CLINICAL MANAGEMENT extra

Evaluating a Surfactant-Containing Polymeric Membrane Foam Wound Dressing with Glycerin in Patients with Chronic Pilonidal Sinus Disease

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GENERAL PURPOSE:

To present an evaluation of a surfactant-containing polymeric membrane foam wound dressing for use on patients with chronic pilonidal sinus disease.

TARGET AUDIENCE:

This continuing education activity is intended for physicians, physician assistants, nurse practitioners, and nurses with an interest in skin and wound care.

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LEARNING OBJECTIVES/OUTCOMES:

After completing this continuing education activity, you should be able to:

1. **Recall risk factors for and pathophysiology of pilonidal sinus wounds.**
2. **Summarize the evidence-based elements of wound assessment and treatment.**
3. **Identify the study methodology and results.**

ABSTRACT

OBJECTIVE: To evaluate the clinical use of a surfactant-containing polymeric wound dressing with glycerin in patients with chronic pilonidal sinus wounds.

METHODS: This case series was conducted in an outpatient dermatology and wound clinic. Sixteen patients aged between 18 and 49 years with chronic nonhealing pilonidal sinus wounds over 4 weeks in duration were recruited.

INTERVENTIONS: Dressing changes were performed daily because of frequent contamination from bowel evacuation, sweating, or frictional forces in the perianal and intergluteal skin. Patients were seen at follow-up visits to the clinic at weeks 4, 8, and 12 from study initiation.

RESULTS: Subjects were predominantly males (81% [n = 13]) with a mean age of 23 years. At study initiation, the mean wound duration was 3.2 months, and mean surface area was 3.3 cm^2 (0.18-19.6 cm^2). The majority of wounds showed signs of superficial infection (63% [n = 10]) and deep infection (88% [n = 14]). At week 12, 10 wounds (63%) had closed, 1 (6%) had decreased in surface area, 2 (13%) had increased in size, and 3 (19%) of the patients were lost to follow-up. Mean pain score was 3.4 at first visit; most patients reported reduction in pain scores by weeks 4 and 12. Participants reported improved mobility and ability to self-apply dressing. No adverse reactions were observed.

CONCLUSIONS: Use of a surfactant-containing polymeric membrane foam wound dressing with glycerin may have facilitated wound closure in 10 of 13 patients who completed the 12-week study.

KEYWORDS: chronic wound, chronic nonhealing pilonidal sinus, dressing changes, pilonidal sinus, surfactant-containing polymer dressing, wound dressing

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INTRODUCTION

Pilonidal sinus is a relatively common anorectal wound that often presents as a deep midline natal cleft ulcer above the anal opening.[1] Pilonidal sinus wounds are twice as common in men as in women and usually affect patients between the ages of 15 and 30 years.[2,3] These wounds occur predominately in hirsute male individuals with a deep natal cleft. Typically, a foreign body reaction is initiated by the hair follicles that grow into the natal cleft. Midline pits may form spontaneously from shed hairs or from a previous surgical excision, causing hair tips to become trapped.[4] Hair follicles then turn inward on the sides of the natal cleft, and the sharp tips of the hair follicles penetrate the dermal tissue (Figure 1). An inflammatory process (folliculitis) spreads down the hair follicle and to adjacent hair follicles, leading to a subcutaneous abscess.[5,6] This can lead to a chronic wound that fails to progress through the normal phases of wound healing.[7,8] Clumps of hairs often form a keratin plug that can be shed, leaving even larger pitted scars on the skin surface.[6]

Risk Factors

Family history, excessive body hair, smoking, poor hygiene, long periods of sitting, local trauma or irritation, and an anatomically deep natal cleft have all been hypothesized to be pilonidal sinus risk factors.[9] Early surgical interventions are associated with improved outcomes, although a variable percentage of cases progress to chronicity depending on the patient characteristics of the study population.[3,10]

Treatment

The literature supports a holistic approach that[4,9]

- promotes self-management and pain management,
- improves daily activities of living by avoiding movements that create excessive frictional forces (eg, riding a bicycle, long-distance running), and
- addresses treatment locally and systemically including superficial critical bacterial colonization and deep/surrounding infection.

Wound bed preparation paradigm provides a systematic approach to chronic wound management.[11,12] This model provides a framework for treating the wound cause and addressing patient-centered concerns prior to addressing local wound care (treat the whole patient rather than the hole in the patient). The third component, local wound care, includes wound debridement, infection and inflammation management, and moisture balance.

If a potentially healable wound is stalled despite all the wound bed preparation steps, surgical management (often with a second surgical correction of the pilonidal sinus) may be required, and off-midline closure techniques may have the best long-term results.[9] In the wound bed preparation paradigm, this is referred to as the edge effect, because stalled wounds often have a cliff-like edge where new epithelium cannot advance along the sunken dermal base. A healing wound is more like a sandy beach, with a purple

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Figure 1.

CRITICALLY COLONIZED PILONIDAL SINUS WOUND DEMONSTRATING PROINFLAMMATORY TRAPPED HAIR FOLLICLES FROM SURROUNDING SKIN

These hairs need to be clipped with a fine scissors and removed; the patient should consider laser hair removal.

edge of new epithelium growing over a level, pink, firm granulation tissue base.

Wound healing is compromised when the bacterial burden reaches a tipping point known as critical colonization, where local host resistance is compromised and superficial bacterial damage leads to stalled healing. Surface critical colonization must be differentiated from deep surrounding infection to achieve appropriate wound healing.[11] Two mnemonics were developed by Woo and Sibbald[13] to clinically differentiate between superficial critical colonization (NERDS: treat topically) and deep surrounding infection (STONEES: treat systemically). Any 3 NERDS or STONEES signs indicate bacterial damage: NERDS (Nonhealing, Exudate, Red friable granulation tissue, Debris, Smell) and STONEES (Size increase, Temperature, Os, New areas, Exudate, Erythema/Edema, Smell) (Figure 2).[13]

Optimizing the wound bed is necessary to ensure moisture balance and to reduce the bioburden. Bacteria are often in the form of microcolonies surrounded by a glycolipid and glycoprotein covering called a glycocalyx. The glycocalyx protects the bacteria from the environment and often prevents antibacterial agents from entering the biofilm to kill the bacteria. The relatively safe microenvironment allows some bacteria to rest while other organisms are actively metabolizing. Biofilms are common on surfaces with different viscosities such as the perianal area where fecal debris can facilitate biofilm growth. Surfactants have an effect on biofilms by disrupting the glycocalyx.

Wound debridement is a crucial process for removing necrotic and senescent tissue often associated with slough and biofilms.[14–16] Bacterial and moisture reduction along with debridement can promote wound healing by converting a chronic wound to an acute one.[17] The physiologic basis for conversion to an acute wound is multifactorial. Debridement and the use of surfactants will help remove biofilms and bacterial damage. Bacteria release vascular endothelial growth factor that causes the bright red friable tissue on the wound surface often evident with punctate bleeding points on dressings after they are removed. The bacteria also release proinflammatory enzymes that will lead to cell death (surface debris); this stimulates wound exudate as the body's response to injury and leads to nonhealing. The presence of odor signifies the secondary invasion of gram-negative and anaerobic organisms. There is no coincidence that these factors represent the NERDS criteria for bacterial critical colonization of a wound. When these factors are addressed, it is much easier for the wound to progress from the inflammatory to the proliferative stage of wound healing.

The role of surfactants as a method of autolytic/chemical debridement for the reduction of biofilms has been studied.[18–19] Surfactants are increasingly used as wound cleansers and usually have antimicrobials incorporated in their matrix, leading to improved wound closure rates.[18,20] Surfactants are compounds that lower the surface interphase tension. They are composed of hydrophobic tails that form a central core and hydrophilic surface

Figure 2.

PILONIDAL SINUS WOUND WITH SIGNS OF CRITICAL COLONIZATION

The wound demonstrates red friable granulation tissue and cellular debris.

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molecules.[18–20] The surface molecules can have a detergent (cleansing) action to make skin debris more soluble including bacteria often arranged in biofilms. In addition to their detergent action, surfactants may act as wetting agents, emulsifiers, foaming agents, and dispersants.

Study Dressing: Polymeric Membrane Foam Wound Dressing

The study used a polymeric membrane foam wound dressing. The dressing has the following characteristics (Figure 3):

- A polymeric membrane foam pad. This pad conforms to the wound contour, which may facilitate moisture balance on the surface of the wound by absorbing excess moisture;
- Surfactant wound cleanser that can disrupt surface bacteria, including biofilms;
- Glycerin that binds water, providing wound surface hydration. This can help prevent dressing adherence to the wound surface, while lowering the pH, which in turn may decrease wound surface bacterial proliferation (bacteria proliferate most readily in an alkaline environment); and
- Semipermeable thin backing film that provides a moisture level conducive to healing.

Both a rodent acute stab wound animal study and a human case study suggest that this polymeric membrane foam wound dressing can reduce local and surrounding wound inflammation and decrease swelling.[21–23] The polymeric membrane foam wound dressing with a surfactant and glycerin is hypothesized to have inhibitory actions for nociceptive pain receptors, thus alleviating pain.[23] Additional analgesic effects may come from glycerin's ability to lower the surface pH and reduce proinflammatory properties of bacteria, including the release of metalloproteases, resulting in a combination of wound cleansing and reduction of local inflammation.[21,22]

Purpose and Objectives

The purpose of this study was to evaluate the effectiveness of polymeric membrane foam wound dressing in the management of complex and critically colonized pilonidal sinus wounds. The primary objective was to evaluate wound closure rates. Secondary outcome measures included improvement of wound-related pain, documentation of any adverse reactions from study dressings, improvements in activities of daily living, and determining the presence of bacterial damage in chronic wounds using the NERDS and STONEES criteria.[13]

METHODS

This study received ethics approval (#PMSWD001) from the Institutional Review Board Services (Aurora, Ontario, Canada). Patient visits were conducted at the Toronto Regional Wound Healing Clinic, an outpatient dermatology and wound clinic. The study adhered to the principles of the Tri-Council Policy Statement for Ethical Conduct for Research Involving Humans, the Ontario Personal Health Information Protection Act, and the Declaration of Helsinki. Informed consent forms outlining the study purpose, characteristics, and need for photo documentation were signed by the participants.

Study Methods

This study was a case series at a facility that commonly treats patients with nonhealing chronic pilonidal sinus wounds. Patients diagnosed with chronic, nonhealing, pilonidal sinus wounds were approached by the principal investigator or designate for recruitment into the study. Eligible patients were between the ages of 18 and 85 years with a pilonidal sinus wound of 4 weeks' duration or longer. Patients who could not apply their study dressing on a daily basis independent of nursing evaluation visits were excluded.

Figure 3.

A, WOUND DRESSING APPLICATION. B, WOUND DRESSING MAINTAINING MOISTURE BALANCE ON THE WOUND BED

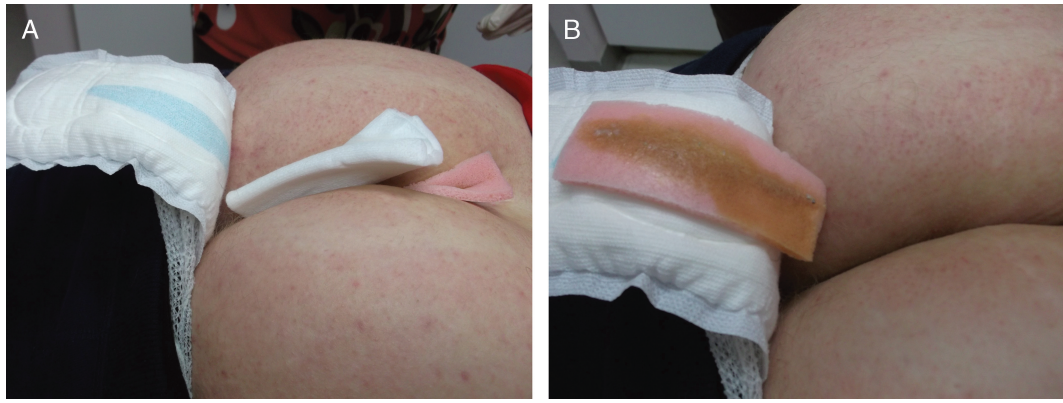

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Table 1.
STUDY DEMOGRAPHICS

Demographic Parameter	Pilonidal Sinus Wounds (n = 16)
Mean age, y	23 years (range 16–49)
Mean body mass index, kg/m^2	27.2 (range 19.7–35.3)
Gender	Males 81% (n = 13)
	Females 19% (n = 3)
Smoking status	Nonsmoker 100% (n = 16)
Comorbidities	Yes 19% (n = 3)
	Kawasaki disease, hypertension, mental illness

Some of the patients were clients of the Mississauga Halton Local Health Integrated Network home care system. The wounds were classified as potentially healable but not healing at the expected rates. These participants may have been referred to the complex patient study because of incomplete diagnoses, excess use of system resources, or requests for expensive therapies (such as negative-pressure wound therapy).

After signing the study consent, the polymeric membrane foam wound dressing was applied directly on the wound base. The patients were enrolled for a period of up to 12 weeks or until complete wound healing was achieved. Care was taken not to excessively flush the wound bed because the dressing contains a cleanser and leaves minimal residue. The dressing was usually changed by the patient on a daily basis, with nursing visits to community home care usually every 1 to 2 weeks. Follow-up visits to the clinic were at weeks 4, 8, and 12 from the study initiation.

Documentation and Data Collection

Demographic data and medical history were recorded for each patient. Specific wound-related parameters were documented at each clinic visit, including wound duration, location, and size along with changes of the surrounding skin. Self-reported pain levels were recorded using the validated numerical rating pain scale (0- to 10-point scale). Photographs of the wounds were also taken at each visit. Wound management and other issues were addressed based on best practice recommendations for pilonidal sinus wounds by Harris et al.[9]

Statistical Methodology

Data from the patient charts were transferred into SPSS version 21 (IBM, Armonk, New York) by a member of the study team. *t* tests were used to compare means before and after treatment for wound surface area reduction over 12 weeks or until wound closure was achieved. Other parameters recorded were analyzed using parametric and nonparametric statistics to determine changes to pain, activities of daily living, adverse effects, and NERDS and STONEES bacterial burden criteria.

RESULTS

Demographics and Wound Characteristics

A total of 16 patients were recruited. The study population comprised predominantly younger males as outlined in Table 1. The average wound duration at first visit was 3.2 months, and mean surface area was 3.3 cm^2 (0.18–19.6 cm^2). All but 1 patient had prior wound-related surgical interventions (94% [n = 15]).

Wound Closure

At week 4, 40% of the group (n = 6) achieved wound closure, and 47% (n = 7) had a larger than 30% reduction in surface area, whereas 13% of wounds (n = 2) increased in size. At week 12, a total of 10 wounds (62.5%) closed (Figure 4). Of the remaining patients, 6% (n = 1) decreased in surface area, whereas 12.5% (n = 2) increased in size, and 19% (n = 3) were lost to follow-up. The patients lost to follow-up were contacted but could not attend follow-up visits because of work, educational programs, and/or travel commitments.

Pain

The mean pain score was 3.4 at first visit. At week 4, 38% (n = 6) had no pain, whereas 56% (n = 9) reported improvement in pain scores, and 6% (n = 1) reported that their pain score did not change from the previous visit. For the 7 patients who were seen at week 12 (final visit), 71 % (n = 5) had no pain, and 29% (n = 2) reported a decrease in pain. No patients reported increased pain at week 12. Healed patients were discharged to their primary care provider.

Activities of Daily Living

Participants reported a positive effect on their activities of daily living, citing ease of dressing application, improved mobility,

Figure 4.
HEALED PILONIDAL SINUS WOUND

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and the ability to apply dressings themselves. There were no dressing-related adverse effects recorded in this study. However, patient feedback included comments on the dressing occasionally slipping away from the pilonidal sinus wound bed during ambulation or physical activity.

Signs of Bacterial Infection: NERDS and STONEES

When the NERDS and STONEES criteria[13] were applied, superficial and deep/surrounding infections were present in the majority of the wounds. There were 3 or more NERDS criteria met in 63%

Table 2.
TEN STEPS TO OPTIMIZE CARE FOR PILONIDAL SINUS WOUNDS[9]

Clinical Pathway	Recommendations
History of pilonidal sinus disease	History of previous boils or furuncles in or around natal cleft
	Onset and duration of symptoms
	Surgical interventions
Examination of the pilonidal sinus wound in the modified jackknife position	Visualize completely the natal cleft and pilonidal sinus wound
	Look for sinuses, cysts, pits, tracts
	Hypergranulation tissue is sign of chronic inflammation or infection
	Classify according to severity of the pilonidal sinus disease[30]
Assess periwound natal cleft and hair distribution	Look for coexisting hidradenitis suppurativa
	Differential diagnosis: anal fistula, perianal Crohn disease, furuncles, perianal ulcers
	Hair in the natal cleft may be the focus of infection, will have to be removed
Evaluate for potential untreated deep or surrounding infection	Use NERDS and STONEES[13] to differentiate superficial from deep infection
	NERDS—treat topically, STONEES—treat systemically
	Broad-spectrum and anti-inflammatory antibiotics
Manage pain	Pain can affect activities of daily living
	Systemic approach using the WHO pain ladder[29]
	Treat both nociceptive (eg, aspiring) and neuropathic pain (eg, gabapentin)
Evaluate activities of day living and appropriate functional recommendations to facilitate healing	Sitting for long periods can cause friction trauma to buttock and natal cleft Certain sports (swimming, running, soccer, hockey, baseball) can aggravate pilonidal sinus disease
	Walking and modified exercises/sports are alternatives
	Plan of care should address patients' needs and preferences
Document the wound characteristics	Wound measurements
	Number of openings, tracts, sinuses, abscesses or nodules, undermining or pocketing
Wound bed preparation approach	Debridement—sharp (curetting), autolytic (alginates, surfactants), mechanical (handheld shower) for cleansing
	Localized infection—NERDS and STONEES[13]
	Moisture balance—pilonidal sinus wounds are highly exudative and require appropriate absorbent dressings and more frequent dressing changes
Education and patient management of periwound environment	Local hygiene—use wound healing washes, handheld showerhead
	Clean after bowel movements in a downward direction
	Hair removal—clip/remove hairs on the surrounding skin at regular intervals Activities of daily living—avoid high friction activities and sitting for long periods, correct constipation and nutrient deficiencies
Refer for early surgical management	Mainstay of treatment of pilonidal sinus disease
	Earlier interventions associated with lower recurrence rates
	Many different surgical techniques utilized

Abbreviations: NERDS, Nonhealing, Exudate, Red friable granulation tissue, Debris, Smell; STONEES, Size increase, Temperature, Os, New areas, Exudate, Erythema/Edema, Smell; WHO, World Health Organization.

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(n = 10) patients, and 3 or more STONEES criteria were met in 88% (n = 14). The surface critical colonization was treated with the study wound dressing with added ionized silver. For deep and surrounding infection, systemic antimicrobial agents used in these patients included an amoxicillin and clavulanic acid combination, ciprofloxacin, or moxifloxacin with or without metronidazole. In cases where there were obvious signs of inflammation, doxycycline (100 mg daily) was used for its anti-inflammatory action. All patients in this difficult-to-heal cohort were treated with systemic antimicrobials during part of the study period.

DISCUSSION

The patient demographics in this case series reflect published characteristics of populations living with pilonidal sinus wounds. There was a predominance of overweight/obese younger males with few comorbidities.[24] The majority of patients had a prior pilonidal sinus-related surgical intervention, a finding that aligns with evidence that appropriate and timely surgical management is a mainstay of treatment for this condition.[6,9,25,26] The wound size was relatively heterogeneous, ranging from a pinpoint to an extremely large wound area, necessitating a range of polymeric membrane foam wound dressing application procedures. This polymeric membrane foam wound dressing was well suited to treat these areas, with a dense concentration of bacteria-containing hair follicles, because of the beneficial properties of the surfactant, glycerin, and added ionized silver if surface critical colonization was noted.

The steps for optimizing wound bed preparation for pilonidal sinus wounds by Harris et al[9] are outlined in Table 2. Localized infection from colonization and formation of biofilms are very common in pilonidal sinus wounds.[9,27] As per the recommendations of care for pilonidal sinus,[9] patients with only superficial infection were treated topically with the study dressing with added ionized silver. Those individuals with deep and surrounding infection were treated with oral antimicrobial agents, in addition to the study dressing with added ionized silver, when there were 3 or more STONEES criteria present.

A wound is considered to be in a healing trajectory when the surface area decreases by 30% or greater by week 4. In this cohort, by week 4, the surfactant, moisturizing, antimicrobial, and cleansing properties of the dressing played an important role in optimizing the wound bed, contributing to wound closure in the majority of patients.

Pain is an important factor affecting patients with wounds, including pilonidal sinus wounds.[9,28] Approximately half of the patients presented at week 0 complaining of pain, with an average score of 3.4 on the chosen numerical rating pain scale. Pain was treated following the guidelines of the World Health Organization pain ladder[29] along with nortriptyline and/or pregabalin for neuropathic pain. All patients reported improvements in pain scores by week 12. This reduction in pain can likely be attributed to appropriate treatment of wound infection and to the analgesic effects of the study dressing. The increased ability of patients to self-manage with the study dressing led to a decrease in the frequency of nursing visits, potentially reducing healthcare costs.

Based on Harris and colleagues' recommendations of care,[9] other treatment administered included clipping of periwound hair in all patients, with referral for laser hair removal also recommended for most patients in the cohort. Laser hair removal does not work for patients if their skin and hair color is the same (ie, the combination of black hair and black skin does not allow the laser to treat by color recognition).

Ultimately, the treatment chosen for this study combined with the wound bed preparation principles facilitated the healing of stalled but healable chronic pilonidal sinus wounds.

Limitations

One of the limitations of the study is that it was conducted on a relatively young, healthy, nonsmoking cohort and may not reflect generalizability to other populations. Further, because of the location of the wounds, the dressing was not changed every 3 days as per product monograph. Patients were given the option to change it as required, mostly on a daily basis, but in some cases twice per day. Local hygiene and cleaning of the area were emphasized, but it was made clear that excessive flushing of the wounded skin could potentially compromise the surfactant property of the dressing.

CONCLUSIONS

Use of a surfactant-containing polymeric membrane foam wound dressing with glycerin may have facilitated the complete wound closure in 10 of 13 patients who completed the 12-week study. Improved pain scores, improvements in activities of daily living, and no adverse reactions from the surfactant-containing polymeric foam dressing were observed in the study population.

PRACTICE PEARLS

- Pilonidal sinus wounds are most common in young males 15 to 30 years old with a deep, hairy natal cleft.
- The wound bed preparation model can be used for optimal management of these wounds: treating the cause (early surgery has the best outcomes), patient-centered concerns (including pain management and activities of daily living), and local wound care (the patient may benefit from debridement, local critical colonization/inflammation treatment, and moisture management).
- Local wound care for pilonidal sinus wounds may benefit from a surfactant-containing polymeric membrane foam wound dressing with glycerin.
- Perianal hygiene including excess hair removal, downward cleaning after bowel movements, and gentle antiseptic cleansers is essential.

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- Read the article beginning on page 298. For nurses who wish to take the test for CE contact hours, visit http://nursing.ceconnection.com. For physicians who wish to take the test for CME credit, visit http://cme.lww.com. Under the Journal option, select *Advances in Skin and Wound Care* and click on the title of the CE activity.
- You will need to register your personal CE Planner account before taking online tests. Your planner will keep track of all your Professional Development online CE activities for you.
- There is only one correct answer for each question. A passing score for this test is 13 correct answers. If you pass, you can print your certificate of earned contact hours or credit and access the answer key. Nurses who fail have the option of taking the test again at no additional cost. Only the first entry sent by physicians will be accepted for credit.

Registration Deadline: June 5, 2020 (nurses); July 31, 2019 (physicians).

PAYMENT

- The registration fee for this test is $17.95 for nurses; $22.00 for physicians.

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