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University of Minnesota

Negative Pressure Wound Therapy in Obese Patients Undergoing Laparotomy for Gynecologic or Other Abdominal Cancer: A Randomized Controlled Trial

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07/30/2013	original to Kinetic Concepts Inc. (KCI)		07/30/2013
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Synopsis

Overview:
Most gynecologic and many intra-abdominal malignancies are treated with an initial surgical procedure. Over the past 20 years there has been a dramatic increase in obesity rates in the US with more than one third (35.7%) of US adults being obese (BMI > 30kg/m^2) or morbidly obese (BMI>35 kg/m^2). There is a direct link between obesity and wound complications following surgery with an increasing BMI leading to increasing rates of complications. Negative pressure wound therapy (NPWT) is a system that utilizes sub-atmospheric pressure to improve wound healing by increasing the formation of granulation tissue. NPWT has been shown to improve outcomes in both the orthopedic and cardiothoracic surgery populations. To date, there is no prospective study evaluating the application of prophylactic NPWT in laparotomy patients.

Primary Objective:
To evaluate the rate of wound complications with negative pressure wound therapy (NPWT) as compared to standard surgical closure and post-operative wound care in obese patients (BMI ≥35 kg/m^2) undergoing laparotomy for a suspected gynecologic malignancy or other abdominal cancer.

Secondary Objective:
To compare the time between surgery and the start of anti-cancer therapy (chemotherapy and/or radiation therapy) between those patients diagnosed with a malignancy who received NPWT and those who received standard surgical closure

Patient Population:
Morbidly obese (BMI ≥ 35 kg/m^2) adult patients presenting for surgical treatment of a known or suspected gynecologic malignancy or other abdominal cancer by laparotomy incision

Study Procedures:
After screening and obtaining written consent, but prior to surgery 1:1 randomize to either:

- Negative pressure wound therapy (NPWT)
- Standard surgical closure

Assess wound complications at 1st post-operative visit (10-14 days after initial procedure)

If no cancer diagnosis, final study assessment at 1st post-operative visit

If cancer diagnosis is made, chart review at 3 months post-surgery to determine time between surgery and start of anti-cancer therapy (chemotherapy and/or radiation therapy)

Enrollment Goal:
200 patients randomized over 24 months

1.0 Introduction and Overview

Up to 90% of type I (estrogen-dependent) endometrial cancer patients are obese[1] and obesity is considered a risk factor for both endometrial and ovarian cancers[2]. Most gynecologic malignancies are treated with an initial surgical procedure. A number of colorectal diseases are also increased with obesity including diverticular disease and colorectal cancer[15,16, 17]. A central challenge for surgeons is the increase in the rates of wound complications following surgery given the rise in obesity. The rate of wound complications for gynecologic oncology procedures is 34% overall and is highly correlated with BMI[4]. Patients with a BMI of ≥40 kg/m^2 had a 10 fold increase in the risk of wound complications compared to normal weighted patients[6]. Some patients are able to circumvent this problem with a minimally invasive approach to their surgery; however, obesity increases the risk of conversion to an open procedure. Wound complications are not only distressing to patients but can also delay necessary adjuvant therapy such as chemotherapy and radiation.

Negative pressure wound therapy (NPWT) is a system that utilizes sub-atmospheric pressure to improve wound healing by increasing the formation of granulation tissue. The mechanism for this improved wound healing is thought to be increased local blood flow, mechanical stress at the wound surface, removal of factors that inhibit wound healing and decreased bacterial burden. To date there are good data to show the benefit of using NPWT to treat wound complications that arise post-operatively. In the orthopedic and cardiothoracic surgery literature there is evidence to suggest that prophylactic NPWT placed over a closed incision decreases wound dehiscence and infection rate, with a 40% decrease in orthopedic patients and 4-fold decrease in morbidly obese cardiothoracic patients. However, to date, there is no prospective study evaluating the application of prophylactic NPWT in laparotomy patients.

2.0 Study Objectives

The primary goal of this study is to evaluate if the use of prophylactic negative pressure wound therapy (NPWT) over a closed incision improves postoperative outcomes and cancer care for morbidly obese (BMI ≥35 kg/m^2) patients undergoing laparotomy for treatment of a suspected gynecologic or other abdominal malignancy is comparable or better to wound healing after standard surgical closure and wound care.

This comparison will be achieved by:

- Assessing the incidence of wound complications, specifically, dehiscence and infection at the 1st post-operative visit (10-14 days after surgery)
- documenting the time from surgery to the start of anti-cancer treatment in a subset of patients receiving a cancer diagnosis by chart review approximately 3 months after surgery

3.0 Background and Significance

The obesity epidemic is a growing problem in the US and its effects are felt very heavily on the gynecologic oncology population. Both endometrial and ovarian cancers are increased in the obese populations[1,2], and the majority of gynecologic malignancies are initially treated with a surgical procedure. A number of colorectal diseases are also increased with obesity including diverticular disease and colorectal cancer[15,16, 17]. Risks and complications of surgery are much greater in the obese population. The reported rate of wound complications in the gynecologic oncology population is 34-40% depending on the location[4]. Wound complications are highly correlated with patient BMI. These wound complications can lead to a delay in necessary adjuvant therapies such as chemotherapy and radiation. It is known that delays in the initiation of adjuvant therapy can have a negative impact on survival.

NPWT is a system that uses sub-atmospheric pressure to alter the physiologic and chemical environment of the wound bed. It is postulated that this works through several different mechanisms including increased local blood flow, increased mechanical stress leading to increases in cellular proliferation, more effective removal of factors that inhibit wound healing including bacteria and fluid[7,8]. Studies using NPWT in an open laparotomy incision to facilitate healing by secondary intention show that it leads to decreased wound healing time[10]. However, to date, there are few studies evaluating the use of prophylactic NPWT over a closed incision, and most of the existing data is in the orthopedic and cardiothoracic surgery literature. The use of prophylactic NPWT over orthopedic wounds has been shown to decrease wound dehiscence and infection rates by 40%, and has decreased the rate of wound complications 4-fold in obese patients undergoing cardiothoracic surgery[12,13]. However, it is unclear if this same benefit will be seen with abdominal laparotomy incisions.

4.0 Wound Complications at the University Of Minnesota

We performed a retrospective chart review of all patients with a BMI $\geq$ 30 kg/m^2 who have undergone a laparotomy for a known or suspected gynecologic malignancy at our institution in the past 6 months. We found that of 51 obese patients to undergo a laparotomy, 13 (25%) had some form of wound complication, either a wound dehiscence or infection. This is on par with what is reported in the literature. Further, 5 of the 51 patients were readmitted to the University of Minnesota hospital due to their wound complications, for a readmission rate of almost 10%. The results of this chart review were used to inform our sample size calculations.

5.0 Research Design

This is a randomized controlled trial in which eligible patients will be randomized to either a control or intervention group. All patients undergoing laparotomy for a known or suspected gynecologic or other abdominal cancer will be approached for eligibility. Once all eligibility criteria are met, the patient will be consented both with verbal and

written consent procedures. Following consent the patient will be randomized to either: 1) routine closure of the surgical site (control arm); or 2) closure of the wound with a prophylactic NPWT placed over the closed surgical incision. The standard surgical closure consists of closure of the fascia with a looped PDS suture in a running fashion either with the use of a mass closure technique or a Smead Jones closure at the discretion of the operating surgeon, closure of the subcutaneous space if >2 cm deep, followed by staple or suture closure of the skin. These same steps will be followed for the NPWT group with the addition of placement of the NPWT system over this closed incision. This NPWT system will be removed on post-operative day number 2 or 3, prior to patient discharge from the hospital. The staples, if used, will then be removed in the usual time frame of anywhere from 10 to 21 days post-operatively. This will also allow for standardized evaluation of the patient's wound to determine if there have been any wound complications since their surgery. Patients will be followed for the development of any wound complications including infection, dehiscence and evisceration for 4 weeks after surgery. For patients who develop a wound complication, we will track required therapies, including readmission to the hospital, reoperation, antibiotic therapy, wound opening with healing by secondary intention, including method of wound care and duration of wound healing. For patients requiring adjuvant therapy (chemotherapy and/or radiation), we will record duration from time of surgery to initiation of adjuvant therapy.

6.0 Patient Selection

Study entry is open to adult patients regardless of gender, race or ethnic background. While there will be every effort to seek out and include minority patients, the patient population is expected to mirror the obese patient population at the University Of Minnesota.

Inclusion Criteria

6.1 Known or suspected gynecologic or other abdominal malignancy (such as colorectal, liver, pancreatic, kidney and stomach) for which laparotomy is planned

6.2 Obese – defined as a Body Mass Index (BMI) ≥ 35 kg/m^2 as calculated in the Epic computer record

6.3 18 years of age or older

6.4 Able and willing to provide written consent

Exclusion Criteria

6.5 Known true tape allergy

6.6 Sensitivity to silver

6.7 History of intolerance to Negative Pressure Wound Therapy

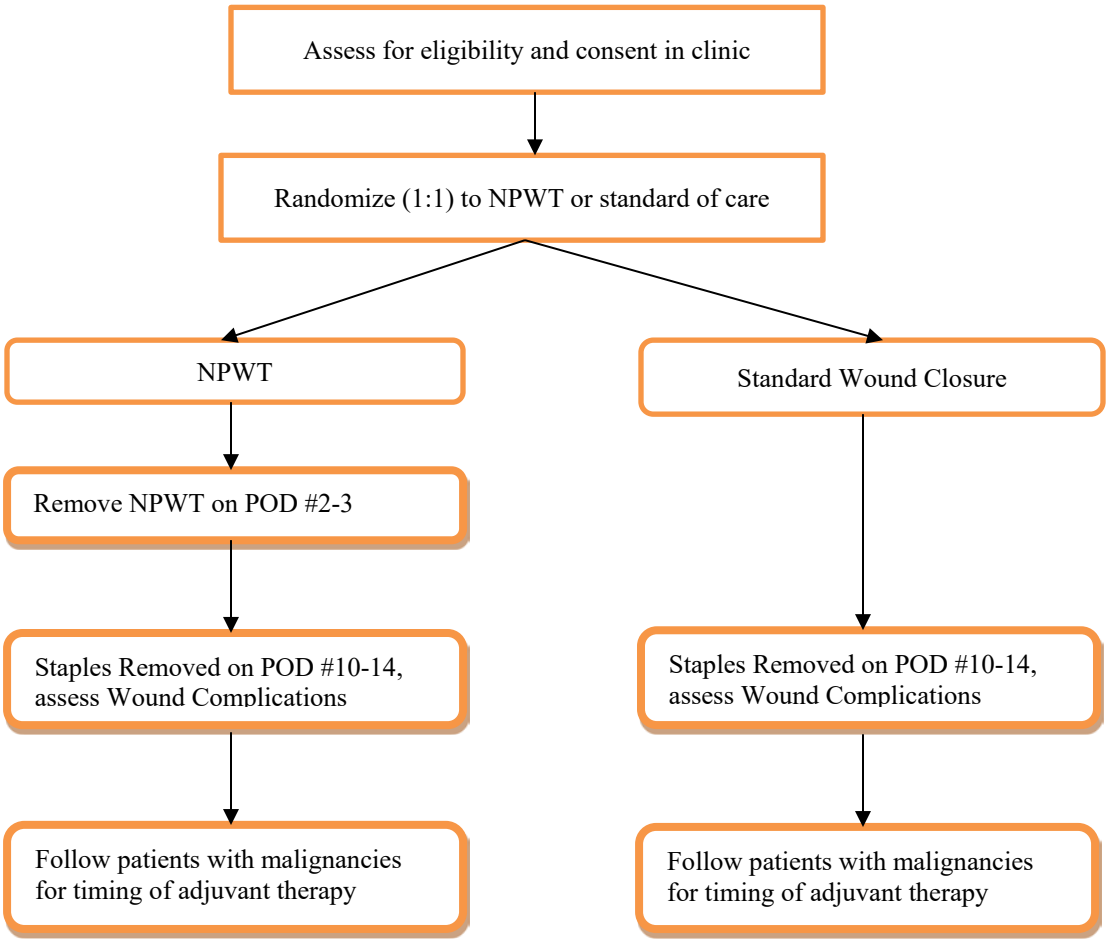
7.0 Patient Registration and Randomization

Patients will be registered into OnCore after written consent is provided and eligibility is confirmed (appendix I), but prior to the performance of any research related procedures.

Randomization will occur at the time of registration. To prevent bias and minimize the possibility of confounding, consenting patients will be randomly assigned 1:1 to either NPWT or standard of care.

8.0 Study Procedures

8.1 Study Plan



8.2 Assigned Care (Standard Closure and Wound Care vs. Standard Closure with Negative Pressure Wound Therapy)

8.2.1 Standard Closure and Wound Care

The standard surgical closure consists of closure of the fascia with a looped PDS suture in a running fashion either in with the use of a mass closure technique or a Smead Jones closure at the discretion of the operating surgeon, closure of the subcutaneous space if >2 cm deep, followed by staple or suture closure of the skin.

Post-operative wound care will be standard of care per institutional guidelines.

8.2.2 Standard Closure and Negative Pressure Wound Therapy

The same standard surgical closure as used by the standard of care group will be used for patients randomized to prophylactic placement of the Prevena™ Incision Management System. As in the previous section it consists of closure of the fascia with a looped PDS suture in a running fashion either in with the use of a mass closure technique or a Smead Jones closure at the discretion of the operating surgeon, closure of the subcutaneous space if >2 cm deep, followed by staple or suture closure of the skin.

The Prevena™ Incision Management System will be placed over the closed incision. It will be removed on post-operative day 2 or 3 as clinically indicated and prior to the patient's discharge from the hospital.

8.3 Risks of Study Participation

8.3.1 Standard of Care

Risks to the patients randomized to standard of care will be no different than undergoing the same surgical procedure without participating in this study.

8.3.2 Negative Pressure Wound Therapy (NWPT)

NPWT has very few complications associated with its use. There are few reports of fistula development with the use of NPWT but these are in patients where the NPWT has been placed directly over intestines and not on a closed incision. Additionally, NPWT is widely used in treatment of an open wound, and placed directly over the fascia with few reported complications. When large amounts of fluid are removed from an incision large fluid losses can lead to hemodynamic changes in patients; however, it is anticipated that this fluid loss would be much greater in an open wound (NPWT is placed directly over the fascia and within the subcutaneous tissue) than over a closed wound. Fluid status will be followed closely and managed per the standard postoperative protocol.

There are also some less serious complications such as local cutaneous reactions (rash, redness, pruritis, urticarial), allergic reaction, maceration, minor soft tissue damage, skin stripping, minor bleeding, pain, bruising. All patients will be monitored closely for signs of skin irritation and will be treated appropriately with barrier creams as needed. In cases where NPWT is used to aid in healing by secondary intention, the NPWT is in place for weeks to months with minimal skin irritation; it is anticipated that this risk of irritation will be even lower when the NPWT device is in place for only 2-3 days.

There are some other uncommon risks associated with the NPWT including,

bleeding complications (associated with the surgical procedure, concomitant therapies and co- -morbidities), first degree burn (if device gets warm), exposure related infection, localized infection, physical discomfort, minor desiccation (due to dressing leak), moderate soft tissue damage (i.e. due to trip hazard, tubing entanglement) and deterioration of the wound (due to lack of visibility of incision site through dressing.

8.3.3 All Patients, Regardless of Post-Operative Care

There is a small risk of loss of confidentiality; however steps will be taken to minimize this by assigning the patient a unique patient identifier at the time of study enrollment to be used in place of direct identifiers. A master list will be kept in OnCore, the Cancer Center's password protected clinical database that resides on the University of Minnesota server.

8.4 Supportive Care

Optimal patient care will be given to all patients regardless of their post-operative wound care assignment per institutional guidelines, including those for infection control.

8.5 Duration of Study Participation

It is expected the duration of study participation will be less than 2 months.

All patients will be assessed for wound complications (including infection, dehiscence and evisceration) at their 1st post-operative visit approximately 10-14 days after surgery.

Patients will continue to be tracked for wound complications for a minimum of 4 weeks after surgery by review of clinic notes/medical records. For patients who develop a wound complication, the type of complication, treatment received and outcomes will be captured.

For patients with a cancer diagnosis that requires anti-cancer therapy (chemotherapy and/or radiation), the therapy start date of therapy will be recorded.

9.0 Prevena™ Incision Management System[14]

The Prevena Incision Management System will be provided by Kinetic Concepts Inc. (KCI) for the purposes of this study.

9.1 Indication for Use

The Prevena Incision Management System is intended to manage the environment of surgical incisions that continue to drain following suturing or stapling by maintaining a closed environment and removing exudate by negative pressure

wound therapy. This study intends to use the device according to its approved indications.

9.2 Optimum Use Conditions

For maximum benefit is should be applied immediately post-surgery and used continuously for a minimum of two days and up to a maximum of seven days. For the purposes of this study the device will be used for two to three days with removal prior to discharge from the hospital.

9.3 Contraindications

Sensitivity to silver – potential participants of this study with a history of this sensitivity will be excluded per section 6.6.

9.4 Warnings – refer to the Clinician Guide for full details http://www.kci1.com/cs/Satellite?c=Page&childpagename=KCI1%2FKCILayout&cid=1229636259704&pagename=KCI1Wrapper

- Bleeding – before applying, ensure that hemostasis has been achieved and tissue planes have been approximated. If active bleeding develops or frank blood is seen in the tubing or canister leave the Dressing place, but turn off the device and provide immediate medical assistance.
- Infected wounds – monitor the wound, peri-wound area, exudate, and patient's general clinical status for signs of infection; if infection develops Prevna Therapy should be discontinued
- Allergic response – the Prevena Incision Dressing has an acrylic adhesive coating and a skin interface layer lined with silver which may present a risk of an adverse reaction in patients with known hypersensitivity. Patients with a known silver or tape sensitivity are not eligible for this study.
- Defibrillation – remove the Prevena Incision Dressing if defibrillation is required in the area of the dressing placement
- Magnetic Resonance Imaging (MRI) – the Prevena Therapy Unit is unsafe in the MRI environment and interruption of therapy during an MRI may reduce its effectiveness. The Dressing can typically stay in place during the MRI.
- Other diagnostic imaging - the Prevena Incision Dressing contains metallic silver which may impair visualization with certain imaging modalities.
- Hyperbaric Oxygen Therapy – do not take the Prevena Therapy Unit or the Prevena Incision Dressing into the chamber
- Canister full – if any time the canister becomes full of fluid as indicated by the Maximum Capacity Alert or visual inspection, turn off the therapy unit and attend to the canister.

Refer to the Prevena Incision Management System website with links to the Clinician Guide for complete device details. http://www.kci1.com/KCI1/prevena#

10.0 Statistical Considerations

10.1 Data Analysis

The patient population demographics will be descriptively summarized both combined and by treatment randomization. All analyses will be conducted under the intention-to-treat principle and all deviations and adverse events will be reported.

Our primary aim is to compare rate of wound complications (wound dehiscence or infection) identified within first month after surgery by treatment group (standard of care or NPWT). As this is a large randomized trial, the comparison will first be made using a Chi-squared test as we anticipate approximate balance in all measured and unmeasured confounders. These results will be supplemented using logistic regression, including demographics and clinical variables (including surgeon) as appropriate.

Our secondary aim is compare the time from surgery to starting adjuvant therapy among those with confirmed malignancies. This will be measured in days and will be available regardless if patients undergo treatment at our study facilities as their surgeon will manage their care and maintain contact up to 6 months regardless of follow-up location. The effect of NPWT on the length of the number of days until treatment will be assessed using Poisson regression, adjusting for over-dispersion if necessary. As stated above, we will supplement these results adjusting for demographic and clinical variables as appropriate.

For all analyses, p-values of less than 0.05 will be considered statistically significant and will be performed using SAS software version 9.3 (Cary, NC).

10.2 Sample Size Calculations

As stated in the Section 4, we retrospective chart review of this patient population found 25% rate of wound complications. Group sizes of 97 each (194 total) achieves 80% power to detect a difference between the group proportions of -0.15; in other words, assuming the standard of care group has a complication rate of 25%, we could detect a complication rate in the NPWT group of 10% as being statistically significantly lower using a two-sized Z-test with a significance level of 0.05. This represents a clinically significant change in complication rates while remaining a feasible number to recruit within the study sites. Our proposed sample size is therefore 200 (100 in each group).

The secondary aim is not to formally test hypotheses but rather to describe this outcome and calculate preliminary estimates of differences. Among women undergoing this procedure at our study sites, approximately 70% will be

diagnosed with a malignancy, resulting in a sample size of 140 for this analysis. Among women in the standard of care group, we anticipate they will begin adjuvant therapy within 4-6 weeks after surgery. This sample size is more than sufficient (>90% power) to detect a difference of 1 day in time between surgery and beginning adjuvant therapy.

11.0 Administrative Considerations

11.1 Conduct of the Trial

The study will be conducted in accordance with the appropriate local regulatory requirement(s).

The University Of Minnesota IRB will review all appropriate study documentation in order to safeguard the rights, safety and well-being of the patients. The study will only be conducted at sites where IRB or Campus Administrator approval has been obtained. The protocol, consent document, written information given to the patients, annual progress reports, and any revisions to these documents will be provided to the IRB by the investigator.

Essential clinical documents will be maintained to demonstrate the validity of the study and the integrity of the data collected. Master files should be established at the beginning of the study, maintained for the duration of the study and retained for a minimum of 6 years after the file has been terminated with the IRB.

11.2 Data Management

Electronic data will be entered by a co-investigator and will be stored on a secure server. Study data will be de-identified before data analysis. Only the researchers directly involved with the study will have access to the data.

11.3 Data and Safety Monitoring Plan

This is a minimal risk, non-therapeutic study.

The Principal Investigator and key research staff will be responsible for preparing reports annually in concordance with this study's Data Monitoring Plan to be reviewed by the University of Minnesota Cancer Center Protocol Review Committee and Institutional Review Board. These reports will focus on recruitment, retention, losses to follow-up, and adherence to protocol. Although the safety concerns for this project are expected to be minimal, reports will include a section on reports of adverse events that may be related to the study procedures.

11.4 Event Reporting to the IRB and Cancer Center's Data and Safety Monitoring Council (DSMC)

Safety concerns for this project are expected to be minimal with skin irritation as the primary expected concern. Any events meeting an unexpected, serious

adverse event defined as reportable (such as hospitalization) on the IRB's website at http://www.research.umn.edu/irb/ae/. The DSMC will be copied on all reports to the IRB.

In addition, to be in compliance with local and federal regulations the following events/problems will be reported to the IRB and DSMC within the 10 working day time frame:

- Any serious event (including on-site and off-site adverse events, injuries, side effects, deaths or other problems) which in the opinion of the local researcher was unanticipated, involved risk to subjects or others, and was possibly related to the research procedures
- Any serious accidental or unintentional change to the IRB-approved protocol that involves risk or has the potential to recur;
- Any deviation from the protocol taken without prior IRB review to eliminate apparent immediate hazard to a research subject;
- Any publication in the literature, safety monitoring report (including Data and Safety Monitoring Reports), interim result or other finding that indicates an unexpected change to the risk/benefit ratio of the research;
- Any breach in confidentiality that may involve risk to the subject or others;
- Any complaint of a subject that indicates an unanticipated risk or that cannot be resolved by the research staff.

12.0 References

1. Nickles Fader A, Nieves Arriba L, Frasure HE, von Gruenigen VE. Endometrial cancer and obesity: Epidemiology, biomarkers, prevention and survivorship. Gyn Onc. 114: 121-27, 2009.

2. Olsen CM, Green AC, Whiteman DC, Sadeghi S, Kolahdooz F, Webb PM.. Obesity and the risk of epithelial ovarian cancer: A systematic review and meta-analysis. Eur J of Cancer. 43: 690-709, 2007.

3. Schouten LJ, Goldbohm RA, van den Brandt PA. Anthropometry, physical activity, and endometrial cancer risk: results from the Netherlands Cohort Study. J Natl Cancer Inst. 96: 1635-38, 2004.

4. Nugent EK, Hoff JT, Gao F, Massad LS, Case A, Zighelboim I, Mutch DG, Thaker PH. Wound complications after gynecologic cancer surgery. Gyn Onc. 121: 347-52, 2011.

5. Iglesias DA, Westin SN, Rallapalli V, Huang M, Fellman B, Urbauer D, Frumovitz M, Ramirez PT, Soliman PT. The effect of body mass index on surgical outcomes and survival following pelvic exenteration. Gyn Onc. 125: 336-42, 2012.

6. Giugale LE, Di Santo N, Smolken ME, Havrilesky LJ, Modesitt SC. Beyond mere obesity: Effect of increasing obesity classes on hysterectomy outcomes for uterine cancer/hyperplasia. Gyn Onc. 127: 326-32, 2012.

7. Venturi ML, Attinger CE, Mesbahi AN, Hess CL, Graw K. Mechanisms and Clinical Applications of theVacuum-Assisted Closure (VAC) Device: A Review. Am J Clin Dermatol. 6(3): 185-194, 2005.

8. Morykwas MJ, Argenta LC, Shelton-Brown EL, McGuirt W. Vacuum-assisted closure: A new method for wound control and treatment: Animal studies and basic function. Annals of Plastic Surgery. 38(6): 553-62, 1997.

9. Dhir K, Reino AJ, Lipana J. Vacuum-Assisted Closure Therapy in the Management of Head and Neck Wounds. Laryngoscope. 119: 54-61, 2009.

10. Schimp VL, Worley C, Brunello S, Levenback CC, Wolf JK, Sun CC, Bodurka DC, Ramireza PT. Vacuum-assisted closure in the treatment of gynecologic oncology wound failures. Gyn Onc. 92: 586-91, 2004.

11. Antony S, Terrazas S. A Retrospective Study: Clinical Experience Using Vacuum-Assisted Closure in the Treatment of Wounds. J of the Nat Am Med Assoc. 96(8): 1073-1077, 2004.

12. Stannard JP, Volgas DA, McGwin G, Stewart RL, Obremskey W, Moore T, Anglen JO. Incisional Negative Pressure Wound Therapy after High-Risk Lower Extremity Fractures. J Orthop Trauma. 26 (1): 37-41, 2012.

13. Grauhan O, Navasardyan A, Hofmann M, M€uller P, Stein J, Hetzer R. Prevention of poststernotomy wound infections in obese patients by negative pressure wound therapy. J Thorac Cardiovasc Surg. 143: 1-6, 2012.

14. Prevena™ Incision Management System – Clinician Guide http://www.kci1.com/cs/Satellite?c=Page&childpagename=KCI1%2FKCILayout&cid=1229636259704&pagename=KCI1Wrapper accessed August 9, 2013.

15. Rosemar A, Anger˚as U, Rosengren A. Body mass index and diverticular disease: a 28-year follow-up study in men. DisvColon Rectum 2008; **51**: 450–455.

16. Renehan AG, Tyson M, Egger M, Heller RF, Zwahlen M. Body-mass index and incidence of cancer: a systematic review and meta-analysis of prospective observational studies. Lancet 2008; **371**: 569–578.

17. Russo A, Franceschi S, La Vecchia C, Dal Maso L, Montella M, Conti E et al. Body size and colorectal-cancer risk. Int J Cancer 1998; **78**: 161–165.

Appendix I – Patient Eligibility Checklist

Negative Pressure Wound Therapy in Obese Patients Undergoing Laparotomy for Gynecologic or Other Abdominal Cancer: A Randomized Controlled Trial

Eligibility Checklist – page 1 of 1

Patient initials ☐☐☐☐ Patient ID ☐☐☐☐ (assigned in OnCore)

INCLUSION CRITERIA

A "NO" response to any of the following disqualifies the patient from study entry.

		Yes	No
1.	Known or suspected gynecologic or other abdominal malignancy (such as colorectal, liver, pancreatic, kidney and stomach) for which laparotomy is planned	☐	☐
2.	Obese – defined as a Body Mass Index (BMI) ≥ 35 kg/m^2 as calculated in the Epic computer record	☐	☐
3.	18 years of age or older	☐	☐
4.	Able and willing to provide written consent	☐	☐

EXCLUSION CRITERIA

A "YES" response to any of the following disqualifies the patient from study entry.

		Yes	No
5.	Known true tape allergy	☐	☐
6.	Sensitivity to silver	☐	☐
7.	History of intolerance to Negative Pressure Wound Therapy	☐	☐

Date consent form signed: _____

Having obtained consent and reviewed each of the inclusion/exclusion criteria, I verify that this patient is:

☐ Eligible ☐ Ineligible Date registered _____

_____ _____

Signature of person verifying eligibility Date

Treatment Assignment: ☐ - SOC ☐ - NPWT