Surgical Application of Vac Dressings In Obese Patients to Reduce Wound Complications

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JHM IRB - eForm A – Protocol

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1. Abstract

In an attempt to decrease wound infection incidence and improve healing time of open surgical wounds, vacuum assisted closure (VAC) was developed. This innovative technique provided contained controlled wound irrigation without bacterial aerosolization. A newer customizable subset of the Prevena incision Management System™ called Prevena Peel and Place™ has been released a few months ago. The new model can be cut to specific wound sizes and has a connector that can be attached to the already widely available VAC machines. The versatility and the comparability to older models of Prevena Peel and PlaceTM have not been tested to this date.

We believe that a randomized clinical trial evaluating the use of the Prevena Incision Management System™ for homecare and the use of Prevena Peel and Place™ for inpatients in special populations is warranted. Obese patients (BMI≥30) undergoing open surgery will have decreased surgical site infection rates, improved healing time, better quality of life (QOL) and lower readmission rates with use of Prevena in the post-operative management of surgical incisions.

2. Objectives (include all primary and secondary objectives)

Specific Aim 1: To determine whether application of an incisional wound PrevenaTM dressing (peel and place or customizable) in the obese (BMI ≥30) surgical patient will reduce surgical site infections (SSI) when compared to the standard of care dressing.

Hypothesis 1A: Obese patients (BMI ≥30) who undergo any elective open surgery will have a significant reduction in SSI and other wound complications (such as dehiscence, seroma and hematoma) when compared to the standard of care dressing presently used.

Brief Methodology: Obese patients who are scheduled to undergo any elective open surgery are eligible and have consented and enrolled in the study will be randomized to undergo either incisional wound PrevenaTM or standard of care dressing application immediately following the surgical procedure.

Specific Aim 2: To determine whether obese patients who have incisional wound PrevenaTM applied during their surgical procedure have a lower skin bacterial count upon removal of PrevenaTM as compared to those obese patients who had a standard of care dressing placed.

Hypothesis 2A: Obese patients who have the Prevena system applied to their incision will have a lower bacterial skin count upon removing Prevena on post-operative day #5-7 as compared to those who had a standard of care dressing placed.

Specific Aim 3: To determine whether obese patients who have incisional wound PrevenaTM applied during their surgical procedure have better quality of life assessment as compared to those obese patients who have a standard of care dressing.

> **Hypothesis 3A:** Obese patients who have the Prevena system applied to their incision will experience less wound complications and improved quality of life scores using the SF-36 (appendix A).

Specific Aim 4: To determine whether obese patients who have an incisional wound PrevenaTM applied during their surgical procedure have decreased readmission rates compared to those obese patients who have a standard of care dressing.

> **Hypothesis 4A:** Obese patients who have the Prevena system applied to their incision will experience a decreased readmission rate within 30 days of the operation.

The primary outcome measure: the incidence of postoperative surgical site infection (according to CDC/NHSN protocol) in open surgery.

The secondary outcome measures: other wound complications (such as dehiscence, seroma and hematoma), skin bacterial count after treatment, wound healing time, quality of life reporting and readmission rates between the two groups.

3. Background

Surgical site infections (SSI) are one of the most common postoperative complications accounting for 38% of all nosocomial infections. (1) SSI lead to prolonged hospitalization by approximately 10 days and a 2 to 3 fold increase in health care costs. (2–4) With the introduction of laparoscopic surgery, endovascular surgery, improved sterilization, dressing techniques and antibiotic prophylaxis, there has been a marked decrease in SSI. However, not all surgical procedures can be performed with minimally invasive techniques and still many surgeries performed worldwide today are via an open incision, leaving special populations (obese and diabetic surgical patients) with continued high SSI rates.

Patient-related risk factors for surgical wound infections include age, diabetes, smoking, compromised immunity and obesity. (5) It is well-documented in the literature that obesity is associated with stress, anxiety and depression, all situations which can cause an impaired immune response and as a result delayed wound healing. (6) Moreover, local factors such as decreased vascularity in adipose tissue, friction, skin folds harboring micro-organisms and increased wound tension all lead to impaired healing in obese patients. (7)

Bariatric patients undergoing open Roux-en Y gastric bypass surgery have an estimated surgical site infection rate of 10-20%. (8,9) Obesity by itself is estimated to increase the risk of developing surgical site infection 2 fold. (10) In addition, vascular surgery patients seem to have similar wound infection rates. Groin incisions in vascular surgery have an overall SSI rate higher than predicted by Center for Disease Control National Nosocomial Infections Surveillance Risk Category System, and it reaches 10% to 20% after lower-limb bypass grafting procedures.(11)

In an attempt to decrease wound infection incidence and improve healing time of open surgical wounds, vacuum assisted closure (VAC) was developed. The original study reported enhanced bacterial clearance

and improved tissue granulation. (12) The use of VAC in selected patient groups such as the elderly, diabetics and infected abdominal wounds has gained substantial popularity in the last 5 years.

Recently, similar techniques were employed in the Prevena Incision Management System™ for use on *clean closed surgical incisions*. Initial results in Plastic surgery comparing the use of Prevena versus standard dressing for skin flaps had better SSI rates (3% vs 20%).(14) Similarly, a study in vascular surgery patients found a large difference in SSI occurrence (6% Prevena vs. 30% non-Prevena, P<0.0011). (15)

We believe that a randomized clinical trial evaluating the use of the Prevena Incision Management System™ (both the peel and place and customizable options) for patients in special populations is warranted. Obese patients (BMI≥35) undergoing any open surgery will have decreased surgical site infection rates, improved healing time, better quality of life (QOL) and lower readmission rates with use of Prevena in the post-operative management of surgical incisions.

1. Study Procedures

a. Study design, including the sequence and timing of study procedures (distinguish research procedures from those that are part of routine care).

Prospective single blinded randomized clinical trial.

Screening

Candidates will be screened for eligibility for the study when evaluated for any of the surgical procedures described by the PI and CO-PIs. The screening will take place in inpatient or outpatient clinic at either Johns Hopkins Bayview Medical Center or Johns Hopkins Hospital. These surgeries will be elective in nature. Women of child bearing age will be given a urine pregnancy test preoperatively as per standard of care. Those who are pregnant or plan on becoming pregnant for the duration of the study are excluded. Candidates who meet the general inclusion / exclusion criteria will be approached for consent. All HIPAA patient privacy regulations will be observed during discussions with patients.

Consent

Patients will be recruited by the surgery services at Bayview Medical Center or Johns Hopkins Hospital. Patient history and routine preoperative tests will be used to identify comorbidities (such as diabetes, immunosuppression and smoking). Hopkins IRB approved consent designee for this study will meet with the patients prior to the operation to discuss the purpose of the trial and the subject's role, should they choose to participate. The patient will be informed in detail about the study and all their questions will be answered before signing the consent form. The patient will be given ample time to consider the study and will also be given a chance to review the informed consent form (ICF). They will have the option of taking the ICF home or having it mailed or emailed to them before making any decisions. No study related procedures would be performed before written informed consent process. All HIPAA privacy regulation applies here and patient rights as well as responsibilities are incorporated in the informed consent process.

Enrollment

Once enrolled, patients will be randomized to one of two groups: one group will receive an incisional wound Prevena (experimental) while the other group will receive the standard dressing (control). Randomization will be divided into 4 strata based on the patient's diabetes and smoking statuses (Diabetic smoker/ diabetic non-smoker/ non-diabetic smoker/ non-diabetic non-smoker). The 4 strata have been computer-generated using a in a 1:1 ratio of Prevena vs standard dressing in each

strata. Given the sample size of the study each strata has been generated to include up to 60 patients. A patient is considered enrolled after he/she has been randomized.

Peri-operative wound management

Antibiotic Prophylaxis:

All patients will receive perioperative standard of care intravenous antibiotics at the surgeon's discretion. The antibiotics will be given for 24 hours following surgery.

All patients will be prepped and draped in the normal sterile fashion using Chlorhexidine skin prep.

The incisions will be made using a skin knife. Both groups will undergo approximation of the subcutaneous tissue using 2.0 or 3.0 Vicryl interrupted sutures. For skin closure:

1) The incisions will be re-approximated using skin staples at least 1 cm apart (to allow drainage from the subcutaneous tissue).

   OR

2) 2.0/3.0 Nylon interrupted or vertical mattress sutures at least 1 cm apart (to allow drainage from the subcutaneous tissue) will be used.

Swabbing (Bacterial Wound Cultures)

On the day of surgery while in the operating room, once the skin has been closed and just prior to placing the sterile dressing / Prevena, a moistened swab is applied to the wound starting at the most superior/proximal aspect of the incision and running it along the incision line for the length of the incision then rotating the swab 180 degrees and applying the moistened swab from the inferior/distal end of the incision and running it back along the incision line.
After swabbing and according to the randomization, either a NPWT **Prevena™** or sterile gauze and a transparent film dressing will be applied to the incision.

Postoperative wound management

As it will be stated and agreed upon in the informed consent, the dressings in both groups will be removed on post-operative day(POD) # 5-7 (or sooner if redness or signs of infection are noted), by the provider/research coordinator in the clinic or on the ward if they are an inpatient. Then the provider/research coordinator will repeat the swabbing procedure mentioned above. Once swabbing is complete, an NP or a PA who are blinded to the study, will come in and asses the wound for healing, infection and other complications.

Follow Up

The patient will be advised to contact the hospital if any of the following signs develop at any time after the procedure (before and in between follow ups):

a. Fever
b. Warm, red, painful, swollen wound
c. Blood or pus coming from the wound
d. Foul odor coming from the wound

1) **POD #1-2:** The patient will receive a personal interview within 24-48 hours of the surgery while still hospitalized by an RN. A Short-Term Prevena Recovery Questionnaire (appendix B) will be completed during the interview regarding the patient's recovery. The most important questions will be tailored towards identifying any allergic reaction symptoms to the treatment option. Other questions include: tolerance, nutrition habits, voiding and bowel movements and any signs of wound infection.

2) **POD #5-7:** An examination by an independent nurse practitioner or physician assistant who is blinded to the treatment groups will be performed. Any surgical site infections or complications will be diagnosed using the Center for Disease Control and Prevention guidelines. If there are any complications (i.e. delayed healing, infection), the patient will be scheduled for weekly follow up with the NP, PA or MD until complete wound healing.

3) **POD #12 to 14:** Patients will return to clinic for staple or suture removal by the surgeon, the NP or PA. A secondary wound assessment will be performed as in step (2). In the same visit an SF-36 questionnaire (appendix A) will be completed by the patient to evaluate the therapy's impact on QOL.

4) **POD # 30± 5 days**: The patient will receive a phone call or personal interview (if still hospitalized) from one of our team members. A Long-Term Prevena Recovery Questionnaire (appendix C) will be completed during the calls regarding the patient's recovery. Questions about any possible wound complications include: incision check-up (changes in wound appearance and any of the signs mentioned above), development of any new symptom (fever, bowel habit changes, and nutrition habits).

Note: This time frame for follow up was chosen because:

a. It will minimize data lost to follow up.
b. It will maximize the opportunity for detection of infection, since the majority of SSIs are apparent by postoperative day 3-5.
c. The standard of care at the Johns Hopkins surgical department includes a post-op check and visit 5 to 14 days following surgery.

b. Study duration and number of study visits required of research participants.

Based on the annual number of open procedures at John Hopkins Medical Institutes the investigators anticipate completing the inclusion of patients within a two-year period. Therefore, we plan to enroll a total of **n= 108** patients over two years.

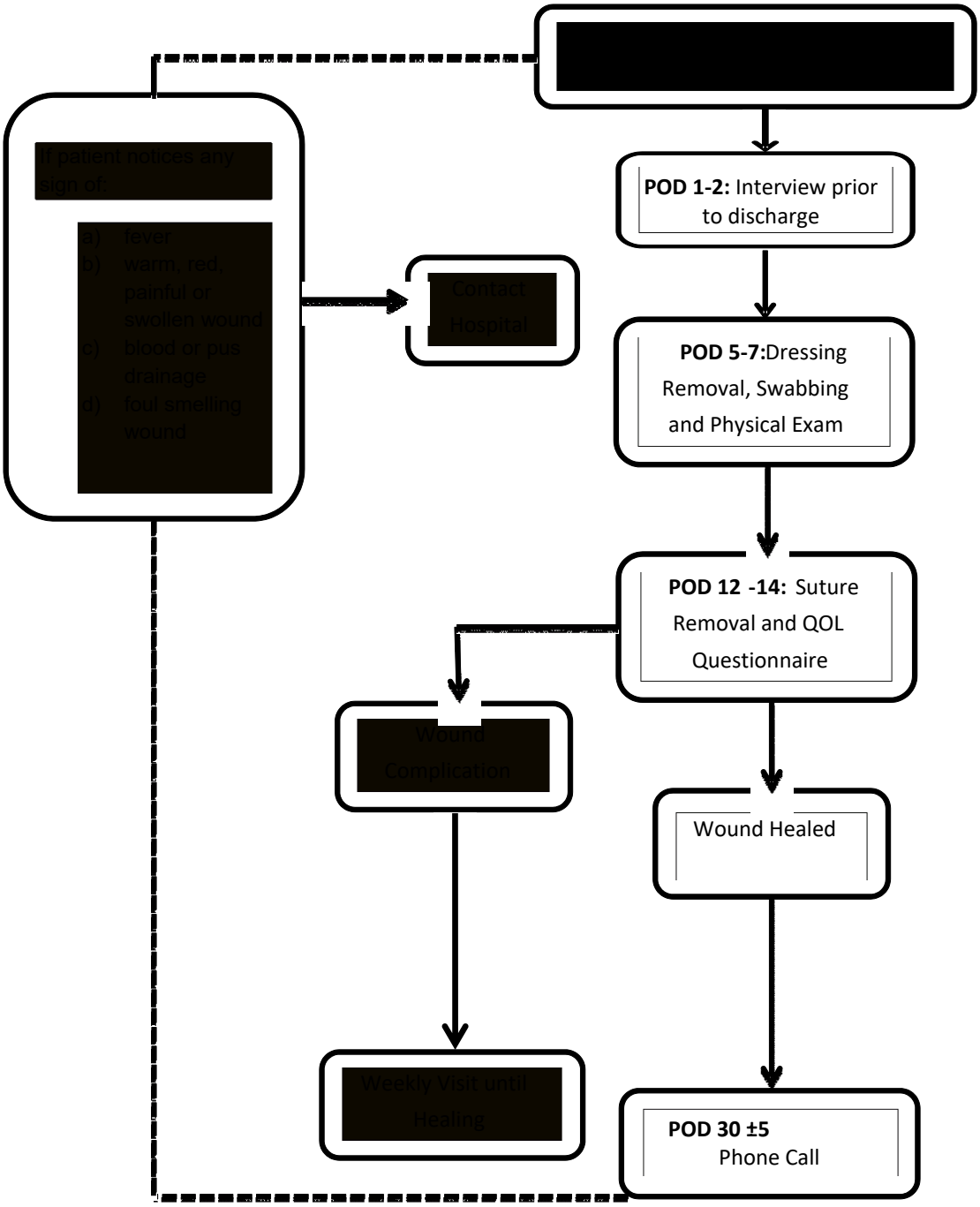
Each eligible patient will have an equal chance of being in either group (Prevena vs. standard dressing) regardless of age or comorbid conditions. However, at 6-month intervals a statistical analysis will compare covariates between the two groups. If there are any statistically significant differences between the Prevena/ Non-Prevena groups in numbers of diabetics, smokers or immuno-compromised patients (such as being on steroids) an attempt will be made to equalize the numbers on both sides for the following 6-month period. Once randomized, the participant will undergo the specified procedure and at the conclusion of the case when the incision is closed have either Prevena vs. Standard of Care dressing applied. The dressing will be monitored over a 5 day period where it will then be removed. The participant will be followed thereafter until their sutures/skin staples are removed (Figure 1).

Each participant will be followed though POD 30-35. This time frame for follow up was chosen because:

a. It will minimize data lost to follow up.
b. It will maximize the opportunity for detection of infection, since the majority of SSIs are apparent by postoperative day 3-5.
c. The standard of care at the Johns Hopkins surgical department includes a post-op check and visit 5 to 14 days following surgery.

Participants will be seen on the day of surgery, POD1-2, POD 5-7, POD 12-14, and POD 30±5 for a total of 5 encounters.

Figure 1: Incisional Wound Dressing Protocol



INNOVATIONS AND LIMITATIONS

With the overwhelming rise in obesity in the US more and more patients will present for open surgical interventions. Thus, we need better methods to reduce wound complications and morbidity. Any decrease in wound complication rates translates into improved health costs. According to our own experience at our institution, Prevena¬¬ is a very promising product. It may be instrumental in lifting a large burden of health costs related to wound infections and increased hospitalization, especially for the obese patient. We believe that this randomized controlled study we propose may pave the way for Prevena to become the standard of care in the near future.

Innovation: There are several innovative aspects to this proposal. First, this is the first randomized controlled study of this size to assess the effect of Prevena use on wound infection rate. Second, this is the first study to assess the use of Prevena in the obese population. While, wound infection rates are kept to a minimal in clean abdominal surgeries in normal weight adults, obese patients are particularly at risk of high infection and complication rates. In our opinion, these are the surgical patients that yield the best cost-to-benefit ratio for Prevena use. Third, this is the first study to assess the effect of Prevena use on ALL possible wound complication rates (dehiscence, delayed healing, abscess formation…etc). Fourth, we will be studying larger numbers of participants than previous human studies that have examined the use of Prevena in the past. Finally, we will be assessing the bacterial count after Prevena versus standard dressing care use. We believe that this may support stronger evidence that the Prevena system decreases wound infection rates and promotes faster and more successful healing.

Potential Problems and Alternative Strategies: We acknowledge that the patient may not tolerate the Prevena dressing (patient adherence) – though we received very positive results from patients we piloted Prevena on and many say that they like the way it feels. However, if at any time a patient develops an allergic reaction or is unable to tolerate the Prevena dressing (such as severe incision site skin irritation or discomfort) it will be replaced by standard gauze dressing and the patient's hypersensitive reaction will be treated according to best medical management. In such case of crossover between the two treatment groups a sensitivity analysis will be performed to decide whether the number of crossover cases will have a significant effect on the outcome of the study. However, all protocol deviation cases and secondary outcomes will be reported in our final paper.

c. Blinding, including justification for blinding or not blinding the trial, if applicable.

This is a prospective single blinded randomized clinical trial. It is blinded in order to minimize any potential bias the participants may have for or against the new Prevena in comparison to the standard of care dressing.

d. Justification of why participants will not receive routine care or will have current therapy stopped.

All participants will receive routine care and will not have current therapy stopped.

e. Justification for inclusion of a placebo or non-treatment group. **Not applicable**

f. Definition of treatment failure or participant removal criteria.

In case of intolerance or development of an allergic reaction (such as severe incision site skin irritation or discomfort) it will be replaced by standard gauze dressing and the patient's hypersensitive reaction will be treated according to best medical practice.

g. Description of what happens to participants receiving therapy when study ends or if a participant's participation in the study ends prematurely. **Not applicable**

2. Inclusion/Exclusion Criteria

Inclusion criteria:
1. Must be at least 18 years of age.
2. Patient has been informed of the nature of the study, and has provided written informed consent, approved by the appropriate Institutional Review Board (IRB) / Medical Ethics Committee (MEC) of the respective clinical site.
3. Patient meets the criteria for and is undergoing open surgery at Johns Hopkins Medical Institutes.
4. Patient with BMI≥ 30 at the time of surgery
5. Patient agrees to return for all required clinical follow up for the study.

Exclusion criteria:
1. Known allergic reaction to acrylic adhesives or silver.
2. Known history of intolerance to any component of Prevena Incision Management System™.
3. Very fragile skin around incision site.
4. Bleeding disorder or refuses blood transfusion.
5. Malignancy or other condition limiting life expectancy to <5 years.
6. Pregnancy.

3. Drugs/ Substances/ Devices

a. The rationale for choosing the drug and dose or for choosing the device to be used.

Obese patients (BMI≥30) undergoing open surgery procedures will have decreased surgical site infection rates, improved healing time, better quality of life (QOL) and lower readmission rates with use of Prevena in the post-operative management of surgical incisions.

b. Justification and safety information if FDA approved drugs will be administered for non-FDA approved indications or if doses or routes of administration or participant populations are changed. **Not applicable**

c. Justification and safety information if non-FDA approved drugs without an IND will be administered. **Not applicable**

4. Study Statistics

a. Primary outcome variable: Postoperative surgical site infection incidence

b. Secondary outcome variables:
   1. Other wound complications (such as dehiscence, seroma and hematoma)
   2. Skin bacterial count after treatment

3. Wound healing time
4. Quality of life scores (SF-36 or VQL)

c. Statistical plan including sample size justification and interim data analysis.

Power and sample size were calculated using SamplePower 2, alpha set at .05, and power of at least 80%. Current literature values suggest a similar SSI rate of 17-24%.(14, 15)

The use of Prevena has been tested in a small retrospective study (52 Prevena devices) of groin incisions in vascular surgery that yielded a large difference of 24% in SSI rates (Prevena 6%, Non-Prevena 30%).(15) Another retrospective study of Prevena use in plastic surgery showed a difference of 17% in SSI rates in patient groups receiving skin grafts (Prevena 3%, Non-Prevena 20%).(14) However, to this date the use of Prevena has not been documented in obese patients.

For a difference of 24% between control and Prevena groups, 27 patients per group (N=54) are needed to achieve power of 80%. Decreasing the group difference to 20% requires 39 patients per group (N=78) for power of at least 80%. Decreasing the group difference even further to 17% requires 54 patients per group (N=108) for power of at least 80%. To detect a smallest difference of 17%, we estimated the need for a total of 108 patients to be enrolled in this study.

d. Early stopping rules.
    1. Inability to tolerate the Prevena Wound VAC
    2. Allergic reaction to the Prevena Wound VAC
    3. Evidence of wound infection during the use of Prevena Wound VAC
    4. Fever of >38.0 during the time the Prevena Wound VAC is in place (the wound VAC should be removed and infection of the skin ruled out)
    5. Statistical evidence that the Prevena Wound VAC has better outcomes versus the standard of care wound dressing*

*we will carry out a review of the outcomes every 6 months in this study

In order to alleviate the possibility of diabetes and smoking influencing a patient's wound healing outcomes, we stratified our randomization groups into 4 strata:

1) Diabetic Smoker
2) Diabetic Non-smoker
3) Non-diabetic Smoker
4) Non-diabetic non-smoker

Given our sample size we ran the randomization schemes for up to 60 patients in each strata.

5. Risks

a. Medical risks, listing all procedures, their major and minor risks and expected frequency.

Generally speaking there is minimal risk in participating in this study. If the patient is randomized to the standard of care they will receive our Centers standard of care for incisional wounds. If the patient is randomized to the Prevena incisional wound VAC system they may experience the following:

1. Discomfort and inability to tolerate the incisional wound VAC system: In this situation the dressing will be inspected by the Principle Investigator or wound nursing team who will ensure that the VAC system is properly placed and working correctly. In the event that the patient is still unable to tolerate the device, it will be removed and the patient will be excluded from the study.

2. Skin abrasion or irritation: If on inspection the skin edges at the incision appear to be red or irritated the incisional wound VAC will be removed and the incision inspected. The patient would be removed from the study.

3. Allergic reaction to the device: If at any time during the study the patient appears to have an allergic reaction to the incisional wound VAC device. The Principle Investigator will determine if the dressing needs to be removed and the patient will be removed from the study.Redness or erythema, fever, signs of infection: Should there be any concern for infection under the incisional wound VAC, it will be removed immediately and the incision assessed by the Principle Investigator, Nurse Practitioner or Physician Assistant. Appropriate standard of care will be initiated should the wound indeed be infected. This may include opening and draining the incision, wet to dry dressing changes and antibiotics treatment.

b. Steps taken to minimize the risks.

Follow standard surgical procedures and placement of wound dressing or Prevena Wound VAC.

c. Plan for reporting unanticipated problems or study deviations.

All events will be reported to the JHM IRB as required by the JHM IRB reporting guidelines posted on the JHM IRB website.

d. Legal risks such as the risks that would be associated with breach of confidentiality.

There should be no legal risks by participating in this study. None beyond those associated with routine care.

e. Financial risks to the participants.

None beyond those associated with routine care.

6. Benefits

a. Description of the probable benefits for the participant and for society.

No direct benefits for study subjects, but the results of this work may improve care of future bariatric patients.

7. Payment and Remuneration

a. Detail compensation for participants including possible total compensation, proposed bonus, and any proposed reductions or penalties for not completing the protocol.

There is no compensation to participate in this study. We are randomizing patients to standard of care dressing versus the Prevena Wound VAC dressing (which is being provided by the sponsor). There are no extra visits or extra time involved above and beyond the standard of care for the patient.

8. Costs

a. Detail costs of study procedure(s) or drug(s) or substance(s) to participants and identify who will pay for them.

Costs of the Prevena Wound VAC and the microbiology swabs are being covered by the study. Participants (or insurance) are responsible for paying the cost of the routine standard of care and follow-up clinical examination visits that are included following bariatric surgery.

APPENDIX A (SF-36 Questionnaire)

Standard Form – 36 (SF-36)	
Patient Name:	Date:

Standard Form 36 Survey: The SF-36 Form is one of many outcomes assessments designed by the Medical Outcomes Trust in Boston, MA. It is designed to approximate the improvement in health status from a medical intervention.

INSTRUCTIONS: This survey asks for views about your health. This information will help keep track of how you feel and how well you are able to do your usual daily activities. Answer every question marking the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is: (Circle One)	1. Excellent 2. Very Good 3. Good 4. Fair 5. Poor

2. Compared to one year ago, how would you rate your health in general at this time? (Circle One)	1. Much better now than one year ago 2. Somewhat better now than one year ago 3. About the same as one year ago 4. Somewhat worse than one year ago 5. Much worse now than one year ago

3. The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?
(Circle the appropriate number for each question)

Activities	**Yes, limited a lot**	**Yes, limited a little**	**No, not limited**
a. Vigorous activities, such as running, lifting heavy Objects, or participation in strenuous sports	1	2	3
b. Moderate activities, such as moving a table, Vacuuming, bowling or golfing	1	2	3
c. Lifting or carrying groceries	1	2	3
d. Climbing several flights of stairs	1	2	3
e. Climbing one flight of stairs	1	2	3
f. Bending, kneeling, or stooping	1	2	3
g. Walking more than a mile	1	2	3
h. Walking several blocks	1	2	3
i. Walking one block	1	2	3
j. Bathing or dressing yourself	1	2	3

4. During the past 4 weeks, have you had any of the following problems with your work or other regular activities as a result of your physical health? (Circle the appropriate number for each question)		
a. Cut down on the amount of time you spent on work or other activities	Yes = 1	No = 2
b. Accomplished less than you would like	Yes = 1	No = 2
c. Were limited in the kind of work or other activities	Yes = 1	No = 2
d. Had difficulty performing the work or other activities (For example – requiring an extra effort)	Yes = 1	No = 2

5. During the past four weeks, have you had any of the following problems with your work or other regular daily activities as result of any emotional problems (such as feeling depressed or anxious)? (Circle the appropriate number for each question)		
a. Cut down on the amount of time you spent on work or other activities	Yes = 1	No = 2
b. Accomplished less than you would like	Yes = 1	No = 2
c. Didn't do work or other activities as carefully as usual	Yes = 1	No = 2

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors or groups? (Circle one)	1. Not at all 2. Slightly 3. Moderately 4. Quite a bit 5. Extremely

7. How much bodily pain have you had during the past 4 weeks? (Circle one)	1. None 2. Very mild 3. Mild 4. Moderate 5. Severe 6. Very severe

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)? (Circle one)	1. Not at all 2. Slightly 3. Moderately 4. Quite a bit 5. Extremely

9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks: (Circle one number on each line)

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
a. Did you feel full of pep?	1	2	3	4	5	6

b. Have you been a very nervous person?	1	2	3	4	5	6
c. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
d. Have you felt calm and peaceful?	1	2	3	4	5	6
e. Did you have a lot of energy?	1	2	3	4	5	6
f. Have you felt downhearted and blue?	1	2	3	4	5	6
g. Did you feel worn out?	1	2	3	4	5	6
h. Have you been a happy person?	1	2	3	4	5	6
i. Did you feel tired?	1	2	3	4	5	6

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives etc.)?(Circle one)	1. All of the time 2. Most of the time 3. Some of the time 4. A little of the time 5. None of the time

11. How TRUE or FALSE is each of the following statements to you? (Circle one for each line).					
	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
a. I seem to get sick easier than other people	1	2	3	4	5
b. I am as healthy as anybody I know	1	2	3	4	5
c. I expect my health to get worse	1	2	3	4	5
d. My health is excellent	1	2	3	4	5

APPENDIX B (Short-Term Prevena Recovery Form)

Short-Term Prevena Recovery Form

Pt Initials_____ Bayview No_____ Date of operation_____ Width of foam used: _____

	POD#1	POD#2	Condition at Discharge
Seal intact Y/N			
Drainage Amount (in ml)			
Drainage type (Serosang, Sang, Serous, Purulent)			
Odor Y/N			
Erythema Y/N			
Ecchymosis Y/N			
Edema Y/N			
Seroma Y/N			
Incision intact Y/N			
Patient's tolerance to VAC 1=excellent 2=good 3=fair 4=poor			
NPO Y/N			
Voiding Y/N			
Last name of person completing evaluation			

Time to first ambulation following surgery (specify unit please): _____

Comments_____

_____

_____

_____

_____

_____

**********Please return questionnaire to designated bin**********

Appendix C (Long-Term Prevena Recovery Form)

Long-Term Prevena Recovery Form

Pt Initials_____ Bayview No_____ Date of operation_____

	POD#30
Incision Closed/Intact Y/N	
Incision Redness Y/N	
Skin Discoloration Around Incision Y/N	
Incision Foul Odor Y/N	
Incision Painful/ Swollen Y/N	
Incision Leaking Blood/Pus Y/N	
Fever/Chills Y/N	
Change in Bowel Habits Y/N If Yes Diarrhea/Constipation	
Patient's Overall Experience 1=excellent 2=good 3=fair 4=poor	

Date of Interview_____

Was the interview by: Phone_____ Personal Interview _____

Comments_____

APPENDIX D: A Case Report

A 67 year old white female was transferred emergently to Johns Hopkins Bayview Medical Center from an outside hospital. She had presented to her local ER with an acute onset of severe chest pressure ("it felt like an elephant was standing on my chest") followed by worsening epigastric pain. Her past medical and surgical history is significant for hypertension, hyperlipidemia, seizures and s/p laparoscopic Roux-en Y gastric bypass in 2004. She had lost approximately 100lbs with the procedure; however, unfortunately she gained all of this weight back and was now 300lbs with a calculated BMI of 54.5. As a consequence of her weight gain she suffered from back and knee pain and was taking 600mg of Advil twice daily for the last 6 months. When she had this acute onset of chest and abdominal pain she also took 6 baby aspirin as she feared she was having a heart attack.

A CT scan of her abdomen revealed free air. She was rushed emergently to the OR as a level 1. Upon entry into her abdomen the surgeons were met with murky gastric contents throughout. The patient had a complete blow-out of her gastrojejunostomy due to a perforated marginal ulcer.

The patient underwent takedown of her gastrojejunostomy and removal of her Roux limb, a gastrogastrostomy – reversal of her gastric bypass. Given the patient's size (BMI=54), the friable tissue, inflammatory changes and the patient being hypercoagulable (EBL=1.5 L), the operative time was approximately 6 hours. The abdomen was thoroughly washed-out; two Jackson Pratt drains were placed at the anastomosis and the fascia was closed with a looped 0 Maxon suture in a running fashion. The subcutaneous tissue (5 cm deep) was re-approximated with 2.0 Vicryl in an interrupted fashion in two layers. The skin was re-approximated using skin staples placed at least 1 cm apart.

Finally, an incisional wound VAC dressing was placed. The VAC dressing was left in situ until POD #5 when it was removed (Fig. 1). The patient has done remarkably well post-operatively. She had an UGI completed on POD#3 and her diet was advanced. She has remained afebrile with stable vital signs and a normal WBC. The abdominal incision is clean, dry and intact without any signs of infection.

Figure 2: Abdominal Incision on POD #5 after Removal of the Incisional Wound VAC

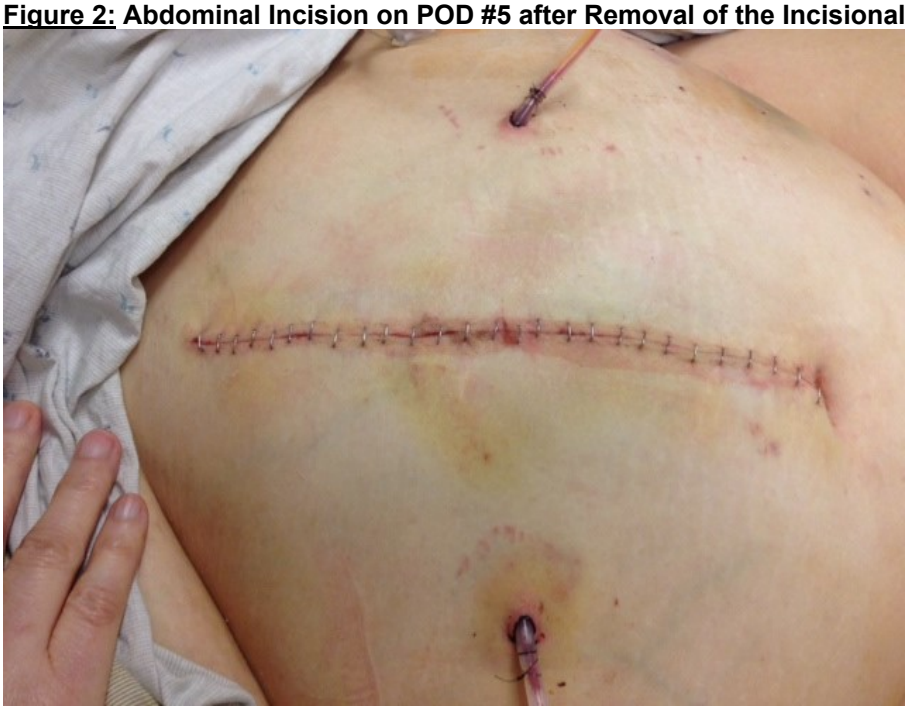
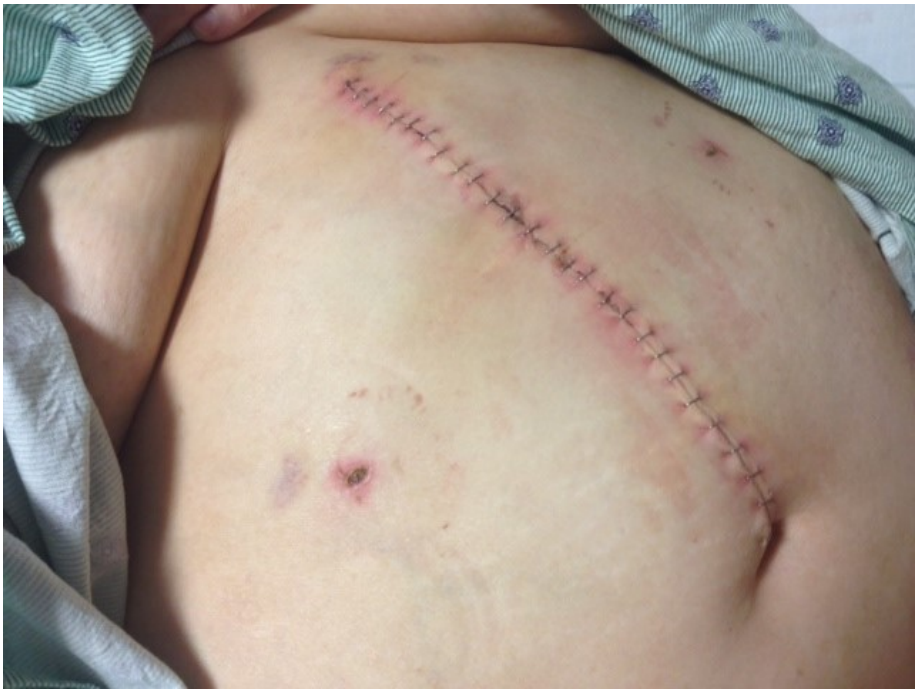
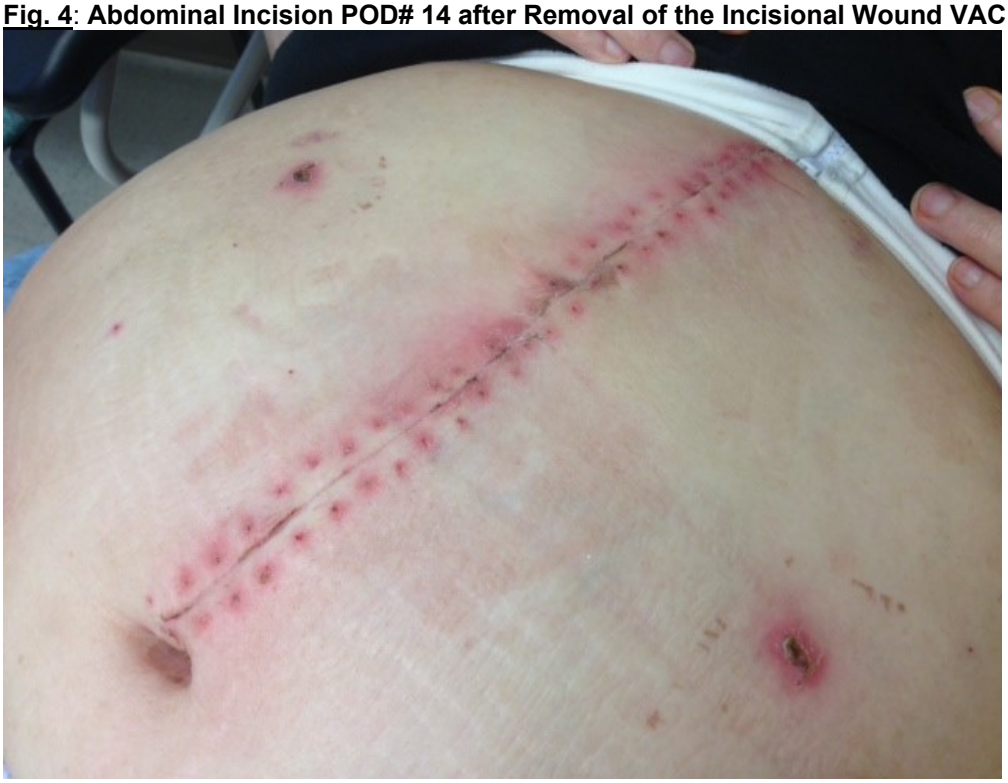


Figure 3: Abdominal Incision on POD # 10 after Removal of the Incisional Wound VAC



* On Post-operative day 10, there is minimal irritation secondary to the skin staples. There is no sign of infection or seroma. The skin edges remain well approximated without any drainage. WBC is normal.

Fig. 4: **Abdominal Incision POD# 14 after Removal of the Incisional Wound VAC**



*****On Post-operative day 14, the patient returned for post-operative check-up. The skin staples were removed and there is minimal irritation secondary to the skin staples. There remains no sign of infection or seroma. The skin edges remain well approximated without any drainage. WBC is normal and the patient is doing extremely well.

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