

QUADRIPLEGIC CENTRE

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THE USE OF OPAL001 CREAM AND LOTION CASE STUDIES



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TABLE OF CONTENTS

Summary	3
Discussion	6
Pressure ulcers	6
The Quadriplegic Centre	7
Descriptive Study	9
Conclusion	12
CASE STUDY: Number 1	14
CASE STUDY: Number 2	16
CASE STUDY: Number 3	19
CASE STUDY: Number 4	21
CASE STUDY: Number 5	23
CASE STUDY: Number 6	25
CASE STUDY: Number 7	28
CASE STUDY: Number 8	30
CASE STUDY: Number 9	32
CASE STUDY: Number 10	34
CASE STUDY: Number 11	36
CASE STUDY: Number 12	38
References	40
Glossary of terms	41



Summary

In November 2003 OPAL001 cream and lotion were introduced to the Quadriplegic Centre by the pharmacist as a therapeutic product for the healing of chronic pressure ulcers. Initially, 7 residents were treated, between November 2003 and January 2004. The regimen for the application of the OPAL001 products on these residents varied slightly according to the discretion of the clinical nurse on duty. Generally, the OPAL001 lotion was applied in the evening directly into the wound and the cream applied in the morning to the surrounding skin.

When it became obvious that in every case the pressure ulcers showed signs of healing, despite variations in the treatment regimen, the researcher was invited to undertake a systematic investigation into the efficacy of the OPAL001 products on a selection of residents. This was a difficult task since there was an insufficient number of residents who met the criteria for such an investigation.

Subsequently, 4 residents were recruited between January 2004 when the descriptive study commenced and June 2004 when OPAL001 was removed from the Quadriplegic Centre by Phoenix Eagle. One resident diagnosed with pyoderma gangrenosum was keen to try OPAL001 as an alternative treatment for his disease. Thus, there was a total of 12 residents at the Centre treated with OPAL001 products.

All treatments with OPAL001 were undertaken with the full knowledge and permission of the resident concerned and his or her general medical practitioner. Apart from the person suffering from pyoderma gangrenosum, each resident was confined to bed to relieve pressure on the wound from the wheelchair cushion and footplate during the period of treatment with OPAL001, although in most cases they were able to sit in their



wheelchair again before complete healing. On commencement of the OPAL001 treatment each resident's current topical wound treatment regimen was ceased. The pressure ulcers varied in length, width and depth. Most were considered chronic wounds which had failed to heal through an orderly and timely process and were prone to recurrent wound breakdown. Some of the wounds were infected with various microorganisms, as evidenced by malodorous exudate and inflammation.

Within 24-48 hours there were observable positive differences in all of the pressure ulcers that were treated. The wounds appeared clean and healthy as evidenced by granulating tissue and a decrease in the amount of exudate. Moreover, all signs of infection had disappeared.

The majority of the wounds were sufficiently healed within 1-2 weeks to allow the residents to return to their wheelchairs during the day and resume their normal activities. 8 of the 11 residents whose pressure ulcers were treated with OPAL001 had complete healing within 3 weeks.

Remarkably, some residents treated with the OPAL001 products have not experienced a reoccurrence of a pressure ulcer in the same location. This was an unexpected outcome since people who have limited mobility and who sit in wheelchairs for lengthy periods are at a high risk of developing pressure ulcers on a continual basis, especially over the sacral area. People who have suffered from a pressure ulcer previously are particularly susceptible to developing pressure ulcers in the same location.

It was particularly significant that no resident suffered any adverse reactions from application of the OPAL001 products.



The table below summarises the significant facts in each case history. Note that all time periods are with reference to commencement of OPAL001 treatment.

Table 1. Summary of Case Studies

Case No.	Location of Ulcer	Stage	How long Ulcer had existed	How long to observable improvement	How long to use of wheelchair	How long to complete healing	
1	buttock	II	2 months				
	Use of cream only			No change			
	Use of cream & lotion			24 hours	6 days	6 days	
2	buttock	IV	2 years				
	Use of cream only		skin:24 hrs	No change to sinus			
	Use of cream & lotion		sinus: 48 hrs	2 weeks	3 weeks		
3	buttock	II	6 weeks	48 hours	1 week	2 weeks	
4	buttock	II	1 week	48.hours	10 days	15 days	
5	buttock	II	5 weeks	immediate	3 days	1 week	
6	hip	IV	19 months	48 hours	2 weeks	3 weeks	
7	hip	III	1 week	24 hours	1 week	2 weeks	
8	This resident did not have a pressure ulcer. He was suffering from pyoderma gangrenosum						
9	foot	II	new ulcer	48 hours			
	The healing process was delayed due to non-compliance & the pressure ulcer being knocked during treatment						
10	ankle	II	2 years	immediate			
	The healing process was delayed due to non-compliance & the ulcer being knocked during treatment						
11	buttock	II	new ulcer	24 hours	5 days	5 days	
12	heel	III	13 months	48 hours		14 weeks	
	The healing process was delayed due to friction of the bed-sheets and continual spasms of leg during treatment						



Discussion

Pressure ulcers

A pressure ulcer is defined as 'trauma to the skin and its underlying structures as a result of pressure, shearing force and friction' (Carville, 2001, p.127). Other terms in common usage are decubitus ulcer, bed-sores and pressure sores. Pressure is the primary etiologic factor that causes sloughing of necrotic tissue resulting in ulceration (Yarkony, 1994).

Pressure ulcers occur in areas of concentrated pressure between bones and skin surfaces especially those that support body weight. The most common sites of pressure ulcers are the sacrum, ischium, trochanters and heels. A major complication of pressure ulcers is that the person may develop bacteremia, sepsis, multisystem organ failure and death (Thomas, 1996).

Pressure ulcers can be categorised into the following stages:

- Stage I The superficial layers of the epidermis are intact but there is erythema or discolouration.
- Stage II Superficial loss of skin integrity with damage to the epidermal and dermal layers of the skin. Erythema of surrounding tissue, which may be hot, painful and oedematous. Low-moderate exudate may be present.
- Stage III Loss of subcutaneous tissue with cavity formation. Low-moderate-high exudate is present.
- Stage IV Loss of subcutaneous tissue with cavity formation involving bone and/or tendon. Moderate-high exudate is present. (Carville 2001, p.45)

The true cost of managing and healing a pressure ulcer is difficult to ascertain. Most studies that purport to measure costs associated with wound care take no account of the costs associated with maintaining and enhancing the quality of life. These include assistance in undertaking and maintaining activities of daily living, days lost from work and litigation (Khachemoune, 2001). A further important factor contributing to the



under-measuring of the cost of managing pressure ulcers may be attributed to the fact that there are institutions that believe that the presence of a pressure ulcer is a reflection on the quality of care provided.

Pressure ulcers consume resources in the form of dressing changes, nursing care, physical therapy, medications, nutritional support and the services of medical practitioners. The cost of wound products varies between manufacturers. In the United States approximately 1.6 million patients in acute care settings develop pressure ulcers annually, representing a cost of \$2.2 to \$3.6 billion to the US health care system (Beckrich and Aronovitch, 1998). In 1997, it was estimated that pressure ulcers in the general community in Australia cost \$350 million per annum (Woolridge, 1997). In 1999, the average cost of healing a pressure ulcer in the Western Australia community for one person was estimated as being \$1,096 (Carville, 1999).

Pressure ulcers in spinal cord injured people increase morbidity and mortality and place high demand on health care resources. Importantly they are a preventable complication for the spinal-paralysed person. A single indiscretion in care can lead to persistent or repeated ulceration with resultant hospitalisation, loss of independence and complete disruption of any social adjustment.

The Quadriplegic Centre

The Quadriplegic Centre is a 100 bed rehabilitation hospital in Perth, Western Australia. It provides high-level residential care for persons with paralysis as a consequence of spinal cord injury and disease of the spinal cord. The Centre promotes excellence in spinal nursing and rehabilitation of its residents. Rehabilitation involves a reintegration into society and is an individual ongoing, dynamic process.



The philosophy of the Quadriplegic Centre revolves around the acknowledgment of each resident's right to manage their own rehabilitation process. Health professionals at the Centre accept that they have a duty of care to maintain each resident's dignity and self-respect and to enable him or her to lead a life that is as independent and fulfilling as possible. They believe that people who are disabled through a spinal cord injury or disease can successfully overcome the physical and psychosocial changes that impact upon the normal activities of daily living and live in a state of wellness.

The success achieved in the pursuit of wellness is dependent upon the encouragement and support of the health care team, the active participation of family members and friends and the internal motivation of the resident. The health care team accepts the responsibility of facilitating the growth and development of the residents and of providing appropriate information to allow them to make informed decisions.

Residents at the Quadriplegic Centre normally spend most of their day sitting in a wheelchair. They enjoy the freedom to participate in both private and social activities, especially at the recreation centre which provides a myriad of opportunities for such activities. People in wheelchairs, however, are in the high-risk category of susceptibility to pressure ulcers. Up to 85% of spinal cord injured people will develop a pressure ulcer in their lifetime with 70% developing multiple ulcers (Byrne & Salzberg, 1996).

The nursing staff at the Quadriplegic Centre diligently monitor skin integrity and the Centre provides measures to prevent the formation of pressure ulcers, including the use of pressure relieving devices such as air-filled and Roho mattresses and cushions. Nursing staff turn most residents from side to side every two hours during the night to relieve pressure on skin and tissues.



At the first sign of erythema (a stage I pressure ulcer) the resident is encouraged to remain in bed to prevent deterioration to stage II. It remains the resident's decision, however, to follow this advice. Most residents find it irksome and frustrating, but realise that a small area of decrease in skin integrity will heal quicker when pressure on the area is removed.

At the Quadriplegic Centre every effort is made to prevent the occurrence of pressure ulcers. The medical and nursing staff have the expertise, including access to the most recent developments, to successfully minimise the formation of pressure ulcers and to treat them accordingly. It is not uncommon, however, for people to be admitted from other hospitals and from home with pressure ulcers, including stage III and stage IV ulcers. Additionally, pressure ulcer management can be difficult since residents at the Centre with a pressure ulcer will often spend extended periods of time in wheelchairs even though they have been advised to remain on bed rest until the ulcer has healed.

As well as having a physical component, the healing of pressure ulcers also has a psychosocial component. The psychosocial factors include the paralysed person's ability to maintain the best possible quality of life. It is not uncommon for such a person to remain in bed for months and even years to allow healing to take place, especially in the case of a stage IV pressure ulcer. This factor, coupled with restrictions on social activities, a degree of isolation and limitations on the normal activities of daily living, is associated with a decrease in self-esteem and depression.

Descriptive Study

Between January and June 2004 five residents (Case Studies Numbers 8 to 12) were participants in a simple descriptive study aimed at investigating the efficacy of OPAL001 cream and lotion.



One of these residents did not have a pressure ulcer, but requested to be included in the study (see case study 8 for further details). The study design provided for treatment of each resident's pressure ulcer with OPAL001 cream and lotion for a period of 7 days, as from the anecdotal evidence of the previous case studies it was expected that a positive effect would be observed within this time frame. Treatment was extended beyond the 7 days where it was observed that the pressure ulcer was granulating, but more time was required for complete healing.

The descriptive study was terminated after 6 months when the OPAL001 products were removed from the Centre on the advice of Phoenix Eagle. This placed a severe limitation on the number of residents who met the eligibility criteria for inclusion in the study. Few residents at the Quadriplegic Centre develop pressure ulcers because of the excellence in maintaining prevention strategies. Over a 3 year period from 2001 to 2003 an annual average of 15 residents were treated for pressure ulcers.

The primary purpose of the descriptive study was to examine whether the treatment with the OPAL001 products could lead to the healing of stage II and III pressure ulcers in a very short period of time. Accordingly, residents who manifested any of the following criteria were excluded from the study as it was felt that, given the low sample size, these factors would confound the results:

- stage IV pressure ulcers
- sinus tracking
- diabetes
- symptoms of systemic infection.

All participants in the study were over 18 years of age and gave their written consent to participate in the study. They were aware that the OPAL001 was a new experimental



substance made from a fruit extract and that a small amount of the cream would be placed on the inside of the arm to test for any allergic reaction. The participants were informed that the application of the OPAL001 cream would cease immediately if an adverse reaction occurred and that the arm would be washed with milk. (None of the participants showed any allergic reactions.) Participants consented to remain on bed rest for the length of the trial if the wound was on the sacral area. They also consented to have daily photographs taken of the wound.

All of the primary nurses were educated in the treatment regimen and the required documentation. Wound location, the level of neurological impairment, urine and bowel continence, current medications (being used for other conditions), nutritional status, and weight of the resident were also documented. Previous pressure ulcer treatment was also noted. A daily record was kept for use in evaluating the efficacy of the OPAL001 treatment. Photographs were taken of the wound together with physical measurements using specially designed graph paper.

All participants received the same daily treatment of OPAL001 cream and lotion and a covering of a non-adherent dressing. The cream $(1^{1}/_{2} \text{ ml})$ was applied each morning to the skin at a distance of 15 centimetres in all directions around the wound. The lotion (enough to wet a cotton bud) was applied directly into the wound in the evening.



Conclusion

Whilst research into pressure ulcers is in its infancy in Australia, accumulated data suggests that they are a significant problem. A major factor of pressure ulcer treatment on a spinal paralysed person is the length of time they have to remain in bed. This not only restricts their ability to undertake the normal activities of daily living, but also contributes to mental health problems such as depression.

Healing of chronic wounds such as pressure ulcers is a complex and complicated phenomenon. Many factors such as diseases, nutrition, medications and in particular immobility may predispose an individual to develop such ulcers. It evident from the case studies presented that not all chronic wounds heal in the same way and at the same rate. This concurs with the literature which suggests that some chronic wounds follow a normal healing course whilst others are problematic (Bates, 1996). The residents who elected to be treated with the OPAL001 products had a variety of healing times, which were probably associated with variables such as age, general health and skin condition.

Management of pressure ulcers at the Quadriplegic Centre is dependent on the resident's ability to make an informed decision regarding prevention and treatment. Often the duration of healing time is related to the resident following the advice of the nursing staff. People with limb paralysis who elect to remain in their wheelchair for extended periods are more likely to develop pressure ulcers and experience a delay in healing time of the wound once developed, and in some cases healing will not take place at all. Removal of pressure is the primary treatment and the minimisation of pressure is the principal factor in preventing the formation of pressure ulcers.

The literature suggests that nurses with experience in wound care typically 'just know' when a wound is healing (Bates, 1996). The nurses at the Centre believed that the



pressure ulcers treated with OPAL001 healed more quickly compared to other treatments. The evidence also suggests that the OPAL001 had an anti bacterial effect and prevented further infection. Importantly, no resident suffered any ill effects from the OPAL001 treatment. The evidence from the case studies, summarised in the table above, suggests that the OPAL001 cream and lotion had a significant effect on the healing process. Importantly, the evidence also suggests that the treatment with the OPAL001 cream and lotion inhibited the reoccurrence of pressure ulcers after healing.

It is recommended that a formal clinical trial with a larger sample population be undertaken to test the anecdotal evidence that the OPAL001 products have the capacity to significantly improve the quality of life of people who have developed pressure ulcers and to inhibit the development or reoccurrence of pressure ulcers in persons in the high risk category.

The anecdotal evidence suggests that the OPAL001 cream and lotion can fundamentally improve the quality of life for the spinal paralysed person. They may also potentiate the healing of pressure ulcers and in some instances may act to prevent further infection and the reoccurrence of pressure ulcers in the same location. Additionally, this anecdotal evidence indicates that the apparent rapidity of healing, and in some cases the healing of pressure ulcers that were not able to be healed by other treatments, results in a significantly reduced cost of care.

A number of batches of the OPAL001 cream and lotion, known at the time as A cream and A lotion, were delivered to the Quadriplegic Centre over a number of months. Every batch of cream and lotion that was delivered had a noticeable healing effect. This suggests that notwithstanding the reported inconsistency between batches in chemical fingerprinting studies every batch of OPAL001 manufactured by Phoenix Eagle that was delivered to the Quadriplegic Centre contained the active pharmaceutical ingredients.



Introduction

This 69-year old male resident was the first to be treated with OPAL001 at the Quadriplegic Centre. He sustained a T¹0 spinal cord injury following a road traffic accident in 1998. At this stage he could transfer by himself from bed to chair and perform his own toileting despite having no sensation or motor function below his waist. In 1999, he suffered a stroke, which further reduced his functional abilities and severely curtailed his independence and his normal activities of daily living.

The resident had to be mechanically hoisted from bed to chair which posed a problem for the nursing staff as he weighed 110kgs. His weight made it difficult to place the hoist sling and push the hoist into position thereby increasing the possibility of damage to the skin in the sacral area.

The resident had fair soft skin which was difficult to dry completely in the folds of skin especially in the gluteal crease. The resident subsequently experienced a skin tear to his buttock close to the gluteal crease. This was classed as a stage II pressure ulcer. The resident was encouraged to stay in bed once the skin tear had occurred, but he became frustrated and verbally abusive at this prospect.

He wanted to spend the day in his wheelchair so he could paint and smoke. (He smoked 50 cigarettes a day.) In line with the Centre's policy, his wishes were respected and he was assisted into his wheelchair each day.

Previous treatments and results

The constant unrelenting pressure on his buttocks of sitting in a wheelchair caused the skin tear to develop into a stage II pressure ulcer over a two month period. This was



despite the pressure ulcer being treated with topical solutions such as betadine and being covered with a non-adherent dressing. The pressure ulcer was showing no sign of healing at the time the OPAL treatment was commenced.

Products supplied and results

The resident remained in bed from the commencement of treatment until the wound healed. At the time the treatment with OPAL001 cream commenced in November 2003, the lotion was not available. The cream was applied daily to the skin around the wound and covered with a non-adherent dressing, but this caused no change in the appearance of the wound. After 10 days of this treatment the lotion became available. The lotion was applied directly into the wound on a daily basis whilst application of the cream was continued around the wound. Within 24 hours of this combined treatment with the OPAL001 products, granulation commenced. The wound was completely healed within 6 days.

Comments and observations

During the 10-day period when only the cream was applied the wound appeared to remain static; that is the size and depth of the wound did not change. Once the lotion was applied to the wound, however, granulating tissue began to appear. These facts suggest that while the resident's pressure ulcer did not deteriorate with bed rest and the application of the OPAL001 cream it was the application of the lotion directly on the wound that directly contributed to the healing process.

To date there has not been a reoccurrence of the pressure ulcer despite the resident being hoisted twice a day and refusing to lie on his side when in bed. Significantly, there was no scar tissue. Given that the resident had fair and fragile skin any wound would have been expected to result in a scar or the formation of scar tissue.



Introduction

This 70-year old female resident has suffered from multiple sclerosis for 35 years. During that time she had decreasing mobility which resulted in incomplete quadriplegia. She was admitted to the Quadriplegic Centre in October 2001, having been transferred from the spinal unit at Royal Perth Hospital where she had undergone Z plasty for a chronic pressure ulcer over her left ischium. This surgical procedure involved incising the buttock in the shape of a Z and refashioning the area with healthy tissue to cover the wound.

On admission to the Quadriplegic Centre the wound had not healed and had developed into a stage IV pressure ulcer, with a sinus tunnelling in the subcutaneous tissue. The skin surrounding the wound was excoriated. The resident presented with a poor appetite and was reluctant to drink water. She also had frail and sensitive skin. The moist areas such as the groin, gluteal crease and the area under her breasts were particularly prone to skin breakdown.

During the following two years the sinus was treated with a variety of medications. At times the wound appeared to improve allowing the resident the opportunity to sit in her wheelchair for short periods of time, which helped in preventing psychosocial problems such as depression. However, for the most part she was unable to sit in a wheelchair.

Prior to the application of OPAL products it was difficult to estimate the exact depth of the sinus. It was concluded by the experienced nurses that it would have extended through the muscle and maybe to the bone (stage IV) as 60 mls of saline could be flushed into the wound. This was a significant amount of fluid and indicated that the sinus was extensive. The saline leaking back out of the wound was a brownish yellow,



malodorous fluid, indicating the presence of stale blood and bacteria. A large absorbent dressing was needed to absorb the exudate.

Previous treatments and results

Prior to the application of the OPAL001 cream the resident's excoriated area on the buttocks was treated with various ointments and solutions including clotimazole, betamethasone, betnovate, bactraban and betadine. It was also covered with a duoderm dressing. The sinus was syringed with normal saline. These treatments had little effect in reducing the inflammation and no effect on the sinus. It was decided that because of the infection in the sinus that diluted vinegar (weak acetic acid) might be effective in reducing the infection if it was syringed into the cavity. The sinus cavity began to marginally improve, but the excoriated area remained unchanged.

Products supplied and results

Initially, 3 weeks prior to the OPAL001 lotion being made available, OPAL001 cream was applied daily directly onto the excoriated area, whilst vinegar was syringed into the sinus. There was an immediate reduction in the inflammation of the excoriated area.

When the OPAL001 lotion arrived it was syringed daily into the sinus replacing the vinegar. Within 2 days the colour of the fluid changed to a transparent colour and the sinus started to close. Within 2 weeks of commencement of treatment with the lotion the wound was sufficiently healed for the resident to be able to sit in her wheelchair for short periods of time. The pressure ulcer was completely healed within 3 weeks.

Comments and observations

It is not uncommon for chronic wounds to be contaminated with micro-organisms, yet rarely do organisms on the surface of wounds cause infection (Rudensky, Lipshits, &



Isaacsohn et al, 1992). The wound of this resident, however, was infected with *Pseudomonas aeruginosa* bacteria when she was admitted to the Centre. This particular organism seldom attacks those in good health. It thrives in deep dark tissues and can multiply rapidly in water. It is known that a mildly acidic environment (pH 5.8-6.6) can decrease *Pseudomonas aeruginosa* (Rolstad, Ovington, & Harris, 2000). The acetic acid was useful in reducing the bacteria, but the acid probably irritated the surrounding skin. Once OPAL001 cream was applied to the skin the area became pink and healthy. Similarly, the OPAL001 lotion contributed to the accelerated healing of the sinus as evidenced by the sinus rapidly becoming less malodorous and the exudate diminishing in volume and returning to a clear colour.

Other complications to the healing process were the medications the resident was taking for her pain and her diminishing fluid intake. The analgesics whilst keeping her pain under control would have added to her immobility as she would have been less likely to relieve pressure on her sacral area. They would also have diminished her ability to self administer fluid. A further contributing factor which inhibited healing was the continual leakage of faecal matter from her bowels into the wound.

The excoriated area and sinus had not noticeably improved in 2 years of best-practice treatment at the Quadriplegic Centre. Yet within in 14 days of treatment with OPAL001 cream and lotion the pressure ulcer was sufficiently healed to enable her to sit in a wheelchair. Significantly, neither the excoriation nor the sinus has reappeared.

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CASE STUDY: Number 3

Introduction

This 85-year old male resident was admitted to the Quadriplegic Centre in 2000 after damaging his spinal cord following a fall from bed at home. He had no motor function below C⁵, but had total sensation. He had no history of previous pressure ulcers. The resident emigrated from China in 1995 and spoke very little English. Interpretation of important information was conveyed by his wife and a Chinese nurse.

During the day the resident enjoyed being in his wheelchair for short intervals, but was unhappy lying on his side when in bed. Consequently, the resident remained on his back for extended periods of time especially during the night.

Pressure ulcers commonly develop very rapidly if there is a high intensity of pressure such as is placed on the buttocks when in a wheelchair or lying on one's back in bed. They develop more slowly in areas subject to low intensity pressure such as the heels and elbows. Regular checks of the skin over bony prominences for redness (erythema or stage I) are performed whenever residents are turned in bed and when dressing.

There are no medications that can prevent pressure ulcers from deteriorating if pressure is not relieved on the wound. Healing of a pressure ulcer is effected by relieving the pressure and dressing the ulcer if the skin has broken (stage II) to prevent infection and to assist the repair of damaged tissues.

In December 2003, the resident developed erythema in the gluteal crease. This developed to a stage II pressure ulcer over the next 6 weeks as a result of his refusal to lie on his side when in bed.



Previous treatments and results

The stage II pressure ulcer was not treated with any other medications as it developed at a time when the OPAL products were available. Nursing staff had witnessed the results of using the OPAL001 cream and lotion on other residents and believed that this resident's wound would benefit from the same treatment.

Products supplied and results

OPAL001 cream was applied to the skin surrounding the wound and the lotion was applied directly into the wound as directed by the pharmacist. Within 48 hours the wound showed noticeable signs of healing, that is granulation had commenced and the wound appeared less red. The ulcer was sufficiently healed within 7 days to allow the resident to sit in his wheelchair for short periods of time. It had completely healed by the end of the second week.

Comments and observations

This resident remained on complete bed rest during treatment with the OPAL001 products, apart from sitting in his wheelchair for short periods of time in the second week. During this time the resident was encouraged to lie on his side, but this was difficult to achieve at all times as he preferred lying on his back. A Roho mattress was provided to aid in relieving pressure on the buttocks.

It is impossible to apportion the rate of healing between the bed rest and the use of the OPAL 001 cream and lotion. The nurses involved thought that the ulcer healed far more quickly than conventional treatment. Significantly, there has been no reoccurrence of the pressure ulcer.



Introduction

This 63-year old female resident had suffered from multiple sclerosis for 15 years and was admitted to the Quadriplegic Centre in 1998. Over that time she had many pressure ulcers due to her dry, fragile and sensitive skin. Her skin was kept supple with antiseptic bepanthen cream to prevent further occurrence. She understood that she needed a strict regimen to relieve pressure on her sacral area, but was not prepared to stay on bed rest preferring to sit in her wheelchair for most of the day. It takes very little force or friction to cause skin breaks of people who have fragile sensitive skin, especially in body areas that are in constant contact with clothes or bed clothes that are under pressure from body weight. Despite adherence to standard techniques for preventing pressure ulcers her skin broke (stage II) in the gluteal crease in October 2003.

Previous treatments and results

Prior to treatment with OPAL001 the pressure ulcer was treated for 7 days with betadine, but showed little sign of healing. It is usual to cover a wound with a suitable dressing but in this case the pressure ulcer could not be covered with a dressing as the resident was allergic to adhesive tape.

Products supplied and results

As the wound failed to heal in response to treatment with betadine, a daily treatment with OPAL001 cream applied directly onto the wound was commenced. At the time it was felt that the lotion would evaporate too quickly causing the cells on the surface of the wound to dry out, but that the nature of the cream would allow it to adhere sufficiently to protect underlying tissue without a dressing.



On commencement of treatment with the OPAL001 cream the resident was assisted to move from side to side to relieve pressure from the mattress whilst on strict bed rest. The wound began to show signs of granulation within 48 hours and in 10 days there was sufficient healing to allow the resident to get up into her wheelchair for short periods of time. The pressure ulcer had completely healed in a further 5 days.

Comments and observations

The resident's sensitive, dry skin and allergic reaction to adhesive dressings made the care of this wound particularly challenging. Normally dressings are placed on pressure ulcers to allow the resident to move freely whilst protecting the ulcer from friction caused by material including clothing and bed clothes. Dressings also keep the wound moist and at a constant temperature whilst providing a barrier from micro-organisms. This is the optimal environment for wound healing (Rolstad, Ovington & Harris, 2000).

It was felt that the stage II ulcer should have healed in a shorter time than 15 days given the history of other residents on the same treatment. This longer healing time may have been related to the resident's disease process. People with multiple sclerosis often have compromised immune systems. This means they are more susceptible to contracting infections and take longer to heal. This resident had a history of multiple skin integrity problems such as rashes, blisters, cellulitis, patches of urticaria and skin breaks in her groins and gluteal crease. Since treatment with OPAL001 products some of these skin integrity problems have not returned and there has been no reoccurrence of pressure ulcers in the sacral area.



Introduction

This 72-year old female resident had suffered from multiple sclerosis for 24 years and was admitted to the Quadriplegic Centre in 1998. She had a healthy appetite, but was unable to feed herself because of the limited mobility in her arms and hands. Consequently, a percutaneous endoscopic gastrostomy tube was inserted into her stomach to allow nutritious fluid to be administered and absorbed.

The resident was a quadriplegic. She had a very supportive family who took her out on frequent occasions, which meant she sat in her wheelchair for long periods of time. The wheelchair has no springs and the jarring in the motor vehicles caused constant friction and pressure on her sacral area. Additionally, continual sweating meant that there was a high risk of a decrease in skin integrity, particularly in the gluteal crease. In October 2003 over a period of 2-3 weeks a stage I pressure ulcer developed over the sacral area. Despite standard preventive treatment such as towelling the skin dry following showering and toileting and the fitting of an appropriate cushion in the wheelchair, the skin broke and the pressure ulcer developed to stage II, with the surrounding skin becoming inflamed. Once the skin broke the resident was confined to bed and the standard treatment of keeping pressure off the wound commenced.

Previous treatments and results

Initially, the wound was treated with betadine and covered with a tegaderm dressing for one week and then a biatain dressing was applied, also for one week. This form of dressing is semi-occlusive and is able to keep the wound moist. Dressings were, however, difficult to keep in place because of continual sweating. None of these treatments appeared to have any effect on the wound. On the third week OPAL001 treatment was commenced.



Products supplied and results

For two days OPAL001 cream was applied daily to the skin surrounding the pressure ulcer, but seemed to be ineffective. This was probably associated with the amount of sweat present. Consequently, the cream was ceased and OPAL001 lotion was applied daily directly on to the wound. The pressure ulcer immediately showed signs of granulation. This treatment continued for 3 days until the wound was sufficiently granulated for the resident to resume her normal activities of daily living in her wheelchair. The wound took a further 4 days to completely heal.

Comments and observations

This resident's wound was particularly challenging to treat as adhesive dressings would not adhere to her buttocks. It was anticipated that the healing time would be significantly extended as the wound remained uncovered.

Surprisingly, however, the gel-like nature of the lotion adhered sufficiently to the wound to allow it to remain moist. Normally dressings perform this task by providing an optimal environment for granulation to occur. The resident was positioned on alternate sides free from the pressure of bedclothes which also allowed air to circulate around her sacral area.

Whilst the resident on occasions had suffered from excoriation in the gluteal crease, she had never previously developed a pressure ulcer whilst she was living at the Centre. It is unknown if she had suffered from pressure ulcers prior to admission to the Centre.



Introduction

This 69-year old female resident was admitted to the Quadriplegic Centre in 1998 having been confined to a wheelchair since 1968 with polyarthritis. Although she had a limited range of mobility she had full sensory perception. Her appetite was poor and she had difficulty feeding herself. Her skin was frail and dry. The resident suffered from extreme pain in her joints for which she was taking strong analgesics. She was also taking a mixture of other drugs including sedatives which rendered her confused and unable to tolerate a normal diet. Despite the nursing staff strongly recommending to her that she stay in bed so that the pressure could be relieved on her ischium, she insisted on sitting in her wheelchair for extended periods during the day so she could smoke. This combination of factors not only hindered the healing of the stage I pressure ulcer that had formed but caused it to develop into a stage IV pressure ulcer over a period of 19 months.

The pressure ulcer developed over the left ischium with two sinus tracks (see glossary) running deep into the tissues. One sinus tracked approximately 13 cms and the other 2 cms into a blind pocket. There was a bridge of granulated tissue between the sinuses. It was anticipated that this bridge would eventually break down leaving a large crater in the subcutaneous tissue.

Previous treatments and results

The pressure ulcer that had developed was treated with various products including intrasite gel, biatain, calcium alginate and kaltostat. These are dressings impregnated with substances that assist in the healing of chronic wounds such as pressure ulcers. These treatments were used over a 19 month period prior to OPAL001 treatment. The resident decided to stay in bed one month prior to commencing the OPAL001 treatment.



Neither bed rest nor the various applications of products changed the appearance of the wound. One of the sinuses was packed with 2 metres of ribbon gauze soaked in saline. There was a large amount of exudate which necessitated covering the wound with a non-adhesive absorbent dressing. The exudate was malodorous and coloured with a mixture of blood and pus which clearly indicated that the ulcer was infected. There were no signs of bacteraemia such as fever.

Products supplied and results

In October 2003 the resident received daily treatments to the pressure ulcer and sinus with OPAL products. The cream was applied in the morning to the surrounding skin and the lotion was applied with a syringe directly into the sinus in the evening.

After 48 hours of the OPAL001 treatment the exudate appeared transparent and the amount had decreased. It was also evident that the tissues in the sinus were undergoing rapid granulation.

There was a potential problem in that the granulation could close the opening of the sinus before healing had been completed at its base. Should this have occurred, it would have left a closed cavity prone to infection and further breakdown of tissue. To prevent this from occurring OPAL001 cream was applied directly to the edges of the sinus opening with a swab stick. Normally, the swab stick would have been socked in saline. The sinus was kept open with a small wick (5cms) soaked in the OPAL001 lotion.

After 72 hours it was apparent that granulation was rapidly ascending from the base. At this stage the wound was sufficiently granulated to discontinue the OPAL cream on the swab stick. The granulation in the bridge increased and finally covered the smaller



sinus opening. The resident's wound was sufficiently healed (no breaks in the skin) within 2 weeks of the commencement of the OPAL001, treatment to allow her to resume her normal activities of daily living in her wheelchair. As the pressure ulcer had been a stage IV, that is loss of subcutaneous tissue, the damage to the tissues left the resident with a small depression on her buttock. Complete healing, that is epithelialisation, took place following 3 weeks of OPAL001 treatment.

Comments and observations

In the experience of the nursing staff at the Quadriplegic Centre a stage IV pressure ulcer of a resident who stays in bed, takes a minimum of 4 months to heal in optimum conditions. In an individual who refuses bed rest during the day it is not uncommon, for the healing time of such wounds to be 12 months or longer. The tissue damage of such an ulcer includes muscle and subcutaneous tissue. This accounts for the long healing process and a residual healed cavity. Whilst new cells form and grow quickly in the dermis and epidermis, muscle and subcutaneous tissue are not regenerated at the same rate. Healing of such a pressure ulcer is, therefore, a lengthy process. It is important that cells in the dermis and epidermis do not regenerate too quickly as they will close the surface of the wound and leave a crater underneath. The crater can become infected which will cause the epidermis and dermis to disintegrate. Wounds should, therefore, granulate in an ascending manner. In this case study the nurses who dressed the resident's wound were continually amazed at the daily rate of granulation. Although the resident is left with a small depression in the skin over the ischium the skin surface



Introduction

This 79-year old female resident suffered a spinal cord injury in a bomb blast in 1976. This trauma destroyed her left hip joint, kidney and lower jaw. The resident took daily antibiotics to prevent osteomyelitis from the shrapnel. She was admitted to the Quadriplegic Centre in January 2004 from the spinal unit at Royal Perth Hospital, having undergone Z plasty for a large pressure ulcer over the left ischium. The surgery was successful with the wound being completely healed by the time of admission.

The resident's skin was fair and dry which increased her risk of developing pressure ulcers. The resident insisted on sitting in her wheelchair every day. Unfortunately, her wheelchair cushion was ill-fitting; it was uneven and totally unsuitable for somebody without a hip. This exacerbated the pressure on her ischium and undoubtedly contributed to the eventual development of a pressure ulcer in the same location. Despite frequent attempts by the nursing staff to position her comfortably in the wheelchair, nine months after admission to the Quadriplegic Centre the skin broke (stage II) over the right ischium.

Previous treatments and results

The pressure ulcer was treated with betadine and dressed with biatain for one week. Biatain was sufficiently pliable to mould to fit the cavity of the missing hip joint and its polyurethane foam provided a soft cushion.

Despite being treated with betadine and dressed with biatain the wound became sloughy. The pressure ulcer was surgically debrided immediately prior to treatment with OPAL001 lotion and cream. It was only after the surgery that the full extent of the



wound was able to be assessed, it being revealed that there was a loss of subcutaneous tissue creating a small cavity, i.e. it had developed into a stage III pressure ulcer. The use of surgical techniques to debride necrotic tissue has proven over time to be the most expedient method of treating chronic wounds (Dolynchuk, 2001). The primary benefit of surgical debridement is that the removal of the necrotic tissue may reduce the underlying infection sufficiently to allow tissue regeneration to commence.

Products supplied and results

Since the previous treatment with betadine and biatain had not prevented tissue necrosis (cell death) it was decided to treat the wound daily with OPAL001 cream and lotion. The cream was applied to the skin surrounding the wound in the morning and the lotion directly into the wound at night. With this treatment the wound showed signs of granulation after 24 hours and within 7 days it was healed sufficiently for the resident to transfer into her wheelchair with new cushion for short periods. By the following week the wound had healed completely.

Comments and observations

The resident's pressure ulcer was treated for 11 months in the spinal unit at Royal Perth Hospital prior to the Z plasty being performed. It is unknown what treatment was used to treat the wound prior to the surgery. The spinal unit, however, would have used bed rest and frequent turns to relieve pressure over the resident's ischium.

In the experience of the clinical nurses at the Centre, a stage III pressure ulcer would normally have taken significantly longer than 7 days after debridement to heal sufficiently for the resident to be able to cease bed rest.



Introduction

This 68-year old male resident has been at the Quadriplegic Centre since 1970. He was a quadriplegic having sustained a spinal cord injury at C⁵ in 1970. Additionally he suffered from pyoderma gangrenosum (see glossary). This disease was manifested by inflamed and sloughy patches on both knees.

Previous treatments and results

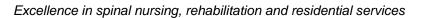
Over the years the resident had experienced several different treatments for pyoderma gangrenosum including antibiotics. None of these were successful.

Products supplied and results

Although the resident's wound was not caused by pressure he requested treatment with OPAL001 as he was aware of its success on other residents. OPAL001 products were applied to the right knee in order to measure a difference against the left knee. The OPAL001 was applied and covered with a non-adhesive dressing to provide protection from his trousers. The resident refused to stay on bed rest and did not present himself for treatment with the OPAL001 on numerous occasions. Initially the wound looked clean and dry and appeared to have some granulation around the edges, but after five months of inconsistent application the resident refused further treatment.

Comments and observations

It was at the resident's request that the OPAL001 products were applied to his right knee. The resident was an active and assertive man spending most of the day in his wheelchair and refusing to stay on bed rest. This made it difficult to maintain a regimen of treatment as he often left the Centre when his dressings needed to be changed. The OPAL001 treatment was discontinued after 5 months, at his request, as he felt that there





was no appreciable difference compared to his left knee. The nursing staff involved in his treatment, however, believed that initially the wound looked drier and cleaner and that had he persevered with the treatment regimen that there may have been a more significant improvement.



Introduction

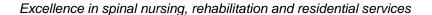
This 32 year old female resident was the first to commence the OPAL001 treatment in the descriptive study. She was admitted to the Quadriplegic Centre in 1990, having sustained a spinal cord injury at C⁵/C⁶ in a motor vehicle accident earlier that year. She weighed 106kg, and this made it difficult to position her in a hoist sling when she was being taken out of bed. She continually refused to wear shoes to protect her feet when sitting in her wheelchair. Consequently, a knock on the footplate caused the skin to break on the outer aspect of her left foot, thereby creating a stage II pressure ulcer.

Previous treatments and results

Prior to being admitted to the Quadriplegic Centre a stage III pressure ulcer on the base of her left small toe was treated with various unknown medications and dressings. The wound not only failed to heal but deteriorated to such an extent that the toe had to be amputated. The development of the current pressure ulcer coincided with the introduction of OPAL001 at the Centre. Thus, no other products were used to treat the current pressure ulcer.

Products supplied and results

OPAL001 treatment was commenced in January 2004 and discontinued in March. The cream was applied in the morning to the skin surrounding the wound and the lotion was applied directly into the wound. Within 48 hours of the commencement of treatment granulation had commenced. On the 5th day of treatment the resident, who had refused to stay in bed, knocked the wound on the foot plate. At this time the pressure ulcer exhibited 50% granulation and had reduced by ½ cm. This trauma caused destruction of approximately 50% of the wound.





During the following 8 weeks of treatment the resident knocked her wound twice, further delaying healing. The pressure ulcer finally healed 6 months from the time of the initial trauma.

Comments and observations

This resident refused to stay in bed during treatment with the OPAL001. Whilst in her wheelchair she continually knocked her wound on the footplate which delayed the healing process. It was decided to discontinue the treatment after 8 weeks because of this repeated trauma.



Introduction

This 30 year old male resident was admitted to the Quadriplegic Centre in 2003 having sustained a T³ spinal cord injury in a motor vehicle accident in 2001. His weight was 99kg and his nutritional status was good. He was admitted with a stage II pressure ulcer on his left malleolus that had been unsuccessfully treated since the accident.

Previous treatments and results

The pressure ulcer had been treated for 2 years prior to admission to the Quadriplegic Centre. At the time of admission OPAL001 was being used on other residents and had shown positive effects on healing of pressure ulcers with no adverse effects. It was therefore decided to treat the pressure ulcer with the OPAL001 products.

Products supplied and results

The OPAL001 treatment was commenced in January 2004, and the resident was advised to remain on bed rest. The treatment regimen consisted of daily application of the cream to the skin surrounding the wound in the morning and of the lotion directly into the wound in the evening. For the first 7 days the resident was compliant with the regimen which resulted in some healing taking place; that is the slough diminished, the wound exhibited some granulation and it decreased in size by 1 cm.

Unfortunately, the resident became non-compliant with the treatment regimen opting to sit in his wheelchair and missing some of his treatments. The nursing staff continued to treat the wound intermittently with OPAL001 over the next 6 months. During this time the resident often refused to wear a dressing or a sock to cover the wound. Treatment with OPAL001 was ceased in June 2004 at which stage the wound was free of slough and had reduced in size by 2 cms, but remained as a stage II pressure ulcer.



Comments and observations

This chronic wound had been unsuccessfully treated for 2 years prior to admission to the Quadriplegic Centre and the commencement of treatment with OPAL001. After the commencement of the OPAL001 treatment the slough began to immediately disappear and granulation commenced. The wound, however, did not completely heal.

During treatment the resident refused to stay in bed and at times would not wear shoes. Consequently, he continually knocked his malleolus on the side of his wheel chair. Additionally, the resident liked to visit friends and enjoy a social life outside the Centre. He was, therefore, unavailable for continuous daily treatments with OPAL001.

Finally, after 6 months the wound was diagnosed as a venous ulcer. It was decided to apply a pressure bandage to the resident's leg as this is the current treatment for such an ulcer. The OPAL001 products were not used under the bandage. The ulcer took a further 3 months to heal.

In summary, there is no doubt that the OPAL001 treatment had the effect of removing slough and providing a surface for granulation to commence. A shorter healing time might have been achieved if the resident had complied with the treatment regimen, that is bed rest and twice daily dressings.



Introduction

This 55-year old female resident was diagnosed with multiple sclerosis in 1981 and was admitted to the Quadriplegic Centre in 2000. She also had multiple myeloma and asthma. The multiple sclerosis had affected the movement in her legs and feet, but she had complete sensory perception. The resident was incontinent to both bowel and bladder and suffered frequent spasms in legs. Her weight was 102 kg which made it difficult to prevent sweating particularly in the gluteal crease.

This resident experienced regular (approximately monthly) breakdown of skin over the sacrum. In many cases the break-down developed into a pressure ulcer. In most cases these would heal in 3–4 weeks after the standard treatment. These frequent breakdowns in skin integrity had severely restricted her activities of daily living.

As the skin over the sacral area was frail with little subcutaneous tissue it did not take much pressure for the skin to break-down. This occurred in March 2004. Healthy tissue under pressure will initially present with erythema, that is initially develop as a stage I pressure ulcer, but frail tissue will often miss this stage and show initially as a stage II pressure ulcer. In these circumstances the first sign of damage is a break in the skin, that is a superficial loss of epidermis which is classified as a stage II pressure ulcer.

Previous treatments and results

Past treatment for pressure ulcers had been immediate bed rest with the application of betadine and a non-adhesive dressing. Occasionally, biatain was applied when the ulcer deteriorated to a stage III. Most previous pressure ulcers had taken 3 to 4 weeks to heal.



Products supplied and results

OPAl001 commenced in March 2004. The pressure ulcer showed signs of granulating tissue within 24 hours following the OPAL001 treatment and by the third day exhibited 75% granulation. The wound had healed completely by the end of the 5th day.

Comments and observations

Six months has elapsed since treatment with OPAL001 and there has been no further breakdown of the skin in the sacral area. The resident stated she was very happy because she could spend more time in her wheelchair enjoying social activities. She was also looking forward to going home when domiciliary care was arranged.



Introduction

This 50-year old male resident was admitted to the Quadriplegic Centre in 2001 suffering from multiple sclerosis, spasms and some cognitive dysfunction. He had full sensory perception with reduced purposeful movement in his arms and legs. He weighed 51 kilograms and was disinterested in food even though nursing staff encouraged him to eat a well-balanced diet and assist him with his meals.

The resident's feet were protected from trauma with shoes and elastic stockings. In March 2004, however, a severe spasm and a loose fitting shoe caused a friction ulcer to form on his right heel. The force of the spasm broke the skin and, therefore, the wound was categorised as a stage II pressure ulcer.

Previous treatments and results

The pressure ulcer was treated for 2-3 weeks with purilon hydrogel and biatain dressings. Despite this treatment the wound became sloughy with a patch of black necrotic tissue in the centre. By the time the OPAL001 treatment was commenced in April 2004 the wound had deteriorated into a stage III pressure ulcer.

Products supplied and results

The ulcer began to granulate within 48 hours and after 4 days of the OPAL001 treatment the slough and necrosis had disappeared, leaving 25% of the wound covered with granulating tissue and a residual crater of approximately 2 mm. The treatment with OPAL001 continued for 14 weeks. During that time the wound slowly continued to granulate and eventually the crater disappeared.



Comments and observations

This resident suffered from severe spasms associated with his multiple sclerosis. The condition caused him to continually knock his feet on the foot pedal of his wheelchair and on the mattress of his bed. Although the resident was confined to bed during the duration of the OPAL001 treatment, it was difficult to keep his foot stationary. This constant problem with friction on the bed sheets, probably contributed to the delayed healing of the pressure ulcer. Compounding the problem of healing was the resident's failure to eat a well balanced diet and the poor skin condition.

It is worth noting that under normal circumstances necrotic/sloughy tissue is surgically removed. This allows granulation to take place and reduces the risk of bacterial growth. It also allows visualisation of the wound base and wall. The procedure can often be painful and may take weeks to remove all non-viable tissue (Ramundo and Wells, 2000). In this case the OPAL001 products performed the same task in four days.

The table below summarises the significant facts in each case history. Note that all time periods are with reference to commencement of OPAL001 treatment.

Table 1. Summary of Case Studies

Case No.	Location of Ulcer	Stage	How long Ulcer had existed	How long to observable improvement	How long to use of wheelchair	How long to complete healing	
1	buttock	II	2 months				
	Use of cream only			No change			
	Use of cream & lotion			24 hours	6 days	6 days	
2	buttock	IV	2 years				
	Use of cream only		skin:24 hrs	No change to sinus			
	Use of cream & lotion			sinus: 48 hrs	2 weeks	3 weeks	
3	buttock	II	6 weeks	48 hours	1 week	2 weeks	
4	buttock	II	1 week	48.hours	10 days	15 days	
5	buttock	II	5 weeks	immediate	3 days	1 week	
6	hip	IV	19 months	48 hours	2 weeks	3 weeks	
7	hip	III	1 week	24 hours	1 week	2 weeks	
8	This resident did not have a pressure ulcer. He was suffering from pyoderma gangrenosum						
9	foot	II	new ulcer	48 hours			
	The healing process was delayed due to non-compliance & the pressure ulcer being knocked during treatment						
10	ankle	II	2 years	immediate			
	The healing process was delayed due to non-compliance & the ulcer being knocked during treatment						
11	buttock	II	new ulcer	24 hours	5 days	5 days	
12	heel	III	13 months	48 hours		14 weeks	
	The healing process was delayed due to friction of the bed-sheets and continual spasms of leg during treatment						



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Glossary of terms

Bacteraemia bacteria in the blood

Cellulitis inflammation of the tissue, characterised by redness, heat,

swelling and pain

Dressing the material applied or the application itself of material to a

wound

The main aim of applying a wound dressing is to create an environment that is conducive to healing. There is no dressing suitable for every wound or every person. Therefore, the choice of dressing must be determined after assessing the needs of the

person and the wound. (Carville, 2001 p.160)

Erythema redness of the surface of the skin due to vasodilation

Epithelium cellular avascular layer covering all the free surfaces,

cutaneous, mucous, and serous including glands and other

structures

Epithelialisation regeneration of epithelium over the wound

Excoriation a break in the skin surface usually covered with blood and

serous crust

Exudate wound fluid which may contain serum, bacteria, leucocytes

and cellular debris

Foam Dressing polyurethane foam dressing in sheets or cavity-filling shapes

Some Foam Dressings incorporate a semi-permeable waterproof, adhesive layer as an outer layer. e.g. Biatain.

Granulation the growth of new blood vessels and connective tissue in the

wound bed

Granulation is a reliable indicator of healing.

Granulation occurs before the combined processes of wound

contraction and epithelialisation. (Flanagan, 1998)





Necrosis death of tissue

A wound is greatly compromised in the midst of necrosis. *Necrotic tissue must be removed for optimal healing to take*

place. (Rolstad, Ovington & Harris, 2000)

Non-adherent Dry Dressing a thin polyester film or non-stick agent, attached or bonded to a cotton and/or acrylic absorbent pad, e.g. Melolin

Pyoderma gangrenosum a painful, necrotising, inflammatory skin disease which has a granulating wound bed exuding purulent fluid

The exact cause of the disease is unknown, but has been associated with an autoimmune response following trauma.

(Hayes, 2004)

Sinus a tract that can extend from a wound into deeper tissue,

resulting in dead-space potential for abscess formation

Sinus tracking a result of subcutaneous fat necrosis

The extent of sinus tracking is directly related to the severity of the necrosis. The presence of non-viable or necrotic tissue in the wound is often associated with altered tissue oxygen and increased bacterial burden.

Slough white/yellow stringy necrotic tissue

42