Effectiveness of topical negative pressure/closed incision management in the prevention of post-surgical wound complications: a systematic review protocol

Kylie Sandy-Hodgetts BSc MBA (PhD Candidate)¹
Robin Watts AM PhD MHSc BA DipNEd RN FRCNA²

1. Curtin University School of Nursing and Midwifery, Perth, Western Australia
2. The Western Australian Group for Evidence Informed Healthcare Practice: a collaborating centre of the Joanna Briggs Institute (WAGEIHP), School of Nursing and Midwifery, Curtin University of Technology, Perth Western Australia

Corresponding author
Kylie Sandy-Hodgetts
kylie.sandy-hodgetts@curtin.edu.au

Review question/objective

The aim of this review is to identify the effectiveness of topical negative pressure in the prevention of post-surgical wound complications.

More specifically, the objective is to identify:

The effectiveness of topical negative pressure in the prevention of post-surgical site infections, wound dehiscence, wound breakdown and/or wound complications in adults compared to other methods that assisting wound healing.

Background

The worldwide volume of surgery is considerable, with an estimated 234.2 million major surgical procedures carried out every year across the globe.¹ In Australia during 2010-11, 22 million admissions involved a surgical procedure.² Wound healing by primary intention following surgery is assisted by the use of sutures, staples, glue, adhesive tape wound dressings or topical negative pressure, and healing commences within hours of closure.³ Failure of the wound to heal may be due to a number reasons; patient related factors,⁴ ⁵ technical reasons of suture breakage or knots slipping,⁶ infection or dehiscence,⁴ ⁵ ⁷ ⁸ or compromised immunity.⁶

Surgical wound complications are often reported as a surgical site infection (SSI) and/or more seriously a wound breakdown, also known as wound dehiscence. This is where the wound has separated at the margins within a 30 day period following surgery, and may be due to an infection, patient related or mechanical factors. Surgical wound dehiscence (SWD) is defined by the Centres of Disease Control and Prevention (CDC)⁹ as an SSI, and is the most widely referred to classification by clinicians.
Surgical wound breakdown in this context is known as a deep or organ space infection, and this definition only accounts for microbial causes for the wound breakdown, not non-microbial causes. The CDC definition is not consistently used by all when reporting surgical wound complications and this complicates the process in determining incidence and prevalence of surgical wound dehiscence.

In the United Kingdom, SSI constitutes 20% of all health care related infections, and at least 5% of admitted patients will develop an SSI.\textsuperscript{10} In North America, the fiscal estimate of SSI is reportedly USD 10 billion annually in direct and indirect medical costs.\textsuperscript{11} The estimated costs attributable to SSI in Europe range from 1.47 to 19.1 billion Euros.\textsuperscript{10} In Australia, estimated costs associated with SSI are AUD60 million per year.\textsuperscript{12, 13} In each of these countries, it is difficult to tease out which wounds are superficial infections and which are deep or a wound dehiscence; therefore estimating the economic impact of surgical wound dehiscence is speculative at best. However, further additional costs associated with delays in healing and reduced quality of life for the patient, family and the wider community are also difficult to ascertain from a fiscal point of view. More importantly, the use of an optimal therapy to improve wound healing outcome following surgery and prevent wound complications remains to be determined.

Topical negative pressure (TNP) has been in use on wounds since the 1990s.\textsuperscript{14-19} This review will consider studies that evaluate the use of TNP following surgery and the occurrence of wound complications, such as SSI and SWD. Research into the use of TNP has determined that its therapeutic effects include reduction in edema, increase in skin perfusion,\textsuperscript{19, 20} and increased granulation tissue formation.\textsuperscript{21} TNP is a mode of therapy used in wound care and consists of a device (pump) attached to a dressing via tubing placed over a wound using a packing material (either foam or gauze), and the device generates a negative pressure (suction) force at the wound bed interface. The packing material is covered by a drape which creates a closed healing system. The delivery of negative pressure to the wound site ranges from 50mmHg to 125mmHg. TNP devices in wound care are available in many countries, and this review will look at any study that has used a TNP device following surgery.

TNP also known as negative pressure wound therapy (NPWT), is now widely used around the world to treat a number of wound indications, and has been extensively researched. In 2011 Krug et al., estimated that over 1,000 peer reviewed articles reporting on studies that had examined the clinical effectiveness and safety of NPWT had been published.\textsuperscript{22}

In the last five years, there have been a number of systematic reviews conducted of published studies on NPWT.\textsuperscript{23, 24} Several of these reviews had the specific objective of working towards building an international consensus on the use of NPWT, and have developed evidence-based recommendations for this purpose. In 2007, Kanakaris, et al.\textsuperscript{23} examined the efficacy of TNP in the management of wounds resulting from lower extremity trauma or burns. The authors concluded that the effectiveness of NPWT was comparable to standard dressing and wound coverage methods in the acute phase of blunt, penetrating and/or thermal trauma in this region. However given the types of study designs used by the 16 included studies (e.g. retrospective case series), the evidence lacked strength and coverage of all aspects of NPWT.

Two systematic reviews used to build consensus were published in 2011. Birke-Sorensen et al.\textsuperscript{24} focused on treatment variables: different pressure settings, wound fillers, use of a wound contact layer, and the impact of NPWT on bacterial bio-burden. Although 14 recommendations were developed, the expert panel concluded there was relatively weak evidence on which to base these recommendations.
In respect to bioburden, the authors concluded that: “the reduction of bacteria in wounds is not a major mode of action of NPWT” (p.52). The other consensus building review, Krug, et al., focused on the use of TNP in traumatic wounds and reconstructive surgery. Two hundred and eight papers met the inclusion criteria established for the systematic review and from this base, 12 proposed recommendations were developed. Eleven of those reached the 80% agreement level in the following consultation process with practicing clinicians. The findings indicted that the evidence base was strongest for the use of TNP on skin grafts, while it was weakest for primary treatment in burns.

However, despite the existing extensive research on this topic to date, a search of relevant databases did not elucidate a published systematic review that focused on the use of TNP in preventing complications in post-surgical wounds. It is the objective of this systematic review to address that gap in the knowledge. More specifically, the aim of this review is to identify whether TNP, as a mode of therapy, is effective in the prevention of post-surgical wound dehiscence and/or infection. The primary outcome measure for this will be to ascertain whether the intervention group in the study incurred a SSI or SWD with the use of TNP compared to controls.

Keywords
Negative pressure wound therapy; topical negative pressure (TNP); NPWT following surgery; vacuum-assisted closure; surgical wound dehiscence; prevention of surgical site infection; closed incision management (CIM)

Inclusion criteria

Types of participants
This review will consider studies that include male and female adults and children who have had TNP applied to their surgical wound following a surgical procedure in one of these areas, but not confined to: trauma, cardiothoracic, orthopedic, general, vascular or obstetric surgery.

Types of intervention
This review will consider studies that evaluate the use of TNP directly over an incision, following any surgical procedure.

Types of comparator
The comparator will be the standard form of care used by the clinician in the absence of TNP (other dressings such as foams, silicone, gauze or hydrocolloids).

Types of outcomes
This review will consider studies that include, but are not restricted to the following outcome measures:

- Healing wound parameters, e.g. time, wound size, exudate levels
• Surgical site infections – superficial and deep
• Surgical wound dehiscence
• Wound pain
• Wound seroma
• Length of hospital stay

Types of studies

This review will consider both experimental and epidemiological study designs including randomized controlled trials, non-randomized controlled trials, quasi-experimental, before and after studies, prospective and retrospective cohort studies, case control studies and analytical cross sectional studies for inclusion.

This review will also consider descriptive epidemiological study designs including case series, individual case reports and descriptive cross sectional studies for inclusion.

Search strategy

The search strategy aims to find both published and unpublished studies in humans only. A three-step search strategy will be utilized in this review. An initial limited search of MEDLINE and CINAHL will be undertaken, followed by analysis of the text words contained in the title and abstract, and of the index terms used to describe the article. A second search using all identified keywords and index terms will then be undertaken across all included databases. Thirdly, the reference list of all identified reports and articles will be searched for additional studies. Studies published in all languages will be considered for inclusion in this review; 1990 marking when research on humans and academic reporting of the work began to proliferate.

The databases to be searched include:

• MEDLINE
• CINAHL
• EMBASE
• Scopus
• TRIP
• Quality web search tools e.g. Google Scholar, Scirus.com, Agency for Healthcare and Research, NLM Gateway, Medscape.
The search for unpublished studies will incorporate the years 1990-2013 for inclusion in this review; 1990 marking when research on humans and academic reporting of the work began to proliferate in this area. These studies will include grey literature and unpublished material such as conference papers; research reports and dissertations and will be sourced wherever possible. The sources to be searched to locate unpublished studies include:

- Clinical trials.gov,
- World Health Organisation (WHO) International Clinical Trials Registry Platform,
- Australian and New Zealand Clinical Trials Registry,
- Current Controlled Trials,
- Cochrane Central Register of Clinical Trials
- Web of Life Conference Proceedings.

Assessment of methodological quality

Papers selected for retrieval will be assessed by two independent reviewers for methodological validity prior to inclusion in the review using the standardized critical appraisal instruments from the Joanna Briggs Institute Meta-Analysis of Statistics Assessment and Review Instrument (JBI-MAStARI) (Appendix I). Any disagreements that arise between the reviewers will be resolved through discussion, or with a third reviewer.

Data collection

Data will be extracted from papers included in the review using the standardized data extraction tool from JBI-MAStARI (Appendix II). The data extracted will include specific details about the interventions, populations, study methods and outcomes of significance to the review question and specific objectives.

Data synthesis

Quantitative data will, where possible be pooled in statistical meta-analysis using JBI-MAStARI. All results will be subject to double data entry. Effect sizes expressed as odds ratios (for categorical data) and weighted mean differences (for continuous data) and their 95% confidence intervals will be calculated for analysis. Heterogeneity will be assessed statistically using the standard Chi-square method and also explored using subgroup analyses based on the different study designs included in this review. Where statistical pooling is not possible, the findings will be presented in narrative form including tables and figures to aid in data presentation where appropriate. Where appropriate, subgroup analysis such as emergency versus elective surgery will be carried out.

Conflicts of interest

The authors report no conflict of interest.
References


Appendix I: JBI Critical Appraisal instruments

**MAStARI appraisal instruments**

### JBI Critical Appraisal Checklist for Randomised Control / Pseudo-randomised Trial

<table>
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<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
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<td>8. Were outcomes measured in the same way for all groups?</td>
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**Overall appraisal:** Include [ ] Exclude [ ] Seek further info. [ ]

**Comments (including reason for exclusion)**

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doi: 10.11124/jbisrir-2013-909
JBI Critical Appraisal Checklist for Descriptive / Case Series

Reviewer __________________________________ Date ____________________________

Author __________________________________ Year __________ Record Number ______

1. Was study based on a random or pseudo-random sample? [ ] Yes [ ] No [ ] Unclear [ ] Not Applicable

2. Were the criteria for inclusion in the sample clearly defined? [ ] Yes [ ] No [ ] Unclear [ ] Not Applicable

3. Were confounding factors identified and strategies to deal with them stated? [ ] Yes [ ] No [ ] Unclear [ ] Not Applicable

4. Were outcomes assessed using objective criteria? [ ] Yes [ ] No [ ] Unclear [ ] Not Applicable

5. If comparisons are being made, was there sufficient descriptions of the groups? [ ] Yes [ ] No [ ] Unclear [ ] Not Applicable

6. Was follow up carried out over a sufficient time period? [ ] Yes [ ] No [ ] Unclear [ ] Not Applicable

7. Were the outcomes of people who withdrew described and included in the analysis? [ ] Yes [ ] No [ ] Unclear [ ] Not Applicable

8. Were outcomes measured in a reliable way? [ ] Yes [ ] No [ ] Unclear [ ] Not Applicable

9. Was appropriate statistical analysis used? [ ] Yes [ ] No [ ] Unclear [ ] Not Applicable

Overall appraisal: Include [ ] Exclude [ ] Seek further info [ ]

Comments (Including reason for exclusion)

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# JBI Critical Appraisal Checklist for Comparable Cohort/Case Control

**Reviewer**  
**Date**

**Author**  
**Year**  
**Record Number**

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**Overall appraisal:**  
Include [ ]  
Exclude [ ]  
Seek further info. [ ]

**Comments (Including reason for exclusion)**

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*doi: 10.11124/jbisrir-2013-909*
Appendix II: Data extraction instruments

MAStARI data extraction instrument

**JBI Data Extraction Form for Experimental / Observational Studies**

Reviewer .................................  Date .................................

Author .................................  Year .................................

Journal, .................................  Record Number .................................

**Study Method**

RCT  ☐  Quasi-RCT  ☐  Longitudinal  ☐

Retrospective  ☐  Observational  ☐  Other  ☐

**Participants**

Setting

Population

**Sample size**

Group A __________________________ Group B __________________________

**Interventions**

Intervention A

Intervention B

Authors Conclusions:

Reviewers Conclusions:
Study results

Dichotomous data

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Continuous data

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