Wet-to-dry vs Petrolatum & Non-stick Dressings After Hidradenitis Suppurativa Surgery

NCT number NCT05194969
Document Date 8/1/2024

PROTOCOL: INTERVENTIONAL STUDY

Complete Title: Comparison of Wet-to-dry vs Petrolatum and Non-stick Dressing for Second Intention Healing Following Hidradenitis Suppurativa Surgery

Short Title: Wet-to-dry vs Petrolatum & Non-stick Dressings After Hidradenitis Suppurativa Surgery

Drug or Device Name(s):

FDA IND/IDE (if applicable):

Sponsor: University of North Carolina, Chapel Hill

Protocol Date: 8/1/2024

Study Principal Investigator Christopher J. Sayed, MD
UNC School of Medicine Department of Dermatology
Chapel Hill, North Carolina, United States, 27599
Phone: 984-974-3900
email: christopher_sayed@med.unc.edu

Table of Contents

Abbreviations and Definitions of Terms

Abbreviation	Definition
HS	**Hidradenitis Suppurativa**
MID	**Minimal important difference**
NRS	**Numeric Pain Rating Scale**
PUSH	**Pressure Ulcer Scale for Healing**
PWAT	**Photographic Wound Assessment Tool**

PROTOCOL SYNOPSIS

Study Title	
Funder	UNC Department of Dermatology
Clinical Phase	NA
Study Rationale	Hidradenitis suppurativa (HS) is a chronic, severe, inflammatory skin condition characterized by recurring abscesses, nodules, and tunneling sinuses in intertriginous locations such as the groin, buttocks, and axillae. While many patients are managed with medications and lifestyle modifications alone, a subset of HS patients benefit from surgical intervention. Proper wound care following HS surgery is paramount, as facilitating proper healing and minimizing infection can prevent post-operative complications, morbidity and the need for future procedures. This study hopes to answer the question of whether wet-to-dry dressings should be standard of care or whether an alternate form of wound dressings, such as petrolatum with non-stick bandaging, is at least equitable if not superior in effect with fewer drawbacks.
Study Objective(s)	Primary Objectives: - Characterize and compare the 2 regimens via patient-centered outcomes outlined in the validated Wound QOL Survey - Characterize and compare the two bandaging regimens in terms of wound healing after surgical deroofing and excisional procedures using the validated PUSH tool

	- Characterize and compare the 2 bandaging regimens in terms of pain with dressing changes, as measured by the NRS, after surgical deroofing procedures
Test Article(s) *(If Applicable)*	NA
Study Design	Interventional Study Model: Parallel Assignment - This study is a randomized, blinded trial of two postoperative bandaging techniques after HS surgery: wet-to-dry dressings vs. petrolatum with non-stick bandaging. Patients will be followed for a minimum of 6 weeks postoperatively with surveys to be completed at home, including a wound photograph, at weeks 1, 2, 4, and 6 weeks postoperatively. If wounds have not healed by week 6, then final healing may be tracked up to 12 weeks to monitor for complications. Number of Arms: 2 Masking: Triple (Care Provider, Investigator, Outcomes Assessor) - Following the surgical procedure, the principal investigator (PI) exits the exam room. The PI is not present for bandaging administration and training and thus is blinded to the wound dressing technique. The patient is not blinded as bandaging will be administered at home. Allocation: Randomized Enrollment: 74
Subject Population **key criteria for Inclusion and Exclusion:**	Accepts Healthy Volunteers: No Inclusion Criteria: - Male & females ≥ 16 years of age - Patient must have undergone a standard-of-care surgical procedure for HS with planned secondary intention healing of the wound. - Must be able to provide adequate informed consent for themselves - Must be capable of performing either of the recommended wound care regimens on their own or have someone available to consistently assist with wound care. Exclusion Criteria: - Patients with surgically closed wounds (sutures, staples) - Patients with preference for specific types of bandaging protocols - Patients that have not been able to tolerate either wet-to-dry or petrolatum and non-stick bandages in the past

Number Of Subjects	74
Study Duration	Each subject's participation will last at least 6 weeks. Official Dates: April 25th, 2022 – October 30th, 2023 (18 months)
Study Phases **Screening** **Study Treatment** **Follow-Up**	Study Phases: Phase 1 (Day 0): Screening and Enrollment Phase 2 (Weeks 1–Wound closure): survey completion and wound monitoring Phase 3: Data Analysis
Efficacy Evaluations	Primary efficacy evaluation will be completed using the validated PUSH tool, NRS tool, and Wound QOL survey.
Safety Evaluations	Monitoring for signs of wound infection will be included on regularly scheduled patient surveys. If pain scores become worse following bandaging within one of the wound dressing groups during periodic data reviews, then we may need to stop the study early if this becomes significant. Subjects will have the ability to contact us with any concerns and should other unanticipated adverse events be reported we will track them and address any serious adverse events or trends.
Statistical And Analytic Plan	The general goal is to demonstrate non-inferiority between the two bandaging types. The PUSH tool is the primary endpoint utilized to power for non-inferiority between the two wound bandaging techniques. There is no a-priori rationale for any exact non-inferiority margin. Instead, it is estimated that the expected half-width of a 97.5% confidence interval (i.e., the lower extension of a one-sided, Bonferroni-adjusted 98.75% CI) will be 0.61 SDs. Put differently, there would be 80% power to establish that the non-stick dressing is not 0.84 SDs worse than the wet to dry dressing. Utilizing the sample size of 74 patients calculated using the non-inferiority analysis for the PUSH tool actually provides the study sample size necessary to reliably identify a meaningful difference between the other two primary endpoints, the NRS tool and Wound QOL survey. Primary outcome measures will be reported as means and full ranges.
DATA AND SAFETY MONITORING PLAN	We will be compiling and monitoring data on responses on an ongoing basis and reviewing every 2-3 weeks. If one group is demonstrating significantly worse outcomes before the planned end of the enrollment period, we will end the study early and report the results available at that time. All patient data collected in this study will be stored within the secure research software RedCap. Data access will be restricted to the research fellow as the primary data input source. Downloaded

	data will be secured on the UNC hospital cloud and only de-identified data will be sent via email. The principal investigator will not have access to any patient data until the de-identified data is provided for analysis at the conclusion of the study. Data will be coded according to established coding protocol.

BACKGROUND AND RATIONALE

1.1 Introduction

Hidradenitis suppurativa (HS) is a chronic, severe, inflammatory skin disease associated with pain, drainage, odor, and disability characterized by recurring abscesses, nodules, and tunneling sinuses in intertriginous locations such as the groin, buttocks, and axillae. HS has more negative impact on patients' quality of life than all other common dermatologic diseases and is common, affecting ~1% of the general population, with higher risk for females (3:1) and Black patients. The onset is often in adolescence. As HS has been under-studied historically, there is an unmet medical need to develop more effective treatment for this disease. While many patients are managed with medications and lifestyle modifications alone, a subset of HS patients benefit from surgical intervention. Proper wound care following HS surgery is paramount, as facilitating proper healing and minimizing infection can prevent post-operative complications, morbidity and the need for future procedures. While many physicians continue to use wet-to-dry dressings as the standard of care for HS patients post-operatively, it is likely that the drawbacks of this dressing technique outweigh the benefits. This study hopes to answer the question of whether wet-to-dry dressings should truly be standard of care or whether an alternate form of wound dressings, such as petrolatum with non-stick bandaging, is at least equitable if not superior in effect, and associated with fewer drawbacks such as associated pain and time dedicated to dressing changes. This study will be a randomized, single-blind trial of two postoperative bandaging techniques: wet-to-dry dressings vs. petrolatum with non-stick bandaging. Primary outcomes will be tracked using the photographic wound assessment tool (PWAT), pressure ulcer scale of healing (PUSH) tool, and Wound Quality of Life (QOL) Survey. There is potential for this study to apply to surgical interventions outside of HS, as the study addresses the bandaging technique (wet-to-dry) that is standard of care after many surgical procedures.

1.2 Name and Description of Investigational Product or Intervention

Wet-to-dry dressings, consisting of gauze and sterile saline, will serve as the control. Petrolatum and non-stick gauze will serve as the intervention. Petrolatum will be directly applied to the wound surface and then be covered with a non-stick gauze.

1.3 Non-Clinical and Clinical Study Findings

Potential Benefits

There is potential that patients who participate in this research trial will receive additional monitoring compared to patients who do not (as they are receiving follow up surveys), which could help with identifying infection sooner. Analyzing the efficacy of petrolatum with non-stick bandaging at resolving HS postoperative wounds and decreasing pain could help guide dermatologists' treatment of HS and

provide better outcomes for patients in the future, including those in this study that might pursue additional procedures in the future.

Risks

Risks of participation include distress in anticipation of post-operative wound management, pain and discomfort following the procedure and with dressing changes, and infection. However, these risks accompany normal clinical unroofing procedures. There is always a risk of confidentiality breaches, but we will be mindful and attempt to minimize this risk. Normal clinic protocol for post-operative pain management will be followed, which includes opioid and non-opioid analgesics depending on provider and patient preferences and needs. Pain with dressing changes can occur, especially with wet-to-dry dressings. Patients will be informed of this risk during their dressing change postoperatively and during their bandage training session with the nurse. Patients will be instructed to contact the clinic in the event that dressing changes are too painful so that additional pharmacotherapy can be prescribed and other wound management strategies discussed. Patients will be made aware of this risk so that they can opt out of the bandaging protocol if needed.

1.4 Relevant Literature and Data

Bandage Types

Wet-to-Dry Dressings

Wet-to-dry dressings have been the standard for wound care for many wound types for decades, including HS surgical wounds. This dressing technique involves moistening a piece of gauze with normal saline or other cleansing solution, placing the moistened gauze on the wound, allowing the gauze to dry, and then removing and replacing the bandage regularly over a period of days to weeks. Removing the dried gauze acts as a mechanical debridement agent. However, this wound dressing technique presents multiple problems, including a painful dressing change experience for patients, increased bleeding, removal of healthy, viable tissue, and local tissue cooling [1], all of which can impair would healing. Given the fact that other wound bandaging options exist which minimize the aforementioned negative effects, it is imperative to explore whether an alternate wound care strategy would be beneficial for HS patients undergoing surgery.

Petrolatum & Non-stick bandaging

An alternate wound dressing approach is applying a thick layer of petrolatum to the wound once or twice daily to maintain a moist wound base. The petrolatum often feels soothing when applied and seems to minimize wound discomfort [2]. After placement of petrolatum, the wound is covered with nonadherent gauze and tape or another bordered dressing. This bandaging strategy prevents the dressing from sticking directly to a wound base and typically makes bandage changes less painful. Since pain is a major drawback of wet-to-dry dressings, minimizing this experience for HS surgical patients would be highly beneficial. Additionally, this dressing technique keeps the wound bed moist and minimizes wound cooling, which are essential to optimal wound healing [3].

Evaluation Tools

The primary endpoint measures are the Wound QOL score, PUSH, and NRS tools, with the PWAT being an important secondary endpoint.

Wound QOL Score:

The wound QOL score has been used in a variety of different studies to evaluate chronic wounds. Although we will use the Wound Quality of Life (QoL) survey for our main analysis, as it is more comprehensive and we think readers will find it more persuasive, we don't have direct data on what to expect. The minimal important difference (MID) in Wound-QoL-17 overall score was determined in a German sample of 227 patients with chronic wounds and was found to be approximately 0.5 [4]. This means that a decrease of the Wound-QoL-17 total score of 0.50 or more in a group of patients can be assumed to indicate patient-relevant change. The global score ranges from 0 (= no impairment) to 4 (= maximum impairment).

PUSH

The pressure ulcer scale for healing (PUSH) tool is a well-validated and accurate measure of healing for chronic wounds that heal by secondary intention [5]. However, it has not been used frequently by the principal investigator as a measure of wound healing. Given the principal investigator's unfamiliarity in the clinical variance of PUSH scores between patients, we plan to power for non-inferiority between the two wound bandaging techniques in terms of wound healing as opposed to superiority of one bandaging type over the other.

NRS

The numerical rating scale (NRS) for pain ranges from 0-10. From prior studies on the NRS, we know that the minimal clinically significant difference in pain on the scale is approximately 1.3 points [6].

PWAT

The photographic wound assessment tool (PWAT) has been used in a wide variety of studies to monitor chronic wounds [7]. While it is not a primary endpoint for which the study is powered, it will still be completed and analyzed as a secondary outcome of interest.

1 STUDY OBJECTIVES

The purpose of this study is to determine whether wet-to-dry dressings should truly be standard of care or whether an alternate form of wound dressings, such as petrolatum with non-stick bandaging, is at least equitable if not superior in effect, and associated with fewer drawbacks such as associated pain and time dedicated to dressing changes.

1.4 Primary Objectives

Primary Outcome Measures:

1. Change in Wound QOL Survey Score Over Time
    a. A validated Wound Quality of Life (QOL) Survey will be administered that focuses on patient-reported outcomes of level of wound pain, pain with dressing changes (application and removal), satisfaction with the bandaging, and ease of application of the bandaging, all

17 elements on a 0-4 scale. Total score ranges from 0 to 4 with higher scores indicating a worse outcome.

- Time Frame: Administered at 1, 2, 4 and 6 weeks post-surgery

2. Change in PUSH Score Over Time
    a. The pressure ulcer scale for healing (PUSH) tool is a validated means of measuring wound healing over time, specifically wounds that heal via secondary intent, by taking into account things like wound size and wound exudate, among others. Scores range from 0-17 with higher scores indicating inferior wound healing.
    - Time Frame: Completed at 1, 2, 4 and 6 weeks post-surgery utilizing images submitted by patients

3. Change in Pain with Dressing Changes
    a. The numeric rating scale (NRS) will be used, where patients will be asked to rate pain with dressing changes and general pain on a scale from 0-10 with higher scores indicating worse pain. This information will be collected in the patient survey that is sent post-operatively.
    - Time Frame: Collected at 1, 2, 4 and 6 weeks post-surgery

Secondary Objective

The PWAT will be an important secondary endpoint for evaluation and comparison with the primary endpoints. Other patient-reported outcomes including interference with daily activities/exercise, assistance needed with bandaging changes, bandage change difficulty, and likelihood to use this bandage type in the future will be assessed. Additionally, patient-reported wound healing will be recorded. This will include questions such as “To what degree is the wound healed?” with answers on a 10-point scale ranging from “completely healed, somewhat healed, not healed.” Number of days to wound healing/resolution will be asked on all surveys 4 weeks and later. Patients will also be asked whether or not they believe their wound is showing signs of infection.

2 INVESTIGATIONAL PLAN (brief overview)

2.1 Study Design

Type of design: Randomized Controlled Trial

This will be a randomized, blinded trial of two postoperative bandaging techniques: wet-to-dry dressings vs. petrolatum with non-stick bandaging (see **Table 1).** Primary outcomes will be tracked using the PWAT, PUSH tool, and Wound QOL Survey (described below). Screening will be performed during regularly scheduled clinic visits with the principal investigator. Informed consent will be signed by the subject. A physical exam will be performed to assure that HS lesions suitable for surgical deroofing are present. Once subjects are deemed appropriate for the study, on the day of surgery the surgical sites will be marked with a skin marker and documented by body location. The surgical deroofing or excision procedure will then be performed by the principal investigator.

Study Phases are as follows:

Phase 1 (Day 0): Screening and Enrollment – patient's surgical date

Phase 2 (Weeks 1–Wound closure): patient survey completion and wound monitoring

Phase 3: Data Analysis

On the day of enrollment (patient's surgical date), patient age, sex, race, smoking history, and immunomodulatory medication use will be recorded. Assessment of wound size will also be measured by the PI on the day of surgery. The surgical procedure will be completed as it normally wound if the patient were outside the study. After the PI leaves the room, the patient is randomized to their treatment group and given their wound bandaging supplies and detailed instructions regarding the study protocol.

Patients will be instructed to expect receipt of a virtual RedCap questionnaire via electronic mail 1-week post operatively and 2-weeks postoperatively. Questionnaires will continue to be sent every 2 weeks until the wound has fully closed. Disposable rulers will be provided that will be placed beside the wound for scale and patients will be instructed how to measure their wounds. The photos will be depersonalized and examined by the PI. Objective wound assessment will be completed using two standardized assessment tools. Wound assessment will be completed with the validated photographic wound assessment (PWAT) tool and the photographs will also be used to score and track wounds using the validated pressure ulcer scale for healing (PUSH) tool.

If at any point patients develop a wound complication or wound like to have their wound examined or checked, they will be given contact information for the research fellow to schedule a follow-up visit.

2.2 Allocation to Treatment Groups and Blinding

Following the surgical procedure, the principal investigator (C.S.) will exit the exam room. The principal investigator will thus be blinded to the wound dressing technique as he will not be present for bandaging administration, but the patient will not be blinded as they themselves will be administering the bandaging at home. The research fellow will complete randomization via the RedCap randomization algorithm and inform the patient of their assigned group.

2.3 Study Duration, Enrollment and Number of Subjects

Duration: primary and secondary outcome data will be recorded for up to 6 weeks, and if wounds are not healed by week 6, then subjects may be followed out to 12 weeks for safety.

Planned enrollment: minimum 72, maximum 100. Actual: 74

2.4 Study Population

Accepts Healthy Volunteers: No

Inclusion Criteria:

- Male & females ≥ 16 years of age
- Patient must have undergone a standard-of-care surgical procedure for HS with planned secondary intention healing of the wound.
- Must be able to provide adequate informed consent for themselves

- Must be capable of performing either of the recommended wound care regimens on their own or have someone available to consistently assist with wound care.

Exclusion Criteria:

- Patients with surgically closed wounds (sutures, staples)
- Patients with preference for specific types of bandaging protocols
- Patients that have not been able to tolerate either wet-to-dry or petrolatum and non-stick bandages in the past

3 STUDY PROCEDURES (what will be done)

3.1 Screening/Baseline Visit procedures

Subjects with a diagnosis of hidradenitis suppurativa will be identified in a subspecialty clinic dedicated to hidradenitis suppurativa in the UNC Dermatology Clinic. Subjects will be selected for potential enrollment on the day of surgery. The research fellow will approach the patient and inform them of their eligibility and describe study details. If patient agrees, informed consent will be obtained and enrollment initiated. Baseline demographics will be obtained, including medical history, BMI, age, sex, race, etc.

3.2 Intervention/Treatment procedures (by visits)

After study enrollment, patient will undergo their previously-scheduled surgery. The PI will exit the room, and the patient will be randomized to their treatment group. Bandaging of their wound will be completed, bandaging supplies will be given, and detailed follow-up instructions will be provided.

3.3 Follow- up procedures (by visits)

Patients will have no scheduled follow-up visits in person. They will instead receive surveys at weeks 1, 2, 4, 6, and after if necessary. However, patients may schedule an in-person visit at any time.

3.4 Unscheduled visits

Patients may schedule an in-person visit at any time if they have concerns regarding wound healing or general questions regarding the process. They are encouraged to contact the research fellow for research study specific questions.

3.5 Subject Completion/ Withdrawal procedures

If at any point the patient desires to withdraw from the study, he/she may do so for any reason.

3.6 Screen failure procedures

If a patient does not meet inclusion criteria at enrollment, normal clinical care will resume with no detriment to the patient.

4 STUDY EVALUATIONS AND MEASUREMENTS (how measurements will be made)

- **List variables that will be abstracted from medical charts**

Baseline demographics including age, sex, race, BMI, smoking history, among others will be recorded from the medical chart and verified with the patient on the day of enrollment.

- **Describe baseline evaluation**

Baseline evaluation will include identifying surgical site, evaluating if surgical site is optimal for study inclusion, assessment of patient's overall general health,

- **Describe how measurements will be taken.**

Patient's upload a photo of their wound with each online survey they complete, as well answers to questions such as pain with wound dressing changes on a scale 1-10. Wound measurements and wound characterization for the primary and secondary endpoints will then be completed at the conclusion of the study by the PI. Other questions and data will be inputted by patients directly on the survey for future statistical evaluation.

- **Describe rating scales, tests, psychological tools, laboratory evaluations, etc.**

The previously-described PUSH, Wound QOL, and NRS primary endpoints will all be recorded and extrapolated from the online surveys submitted by patients at scheduled intervals.

STATISTICAL CONSIDERATIONS

Our study is powered to detect an effect on our primary endpoints, pain and quality of life. Although we will use the Wound Quality of Life (QoL) survey for our main analysis, as it is more comprehensive and we think readers will find it more persuasive, we don't have direct data on what to expect. Rather, we do have a strong sense, from clinical experience, of what will happen with pain. Using the 0-10 numerical pain scale, we believe the non-stick dressing will reduce pain ratings by 1.3 points at the two-week checkup and estimate the historical SD at that visit is 1.4 units, implying a .93 SD reduction. We calculate we will need 28 patients per arm to achieve 80% power. We add 2 more to account for two planned covariates (pelvic area vs armpit, and initial wound size). Since we expect approximately 20% dropout, we will plan to recruit approximately 74 patients.

There are approximately 6-8 new patients per week, and we conservatively estimate at least 2 will consent to the study. Thus, we should be able to reach our desired sample size in 36 weeks. With 6 weeks of required follow-up, the last patients should be finished by 42 weeks, well within 1 year. If our recruitment and/or retention is better, we will continue to gather data, again yielding better power. Our other primary endpoint is efficacy. We believe the non-stick dressing will not lead to reduced wound healing compared to the traditional wet to dry dressing. We don't have an a-priori rationale for any exact non-inferiority margin. Instead, we estimate that the expected half-width of a 97.5% confidence interval (i.e., the lower extension of a one-sided, Bonferroni-adjusted 98.75% CI) will be 0.61 SDs. Put differently, we would have 80% power to establish that the non-stick dressing is not 0.84 SDs worse than the wet to dry dressing.

Aim 1. Characterize and compare the 2 bandaging regimens in terms of pain with dressing changes after a surgical deroofing procedure

Hypothesis for Aim 1: Rating of pain will be less in the petrolatum and non-stick bandaging group compared to the wet-to-dry group

We are using the numerical rating scale (NRS) for pain that ranges from 0-10. From prior studies on the NRS, we know that the minimal clinically significant difference in pain on the scale is approximately 1.3 points [6]. We believe the non-stick dressing will reduce pain ratings by 1.3 points at the two-week checkup and estimate the historical standard deviation between patients pain ratings at that visit is 1.4 units, implying a .93 SD reduction. Our ability to detect this difference and achieve 80% power is far exceeded by the 74 patients needed to detect non-inferiority via the PUSH tool (see Aim 3). We will report means and full ranges for NRS values in each group across relevant time points.

Aim 2. Characterize and compare the 2 regimens via patient-centered outcomes outlined in the validated Wound QOL Survey and additional questions

Hypotheses for Aim 2: Patient QOL ratings will be more favorable in the petrolatum and non-stick bandaging group compared to the wet-to-dry group

The minimal important difference (MID) in Wound-QoL-17 overall score was determined in a German sample of 227 patients with chronic wounds and was found to be approximately 0.5 [4]. This means that a decrease of the Wound-QoL-17 total score of 0.50 or more in a group of patients can be assumed to indicate patient-relevant change. The global score ranges from 0 (= no impairment) to 4 (= maximum impairment). Preliminary statistical analysis indicated that we would need only 3 patients in each study arm to detect this difference. As a result, the study sample size necessary to meet this number to achieve 80% power is far exceeded by the 74 patients needed to detect non-inferiority via the PUSH tool (see Aim 3). We will report means and full ranges for Wound-QOL values in each group across relevant time points.

Aim 3. Characterize and compare the two bandaging regimens in terms of wound healing after surgical deroofing and excisional procedures using the validated PUSH and PWAT tools

Hypotheses for Aim 3: Wound healing in the petrolatum and non-stick bandaging group will be non-inferior compared to the wet-to-dry group

The pressure ulcer scale for healing (PUSH) tool is a well-validated and accurate measure of healing for chronic wounds that heal by secondary intention. However, it has not been used frequently by the principal investigator as a measure of wound healing. Given our unfamiliarity in the clinical variance of PUSH scores between patients, we plan to power for non-inferiority between the two wound bandaging techniques in terms of wound healing as opposed to superiority of one bandaging type over the other. We don't have an a-priori rationale for any exact non-inferiority margin. Instead, we estimate that the expected half-width of a 97.5% confidence interval (i.e., the lower extension of a one-sided, Bonferroni-adjusted 98.75% CI) will be 0.61 SDs. Put differently, we would have 80% power to establish that the non-stick dressing is not 0.84 SDs worse than the wet to dry dressing.

The photographic wound assessment tool (PWAT) is not a primary endpoint for which the study is powered, but it will still be completed and analyzed as a secondary outcome of interest and reported as means and full ranges.

5 STUDY INTERVENTION (DEVICE, DRUG, OR OTHER INTERVENTION)

- **Description**

Bandage: Petrolatum with Non-Stick Gauze

Petrolatum is a petroleum-based bioinert ointment that is non-irritating to the skin [8]. The petrolatum often feels soothing when applied and seems to minimize wound discomfort [2]. After placement of petrolatum, the wound is covered with nonadherent gauze and tape or another bordered dressing. This wound bandaging technique can be placed over the wound once or twice daily to maintain a moist wound base.

- **Receipt/Storage**

Petrolatum can be safely stored on the shelf at home.

- **Treatment compliance and Adherence**

Apply once to twice daily to the wound base. There are no other strict adherence requirements.

- **Drug Return/Destruction**

Petrolatum can be safely disposed of in normal trash receptacles.

6 STUDY INTERVENTION ADMINISTRATION

- **Randomization procedures**

A stratified block randomization will take place after the principal investigator has left the surgical room following surgery. Randomization will be performed by the research fellow. Each participant is assigned to a particular stratum based on wound size and location, two important covariates to control for in statistical analysis given these variables can impact the Wound QOL survey and other results significantly. After strata assignment, randomization is completed via a RedCap algorithm. A detailed outline of the randomization process and groups can be found in **Figure 1.**

- **Blinding procedures**

Following the surgical procedure, the principal investigator will exit the exam room. The principal investigator will thus be blinded to the wound dressing technique as he will not be present for bandaging administration, but the patient will not be blinded as they themselves will be administering the bandaging at home.

- **Unblinding procedures**

If at any point unblinding occurs, the involved patient will be notified that their further participation in the study is voluntary but their patient data can no longer be used for analysis. There is no penalty or direct harm anticipated to the patient because of unblinding. They can continue to bandage their wound as assigned during randomization or alternatively if desired.

- **Premature Study Closure**

If any of the groups are showing significantly worse outcomes with regard to changes in pain or days to surgical wound resolution before the end of the recruitment period, the study will be ended prematurely.

- **Subject Withdrawal**

If a subject fails to complete a their one-week postoperative survey or are unable to complete the assigned wound care for a full week, they will be withdrawn from the study. All subjects will have the option to withdraw from the study at any time that they wish.

7. SAFETY MANAGEMENT

Patients will be informed that if any complication develops or if they have any concerns, they can reach out to the research fellow directly or to the clinic, whichever they feel is appropriate. Of course, if they reach out to the clinic, they are aware that the blinding to the principal investigator may be compromised, but they will be informed patient safety is the highest priority over potential unblinding.

If pain scores become worse following bandaging within one of the wound dressing groups during periodic data reviews, then we may need to stop the study early if this becomes significant. Subjects will have the ability to contact us with any concerns and should other unanticipated adverse events be reported we will track them and address any serious adverse events or trends.

Patients that require continued care for their hidradenitis suppurativa will be followed in clinic over time. Those with other general medical concerns encountered during the study encounter will be referred to UNC primary care clinics and those that require psychological counseling will be referred to psychiatry or psychologists within the UNC system if needed. The study PI (CS) will actively manage patient needs as part of the standard of care for wound management after all procedures.

8. DATA COLLECTION AND MANAGEMENT

All patient data collected in this study will be stored within the secure research software RedCap. Data access will be restricted to the research fellow as the primary data input source. Downloaded data will be secured on the UNC hospital cloud and only de-identified data will be sent via email. The principal investigator will not have access to any patient data until the de-identified data is provided for analysis at the conclusion of the study. Data will be coded according to established coding protocol.

Quality assurance is built into data collection process by ensuring that source data documents capture data in established/standardized format that aligns with establish coding standards.

Project manager will monitor data throughout the study to ensure all data is source verified. Data will be monitored after the first patient is enrolled, after the first 50% of patients are enrolled, and again at the end of the study (last patient, last follow-up). Regular meetings will be scheduled to ensure that data is cleaned along the way (not just at the end).

Data archiving: coded data will be stored on the Department share drive which is backed up and maintained by the school of medicine. Only study personnel will have access to the study data.

Data from patient surveys will all be collected at the same time so it is unlikely that we will be missing many data points. If patients fail to enter data at specific time points on their surveys we will use the previous value carried forward to the missing data point. The data for patients who do not return their surveys will not be included in the study analysis as it will be too difficult to correctly estimate their responses.

Data Safety Monitoring Plan

We will be compiling and monitoring data on responses on an ongoing basis and reviewing every 2-3 weeks. If one group is demonstrating significantly worse outcomes before the planned end of the enrollment period, we will end the study early and report the results available at that time.

All patient data collected in this study will be stored within the secure research software RedCap. Data access will be restricted to the research fellow as the primary data input source. Downloaded data will be secured on the UNC hospital cloud and only de-identified data will be sent via email. The principal investigator will not have access to any patient data until the de-identified data is provided for analysis at the conclusion of the study. Data will be coded according to established coding protocol.

9. RECRUITMENT STRATEGY

No active recruitment outside of normal clinical practice will occur. Subjects with a diagnosis of hidradenitis suppurativa will be identified in a subspecialty clinic dedicated to hidradenitis suppurativa in the UNC Dermatology Clinic. Patients will be invited to participate in this study on the day of surgery. However, patients will be offered 6-weeks supply of bandaging supplies as partial compensation for their participation. No incentives or reimbursements are directly provided that would be prorated. Patients will not be required to return unused bandaging supplies. Bandaging materials will be required for all patients. The cost of materials or potential for them to be sold is not high enough to significantly coerce patients. Providing the appropriate materials will increase the odds that patients will follow the regimens and not find an alternative that might be easier to obtain or slightly less expensive. Since we will be enrolling older children ages 16-17, we will plan on providing compensation to the subjects and/or the person helping them care for their wounds since they will be providing assent and are likely to complete their questionnaires themselves. Patients will not incur any additional costs because of study participation.

10. CONSENT PROCESS

Written informed consent will be obtained prior to unroofing procedures in an outpatient clinic setting. Consent will be obtained by a research fellow. Consent forms will be printed off and signed with pen in person by the patient and the research fellow. A patient's ability to provide consent will be assessed prior to and during the consent process. If a patient cannot acknowledge understanding of the risks and benefits of participation to the consenter, they will be consented or included in the study.

Children suffer from hidradenitis suppurativa, and the onset of the disease is often in the teenage years. Children ≥ 16 years of age will be included in study recruitment. Specific assent and consent forms have been composed and approved by the UNC IRB that must be printed and signed by both the patient and a parent/legal representative prior to the child participating in the research study. As determined by the UNC IRB, there are no additional or added risks associated with a child's participation in the research study as compared to an adult. Consent from children will require that both the child and a parent/guardian are present in the room during the consent process. Consent forms and assent forms will both be signed.

By signing the informed consent document, the patient will agree that some of the information generated by participating in this study and/or a copy of the consent form may be included in their medical record and that this information may be viewed by other physicians or caregivers who provide healthcare services to them. This will allow the doctors caring for them to know what study medications or tests they may be receiving as a part of the study and know how to take care of them if they have other health problems or needs during the study.
Participants will be asked to sign a separate form ("HIPAA Authorization") to allow researchers to review their medical records.

11. PLANS FOR PUBLICATION

Manuscript submission for publication is planned within 24 months following closure of the study.

12. REFERENCES

[1] – Ovington, L. G. (2001). Hanging wet-to-dry dressings out to dry. *Home Healthcare Now*, *19*(8), 477-483.

[2] – Fajgenbaum, K., Bissette, J., & Sayed, C. (2019). Clinic-Based Surgical Treatment for Hidradenitis Suppurativa. *Current Dermatology Reports*, *8*(3), 149-156.

[3] – Eaglstein, W. H., Davis, S. C., Mehle, A. L., & Mertz, P. M. (1988). Optimal use of an occlusive dressing to enhance healing. *Arch Dermatol*, *124*(3), 392-395.\

[4] – Topp, J., Blome, C., Augustin, M., Mohr, N., Debus, E. S., Diener, H., & Sommer, R. (2021). Determining the Minimal Important Difference for the Wound-QoL Questionnaire. Patient preference and adherence, 15, 1571.

[5] – Stotts, N. A., Rodeheaver, G. T., Thomas, D. R., Frantz, R. A., Bartolucci, A. A., Sussman, C., ... & Maklebust, J. (2001). An instrument to measure healing in pressure ulcers: development and validation of the pressure ulcer scale for healing (PUSH). The Journals of Gerontology Series A: Biological Sciences and Medical Sciences, 56(12), M795-M799.

[6] – Kendrick, D. B., & Strout, T. D. (2005). The minimum clinically significant difference in patient-assigned numeric scores for pain. The American journal of emergency medicine, 23(7), 828-832.

[7] – Thompson, N., Gordey, L., Bowles, H., Parslow, N., & Houghton, P. (2013). Reliability and validity of the revised photographic wound assessment tool on digital images taken of various types of chronic wounds. Advances in skin & wound care, 26(8), 360-373.

[8] – Czarnowicki, T., Malajian, D., Khattri, S., da Rosa, J. C., Dutt, R., Finney, R., ... & Guttman-Yassky, E. (2016). Petrolatum: barrier repair and antimicrobial responses underlying this “inert” moisturizer. Journal of Allergy and Clinical Immunology, 137(4), 1091-1102.

APPENDIX

TableS 1. Study Arms and Interventions

Arms	Assigned Interventions
Active Comparator: Wet-to-dry Dressings Participants in this arm will receive standard of care wet-to-dry dressings.	Device: Wet-to-Dry Dressings This dressing technique involves moistening a piece of gauze with normal saline or other cleansing solution, placing the moistened gauze on the wound, allowing the gauze to dry, and then removing and replacing the bandage regularly over a period of days to weeks
Experimental: Petrolatum with Non-Stick Gauze Participants in this arm will receive petrolatum with non-stick gauze.	Device: Petrolatum with Non-Stick Gauze This dressing approach involves applying a thick layer of petrolatum to the wound once or twice daily to maintain a moist wound base. After placement of petrolatum, the wound is covered with nonadherent gauze and tape or another bordered dressing.

Figure 1. Randomization Process

- The strata chosen for the study are:
  - **Wound size** (10 cm^2 cut-off)
  - **Wound Location** (waist cut-off)