Randomized Controlled Trial of Wound Management With Negative Pressure Dressing Versus Standard Dressing After Revision Arthroplasty.

Jared M. Newman MD, Alison Klika MS, Wael Barsoum MD, Carlos Higuera MD.

Brief Summary

One of the primary causes of un-planned readmission following lower extremity arthroplasty procedures is infection. Continuous wound drainage poses a serious risk for infection and is often initially treated with absorbent dressings and/or oral antibiotics. Studies using negative pressure wound therapy (NPWT) systems have provided some evidence that can effectively treat postoperative wound drainage after arthroplasty procedures and decrease the risk for infection or further reoperation. Some patients with certain comorbidities such as obesity, diabetes and tobacco abuse are at higher risk of wound complications and therefore infection after these procedures. New technology dressings such as silver-coated dressings and NPWT systems may potentially decrease these wound complications and therefore infection. NPWT such as Prevena™ has been shown to decrease tissue edema and wound healing time, and also improve skin graft survival.

These are promising and encouraging results that may justify its use on patients with high risk to sustain wound complications. These findings, although promising, need randomized prospective validation.

The purpose of this study is to compare the use of NPWT (KCI, San Antonio, TX) with standard wound dressings (i.e., Aquacel, ConvaTec, Skillman, NJ) in revision total knee and hip arthroplasty patients.

Additionally, there are no cost-effectiveness studies on this technology, so this question needs to be answered with a cost analysis study comparing current dressings and NPWT such as Prevena™.

Hypothesis and Rationale

We hypothesize that using a NPWT system (i.e., Prevena™) will reduce the number of wound complications, wound drainage and consequently un-planned readmissions and/or reoperations of revision total hip or knee arthroplasty patients at high risk for infection.

Aims

A. To establish the efficacy of negative pressure wound therapy (NPWT) on preventing wound complications that may predispose to re-operation. Including but not limited to drainage, blisters, cellulitis, superficial infection and deep infection.

B. To establish the effect of negative pressure wound therapy (NPWT) on readmission rates and re-operation rates.

C. To establish the potential cost saving effect of the use of negative pressure wound therapy (NPWT) by preventing wound complications, readmissions and re-operations.

Study Population

All patients scheduled for a revision total knee or hip arthroplasty will be considered for the study. If a patient meets inclusion/exclusion criteria, he/she may be approached in 1 of 2 ways:

(1) During a patient's clinical visit. Patients will be given of a copy of the Informed Consent to review.

(2) By phone (see phone script). Those interested in participating in the study will be sent a copy of the Informed Consent by mail, and arrangements will be made to complete the consent process and OrthoMidas preoperative data collection during the patient's preoperative clinical visit just prior to surgery.

The study population will be comprised by all patients undergoing revision joint arthroplasty under the care of doctors Higuera, Barsoum, Murray, Molloy, Bloomfield or Krebs that meet the inclusion/exclusion criteria.

a. Inclusion criteria:

i. Scheduled revision Total Hip or Knee Arthroplasty Procedure (THA, TKA)

ii. Presence of one of the following: BMI greater than 35, use of blood thinners other than ASA after surgery, peripheral vascular disease, depression, diabetes mellitus, current tobacco use, history of prior infection, current use of immunomodulators or steroids, current history of cancer or hematological malignancy, rheumatoid arthritis, renal failure or dialysis, malnutrition, liver disease, transplant status, or HIV.

b. Exclusion criteria:

i. Patient lives >100 miles from hospital

ii. Patient is < 18 years old

iii. Silver allergy

iv. Wound coverage with soft tissue flaps

v. Acute implant failure (i.e. defined as less than 4 weeks since previous surgery in the affected joint or less than 4 weeks of symptoms)

Our expected number of patients to enroll was 160. However, due to screen failures, we will over sample the enrollment to account for these patients.

Informed consent

Consent will be obtained by one of the co-investigators during a clinical visit prior to procedure in the privacy of an examination room or an office. Patients will be informed about the study and inquired about their interest to collaborate. A consent document will be given and key parts of the research study will be explained in lay-terms to the patient to assure full understanding. Any questions regarding the research study will be answered at this time. It will be emphasized that participation is voluntary. Those patients who are willing to participate will be asked to sign the consent document along with the consenting researcher. A signed copy of the consent document will be handed to the patient while another copy is kept in our study file. In the event that an approach prior to the day of procedure is not

feasible, same day of procedure consenting will be attempted. We do not believe that an eventual approach on the same day of procedure would represent an added stress for the patient or a delay to the start of it. Similarly to consent prior to the day of procedure the process will occur in a private setting with ample time to discuss the study's implications.

Research procedures

All enrolled patients assigned by randomization to control and study group will undergo revision surgery arthroplasty for hip or knee following the standard of care technique chosen by the surgeon. Interventions will be divided in three times:

a. Pre-op:

i. Patients will be approached prior to the procedure in the privacy of an examination room or an office to obtain informed consent by authorized research staff. Subjects will be informed about the study and inquired about their interest to collaborate.

ii. Patient data including demographics, medications, comorbidities and prior surgeries will be gathered. No intervention beyond the standard of care will be performed at this stage in any group.

b. Intra-op:

i. Length of incision, thickness of subcuticular fat layer (between skin and fascia) will be measured with a sterile surgical ruler by surgeon and the info relayed to the research fellow present in the case.

ii. Presence of soft tissue defects and integrity of the fascia will be reported.

iii. Study group patients: At the end of the case, after the surgical wound has been closed following the standard of care technique using non-absorbable sutures or staples; wound care will be finished with a sterile negative pressure wound therapy (NPWT) system, Prevena™ (KCI, San Antonio, TX). No intervention beyond the fitting of a Prevena™ dressing will be performed.

iiii. Control group patients: At the end of the case, after the surgical has been closed following the regular technique using non-absorbable sutures or staples; a standard of care sterile wound dressing will be placed. No intervention beyond the standard of care will be performed

c. Post-op:

i. During the hospital stay daily documentation of wound details (drainage, cellulitis changes, blisters, etc.), amount of fluid drained by the NPWT device, use of pain medicine, and range of motion will be gathered from the orthopedic note for all enrolled patients.

ii. Study group patients: subjects will utilize the Prevena™ device for a minimum of 3 days to a maximum of 7 days based on the discharge date. Patients will be discharged with a standard of care dressing and the device restricted to in-hospital use, unless a post-op visit with orthopedic staff (nurse practitioner, physician assistant or physician) is scheduled within the first 7 days

post-surgery. Post-operative visits will be scheduled at 2 and 4 weeks (+-3 days) after surgery with orthopedic staff. Wound details (drainage, cellulitis changes, blisters, etc.), range of motion of the operated joint, time up and go (TUG test), and use of pain medicine will be collected during those visits as well as OrthoMidas questionnaires. A 90-day (+-3 days) postoperative phone call will also be made in order to inquire about further wound complication or surgeries and the OrthoMidas questionnaire will be applied again and can be completed either over the phone or by email with a survey link. In the event that the patient is unable to come in for a postoperative visit, they will be given the option to send a photograph of their incision to one of the research fellows secure Cleveland Clinic email address; the only identifiers will be the patient's email address and the only additional risk involved is that we cannot guarantee the patient's personal internet network security. The photo will be stored on the password protected computer we are using for the other data in this study, as described below under 'Confidentiality of data'.

iii. Control group patients: patients will be fitted with standard of care dressing and discharged with it. Post-operative visits will be scheduled at 2 and 4 weeks (+-3 days) after surgery with orthopedic staff. Wound details (drainage, cellulitis changes, blisters, etc.), range of motion of the operated joint, time up and go (TUG test), and use of pain medicine will be collected during those visits as well as OrthoMidas questionnaires. A 90-day (+-3 days) postoperative phone call will also be made in order to inquire about further wound complication or surgeries and the OrthoMidas questionnaire will be applied again and can be completed either over the phone or by email with a survey link. In the event that the patient is unable to come in for a postoperative visit, they will be given the option to send a photograph of their incision to one of the research fellows secure Cleveland Clinic email address; the only identifiers will be the patient's email address and the only additional risk involved is that we cannot guarantee the patient's personal internet network security. The photo will be stored on the password protected computer we are using for the other data in this study, as described below under 'Confidentiality of data'.

iiii. Adverse outcomes data will be collected from medical history for both groups as far as 90 days post-surgery.

Confidentiality of data

All data will be anonymized by assigning study identification number to each patient. The only document linking study codes to patients will be protected by a password and safely stored on a password protected desktop computer in a locked office in Cleveland Clinic Main Campus. Maintenance of the file and destruction after collection of all pertinent data will be under the principal investigator's guidance.

If transfer of data via a laptop computer or removable device is necessary, the principal investigator will ensure that the laptop or removable device is encrypted and all data has been de-identified.

Statistical Analysis

The experimental data will be analyzed by the Cleveland Clinic Department of Quantitative Health Sciences. Demographic data, outcomes including infection rate and wound complications will be summarized using means and standard deviations, if continuous, or frequencies and percentages if categorical. Analyses will be performed using SAS software and plotting will be created using R software. A significance level of 0.05 will be assumed for all tests, unless specified a priori.

Funding Source

There will be no charges to be billed other than routine care cost during the conduction of this research. KCI USA, Inc. (San Antonio, TX), will provide funding and product for the conduction of this trial. A budget for the conduction of the study has been presented to the Orthopaedic Research department.

Serious Adverse Events/KCI USA, Inc. Reporting Information

Notification of the event will occur via the KCI USA, Inc. SAE Report Form. This form should be completed by the Investigator, or designee, and faxed to KCI USA, Inc. Initial notification of the event may occur via telephone call to a KCI study contact, but must always be followed by written notification using the SAE Report Form by the close of the next business day. The KCI USA, Inc. SAE fax line is available for SAE reporting 24 hours per day and is monitored during normal business hours.

KCI USA, INC. SAE REPORTING BY FAX

Investigation: Randomized Controlled Trial of Wound Management With Negative Pressure Dressing Versus Standard Dressing After Revision Arthroplasty.

Fax Number: 1.800.275.4290

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