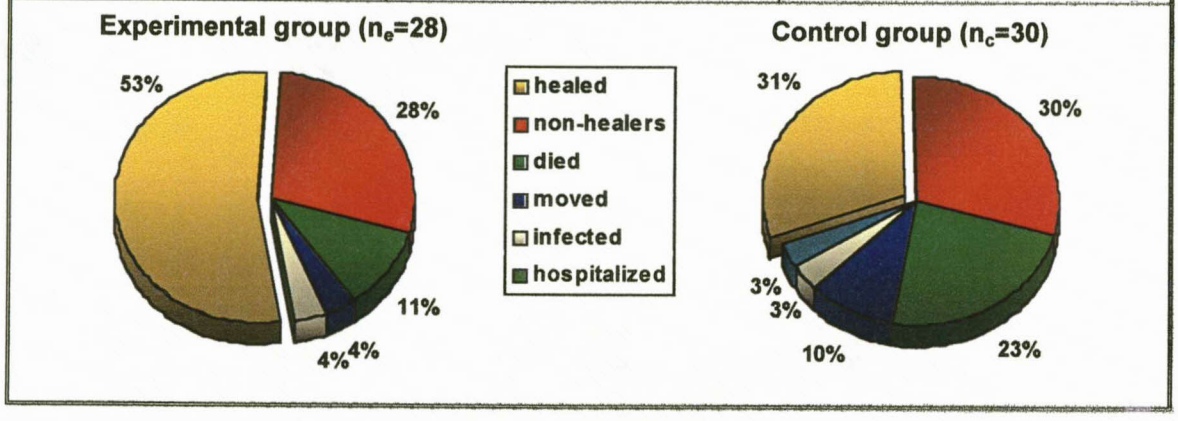
TABLE 7.7: Withdrawals and healing by week

Week/withdrawal reason	Experimental group (n_e=28)		Control group (n_c=30)	
Week one	Frequency	Cf.	Frequency	Cf.
died	1	(1)	1	(1)
moved	1	(1)	3	(3)
healed	0	-	0	-
infected	0	-	0	-
hospitalized	0	-	0	-
Week two				
died	0	(1)	1	(2)
moved	0	(1)	0	(3)
healed	5	(5)	3	(3)
infected	0	-	0	-
hospitalized	0	-	0	-
missed visit	1	(1)	-	-
Week three				
died	1	(2)	3	(5)
moved	0	(1)	0	(3)
healed	2	(7)	1	(4)
infected	1	(1)	1	(1)
hospitalized	0	-	0	-
Week four				
died	0	(2)	2	(7)
moved	0	(1)	0	(3)
healed	3	(10)	3	(7)
infected	0	(1)	0	(1)
hospitalized	0	-	1	(1)
Week five				
died	1	(3)	0	(7)
moved	0	(1)	0	(3)
healed	0	(10)	0	(7)
infected	0	(1)	0	(1)
hospitalized	0	-	0	(1)
missed visit	1	(1)	-	-
Week six				
died	0	(3)	0	(7)
moved	0	(1)	0	(3)
healed	2	(12)	1	(8)
infected	0	(1)	0	(1)
hospitalized	0	-	0	(1)
End of week six				
died	0	(3)	0	(7)
moved	0	(1)	0	(3)
healed	3	(15)	1	(9)
infected	0	(1)	0	(1)
hospitalized	0	-	0	(1)
non-healers	8	(8)	9	(9)

Table 7.8 below provides a summary of the population status at the end of the six-week study period with regard to the frequency and percentage of withdrawals, healers and non-healers for comparison (as can be seen in the graphic representation within the Table).

TABLE 7.8: Population (N=58) status at the end of the study period

	Experimental group (n_e=28)		Control group (n_c=30)	
Status	Frequency	%	Frequency	%
Healed	15	(53,6%)	9	(30%)
Non-healers	8	(28,6%)	9	(30%)
Died	3	(10,7%)	7	(23,3%)
Moved	1	(3,6%)	3	(10%)
Infected	1	(3,6%)	1	(3,3%)
Hospitalized	0	(0%)	1	(3,3%)



7.3.4 Reasons for withdrawals

A discussion of the reasons for withdrawals follows below.

7.3.4.1 Death

Table 7.8 indicates that more patients in the control group died than in the experimental group.

However, none of the deaths in either group were in any way related to the patients' pressure sores or their particular wound treatment.

7.3.4.2 Moved from the geographical area

One patient (3,6%) in the experimental group and three patients (10%) in the control group moved from the geographical area and had to be withdrawn.

7.3.4.3 Infection

Wound infections occurred in the wounds of two patients, one in each group. Notably both patients were assessed as non-compliant with regard to their wound treatment, neither were their living environment hygienic or conducive to wound healing.

7.3.4.4 Hospitalized

One patient in the control group was hospitalized. The reason for hospitalization was not related in any way to the patient's wound or treatment method.

7.3.5 Healers and non-healers

Table 7.8 indicates that the total number of patients who **completed** the study, that is, the *healers* and *non-healers,* was 41. This represents 70,6% of the total study population (N=58).

7.3.5.1 Healers

The wounds of a significant number of patients 15 (53,6%) in the experimental group were healed as opposed to only 9 (30%) in the control group. Notably all the wounds that healed in both groups were classified upon entry as stage two pressure sores.

7.3.5.2 Non-healers

An almost equal number of patients in both groups [8 (28,6%) in the experimental group and 9 (30%)] in the control group - remained for the entire study duration but did not achieve healing.

In the following section the results of the cost analysis related to the treatment of patients that *completed* the study (N=41), will be discussed.

7.4 Cost analysis

A comparative analysis of the treatment cost of the experimental group with that of the control group was performed (See Appendix 9). The proceeding sections will examine the cost analysis of three sub-groups, namely *all patients who completed the study (N=41)*, those whose wounds *healed (N=24)* and the *non-healers (N=17)*.

7.4.1 Cost analysis of patients that completed the study

The cost of treating each patient that **completed** the study (*healers* and *non-healers*) was calculated as described in Section 6.8.1. A determining factor in the cost calculation was the number or frequency of dressing changes.

The frequency of dressing changes of those that completed the study is indicated in the Table below.

TABLE 7.9: Frequency of dressing changes of completers

	Experimental group (n_e=23)	Control group (n_c=18)
Minimum	2	2
Median	10	18
Maximum	40	47
95% confidence interval: [-16; 0]		

From the median values and 95% confidence intervals in Table 7.9 it is clear that the control group had a higher frequency of dressing changes than the experimental group. Subsequently the total treatment costs of the two groups (n_e=23 and n_c=18) were compared. See Table 7.10 below.

TABLE 7.10: Comparison of the total treatment cost for all the patients (N=41) that completed i.e. healers and non-healers

	Experimental group (n_e=23)	Control group (n_c=18)
Minimum	R 58.28	R 82.58
Median	R 677.39	R 955.96
Maximum	R 4 373.49	R 2 754.02
95% confidence interval: [-789.75; 159.12]		

Despite the fact that there were no significant differences between the two groups as far as cost is concerned, it is evident from the 95% confidence interval [-789.75; 159.12] in Table 7.10, that there was a *tendency* for the control group to have higher values indicating that the control treatment tended to be *more expensive* than the experimental treatment.

7.4.2 Cost analysis of patients who were healed

The number of dressing changes in patients who were healed is provided in Table 7.11.

TABLE 7.11: Frequency of dressing changes of patients who were healed

	Experimental group (n_e=15)	**Control group (n_c=9)**
Minimum	2	2
Median	7	11
Maximum	12	24
95% confidence interval: [-12; 1]		

The median values and 95% confidence intervals in Table 7.11 indicate a tendency for patients in the experimental group who were healed, to have fewer dressing changes than those in the control group.

A comparison of the cost analysis of the treatment for patients in both groups who were **healed** (N=24) is provided in Table 7.12.

TABLE 7.12: Cost to achieve healing

	Experimental group (n_e=15)	Control group (n_c=9)
Minimum	R 58.28	R 82.58
Median	R 379.52	R 773.25
Maximum	R 1 102.55	R 1 177.96
95% confidence interval: [-508,28; 159.12]		

Again there were no significant differences between the two groups. However the values of the 95% confidence interval [-508,28; 159.12] in Table 7.12 suggest that the cost to achieve healing in the control group was *higher* than in the experimental group. Conversely, the cost to achieve healing in the experimental group, using advanced wound care methods, tended to be less expensive.

7.4.3 Cost analysis of non-healers

A total of 17 patients who completed the study were classified as **non-healers** at the end of the study period. A comparison of the frequency of dressing changes between patients in this sub-group is presented in Table 7.13.

TABLE 7.13: Frequency of dressing changes of non-healers

	Experimental group (n_e=8)	Control group (n_c=9)
Minimum	11	7
Median	19.5	35
Maximum	40	47
95% confidence interval: [-23; 4]		

The data presented in Table 7.13 also suggest a tendency that non-healers in the control group required more frequent dressing changes than the non-healers in the experimental group. A cost comparison of the treatment of these patients in both groups is provided in Table 7.14.

TABLE 7.14: Cost of non-healers

	Experimental group (n_e=8)	Control group (n_c=9)
Minimum	R 864.39	R 441.67
Median	R 1 646.71	R 2 284.53
Maximum	R 4 373.49	R 2 754.02
95% confidence interval: [-1033.48; 1058.17]		

When comparing the treatment cost for the *non-healers* in both groups there was no significant difference or discernable trend as can be seen by the values of the 95% confidence interval [-1033.48; 1058.17] in Table 7.14.

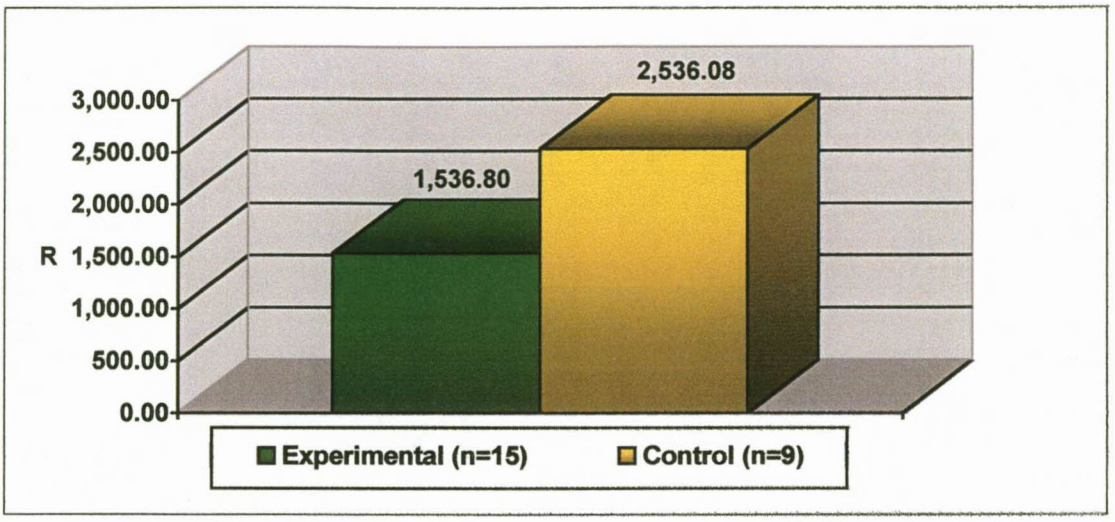
7.5 Cost effectiveness

The total cost of treating patients in the *experimental group* who completed the study was R23 052.02 (See Appendix 9). Fifteen out of 23 patients in this group were completely healed (See Section 7.3.5.1). By dividing the healed group (15) into the total treatment cost (R23 052.02) the cost of achieving healing was **R1 536.08** per patient in the experimental group. The 95% confidence interval [869.1; 2204.5] here indicates the range of treatment cost for the experimental group.

The total cost of treating patients in the *control group* who completed the study was R22 824.71. Nine out of 18 patients in this group were completely healed (See Section 7.3.5.1).

When dividing the healed group (9) into the total treatment cost, the cost to achieve healing in the control group was **R2 536.08** per patient. Similarly the

95% confidence interval [1644.4; 3427.7] here indicates the range of treatment cost for the control group.



GRAPH 7.1: Average treatment cost of healers

Since the values of confidence intervals for the respective groups overlap, we have to assume that there were no statistically significant differences between the groups as far as cost-effectiveness was concerned. However, as Graph 7.1 indicates, there does appear to be a tendency for the control treatment to be more expensive and thus less cost-effective than the experimental treatment.

7.6 Assessment of dressing acceptability

The acceptability of the wound treatment method to patients and caregivers was assessed on completion of the study period by means of the *Assessment of Dressing Acceptability* form.

7.6.1 Patients' assessment of dressing acceptability

Patients indicated their responses to specific statements related to the comfort of the dressings on application and removal. In Table 7.15 the patients' responses with regard to the comfort of the dressing on application indicate that 14 (60,9%) of patients in the experimental group agreed that application was comfortable as opposed to only 6 (33,4%) patients in the control group. No one in the experimental group experienced discomfort on removal of the dressing. However one (5,6%) patient in the control group expressed strong discomfort on dressing removal. Notably a significant number of patients [9 (39,1%) in the experimental group and 11 (61,1%) in the control group] could not report on the comfort of the dressing, as they were unresponsive due to age-related dementia. These patients are indicated as *not applicable* in the Table below.

TABLE 7.15: Patients' assessment of dressing application and removal

Assessment	Experimental group (n_e=23)		Control group (n_c=18)	
'Application of the dressing was comfortable'	Frequency	%	Frequency	%
Agree strongly	10	(43,5%)	2	(11,1%)
Agree a lot	2	(8,7%)	3	(16,7%)
Tend to agree	2	(8,7%)	1	(5,6%)
Tend to disagree	0	-	0	-
Disagree a lot	0	-	0	-
Disagree strongly	0	-	1	(5,6%)
Not applicable	9	(39,1%)	11	(61,1%)
'Removal of the dressing was uncomfortable'	Frequency	%	Frequency	%
Agree strongly	0	-	1	(5,6%)
Agree a lot	0	-	0	-
Tend to agree	0	-	0	-
Tend to disagree	3	(13%)	3	(16,7%)
Disagree a lot	2	(8,7%)	2	(11,1%)
Disagree strongly	9	(39,1%)	1	(5,6%)
Not applicable	9	(39,1%)	11	(61,1%)

7.6.2 Caregiver's assessment of dressing acceptability

According to the data in Table 7.16 below, the caregiver *strongly agreed* that application of dressings in 47,8% of patients in the experimental group was easy as opposed to only one (5,6%) patient in the control group.

The overall ease of dressing application in the experimental group was much higher. This was shown to be statistically significant: 95% confidence interval [1,6; 47,7]. Although the caregiver did not find it difficult to remove any dressings, it does appear that dressing removal in the experimental group was easier than in the control group.

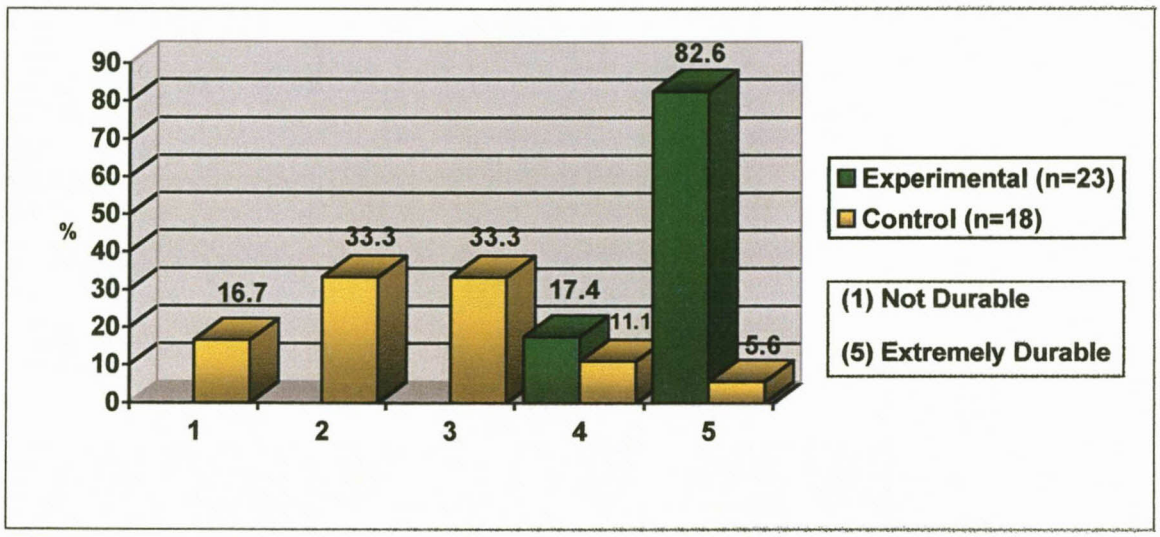
TABLE 7.16: Caregiver's assessment of dressing application and removal

Assessment	Experimental group (n_e=23)		Control group (n_c=18)	
'Application of the dressing was easy'	Frequency	%	Frequency	%
Agree strongly	11	(47,8%)	1	(5,6%)
Agree a lot	9	(39,1%)	2	(11,1%)
Tend to agree	2	(8,7%)	10	(55,6%)
Tend to disagree	1	(4,3%)	5	(27,8%)
Disagree a lot	0	-	0	-
Disagree strongly	0	-	0	-
'Removal of the dressing was difficult'	Frequency	%	Frequency	%
Agree strongly	0	-	0	-
Agree a lot	0	-	0	-
Tend to agree	0	-	0	-
Tend to disagree	1	(4,3%)	10	(55,6%)
Disagree a lot	7	(30,4%)	6	(33,3%)
Disagree strongly	15	(65,2%)	2	(11,1%)

7.6.3 Caregiver's assessment of the durability of dressing

Dressing durability over the six-week study period was assessed by means of a rating scale on the *Assessment of Dressing Acceptability* form. The scale ranged from one (not durable) to five (extremely durable).

Results of the assessment depicted in the graph below clearly show that dressings used to treat patients in the experimental group were **significantly more durable** than those used in the control group: the 95% confidence interval [60,5; 94,2].



GRAPH 7.2: Durability of dressings

7.7 Conclusion

This chapter provided results and discussion of the data analysis. In the following chapter final conclusions and recommendations will be made along with a discussion of the limitations of the study.

CHAPTER EIGHT

Conclusions, limitations and recommendations

8.1 Introduction

In this chapter conclusions will be made, the limitations of the study discussed and recommendations suggested.

8.2 Conclusions

The following conclusions with regard to the objectives of the study, namely cost-effectiveness and acceptability, were drawn:

8.2.1 Cost-effectiveness

From the results of the data analysis presented in the preceding chapter it may be concluded that over a six-week period *more* wounds in the experimental group, treated with advanced wound care products and in particular Smith & Nephew™ products, *healed,* than wounds in the control group treated with the currently available wound care products.

As there were no significant statistical differences between the groups with regard to the *cost* to achieve healing, it may be assumed that the advanced wound care treatment method was not more expensive than the currently used methods. However, there was a *tendency* for the currently used methods to be more expensive. Furthermore, when the cost of treatment for *all patients who completed the study* (healers and non-healers) was compared results indicated a tendency for the advanced treatment method, using Smith & Nephew™ products, to be less expensive.

Consequently it may be concluded that the results of this study indicate a trend for advanced wound care methods to be more *cost-effective* than currently used methods. Although these trends were not considered to be of statistical significance, they are of clinical and practical importance.

8.2.2 Acceptability of treatment modalities

Conclusions regarding the assessment of the acceptability of these treatment modalities to patients with pressure sores and their caregivers in the community over a six-week period were the following:

8.2.2.1 Patients

In this study patients assessed the acceptability of dressings in terms of ease as well as comfort of application and removal. Patients reported that dressings used in the advanced wound care management method (Smith & Nephew™ products) were more acceptable than dressings (mostly gauze or hydrocolloids) used in the current management methods.

8.2.2.2 Caregiver

The caregiver's assessment of dressing acceptability in terms of *ease* of application and removal as well as *durability* over the six-week period indicate that dressings used in the advanced wound care management method (Smith & Nephew™ products) were significantly more acceptable than dressings used in the current management methods.

8.3 Limitations of the study

The following limitations were identified in this study.

Over the 12-month period of data collection the researcher attempted to recruit and include all eligible patients within the Bloemfontein community who met the inclusion criteria. This eventually resulted in a sample population of 41 patients who completed the study. However, it is possible that a larger sample size could have magnified the tendencies that were identified and ultimately of statistical significance. However, a larger sample size would have had additional implications such as an extended data collection period and increased financial costs to the researcher. The lack of significant statistical difference should also be considered in the light of a caveat by Feinstein (1977:258) who stated the following: "Perhaps the most deleterious consequence of using conventional statistical theory in modern clinical science has been the widespread fantasy that a *statistically significant* difference is a *significant* difference."

Despite efforts to obtain objective wound assessments, financial and practical constraints limited the use of more sophisticated assessment methods to monitor the rate of wound healing in the community setting.

The very nature of pressure sore aetiology is such that wounds will often enlarge due to underlying tissue damage before healing can occur and be evidenced as a visible reduction in wound size. Despite the successes of other published trials in which patients were treated for six weeks (Banks & Bale, 1994: 304), this may therefore have been too brief a period in which to observe significant reduction in wound size. However, an extended treatment period would have had financial implications.

8.4 Recommendations

The results of this study indicate that advanced wound treatment using modern (Smith & Nephew™) products, often perceived to be more expensive, tended to be *more cost-effective* than the currently used methods. The study results also indicate a tendency for wounds treated with the advanced treatment method to have a *more rapid rate of healing.* It therefore appears that the advanced treatment method lends itself to better wound care practice with financial benefits to individuals and institutions, yet there is still a tendency for currently used traditional treatment methods to persist. Consequently a paradigm shift towards a more advanced wound care treatment method is needed. However, this will require training and education about modern wound care to patients, caregivers and all health care professionals.

In order to achieve this goal a formal course in wound care as a specialized branch of nursing in South Africa needs to be established. Furthermore, as successful wound care requires a multidisciplinary approach, wound care education should be available to other health professionals to complement their specialized knowledge and skills and thereby contribute to the clinical practice of wound prevention and management.

During the 12-month data collection period of this study the researcher saw evidence of an alarming lack of knowledge with regard to all aspects related to the basic principles *pressure sore prevention and treatment*, not only in patients and caregivers but also in health care workers, which included professional nurses and physicians. The development of a comprehensive best practice model or protocol for *pressure sore prevention and treatment* in community settings could be of enormous value to wound care practitioners and significantly benefit patients with pressure sores in the community.

In addition, a systematic, interdisciplinary and ongoing *quality improvement program* needs to be developed and implemented to facilitate comprehensive, consistent care that can be monitored, evaluated and changed as patient conditions and current knowledge warrant.

Despite the advances in wound care products and much international research on the topic over the past decade, a literature search revealed no published community-based wound care trials in South Africa. This study accentuates the need for more clinical research in wound care in South Africa, in particular nurse-led community-based randomized clinical trials. Accordingly, more attention in nursing education needs to be given to quantitative research techniques and more specifically clinical trial methodology in order to empower nurses to conduct and publish scientific clinical research.

SUMMARY/ OPSOMMING

SUMMARY

The purpose of this research project was to compare the cost-effectiveness and acceptability of an advanced wound care management method, using only Smith & Nephew™ wound care products, to that of currently used methods and/or products as encountered by the researcher in the treatment of pressure sores in the Bloemfontein community.

Prior to commencement the ethical committee of the Faculty of Health Sciences, University of the Orange Free State, approved the study and its procedures.

Fifty-eight patients who met the inclusion criteria (as stipulated in the research protocol) were randomly allocated to an experimental group and a control group. Patients in the experimental group were treated with Smith & Nephew™ wound care products for six weeks. Patients in the control group continued with their current treatment for the same period of time. The researcher personally performed the dressing changes of all patients in both groups free of charge. Furthermore the researcher attempted, where possible, to address all those factors that might have impeded the healing process in each patient. The characteristics and nature of each particular wound determined the frequency of dressing changes. All wounds were assessed and photographed by the researcher at weekly intervals for the six-week period. The study continued uninterruptedly for 12 months until the required sample size was achieved. The treatment methods of both groups were compared in terms of cost-effectiveness and acceptability.

Analysis of the base-line data of patients on entry revealed no differences or biases between the groups and they were therefore comparable. A number of patients were withdrawn from the study as they died, moved from the geographical area, were hospitalized or became infected. Ultimately forty-one patients were included in the cost calculation.

Statistical analysis of the data using 95% confidence intervals revealed no significant differences between the two groups with regard to the rate of healing and cost of treatment. However, the confidence intervals indicated the following discernable *trends*:

- More wounds in the experimental group healed than in the control group.
- The cost of treating wounds with the advanced treatment method appeared to be lower than those treated with currently used methods.
- The cost to achieve healing in the experimental group *tended* to be lower and therefore more cost-effective.

There was also a tendency for patients to find the advanced treatment using Smith & Nephew™ wound care products, more acceptable than the currently used more conventional methods. Moreover, results indicated that the advanced Smith & Nephew™ dressings were significantly more durable.

The findings of this study suggest that individuals with pressure sores and their caregivers in the community stand to benefit from using advanced wound care methods, as they are appropriate, cost-effective and acceptable treatment methods for the treatment of pressure sores. Consequently the following recommendations are made:

- That a wound care course open to all health care professionals on wound healing be instituted.
- That a protocol for the *prevention and treatment of pressure sores* be developed.
- That attention be given to the education of nurses with regard to clinical trial methodology.
- That nurse-led clinical wound care trials be encouraged.

OPSOMMING

Die doel van hierdie navorsingsprojek was om die koste-doeltreffendheid en aanvaarbaarheid van 'n gevorderde wondsorg-bestuursmetode, met die uitsluitlike gebruik van Smith & Nephew™ wondsorgprodukte, te vergelyk met die metodes en/of produkte wat tans in gebruik is soos dit deur die navorser vir die behandeling van druksere in die Bloemfontein gemeenskap aangetref is.

Voor die aanvang van die navorsing het die etiese komitee van die Fakulteit Gesondheidswetenskappe van die Universiteit van die Oranje-Vrystaat die studie en sy prosedures goedgekeur.

Agt-en-vyftig pasiënte wat aan die insluitingskriteria, soos in die navorsingsprotokol gestipuleer is voldoen het, is ewekansig aan 'n eksperimentele en 'n kontrolegroep toegewys. Pasiënte in die eksperimentele groep is vir ses weke met Smith & Nephew™ wondsorgprodukte behandel. Pasiënte in die kontrolegroep het vir dieselfde tydperk met hulle behandeling soos voorheen voortgegaan. Die navorser het persoonlik die wonde van albei groepe versorg sonder om 'n fooi te hef. Die navorser het ook, sover moontlik, gepoog om alle faktore wat moontlik die genesingsproses by elke pasiënt kon strem, aan te spreek. Die aard en eienskappe van elke afsonderlike wond het bepaal hoe dikwels die verbindsels verwissel is. Die navorser het al die wonde elke week vir die ses-weke periode beraam en gefotografeer. Die studie het ononderbroke vir 12 maande voortgeduur totdat die verlangde steekproefgrootte bereik is. Die behandelingsmetodes van beide groepe is vergelyk in terme van koste-doeltreffendheid en aanvaarbaarheid.

'n Analise van die basislyndata van die pasiënte by toetrede het geen verskille of onewewigtigheid tussen die groepe aangetoon nie en hulle was derhalwe vergelykbaar.

'n Aantal pasiënte is aan die studie onttrek omdat hulle gesterf het, uit die geografiese streek getrek het, gehospitaliseer is of geïnfekteerd geraak het. Uiteindelik is 41 pasiënte by die kosteberekening ingesluit.

Statistiese analise van die data met die gebruik van 95% vertouensintervalle het geen beduidende verskille tussen die twee groepe ten opsigte van die tempo van genesing en die koste van behandeling aangetoon nie. Die vertrouensintervalle het egter die volgende waarneembare *neigings* getoon:

- Meer wonde in die eksperimentele groep as in die kontrolegroep het genees.
- Dit wou voorkom of die koste van behandeling met die gevorderde behandelingsmetode laer was as dié met die metodes wat tans in gebruik is.
- Die koste om genesing by die eksperimentele groep te bewerkstellig het *geneig* om laer en daarom meer kostedoeltreffend te wees.

Daar was ook 'n neiging by die pasiënte om die gevorderde behandeling met Smith & Nephew™ wondsorgprodukte meer aanvaarbaar te vind as die konvensionele metodes wat tans in gebruik is. Verder toon die resultate dat die gevorderde Smith & Nephew™ verbindsels beduidend duursamer as die konvensionele tipes is.

Die bevindinge van hierdie studie dui daarop dat indiwidue met druksere en hul versorgers in die gemeenskap voordeel kan trek uit die gebruik van gevorderde wondsorgmetodes, aangesien hulle toepaslik, kostedoeltreffend en aanvaarbare metodes vir die behandeling van druksere is. Gevolglik word onderstaande aanbevelings gemaak:

- Dat 'n wondsorgkursus wat vir alle professionele gesondheidsorgwerkers oop is, ingestel word;
- Dat 'n protokol vir die *voorkoming en behandeling van druksere* ontwikkel word;

- Dat aandag geskenk word aan die opleiding van verpleegkundiges in die metodologie van kliniese proewe;
- Dat verpleegkundige-geleide wondsorgproewe aangemoedig word.

APPENDIX 1

Advertisement

DRUKSERE

Gesoek: Alle persone ouer as 18 jaar met druksere, woonagtig in die Bloemfontein area, wat sou belang stel om ingesluit te word in 'n navorsingsprojek oor die behandeling van druksere. Geselekteerde persone sal *gratis* behandeling vir 6 weke (in oorleg met hul geneesheer) ontvang. Vir meer inligting skakel Nico Small by 0828568001 of (051) 446 3671.

PRESSURE SORES

Wanted: All persons over the age of 18 years living in the Bloemfontein area, suffering from pressure sores who might be interested in enrolment in a research project on the treatment of pressure sores. Selected individuals will receive ***free*** treatment (in collaboration with their attending doctor) for 6 weeks. For more information call Nico Small at 0828568001 or (051) 446 3671.

APPENDIX 2

Smith & Nephew Products

The following Smith & Nephew wound care products were used:

PRODUCT	DESCRIPTION
IntraSite™ Gel	A hydrogel containing a Graft-T-Starch copolymer.
Allevyn™ Hydrocellular Polyurethane Dressing	Polyurethane trilaminate structure with a non-adherent contact layer, absorbent foam central layer and waterproof outer layer.
Allevyn™ Adhesive	Polyurethane trilaminate structure with a non-adherent contact layer, absorbent foam central layer, waterproof outer layer and an adhesive backing and border.
Allevyn™ Cavity	Absorbent polyurethane foam chippings encased in a perforated film.
OpSite Flexigrid™	An adhesive polyurethane film dressing.
Surgipak™ (O.F.S. Dressing Tray)	Pre-sterilised, pre-packed wound trays. Each tray contains 1 plastic bag, 2 hand towels, 1 protection sheet, 1 pair of latex gloves and 5 gauze swabs.

INTRASITE™ GEL APPLIPAK

PHARMACOLOGICAL ACTION
INTRASITE™ GEL APPLIPAK has no direct pharmacological action on the body as it is designed as a topical application for wound management. It acts by absorbing exudate from the wound surface, thereby preventing slough formation. The effective rehydrating action can produce rapid debridement of necrotic wounds and removal of slough without damaging fragile granulation tissue.

INDICATIONS
INTRASITE™ GEL APPLIPAK is a dressing for cavity wounds, extravasation injuries, venous ulcers and decubitus ulcers (pressure sores).

CONTRA-INDICATIONS
INTRASITE™ GEL APPLIPAK is for external use only and should not be taken by mouth.
Hypersensitivity to any of the ingredients. Do not use on exposed muscle tendon or bone. Do not use on deep partial thickness and full thickness burns.

WARNINGS
The initial application of INTRASITE™ GEL APPLIPAK should be under the direction of a health professional.
For external use only.

DOSAGE AND DIRECTIONS FOR USE
Prepare the wound site by irrigating with a sterile solution e.g. saline.
Remove cap and swab the nozzle area of the pack with a suitable antiseptic swab.

Snap the patterned tip off the nozzle.

1. Keeping the nozzle tip clear of the wound surface, gently press the bulb of the pack to dispense gel into the wound. Smooth over the surface of the wound, ensuring a minimum gel depth of 5 mm.
2. Cover the wound with a secondary dressing.

OPSITE™ FLEXIGRID

DESCRIPTION
OPSITE FLEXIGRID is a transparent film dressing, comprised of a polyurethane film with acrylic adhesive. The film is supported on a flexible grid carrier to provide a simple application system.

MODE OF ACTION
When used on wounds, the OPSITE film creates a moist environment by retaining exudate. The film is moisture vapour permeable, allowing excess exudate to evaporate and preventing skin maceration. OPSITE FLEXIGRID is waterproof and aids in the prevention of bacterial contamination of the wound. The film is highly extensible and conformable and is easily adaptable to awkward areas. The grid carrier can be used to map wounds to monitor the healing process.

INDICATIONS
OPSITE FLEXIGRID is indicated for:
The management of superficial wounds (eg. Superficial pressure sores, minor burns, abrasions).
The protection of fragile skin.
The retention of primary dressings (eg. INTRASITE™ Gel, ALLEVYN™ Cavity).
The fixation of catheters.

INSTRUCTIONS FOR USE
1. Clean and dry the application area.
2. Remove the backing paper and side tab.
3. Apply the dressing and smooth down.
4. If required, trace the wound on the green squared carrier before removing.
5. Remove the carrier.
6. To remove the dressing, lift one corner and gently stretch parallel to the skin. The dressing may be left in place for up to 14 days.

PRECAUTIONS FOR USE
OPSITE FLEXIGRID may be used on clinically infected wounds if the following precautions are followed:
The patient should be under medical/clinical supervision.
The dressing should be changed daily.
The patient should be receiving suitable systemic treatment.
Immuno-compromised patients and diabetic patients may require extra supervision. Care should be taken to avoid skin damage on repeated applications on patients with thin or fragile skin.

ALLEVYN™ CAVITY

DEEP WOUND DRESSING

DESCRIPTION
ALLEVYN CAVITY wound dressing consists of highly absorbent hydrocellular granules encapsulated in a soft, perforated honeycomb film. Each dressing is individually packed and sterilised.

MODE OF ACTION
ALLEVYN CAVITY absorbs exudate while maintaining a moist wound environment. It packs the wound, physically preventing premature wound closure and is non-adherent to the wound surface.

INDICATIONS
Cavity wounds including pressure sores, pilonidal sinuses, surgical excisions/incisions to:
- manage wounds prior to delayed primary closure *and*
- *wound healing via secondary intention.*

INSTRUCTIONS FOR USE
1. Clean the wound in accordance with normal procedures.
2. Select an appropriately sized dressing or combination of dressings and insert into the cavity using sterile blunt forceps or gloved hands.
3. Make a note of the number of dressings used in each wound on the patient's records.
4. Hold the dressing(s) in place using a suitable retention dressing, eg. OPSITE™ FLEXIGRID™. Alternatively, an absorbent dressing pad, eg. MULTISORB™ or MELOLIN™ may be used in conjunction with a fixative sheet, eg. HYPAFIX™, or a bandage, eg. TENSOPLUS™ Lite. This is particularly advised when the skin around the wound is of a very fragile or friable nature.

Note A: Where necrotic or sloughy tissue is present in the wound, ALLEVYN Cavity may be used in conjunction with INTRASITE™ Gel.
Note B: ALLEVYN cavity may be used with topical liquid antiseptics if required.
Also see Precautions section.

FREQUENCY OF CHANGE
ALLEVYN CAVITY can be left in place for up to seven days, depending on the clinical condition of the wound.

DRESSING REMOVAL
Remove secondary dressings and carefully remove ALLEVYN CAVITY dressings using either blunt forceps or gloved hands.

PRECAUTIONS
ALLEVYN CAVITY dressings should not be re-used. Do not soak ALLEVYN CAVITY dressings in oxidising agents such as hypochlorite solutions (eg. EUSOL) or hydrogen peroxide, as these can break down the absorbent polyurethane component of the dressing.

ALLEVYN™

HYDROCELLULAR DRESSING

DESCRIPTION
ALLEVYN HYDROCELLULAR dressing combines an absorbent hydrocellular pad sandwiched between a perforated non-adherent wound contact layer and a waterproof outer film.

MODE OF ACTION
ALLEVYN HYDROCELLULAR dressing provides a moist wound healing environment. The dressing is easy to apply and remove. The absence of adhesive makes the dressing especially suitable for use on fragile skin.

INDICATIONS AND PRODUCT CLAIMS
Wound management by secondary intention on shallow, granulating wounds.

INSTRUCTIONS FOR USE
1. Clean the wound in accordance with normal procedures.
2. Select an appropriate size.
3. Prepare and clean the skin surrounding the wound area by removing excess moisture. Any excess hair should be clipped to ensure close approximation to the wound.
4. Apply the white, patterned face to the wound and secure with a dressing retention sheet (eg. HYPAFIX™), tape or bandage. ALLEVYN dressings can be used in conjunction with compression therapy on venous leg ulcers.
5. ALLEVYN dressing can be cut, especially to dress wounds on heels, elbows and other awkward areas.

FREQUENCY OF CHANGE
During the early stages of treatment, ALLEVYN dressings should be inspected frequently; dressings can be left in place undisturbed for up to 7 days, or until exudate is visible and approaches 1.5 cm from the edge of the dressing. The film backing is a waterproof outer layer that aids in the prevention of bacterial contamination of the wound. See below for further information.

DRESSING REMOVAL
To remove ALLEVYN dressings, remove dressing or bandage and lift the dressing away from the wound.

PRECAUTIONS
ALLEVYN dressings should not be reused. Do not use ALLEVYN dressings with oxidising agents such as hypoclorite solutions (eg. EUSOL) or hydrogen peroxide, as these can break down the absorbent polyurethane component of the dressing. Reddening of the skin around the wound following the use of ALLEVYN dressings has been reported rarely. In some cases this relates to irritation of fragile skin, in others, wound exudate remaining in contact with normal skin for prolonged periods may be the cause. Infrequently, cases of sensitivity to the dressing have also been reported. If reddening or sensitisation occur, discontinue use and consult a healthcare professional.

ALLEVYN™ ADHESIVE

HYDROCELLULAR DRESSING

DESCRIPTION
ALLEVYN ADHESIVE dressing combines a centrally located absorbent hydrocellular pad sandwiched between a perforated adherent wound contact layer and a waterproof outer film.

MODE OF ACTION
ALLEVYN ADHESIVE dressing provides a moist wound healing environment. The dressing is easy to apply and remove.

INDICATIONS AND PRODUCT CLAIMS
Wound management by secondary intention healing on shallow, granulating wounds.

INSTRUCTIONS FOR USE
1. Clean the wound in accordance with normal procedures.
2. Select an appropriate size.
3. Prepare and clean the skin surrounding the wound area by removing excess moisture. Any excess hair should be clipped to ensure close approximation to the wound. SKIN-PREP™ wipes may be used prior to application of ALLEVYN ADHESIVE dressing where fragile skin is involved.
4. Remove the outermost protector paper from ALLEVYN ADHESIVE dressing and anchor the dressing at one side.
5. Smooth the dressing over the wound, removing the remaining protector paper. Ensure the dressing is securely in place and the edges are not wrinkled.
6. ALLEVYN dressing can be cut, especially to dress wounds on heels, elbows and other awkward areas.
7. When positioning ALLEVYN ADHESIVE SACRUM DRESSINGS, place the narrow end of the dressing a minimum of 2 cm above the anal sphincter, then smooth the dressing over the sacrum.

FREQUENCY OF CHANGE
During the early stages of treatment, ALLEVYN ADHESIVE dressings should be inspected frequently; dressings can be left in place undisturbed for up to 7 days, or until exudate is visible and approaches 2 cm from the edge of the dressing. The film backing is a waterproof outer layer that aids in the prevention of bacterial contamination of the wound. See below for further information.

DRESSING REMOVAL
To remove ALLEVYN dressings, lift one corner of the dressing and stretch the dressing gently away from the wound.
Sacral dressings should be removed from the top edge and down towards the anus to minimise the chance of transmitting infection.

PRECAUTIONS

ALLEVYN ADHESIVE dressings should not be reused. Do not use ALLEVYN ADHESIVE dressings with oxidising agents such as hypoclorite solutions (eg. EUSOL) or hydrogen peroxide, as these can break down the absorbent polyurethane component of the dressing. In common with all adhesive products, some rare cases of irritation and/or maceration of the skin surrounding the wound have been reported. Infrequently, cases of sensitivity to the dressing have also been reported. It should be noted that inappropriate use or too frequent dressing changes, particularly in patients with fragile skin, can result in skin irritation or stripping. If reddening or sensitisation occur, discontinue use and consult a healthcare professional.

APPENDIX 3

Products used in the control group

The following cleansers, topical treatments and dressings as encountered by the researcher in the community, were used on the wounds of patients in the control group that *completed* the study. A reference to sections in the literature where each item is discussed, is provided in brackets.

Cleansers

- Milton™ (See Section 4.5.2.1 [c])
- Saline (See Section 4.5.2.1 [h])

Topical treatments

- Acriflavin (See Section 4.5.4.2)
- Bactrazine™ (See Section 4.5.4.1)
- Tea tree oil (See Section 4.5.4.4)
- Flagyl™ (See Section 4.5.4.1)
- Aqueous cream (See Section 4.5.4)
- Betadine™ (See Section 4.5.2.1[e])
- Bactrazine™ (See Section 4.5.4.1)
- Johnson & Johnson Nu-gel™ hydrogel (See Section4.5.5.3)
- Aserbine™ cream (See Section 4.5.3.3)

Wound dressings

- Gauze (See Section 4.5.5.9)
- Cotton wool (See Section 4.5.5.9)
- Coloplast™ ulcer dressing (See Section 4.5.5.2)
- Coloplast™ transparent dressing (See Section 4.5.5.2)
- Bactigrass™ (See Section 4.5.5.7)
- Jelonet™ (See Section 4.5.5.7)
- 3M™ Island dressing (See Section 4.5.5)
- 3M Transparent dressing (See Section 4.5.5.1)

APPENDIX 4

Instruments used for data collection

INITIAL PATIENT INFORMATION

1. Patient number:

[ ][ ][ ] [ ][ ][ ] 1-3

2. Date:

[ ][ ][ ][ ] [ ][ ][ ][ ] 4-7

3. Gender:

[ ][ ] [ ] 8

4. Age:

[ ][ ] [ ][ ] 9-10

5. Allergies:

5.1. _____ [ ][ ] 11-12

5.2. _____ [ ][ ] 13-14

5.3. _____ [ ][ ] 15-16

5.4. _____ [ ][ ] 17-18

5.5. _____ [ ][ ] 19-20

6. Weight (in light clothing):

[ ][ ][ ] Kg [ ][ ][ ] 21-23

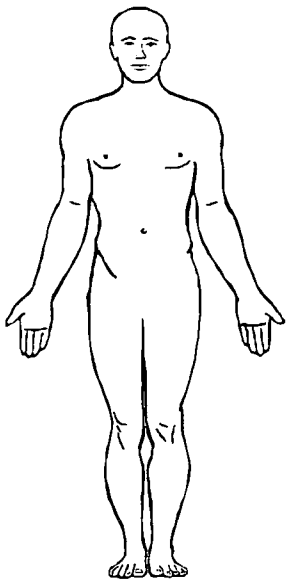
7. Length (without shoes):

[ ][ ][ ] cm [ ][ ][ ] 24-26

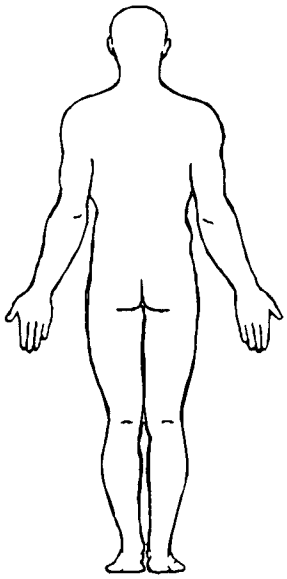
8. Wound site:

(Indicate on the figures below)

27-28



Anterior



Posterior

WEEKLY WOUND ASSESSMENT CHART

1. Patient number:

☐☐☐ 1-3

2. Date:

☐☐☐☐ 4-7

3. Weight (in light clothing):

☐☐☐ Kg 8-10

4. Braden Pressure Sore Risk assessment score:

☐☐ 11-12

5. Wound duration (since onset):

☐☐☐ Weeks 13-15

6. Number of days dressing is in place:

☐ 16

7. Indicate the condition of the wound dressing:

1	In place and intact
2	In place with loose edges
3	In place with crumpled edges
4	Dressing has failed to stay in place
5	Other

(Include a report in the case record)
Specify:_____ ☐ 17

8. Wound dimensions:

8.1 Max length

☐☐☐ mm 18-20

8.2 Max width

☐☐☐ mm 21-23

8.3 Max depth

[ ][ ][ ] mm [ ][ ][ ] 24-26

8.4 Wound volume

[ ][ ][ ] cc [ ][ ][ ] 27-29

8.5 Tracing:

1	Yes
2	No

[ ] 30

9. Pressure sore classification according to the Sterling Pressure Sore Severity Scale:

[ ][ ][ ][ ] Stage [ ][ ][ ][ ] 31-34

10. Level of exudate:

1	High*[1]
2	Medium
3	Low

[ ] 35

10.1 Amount of exudate change:

1	Same as last assessment
2	Increasing*
3	Decreasing
4	Unknown - first assessment

[ ] 36

10.2 Type of exudate:

1	Bloody*
2	Serous
3	Serosanguineous
4	Combination/ Other

Specify:_____ [ ] 37

11. Appearance of the wound bed:

11.1 Necrotic/black tissue*

[ ][ ][ ] % [ ][ ][ ] 38-40

11.2 Slough/yellow tissue*

[ ][ ][ ] % [ ][ ][ ] 41-43

[1] Asterixes (*) refer to observations which may indicate wound infection.

11.3 Granulation/red tissue

[ ][ ][ ] %

[ ][ ][ ] 44-46

11.4 Epitheliating/pink tissue

[ ][ ][ ] %

[ ][ ][ ] 47-49

12. Surrounding skin/ wound margin:

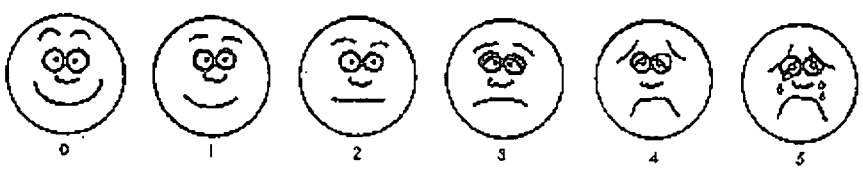
1	Intact	50
2	Erythema*	51
3	Indurated*	52
4	Macerated*	53
5	Oedematous*	54
6	Localised heat around wound margin*	55
7	Fragile*	56
8	Dry-scaling	57

13. Pain:

1	No pain
2	At dressing change*
3	Intermittent*
4	Persistent*

[ ] 58

13.1 Degree of pain (encircle the number under the appropriate facial expression)



Source: Wong-Baker faces rating scale. 1997. AJN. 97(7): 19

[ ] 59

14. Factors that may delay healing:

1	Poor nutrition	60
2	Impaired circulation	61
3	Impaired sensation	62
4	Foreign bodies	63
5	Dehydration	64
6	Non-compliance	65
7	Smoking	66
8	Underlying disease	67
9	Pharmacological agents	68
10	Impaired mobility	69
11	Complementary medicines	70
12	Anaemia	71
13	Mechanical forces	72
14	Systemic infection	73

15. Medication (including over-the-counter drugs and complementary medicines) used in the last two weeks:

1. _____ 74-75
2. _____ 76-77
3. _____ 78-79
4. _____ 1-2
5. _____ 3-4

16. Cleansing solution(s) used:

1. _____ 5-6
2. _____ 7-8
3. _____ 9-10
4. _____ 11-12
5. _____ 13-14

17. Topical treatment applied:

1. _____ 15-16
2. _____ 17-18
3. _____ 19-20
4. _____ 21-22
5. _____ 23-24

18. Dressing(s) used:

1. _____ 25-26
2. _____ 27-28
3. _____ 29-30
4. _____ 31-32
5. _____ 33-34

19. Last dressing applied on:

19.1 Date:

35-38

20. Duration of wound care:

Started:

39-43

Ended:

44-48

21. Are any symptoms of an adverse reaction present?

1	Yes
2	No

49

21.1 If yes, describe symptoms.

1. _____ 50-51
2. _____ 52-53
3. _____ 54-55
4. _____ 56-57
5. _____ 58-59

22. Photograph of the wound:

22.1 Photo number: (patient number/ disk number - file number)

/

22.2 Additional comments:

1. _____ 60-61
2. _____ 62-63
3. _____ 64-65
4. _____ 66-67
5. _____ 68-69

23. Is the patient continuing to partake in the study?

1	Yes
2	No

70

23.1 If no, state reason/s for discontinuation.

1. _____ 71-72
2. _____ 73-74
3. _____ 75-76
4. _____ 77-78
5. _____ 79-80

24. Case record, including adverse event(s) and/or incident(s):

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

* ***Observations which may indicate infection.***

ASSESSMENT OF DRESSING ACCEPTABILITY

1. Patient number:

1-3

2. Date:

4-7

3. Indicate your responses to the following statements:

3.1 'Application of the dressing was comfortable.'

1	Agree strongly
2	Agree a lot
3	Tend to agree
4	Tend to disagree
5	Disagree a lot
6	Disagree strongly
7	Not applicable (no sensation)

8

3.2 'Removal of the dressing was uncomfortable.'

1	Agree strongly
2	Agree a lot
3	Tend to agree
4	Tend to disagree
5	Disagree a lot
6	Disagree strongly
7	Not applicable (no sensation)

9

The following questions are to be completed by the caregiver referring to the aforementioned patient.

4. Indicate your responses to the following statements:

4.1 'Application of the dressing was easy.'

1	Agree strongly
2	Agree a lot
3	Tend to agree
4	Tend to disagree
5	Disagree a lot
6	Disagree strongly

10

4.2 'Removal of the dressing was difficult.'

1	Agree strongly
2	Agree a lot
3	Tend to agree
4	Tend to disagree
5	Disagree a lot
6	Disagree strongly

[ ] 11

5. Indicate on the rating scale below how ***durable*** the wound dressing was over the last 6 weeks, considering the extraneous factors applicable to this patient?

Not Durable | 1 | 2 | 3 | 4 | 5 | ***Extremely Durable***

[ ] 12

RECORD OF DRESSING CHANGES AND PRODUCTS USED

1. Patient number:

[ ][ ][ ] [ ][ ][ ] 1-3

2. Date:

[ ][ ][ ][ ] [ ][ ][ ][ ] 4-7

3. Number of days dressing is in place:

[ ] [ ] 8

4. Indicate the condition of the wound dressing:

1	In place and intact
2	In place with loose edges
3	In place with crumpled edges
4	Dressing has failed to stay in place
5	Other

(Include a report in the case record)
Specify:_____ [ ] 9

5. Level of exudate:

1	High*
2	Medium
3	Low

[ ] 10

5.1 Amount of exudate change:

1	Same as last assessment
2	Increasing*
3	Decreasing
4	Unknown – first assessment

[ ] 11

5.2 Type of exudate:

1	Bloody*
2	Serous
3	Serosanguineous
4	Combination/ Other

Specify:_____ [ ] 12

6. Appearance of the wound bed:

6.1 Necrotic/black tissue*

[ ][ ][ ] % [ ][ ][ ] 13-15

6.2 Slough/yellow tissue*

[ ][ ][ ] %

[ ][ ][ ] 16-18

6.3 Granulation/red tissue

[ ][ ][ ] %

[ ][ ][ ] 19-21

6.4 Epitheliating/pink tissue

[ ][ ][ ] %

[ ][ ][ ] 22-24

7. Surrounding skin/ wound margin:

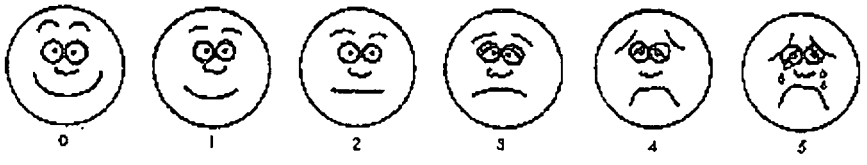
1	Intact	25
2	Erythema*	26
3	Indurated*	27
4	Macerated*	28
5	Oedematous*	29
6	Localised heat around wound margin*	30
7	Fragile*	31
8	Dry-scaling	32

8. Pain:

1	No pain
2	At dressing change*
3	Intermittent*
4	Persistent*

[ ] 33

8.1 Degree of pain (encircle the number under the appropriate facial expression).



Source: Wong-Baker faces rating scale. 1997. AJN. 97(7): 19

[ ] 34

9. Cleansing solution(s) used:

1. _____ [ ][ ] 35-36
2. _____ [ ][ ] 37-38
3. _____ [ ][ ] 39-40
4. _____ [ ][ ] 41-42
5. _____ [ ][ ] 43-44

10. Topical treatment applied:

1. _____ 45-46
2. _____ 47-48
3. _____ 49-50
4. _____ 51-52
5. _____ 53-54

11. Dressing(s) used:

1. _____ 55-56
2. _____ 57-58
3. _____ 59-60
4. _____ 61-62
5. _____ 63-64

12. Last dressing applied on:

12.1 Date:

[ ][ ][ ][ ] [ ][ ][ ][ ] 65-68

13. Duration of wound care:

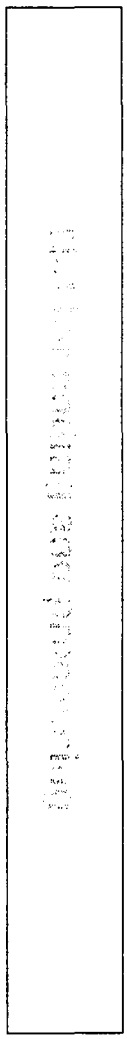
Started:

[ ][ ][ ][ ] [ ][ ] : [ ][ ] 69-73

Ended:

[ ][ ][ ][ ] [ ][ ] : [ ][ ] 74-78

14. Case record, including adverse event(s) and/or incident(s):



- ***Observations which may indicate infection.***

APPENDIX 5

Consent Forms

A COMPARATIVE ANALYSIS OF PRESSURE SORE TREATMENT MODALITIES IN COMMUNITY SETTINGS

Investigator: Mr. N. Small

Pressure sores can effect all people at any age. However, the elderly, the bedridden and the physically disabled are considered to be at greatest risk for pressure sore development. Despite preventive measures, the occurrence of pressure sores remains a costly health problem. The financial cost of treatment is high, while the cost in terms of pain and suffering to the patient is incalculable.

The purpose of this research project is to compare the cost-effectiveness and acceptability of Smith & Nephew™ wound care products to those of other methods and/or products in the treatment of pressure sores in the community. Forty subjects who meet the inclusion criteria (as stipulated in the research protocol) will be randomly allocated to an experimental group and a control group. Subjects in the experimental group will be treated with Smith & Nephew™ wound care products for six weeks free of charge. Subjects in the control group will continue with their current treatment for the same period of time. The investigator will personally perform the dressing changes of all patients in both groups free of charge. The characteristics and nature of each particular wound will determine the frequency of dressing changes. All wounds will be assessed and photographed by the investigator at weekly intervals for the six-week period. The treatment methods of both groups will be compared in terms of cost-effectiveness and acceptability. Results of this study will assist individuals with pressure sores and their caregivers in the community in their choice of an appropriate, cost-effective and acceptable treatment method.

The study and its procedures have been approved by the ethical committee of the Faculty of Health Sciences, University of the Orange Free State. Risks involved in this research are no more than those associated with your current treatment method(s). However, you will be carefully monitored throughout the trial period and should any adverse event occur as a result of the dressings, the treatment will be discontinued and your wound managed appropriately. You are free to ask any

questions about the study or about being a subject and you may call Mr. Small at 0828568001 if you have any further questions.

Photographs taken of the wound(s) will be used for research and educational purposes as well as for any articles that may stem from the research. Should any photograph reveal your face, this area will be blacked out to protect your identity. However, the investigator will ensure that the wound photography and all other study data will not be linked to your name. Your identity will not be revealed while the study is being conducted or when the study is reported or published. All study data will be collected by the investigator, stored in a secure place, and not shared with any other person without your permission.
Your participation in this study is voluntary; you are under no obligation to participate. You have the right to withdraw at any time without penalty.

I, ..., have read this consent form and voluntarily consent to participate in this study. I have been given a copy of this consent form.

....
Subject's signature Date

I have explained this study to the above subject and have obtained his/her voluntary informed consent.

....
Investigator's signature Date

'N VERGELYKENDE ANALISE VAN DRUKSEERBEHANDELINGSMETODES IN DIE GEMEENSKAP

Navorser: Mnr. N. Small

Druksere kan by enige persoon van enige ouderdom voorkom. Die groepe wat egter die grootste risiko loop om druksere te ontwikkel is bejaardes, gestremdes en bedlêendes. Ten spyte van voorsorgmaatreëls bly die voorkoms van druksere 'n frustrerende gesondheidsprobleem. Die finansiële koste van behandeling is duur terwyl die koste in terme van menslike pyn en lyding onberekenbaar is.

Die doel van hierdie navorsingsprojek is om die koste-effektiwiteit en aanvaarbaarheid van Smith & Nephew™ se wondsorgprodukte as drukseerbehandelingsmetode in die gemeenskap, met dié van ander behandelingsmetodes/produkte te vergelyk. Veertig persone wat aan die insluitingskriteria voldoen (soos uiteengesit in die navorsingsprotokol), sal ewekansig aan 'n eksperimentele- en 'n kontrole groep toegewys word. Persone in die eksperimentele groep sal gratis behandeling vir ses weke met Smith & Nephew ™ se produkte ontvang. Dié in die kontrole groep sal voortgaan met hul huidige behandeling vir dieselfde periode. Die navorser onderneem om persoonlik die wondbehandeling van al die pasiënte, in beide groepe, vir die ses weke gratis te behartig. Die aard en eienskappe van elke wond sal bepaal hoe dikwels wondbehandeling gedoen sal word. Die navorser sal alle wonde weekliks beraam en fotografeer. Die behandelingsmetodes van beide groepe sal dan vergelyk word in terme van koste-effektiwiteit en aanvaarbaarheid. Resultate van hierdie navorsingsprojek sal individue met druksere en hul versorgers in die gemeenskap help in hul keuse van 'n toepaslike, koste-effektiewe en aanvaarbare behandelingsmetode.

Die navorsingsprojek is goedgekeur deur die etiese komitee van die Fakulteit Gesondheidswetenskappe van die Universiteit van die Oranje Vrystaat. Risiko's verbonde aan die navorsing is nie meer as dié wat met u huidige behandeling geassosieer word nie.

U sal egter deurlopend gedurende die navorsingsperiode gemonitor word en sou enige nadelige effek as gevolg van die eksperimentele behandeling voorkom, sal die behandeling onmiddellik gestaak word en u wond op 'n toepaslike alternatiewe metode behandel word. Enige vrae wat u omtrent die navorsing sou hê kan u aan Mnr. Small by 0828568001 rig.

Foto's van die wonde sal vir navorsing, opvoedkundige doeleindes en publikasies wat uit die navorsingsprojek mag spruit, gebruik word. Indien enige pasiënt se gesig op 'n foto sou verskyn, sal die gesig area verdonker word om te verseker dat die pasiënt nie herken sal word nie. Die navorser verseker egter dat die foto's en alle ander inligting nie aan 'n naam gekoppel sal word nie. U identiteit sal dus nie tydens of na die navorsing onthul of bekend gemaak word nie. Alle inligting wat deur die navorser versamel word, sal op 'n veilige plek geberg word. Geen inligting sal met 'n ander persoon gedeel word sonder u uitdruklike toestemming nie.

U deelname aan die navorsingsprojek is vrywillig; u is onder geen verpligting om deel te neem nie. U behou ook die reg om u te enige tyd van die projek te onttrek, sonder dat u hoegenaamd benadeel of verkwalik sal word.

Ek, ..., het hierdie toestemmingsvorm gelees en verleen hiermee vrywillig toestemming om aan die navorsingsprojek, wat deur Mnr. N. Small geloods word, deel te neem. Ek het 'n afskrif van hierdie toestemmingsvorm ontvang.

....

Handtekening van proefpersoon Datum

Ek, N. Small, het die omvang en prosedures van die navorsingsprojek aan die bogenoemde proefpersoon verduidelik en sy/haar vrywillige, ingeligte toestemming verkry.

....

Handtekening van navorser Datum

MAQEBA A SA FOLENG KA HARA SETJHABA: PAPISO YA PHUPUTSO MEKGWENG YA PHEKO YA DISO TSE BAKWANG KE KGATELLO

Dipatlisiso ka: Mong. N Small

Diso tse bakwang ke kgatello di ka ama batho bohle mme ba le dilemong dife kapa dife. Le ha ho le jwalo, maqheku, bakudi ba kulelang diphateng le diqhwala ke bona ba angwang haholo ke diso tse bakwang ke kgatello. Le hoja ho na le mekgwa ya thibelo ya tsona, ho ba teng ha diso tse bakwang ke kgatello ho baka bothata bo boholo maemong a bophelo. Ho fumantshwa pheko ho batla tjhelete e ngata haholo, ha ka lehlakoreng le leng bohloko le ho sotleha ha mokudi e le ntho e sa tlo lekanngwa.

Maikemisetso a projeke ena ya dipatlisiso ke ho lekalekanya maemo a bokgoni le kamohelo ya disebediswa tsa pheko tsa ba ha Smith & Nephew ha di bapiswa le mekgwa e meng le tse sebediswang ha ho phekolwa diso tse bakwang ke kgatello ka hara setjhaba. Batho ba 40 ba tla bewa tlasa diteko tsa pheko mme ba ikamahanya le maemo (jwalo ka ha a beilwe metjheng ya dipatlisiso), ka ho fapafapana ba tla hlahlojwa ke sehlopha se etsang diteko le sehlopha se nang le taolo. Batho bao ho etswang diteko ka bona mme ba le sehlopheng se etsang diteko tsa pheko ya maqeba ka disebediswa tsa Smith & Nephew, ba tla fumantshwa kalafo dibekeng tse tsheletseng ntle le tefo kapa mahala. Batho ba sehlopheng sa taolo bona ba tla tswella ka ho fumantshwa kalafo eo ba ntseng ba e fumana nakong eo ya dibeke tse tsheletseng. Le ha ho le jwalo, motho ya hlahlobang dihlopheng tseo tse pedi ke yena ka seqo sa hae ya tla tlamella maqeba ntle le tefo ya letho. Mofuta wa leqeba ka leng le maemo a lona, ke tsona tse tla bontsha hore na leqeba le tlamellwe le ho hlokomelwa jwang. Maqeba ohle a tla hlahlojwa le ho nkuwa ditshwantsho bekeng ka nngwe nakong ena ya dibeke tse tsheletseng. Mekgwa ya phumantsho ya pheko ho tswa dihlopheng tsena tse pedi e tla bapiswa bakeng sa hore na e phethahetse le hore e a amohelwa. Sephetho sa patlisiso ena se tla thusa batho ba nang le diso tse bakwang ke kgatello le bahlokomedi ba bona ka hara setjhaba kgethong ya bona ya mokgwa wa pheko e loketseng, e phethahetseng le e amohelehang.

Dipatlisiso tsena mmoho le metjha ya tsona di dumelletswe ke komiti e ikarabellang ho tsa boitshwaro ha ho etswa diphuputso, e mane Lekaleng la Mahlale a Bophelo Unibesithing ya Freistata. Mathata a teng patlisisong ena ha se a mang ho feta a ntseng a le teng a amanang le mekgwa ya hao ya pheko/kalafo. Le ha ho le jwalo, o tla bewa leihlo ka tlhokomelo nakong yohle ya diteko mme ha ho ka hlaha tshita ka lebaka la ho tlamellwa diso, pheko kapa kalafo e tla emiswa mme leqeba la hao le hlahlojwe hantle. O amohelehile hore o ka botsa potso efe kapa efe e mabapi le patlisiso kapa ho ba e mong ya bewang ditekong mme ha o na le dipotso tse ding o ka letsetsa Mong. Small nomorong ena: 0828568001.

Ditshwantsho tsa maqeba tse nkilweng ka khamera di tla sebedisetswa dipatlisiso le maikemisetso a thuto esita le mahlasedi a ditaba a tla hlahiswa ke dipatlisiso. Haeba setshwantsho se ka hlahisa sefahleho sa hao, karolo eo ya sefahleho e tla takwa ka botsho hore se se bonahale le ho sireletsa botho ba hao. Le ha ho le jwalo, motho ya etsang dihlahlobo o tla netefatsa hore ditshwantsho tsa maqeba le tsohle tse amanang le wena ha di na ho ba le lebitso la hao. Botho ba hao kapa setshwantsho sa hao ha se na ho hlahiswa nakong ya phuputso kapa ha ho fanwa ka sephetho kapa se tsebahatswa. Sephetho sohle sa dipatlisiso se tla bokellwa ke ya etsang dihlahlobo, di bewe tulong e bolokehileng mme di ke ke tsa arolelanwa kapa tsa tsebiswa motho e mong ntle le tumello ya hao. Ho ba le seabo ha hao patlisisong ena ke ka ho rata ha hao; ha o a qobelleha hore o ka ba le seabo. O na le tokelo ya ho ikgula patlisisong nako efe kapa efe ntle le hore o ahlolwe.

Nna,....., ke badile foromo ena e fanang ka tumello mme ke intsha sehlabelo ka ho rata ha ka ho ba le seabo patlisisong ena. Ke filwe khopi ya foromo ena e fanang ka tumello.

....

Lebitso/Tshaeno/Peleketso Mohla

Ke hlalositse patlisiso ena mothong ya boletsweng ka hodimo mme ka batla kutlwisiso le tumello ya hae.

....

Ya fuputsang Mohla

APPENDIX 6

Declaration of Helsinki

WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI

Recommendations guiding physicians in biomedical research involving human subjects

Adopted by the 18th World Medical Assembly
Helsinki, Finland, June 1964

And amended by the
29th World Medical Assembly, Tokyo, Japan, October 1975
35th World Medical Assembly, Venice, Italy, October 1983
41st World Medical Assembly, Hong Kong, September 1989
and the
48th General Assembly, Somerset West, Republic of South Africa, October 1996

INTRODUCTION

1. It is the mission of the physician to safeguard the health of the people. His or her knowledge and conscience are dedicated to the fulfillment of this mission.

2. The Declaration of Geneva of the World Medical Association binds the physician with the words, "The Health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act only in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient."

3. The purpose of biomedical research involving human subjects must be to improve diagnostic, therapeutic and prophylactic procedures and the understanding of the aetiology and pathogenesis of disease.

4. In current medical practice most diagnostic, therapeutic or prophylactic procedures involve hazards. This applies especially to biomedical research.

5. Medical progress is based on research which ultimately must rest in part on experimentation involving human subjects.

6. In the field of biomedical research a fundamental distinction must be recognized between medical research in which the aim is essentially diagnostic or therapeutic for a patient, and medical research, the essential object of which is purely scientific and without implying direct diagnostic or therapeutic value to the person subjected to the research.

7. Special caution must be exercised in the conduct of research which may affect the environment, and the welfare of animals used for research must be respected.

8. Because it is essential that the results of laboratory experiments be applied to human beings to further scientific knowledge and to help suffering humanity, the World Medical Association has prepared the following recommendations as a guide to every physician in biomedical research involving human subjects. They should be kept under review in the future. It must be stressed that the standards as drafted are only a guide to physicians all over the world. Physicians are not relieved from criminal, civil and ethical responsibilities under the laws of their own countries.

I. BASIC PRINCIPLES

1. Biomedical research involving human subjects must conform to generally accepted scientific principles and should be based on adequately performed laboratory and animal experimentation and on a thorough knowledge of the scientific literature.

2. The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted for consideration, comment and guidance to a specially appointed committee independent of the investigator and the sponsor provided that this independent committee is in conformity with the laws and regulations of the country in which the research experiment is performed.

3. Biomedical research involving human subjects should be conducted only by scientifically qualified persons under the supervision of a clinically competent medical person. The responsibility for the human subject must always rest with a

medically qualified person and never rest on the subject of the research, even though the subject has given his or her consent.

4. Biomedical research involving human subjects cannot legitimately be carried out unless the importance of the object is in proportion to the inherent risk to the subject.

5. Every biomedical research project involving human subjects should be preceded by careful assessment of predictable risks in comparison with foreseeable benefits to the subject or to others. Concern for the interests of the subject must always prevail over the interests of science and society.

6. The right of the research subject to safeguard his or her integrity must always be respected. Every precaution must be taken to respect the privacy of the subject and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.

7. Physicians should abstain from engaging in research projects involving human subjects unless they are satisfied that the hazards involved are believed to be predictable. Physicians should cease any investigation if the hazards are found to outweigh the potential benefits.

8. In publication of the results of his or her research, the physician is obliged to preserve the accuracy of the results. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.

9. In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail.

10. He or she should be informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participation at any time. The physician should then obtain the subject's freely-given informed consent, preferably in writing.

11. When obtaining informed consent for the research project the physician should be particularly cautious if the subject is in a dependent relationship to him or her or may consent under duress. In that case the informed consent should be obtained by a physician who is not engaged in the investigation and who is completely independent of this official relationship.

12. In case of legal incompetence, informed consent should be obtained from the legal guardian in accordance with national legislation. Where physical or mental incapacity makes it impossible to obtain informed consent, or when the subject is a minor, permission from the responsible relative replaces that of the subject in accordance with national legislation. Whenever the minor child is in fact able to give a consent, the minor's consent must be obtained in addition to the consent of the minor's legal guardian.

13. The research protocol should always contain a statement of the ethical considerations involved and should indicate that the principles enunciated in the present Declaration are complied with.

II. MEDICAL RESEARCH COMBINED WITH PROFESSIONAL CARE

(Clinical Research)

1. In the treatment of the sick person, the physician must be free to use a new diagnostic and therapeutic measure, if in his or her judgement it offers hope of saving life, reestablishing health or alleviating suffering.

2. The potential benefits, hazards and discomfort of a new method should be weighed against the advantage of the best current diagnostic and therapeutic methods.

3. In any medical study, every patient - including those of a control group, if any – should be assured of the best proven diagnostic and therapeutic method. This does not exclude the use of inert placebo in studies where no proven diagnostic or therapeutic method exists.

4. The refusal of the patient to participate in a study must never interfere with the physician-patient relationship.

5. If the physician considers it essential not to obtain informed consent, the specific reasons for this proposal should be stated in the experimental protocol for transmission to the independent committee (I, 2).

6. The physician can combine medical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that medical research is justified by its potential diagnostic or therapeutic value for the patient.

III. NON-THERAPEUTIC BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS (Non-Clinical Biomedical Research)

1. In the purely scientific application of medical research carried out on a human being, it is the duty of the physician to remain the protector of the life and health of that person on whom biomedical research is being carried out.

2. The subjects should be volunteers – either healthy persons, or patients for whom the experimental design is not related to the patient's illness.

3. The investigator or the investigating team should discontinue the research if in his/her or their judgement it may, if continued, be harmful to the individual.

4. In research on man, the interests of science and society should never take precedence over considerations related to the wellbeing of the subject.

APPENDIX 7

Risk Assessment Scales

THE WATERLOW RISK ASSESSMENT CARD

Build/Weight for height		***Appetite***	
Average	0	Average	0
Above average	1	Poor	1
Obese	2	Nasogastric tube/Fluids only	2
Below average	3	Nothing by mouth/Anorexic	3
Continence		***Sex***	
		Age	
Complete/Catheterised	0	Male	1
Occasional incontinence	1	Female	2
Catheter/Incontinent of faeces	2	14-49	1
Double incontinence	3	50-64	2
		65-74	3
		75-80	4
		81-plus	5
Mobility		***Special risks***	
		Tissue malnutrition	
Full	0	e.g. Terminal cachexia	8
Restless/fidgety	1	Cardiac failure	5
Apathetic	2	Peripheral vascular disease	5
Restricted	3	Anaemic	2
Inert/traction	4	Smoking	1
Chairbound	5		
Skin type		***Neurological deficit***	
Visual risk areas			
Healthy	0	e.g. Diabetes, cerebrovascular accident	
Tissue paper	1	Motor/Sensory paraplegic	4-6
Dry	1		
Oedematous	1		
Clammy	1		
Discoloured	2		
Broken/Spot	3		
Major surgery/Trauma		***Medication***	
Orthopaedic-below waist, spinal	5	Cytotoxics	
On table > 2hours	5	High dose steroids	4
		Anti-inflammatory	
Score: 10+ At risk 15+ High risk 20+ Very high risk			

Source: Birchall, 1993:36.

THE DOUGLAS PRESSURE SORE CALCULATOR

Nutritional status/Hb		***Pain***	
Well-balanced diet	4	Pain-free	4
Inadequate diet	3	Fear of pain	3
Fluids only	2	Periodic	2
Peripheral/parenteral feed	1	Pain on movement	1
Low haemoglobin	1	Continual discomfort	0
Activity		***Skin state***	
Fully mobile	4	Intact	4
Walks with difficulty	3	Dry/red/thin	3
Chairbound	2	Superficial breaks	2
Bedfast	1	Full tissue thickness or cavity	1
Incontinence		***Mental state***	
Continent	4	Alert	4
Occasionally	3	Apathetic	3
Urine	2	Stuporous/sedated	2
Doubly	1	Unco-operative	1
		Comatose	0
Special risk factors			
Deduct 2 for each factor: - Steroid therapy - Diabetes - Cytotoxic therapy - Dyspnoea			
Total score of 18 or below = at risk			

Source: Birchall, 1993:37.

THE NORTON SCORE

A score of 14 or below = at risk	
Physical condition	***Score***
Good	4
Fair	3
Poor	2
Very bad	1
Mental condition	
Alert	4
Apathetic	3
Confused	2
Stuporous	1
Activity	
Ambulant	4
Walk with help	3
Chair-bound	2
Bedfast	1
Mobility	
Full	4
Slightly limited	3
Very limited	2
Immobile	1
Incontinence	
Not	4
Occasionally	3
Usually urine	2
Doubly	1

Source: Birchall, 1993:35.

THE GOSNELL SCALE

GOSNELL SCALE

PRESSURE SORE RISK ASSESSMENT

I.D. .....
Age:..... Sex: .....
Height: ..... Weight: .....
Date of admission: .....
Date of discharge: .....

Medical diagnosis:
Primary: .....
Secondary: .....
Nursing diagnosis: .....
.....

Instructions: Complete all categories within 24 hours of admission and every other day thereafter.

Mental status	**Continence**	**Mobility**	**Activity**	**Nutrition**	
1. Alert 2. Apathetic 3. Confused 4. Stuporous 5. Unconscious	1. Fully controlled 2. Usually controlled 3. Minimally controlled 4. Absence of control	1. Full 2. Slightly limited 3. Very limited 4. Immobile	1. Ambulatory 2. Walks with assistance 3. Chairfast 4. Bedfast	1. Good 2. Fair 3. Poor **TOTAL SCORE:**	

The higher the score, the higher the patient's risk status.

Source: Flanagan, 1997:161.

PRESSURE SORE PREDICTION SCALE

PSPS

PRESSURE SORE PREVENTION AID

PRESSURE SORE PREDICTION SCORE (1988)

	No	No but	Yes but	Yes
Sitting up? (long time)	0	1	2	3
Unconscious?	0	1	2	3
Poor general condition?	0	1	2	3
Incontinent?	0	1	2	3

	YES	Yes & No	NO
Lifts up?	0	1	2
Gets up and walks?	0	1	2

Total Score:

A total of 6 or more = danger
For precise answers see 'Category Examples' below:

Sitting up
Propped up in bed for long periods means a definite 'Yes' answer. Sitting in a chair can be as risky, but wheelchairs are not quite as bad as ordinary chairs – for long periods. On admission decide nursing position to be used.

Unconscious?
Mental confusion may qualify as a 'No but" answer,

Poor general condition?
This may be a sudden/severe illness, or a longstanding disability (for example paralysis); lack of response to pain suggests a poor condition, as also does great age.

Incontinent?
The main point is how often the patient is wet underneath; although poor bladder/bowel control may also mean that the skin is not healthy. On admission discover if patient was incontinent in the last two days.

Lifts up?
When possible the patient is asked to try, without help from anyone else, to 'Lift up'. A 'Yes" answer means that the patient does lift his pelvis clear of the bed (or seat) at the time of asking.

Gets up and walks?
A 'Yes" answer implies normal or nearly normal walking.

Source: Birchall, 1993:37.

APPENDIX 8

Clinical Practice Guidelines

SKIN CARE AND EARLY TREATMENT

The Agency for Health Care Policy and Research (AHCPR) in the United States employed an explicit, science-based methodology along with expert clinical judgement to develop these specific statements and recommendations on maintaining and improving tissue tolerance to pressure in order to prevent injury. Extensive literature searches were conducted and critical reviews and syntheses were used to evaluate empirical evidence and significant outcomes. Peer review and pilot review were undertaken to evaluate the validity, reliability and utility of these guidelines in clinical practice.

Goal: Maintain and improve tissue tolerance in order to prevent injury.

1. All individuals at risk should have a systematic skin inspection at least once a day, paying particular attention to the bony prominences. Results of skin inspection should be documented.

2. Skin should be cleansed at the time of soiling and at routine intervals. The frequency of skin cleansing should be individualized according to the need and/or patient preference. Avoid hot water, and use a mild cleansing agent that minimizes irritation and dryness of the skin. During the cleansing process, care should be used to minimize the force and friction applied to the skin.

3. Minimize environmental factors leading to skin drying, such as low humidity (less than 40 percent) and exposure to cold. Dry skin should be treated with moisturizers.

4. Avoid massage over bony prominences. Current evidence suggests that massage over bony prominences may be harmful.

5. Minimize skin exposure to moisture due to incontinence, perspiration, or wound drainage. When these sources of moisture cannot be controlled, underpads or briefs can be used that are made of materials that absorb moisture and present a quick-drying surface to the skin. Topical agents that act as barriers to moisture can also be used.

6. Skin injury due to friction and shear forces should be minimized through proper positioning, transferring, and turning techniques. In addition, friction injuries may be reduced by the use of lubricants (such as corn starch and creams), protective films (such as transparent film dressings and skin sealants), protective dressings (such as hydrocolloids) and protective padding.

7. When apparently well nourished individuals develop an inadequate dietary intake of protein or calories, caregivers should first attempt to discover the factors compromising intake and offer support with eating. Other nutritional supplements or support may be needed. If dietary intake remains inadequate and if consistent with overall goals of therapy, more aggressive nutritional intervention such as enteral or parenteral feedings should be considered. For nutritionally compromised individuals, a plan of nutritional support and/or supplementation should be implemented that meets individual needs and is consistent with the overall goals of therapy.

8. If the potential exists for improving the individual's mobility and activity status, rehabilitation efforts should be instituted if consistent with overall goals of therapy. Maintaining current activity level, mobility, and range of motion is an appropriate goal of most individuals.

9. Interventions and outcomes should be monitored and documented.

Source:

BERGSTROM, N., ALLMAN, R. M., CARLSON, C. E., EAGLSTEIN, W., FRANTZ, R. A., GARBER, S. L., GOSNELL, D., JACKSON, B. S., KEMP, M. G., KROUSKOP, T. A., MARVEL, E., RODEHEAVER, G. T. & XAKELLIS, G. C.1992. Pressure Ulcers in Adults: Prediction and Prevention. Clinical practice Guideline. Quick Reference Guide for Clinicians, No. 3. Rockville, MD: U. S. Department of Health and Human Services, Public Health Service, Agency for Health Care Policy and Research. AHCPR Publication No. 92-0050. May 1992.

MECHANICAL LOADING AND SUPPORT SURFACES

The Agency for Health Care Policy and Research (AHCPR) in the United States employed an explicit, science-based methodology along with expert clinical judgement to develop these specific statements and recommendations on the protection against the adverse effects of pressure, shear and friction. Extensive literature searches were conducted and critical reviews and syntheses were used to evaluate empirical evidence and significant outcomes. Peer review and pilot review were undertaken to evaluate the validity, reliability and utility of these guidelines in clinical practice.

Goal: Protect against the adverse effects of external mechanical forces: pressure, friction and shear.

1. Any individual in bed who is assessed to be at risk for developing pressure sores should be repositioned at least every two hours if consistent with overall patient goals. A written schedule for systematically turning and repositioning the individual should be used.

2. For individuals in bed, positioning devices such as pillows or foam wedges should be used to keep bony prominences (such as knees or ankles) from direct contact with one another, according to a written plan.

3. Individuals in bed who are completely immobile should have a care plan that includes the use of devices that totally relieve pressure on the heels, most commonly by raising the heels off the bed. Do not use doughnut-type devices.

4. When the side-lying position is used in bed, avoid positioning directly on the trochanter.

5. Maintain the head of the bed at the lowest degree of elevation consistent with medical conditions and other restrictions. Limit the amount of time the head of the bed is elevated.

6. Use lifting devices such trapeze or bed linen to move (rather than drag) individuals in bed who cannot assist during transfers and position changes.

7. Any individual assessed to be at risk for developing pressure sores should be placed when lying in bed on a pressure-reducing device, such as foam, static air, alternating air, gel, or water mattress.

8. Any person at risk for developing a pressure sore should avoid uninterrupted sitting in any chair or wheelchair. The individual should be repositioned, shifting the point under pressure at least every hour or be put back to bed if consistent with overall patient management goals. Individuals who are able should be taught to shift weight every 15 minutes.

9. For chair-bound individuals, the use of pressure reducing devices such as those made of foam, gel, air, or a combination is indicated. Do not use doughnut-type devices.

10. Positioning of chair-bound individuals should include considerations of postural alignment, distribution of weight, balance and stability, and pressure relief.

11. A written plan for the use of positioning devices and schedules may be helpful for chair-bound individuals.

Source:

BERGSTROM, N., ALLMAN, R. M., CARLSON, C. E., EAGLSTEIN, W., FRANTZ, R. A., GARBER, S. L., GOSNELL, D., JACKSON, B. S., KEMP, M. G., KROUSKOP, T. A., MARVEL, E., RODEHEAVER, G. T. & XAKELLIS, G. C.1992. Pressure Ulcers in Adults: Prediction and Prevention. Clinical practice Guideline. Quick Reference Guide for Clinicians, No. 3. Rockville, MD: U. S. Department of Health and Human Services, Public Health Service, Agency for Health Care Policy and Research. AHCPR Publication No. 92-0050. May 1992.

INFECTION CONTROL DURING THE MANAGEMENT OF PRESSURE SORES

The Agency for Health Care Policy and Research (AHCPR) in the United States employed an explicit, science-based methodology along with expert clinical judgement to develop these specific statements and recommendations on the prevention of cross-contamination of pathological organisms during the management of pressure sores. Extensive literature searches were conducted and critical reviews and syntheses were used to evaluate empirical evidence and significant outcomes. Peer review and pilot review were undertaken to evaluate the validity, reliability and utility of these guidelines in clinical practice.

Body substance isolation

Follow body substance isolation (BSI) precautions or an equivalent system appropriate for the health care setting and the patient's condition when treating the pressure sores.

Clean gloves

Use clean gloves for each patient. When treating multiple sores on the same patient, attend to the most contaminated sore last. Remove gloves and wash hands between patients.

Sterile instruments for debridement.

Use sterile instruments to debride pressure sores. Following debridement, monitor for the patient's temperature and be alert for signs of bacteraemia or sepsis.

Dressings

Use sterile dressings. Clean dressings may also be used in the home setting. Disposal of contaminated dressings should be done in a manner consistent with local regulations.

Keep dressings clean

Procedures to keep dressings clean and prevent cross-contamination should be established and rigorously adhered to. These procedures include the following:

1. Strict adherence to BSI and good handwashing between patients.
2. Individual patients should have their own dressing supplies that are protected from inadvertent environmental contamination by water damage, dust accumulation, extreme temperatures, or contact contaminants.
3. Dressings should be kept in the original package or in other plastic packaging. They should be stored in a clean dry place and the entire package should be discarded if any dressings become wet, contaminated or dirty.
4. Caregivers must wash their hands before contact with the supply of clean dressings or dressing supplies. Prior to the dressing or treatment, only the number of dressings necessary for each dressing change should be removed from containers. Once the hands of the caregiver are soiled with wound secretions, they should not come into contact with the remaining clean dressings or other supplies until the gloves are removed and hands are washed. Dressings, instruments and solutions should be obtained from suppliers who can ensure that shipment and handling will not expose the dressings and supplies to damage or contamination.

Disposal

Local regulations vary on the disposal of soiled dressings.

Source:

BERGSTROM, N., ALLMAN, R. M., CARLSON, C. E., EAGLSTEIN, W., FRANTZ, R. A., GARBER, S. L., GOSNELL, D., JACKSON, B. S., KEMP, M. G., KROUSKOP, T. A., MARVEL, E., RODEHEAVER, G. T. & XAKELLIS, G. C.1992. Pressure Ulcers in Adults: Prediction and Prevention. Clinical practice Guideline. Quick Reference Guide for Clinicians, No. 3. Rockville, MD: U. S. Department of Health and Human Services, Public Health Service, Agency for Health Care Policy and Research. AHCPR Publication No. 92-0050. May 1992.

APPENDIX 9

Cost Analysis

1 Cost analysis

As mentioned in the methodology the cost analysis was performed from the perspective of a private wound care practitioner. The cost of each dressing change per patient per group that *completed* the study was calculated. *Completion* implies either **healed** or **completed the six-week** treatment period as specified in chapter 6.

The following were considered in calculating the cost of treatment:

- wound care products and
- wound care tariffs.

1.1 Wound care products

The cost of all the products used in the *experimental group* was obtained from suppliers of Smith & Nephew ™ products in the Bloemfontein area. These products and their prices are listed in table 1 below and reflect the retail price that the patient will pay for each item when purchased through an independent wound care practitioner.

TABLE 1: Price list of products used in the experimental group

Product	Retail price (Cost price + 10%)
OFS Dressing tray	R 7.40
Allevyn™ non-adh. 20cm x 20cm	R 141.99
Allevyn™ adh. 75mm x 75mm	R 27.14
Allevyn™ adh. 12,5cm x 12,5cm	R 41.36
IntraSite™ Gel 15g	R 29.05
Opsite™ 10cm x 12cm	R 9.48

Table 2 below reflects the products used by patients in the control group as encountered by the researcher in the community. In order to arrive at a reasonable cost for these items the researcher obtained the cost for each item from six different suppliers in the Bloemfontein area and calculated an average cost per item.

TABLE 2: Price list of products used in the control group

Product	Price
Sterile latex gloves (pair)	R 3.00
Gauze 75mm x 75mm (pack of 100)	R 13.48
Milton™ (500ml)	R 13.40
Acriflavin (100ml)	R 5.67
Micropore™ tape (48mm x 3m)	R 20.76
Bactrazine™ (50g)	R 57.36
Tea tree oil (10ml)	R 20.30
Flagyl™ (200mg tablets) x 20	R 24.45
Aqueous cream (500g)	R 8.49
Betadine™ (25g)	R 18-10
Coloplast™ ulcer dressing (10 x 10cm)	R 23.65
Coloplast™ transparent dressing (9 x 4cm)	R 24.70
Bactigrass™ (100mm x 100mm)	R 29.08
Jelonet™ (95mm x 95mm)	R 47.95
3M™ Island dressing (9 x 15cm)	R 14.15
3M Transparent dressing	R 16.77
Cotton wool	R 9.10
Johnson & Johnson Nu-gel™ hydrogel (15g)	R 62.06
Aserbine™ cream (50g)	R 39.37

Saline as wound cleanser, was excluded from the cost analysis in both groups since saline can be made by patients and their caregivers in the community setting at a minimal cost (see Section 4.5.2.1[h]). However, for the sake of convenience pre-packed saline containers (Adcock Ingram's 30 ml. Sab-Saline™ ampules) were used in the experimental group. Similarly the cost of a gentle soap to clean the peri-wound area in both groups was excluded in the cost analysis since most patients already used this or a similar item.

However, in order to avoid the introduction of a possible extraneous variable the researcher used the same brand of soap (Protex™ factor 1) to cleanse the peri-wound areas of all wounds in both groups.

1.2 Wound care tariffs

The severity (stage) of the pressure sore and time required to treat the specific wound determined the wound care tariff (See table 3). The following tariffs, as published by the Board of Health Care Funders of Southern Africa (2000), were used in the calculation of the treatment cost.

TABLE 3: Wound care tariffs

Tariff	Pressure sore stage
R 41.40 (a *simple* wound)	Stage 2
R 51.70 (a *moderate* wound)	Stage 3
R 58.60 (an *extensive* wound)	Stage 4

2 Total costs of wound treatment per group

Accurate record was kept of all dressing changes and products used by means of the instruments (see *Weekly Wound Assessment* and *Record of Dressing Changes and Products Used* in Appendix 3). Using the price lists above the researcher was able to calculate the treatment costs. Table 4 below indicates the total treatment cost of each patient in both groups that completed the study. This includes the *healers* and *non-healers.*

TABLE 4: Treatment costs of healers and non-healers

Experimental group n_e=23		Control group n_c=18	
Patient	**Amount**	**Patient**	**Amount**
03 non-healer	R 2 128.17	04 non-healer	R 2 532.52
06 non-healer	R 1 793.58	07 non-healer	R 2 302.60
09 healer	R 753.84	19 healer	R 1 177.96
12 non-healer	R 1 039.94	20 non-healer	R 2 284.53
13 non-healer	R 1 499.84	24 healer	R 911.56
16 non-healer	R 2 851.85	29 non-healer	R 1 209.49
18 healer	R 677.19	32 non-healer	R 2 525.26
22 healer	R 847.44	38 non-healer	R 2 073.42
23 healer	R 677.39	40 healer	R 82.58
26 healer	R 428.32	44 healer	R 864.50
27 healer	R 379.52	45 healer	R 228.44
30 healer	R 375.11	48 healer	R 773.25
34 healer	R 58.28	49 healer	R 902.15
35 non-healer	R 1 332.84	52 non-healer	R 441.67
41 healer	R 210.61	53 healer	R 269.20
42 non-healer	R 4 373.49	54 non-healer	R 2 754.02
43 healer	R 268.89	57 healer	R 491.20
46 healer	R 214.16	60 non-healer	R 1 000.36
47 healer	R 356.22		
50 healer	R 542.97		
55 non-healer	R 864.39		
58 healer	R 1 102.55		
62 healer	R 275.43		

3. Examples of cost calculation

The following are examples of how the cost of treatment for each patient was calculated.

Patient: 03 (Experimental group)

Allevyn™ non-adh. 20cm x 20cm	@ R 141.99 x 5	R 709.95
IntraSite™ Gel 15g	@ R 29.05 x 2	R 58.10
Opsite™ 10cm x 12cm	@ R 9.48 x 19	R 180.12
OFS Dressing tray	@ R 7.40 x 9	R 66.60
Stage 4 Tariff	@ R 58.60 x 19 dressing changes	R 1 113.40
	TOTAL:	**R 2 128.17**

Patient: 04 (Control group)

Milton 1 litre	@ R 26.80 x 1	R 26.80
Gloves	@ R 3.00 x 37	R 111.00
Flagyl™ (200mg tablets) x 20	@ R 24.45 x 2	R 48.90
Acriflavin (100ml)	@ R 5.67	R 5.67
Gauze 75mm x 75mm (pack of 100)	@ R 13.48 x 3	R 40.44
Micropore™ tape (48mm x 3m)	@ R 20.76 x 4	R 83.04
Aserbine™ cream (50g)	@ R 39.37 x 1	R 39.37
Cotton wool	@ R 9. 10 x 1	R 9.10
Stage 4 Tariff	@ R 58.60 x 37 dressing changes	R 2 168.20
	TOTAL:	**R 2 532.52**

APPENDIX 10

Ethics Committee Approval

THE UNIVERSITY OF THE ORANGE FREE STATE

Office of the Director : Administration
Faculty of Medicine

✉ 339 BLOEMFONTEIN 9300 REPUBLIC OF SOUTH AFRICA
☎ (051) 405-3013/4012847 TELEFAX: (051) 4480-967 SA

Enquiries: Mrs Niemand Tel 4053004 28th July 1998

MR N SMALL
SCHOOL OF NURSING
U O F S

Dear Mr Small

ETOVS NR: 142/98
RESEARCHER: MR N SMALL
PROJECT TITEL: CHRONIC WOUNDS IN THE COMMUNITY: A COMPARATIVE ANALYSIS OF PRESSURE SORE TREATMENT MODALITIES.

During their meeting held on the 28th July 1998 the Ethics Committee approved the abovementioned project. With regard to the advertisement the Committee requested that it clearly be stated that participating in this research project will be in co-operation with the medical practitioner of the trial person.

Your attention is kindly drawn to the requirement that a progress report be presented not later than one year after approval of the project.

Would you please quote the Etovs number as indicated above in subsequent correspondence, reports and enquiries.

Yours faithfully

DIRECTOR: MEDICINE ADMINISTRATION
/hs

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