A prospective, randomized, intra-patient, comparative, open, multi-centre study to evaluate the efficacy of a Single-Use Negative Pressure Wound Therapy (NPWT) System (PICO) on the prevention of postsurgical incision healing complications in patients undergoing reduction mammoplasty

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Primary Objective:To assess the difference in healing complications up to and 21 days post-operatively between postsurgical incisions treated with PICO compared with standard of care Incision healing complications will include;* Skin necrosis*...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Ancillary infectious topics
Study type	Interventional

Summary

ID

NL-OMON36873

Source
ToetsingOnline

Brief title
The effectivity of a negative pressure system (PICO)

Condition

- Ancillary infectious topics
- Skin and subcutaneous tissue therapeutic procedures

Synonym
bilaterale mammoplasty

Research involving
Human

Sponsors and support

Primary sponsor: Smith&Nephew, Inc
Source(s) of monetary or material Support: smith & nephew

Intervention

Keyword: Healing complications, Negative Pressure Therapy, PICO, Reduction Mammoplasty

Outcome measures

Primary outcome

To assess the difference in healing complications up to and 21 days

post-operatively between postsurgical incisions treated with PICO compared with

standard of care

Secondary outcome

To assess the aesthetic appearance and scar quality using POSAS-, VAS

Questionnaires and the hydratation, elasticity and the Transepidermal Water

Loss of the scar using the cutometer , the aspects of functional performance of

both dressings, the ease of operation of the PICO pump, any changes in the

surrounding skin condition and the assessment of a difference in the following

economic assessments

Study description

Background summary

A level of surgical site infection (SSI*s) and disruption of sutured tissue are

seemingly unavoidable complications following surgery. Different surgical procedures carry different frequencies of SSI. For example, the incidences range from 0.2% to 1.1% in primary hip joint replacement1; 1.1% in coronary artery bypass grafts2; 2.5% for breast implant surgery3 or 6% in gastrointestinal surgery4. Other negative outcomes from surgery, which may or may not accompany infection, include delayed healing, wound dehiscence, tissue necrosis, seroma and hematoma formation5. The severity of these complications embraces mild cases needing local wound care and antibiotics to serious cases with multiple reoperations and a high mortality rate4. Increased costs are the inevitable consequence of SSI6 and there is intense interest in the identification of risk factors for each procedure so that the costs and mortality and morbidity can be reduced as far as possible in those patients who have much higher than the average risks for developing an SSI7.
Negative Pressure Wound Therapy (NPWT) has been shown to be an effective treatment in the management of acute and chronic open wounds8, but a relatively new, emergent use of NPWT is its application as a post-operative dressing for closed surgical incisions9. Post-operative oedema in the peri-wound tissue is thought to limit tissue perfusion and high levels of wound fluid loss have been correlated with increased risk of post-operative infection and dehiscence10. These issues are particularly important in obese or immuno-compromised patients. Application of NPWT to the closed wound; so called *incisional NPWT* has been reported to improve patient comfort through reduced dressing change and to reduce the period during which post-operative fluid discharges from the incision. Gomoll et al., (2006) had no cases of wound breakdown in 35 patients treated with NPWT using thin strips of polyurethane foam and NPWT set at -75mmHg11. Stannard et al.,(2006) reported the interim results of a randomised trial and found application of NPWT to 44 patients with draining haematomas following high energy trauma reduced mean draining time from 3.1 to only 1.6 days (p=0.03)12. Similarly, in 44 additional patients with sutured incisions over high energy trauma injuries, NPWT reduced drainage from 4.8 to 1.8 days (p=0.02)12. In a subsequent report there was a statistically significant reduction in wound infections in some 250 traumatic orthopaedic injuries13. Reddix et al., (2009) found no post-op wound complications in 19 consecutive high risk obese hip fracture patients (BMI>40 kg/m2) whose closed wounds were treated with NPWT10,14. The application of NPWT to a clean closed incision has other potential benefits related to its mechanisms of action which include protecting the wound, splinting the incision, improved angiogenesis, increased blood flow, reduced oedema, reduction in frequency of seroma and haemostasis15, decreased interstitial fluid, removing infectious material and low frequency of dressing changes16.
One area of surgery which has not yet been studied with respect to the effect that incisional NPWT might have is in postsurgical complications following breast reduction mammoplasty. A recent literature review found that bilateral breast reduction is a relatively common surgery with a high risk of wound healing complications. Analysis of 4 typical publications reveals a weighted mean of 28.6% patients experience some measure of delayed wound healing (parts unhealed by 2 weeks)17,18,19,20. It is apparent that delayed healing is

proportional to the patient*s BMI and it seems likely that the local history and structure of the tissue is the cause of the increased susceptibility to healing complications. This is a relatively high incidence of SSI wound healing complication, albeit of relatively low severity. However, another clinical outcome of compromised skin healing is the legacy of sub-optimal scars that are cosmetically unacceptable, (such as those that are spreading, widened, hypertrophic or keloid) or cause significant morbidity including pruritus, pain and restriction of movement, particularly when over joints21. These cosmetic and functional sequelae can have a significant impact on the patient*s emotional wellbeing and this is certainly the case in medically necessary reduction mammoplasty. Scars have been shown to cause high levels of anxiety and self-consciousness and patients with scars often face aesthetic, physical, psychological, and social consequences that result in substantial emotional and financial costs22. A significant reduction in the frequency of wound healing complications in breast reduction patients would be of demonstrable benefit. Recently, Single-Use Negative Pressure Wound Therapy (NPWT) systems have been introduced with regard to the reduction of postsurgical incision healing complications such as infection and dehiscence. The single use Prevena* device (Kinetic Concepts Inc., San Antonio, TX) was recently studied in primary hip arthroplasty15. Single use disposable NPWT systems have the potential to reduce the economic costs of securing improved outcomes of surgical incisions that appear to be attainable using full sized NPWT systems11,14,13. They also have the potential to represent a much less intrusive experience for the patient. PICO is an example of a light weight single-use NPWT system which has just been introduced into US clinical practice23.The purpose of this clinical study is to determine whether the application of PICO during the immediate postoperative treatment phase can reduce the incidence of delayed wound healing and infection and to assess the medium-term aesthetic appearance and quality of the resultant scar, in patients undergoing bilateral breast reduction surgery in comparison to standard care.

12 REFERENCES

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Study objective

Primary Objective:
To assess the difference in healing complications up to and 21 days post-operatively between postsurgical incisions treated with PICO compared with standard of care
Incision healing complications will include;
* Skin necrosis
* Nipple and Areola necrosis
* Hematoma
* Cellulitis
* Abscess
* Seroma
* Partial or superficial dehiscence
* Suture abscesses or extrusions (*spitting*)
* Infection (deep or superficial)
* Delayed wound healing

Secondary Objectives:
To assess the aesthetic appearance (cosmesis) and scar quality at Day 42, 90, 180 and 365 between post-surgical incision wounds treated with PICO compared with standard care dressings using The Patient and Observer Scar Assessment Scale (POSAS). The Visual Analogue Scale (VAS) and the Cutometer.

To assess the following aspects of functional performance of both dressings;

* Ease of application & removal
* Dressing wear time
* Patient comfort
* Patient pain
* Exudate management
* Patient acceptability

To assess the ease of operation of the PICO pump

To assess any changes in the surrounding skin condition over the course of treatment and within the first 21 days between post-surgical incision wounds treated with PICO compared with the standard care dressings, including the amount of bruising and swelling, and the rate of resolution of the same

Assessment of a difference in the following economic assessments:

* Cost estimation per dressing change (health care professional and materials used)
* Cost estimation for treatment per week and per episode of care
* Costs associated with additional interventions and specific interventions (e.g. hospital re-admissions, additional surgical procedures, additional antibiotics)

Study design

The study will comprise a prospective, randomised, intra-patient, comparative, open-labelled, multi-centre study to determine the efficacy of a Single-Use Negative Pressure Wound Therapy (NPWT) System (PICO) on the prevention of postsurgical wound complications in patients undergoing bilateral reduction mammoplasty.

Intervention

PICO is a Single-Use Negative Pressure Wound Therapy (NPWT) System consisting of a small portable pump, 2 lithium batteries, 2 dressings and 10 fixation strips. PICO is capable of delivering 80mmHg (nominal) negative pressure to the wound surface and managing low to moderate levels of exudate generated by the wound. The kit is intended to be used for a maximum of 7 days. The frequency of dressing changes, as indicated by clinical practice, may result in therapy duration of the kit being less than 7 days.
Indications for use:
PICO is indicated for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via removal of low to moderate levels of exudate and infectious materials. PICO Single-Use Negative Pressure Wound Therapy System is suitable for use in both a hospital and home care setting.
Examples of appropriate wound types include:

* Acute
* Chronic
* Flaps and grafts
* Incision sites
* Partial-thickness burns

* Sub acute and dehisced wounds
* Traumatic
* Ulcers (such as diabetic or pressure)

Contraindications:

PICO is contraindicated for:

* Patients with malignancy in the wound bed or margins of the wound (except in palliative care to enhance quality of life).
* Previously confirmed and untreated osteomyelitis.
* Non-enteric and unexplored fistulas.
* Use on necrotic tissue with eschar present.
* Use over exposed blood vessels, nerves or organs.
* Exposed anastomotic sites.

Study burden and risks

Common reactions to any type of dressing used may include redness, pain, itching or burning at the dressing site. Occasionally a reaction to the adhesive layer (tape) or components that make up the dressings may occur which also causes redness, pain, burning, itching, blistering or skin stripping at the site. If this occurs, the dressings will be removed and an alternative dressing used or without dressing.
The use of the cutometer, which is a non-invasive measuring device, will have no risk at all to the patient.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Pre-surgery
1 * Female patient*s *18 years old
2 - The patient is able to understand the trial and is willing to consent to the trial
Post-surgery;3 * Patient has undergone an elective surgical procedure for bilateral reduction mammoplasty;4 - Patients postsurgical incisions are of similar length

Exclusion criteria

Pre-surgery
Pregnant or lactating females
5 * Pregnant or lactating females;6 * Patients on steroids or other immune modulators known to impact healing which may affect scar appearance;7 * Patients with tattoos in the area of the incisions;8 * Patients with skin conditions (Cutis laxa etc.) that would result in poor healing or widened scars;9 * Patients with a known significant history of scar problems i.e. hypertrophic scaring or keloids;10 * Patients who in the opinion of the investigator may not complete the study for any reason;11 * Patients with a known history of poor compliance with medical treatment;12 * Patients who have participated in this trial previously and who were withdrawn;13 * Patients with known allergies to product components (silicone adhesives and polyurethane films (direct contact with wound), acrylic adhesives (direct contact with skin), polyethylene fabrics and super-absorbent powders (polyacrylates) (within the dressing);Post-surgery;14 - Incisions that are actively bleeding;15 - Exposure of blood vessels, organs, bone or tendon at the base of the reference wound;16 - Incisions >12 inches (30cm) max linear dimension

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-10-2012
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	PICO system
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	20-08-2012
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL40698.068.12