

School of Nursing and Midwifery

Determining the Effectiveness of Prophylactic Topical Silver Dressings in the Treatment of Sacrococcygeal Pilonidal Sinus Wounds Healing by Secondary Intention

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Declaration

I declare that this assignment is my own work and has not been submitted in any form for another unit, degree or diploma at any university or other institute of tertiary education. Information derived from the published or unpublished work of others has been acknowledged in the text and a list of references is given. I warrant that any disks and/or computer files submitted as part of this assignment have been checked for viruses and are reported clean.

Margaret Edmondson

November 2013

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Abstract

Sacrococcygeal pilonidal sinus disease (PSD) is a common, painful condition affecting 26 per 100,000. Surgical procedures used to treat PSD vary and result in either a wound with primary closure or an open wound which heals by secondary intention. Because of the anatomical location of these wounds, there is a high risk of post-operative infection, which can result in delayed wound healing.

A randomised controlled trial (RCT) was conducted to determine if the prophylactic use of nanocrystalline silver alginate dressings could reduce the bacterial burden in these wounds and result in faster healing times as compared to calcium alginate dressings. Forty eight participants, who had undergone a surgical incision or excision procedure for pilonidal sinus disease, and had a wound healing by secondary intention, were recruited to the study. Participants were randomly allocated to receive daily wound care with either a nanocrystalline silver alginate dressing or a calcium alginate dressing, until wound healing was achieved or a maximum period of 8 weeks. Wounds were assessed and measured at recruitment and on a weekly basis to ascertain healing rates. Wound swabs were collected at recruitment and weeks 4 and 8 to determine semi-quantitative bacteriology. The cost of care was analysed to compare cost of care between the treatment groups.

Although, the nanocrystalline silver alginate dressing group had a mean time to wound healing of 46 days as compared to 66 days for the calcium alginate dressing group, this was not a significant finding. The silver alginate dressing group had a

20% greater reduction in wound size over the study period as compared to the calcium alginate dressing group. The daily cost of care provision for the silver alginate dressing group was higher as compared to the calcium alginate dressing, however, there was no difference between the groups for the overall cost of study participation or the cost to achieve wound healing, concluding that the silver alginate dressing was a cost effective management option for pilonidal sinus wounds healing by secondary intention.

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Chapter 1

Introduction

Introduction

Sacrococcygeal pilonidal sinus disease (PSD) is a common, painful condition which frequently results in surgical intervention (Miller & Harding, 2003). It is reported to affect 26 per 100,000 (Sondenaa, Anderson, & Soreide, 1992), with males being affected three times more frequently than females (Surrell, 1994). Surgical procedures used to treat PSD vary and result in either a wound with primary closure or an open wound which heals by secondary intention (McCallum, King, & Bruce, 2007). Post-operative wound infection is a significant risk and results in impaired client wellbeing, delayed wound healing and additional health care expenditure (Harris & Holloway, 2012; McCallum et al., 2007). The risk of wound infection relates to the anatomical location of these wounds and the pathophysiology of this condition, as it is often associated with abscess formation (McCallum et al., 2007). Pilonidal sinus wounds (PSW) healing by secondary intention can take several months to heal (Harris & Holloway, 2012) despite the fact that they commonly affect young individuals with low risk factors for delayed wound healing (Harris & Holloway, 2012).

Calcium alginate dressings are commonly used for pilonidal sinus wounds because of the haemostatic, low adherence and absorption properties of this dressing product (Thomas, 1992). Covert wound infections can be managed with topical antiseptic agents in the form of solutions or dressing products however, local or systemic infections require systemic treatment with antibiotics (Principles of Best Practice, 2008). Silver has a broad spectrum of antimicrobial activity and thus is suitable to

manage covert wound infection, as bacteria found in wounds are usually of mixed species, requiring broad spectrum treatment (Percival, Bowler, & Russell, 2005). Despite wounds resulting from PSD being fairly common, there is little documented evidence to guide clinicians in their management, especially, when healing becomes protracted. The goal is to achieve wound closure in a timely manner without the complications of wound infection or recurrence of the disease (Mohamed, Kadry, & Adly, 2005).

Background

Silver Chain is the largest domiciliary nursing agency in Western Australia (WA) and provides home and clinic based services to clients in the WA community. A major component of the nursing services provided by Silver Chain includes management of acute and chronic wounds.

Clients with acute surgical wounds resulting from pilonidal sinus disease are commonly referred to Silver Chain clinics for management. In 2005, the researcher conducted an audit which revealed that from February 1st, 2005 to January 31st, 2006, Silver Chain provided wound management to a total of 453 clients with a wound relating to pilonidal sinus disease. The episodes of care for these clients ranged from 1 to 424 days with the average length of stay with the nursing organisation being 46 days. The average age of the population affected by pilonidal sinus disease is 21 years and despite the absence of many factors known to delay wound healing in this age group, healing of many of these surgical wounds was delayed.

Common management of pilonidal sinus wounds within the community setting includes daily wound care with a calcium alginate dressing, which is lightly packed into the wound cavity to achieve controlled closure of the wound from the base upwards. Calcium alginate dressings promote moist wound healing and they assist with haemostasis. Intermittent treatment with a topical antimicrobial agent would be implemented should signs and symptoms of overt or covert infection become clinically apparent.

Aim

The purpose of this study was to determine if the prophylactic use of nanocrystalline silver alginate dressings, in sacrococcygeal pilonidal sinus wounds healing by secondary intention, would promote faster healing as compared to calcium alginate dressings.

Objectives

The specific research objectives were to:

1. Determine the healing times associated with the prophylactic use of nanocrystalline silver alginate dressings and calcium alginate dressings in the treatment of sacrococcygeal pilonidal sinus wounds healing by secondary intention.
2. Investigate the antibacterial effectiveness of nanocrystalline silver alginate dressings in the management of sacrococcygeal pilonidal sinus wounds.
3. Evaluate the cost-effectiveness of nanocrystalline silver alginate dressings as compared to calcium alginate dressings in the treatment of sacrococcygeal pilonidal sinus wounds.

Hypothesis

The prophylactic use of nanocrystalline silver alginate dressings in sacrococcygeal wounds, would demonstrate a greater reduction in wound healing time as compared to calcium alginate dressings.

Significance of the Study

There is a dearth of evidence based guidelines for sacrococcygeal pilonidal sinus wounds healing by secondary intention. The literature and protocols that outline management of these wounds are limited to anecdotal evidence and case studies. Despite the risk of infection associated with PSWs there are few studies that have investigated antimicrobial prophylaxis for the management of these wounds with an aim to reduce wound healing times. Chaudhuri, Bekdash and Taylor (2006) compared prophylactic, single dose antibiotic therapy with a broad spectrum, multi drug regimen with 50 patients undergoing pilonidal sinus surgery and found the broad spectrum 5-day treatment more effective than the single dose treatment in preventing wound complications. A further study by Sondanaa et al, 1995 found that wound healing was significantly influenced by single dose antibiotic prophylaxis. This randomised controlled trial (RCT) aimed to provide evidence for guiding treatment, and facilitating faster and more cost effective wound healing. The study aimed to provide a benchmark for pilonidal sinus wound healing times and guidance on wound management for clinicians and health care providers planning management strategies and supply of resources for this client group.

Conclusion

Sacrococcygeal pilonidal sinus disease often requires surgical intervention which results in wounds healing by secondary intention. Due to the anatomical location of the wound there is an increased risk of overt or covert infection which can result in delayed healing. Current management practices for these wounds include the use of calcium alginate dressings with intermittent use of topical antimicrobial dressings when infection presents. The primary aim of this study was to determine if faster healing times can be achieved with the prophylactic use of a nanocrystalline silver alginate dressing as a topical antiseptic. The following chapters will review the current literature on pilonidal sinus disease, wound management, wound infection and use of silver as a topical antimicrobial treatment and outline the methodology, results, discussion and recommendations of the study.

Chapter 2

Literature Review

Introduction

An extensive literature review was conducted using the key words: pilonidal sinus disease, pilonidal sinus, pilonidal abscess, pilonidal fistula, pilonidal cyst, Jeep disease, physiology of wound healing, wound management, wound infection, management of pilonidal sinus wounds, cavity wounds, calcium alginate dressings and silver dressings. Written literature sources published in the last ten years were used for the literature review with the exception of sentinel resources. Electronic sources included CINAHL, Cochrane Library, InterNurse, Ovid, Proquest, PubMed and Science Direct. A hand search of reports, journals and relevant text books was also completed. The literature review was restricted to sources written in English.

Pilonidal Sinus Disease

Pilonidal sinus disease, also referred to as a pilonidal abscess, pilonidal cyst or pilonidal fistula, is an epithelial lined tract, cyst or abscess usually located on the natal cleft of the buttocks, which often contains embedded hair. The word pilonidal is derived from the Latin words pilus, meaning hair and nidus meaning nest (Goligher, 1984; Miller & Harding, 2003).

Pilonidal sinus disease was first described by Hodges in 1880 (Miller & Harding, 2003). During World War II it was commonly found amongst military personnel, and was thought to result from driving or riding in Jeeps, trucks and tanks, hence is often referred to as 'Jeep disease' (Buie, 1944).

Epidemiology of Pilonidal Sinus Disease

The incidence of pilonidal sinus disease is 26 per 100,000 and is more common in people of European origin than in those of Asian and African origin (Surrell, 1994). This is likely due to the differing characteristics of hair and hair growth patterns (Buie & Curtis, 1952). In 2000-2001, in the United Kingdom (UK), 11,534 hospital admissions for pilonidal sinus disease were reported with a mean stay of 4.3 days (Lanigan & Dyne, 2012). The onset of PSD is rarely reported both before puberty and after the age of 40 years (Miller & Harding, 2003) with the average age of presentation for males being 21 years and 19 years for females (Notaro, 2003; Ringelheim, Silverberg, & Johnson-Villanueva, 2006). It is three times more likely to occur in males than females (Surrell, 1994) and many individuals affected by this condition are hirsute. Increased incidence of this disease has been associated with obesity, sedentary occupation, local tissue irritation, local trauma prior to onset and a family history (Dwight & Maloy, 1953; Holmes & Turner, 1969; Notaro, 2003).

Pathophysiology of Pilonidal Sinus Disease

The origin of sacrococcygeal pilonidal sinus disease is not fully understood, it was originally considered to be a congenital condition. It was postulated that individuals with the disease had caudal segments of the neural canal remaining, which resulted in multiple small cysts in contact with the skin surface. As the cysts increased in size they ruptured, resulting in the formation of sinus tracts (Ringelheim et al., 2006).

This theory, however, came into question following World War II with the increased prevalence of the disease amongst soldiers. Over 78,000 soldiers received treatment for pilonidal sinus disease during 1941 – 1944 (Lanigan & Dyne, 2012). In addition to

this, pilonidal sinus disease has been reported in other parts of the body, including the umbilicus and inter-digital spaces of barber's and sheep shearer's hands (Ringelheim et al., 2006).

Recent studies suggest that PSD is an acquired disease as a result of hair, hormones, friction and infection (Harris, Laforet, Sibbald, & Bishop, 2012; Miller & Harding, 2003). It is thought to be related to the increased production of sex hormones at puberty which affect the growth of the pilosebaceous glands and hair follicles (Harris et al., 2012; Price & Griffiths, 1985) which correlates with the age of onset of pilonidal sinus disease. Obstruction of hair follicles from keratin and debris can further perpetuate follicle enlargement with eventual rupture into the subcutaneous tissue causing abscess and sinus formation (Bascom, 1981). Visible pits in the midline of the natal cleft are associated with pilonidal sinus disease and microscopically have the appearance of enlarged hair follicles (Miller & Harding, 2003). In addition to the hormonal effects, it has also been suggested that the enlargement of the hair follicle is due to a combination of over stretching in the sacrococcygeal area, due to the applied weight of the buttocks and the angle of the sacrococcygeal joint (Bascom, 1981). Activities that increase the magnitude of force created by the overstretching in the sacrococcygeal area, such as bouncing on a hard seat, as in the case of "Jeep disease", or local trauma, can contribute to follicle rupture (Miller & Harding, 2003).

Hair entry into the follicles, arising from the natal cleft in hirsute individuals or from head or back hair falling into the natal cleft (Bascom, 1983; Miller & Harding, 2003), was once thought to be the primary cause of the development of pilonidal sinus

disease. Hair acts as a foreign body on entering the follicles and can initiate an inflammatory response, subsequent infection, abscess formation or sinus disease (Bascom, 1983; Karydakis,1992; McCallum et al., 2007). However, it is now thought that follicle enlargement precedes this, as only half of the cases are found to have hair in the sinus at operation (Bascom, 1981).

Management of Pilonidal Sinus Disease

Although pilonidal sinus disease has been surgically treated for over 100 years, management remains controversial with various different surgical procedures employed. However, none of these procedures satisfies all the requirements for ideal treatment, namely rapid healing, no need for hospital admission, minimal patient inconvenience and low recurrence (Mohamed et al., 2005).

Sacroccygeal PSD can be acute or chronic. In the acute phase it presents with a painful abscess in the natal cleft. Treatment methods for this phase include conservative non-surgical management with systemic antibiotics or surgical management with incision, drainage and curettage of the abscess plus or minus systemic antibiotics (Harris & Holloway, 2012). Chronic PSD presents as painful single or multiple discharging sinuses in the natal cleft. Surgical interventions include limited or wide excision of tissue affected by the pilonidal sinus. Both of these procedures can result in an open wound, however, they are often managed with primary wound closure, which may involve surgical reconstruction, depending on the extent of tissue excised (Facharzt, 2007; Mohamed et al., 2005).

Healing of open wounds occurs by secondary intention which involves the formation of new granulation and epithelial tissue and wound contraction. Pilonidal sinus wounds healing by this method of wound closure can take between 2 to 6 months with some anecdotal reports indicating healing times of one to two years (Harris & Holloway, 2012). Recurrence of PSD varies depending on the modality of treatment and ranges from 40 to 60% following incision and drainage of the abscess, 37% for incision and primary closure and 7.3 to 9.6% for more complex surgical reconstructive procedures such as rotational flaps and Z-plasty (Banerjee, 1999; Bascom, 1981; Torkington, 2004).

A systemic review conducted by The Cochrane Collaboration (2007) assessed the effects of open versus closed surgical treatment of pilonidal sinus disease in relation to time to heal, wound infection and rate of recurrence of pilonidal sinus. A total of 18 studies were included in the review. Seven studies reported on time to healing and compared open versus closed methods of treatment. Median time to wound healing amongst all studies ranged from 10.3 to 70 days, with all seven trials reporting quicker time to wound healing after primary closure (Gencosmanoglu, 2005; Hameed, 2001; Khawaja, Bryan, & Weaver, 1992 ; Rao, Zawislak, & Gilliland, 2001; Sondanaa et al., 1992).

The rate of surgical site infection (SSI) following surgical intervention for PSD was relatively low except for two studies where the infection rate following open surgical procedures was 22% and 14% respectively (Fazeli, Adel, & Abaschi, 2006; Sondanaa et al., 1992). However, no difference in post-operative infection rates was reported in the pooled data of all the studies (McCallum et al., 2007).

Recurrence rates were reported in 11 studies, and although relatively low overall, analysis of pooled data suggested a 58% lower risk of recurrence after surgical treatment and wound healing by secondary intention as compared to surgical treatment and primary wound closure (al-Hassan, Francis, & Neglen, 1990; Fazeli et al., 2006; Fuzun et al., 1994; Gencosmanoglu, 2005; Hameed, 2001; Khawaja et al., 1992 ; Kronborg, Christensen, & Zimmermann-Nielsen, 1985; Miocinovic, Horzic, & Bunoza, 1999; Mohamed et al., 2005; Sondena et al., 1992; Testini et al., 2001).

The impact of PSD on a person can have a negative effect on their quality of life due to pain, wounding and recurrent infection. Additionally, it can disrupt many aspects of their life including work, education, socialisation and intimacy (Harris & Holloway, 2012). A retrospective study by Haitham et al. (2007) found that patients with SSI had more lost time from work and longer times to wound healing. Lost time from work has the potential to lead to financial constraints and stress, which could further impact on wound healing.

Physiology of Wound Healing

Acute wounds are defined as "a disruption of the integrity of the skin and underlying tissues that progress through the healing process in a timely and uncomplicated manner", (Bates-Jensen & Woolfolk, 2007, p.322). Typically, surgical wounds healing by primary or secondary intention are considered to be acute, unless wound healing is complicated by intrinsic or extrinsic factors such as age, comorbid conditions or infection (Carville, 2012).

Regardless of the aetiology of the wound, the repair processes are similar. A coordinated physiological response occurs to initiate haemostasis and stimulate the inflammation, proliferation/reconstruction and maturation or remodelling phases of wound healing (Young & McNaught, 2011). Each of the phases in wound healing can overlap, however they remain distinct in relation to time after injury (Holloway, Harding, Stechmiller, & Schultz, 2012).

Haemostasis occurs at the time of tissue injury with constriction of capillaries to stem bleeding (Carville, 2012; Holloway et al., 2012). The reduced blood flow and tissue hypoxia, promotes the release of vasoactive metabolites to cause a reflex vasodilatation. Simultaneously, histamine is released from the mast cells which further enhances vasodilatation and increases vascular permeability (Young & McNaught, 2011). The increase blood flow results in the typical signs of inflammation that occur soon after injury, namely erythema, swelling, heat and discomfort at the site of the injury (Carville, 2012). Formation of a blood clot also aids in haemostasis and occurs through three mechanisms. The *intrinsic pathway*, which results in the formation of a fibrin plug, *the extrinsic pathway*, which results in thrombin activation and *platelet activation* which not only assists with clot formation but also produces growth factors and cytokines which aid in regulating the healing cascade (Young & McNaught, 2012).

The inflammatory phase of healing follows haemostasis with a key aim to prevent infection, it lasts from time to injury to day 4 (Carville, 2012). Through a process of chemotaxis, neutrophils, macrophages and T-lymphocytes infiltrate the wound to destroy bacteria and wound debris (Carville, 2012; Young & McNaught, 2012).

Neutrophils produce protein digesting enzymes, such as matrix metalloproteinases and serine proteases to facilitate their migration into the extra-cellular matrix (ECM) and kill bacteria by the process of phagocytosis (Carville, 2012; Holloway et al., 2012). Macrophages phagocytose devitalised tissue and bacteria in addition to releasing a variety of growth factors and cytokines to stimulate angiogenesis and the recruitment of fibroblast for the production of collagen (Schultz, Ladwig & Wysocki, 2005).

The reconstructive phase of wound healing is characterised by the development of new granulation and epithelial tissue, angiogenesis and wound contraction, it occurs from day 2 to day 24 (Carville, 2012). The macrophages bind to the ECM and continue to release growth factors to stimulate angiogenesis, collagen synthesis and fibroblast proliferation (Schultz et al., 2005). The provisional ECM is denatured and replaced with granulation tissue which is comprised of collagen fibres, glycosaminoglycans, elastin and capillary loops (Doughty & Sparks-Defriese 2007). Myofibroblasts have a contractile ability and contract to draw the wound edges together to reduce the wound surface area and the amount of tissue replacement required. Epithelial cells migrate over the granulation tissue from surrounding wound edges or from hair follicles sweat and sebaceous glands in the wound (Carville, 2012).

The maturation or remodelling phase of wound healing involves the reorganisation of the tissues to minimise scarring and improve tensile strength of the wound and occurs from day 24 to 1 year, following complete re-epithelialisation of the wound (Carville, 2012). It is anticipated, therefore, that acute wounds following a normal

healing process would be fully re-epithelialised within 24 days of injury (Holloway et al., 2012).

Principles of Wound Management

When a person has a wound it is important that the wound is managed appropriately to optimise time to healing and minimise the risk of complications. Inappropriate wound management can result in delayed healing, increased health care costs, prolonged patient suffering and lost time from work. Optimal wound care involves addressing every aspect of the patient and their wound in order to maximise their quality of life whilst the wound is present (Wounds UK, 2008).

The Australian Wound Management Association (2010) recommend a comprehensive assessment of the person with a wound that reflects the health, cultural and environmental factors that have the potential to impact on wound healing. Initial and ongoing wound assessments that result in documented evidence of the wound provide objective data to enable the clinician to monitor progress of the wound, identify complications of wound healing and implement appropriate strategies to facilitate healing. Acute wounds usually proceed through the phases of wound healing in a timely fashion, resulting in frequent changes to wound dimensions and clinical appearance. This necessitates the need for regular documented assessments of the wound and the person to accurately capture the healing continuum.

Assessment of a wound and prediction for healing is a complex process. Repeated measurement of wound dimensions are important components of this process to

provide objective parameters for baseline wound size and ongoing monitoring of healing. Additionally, determining the percentage of reduction of the wound area over time is useful to monitor response to treatment (Flanagan, 2003). Various methods of wound measurements have been utilised in clinical practice and research to ascertain wound surface area including, diameter product measurements (multiplication of wound dimensions length, width and depth), contact tracing of the wound margin, square counting (tracing of wound on a grid) and planimetry (surface area of tracing or digital wound image). Diameter product measurements can be limited, especially when calculating wound surface area as they do not provide a precise overall wound size, especially for irregular shaped wounds which may be over or under estimated (Majeske, 1992). In addition, with serial measures, although the wound dimensions may change, once multiplied the surface area could remain static (Flanagan, 2003). Identifying wound surface area by contact tracing of the wound perimeter or from a 2 dimensional digital image can be more accurate however, factors such as patient positioning, tissue distortion and body curvature can decrease accuracy (Plassmann, 1995). Rogers, Bevilacqua, Armstrong, and Andros (2010) compared 3 dimensional digital planimetry, using the SilhouetteMobile® camera to standard ruler measurements and found this method to be more accurate, with ruler measurements overestimating the wound size by approximately 40%. However, regardless of modern technology, multiple factors including anatomical location of the wound can still impact on accuracy and although this can be improved with consistency in methodology and patient positioning (Baranoski, Ayello, & Langemo, 2012), more research is required to validate this method of wound measurement.

Diameter product measurements are commonly used in clinical practice as this method is inexpensive and readily available (Baranoski et al., 2012). Although it is usual to use 3 dimensional linear measurements, that is length, width and depth, only 2 dimensional linear measurements were used in this study due to the anatomical positioning of wounds in the sacrococcygeal area preventing accurate assessment of width, hence it was not measured. Two dimensional linear measurements of multiplication of length and depth were used to assess baseline wound size and monitor wound progression. Marks, Hughes, Harding, Campbell, and Ribeiro (1983), explored the relationship between the size and healing of surgical wounds and identified a correlation of 0.89 for pilonidal sinus wounds using the greatest of the wound dimensions. It was determined that any one of the wound measurements i.e. length, width or depth could be used to predict healing.

Factors Affecting Wound Healing

Delays in acute wound healing can occur from several factors including wound infection (Bates-Jensen & Woolfolk, 2007; Carville, 2012). Surgical site infections have been reported to be between 2-13% in Australia, depending on the surgical procedure undertaken (Department of Health and Aging, 2001), with most of the cases appearing after discharge from hospital (Nicholas et al., 2006). Wound infection delays healing by prolonging the inflammatory phase and disrupting the proliferative phase of wound healing, thereby reducing the tensile strength of the new wound tissue (Gardner & Frantz, 2012).

Surgically created wounds are contaminated by bacteria soon after wounding and often the wound provides an environment that is conducive to the growth of micro-

organisms. The potential for bacteria to produce harmful effects to the wound and the patient is influenced by the number and type of bacteria and the ability of the patient's immune system to resist the bacteria (Healy & Freedman, 2006). Higher numbers of bacteria in the wound environment have a greater ability to overcome the patient's immune resistance and hence cause infection. In addition, some bacteria are more virulent than others and therefore have a greater capacity to produce disease (Principles of Best Practice, 2008). Wound infection is more likely to occur in patients with contaminated or dirty wounds (Briggs, 1997) or following surgery involving abscesses where significant numbers of bacteria may already be present (Wilson, 1995), which is often the case with pilonidal sinus wounds.

In acute wounds, the signs and symptoms of wound infection are typically heat, new or increasing pain, oedema, local warmth, purulent exudate and erythema (Cutting & Harding, 1994). However, covert infection or critical colonisation may not be so obvious and may have more subtle signs and symptoms such as changes in granulation tissue, increased exudate and static or delayed healing (Principles of Best Practice, 2008).

Other common factors that impair wound healing in the younger person include malnutrition, reduced tissue oxygenation, non-viable tissue, excessive pressure, shear or friction, psychophysiological stress, co-morbid conditions and adverse effects of treatment (Stotts, Wipke-Tevis, & Wopf, 2007).

Wound healing is dependent on an adequate nutritional state and can be impaired by either inadequate intake of nutrients or pre-existing malnutrition (Stotts et al.,

2007). Nutrients that are essential for healthy skin and repair following injury include protein, amino acids, carbohydrates, lipids, vitamins, minerals and water (Lansdown, 2004). Protein requirements increase during wound healing and when intake is not sufficient it can result in decreased fibroblast proliferation, angiogenesis, collagen synthesis and remodelling (Stotts et al., 2007). As with protein, there is also an increase requirement for carbohydrates due to the increased energy requirements to meet the hyper-metabolic response that occurs with wounding. When there is insufficient carbohydrate intake, body protein is utilised for energy. Hence, protein is diverted to provide the required glucose for cellular maintenance rather than for tissue repair (Ord, 2007 ; Stotts et al., 2007). Insufficient intake of lipids can reduce the intake of fat soluble vitamins A, D, E and K. Deficiency in vitamin A can impair healing by affecting the inflammatory response and decreased collagen formation can result from deficiencies in vitamin B and C, zinc, iron, copper and magnesium (Ord, 2007 ; Stotts et al., 2007).

Young people may experience a change in their nutritional intake as their body develops and they become more independent with food choices, which has the potential to put them at risk of nutritional deficits. There is an abundance of guidelines available on the nutritional requirements for adolescents, however, there is limited evidence available on their nutritional status. Song, Schuette, Huang, and Hoer-r (1996) studied a 24 hour dietary intake of 2,489 young adults and found that although their mean intake of the five major food groups was above the recommended amount, at least 89% of the young adults consumed less than the recommended number of servings from more than one food group including grains, vegetables, fruit, dairy and meat. A survey of adolescent nutritional intake by the

Australian Institute of Health and Welfare (2007) found that 34% of males and 53% of females aged 18 years were consuming less than the estimated average requirements of daily energy intake and only 26% of adolescents aged between 15 and 19 years consumed at least 3 serves of fruit per day.

It is well documented that smoking has the potential to impair wound healing by several mechanisms. The components of tobacco namely nicotine, carbon monoxide and hydrogen cyanide are thought to be responsible for the harmful effects. Nicotine is a potent vasoconstrictor and increases platelet aggregation resulting in an increased risk of micro-vascular thrombosis and ischaemia (Rayner, 2006). Carbon monoxide reduces the oxygen carrying capacity of haemoglobin and lowers oxygen saturation, whereas, hydrogen cyanide inhibits the cellular transport of oxygen. Hence, a major adverse effect of smoking is wound hypoxia (Rayner, 2006; Stotts et al., 2007). It is postulated that smoking a single cigarette creates a vasoconstrictive effect that can last up to 90 minutes and smoking a packet of cigarettes a day results in tissue hypoxia for 24 hours (Smith & Smith, 2012).

Various lifestyle and occupational factors have been suggested as predisposing factors for pilonidal sinus disease including sedentary lifestyle, local irritation and trauma to the sacrococcygeal area prior to onset (Dwight & Maloy, 1953; Holmes & Turner, 1969; Notaro, 2003). The significant increase in this condition amongst soldiers in World War II was thought to be due to the repeated bouncing and jolting from riding in military vehicles (Jeeps) resulting in irritation and trauma to the sacrococcygeal area (Buie, 1944). However, pressure, shearing and friction forces can be potential problems not only from physical activity but also from sedentary

activities such as prolonged sitting. Additionally, smoking and obesity have been reported as independent risk factors for infection specifically relating to pilonidal sinus disease (Haitham et al., 2007).

Management of Pilonidal Sinus Wounds

Controversies exist in relation to surgical procedures to treat pilonidal sinus disease and the resultant post-operative management. However, in relation to the literature, there is significantly less available relating to the post-operative management of these wounds as compared to the surgical procedures. It has been suggested that the shape of the post-operative wound base may have an effect on healing of PSWs and disease recurrence. Pilonidal abscesses treated by surgical incision and drainage often result in a narrow wound base where excision of the pilonidal sinus is likely to result in a wound with a wide base due to tissue resection. No studies have compared healing based on the shape of the post-operative wound. Pilonidal sinus wounds healing by secondary intention result in a cavity and thus have a tendency to heal from the base and sides (Marks et al., 1983) and lightly packing such wounds with a suitable wound dressing product will facilitate this healing, preventing early closure and reducing the likelihood of abscess formation (Carville, 2012) or in the case of PSD, recurrence.

Although effective wound management will promote wound healing and minimise the risk of infection, there is no consensus as to which wound dressing is the most appropriate for PSWs. Moist wound healing is widely accepted by most clinicians as best practice to support the physiological process of wound repair. Epithelial cells require a moist environment to enable their migration across the wound bed to

resurface the wound area (Baronoski, Ayello, McIntosh, Montoya, & Scarborough, 2012). Consequently, dressings that are used on PSWs need to be moisture retentive or moisture balanced to optimise wound healing. Generally, the dressing, needs to promote client comfort, be flexible to match the contours of the natal cleft and wound, retain moisture at the wound interface and be cost effective (Carville, 2012; Harris & Holloway, 2012).

Traditionally, in Australia, PSWs have been managed with saline soaked gauze dressings and although more contemporary dressings are now being used; this suboptimal practice continues to be employed in some sectors. Saline soaked gauze dressings have a tendency to dry the wound bed and subsequently increase the client's level of pain especially at dressing changes (Harris & Holloway, 2012). Stewart et al., (2004) reported low pain scores for patients with PSWs, however, a further study by Stewart, Donoghue, and Mitten-Lewis (2008) found that pilonidal sinus wounds were more painful at dressing changes than at rest or during activity, with higher pain levels being reported by participants using saline soaked gauze. Price et al., (1994), studied quality of life on 80 individuals with surgical wounds (78% had a PSW) and identified that pain negatively impacted on the person's ability to sleep and diminished their appetite, at a time when they have increased nutritional requirements. Furthermore, pain can activate a stress response, which has the potential to impede normal wound healing (Woo, Harding, Price, & Sibbald, 2008). In addition to this, saline soaked gauze dressings are costly due to the requirement for frequent dressing changes in an attempt to avoid the dressing drying out (Carville, 2012; Ryan, 2008). Frequent dressing changes, not only result in increased wound product use but also increased nursing time.

A study conducted by Viciano et al. (2000), compared two different hydrocolloid dressings with a gauze dressing for 38 patients with pilonidal sinus wounds. The study reported median healing time of 68 days for the gauze dressing and 65 days for the combined hydrocolloid dressings, concluding that the hydrocolloid dressing did not reduce healing time. Stewart et al. (2008) studied 55 patients who had undergone surgical excision of pilonidal sinus for 12 weeks. The participants used a variety of wound dressings including calcium alginate, hydrofibre, saline gauze, petroleum gauze, silver foam and povidine iodine packs. Although, 60% of participant's wounds were healed by 12 weeks, the study found no correlation between dressing type and wound healing.

Calcium Alginate Dressings

Calcium alginates have been used for clinical purposes since the 1940s (Thomas, 1992). Calcium alginate wound dressings are derived from calcium salt of alginic acid which is obtained from certain species of brown seaweed (Thomas, 1992). They are designed as primary wound dressings and when in contact with serum, wound exudate, or solutions containing sodium ions, the insoluble calcium alginate is converted to the soluble sodium salt, and a soft, hydrophilic, gas permeable gel is produced. The gelled product conforms to the contours of the wound and provides a micro-environment that facilitates wound healing (Thomas, 2006).

Calcium alginate rope dressings are a suitable choice for packing cavity wounds and are therefore a suitable choice for PSWs. The gel formed by calcium alginate

dressings when in contact with wound fluid provides a moist environment at the wound interface.

Calcium alginates have been compared to the use of saline-soaked gauze dressings for packing abscess cavities following surgical incision and drainage and were found to perform significantly better in relation to ease of removal ($p < 0.01$) and reduction in pain on removal of dressing ($p < 0.01$), (Dawson, Armstrong, Fulford, Faruqi, & Galland, 1992). In addition, calcium alginates have been shown to have haemostatic properties. A study by Groves and Lawrence (1986), demonstrated that alginates were able to produce significant haemostasis within 5 minutes of surgery and absorbed nearly three times as much citrated blood as surgical gauze when used on skin graft donor sites. The evidence available regarding calcium alginate dressings in relation to haemostasis and reduced level of pain on dressing removal were considerations for the researcher in selecting this product for the study.

Additionally, achieving haemostasis post wounding is of primary importance. The calcium alginate selected for use in this study was done so to minimise confounding factors, it is manufactured by the same company as the nanocrystalline silver alginate dressing and is therefore the same except for the silver component.

Silver Dressings

Wound dressings containing antiseptic properties, such as silver, are used to manage wounds with covert or overt infection. The use of silver as an antimicrobial agent dates back to ancient Greek and Roman times when silver coins were used to sterilise drinking water (White, 2001). It has been used as an antibacterial for

medical purposes since the 18th century (Graham, 2005) and by the early 20th century silver was used to treat bacterial infections in wounds (White, 2001). The use of silver diminished following the discovery of antibiotics in the 1930's, however the emergence of antibiotic resistant strains of bacteria such as methicillin resistant *Staphylococcus aureus* (MRSA) and vancomycin resistant enterococcus (VRE) has renewed the interest in topical antimicrobial agents including silver (DTB., 2010).

Ionic silver is a potent antimicrobial and is effective at low concentrations against a broad range of micro-organisms including Gram-positive and Gram-negative bacteria, MRSA, VRE, fungi, protozoa and viruses (DTB., 2010; Herman, 2006; Russell & Hugo, 1994). Antiseptic agents have a reduced propensity to induce bacterial resistance than antibiotics, therefore, they are useful to treat localised skin and wound infections (Percival et al., 2005).

The exact mechanism of silver's antimicrobial effect is not fully understood, however it is thought to bind to tissue proteins causing structural changes in the bacterial cell walls and intracellular and nuclear cell membranes resulting in cell death (Lansdown, 2002; Percival et al., 2005). In addition, silver binds to and denatures bacterial deoxyribonucleic acid (DNA) and ribonucleic acid (RNA) preventing replication and reducing microbial metabolism and growth (DTB., 2010; Lansdown, 2002; Percival et al., 2005). Silver's broad spectrum antimicrobial activity in addition to its relatively safe nature have contributed to its increased use in wound management, particularly as bacteria found in wounds are usually of mixed species, requiring broad spectrum treatment (Percival et al., 2005).

The increased demand for antimicrobial dressings, has seen the number and variety of silver dressings on the market grow, with silver being added to contemporary dressings which include calcium alginate, activated charcoal, semi-permeable films, hydrocolloids and polyurethane foams (Cutting, White, & Hoekstra, 2009). The majority of studies relating to the antimicrobial activity of silver dressings have investigated the efficacy of nanocrystalline silver, as it is able to maintain a higher level of active silver cation (5mg/l – 40mg/l) than other silver dressings (Leaper, 2011).

Nanocrystalline silver wound dressings have been found to rapidly deliver silver and in higher amounts than other types of silver dressings due to the greater surface area created by the nanoparticles. This results in a significantly faster reduction of bacteria than experienced with other forms of silver dressings (Brett, 2006; Wilkinson, White, & Chipman, 2011), as the level of silver has been found to be directly proportional to the rate of kill of the micro-organisms (Ovington, 2001). Nanocrystalline silver is present in the Acticoat™ range of wound care dressings manufactured by Smith & Nephew. A study by Thomas and McCubbin (2003), compared the antibacterial effect of four different types of silver dressings, and concluded that Acticoat™ had marked antimicrobial activity with a rapid onset of action as compared to the other dressings.

In addition to the antimicrobial effects of silver, scientific studies have demonstrated an anti-inflammatory and pro-healing effect of nanocrystalline silver, which is independent of the antimicrobial effect (Bhol & Schechter, 2004; Nadworny, Landry, Wang, Tredget, & Burrell, 2010; Nadworny, Wang, Tredget, & Burrell, 2008).

Histological data suggested nanocrystalline silver promoted healing by enhancing rates of tissue repair including formation of new granulation and epithelial tissue (Nadworny et al., 2010).

The increased use of silver in wound management has led to an increased concern regarding the potential for resistant strains of bacteria. However, because antiseptics have multiple mechanisms of action, bacterial resistance is less likely than that caused by antibiotics, which have a single targeted effect (Leaper, 2011). To date, there have been no reports that have demonstrated a link with bacterial resistance to contemporary silver dressings (Leaper, 2011). It is postulated that the risk of resistance from silver dressings can be minimised by utilising dressings with high levels of silver that facilitate a rapid antibacterial effect and thus reduces the possibility of bacterial mutation and resistance (Ovington, 1999, 2001).

Some authors express concerns about the systemic absorption of silver and the potential for hypersensitivity and toxicity which stems from the known cytotoxic effects of nitrate ion, a strong oxidising agent, found in silver nitrate (European Wound Management Association, 2006). Early use of silver formulations, such as solutions and creams, for treating open wounds has been associated with several side effects, including cytotoxicity, staining of skin and fabric, methaemoglobinaemia, electrolyte disturbance and retardation of wound healing (European Wound Management Association, 2006). The cytotoxicity of silver sulfadiazine is associated with release of the sulphonamide rather than silver, and has been associated with severe blood and skin disorders including burning, itching and rashes. Leucopenia and argyria a skin decolourisation resulting from elemental silver deposition, have

also been recognised with the use of silver (Mehta, 2005). Silver impregnated dressings that facilitate controlled release and deposition of silver, ensure antimicrobial activity whilst reducing the potential risk of toxicity and other side effects (Walker, Cochrane, & Bowler, 2006). A study by Honari, Gibran, Engrav, Carlson, and Heimbach (2001), compared the effects of silver sulphadiazine (SSD) to nanocrystalline silver on patients with MRSA over 8 months and found nanocrystalline silver had no negative effects on healing rates.

Despite the scientific evidence available regarding the antimicrobial effects of silver, there is a lack of good-quality clinical trials to support the extensive use of silver impregnated wound care products (European Wound Management Association, 2006). Considering, the British National Health Service reported expenditure of £25 million in 2006 on silver impregnated wound care products, further clinical trials are required (DTB. 2010).

An international consensus document on the use of silver in wound care recommends that antimicrobial dressings, including silver are used initially for 2 weeks to treat overt or covert wound infection with evaluation of the patient, wound and management following this time to evaluate effectiveness (Wounds International, 2012). In addition, it supports the use of silver dressings for prophylactic use as a barrier to microorganisms in wounds at high risk of infection such as wounds near the anus (Vowden, Vowden, & Carville, 2011; Wounds International, 2012).

Conclusion

Pilonidal sinus disease has been surgically treated for more than a hundred years, despite this, there is little guidance available for the management of PSWs. Due to the anatomical location and pathophysiology of this condition PSWs are at increased risk of infection which can delay wound healing. Calcium alginate wound dressings are often used for PSWs healing by secondary intention, however intermittent treatment with a topical antimicrobial dressing is often required to maintain the wounds bacterial balance. Silver is a broad spectrum topical antimicrobial agent that is widely used in the management of wound infection and it is available in a variety of contemporary dressing products. Nanocrystalline silver delivers a high level of silver to achieve a rapid and sustained bactericidal effect and is reported to be relatively safe when used to manage wound infections.

Chapter 3

Methodology

Study Design

A randomised controlled trial (RCT) was conducted to investigate the prophylactic effect of nanocrystalline silver alginate dressings as compared to calcium alginate dressings in pilonidal sinus wounds healing by secondary intention, following surgical excision or incision.

Study Population

Clients referred to Silver Chain metropolitan nursing services with a sacrococcygeal wound healing by secondary intention, following surgical excision or incision of a pilonidal sinus and who met the inclusion criteria were invited to participate. The client's treating surgeon was informed in writing of each client's consent to participate. In addition, study information was forwarded to surgical departments of public and private hospitals within Western Australia's metropolitan area to inform them of the study and to invite them to refer their clients for recruitment.

Participants were randomly assigned to either receive a nanocrystalline silver alginate dressing (experimental group) or a calcium alginate dressing (control group) as treatment for their pilonidal sinus wounds.

The required sample size for the study was calculated based on a mean healing rate of 46 days (SD 10 days) and an effect size of a 6 day reduction in the time taken to heal in the intervention group (46 days versus 40 days) with a significance level of 0.05 and power set to 80%. The above calculation resulted in the need to recruit 30

participants per group. However, as potential crossover of clients from the calcium alginate group to the nanocrystalline alginate group was a possibility if a client in the calcium alginate group should have developed signs and symptoms of infection, a maximum of 44 clients per group was determined necessary.

Inclusion Criteria

The study inclusion criteria were:

- Aged 16 – 40 years,
- Day 2 - 7 post-operative (on referral to Silver Chain),
- Able to provide consent (parental consent was obtained for clients under 18years of age).

Exclusion Criteria

The study exclusion criteria were:

- Under 16 years of age,
- Known allergy to silver or calcium alginate dressing products,
- Pregnant or lactating women,
- Failure to provide consent or obtain parental consent if under 18 years,
- Inability to have wound dressed on daily basis for duration of the study period or until wound healing was achieved.

Recruitment

Due to the geographical spread of Silver Chain's community clients, it was not feasible or practical for the principal nurse researcher (the student, Margaret Edmondson) to recruit and collect data for all participants. Thus, it was decided to appoint study research nurses at each service centre to facilitate and supervise

recruitment of participants and data collection. Nurses described as study research nurses were registered nurses employed by Silver Chain in the metropolitan area, who had advanced wound care skills and previous experience in data collection for research purposes. The study research nurses were educated by the principle nurse researcher to recruit study participants, collect study data and perform the study wound care protocols. The scheduled visiting nurses were registered or enrolled nurses employed by Silver Chain in the metropolitan area, who delivered client care to study participants on the days data collection was not required. The scheduled visiting nurses were educated to identify potential study participants and perform the study wound care protocols.

All clients referred to Silver Chain who met the study criteria and who did not meet any of the exclusion criteria were invited to participate in the study. If the client (or their authorised representative) expressed interest in participating in the study, they were given the Study Information Sheet (Appendix I) and Consent Form (Appendix II) and informed that a research nurse would contact them. The research nurse then contacted the client within 24 hours by telephone and enquired whether they, or their representative, had read the Study Information Sheet and if they had any questions. The research nurse then made an appointment with the client to attend the next scheduled visit for wound care and to enrol the client in the study. At that visit, the client was given the opportunity to ask any further questions and they were asked to sign the Consent Form if they wished to participate.

If consent was not obtained, the research nurse provided usual care for the client in accordance with the current wound care plan and Silver Chain services were

continued as before. When an individual had given consent to participate in the study, the research nurse opened a randomly selected envelope which informed the nurse of the randomised selected dressing to be used. The nurse then implemented the care defined by the study protocol for the dressing group the individual was randomised to.

Randomisation

The allocation of study numbers to intervention and control groups was done using the Excel Microsoft software random number function. Envelopes were numbered sequentially and a slip of paper indicating group allocation was sealed inside. These study envelopes were prepared centrally by the principle research nurse and randomly divided and distributed to the service centres where they were accessible to the research nurse(s) working out of that centre. The research nurses used the envelopes from the service centres sequentially when they recruited clients. If the client was not recruited to the study, the unused envelope was returned to the service centre.

Data Collection Procedure

Data collection involved the completion of an Initial Data Collection Form (Appendix III) and subsequent Weekly Data Collection Forms (Appendix IV); wound measurement, photograph and swabs. Demographic and other routinely collected service data was extracted from Silver Chain's client database, ComCare.

The data collection protocol included:

- Demographic data and clinical data relating to the client, which were collected as a normal part of care in Silver Chain, were sourced from ComCare (Silver Chain's client database).

- Completion of the Initial Data Collection Form at recruitment,
- Completion of Weekly Data Collection Form at weekly intervals for a maximum period of 8 weeks,
- Digital images of the wound at recruitment and each week for a maximum period of 8 weeks as per Wound Photograph Protocol for Pilonidal Sinus Study (Appendix V), to confirm the anatomical location of the wound and compare the clinical appearance of the wound tissue with the documented wound assessment.
- Wound swabs at recruitment and weeks 4 and 8, for microscopic culture and sensitivity analysis. Although, the precise technique for wound swab collection has not been identified or validated, the Z-technique of moving the swab across the wound surface in a zig-zag pattern whilst rotating and applying pressure (Cooper, 2010), was utilised for this study to optimise collection of organisms within the wound. A protocol for wound swab collection (Appendix VI) was provided to all staff involved in data collection to facilitate consistency of swab collection.
- Additional swabs were taken if wound infection was suspected, to confirm diagnosis, isolate pathogens and determine susceptibility, should systemic antibiotic therapy be required.
- The length and central depth (perpendicular to the skin surface) of the wound were measured at recruitment and at weekly intervals using the Visitrak™ calibrated sterile measurement probe. Wounds in the sacrococcygeal area, due to the tissue curvature in this area do not necessarily demonstrate a width in the normal anatomical position. Hence, width was not used as a measure towards healing as it was unable to be measured accurately. Other researchers

(Marks et al., 1983) have used two-dimensional wound measures as predictors to wound healing in similar circumstances.

To assess for factors other than wound infection that may delay wound healing the Charlson Comorbidity Index (CCI) was used. Although the CCI is used to predict mortality it has been used in other wound related studies to identify co-morbid conditions that have the potential to impair wound healing (Miller et al., 2010). In addition to this, malnutrition was further assessed using the Home and Community Care Nutritional Screening and Monitoring Tool (HACC-NSMT). There is limited availability of validated tools to adequately assess nutrition and although the HACC-NSMT tool is designed to assess for changes in weight, appetite and barriers to adequate nutrition rather than the composition of the food a person is eating, it provided a degree of assessment for potential nutritional deficits.

Study Intervention

Study participants were randomly assigned to receive either a nanocrystalline silver alginate dressing (Acticoat Absorbent™) or a calcium alginate dressing (Algisite™). Both of these products are manufactured by Smith and Nephew, hence the products are the same apart from the nanocrystalline silver component of the Acticoat™ and were selected to minimise any confounding factors. The manufacturers of the products made no financial contribution to the study; products were purchased by the organization for client use. Wound treatments in both groups involved daily wound dressings for 8 weeks or earlier if wound healing had occurred. Healing was defined as 100% epithelialisation of the wound bed.

The care plan for the allocated treatment was written in the client's home record at the study recruitment visit. All Silver Chain metropolitan domiciliary nurses received education in regard to the study protocol and the randomised treatment regimens prior to commencement of the study. The designated research nurses provided the treatment for the client at recruitment and at weekly data collection visits; whilst the client's scheduled visiting nurse provided the treatment on intervening visits. Thus neither the research nurse nor the visiting nurse was blind to group assignment. Wound management involved the client showering, prior to dressing changes. If the client was receiving clinic based care, a temporary sterile dressing pad was provided to the client to apply after showering at home to protect the wound during transit to the clinic. Wounds were cleansed with sterile water prior to the application of the randomized dressing and an absorbent pad was applied as a secondary dressing to absorb wound exudate, which was secured with dressing tape.

Protocol When Signs of Infection Identified

If clients developed signs and symptoms of local wound infection, as determined by the presence of increased, malodorous or purulent exudate, friable or bridging of granulation tissue and increased pain (Principles of Best Practice, 2008), additional data was collected including the completion of a Weekly Data Collection Form (Appendix IV), wound image and wound swab. Wound swabs for microscopic culture and sensitivity were collected from participants to determine semi-quantitative bacteriology. The client's medical practitioner was notified and a copy of the wound swab result was forwarded to him/her.

Clients in the calcium alginate group who displayed signs or symptoms of critical colonisation or infection had their dressing regime changed to the nanocrystalline silver alginate dressing and the care plan was changed accordingly. Clients in the nanocrystalline silver alginate group displaying signs or symptoms of critical colonisation or infection continued with the nanocrystalline dressing. Clients in both groups who developed signs and symptoms of localised (erythema, increased skin temperature, purulent exudate) or systemic infection (signs of local infection plus pyrexia and/or general malaise, rigours) were referred to their treating medical practitioner for consideration systemic antibiotic treatment.

When the signs and symptoms of local or systemic infection were no longer present, and any prescribed treatment completed, further data was collected, which included completion of Weekly Data Collection Form, wound image and collection of wound swab. Clients originally in the calcium alginate group were recommenced with the calcium alginate dressing and the care plan was updated accordingly. Clients in the nanocrystalline silver alginate group continued with the nanocrystalline silver alginate dressings. Clients that had recurrent episodes of local or systemic infection during the 8 week study period had the above procedure repeated.

On completion of the study period, ongoing treatment for wounds that had not healed was determined by the visiting nurse based on the assessment outcome of the wound at the final study data collection point (week 8).

The anti-inflammatory property of the nanocrystalline silver alginate dressing was a consideration in the timeframe for recruitment to this study due to the potential of the

dressings to interfere with the normal inflammatory phase of wound healing which occurs from days 0 to 4 of wounding.

Data Analysis

For data analysis purposes the dataset was split into a 'participant' file of 48 records, and a 'wound' file of 576 records. Essentially, the participant file held one record per person, while the wound file held one record for each wound observation (several records per person). Chi-square tests were conducted initially to ascertain any differences between the two treatment groups. A Wilcoxon-2-sample test was used to analyse age and wound size at baseline due to skewed data. Data analysis was performed using Statistical Analysis Software (SAS) version 9.2 (SAS Institute Incorporated, Cary, NC, USA, 2008).

The size of the wound at each time point was estimated by the multiplication of the wound length and depth. In usual circumstances, three dimensional measures, including length, depth and width are used for wound assessment. However, due to anatomical positioning and tissue curvature associated with wounds in the sacrococcygeal area accurate assessment of width was not possible and hence it was not measured. Single and two dimensional measurements have been utilised in other studies to predict wound healing (Marks et al., 1983).

As well as the size of the wound, each wound observation included a variable indicating whether the wound had 'healed' or not. From these observations, the time (days) to healing was able to be calculated. For the purpose of the study, the wound was classified as healed when there was 100% epithelialisation on the wound

surface. The purpose of the analysis was to identify factors associated with changes in wound size and with wound healing.

Differences in time to heal between the treatment groups ('intention to treat' as randomised) were examined by plotting a Kaplan Meier (KM). This is a univariate comparison as the KM curves cannot take into account any of the wound characteristics which may be associated with healing, for example, wound size. In order to take possible confounding variables into account for time to wound healing, a multivariate Cox proportional hazards regression was also conducted. This analysis was able to examine the relationship between the primary outcome measure, days to heal and potential confounders/key covariates such as presence of infection, wound size at recruitment, co-morbidity index score and nutrition.

The second analysis was a repeated measures regression to identify factors associated with changes in wound size over time. This was implemented as a random effects regression model. Wound size measurement was skewed by some large measurements; hence a logarithmic transformation was applied to improve normality and the median and range was used to report results rather than the mean. This type of analysis was used so that the correlations between measurements on the same person could be taken into account. The person identifier was named as the random effect. The percentage change in wound size from baseline to each time point was calculated, and used as the dependent variable. For the purpose of this regression model, the wound size was coded to zero when the wound was healed to enable application of the model to the whole dataset rather than only wounds which had not healed. All independent variables were initially included, and then the least

significant was dropped from the model one at a time, until all variables remaining in the model were statistically significant ($p < 0.05$). Independent variables were: age, gender, dressing group, smoking, clinical signs of infection at baseline, presence of leucocytes at baseline, initial antibiotics (taken within the first 2 weeks) and occupation (manual or non-manual).

It was planned that should there be significant numbers of clients whose treatment changed during the course of the study, the analyses would be repeated for the “actual treatment” groups. This did not turn out to be necessary.

Costs of the dressing groups were calculated using planned rather than actual costs. This method was adopted due to difficulties in determining the accuracy of data in regards to number of dressings used and time taken to perform each dressing change. Although Silver Chain captures actual service records for clients, it is a partly manual process and is subject to human error. Nursing staff are required to manually note the time they start and finish a client’s care, which is then entered onto the client data base against the respective client’s record. Furthermore, the exact details and amount of wound products used are not directly linked to the client, so it is not possible to accurately track product usage in relation to individual clients. Electronic systems are currently under development at Silver Chain which will facilitate more accurate capture of care times and product use. This will not only provide accurate information for the organisation and funders but will also provide accurate assessment of care costs for future research projects.

The cost included the nursing time (hourly rate of nursing time averaged over a 7 day period to take into account after-hour penalties) and dressing consumables (dressing pack, 0.9% sodium chloride sachet, the randomised silver alginate or calcium alginate dressing and the secondary absorbent dressing) were calculated per day and this was multiplied by the number of days the participant was on the study. The allocated dressing was used for two consecutive days. Each dressing had a portion used on the day of opening and the remainder was resealed in its original package for further use the following day. Any remaining dressing product after this time was disposed of. Costs for wound swabs were not included in the comparison, as this would not be considered a routine component of wound management for these clients.

Ethical Procedures

Permission to conduct this study was approved by the Silver Chain Human Research Ethics Committee and from the Human Research Ethics Committee at Curtin University. The study was conducted in accordance with the National Health and Medical Research Council ethical guidelines as stated in the National Statement on Ethical Conduct in Human Research 2007.

Written consent was obtained from eligible participants after they had viewed the Study Information Sheet and agreed to participate. The database was stored in the Research Directory on the Silver Chain network to which only members of the research team had access. The manufacturer's of the dressing products, Smith & Nephew did not supply dressing products or provide any financial assistance for this study.

Conclusion

This RCT was conducted within the metropolitan service centres of Silver Chain to investigate the efficacy of the prophylactic use of nanocrystalline silver alginate wound dressings promoting reduced healing times as compared to calcium alginate dressings in PSWs. It was calculated that each study group would require 44 participants. Participants meeting the inclusion criteria were randomised to dressing groups and received daily wound care for the duration of their participation in the study. Data relating to the participant and the progress of the wound was collected and analysed using SAS. Ethics approval for the study was obtained from both Curtin University and Silver Chain Human Research Ethics Committee.

Chapter 4

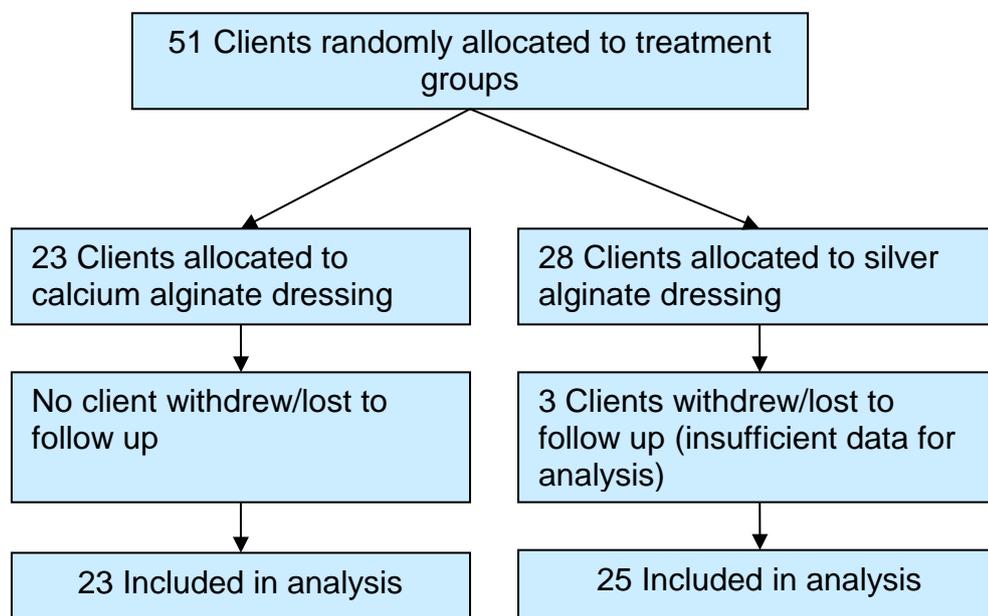
Results

Introduction

Participant recruitment occurred from September 2008 to February 2010. The initial plan was to recruit participants over a 12 month period, however the recruitment target had not been achieved within 12 months, so recruitment was extended for a further 3 months with an aim to achieve the target of 88 participants. During the recruitment phase of the study the tertiary hospitals in WA commenced Hospital-in-the-Home Programs and as a result, referrals of clients with pilonidal sinus wounds to Silver Chain diminished. Despite meetings and discussions regarding the study with the tertiary hospitals the referrals to Silver Chain did not improve, with only three more participants being recruited in the additional 3 month period. Discussions between the researcher and university supervisors resulted in a decision to cease study recruitment.

A total of 51 participants met the inclusion criteria and were admitted to the study. Random allocation to the treatment groups resulted in 28 participants in the silver alginate (SA) dressing group and 23 participants in the calcium alginate (CA) dressing group. All clients with at least two wound measurements, for whom a healing rate could be calculated, were included in the analysis. All analyses were by intention to treat. One participant withdrew from the study due to personal reasons and two were lost to follow up as they were unable to be contacted following the initial assessment and recruitment. As a result a total of 48 participants were included in the analysis, 25 within the SA dressing group and 23 within the CA dressing group Figure 1. No adverse events occurred during the study period.

Figure 1: Participant Flowchart



Demographic and Comorbidity Profile

The descriptive statistics displayed in Table 1, show the distribution of people and their characteristics between the two dressing groups. The demographics and other characteristics of the two dressing groups were compared to assess their equivalence and identify any differences. The two dressing groups were found to be equivalent on potential confounders.

The study included 69.4% male (n = 34) and 28.6% (n = 14) female participants.

There was no significant difference (p = 0.24) in the gender distribution between the two dressing groups. There was 64% (n =16) male and 36% (n = 9) female in the SA dressing group and 78% (n = 18) male and 22% (n = 5) female in the CA dressing group ($\chi^2=1.18$, DF=1, p=0.24).

The age of participants across both dressing groups ranged from 16-38 years, with a mean age of 22.2 years for all participants. The mean age for males across both dressing groups was 22.7 years and the mean age for females across both dressing groups was 21.1 years. There was no significant difference identified in relation to age between the dressing groups ($z = 29$, $df = 46$, $p = 0.77$), with an age range in the SA dressing group of 16-30 years, resulting in a mean age of 21.8 years and an age range in the CA dressing group of 16 – 38 years, resulting in a mean age of 22.7 years.

There was no significant difference relating to the country of birth of participants between the groups ($df = 2$, $p = 1.0$). Within the SA dressing group 77% ($n = 17$) of participants were born in Australia, 9% ($n = 2$) in the United Kingdom and 14% ($n = 3$) from other countries. Within the CA dressing group 78% ($n = 18$) of the participants were born in Australia, 4% ($n = 1$) in the United Kingdom and 17% ($n = 4$) in other countries.

As anticipated with a young population, the participants performed well on the Charlson Comorbidity Index (CCI), where zero indicates excellent health and 37 indicates poor health. There was no significant difference between the dressing groups on this index ($df = 1$, $p = 1.0$): 96% ($n = 24$) of participants in the SA dressing group had a score of zero and 100% ($n = 21$) of participants in the CA dressing group had a score of zero. One participant (4%) within the SA dressing group reported a co-morbid condition of gastro-oesophageal reflux disease.

The risk of malnutrition amongst the study sample was low with a mean score of 0.17 on the Home and Community Care (HACC) Nutritional Risk Screening and Monitoring Tool for which a score of zero indicates no risk and a score of 11 indicates high risk. The most common nutritional concern was reduced appetite at time of admission to Silver Chain with 6% (n = 3) of participants across both dressing groups experiencing this problem. There was no significant difference (df = 1, p=0.39) between the dressing groups relating to nutrition with 92% (n = 23) of the SA group scoring zero and 81% (n = 17) of the CA group scoring zero.

Smokers accounted for 33% (n = 16) of the participants. There was no significant difference between the treatment groups for current smokers ($\chi^2 = 0.92$, DF = 1, p = 0.34). Within the SA dressing group 29% (n = 7) of participants were smokers and 43% (n = 9) of the CA dressing group were smokers.

During study participation the majority of participants (82%) reported being either employed or engaged in full time studies. Only 18% of participants were identified as being unemployed, 4% (n = 1) in the SA dressing group and 14% (n = 3) in the CA dressing group. Students accounted for 37% (n = 9) of the SA dressing group and 18% (n = 4) of the CA dressing group. Tradesmen (refers to males and females) accounted for 33% (n = 8) of the SA dressing group and 32% (n = 7) of the CA dressing group. Other occupations identified were retail industry workers 4% (n = 1) for SA dressing group and 14% (n = 3) CA dressing group, office based workers 8% (n = 2) for SA dressing group and 23% (n = 5) for CA dressing group, and other occupations accounted for 12% (n = 34) for SA dressing group and none for the CA

dressing group. There was no significant difference relating to occupation group (df = 5, $p = 0.17$).

Occupation was further classified into manual and non-manual labour based on the occupational activity of the employment. Non-manual labour (full time study and office work) was the most common type of employment activity with 67% (n = 16) of participants in the SA dressing group and 68% (n = 15) of the CA dressing group. Those employed in occupations that comprised manual labour were identified to be 33% (n = 8) of the SA group and 32% (n = 7) of the CA dressing group. There was no significant difference between non-manual and manual occupational activities ($\chi^2 = 0.01$, DF = 1, $p = 0.92$).

The surgical procedure used to treat the participants' pilonidal sinus disease was not shown to have a significant difference between the dressing groups ($\chi^2 0.25$, df = 4, $p = 0.60$). Two surgical procedures were performed and they were incision and drainage of pilonidal abscess and excision of pilonidal sinus. Incision and drainage was performed on 72% (n = 18) of the SA dressing group and 78% (n = 18) of the CA dressing group. Excision was performed on 28% (n = 7) of the SA dressing group and 22% (n = 5) of the CA dressing group.

The shape of the post-operative wound was identified as having a narrow base or wide base. The narrow based wounds resulting from incision and drainage of pilonidal abscesses, whilst the wide based wounds resulted from excision of a pilonidal sinus. Overall, there was no significant difference identified pertaining to wound shape ($\chi^2 = 1.31$, DF = 1, $p = 0.25$). Narrow wound bases were identified for

60% (n = 15) of participants in the SA dressing group and 44% (n = 10) of the CA dressing group. Wide wound bases were identified for 40% (n = 10) of the SA dressing group and 57% (n = 13) of the CA dressing group.

It was not possible to perform statistical analysis on the participants' use of antibiotics prior to surgery for their pilonidal sinus disease as there was too much missing data in relation to this question. However, there was no significant difference ($\chi^2 = 2.01$, DF 1, $p = 0.15$) between the groups for antibiotic usage in the first two weeks post-surgery with 72% (n = 18) of the SA dressing group and 52% (n = 12) of the CA dressing group reported as taking antibiotics during this time.

A range of dressing products were reported as being used prior to participation in the study and this was not shown to have a significant effect (Fishers exact, $df = 4$, $p = 0.60$) on the outcome of the study. The most commonly reported dressing in use was calcium alginate, with 67% (n = 16) of the participants in the SA dressing group and 80% (n = 16) of the participants in the CA dressing using this product prior to study commencement. This was followed by saline-soaked gauze which was used by 17% (n = 4) of the SA dressing group and 5% (n = 1) of the CA dressing group.

The baseline median wound size was not found to be significantly different between the treatment groups, with the median wound size of 644mm² for the SA dressing group and 900mm² for the CA dressing group ($z = 1.07$, $df = 46$, $p=0.29$).

Table 1: Characteristics of Study Participants (p-values were obtained from the Chi-square test unless marked otherwise).

Variable	Silver Alginate (N=25)	Calcium Alginate (N=23)	p-value
Gender			0.28
Male	16 (64%)	18 (78%)	
Female	9 (36%)	5 (22%)	
Age (mean, range) §	21.8 (16 to 30)	22.7 (16 to 38)	0.77
Nationality*			1.0
Australia	17 (77%)	18 (78%)	
UK	2 (9%)	1 (4%)	
Other	3 (14%)	4 (17%)	
Surgical procedures			0.62
Incision & drainage	18 (72%)	18 (78%)	
Excision	7 (28%)	5 (22%)	
Occupation group*			0.17
Retail	1 (4%)	3 (14%)	
Trade	8 (33%)	7 (32%)	
Office	2 (8%)	5 (23%)	
Student	9 (37%)	4 (18%)	
Other	3 (12%)	0	
Unemployed	1 (4%)	3 (14%)	
Occupation activity			0.92
Non-manual	16 (67%)	15 (68%)	
Manual	8 (33%)	7 (32%)	
Wound shape			0.25
Narrow	15 (60%)	10 (44%)	
Wide base	10 (40%)	13 (57%)	
Current smoking			0.34
Yes	7 (29%)	9 (43%)	
No	17 (71%)	12 (57%)	
Nutritional risk score*			0.39
0	23 (92%)	17 (81%)	
1 or 2	2 (8%)	4 (19%)	
CCI score*			1.0
0	24 (96%)	21 (100%)	
1	1 (4%)	0	
Antibiotics taken prior to surgery			Statistical analysis not interpretable, due to missing data
Yes	12 (86%)	5 (42%)	
No	2 (14%)	7 (58%)	
Antibiotics in first 2 weeks post-op			0.15
Yes	18 (72%)	12 (52%)	
No	7 (28%)	11 (48%)	
Dressing before study*			0.60
Saline soaked gauze	4 (17%)	1 (5%)	
Hydrogel	1 (4%)	0	
Alginate	16 (67%)	16 (80%)	
Hydro fibre	2 (8%)	3 (15%)	
Other	1 (4%)	0	
Wound size at baseline (median and range) §	644 (18 to 3150)	900 (54 to 6600)	0.29
* p-value calculated from Fisher's Exact Test			
§ p-value calculated from the Wilcoxon 2-sample test (non-parametric)			

Time (Days) to Wound Healing

The first analysis in relation to wound healing was undertaken to identify if there was any difference in the proportion of wounds that healed during the study between dressing groups.

Table 2: Total Number of Wounds Healed

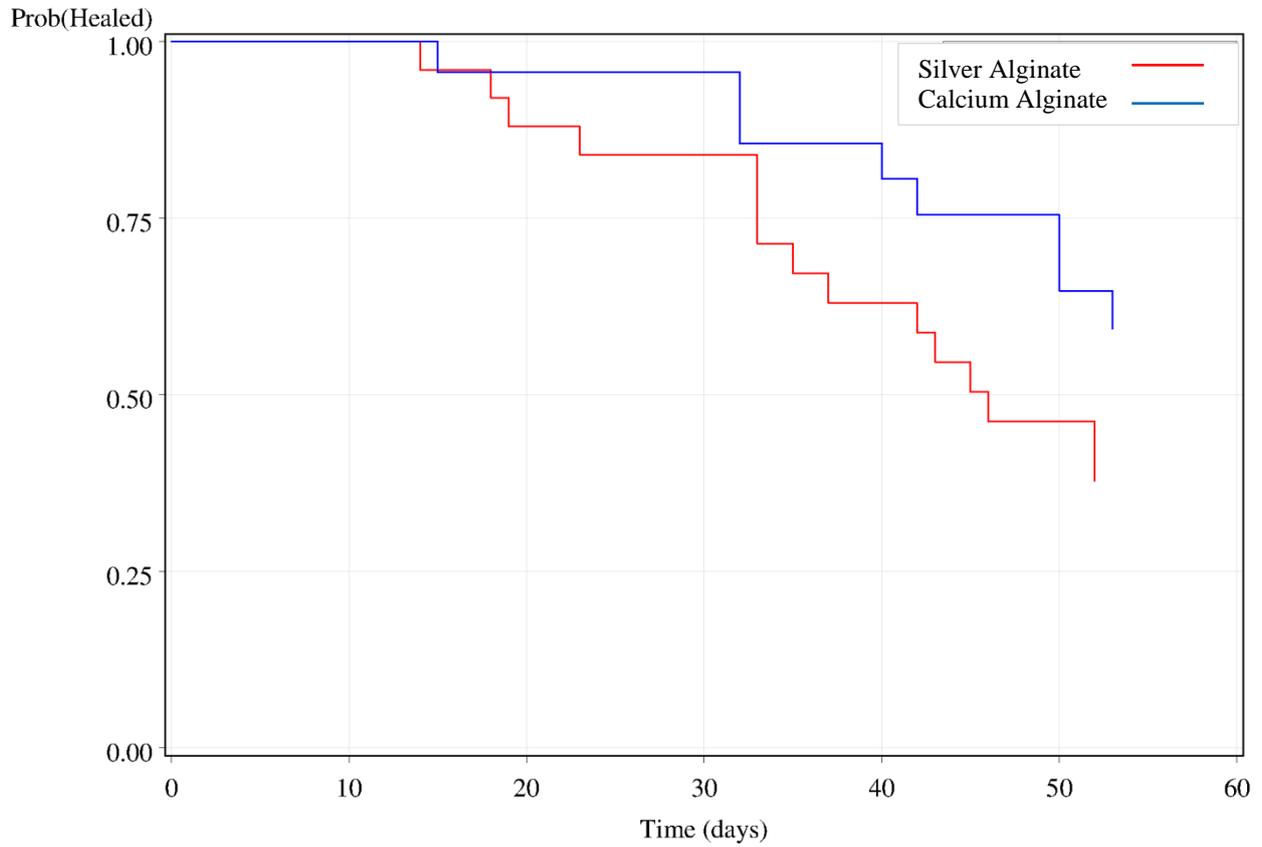
Dressing Group		p-value (Chi-square)
Silver Alginate (N = 25)	Calcium Alginate (N = 23)	0.0806
15 (60%)	8 (35%)	

The total number of wounds healed between dressing groups is shown in Table 2, there was no statistical significance in the total number of wounds healed during the study period ($\chi^2 = 3.05$, DF = 1, $p = 0.0806$).

Further analysis sought to determine any difference between treatment groups in the time to wound healing. The Kaplan-Meier (KM) curves were constructed for time to wound healing for each dressing group and these were then compared using the Log-rank test.

The Log-rank test to compare the KM curves for the different dressing groups displayed in Figure 2 showed no significant difference between groups ($\chi^2 = 1.94$, df = 1, $p = 0.1636$). The SA dressing group had a shorter time to wound healing with a median of 46 days (95% CI = 33-61) as compared to 66 days (95% CI: 50-89) for the CA dressing group, but this was not statistically significant. Due to the relatively small numbers of participants, the difference in time to wound healing would need to be larger in order to be statistically detectable (with $\alpha = 0.05$).

Figure 2: Kaplan Meir Survival Curves



The Cox proportional hazards model displayed in Table 3, also showed no significant difference between dressing groups ($p = 0.53$) after adjustment for initial wound size and other wound and person characteristics.

Table 3: Cox Proportional Hazards Model for Healed Wounds

Variable	Hazard Ratio	95% Confidence Interval	p-value
Dressing: Silver alginate	1 (reference)		
Calcium alginate	0.81	0.43 to 1.55	0.53
Initial wound size: Small ($\leq 377\text{mm}^2$)	4.36	1.90 to 9.98	0.0005
Medium ($377-1200\text{mm}^2$)	1 (ref)		
Large ($1200+\text{mm}^2$)	0.36	0.15 to 0.87	0.0227

Overall, the initial wound size was the only variable which was found to be significantly associated with time to wound healing. When compared to medium sized wounds, the smaller wounds healed significantly quicker ($p = 0.0005$, Hazards Ratio (HR) > 1 indicated a greater chance of healing), while the larger wounds were significantly slower to heal ($p = 0.0227$, $\text{HR} < 1$). The dressing type variable was added into the model, and found not to be associated with wound healing. Similarly, the other variables: age, gender, smoking, clinical signs of infection, presence of leucocytes at baseline, initial antibiotics (taken within the first 2 weeks) and occupation (manual or non-manual) were not found to have a significant relationship with wound healing.

Changes in Wound Size Over Time

It was found that the wound size measurement was not normally distributed (skewed by some large measurements in some wounds), and hence a logarithmic transformation was applied to improve normality. After adjustment for the highly significant ($F_{1,337} = 111.5$, $p = <0.0001$) change in wound size over time (days from baseline), the wound size reduction appeared to be significantly associated with the dressing group ($F_{1,337} = 5.9$, $p = 0.0160$), and the presence of leucocytes at baseline ($F_{1,337} = 22.7$, $p = <0.0001$). It appeared that the SA dressing group was

associated with a significantly faster wound size reduction over time as compared to the CA dressing group as displayed in Figure 3 and Table 4.

Figure 3: Change in Wound Size Over Time (Black line = SA dressing group, red line = CA dressing group. Dots = individual participant measurements; lines = median measurements at each week. Wounds classified as healed are not included).

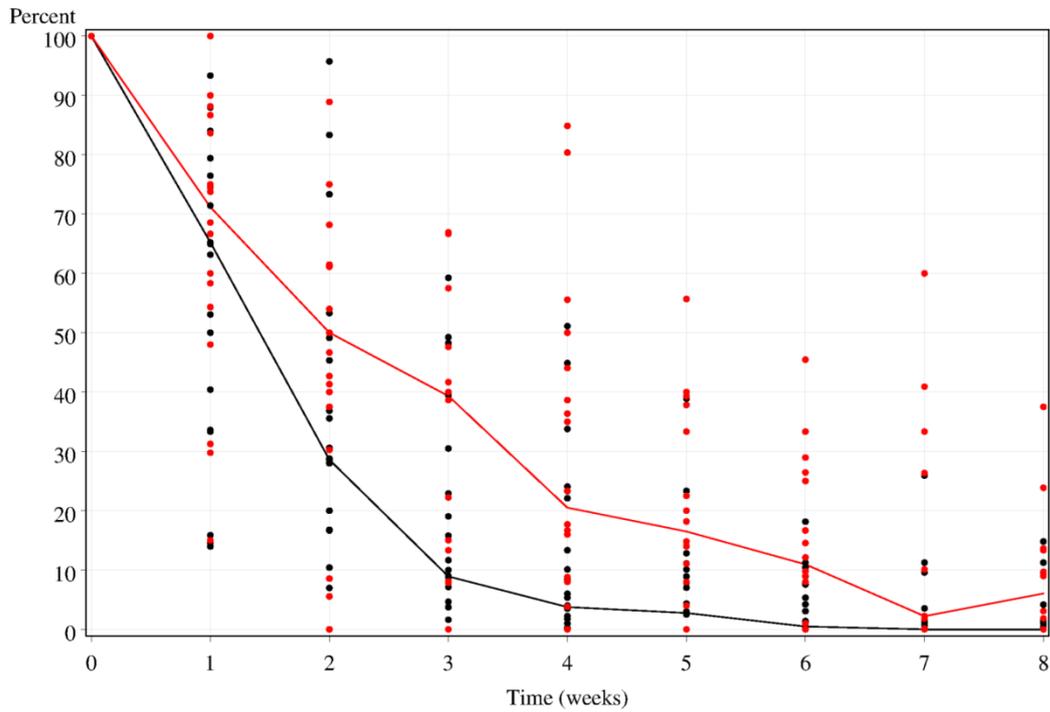


Table 4: Change in Wound Size Over Time

Week	Silver Alginate (N=25)		Calcium Alginate (N=23)	
	Number of Healed Wounds (accumulative total)	Size as % of baseline (range)	Number of Healed Wounds (accumulative total)	Size as % of baseline (range)
1	0	65.2 (14.0 to 333.3)	0	71.2 (15.0 to 100.0)
2	1	33.1 (7.0 to 95.7)	1	50.0 (5.6 to 527.8)
3	3	13.7 (1.6 to 59.3)	1	41.7 (7.9 to 311.1)
4	4	7.2 (0.1 to 51.1)	1	35.7 (3.8 to 259.3)
8	15	4.2 (0.4 to 14.8)	8	11.5 (1.9 to 37.5)

Table 4 shows the change in wound size over time, the weekly values for the median wound size and range are expressed as a percentage of the baseline value for unhealed wounds, for each dressing type. The median and range were used due to skewed wound measurement data. Participants with healed wounds were excluded from the size calculations as they healed. The results appear to demonstrate a more rapid healing rate for the SA dressing group as compared to the CA dressing group.

Table 5: Percentage Change in Wound Size from Baseline (using all data up to week 8).

Variable	Coefficient (95% CI)	*LS Mean (95% CI)	p-value
Dressing			0.0170
Silver alginate	-19.7 (-35.9 to -3.5)	28.7 (17.7 to 39.7)	
Calcium alginate	0 (reference)	48.4 (36.6 to 60.2)	
Week number	-11.6 (-13.1 to -10.0)		<0.0001

*The Least Squares (LS) mean is a mean percentage of wound size averaged across all the weeks of the study, which gives an indication of the difference between dressing groups.

A random effects regression model was used to identify factors associated with the percentage change in wound size from baseline as displayed in Table 5. Overall, for each week of the study, it appeared that the wound size reduced on average by 11.6% from baseline. However, the SA dressing appeared to result in smaller

wound sizes than the CA dressing at each time point. The average change of wound size from baseline was approximately 20% greater with the SA dressing group than the CA dressing group.

Further analysis was conducted to explore the trend that silver containing dressings result in faster wound healing in the first 2 weeks of use, which has been demonstrated in other studies (Miller et al, 2010). The random effects model was therefore applied to the dataset in stages: 0-2 weeks and 3-8 weeks. The dependent variable for the 0-2 week period was the same as above (percentage change in wound size from baseline). However, the dependent variable for the second period (3-8 weeks) was the percentage change in wound size from week 2. The purpose of this analysis was to compare the changes from week 3 onwards, essentially disregarding any differences that may have appeared up to week 2. The results are shown in Table 6.

Table 6: Percentage Change in Wound Size Between Baseline-2 Weeks and Weeks 3-8

Time Period	Variable	Coefficient (95% CI)	LS Mean (95% CI)	p-value
Baseline-2 weeks	Dressing: Silver alginate	-15.4 (-35.4 to 4.6)	66.8 (53.3 to 80.3)	0.1290
	Calcium alginate	0 (reference)	82.2 (67.5 to 96.9)	
	Week number	-24.2 (-35.3 to -13.2)		<0.0001
3-8 weeks	Dressing: Silver alginate	-14.2 (-40.8 to 12.3)	46.9 (29.2 to 64.6)	0.2915
	Calcium alginate	0 (reference)	61.1 (41.3 to 81.0)	
	Week number	-16.2 (-21.0 to -11.3)		<0.0001

Overall, there was a very significant change in wound size over the first 2 weeks amongst participants (24% reduction from baseline per week). However, the difference between the dressing groups, whilst suggestive of an advantage for SA, was not statistically significant (p = 0.13). Overall the reduction in wound size from

week 3 onwards was less than the first 2 weeks (16% reduction from week 2) and the dressing group remained not significant, although there was still a suggestion that the SA dressing group had greater wound size reduction as compared to the CA dressing group.

Wound Swabs

Wound swabs were collected from participants at recruitment and during weeks 4 and 8 of the study period if the wound remained unhealed. The swabs were sent for laboratory analysis for microscopic culture and sensitivity. Many of the participants had healed wounds prior to week 4; therefore only one swab was available for these participants, which limited overall comparative analysis. Analysis was further limited due to missing data, small numbers and varying reporting methods from the pathology company used to analyse the wound swabs. This resulted in difficulties in determining the antimicrobial effectiveness of the nanocrystalline silver alginate dressing. A total of 99 swabs were collected from 48 participants during the study period as presented in Table 7 and the descriptive pathology is displayed in Table 8.

Table 7: Total Number of Swabs Collected

Data Collection Point	Number of Participants	Number of Swabs
Recruitment	48	47
Week 4	37	36
Week 8	18	16
Total		99

Table 8: Descriptive Pathology Data (numbers in the cells are the number of cases)

Variable	Silver Alginate (N=25)			Calcium Alginate (N=23)		
	Week 0	Week 4	Week 8	Week 0	Week 4	Week 8
Leucocytes						
Missing/NR*	0	6	18	2	8	13
Not seen	2	9	3	0	0	3
Occasional	5	4	0	6	2	3
+	7	2	1	7	8	1
++	7	4	2	4	2	1
+++	4	0	1	4	3	2
Bacteria						
Missing/NR	7	12	22	14	18	19
Not seen	18	13	3	9	5	4
Gram Positive Cocci						
Missing/NR	22	21	22	13	14	19
Occasional	2	3	1	10	6	2
Some (+ or more)	1	1	2	0	3	2
Gram Positive Bacilli						
Missing/NR	20	25	23	17	20	21
Occasional	4	0	2	4	2	1
Some (+ or more)	1	0	0	2	1	1
Gram Negative Bacilli						
Missing/NR	22	24	24	19	22	22
Occasional	3	1	0	1	1	1
Some (+ or more)	0	0	1	3	0	0
*NR= not reported						

The most frequent pathogen isolated from wound swabs was staphylococcus aureus. At recruitment it was isolated in 4% (n = 1) of the SA dressing group and 17% (n = 4) of the CA dressing group. At 4 weeks it was isolated in 16% (n = 4) of the SA dressing group and 26% (n = 6) of the CA dressing group and at 8 weeks 20% (n = 5) of the SA dressing group and 30% (n = 7) of the CA dressing group. Mixed coliforms were isolated in 8% (n = 2) of the SA dressing group at recruitment with none isolated in weeks 4 and 8. In the CA dressing group, mixed coliforms were isolated in 17% (n = 4) at recruitment, 4% (n = 1) at week 4 and none at week 8. The frequency of organisms identified from the wound swabs is displayed in Table 9.

Table 9: Number of Wounds in Which Micro-organisms are Present

Variable	Silver Alginate (N=25)			Calcium Alginate (N=23)		
	Week 0	Week 4	Week 8	Week 0	Week 4	Week 8
MA	2				1	1
MColi	2			4	1	0
SA	1	4	5	5	6	7
SMI			1		1	1
STRB			1	1	2	1
STRG	1	1	1	1		
No of organisms						
None	19	21	19	12	12	13
1	6	3	4	11	11	10
2 or more	0	1	2	0	0	0

Legend: MA = Mixed anaerobes, MColi = Mixed Coliforms, SA = Staphylococcus Aureus, SMI =Streptococcus Milleri , STRB = Streptococcus B, STRG = Streptococcus G.

The number of wounds with organisms between dressing groups was compared at each swab collection point to see if there was any difference in the number of micro-organisms over the study period. The results are displayed in Table 10. The p-values were obtained from Chi-square tests (statistic is shown). All tests were based on 1 degree of freedom (no organisms vs some organisms)

Table 10: Number of Wounds with Micro-organisms at Each Swab Collection Point.

Week	Silver Alginate	Calcium Alginate	p-value (Chi-square)
0	6	11	0.0847
4	4	11	0.0175
8	6	10	0.1527

There was no significant difference between the groups at recruitment in relation to the isolation of micro-organisms from wound swabs, the SA dressing group had 24% (n = 6) participants with micro-organisms isolated from wound swabs, as compared

to 47% (n = 11) of the CA dressing group ($\chi^2 = 2.97$, DF = 1, p = 0.0847). At week 4, there was a statistically significant difference between the groups in relation to the presence of micro-organisms isolated from wound swabs ($\chi^2 = 5.65$, DF = 1, p = 0.0175), however as the numbers were relatively low the significance of this may be inaccurate. At week 8, again there was no statistical significance between the proportion of wounds in each dressing group with micro-organisms isolated from wound swabs ($\chi^2 = 2.05$, DF = 1, p = 0.1527).

The participants that had micro-organisms identified from their wounds were reviewed for clinical signs of overt or covert infection at the time the swab was collected. The clinical signs of infection identified were purulent exudate, changes in granulation tissue, erythema, localised heat, increased or new pain and malodour as displayed in Table 11. Participants may have had more than one clinical sign of infection.

Table 11: Clinical Signs of Overt or Covert Infection at Time of Swab Collection

Pathogen *	Clinical Signs of Infection Present**	No of Cases with Reported Clinical Signs of Infection & Pathogen	Total No of Cases with Pathogens Identified
Staphylococcus aureus	<ul style="list-style-type: none"> • Changes in granulation tissue*** • Erythema • Localised heat • Increased pain • Purulence 	7	28
Streptococcus G	<ul style="list-style-type: none"> • Malodour 	1	4
Streptococcus B	<ul style="list-style-type: none"> • Nil 	0	5
Mixed Coliforms	<ul style="list-style-type: none"> • Changes in granulation tissue • Erythema 	6	7
Streptococcus Milleri	<ul style="list-style-type: none"> • Changes in granulation tissue • Increased pain 	1	3
Mixed Anaerobes	<ul style="list-style-type: none"> • Changes in granulation tissue 	2	4
<p>*Participants may have had more than one pathogen isolated. * * Participants may have had more than one clinical sign of infection. ***Changes in granulation tissue included bright red, friable, bridging and/or hypergranulation.</p>			

As it was not possible to ascertain the antibacterial effectiveness of the nanocrystalline silver alginate dressing due to the reduced number of participants under study and the limited data obtained, an independent microbiologist was asked to review the results to ascertain any clinical significance and none was reported.

Costs

The mean cost per participant between the two groups was not statistically significant when analysed ($t = 0.57$, $df = 46$, $p = 0.5697$), as shown in Table 12.

Table 12: Costs for all Participants (Nursing Time & Consumables)

Dressing Group	Daily Cost	Mean Cost per Participant	p-value (t-test)
Silver Alginate	\$78.64	\$3337.50	0.5697
Calcium Alginate	\$69.28	\$3168.80	

The daily cost per participant was lower for the CA dressing group than the SA dressing group. However, although not a significant finding, the mean cost per participant for the length of study participation (healed and non-healed wounds) was marginally less for the SA dressing group due to the reduced number of days the SA dressing group participants were under study.

Table 13: Cost for Healed Wounds (Nursing Time and Consumables)

Dressing Group	Number of Healed Wounds	Mean Cost per Participant for Healed Wound	p-value (t-test)
Silver Alginate	15(60%)	\$2752.40	0.9358
Calcium Alginate	8 (35%)	\$2719.20	

The cost to achieve wound healing was compared for both dressing groups and no statistical significance was found in relation to cost for wounds that healed ($t = 0.08$, $df = 21$, $p = 0.9358$).

Conclusion

The study was not able to demonstrate a statistically significant difference in time to wound healing between dressing groups using either a univariate (KM analysis) or multivariate analysis (Cox model), and this was possibly due to the relatively small

number of participants enrolled in the study. However, after adjustment for covariates, the random effects regression model demonstrated a significantly faster reduction in wound size in the SA dressing group as compared to the CA dressing group. Wound swab analysis identified several different pathogens present in the pilonidal sinus wounds; however due to limitations with analysis the significance of these in relation to wound healing was not able to be demonstrated. There was no significant difference found in relation to cost of care for all participants and for healed wounds between the dressing groups.

Chapter 5

Discussion

Introduction

The aim for pilonidal sinus wounds healing by secondary intention is to achieve controlled closure of the wound in a timely manner and to minimise the risk of infection and recurrence. The anatomical location and nature of PSWs predispose them to overt and covert infection which can result in delayed wound healing. The literature review revealed limited studies on the management of PSWs healing by secondary intention. Although, several different wound care products have been studied in relation to wound healing for PSWs, there was limited consideration given to the increased risk of infection of these wounds and there remains no consensus on the most appropriate management option. This study sought to determine if the prophylactic use of nanocrystalline silver alginate dressings, in sacrococcygeal pilonidal sinus wounds would promote faster healing as compared to calcium alginate dressings.

Wound Healing

It was hypothesised that this study would show a faster wound healing rate with a silver alginate dressing as compared to a calcium alginate dressing for sacrococcygeal pilonidal sinus wounds healing by secondary intention. However, although the results suggested a trend for faster wound healing: 46 days with the SA dressing group as compared to 66 days with the CA dressing group, the difference was not statistically significant. A difference of this magnitude may however have been statistically significant in a larger study. Overall, the analysis identified initial

wound size as the only variable which was statistically significant in relation to wound healing, that is smaller wounds were significantly faster than larger wounds to heal.

Further analysis of wound healing identified that the change in wound size over time was significantly associated with the dressing group. The SA dressing group had on average a 20% better wound size reduction over the study period than the CA dressing group. Additionally, there was a higher percentage (60%, n = 15) of wounds healed in the SA dressing group than the CA dressing group (35%, n = 8).

Additionally, comparison of percentage of change in wound size between baseline and week 2 and week 3-8, showed a rapid reduction in wound size in the initial 2 weeks of study participation, and although not a significant finding this was better for the SA dressing group. This is a similar finding to Miller et al. (2010), who identified swifter wound healing in the first 2 weeks of treatment with a nanocrystalline silver dressing as compared to cadexomer iodine dressings for community patients with leg ulcers. Based on these findings, nanocrystalline silver alginate dressings would be an appropriate choice of dressing for sacrococcygeal PSWs healing by secondary intention. Further research is, however, required to explore these findings to determine if the improved healing rate is related to either the antimicrobial, anti-inflammatory or pro-healing effects of the nanocrystalline silver or a combination of these properties.

The presence of leucocytes at recruitment was also found to be associated with change in wound size over time. However, there was a significant amount of missing data relating to this, as leucocytes were not consistently reported by the laboratory.

Leucocytes are cells of the immune system which defend the body against infections and foreign materials; however they also aid the removal of damaged and devitalised tissue and play a role in the normal physiological process of wound healing (Carville, 2012). As study recruitment occurred from day 2 to 7 post surgery, their presence in the wound could be related to normal physiological healing. The inflammatory phase of wound healing occurs from day 0 to 4 of wounding and involves an increase in localised blood flow and immune response. Inflammation presents clinically with erythema, oedema, exudate and pain (Carville, 2012). Wound infection can initiate an inflammatory response within the wound and can present clinically with similar signs.

Identifying wound infection requires assessment of the person as well as the wound. Clinically it is based on signs and symptoms of the person, the wound and the surrounding skin (Sibbald & Ayello, 2007). Wounds contain bacteria soon after they occur, however, the potential for bacteria to produce harmful effects is influenced by the number and virulence of the bacteria and host resistance (Principles of Best Practice, 2008). Wounds can remain in bacterial balance when the wound is contaminated or colonised with organisms without causing tissue damage. However, this can progress to a bacterial imbalance, that is covert or overt infection, when a host response occurs (European Wound Management Association, 2006; Principles of Best Practice, 2008; Sibbald & Ayello, 2007). Classic signs and symptoms of infection are used to identify overt infection, however, signs of covert infection may be more difficult to identify, as the signs are not widely recognised (Gardner et al., 2001). Differentiating overt and covert infection from a clinical aspect can be aided by the use of various tools and guidelines such as, Gardener et al., (2001) Clinical

Signs and Symptoms Checklist or NERDS and STONES mnemonics (Sibbald & Ayello, 2007). NERDS can aid diagnosis of superficial infection (**N**on healing, **E**xudative, **R**ed and bleeding granulation tissue, **D**ebris in the form of slough or necrotic tissue, **S**mell (from wound), whereas, STONES can aid diagnosis of deep tissue infection (**S**ize is bigger, **T**emperature is increased, **O**s can probe to bone, **N**ew areas of breakdown, **E**xudate, erythema oedema, **S**mell from wound (Sibbald & Ayello, 2007). The authors suggest that when two or three of the signs for NERDS or STONES are present, a diagnosis of localised or deeper tissue infection can be made respectively.

Not all participants that were identified as having organisms identified in wound swabs showed signs of overt or covert infection. In relation to *Staphylococcus aureus*, only seven (25%) of the 28 participants who had this organism isolated in wound swabs, showed clinical signs of infection at the time the wound swab was collected. This would support the theory related to wound bio-burden that identifies that contaminated or colonised wounds fail to initiate a host response and hence, have no clinical changes or signs of infection, whereas covert or overt wound infection will initiate a host response and clinical signs of infection will be evident (Principles of Best Practice, 2008).

Recent research in relation to wound infection has focused on the presence of biofilms, which are communities of micro-organisms encased in a protective matrix and attached to the wound bed (Woo et al., 2008). They have been found by electron microscopy to be present on 60% of chronic and 6% of acute wounds (Australian Wound Management Association, 2010). Micro-organisms within biofilms

develop a tolerance to the immune system, antibiotics and topical antimicrobials thereby making them resistant to factors that would normally kill the microbe in its planktonic state (Woo et al., 2008). Although biofilms were not a consideration when planning this study as little was known about them in relation to wound healing, emerging evidence suggests they can contribute to delayed wound healing (Australian Wound Management Association, 2010). It has been suggested, that a broad spectrum antimicrobial that kills rather than inhibits growth of micro-organisms is more appropriate for the prevention of biofilm formation, with the aim that the planktonic microbes would be killed prior to the formation of the biofilm (Phillips, Wolcott, Fletcher, & Schultz, 2010). The percentage of biofilms in acute wounds is reportedly low as compared to chronic wounds, which suggests that biofilms are more likely to develop the longer the wound is present. There is therefore a potential risk that PSWs healing by secondary intention would be at increased risk of biofilm formation due to the often lengthy healing times. However, further research is required to fully understand the potential role biofilms play in PSW healing.

The silver alginate dressing used in the study was selected primarily to reduce potential confounders, as it was equivalent to the calcium alginate dressing apart from the silver component. However, consideration was given to current evidence and the product's antimicrobial properties in relation to the concern regarding prophylactic use of topical antimicrobial agents in the development of resistant strains of bacteria. Although to date, there has been no reported evidence, demonstrating a link with bacterial resistance and the clinical use of modern silver dressings (Leaper, 2011). The risk of resistance from silver dressings can be minimised by utilising dressings with high levels of silver that facilitate a rapid

bactericidal effect (Ovington, 1999, 2001). The nanocrystalline dressing used in this study has been shown to sustain a high level of active silver cation of 70 to 100 parts per million (ppm) (Edwards-Jones, 2006; Leaper, 2011), which is three to five times higher than the levels required for a bactericidal effect (Edwards-Jones, 2006). The prophylactic use of topical antiseptics to prevent wound infection is supported by international consensus (Principles of Best Practice, 2008), when there is an increased risk of infection. Pilonidal sinus wounds are at increased risk of infection as they are often associated with abscess formation (Wilson, 1995). The study results suggest that the majority of study participants, 72% (n = 18) in the SA dressing group and 78% (n = 18) in the CA dressing group presented clinically with a pilonidal abscess, as incision and drainage was the most common surgical procedure performed. Additionally, the sacrococcygeal area is in close proximity to the perineum, where large numbers of both Gram-positive and Gram-negative rods of faecal origin are present (Percival, Emanuel, Cutting, & Williams, 2012) thereby increasing the potential for wound infection.

Although the diagnosis of bacterial imbalance is made clinically, wound swabs may be required to guide treatment decisions especially when systemic treatment is required (Healy & Freedman, 2006; Sibbald & Ayello, 2007). Multiple organisms were identified from participants' wound swabs, including mixed anaerobes, mixed coliforms (including *Escherichia coli*), *Staphylococcus aureus*, *Streptococcus milleri*, *Streptococcus B*, and *Streptococcus G*. This has some similarity to the most frequently isolated pathogens in surgical site infection (SSI) as stated in the Centres for Disease Control and Prevention Guideline: for the prevention of surgical site infection (1999), which has recognised *Staphylococcus aureus*, coagulase-negative

Staphylococci, Enterococcus, Escherichia coli, Pseudomonas aeruginosa, and Enterobacter as being the most common organisms (Bowler, Duerden, & Armstrong, 2001).

The most common organism identified from the wound was Staphylococcus aureus. The normal levels of bacteria on adult skin has been estimated at between 6×10^2 and 2×10^6 bacteria/cm² with Staphylococcus aureus, being a frequent isolate (Percival et al., 2012). Although it is only transiently carried on intact skin, approximately 30% of healthy adults are colonised with Staphylococcus aureus usually in the anterior nares, vagina and perianal area and it is a prominent pathogen in wound infections (Percival et al, 2012). It was observed that there was a higher percentage of Staphylococcus aureus isolated from wound swabs taken from participants in the calcium alginate dressing group as compared to the silver alginate dressing group. However, the significance of this observation was unable to be determined due to the low numbers. The total number of participants with micro-organisms identified in wound swabs was compared between dressing groups at recruitment and weeks 4 and 8. Although a statistically significant difference was observed at week 4, indicating this was less for the SA dressing group, this may not be accurate due to the low numbers involved. Additionally, although not a statistically significant finding, the SA dressing group had a lower number of people with micro-organisms on recruitment than the CA dressing group. Further research is required to determine the micro-flora of PSWs healing by secondary intention and the in vivo bactericidal effect of nanocrystalline silver dressings in relation to Staphylococcus aureus.

It was anticipated that normal bowel flora would be the most frequent isolate from the wound swabs, due to wound locality and the presence of bowel flora in this area; however, mixed coliforms were present in the wounds of only 2 participants (8%) at recruitment of the SA dressing group and 4 participants (17%) at recruitment and 1 (3%) participant at week 4 of the CA dressing group. It is postulated that the low level of bowel flora isolated in wound swabs could be related to study participants having a shower prior to wound dressing changes, especially as the highest incidence of bowel flora was isolated from wound swabs collected at time of recruitment. However, further research would be required to confirm this due to low numbers limiting analysis.

Overall, 35% (n = 17) of study participants at recruitment, 41% (n = 15) at week 4 and 87% (n = 14) at week 8 had microorganisms isolated in wound swabs. The increased percentage of bacteria identified in the wound swabs over time could potentially correlate with the increased length of time that the wound was present; however this requires further investigation to confirm this assumption and to determine the clinical significance of these findings relating to effect on wound healing.

Participant Demographics

The demographics of study participants were similar to what has been found in other studies. In relation to gender, there was 69.4% male and 28.6% female which matches others' findings which indicated that PSD is 3-4 times more likely to occur in males than females (Harris & Holloway, 2012; Sondenaar et al., 1992; Surrell, 1994). The increased tendency for it to occur more frequently in males may be linked to the

amount and distribution of body hair on males as compared to females as increased incidence has also been reported in hirsute individuals (Dwight & Maloy, 1953; Holmes & Turner, 1969; Notaro, 2003).

The age range of study participants was 16 – 38 years again reflecting findings in other studies that identified that pilonidal sinus disease is rare before puberty and after the age of 40 years (Miller & Harding, 2003). This study identified the average age of presentation for males as 22.7 years and for females of 21.1 years, which is similar to the average age of affected individuals in other studies. For example, Notaro (2003), identified an average age of presentation for males as 21 years and 19 years for females.

Banerjee (1999), reported that pilonidal sinus disease was more prevalent in persons of European origin than in those of Asian and African origin. Although no rationale was provided for this Buie and Curtis (1952) suggested it was linked to different hair characteristics and growth patterns. This study was not able to support this finding as the demographic data collected by Silver Chain in relation to ethnicity is 'country of birth', which does not identify true ethnicity. Australia has a diverse cultural background with over a quarter of the population (26%) being born overseas (Australian Bureau of Statistics, 2011). Although, 73% of study participants were identified as being born in Australia, they could be second or third generation Australians with either parents or grandparents being born overseas and hence having alternate ethnic characteristics. The study did not show any significant difference between participants and their country of birth.

Costs of Care

The findings of this study suggest, that the use of nanocrystalline silver alginate dressings for PSWs healing by secondary intention is a cost effective option.

Although the daily cost of care was less for the CA dressing group, the faster rate of wound size reduction for the SA dressing group resulted in comparable costs for both groups.

Limitations

The study only included a small number of clients with sacrococcygeal pilonidal sinus wounds thereby limiting the statistical analysis.

The study was limited to follow up of clients for 8 weeks and many of the wounds remained unhealed at this time. Had follow up occurred until wound healing was achieved for all participants, healing times between the groups may have been different. Additionally, due to the limited timeframe of the study it was not possible to establish rate of recurrence of PSD between the dressing groups.

Although there are multiple topical antimicrobial wound dressings available that would be suitable to use on pilonidal sinus wounds, this study was not designed to assess the effectiveness of all these products. Establishing the effects of other broad spectrum topical antimicrobial agents for prophylactic use on sacrococcygeal pilonidal sinus wounds healing by secondary intention requires further investigation.

Recommendations

This study was conducted on community clients with wounds healing by secondary intention following surgical intervention for sacrococcygeal pilonidal sinus disease.

The recommendations therefore can only be specifically related to this cohort of individuals.

There are ten recommendations that result from the findings of this study and they are:

1. The principle recommendation that arose from the findings of this study is a need to repeat this study with a larger number of individuals incorporating Hospital-in-the-Home (HITH) programs.
2. Prophylactic use of silver alginate dressings should be considered a suitable wound management option for PSWs in the sacrococcygeal area, when the wound is healing by secondary intention and when there is an increased risk of infection.
3. Further study is required to establish the relationship of the bacterial burden and delayed healing in PSWs due to the small number of participants and the limitations with data analysis.
4. Further investigation is required to ascertain the role of biofilm formation in PSWs and the relationship with wound healing.

5. Additional studies using other broad spectrum topical antiseptic wound products such as iodine preparations, wound honey and polyhexamethylene biguanide (PHMB) would ascertain whether it was the antimicrobial effect or the anti-inflammatory effects of the nanocrystalline silver that contributed to a faster wound size reduction and shorter healing time.
6. Further studies are conducted to identify rate of recurrence of pilonidal sinus disease following the treatment of the PSW with nanocrystalline silver dressings.
7. Further studies are conducted on validity and reliability of wound measurements to establish the most accurate and reliable method of wound measurement.
8. Further study is undertaken to identify the correlation between clinical signs and symptoms of infection and pathology for the purposes for diagnosing wound infection.
9. Future studies to examine in more detail the cost of treatment for PSD including the cost to achieve wound closure.
10. It is also recommended that further studies incorporate other factors that may affect the healing rates of PSWs including number of operations the client has undergone for PSD, if the surgery was performed as an emergency or elective procedure and if the client is obese or developed infection during wound healing.

Although it is recommended that the study be repeated with a larger number of individuals, the recommendations that result from this study could, with all due care, be extrapolated to individuals with a sacrococcygeal pilonidal sinus wound healing by secondary intention until further study can be conducted.

Chapter 6

Conclusion

Sacrococcygeal PSWs are at increased risk of infection due to the anatomical location of the wound and the common presentation of abscess formation of this condition. It was hypothesised that the prophylactic use of a topical silver alginate dressing would result in faster healing of PSWs. Although a statistical significance could not be determined for time to wound healing between the groups, the SA dressing group demonstrated faster wound size reduction as compared to the CA dressing group.

Silver alginate dressings were demonstrated to be comparable to the calcium alginate dressings in total cost of care for healed wounds.

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Declaration:

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Appendix I

Curtin University School of Nursing and Midwifery

Study Information Sheet

Study Title: A Randomised Controlled Trial to determine the effectiveness of Nanocrystalline Silver compared to Calcium Alginate Dressings following surgical excision of a sacrococcygeal pilonidal sinus.

Lay title: A study to compare the effectiveness of a Silver dressing for the treatment of wounds following surgical removal of pilonidal sinus.

You are being asked to participate in a research study. Please take your time to read this information statement and the attached consent form, which if you agree to take part, you will be asked to sign. Please discuss any questions you may have about the project with the nurse, either on the telephone when she rings you to confirm when she will be visiting you or when she visits.

What is this study about?

Pilonidal sinus is a condition arising from an ingrown hair; usually this occurs at the base of the spine. This is known as the sacrococcygeal area. Infection often develops which results in the formation of an abscess. An operation may be required to remove the ingrown hair and drain the abscess. After the operation, the patient will have a wound that will require dressings until it is fully healed.

This study will compare the effectiveness of a topical nanocrystalline silver alginate dressing (Acticoat Absorbent™) when used to dress wounds resulting from surgical removal of pilonidal sinus against a calcium alginate dressing (Algisite™) which is the usual treatment for this condition.

Wounds almost always have some bacteria in them. Bacteria often won't have any negative effect on the wound, however, if there are too many bacteria in the wound, healing of the wound may slow down or infection may develop. If this happens, dressings called *antimicrobials* are used. Silver is an antimicrobial and dressings impregnated with silver are commonly used to treat wounds that are deemed to have high levels of bacteria. The location of wounds following surgery for pilonidal sinus disease puts them at a higher risk of being contaminated by bacteria due to the bacteria that is normally present in the bowel. The study aims to find out if the use of a silver dressing following surgery will prevent bacteria growing in the wound and speed up healing time compared to the traditional treatment of calcium alginate dressings, because we don't know if one is better than the other.

A randomised controlled trial, in which people are randomly assigned to receive one treatment rather than the other, is considered to be the best way of comparing two different treatments.

Who is conducting the study?

The project is being conducted by Margaret Edmondson who is employed by Silver Chain as a Clinical Nurse Specialist. She is conducting the research as part of an academic degree, with support from Dr Keryln Carville, Associate Professor in Domiciliary Nursing and Dr Gill Lewin, Silver Chain Research Manager.

Who is invited to participate?

You are being asked to participate in this study because you have a wound resulting from surgical excision of pilonidal sinus.

What will happen if you agree to take part in the project?

If you agree to participate in this study you will be asked some questions about yourself which will help us understand your wound and what sorts of things may affect its healing. You will be randomly allocated to one of the two treatment groups. The nurse treating your wound will see you to treat your wound just as she would in normal circumstances. Every week the nurse will assess the wound and photograph it, so that we can see how it is progressing. To ensure your privacy, the nurse will ensure that this photo will not include any identifying marks.

Your participation in the study will be for 8 weeks or until your wound heals, whichever happens sooner. If you are allocated to the silver treatment group you will receive the silver impregnated dressing for the duration of the study. If you are allocated to the calcium alginate treatment group you will receive this dressing for the duration of the study unless your wound shows signs of infection. If this occurs you will then receive the silver dressing until the signs of infection are no longer present when you will revert to the calcium alginate dressing..

At the end of the study period we will ask you to complete a brief questionnaire. This questionnaire will ask what you thought of the treatment you received. We will provide you with a stamped, addressed envelope to return the questionnaire to us.

We will, with your permission, inform your doctor, and any other health professionals involved in providing your wound care, that you are participating in this study. We will also ask that they follow the study care plan if they need to dress your wound at any time during the study period.

Risks and benefits

There are no risks to you in taking part in this study as you will continue to have your wound managed just as you would normally. The only difference in treatment is how the choice of dressing is made. In the unlikely event that the dressing being used is found not to suit you, it will be changed, as is normal practice.

The project may benefit other people in the future having wounds resulting from surgical excision of pilonidal sinus disease by helping us identify which, if either, dressing works best.

Voluntary participation

It is important for you to know that you do not have to take part in this project and if you decide not to be involved, the wound care and other services provided to you by Silver Chain now, or in the future, will in no way be affected. If after agreeing, you either wish to stop the treatment you have been receiving or change your mind about being in the study, you may withdraw your consent at any time, simply by telling the nurse providing your care or by ringing Dawn Woods, Research Support Officer on 9201 6758. We would then stop collecting the study information and if you wish to no longer be part of the study, destroy all project records containing your information.

How will your privacy be protected?

If you do decide to take part in the study, all information relating to you that is used as part of the study, and is not required by those providing your care will be kept strictly confidential. To protect your privacy, your name will not be kept on any study data but will instead only be identified with an identification number. The results of this study will be presented to Curtin University of Technology for academic assessment, reported at conferences and in journal articles but this will not involve the reporting of any personal information. In accordance with national research guidelines, all study

records will be stored for seven years by the Research Department in a secure location and will then be destroyed.

What if you have any concerns or a complaint about how the study is conducted?

Approval for this study and its procedures has been given by both Silver Chain and Curtin University, Human Research Ethics Committees. Any concerns or complaints about the conduct of the study should be directed to Dawn Woods, Research Support Officer on 9201 6758 or to the Chairperson of the Silver Chain Human Research Ethics Committee, Silver Chain House, 6 Sundercombe Street, Osborne Park 6017.

Who to contact if you have any questions about the study?

If you have any questions about this study please discuss them with the nurse during your appointment. Should you still wish to ask any further questions please feel free to call **Margaret Edmondson, Clinical Nurse Specialist on 9242 0242** or **Keryln Carville, Associate Professor of Domiciliary Nursing at Curtin University of Technology on 9242 0242.**

Thank you for taking the time to read this statement.

Margaret Edmondson
Clinical Nurse Specialist

Appendix II
Curtin University School of Nursing and Midwifery
Study Consent Form

Study Title: A Randomised Controlled Trial to determine the effectiveness of Nanocrystalline Silver Alginate Dressings compared with Calcium Alginate Dressings following surgical excision of a sacrococcygeal pilonidal sinus.

Lay Title: A study to compare the effectiveness of a Silver dressing for the treatment of wounds following surgical removal of pilonidal sinus.

Client Name: _____

Study Number: _____

Address: _____

- I have read the Information Statement about this study and any questions I have asked have been answered to my satisfaction.
- I agree to participate in this study, realising that I may withdraw at any time.
- I agree that my general practitioner (GP) and other relevant health care professionals will be advised of my participation in this study and that if possible they should follow the study protocol when dressing my wound.
- I agree to photographs of my wound being taken as part of this study and understand that they will not include any visually identifying information e.g. my face, a birthmark, tattoo etc.
- I agree that information Silver Chain has collected during the process of providing my care may be linked with the data collected for this study, provided that I am not identifiable.
- I agree that the research data (including wound photographs) collected for this study may be presented and published, provided that I am not identifiable.

Signed: _____

*Participant/Authorised Representative/Parent or Guardian
(for clients under 18 yrs)*

Name: _____

(PLEASE PRINT)

Date: _____

Relationship if authorised representative: _____

Appendix III

Curtin University School of Nursing and Midwifery

Initial Data Collection Form

1	STUDY NUMBER: _____ ENVELOPE NUMBER: _____ (client PID plus service centre initials e.g. SO for South)
2	Date of recruitment ___ / ___ / ___ (dd/mm/yy)
3	Date of surgery ___ / ___ / ___ (dd/mm/yy)
4	Occupation (please specify) _____
5	Type of surgical procedure performed (if known) _____
6	Were antibiotics taken immediately prior to surgery? <input type="checkbox"/> ₁ Yes <input type="checkbox"/> ₂ No
7	When did you have surgery following diagnosis of pilonidal sinus disease? <input type="checkbox"/> ₁ Within 48 hours <input type="checkbox"/> ₂ Within 2 weeks <input type="checkbox"/> ₃ Within 4 weeks <input type="checkbox"/> ₄ Over 4 weeks
8	Is the wound shape: <input type="checkbox"/> ₁ V (narrow base) <input type="checkbox"/> ₂ U (wide base)
9	What dressing treatment is the client randomised to receive? <input type="checkbox"/> ₁ Acticoat Absorbent™ <input type="checkbox"/> ₂ Algisite™
10	Wound dimensions Length _____ mm Central Depth (perpendicular to skin) _____ mm

Antibiotics for other reasons	2 <input type="checkbox"/>
Drug _____	Dose _____ Route _____
Start date __ / __ / __ (ddmmyy) _	Stop date __ / __ / __ (ddmmyy)
NSAIDs	3 <input type="checkbox"/>
Anticoagulants	4 <input type="checkbox"/>
System steroids	5 <input type="checkbox"/>
Topical or inhalation steroids	6 <input type="checkbox"/>
Cytotoxics	7 <input type="checkbox"/>
Betablockers	8 <input type="checkbox"/>
Immunosuppressants	9 <input type="checkbox"/>

CHARLSON COMORBIDITY INDEX

16 Does the client have any of the following (tick all that apply)?

- | | |
|--|---|
| 1 <input type="checkbox"/> HIV AIDS | 9 <input type="checkbox"/> Leukaemia |
| 2 <input type="checkbox"/> Cerebrovascular disease | 10 <input type="checkbox"/> Lymphoedema |
| 3 <input type="checkbox"/> Chronic pulmonary disease | 11 <input type="checkbox"/> Malignant lymphoma |
| 4 <input type="checkbox"/> Congestive heart failure | 12 <input type="checkbox"/> Myocardial infarction |
| 5 <input type="checkbox"/> Connective tissue disease | 13 <input type="checkbox"/> Peripheral vascular disease |
| 6 <input type="checkbox"/> Dementia | 14 <input type="checkbox"/> Rheumatoid arthritis |
| 7 <input type="checkbox"/> Gastric ulcer disease | 15 <input type="checkbox"/> None of the above |
| 8 <input type="checkbox"/> Hemiplegia | |

17 Is the client a current smoker? 1 Yes 2 No

Does the client have any of the following?

- 18 Liver disease? 1 None 2 Mild 3 Moderate 4 Severe
- 19 Renal disease? 1 None 2 Mild 3 Moderate 4 Severe

20 Malignant None Non Metastatic Metastatic
 Solid tumour

NUTRITIONAL RISK SCREEN TOOL

21 Does the client have any

- Obvious underweight frailty
- Unintentional weight loss
- Reduced appetite/food or fluid intake
- Mouth or teeth problems
- Swallowing problems
- Follows a special diet
- Needs assistance to shop for food
- Needs assistance to prepare food
- Needs assistance to feed self
- Obvious overweight affecting life quality
- Unintentional weight gain

22 Please indicate the amount of time you spent at this visit attending to the care of the study ulcer (including setting up, providing and documenting care to study ulcer, excluding data collection, other treatment unrelated to the study ulcer).

- 0-15 minutes 16-30 minutes 31-45 minutes
- 46-60 minutes 61-90 minutes >91 minutes

23 Was a photograph taken at this visit? Yes No

24 Additional Comments _____

Name of Nurse completing form:
 (Please print)

Appendix IV

Curtin University School of Nursing and Midwifery

Weekly Data Collection Form

1 Client Study No: _____ (client PID plus service centre initials e.g. SO for South)

2 Date ___ / ___ / ___ (dd/mm/yy)

3 Study Week: Week 1 Week 2 Week 3 Week 4
 Week 5 Week 6 Week 7 Week 8

4 Wound Dimensions

Length _____ mm Central Depth (perpendicular to skin)
_____ mm

5 How many visits to change the dressing for this wound have occurred in the last week (including this visit)? _____

6 Has the study wound healed? No
 Yes Date of healing ___ / ___ / ___
(dd/mm/yy)

(if Yes go to question 10)

7 Exudate Amount: Nil Low Moderate Heavy

8 Exudate Type: Serous Haemoserous Sanguinous
 Purulent Other _____

9 Are any of the following evident in the wound or surrounding skin (tick all that apply)?

- | | |
|---|---|
| <input type="checkbox"/> Increasing pain in the wound | <input type="checkbox"/> Bright red granulation tissue |
| <input type="checkbox"/> Erythema | <input type="checkbox"/> Discolouration of granulation tissue |
| <input type="checkbox"/> Oedema | <input type="checkbox"/> Friable granulation tissue |

Betablockers 8

Immunosuppressants 9

CLIENT DISCHARGE

12 Has the client been discharged since the last weekly assessment?

₁ Yes

₂ No (go to question 15)

Please write the date of discharge ___ ___ / ___ ___ / ___ ___ (dd/mm/yy)

13 Please indicate the reason for discharge

Wound healed 1

Client moved to permanent care 2

Receiving terminal care 3

Client died 4

Client terminated care 5

Other (please specify) 6

14 Was the discharge related to the study wound?

₁ Yes

₂ No

Comments

CLIENT ON HOLD

15 Has the client's care been on hold since the last weekly assessment?

₁ Yes

₂ No (go to question 18)

If yes, what was the reason?

Respite admission ₁ In date: ___ / ___ / ___ (dd/mm/yy)

Out date: ___ / ___ / ___ (dd/mm/yy)

Hospital admission ₂ In date: ___ / ___ / ___ (dd/mm/yy)

Out date: ___ / ___ / ___ (dd/mm/yy)

Holiday ₃ In date: ___ / ___ / ___ (dd/mm/yy)

Out date: ___ / ___ / ___ (dd/mm/yy)

16 Was the respite or hospital admission related to the study wound?

₁ Yes

₂ No

If yes, please give details

17 Was the study treatment continued during the on hold period?

₁ Yes

₂ No (If no, for how long was the study treatment NOT applied

for? _____ days.

USE OF STUDY DRESSING

18 Has there been any change in the use of the allocated study dressing since the last weekly assessment (i.e. stopping, restarting or changing)?

₁ Yes

₂ No (go to Question 20)

Please write the date(s) that treatment changed

1: ___ / ___ / ___ (dd/mm/yy)

2: ___ / ___ / ___ (dd/mm/yy)

19 Please confirm that the treatment was changed because

	#1	#2
Adverse event to study dressing	<input type="checkbox"/> ₁	<input type="checkbox"/> ₁
Signs of infection in Algisite allocated client	<input type="checkbox"/> ₂	<input type="checkbox"/> ₂

Critical infection in Algisite client now resolved	3 <input type="checkbox"/>	3 <input type="checkbox"/>
Client requested change in dressing	4 <input type="checkbox"/>	4 <input type="checkbox"/>
Other health professional requested change in dressing	5 <input type="checkbox"/>	5 <input type="checkbox"/>
Other (please specify)	6 <input type="checkbox"/>	6 <input type="checkbox"/>

ADHERENCE TO CARE PLAN

20 Has the treatment care plan been adhered to since the last weekly assessment?

Yes 1

No – client did not adhere 2

No – Silver Chain staff did not adhere 3

No – other care provider did not adhere 4

No – other care provider did not adhere 5

No – other (please specify) 6

21 Please indicate the amount of time you spent at this visit attending to the care of the study wound (including setting up, providing and documenting care to study wound, excluding data collection and other treatment unrelated to the study wound).

1 <input type="checkbox"/> 0-15 minutes	2 <input type="checkbox"/> 16-30 minutes	3 <input type="checkbox"/> 31-45 minutes
4 <input type="checkbox"/> 46-60 minutes	5 <input type="checkbox"/> 61-90 minutes	6 <input type="checkbox"/> >91 minutes

22 Was a photograph taken at this visit? 1 Yes 2 No

23 Additional Comments _____

Name of Nurse completing form:
(Please print)

Appendix V

Curtin University School of Nursing and Midwifery

WOUND SWAB SPECIMEN COLLECTION FOR PILONIDAL SINUS STUDY

Rationale

- To collect a wound swab/specimen that minimises contamination by micro-organisms.
- To use the most appropriate method for wound swab/specimen collection.
- To understand the problems that normal flora can cause with wound swab/specimen collection.

CliniPath Laboratory Requirements

For the purpose of the Pilonidal Sinus Study

- 1 Clinipath Pathology request forms, sterile wound swabs and biohazard collection plastic bags will be made available by Clinipath Pathology in all Silver Chain metropolitan service centres. **If you require extra supplies of the above, please call Chris on 9476 5277.**
- 2 All laboratory costs will be paid by the Silver Chain. This is not a Medicare rebateable item, nor are any costs incurred by the client.
- 3 The RN/EN who takes the wound swab can sign the pathology request form (a doctor's signature is not required).
- 4 The pathology request form must be filled out in a legible manner ensuring that all necessary information is supplied. Ensure that the pathology laboratory is provided with the following information:
 - Study number (PID / Base)
 - Identify on the form if the swab is the recruitment, week 4 or week 8 swab or tick other if it is before or after antibiotic therapy
 - Record on the client form:
 - full name
 - address
 - telephone number
 - sex
 - date of birth
 - wound site
 - date and time of specimen collection
 - record the name and address of the General Practitioner (GP) or surgeon so that a copy of the results can be sent by Clinipath Pathology to the treating doctor.

- 5 Add CNS's name and email address so that an electronic copy of the results can be forwarded to the base.
- 6 A completed pathology request form must accompany the collected specimen.

Equipment

- Disposable gloves if required
- Sterile specimen swab stick in container
- Sealable plastic biohazard bag with separate compartment for specimen collection request form
- Clinipath Pathology request form
- Sterile dressing pack
- Sterile water sachet/s

Procedure

Note: The wound swab is collected after washing wound as per care plan.

- 1 Attend hand hygiene.
- 2 Collect equipment
- 3 Open dressing pack and pour a small amount of sterile water into one gallipot to be used to moisten the dry sterile specimen swab stick if required; pour remainder (or open additional sterile water) into the second gallipot for wound cleansing.
- 4 Attend hand hygiene and don unsterile gloves if required
- 5 Remove old dressing and discard appropriately.
- 6 Use an aseptic technique to clean and dry wound. Endeavour to remove remnants of dressing debris, visible exudate and loose devitalized tissue. Do not contaminate the sterile water that may be used to moisten the sterile specimen swab stick.
- 7 Carefully remove sterile wound swab from the container without touching the stick or wound contact surface.
- 8 If the wound is dry moisten the dry swab stick in sterile water (not the water used to clean the wound) prior to swabbing the wound. Swab the wound in a zigzag and rolling motion across the wound (Figure 1), but avoid contact with the wound edges.
- 9 Reinsert the swab into the container, avoiding contamination by contact with external surfaces of the specimen container.
- 10 Attend to dressing regime in accordance with the study protocol outlined on the care plan.
- 11 Correctly label the specimen with:

- Silver Chain study number (PID / Base) including which number swab it is in the series.
 - client full name
 - date of birth
 - date and time of specimen collection
 - wound site
- 12 Insert the specimen and completed paper work into the biohazard bag and place in the refrigerator. **Telephone Clinipath on 9476 5235 (Carly or Julie) and ask for a “Silver Chain pickup at (give either clinic or client’s address)”**.
- 13 Document in the client’s notes and study assessment form that the wound specimen has been collected and what number swab it is as per study protocol.

Pathology Results

- 1 The CNS should receive a PDF form detailing the results within 48 hours of collection. **If not, please follow up with Margaret Edmondson on 92429242Clinipath on 9476 5252.**
- 2 The pathology results are to be filed in the client’s notes.
- 3 A copy of the pathology results will be sent by Clinipath to the treating doctor for his/her attention and action if required. **Should the treating doctor choose to put the Client on antibiotics, the Client will remain on the study but please ensure details of antibiotics including starting and completion dates are entered onto data collection form.**
- 4 A copy of the pathology results will also be sent to the Silver Chain Research Department.

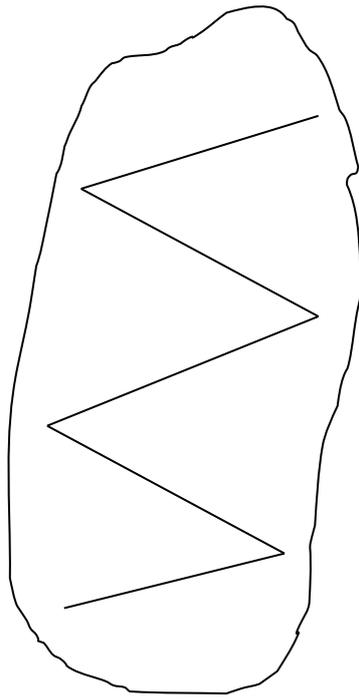
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Ratliff, C., & Rodeheaver, G. (2002). Correlation of semi-quantitative swab cultures to quantitative swab cultures form chronic wounds. *Wounds*, 14(9), 329-333.

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Figure 1: Zigzag Swab Method



Appendix VI

Curtin University School of Nursing and Midwifery

Wound Photograph Protocol for Pilonidal Sinus Study

Wound photographs are an essential part of the data collection process for the Pilonidal Sinus Study to verify anatomical location and clinical characteristics of the wound.

When to Take Photographs

- Initial first assessment and at weekly intervals (as part of data collection).
- At the end of the 8 week study period or when wound heals (whichever is first).
- If overt or covert infection necessitates the changing of client's dressing from calcium alginate to nanocrystalline silver alginate dressings photographs shall be taken before and after.

Specific Requirements

- Informed consent must be obtained from the client and recorded on "consent to services form" in Home Notes, with date and client's/carer's signature.
- Photographs should not identify participants, i.e. should not show faces, tattoos, etc.
- Do not include client's name within photo to ensure confidentiality.

How to Take Photographs

- Complete calibration label/sticker as follows:
- Study number (PID/Base)
- Date photo taken
- Position calibration label on the skin, next to the wound, with the arrow on the label pointing to the person's head and within the frame of the photo.
- Take one photograph showing wound and anatomical location
- Ensure plain background without any patterned sheets, carpets etc.
- Position cameras ½ metre from and perpendicular (90 degrees) to the wound.

- Keep camera steady when photographing to ensure clear pictures and ensure wound image and writing is in focus prior to taking photo.

If possible don't use the flash but check the quality of the photo and take another if additional lighting required before sending.

Subsequent photographs should be taken from the same angle and distance.

Refer to camera's user guide for further information.

Useful Tips

- Batteries for the camera should be inserted prior to use and removed afterwards as the camera continues to drain the batteries even when switched off. Rechargeable batteries will be available at all bases.
- Different models of digital cameras will operate differently; it is therefore essential to follow manufacturer's instructions when using cameras and to get some practice with the camera prior to taking client photos.

Where to Send the Memory Card

Please write 'PSS' and your service centre on the memory card used for the trial and try to only use these memory cards for PSS photos.

At the end of each week send memory card, in the plastic box provided, to:

Gale Cargill
Silver Chain
6 Sundercombe Street
Osborne Park WA 6017

Images will be downloaded and deleted from the memory card which will be returned to the CNS at the Service Centre.

Each camera has at least two memory cards and will hold up to 200 pictures.

Please contact Margaret Edmondson Study Coordinator on 92420242 should you have any queries.