Cover page

Title: THE EFFECT OF PICO DRESSINGS ON SURGICAL SITE INFECTION FOLLOWING BOWEL RESECTION: A RANDOMISED CONTROLLED TRIAL

Short title: PICO dressing use following bowel resection

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Investigation Site: Palmerston North Hospital

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**Project summary/overview**

*Rationale*

Surgical site infection is a common problem in General Surgical patients with a large burden placed on the healthcare system(1). There have been multiple studies showing a reduction in surgical site infection in orthopaedic, vascular and gynaecological surgical patients (2–5) with the use of negative pressure wound therapy.

*Method*

This study is a prospective, randomized controlled trial to be conducted at a single site (Palmerston North Hospital). It is an open-label trial with the primary endpoint comparing negative pressure wound therapy (PICO dressing) with standard adhesive dressings on the incidence of surgical site infection in General Surgical patients undergoing bowel resection with open or hybrid laparoscopic surgery.

*Objective*

To determine if the use of PICO dressings reduces surgical site infections in General Surgical patients undergoing bowel resection

*Outcomes*

Primary outcome: incidence of superficial (and deep) surgical site infection (SSI)

Secondary outcomes: participant satisfaction, length of stay, cost-benefit analysis

*Population*

All consecutive general surgical patients aged over 18 undergoing acute or elective bowel resections through an open or laparoscopically hybrid abdominal incision at Palmerston North Hospital.

*Project timeframe*

30-day follow up for patients. Project timeframe of approximately 1.5 years for data collection.

*Expected outcomes*

We expect to see a statistically significant reduction in SSI in the intervention group

**Background / justification for project**

Surgical site infection (SSI) is a common problem in surgery, with the highest incidence occurring with abdominal surgery with rates up to 35% quoted in the literature (5). This leads to increased healthcare costs as well as a poorer patient satisfaction (6).

Negative pressure wound therapy (NPWT) consists of a closed suction system where constant negative pressure is applied to a surface. Its use on closed surgical wounds is well documented, with its benefits possibly being from improved tension distribution, lymphatic drainage and reduced rates of seroma and haematoma formation (3).

The World Health Organisation has included the use of NPWT as a method of reducing SSI, however the evidence base for this was rated as “very low quality of evidence” (7). A recent meta-analysis in 2017 concluded that the use of NPWT reduced the number of wound infections (3), however there was only a single RCT which specifically looked at wound infection in laparotomy wounds, the majority of which were for gynaecological operations (5). A more recent RCT, not included in the meta-analysis, investigated the use of NPWT on class 2 contaminated open abdominal incisions and found no improvement (8).

There is ongoing clinical equipoise regarding the use of NPWT therefore further studies are required to ascertain its use in general surgical patients. This study aims to use a specific brand of NPWT – the PICO dressing - to add to this growing body of evidence.

**Objectives**

The aim of this study is to determine if the use of PICO dressings on surgical wounds in general surgical patients undergoing open bowel resections will lead to a lower incidence of surgical site infection.

The Null hypothesis is that there is no difference in SSI when using a PICO dressing.

*Primary outcome* - Incidence of superficial (and deep) surgical site infection (SSI)

*Secondary outcomes* - Length of stay, cost analysis, participant satisfaction survey

**Methodology**

*Study*

The study is a prospective, randomized controlled trial to be conducted at a single site (Palmerston North Hospital, Palmerston North, New Zealand). It is an open-label trial with the primary endpoint comparing negative pressure wound therapy (PICO dressing) with standard adhesive dressings on the incidence of surgical site infection.

*Sample size*

Sample size has been calculated using α of 0.05 and β of 0.2 with a baseline wound infection rate approximated from the literature at 35% and an expected wound infection rate reduction to 10% (5). Assuming an attrition rate of 10% we will require 56 participants in each group (total 112).

*Baseline and perioperative data to be collected*

|  |  |  |  |
| --- | --- | --- | --- |
| *Demographics* | *Risk factors* | *Surgical factors* | *Perioperative factors* |
| Sex | Age | Operative urgency | Hypothermia |
| Age | Charlson comorbidity index | Wound classification | Hypoxia |
| Indication for surgery | Sepsis | Skin preparation solution | Ongoing antibiotic use |
| Ethnicity | Smoking | Prophylactic antibiotics | Stoma presence |
| ASA | Malnutrition | Prosthesis use (e.g. mesh) | Peritoneal lavage |
|  | Previous chemo/radiotherapy | Drain use | Wound wash |
|  | Corticosteroids | Use of wound protector  | PICO size |
|  | BMI (>35) | Preoperative bowel preparation | Wound length |
|  |  |  | Distant site infection e.g. UTI, pneumonia |

*Assessments of outcomes*

Wound assessment

The presence of SSI will be assessed every day following dressing removal until discharge, at routine clinic follow up (usually at 3 weeks post op), at 30 days following the operation through a structured telephone interview, or at any time during the study period if the participant or surgical team has concerns about the development of an SSI in the incision.

Wound infection/ SSI definition

SSI is defined by the Center for Disease Control and Prevention (CDC) (9) criteria as follows:

Infection occurring within the first 30 post-operative days with at least one of the following:

* Purulent drainage from the incision
* Organisms isolated from an aseptically obtained culture of fluid or tissue from the incision
* The incision is deliberately opened by a surgeon AND the patient has at least one of the following signs/symptoms of infection: Pain or tenderness, localized swelling, redness, heat
* Diagnosis of SSI by a doctor.

Deep space infection (DSI) is defined as an infection occurring within 30 days that occurs within the abdominal cavity at the site of resection or distant to it and is diagnosed in any of the following ways:

1. CT scan of the abdomen shows a fluid collection with CT evidence of infection e.g. rim-enhancement, gas within the collection, surrounding stranding
2. Insertion of drain (percutaneous or open) that leads to the drainage of purulent fluid (irrespective of a positive culture being obtained)
3. The finding on re-operation of purulent fluid in the abdominal cavity

In the PICO group:

* Record whether PICO changed and reasons for this

Standard dressings group

* Frequency and type of dressing changes recorded

Both groups

* Wound infection rates
* Introduction of antibiotics
* Need for bedside drainage of wounds
* Return to theatre
* Other infective complications including leak and deep space infections, return to theatre
* Allergic reaction to dressing
* Observer component of the Patient and Observer Scar Assessment Scale (POSAS) (10).

Participant assessment

* By structured questionnaire at 30-day assessment (by phone or at outpatient clinic – investigator to fill in the form)
* GP or district nurse visits for wound problems
* Antibiotic use
* Satisfaction with wound appearance (1-10 with visual aid)
* Satisfaction with dressing type (1-10 with visual aid)
* Participant component of the Patient and Observer Scar Assessment Scale (POSAS) (10)

Impact of wound infection

* Readmission rates
* ED or outpatient clinic reviews for wound infections
* Need for District Nursing care
* GP visits for wound infection
* Antibiotic usage rates

Cost analysis

* A composite measure of costs of length of stay, dressing costs, readmission costs, return to theatre

*Participants*

The study population is all patients aged over 18 attending Palmerston North hospital who are undergoing either elective or acute bowel resections

Inclusion criteria

* All adults (aged 18 and over) undergoing elective or emergency small or large bowel resection
* No restrictions are made on the basis of wound classification
* Incision type – abdominal laparotomy, hybrid (laparoscopically-assisted) with an extra-corporeal anastamosis, laparoscopic converted to open

Exclusion criteria

* Pregnancy
* Sensitivity or allergy to adhesive materials
* Inability to give informed consent
* Upper gastrointestinal surgery (pancreaticoduodenectomy, Ivor lewis oesophagectomy, bariatric surgery, gastrectomy, cholecystectomy)
* Open abdomen
* Patients undergoing category “P1” emergency surgery

*Procedure*

Abdominal skin closure will be standardised with the use of skin clips 1 – 1.5cm apart.

Dressings

Treatment group: Application of a PICO dressing with reinforcement of the wound edges using adhesive tape supplied with dressing. Dressing should be left on for 5 days. Then replaced with simple dressings. If the PICO loses suction and this cannot be fixed by reinforcement prior to 5 days it can be replaced with another PICO dressing. The PICO can only be changed once. All surgeons will be educated with the proper application of the PICO dressing prior to commencement of the study.

Control group: Application of a dressing, to the preference of the operating surgeon. Dressings to be changed at the discretion of the team / nursing staff.

*Recruitment*

For elective cases recruitment should be undertaken in the outpatient clinic

For emergency cases participants should be recruited once the decision is made to proceed to theatre

For cases where it is uncertain whether a resection will be taking place (e.g. possible small bowel resection in laparotomy for small bowel obstruction) participants should be recruited but only included if a resection indeed takes place

*Randomisation*

Randomisation will be done on a 1:1 basis using an online random number generator, with randomization codes placed in a sealed envelope with study ID code stickers and other documentation. The envelopes should be opened in order and only once the wound is closed.

**Statistical analysis**

All analysis will be pre-specified and conducted according to the intention-to-treat principle. The proportion of SSIs amongst all participants will be compared between the PICO and adhesive dressing arms using a chi-square test. An absolute risk increase/reduction for SSI will be presented for the use of PICO, as well as the number needed to treat to prevent a single SSI. Participants lost to follow-up will be considered to have developed an SSI for the purposes of primary analysis. Furthermore, despite instructions to contact or return to clinic if any concerns of an SSI arise, any incisions diagnosed or treated for an SSI by any physician will be considered as having had an SSI.

Baseline characteristics of the two groups will be recorded, including body mass index (BMI), self-reported smoking status and co-morbidities. In the event that any of the baseline characteristics are found to differ significantly between the intervention and standard care groups by chance, secondary analyses will be performed using multivariable logistic regression to adjust for the effect of differences in the baseline characteristics on the primary outcome. Results will then be presented as an adjusted odds ratio.

Secondary outcomes will be compared between groups using a chi-square for categorical variables (i.e., need for home care, proportion receiving antibiotics). Non-normally distributed continuous variables (length of hospital stay, duration of home care treatment, number of return visits) will be compared using the Mann-Whitney U-test. A p-value of less than 0.05 will be considered significant.

**Ethics**

*Participant safety*

Participants will be attended to regularly by their regular surgical teams. The use of PICO devices have not previously been shown to have any deleterious effects on patient physical or emotional outcomes (5,8). Participants will be regularly followed up and any serious adverse events will be investigated accordingly. Known allergic reaction to adhesives in dressings is an exclusion criterion for this study so we think there is a low risk to allergy from these products. Even so, should allergy occur the dressings will be removed and appropriate treatment given. An ACC claim will be filed where appropriate.

*Informed Consent*

Participants will be consented prior to enrolment in the trial with the aid of the standard consent form and participant information sheet. They will be informed regarding their right to withdraw consent at any stage during treatment.

*Confidentiality*

No personally identifiable data will be gathered from patients. Participants will be allotted a unique identifier number (UIN) on enrolment in the trial. NHIs will be cross referenced to their UIN for the duration of the trial and this information will be destroyed at the completion of data collection.

*Data storage*

Hard copies of data gathered will be stored in a locked cabinet within the consultant’s office in Palmerston North Hospital which is only accessible by key. All electronic data will be encrypted and password accessible only.

*Relevant consultation*

Once HDEC approval has been granted we will be able to apply for locality approval which requires that the project is reviewed by the Māori Research Review committee as well as the local ethics committee.

*Ethical considerations*

Autonomy – Participants will be given the relevant participant information sheet on recruitment and have a discussion with their attending surgical team regarding the study. The issue of coercion will be addressed with education sessions with registrars and consultants involved in recruiting. Informed consent will be difficult to gain in the very high acuity “P1” surgery and so these people will not be recruited. In addition, people who are unable to give their own informed consent for surgery are also excluded from recruitment e.g. a person with dementia.

Justice – The PICO dressing is more expensive than standard surgical dressings. Wound infection has a large cost burden on healthcare with increased use of antibiotics, length of hospital stay, need for district nurse follow up and input from general practitioners. We will perform a cost analysis to determine whether the expense incurred from the use of the PICO dressing would be offset by its reduction in wound infection rate. If the study shows a reduction in wound infection rate, it could justify the use of this more expensive wound dressing.

Beneficence – The aim of this study is to improve outcomes for people undergoing major abdominal surgery. The literature suggests PICO dressings can reduce the incidence of post-operative wound infection in general. If this study shows that the PICO dressing is also effective in abdominal wounds then this would lead to benefits for patients undergoing these operations.

Non-maleficence – This intervention has not been shown to cause harm, however we will monitor participants for any adverse events. If there is a large discrepancy between participant groups we will investigate the reasons for this and halt/stop the trial if indicated.

*Māori Participants*

This study is not looking specifically at Māori as, at this stage, there is no evidence to our knowledge that wound infection rates are influenced by ethnicity. However, diabetes, obesity and smoking are more prevalent in Māori (almost double the non-Māori population)(11) and these conditions are associated with higher rates of wound infection. Therefore if there is benefit displayed with the use of PICO dressings it may lead to reduced risk in Māori undergoing surgery who in general are more likely to have other risk factors for wound infection.

We will provide Māori with access to our liaison support services and will involve their whānau in consent and decision making if desired. There is no koha offered for this trial. Currently we do not have funding to offer reimbursement for travel costs at the 30 day follow up but this will be discussed at the local approval process for the study.

**Project Management**

*Participating site*

Palmerston North Hospital. The General Surgical department currently consists of 7 general surgeons, all of whom will be involved with recruitment and treatment. The assessment of wound infection will be made by the team leading the care of the patient. Data will be gathered by registrars and trainee interns at the hospital with an interest in clinical research.

*Data ownership*

Once the data collection is completed and the cross referenced between the UIN and the NHI has been destroyed, the data will be anonymous. As such, the data will belong to the CI, Alexandra Gordon.

*Risk management of project*

Throughout the study we will continually monitor participant outcomes (wound infection/patient satisfaction/allergic reactions) to check that the PICO dressings are not associated with any significant adverse events/effects.

*Approximate Timetable*

October 2018 – Apply for HDEC

October/November 2018 – Apply for locality approval + Māori Research review

Dec/Jan 2019 – Begin Recruitment

May 2020 – Possible completion of participant recruitment

May 2020 – August 2020 – Write up, data interpretation

*Resources*

This trial should not need extra funding in terms of dressings as the PICO dressings are currently available to use as needed for general surgical patients.

We will undertake the phone interviews as part of the study team – this will not be at any additional cost apart from our own time. The large majority of patients who have had major surgery will be followed up by their attending consultant.

**THE USE OF PICO DRESSINGS IN THE PREVENTION OF SURGICAL SITE INFECTION: INFORMATION FOR RECRUITERS**

Thank you for considering your patient for recruitment to the PICO trial.

All patients aged over 18 attending Palmerston North hospital who are undergoing either elective or acute bowel resections are eligible for enrolment to this trial

Inclusion criteria

* All adults (aged 18 and over) undergoing elective or emergency small or large bowel resection
* No restrictions are made on the basis of wound classification
* Incision type – abdominal laparotomy, laparoscopic assisted with an extra-corporeal anastamosis, laparoscopic converted to open

Exclusion criteria

* Pregnancy
* Sensitivity or allergy to adhesive materials
* Inability to give informed consent
* Upper gastrointestinal surgery (pancreaticoduodenectomy, Ivor lewis oesophagectomy, bariatric surgery, gastrectomy, cholecystectomy)
* Open abdomen
* Patients undergoing category “P1” emergency surgery

WOUND CLOSURE

Wounds should be closed with skin clips placed 1-1.5cm apart

RANDOMISATION

If you are certain a bowel resection will be involved with your operation please obtain the topmost brown envelope located in the alcove between theatre 5 and 6. This will determine whether your patient will be in the intervention or control arm of the study.

If it is not certain that the participant will be having a resection, still retain the envelope but only open the envelope once the decision for resection has been made. This also applies if it is not certain whether the patient will fulfil other inclusion criteria.

FOLLOW UP

Ongoing data collection will be performed by researchers involved with the study through review of the clinical notes and discussion with members of the surgical/nursing team. Information will be gathered at routine outpatient visits as well as a structured telephone interview at 30 days.

**THE USE OF PICO DRESSINGS IN THE PREVENTION OF SURGICAL SITE INFECTION: PATIENT QUESTIONNAIRE**

UIN: ……………

**Demographics**

NHI: ………………………………………

DOB: ………………………………………

Top of Form

Sex:  Male  Female

Bottom of Form

Top of Form

Ethnicity:  NZ European  NZ Māori  Pacific islander ………………

  Asian  Other …………….

Bottom of Form

**Medical history**

*Do you have/ have you ever had any of the following conditions?*

Top of Form

COPD  No  Yes  Unsure Comments:…………………

Bottom of Form

Anaemia  No  Yes  Unsure Comments:…………………

Diabetes  No  Yes  Unsure Comments:…………………

Liver disease  No  Yes  Unsure Comments:…………………

Cancer  No  Yes  Unsure Comments:…………………

* Previous chemotherapy  No  Yes Comments:…………………
* Previous radiotherapy  No  Yes Comments:…………………

Kidney disease  No  Yes  Unsure Comments:…………………

Heart failure  No  Yes  Unsure Comments:…………………

Heart attack  No  Yes  Unsure Comments:…………………

Peripheral vascular  No  Yes  Unsure Comments:…………………

 disease

Stroke  No  Yes  Unsure Comments:…………………

Dementia  No  Yes  Unsure Comments:…………………

Stomach ulcers  No  Yes  Unsure Comments:…………………

Connective tissue  No  Yes  Unsure Comments:…………………

 disorders

HIV or AIDS  No  Yes  Unsure Comments:…………………

Other medical conditions:

…………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

**Medications**

*Please provide a list of all medications you are taking*

…………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

**Social factors**

*Are you a smoker?*

 No

 Yes

*Do you drink any alcohol?*

 No

 Yes *How much alcohol do you drink in an average week?* ……………………………………

*To be completed by nursing or study staff*

**Anthropometric measurements**

Height: ………………………………………

Weight: ………………………………………

BMI: ………………………………………

**Preoperative blood tests**

On admission for acute admission or in preadmission for elective cases

Haemoglobin (g/L): ………………………………………..

White cell count (x109/L): ………………………………………..

Neutrophil count (x109/L): ………………………………………..

Creatinine (micromole/L): ………………………………………..

eGFR (ml/min/1.73m2): ………………………………………..

Albumin (g/L): ………………………………………..

CRP (mg/L): ………………………………………..

**THE USE OF PICO DRESSINGS IN THE PREVENTION OF SURGICAL SITE INFECTION: PERIOPERATIVE ASSESSMENT**

UIN: ……………

**Surgical factors**

Operation name: ……………………………………………………………………………………

Access method:  Open Laparoscopically-assisted  Laparoscopic converted to open

Top of Form

Operative urgency:  Elective  Acute

Bottom of Form

Bowel preparation  No  Yes

Skin preparation solution  Aqueous  Alcoholic  Betadine

used:  Chlorhexidine

Wound classification:  Clean  Clean-contaminated  Contaminated  Dirty

Prophylactic antibiotics  No  Yes: *type and dose* …..……………..………….

Peritoneal lavage  No  Yes: *describe ……….*………………….……….

Stoma presence  No  Yes: *type …………*………………….………..

  Already present

Insertion of mesh  No  Yes: *type …………*…………………….……..

Intraabdominal drain  No  Yes

Superficial drain  No  Yes

**Anaesthetic factors**

ASA score  1  2  3  4  5

Hypoxia during case  No Yes

Hypothermia assessment

* Temperature monitored  No Yes

intraoperatively

* Warming methods used  Warm blankets  Bair hugger
	+ - *  Other: …………………………………………………………….
* Temperature on arrival to PACU: …………………………………………………...…………………

**Wound factors**

Wound protector used  No Yes: *describe ……….*………………….………..

Wound wash  No Yes: *describe ……….*………………….………..

Wound length (in cm): ……………………………

Dressing used: …………………………..

**THE USE OF PICO DRESSINGS IN THE PREVENTION OF SURGICAL SITE INFECTION: DAILY POST OPERATIVE WOUND ASSESSMENT FORM**

UIN: ……………

Dressing Type: ……………………………………………….

Length of Stay: ……………

Adverse events (note day and Clavien-Dindo classification): ……….........................................

…………………………………………………………………………………………….…………………………………………………………………………………………….

**Day 1**

Purulent Discharge from incision Organisms isolated from aseptically obtained culture

Incision opened by Surgeon Wound pain/tenderness Localised swelling Redness Heat

Diagnosis of surgical site infection by surgeon

Dressing changed (and to what type): ………………………………..

Return to theatre

Antibiotics given IV Oral

**Day 2**

Purulent Discharge from incision Organisms isolated from aseptically obtained culture

Incision opened by Surgeon Wound pain/tenderness Localised swelling Redness Heat

Diagnosis of surgical site infection by surgeon

Dressing changed (and to what type): ………………………………..

Return to theatre

Antibiotics given IV Oral

**Day 3**

Purulent Discharge from incision Organisms isolated from aseptically obtained culture

Incision opened by Surgeon Wound pain/tenderness Localised swelling Redness Heat

Diagnosis of surgical site infection by surgeon

Dressing changed (and to what type): ………………………………..

Return to theatre

Antibiotics given IV Oral

**Day 4**

Purulent Discharge from incision Organisms isolated from aseptically obtained culture

Incision opened by Surgeon Wound pain/tenderness Localised swelling Redness Heat

Diagnosis of surgical site infection by surgeon

Dressing changed (and to what type): ………………………………..

Return to theatre

Antibiotics given IV Oral

**Day 5**

Purulent Discharge from incision Organisms isolated from aseptically obtained culture

Incision opened by Surgeon Wound pain/tenderness Localised swelling Redness Heat

Diagnosis of surgical site infection by surgeon

Dressing changed (and to what type): ………………………………..

Return to theatre Antibiotics given IV Oral

**THE USE OF PICO DRESSINGS IN THE PREVENTION OF SURGICAL SITE INFECTION: ASSESSMENT FORM AT ROUTINE OUTPATIENT VISIT**

UIN: ……………

Wound infection occurred Yes No

Antibiotics used for wound infection Yes No

Wound opened for infection Yes No

Readmission Yes No

 Reason: ………………………………………………………….

ED or Hospital Outpatient review for wound infection: Yes No

Number of visits: …………………………………… Don’t know

Have you seen your GP for any wound problems Yes No

Number of visits: …………………………………… Don’t know

Have you had district nurse follow up Yes No

Number of visits: …………………………………… Don’t know

**Observer assessment**

**Best scar Worst scar imaginable**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| Vascularity |  |  |  |  |  |  |  |  |  |  |
| Pigmentation |  |  |  |  |  |  |  |  |  |  |
| Thickness  |  |  |  |  |  |  |  |  |  |  |
| Relief |  |  |  |  |  |  |  |  |  |  |
| Pliability |  |  |  |  |  |  |  |  |  |  |

**Patient assessment**

**Best scar Worst scar imaginable**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| Pain |  |  |  |  |  |  |  |  |  |  |
| Itch |  |  |  |  |  |  |  |  |  |  |
| Colour  |  |  |  |  |  |  |  |  |  |  |
| Stiffness |  |  |  |  |  |  |  |  |  |  |
| Thickness |  |  |  |  |  |  |  |  |  |  |
| Irregularity |  |  |  |  |  |  |  |  |  |  |

**Overall satisfaction with wound appearance**

1 2 3 4 5 6 7 8 9 10

**Overall Satisfaction with dressings**

1 2 3 4 5 6 7 8 9 10

**THE USE OF PICO DRESSINGS IN THE PREVENTION OF SURGICAL SITE INFECTION: ASSESSMENT FORM 30 DAY FOLLOW UP (structured phone interview)**

UIN: ……………

Wound infection occurred Yes No

Antibiotics used for wound infection Yes No

Wound opened for infection Yes No

Readmission Yes No

 Reason: ………………………………………………………….

ED or Hospital Outpatient review for wound infection: Yes No

Number of visits: …………………………………… Don’t know

Have you seen your GP for any wound problems Yes No

Number of visits: …………………………………… Don’t know

Have you had district nurse follow up Yes No

Number of visits: …………………………………… Don’t know

**Satisfaction with wound appearance**

1 2 3 4 5 6 7 8 9 10

**Satisfaction with dressings**

1 2 3 4 5 6 7 8 9 10

**THE USE OF PICO DRESSINGS IN THE PREVENTION OF SURGICAL SITE INFECTION:**

**PARTICIPANT INFORMATION SHEET**

Study title: *The use of PICO dressings in the Prevention of Surgical Site Infection*

Locality: **Palmerston North hospital** Ethics committee re.:

Lead Investigator: Ms. Alexandra Gordon Contact Phone Number: (06) 356 9169

You are invited to take part in a study on the best use of dressings on your abdominal wound. Whether or not you take part is your choice. If you do not want to take part, you do not have to give a reason, and it will not affect the care that you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This Participant Information Sheet will help you decide if you would like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is 4 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

## What is the purpose of the study?

This study is being performed to determine if using a dressing with suction is better at preventing complications with your wound than the usual standard dressing we use for abdominal operations. We believe that the suction dressing will reduce the likelihood of having a wound infection, but there is not definite proof of this in the medical literature.

We are performing a “randomized controlled trial” to help answer this question. This type of trial means that we recruit participants for the trial then randomly assign them with the help of a computer program to either have the usual standard dressing placed on their wound or the suction dressing. By randomly selecting participants into each group we help reduce the chance of factors other than the dressing changes our results. We will follow up both groups of participants to see if there are any differences in wound healing.

This study is funded by Mid Central District Health Board. You can contact the lead investigator (Ms. Alexandra Gordon), who is a General Surgeon at Palmerston North Hospital, if you have any other questions.

This study has had ethics approval both locally and through the Health and Disability Ethics Committee.

## What will my participation in the study involve?

You have been chosen to participate in this study as you fit the required criteria. The main criteria are that you are having an abdominal operation which will likely require you to have some bowel cut out.

If you are assigned to the regular dressing group you will have the usual dressing that your surgeon regularly uses for abdominal surgery. If you are assigned to the suction dressing group you will have a “PICO” dressing placed on your wound which is a dressing that provides light suctioning. There will be no change in how the operation will be performed otherwise.

You will be looked after the operation by your regular surgical team. There is a chance that a member of the research team will visit you while you are on the ward to check for wound issues. Most of the information we need will be able to be taken from your medical records which are kept by your regular surgical team.

We will need to gather your health data as part of this study. This includes information on your age, ethnicity, other medical conditions, height, weight, smoking status, and the details of your operation.

As part of the study we would like to phone you for a brief participant satisfaction survey at 30 days to assess your experience with your wound care. We will also collect information during your hospital stay and at your routine outpatient follow up.

All information which we gather will be kept in a secure location and information will be anonymised.

## What are the possible benefits and risks of this study?

We don’t believe that the suction dressing poses any health risks to participants. There have been no documented complications from using the dressing.

By taking part in this study you are helping to advance our understanding of wound care after operations. If we find an advantage in the use of the suction dressing it may change how we manage wounds after major surgery.

## Who pays for the study?

This study will be funded by Mid Central DHB.

## What if something goes wrong?

If you were injured in this study, which is unlikely, you would be eligible **to apply** for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.

## What are my rights?

It is your right to choose whether you would like to participate in this study or not.

It is your right to withdraw from the research at any time without any disadvantage to your ongoing treatment.

You have a right to request access to information which we have collected about you during the study period.

You have a right to know about any new information that becomes available during the study about the benefits or adverse effects of the suction dressing.

We will keep your health information in a secure location. Once we have finished collecting information all health information will be made anonymous.

## What happens after the study or if I change my mind?

After the study, you will have ongoing follow up with your surgeon or GP depending on the surgery that you have had. Our results will be sent to medical journals to be published and we hope that this will influence how surgeons manage abdominal wounds.

You are welcome to change your mind at any stage during the study time. If you have a suction dressing and choose to withdraw from the study it is simple to change the dressing back to the standard wound dressing used by your surgical team.

Your health information will be stored securely during the study period. After the completion of the study all information will be made anonymous and may be used in future research projects. None of the information will be able to be traced back to you.

We will send out our results to participants at the end of the study period for your interest if you wish.

## Who do I contact for more information or if I have concerns?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

 *Alexandra Gordon, General Surgeon, Palmerston North Hospital*

 *Telephone number* (06) 356 9169

 *Email* Alexandra.gordon@midcentraldhb.govt.nz

If you want to talk to someone who isn’t involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@hdc.org.nz

For Maori Health support please contact :

*(to be completed)*

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

 Phone: 0800 4 ETHICS

 Email: hdecs@moh.govt.nz

**THE USE OF PICO DRESSINGS IN THE PREVENTION OF SURGICAL SITE INFECTION:**

**PARTICIPANT CONSENT FORM**

 **REQUEST FOR INTERPRETER**

|  |  |  |  |
| --- | --- | --- | --- |
| English | I wish to have an interpreter. | Yes | No |
| Deaf | I wish to have a NZ sign language interpreter. | Yes | No |
| Māori | E hiahia ana ahau ki tetahi kaiwhakamaori/ kaiwhaka pakeha korero. | Ae | Kao |
| Cook Island Māori | Ka inangaro au i tetai tangata uri reo. | Ae | Kare |
| Fijian | Au gadreva me dua e vakadewa vosa vei au | Io | Sega |
| Niuean | Fia manako au ke fakaaoga e taha tagata fakahokohoko kupu. | E | Nakai |
| Samoan | Ou te mana’o ia i ai se fa’amatala upu. | Ioe | Leai |
| Tokelauan | Ko au e fofou ki he tino ke fakaliliu te gagana Peletania ki na gagana o na motu o te Pahefika | Ioe | Leai |
| Tongan | Oku ou fiema’u ha fakatonulea. | Io | Ikai |
| Other  | State language: | Yes | No |

**Please tick to indicate you consent to the following**

|  |  |  |
| --- | --- | --- |
| I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.  |  |  |
| I have been given sufficient time to consider whether or not to participate in this study. |  |  |
| I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study. |  |  |
| I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet. |  |  |
| I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care. |  |  |
| I consent to the research staff collecting and processing my information, including information about my health. |  |  |
| If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed. | Yes 🞏 | No 🞏 |
| I consent to my GP or current provider being informed about my participation in the study and of any significant abnormal results obtained during the study. | Yes 🞏 | No 🞏 |
| I understand that there may be risks associated with the treatment in the event of myself or my partner becoming pregnant. I undertake to inform my partner of the risks and to take responsibility for the prevention of pregnancy. |  |  |
| I agree to an approved auditor appointed by the New Zealand Health and Disability Ethic Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study. |  |  |
| I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study. |  |  |
| I understand the compensation provisions in case of injury during the study. |  |  |
| I know who to contact if I have any questions about the study in general. |  |  |
| I understand my responsibilities as a study participant. |  |  |
| I wish to receive a summary of the results from the study. | Yes 🞏 | No 🞏 |

**Declaration by participant:**

I hereby consent to take part in this study.

|  |
| --- |
| Participant’s name: |
| Signature: | Date: |

**Declaration by member of research team:**

I have given a verbal explanation of the research project to the participant, and have answered the participant’s questions about it.

I believe that the participant understands the study and has given informed consent to participate.

|  |
| --- |
| Researcher’s name: |
| Signature: | Date: |

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