

The benefit of PICO™ Single Use NPWT System to reduce surgical site complications: summary of a meta-analysis with implications for clinical practice



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A simplified summary of a meta-analysis is described in this article, which shows the ability of a PICO™ Single Use Negative Pressure Wound Therapy System (Smith & Nephew) to reduce surgical site complications, including surgical site infection, dehiscence and length of stay.

About 250 million major surgical procedures are performed worldwide each year and Caesarean section is one of the most common major surgical procedures. Complications that may affect closed surgical incisions include surgical site infection (SSI), dehiscence, seroma, haematoma, delayed healing, as well as poor quality or abnormal scarring (World Union of Wound Healing Societies [WUWHS], 2016).

Improving outcomes for patients with closed surgical incisions by reducing rates of surgical site complications (SSC) could have a significant impact on patients' lives, and societal and healthcare costs. SSIs in particular are financially costly, but up to 60% of SSIs are thought to be preventable by the incorporation of an evidence-based, SSI care bundle.

Negative pressure wound therapy (NPWT), as a postoperative dressing, is one of those options that could be included in this SSI care bundle (WUWHS, 2016).

Using NPWT

Key globally recognised documents support the use of NPWT to reduce the occurrence of SSC, such as surgical site infections and surgical wound dehiscence (WUWHS, 2016; 2018; World Health Organization [WHO], 2016; National Institute for Health and Care Excellence [NICE], 2018). These include:

- WUWHS consensus document — *Closed Surgical Incisions Management* (WUWHS,

2016) advocates the use of NPWT in high risk patients; surgery that has a high incidence of surgical site complications; surgery that has a high consequence when such a complication occurs. This document also provides an algorithm that helps to decide when NPWT should be used prophylactically [Figure 1]

- The WHO guidelines for prevention of SSI suggests the use of prophylactic NPWT in closed surgical incisions in high risk wounds. This was a conditional recommendation due to considered low-quality evidence and only if financial resources allowed and only in adults, although that is still one of the highest recommendations offered by the WHO to prevent SSI
- The WUWHS consensus document — *Surgical Wound Dehiscence (SWD)* (WUWHS, 2018) advocates the use on NPWT in the management of dehisced wounds of all grades. It highlights that single use NPWT (sNPWT) is increasingly being used to prevent SWD. It considers closed incision prophylactic NPWT if a patient has risk factors for SSC.

There are also a number of meta-analyses which have been published but these combine traditional and single use NPWT from all companies and at varying levels of negative pressure comparing with standard care for closed surgical incisions (Semsarzadeh et al, 2015; Watts and Sandy-Hodgetts, 2015; De Vries et al, 2016; Hyldig et al, 2016). This causes

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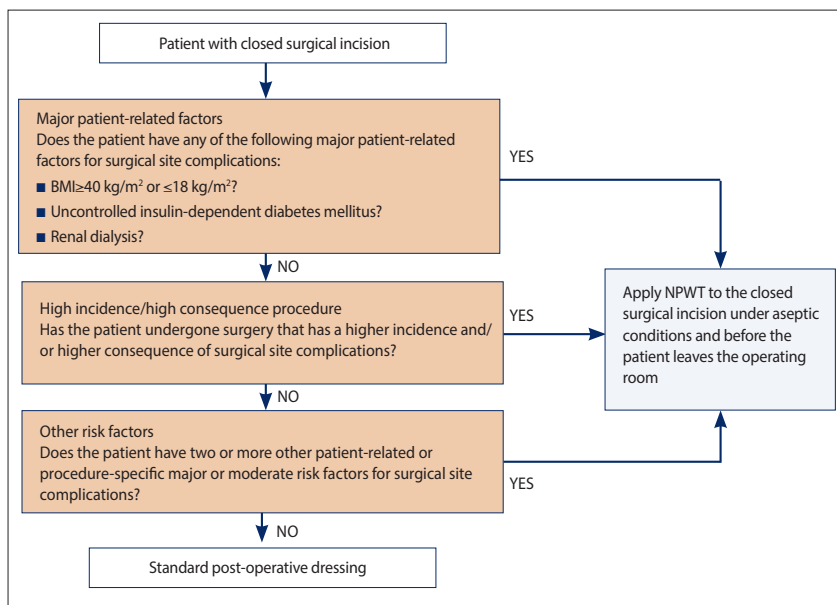


Figure 1. Algorithm for use of NPWT for the prevention of surgical site complications (WUWHS, 2016).



Figure 2. PICO 7 sNPWT and dressing.

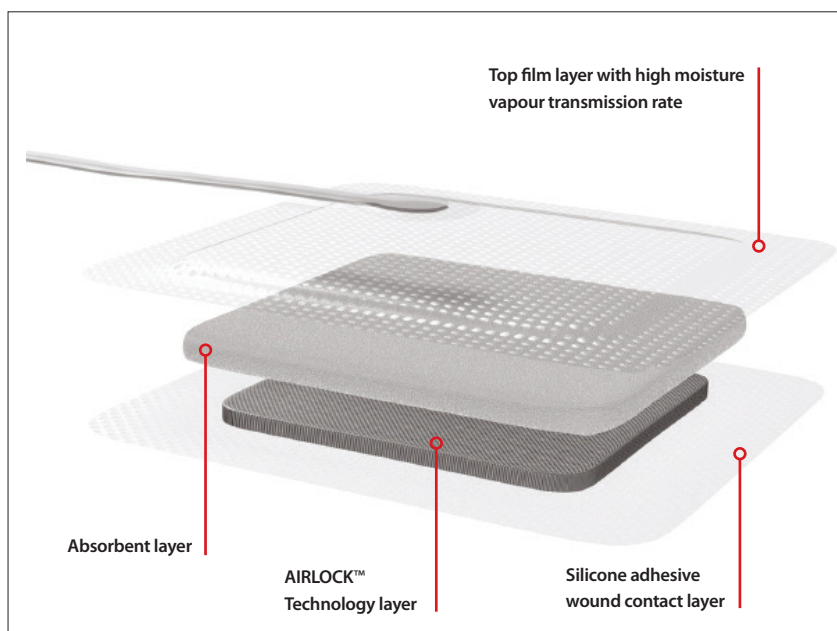


Figure 3. How the PICO dressing works.

wide zone of injury, not just the surgical incision to help improve wound healing (Karlakki et al, 2013; Malmsjö et al, 2014; WUWHS, 2016; Ambler and Casey, 2018). It has specifically designed features, including:

- There is no need for an exudate collection canister, as at least 80% of wound fluid is evaporated, thereby reducing the risk of maceration (Malmsjö et al, 2014; Data on file, 2017a; Ambler and Casey, 2018)
- The whole system is portable and disposable (Malmsjö et al, 2014)
- The dressing has been shown *in vitro* to reduce lateral tension across a closed surgical incision (Loveluck et al, 2016)
- An *in vitro* study showed that the dressing prevented 99.9% of bacterial movement to the wound contact layer ensuring that bacteria are locked away from the surgical wound (Data on file, 2017c; McManus and Woodmansey, 2018)
- An *in vitro* study showed that a compressive force approximately equivalent to an adult sitting on the whole dressing area had no impact on the device to deliver negative pressure to the underside of the dressing (Data on file, 2017b).

methodological heterogeneity and usually a judgment of low-quality evidence with downgrading the conclusions that can be made on the data (Semsarzadeh et al, 2015; De Vries et al, 2016; Hyldig et al, 2016).

PICO™ sNPWT

The PICO™ sNPWT system and dressing with AIRLOCK™ Technology (Smith & Nephew) delivers continuous negative pressure of -80 mmHg (nominal) (Malmsjö et al, 2014; Data on file, 2017; Ambler and Casey, 2018) [Figures 2 and 3]. Negative pressure is delivered across the

NICE in the UK has recently published a Medtech innovation briefing (MIB) specifically for PICO sNPWT (NICE, 2018). They advise that the prophylactic use of PICO sNPWT, an active therapy, is a potentially more effective alternative to standard surgical dressings for the prevention of SSCs in patients with

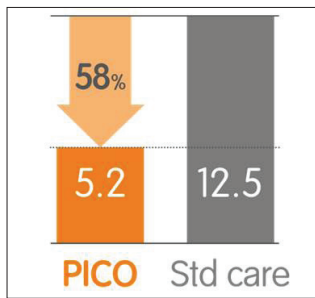


Figure 4. Relative risk of SSI with PICO sNPWT treatment compared with standard care.

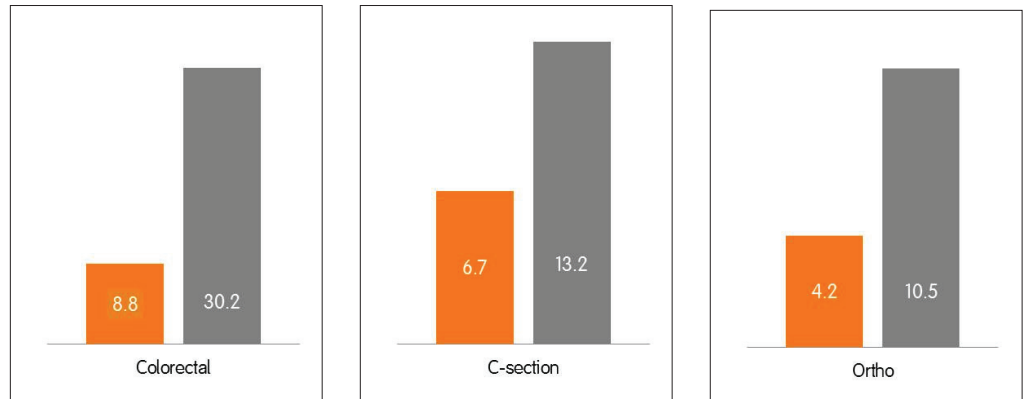


Figure 5. Relative risk of SSI with PICO sNPWT treatment compared with standard care according to surgical indication.

elevated risk of SSC. These key risk factors for the development of SSI were listed as (WUWHS, 2016; NICE, 2018):

- High BMI (especially BMI \geq 35) (Wloch et al, 2012; Nherera et al, 2017)
- Poor physical status (ASA \geq 3) (Nherera et al, 2017)
- Uncontrolled, insulin-dependent diabetes mellitus
- Renal dialysis
- Emergency surgery
- Extended duration of surgery (>75th percentile)
- Elective procedures that have high SSI rates.

Meta-analysis methodology

Due to the increasing numbers of clinical papers being published, specifically related to PICO sNPWT and focusing on the closed surgical incision indication, the authors were able to perform a meta-analysis on the occurrence of surgical site complications and health economic data. By using this single type of NPWT with a fixed level of negative pressure, there is a reduced variability and heterogeneity compared to that which was seen in all previous NPWT meta-analyses; a step change in the field. This included a peer-reviewed publication, but there is value in this more accessible summary (Strugala and Martin, 2017). It should be noted that this is a fast-moving field and new studies continue to be published after the analysis was performed and will be summarised later.

A review of clinical studies in which PICO sNPWT system was used as a preventative measure on surgical closed incision sites was carried out. There was requirement for comparison of sNPWT to a control group with matched populations (i.e. not low-risk patients with standard care and high-risk patients with sNPWT). Any surgical indication was considered

and also any size of study. Clinical endpoints of interest were:

- The frequency of surgical site infection using standard criteria (principally those advocated by the US Centers for Disease Control [CDC])
- The frequency of wound dehiscence
- The length of hospital stay.

All studies were included if they met these criteria. Based on extraction of the key study data in the PICO sNPWT arm and standard care arm, a unique meta-analysis was performed using RevMan software (Version 5.3) and risk ratio reported. There were a total of 1,863 patients in the meta-analysis (Strugala and Martin, 2017). A total of 1,061 incisions were treated with PICO sNPWT and there were 1,141 incisions in the standard care arm. This was based on 16 articles, which included 10 randomised controlled trials (RCT) and six observational studies.

Meta-analysis results

SSI was assessed in 16 studies and 1,839 patients. On average, the rate of SSI in the standard care group was 12.5% and the rate was reduced by 58% to 5.2% in the PICO sNPWT treated group [Figure 4] (Risk ratio = 0.43 [95% CI 0.32–0.57] $P<0.001$). The number needed to treat (NNT) was 14.

When looking at only the 10 RCT studies there was a significant reduction in SSI risk with the PICO sNPWT treated group compared to the standard care group (risk ratio = 0.49 [95% CI 0.34–0.69] $P<0.001$).

A sub-analysis was performed based on surgical specialities and the impact of PICO sNPWT on SSI was statistically significant irrespective of surgery or inherent SSI rate [Figure 5].

- SSI in Colorectal Surgery (RR = 0.29 [95% CI 0.15–0.57] $P<0.001$)

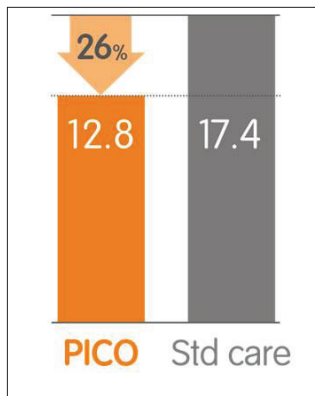


Figure 6. Relative risk of dehiscence with PICO® sNPWT treatment compared with standard care.

Table 1. Details of recent published clinical studies comparing PICO sNPWT to standard care.

Reference	Type of surgery	n =	Surgical site infection	Dehiscence	Length of stay
Hyldig et al (2018)	Caesarean section RCT (BMI>30)	876	✓	✓	
Dingemans et al (2018)	Foot and ankle trauma (surgical repair)	94	✓	✓	
Fleming et al (2017)	Vascular peripheral arterial surgery (groin incision)	151	✓		
Gupta et al (2017)	Laparotomy (Whipple's resection/pancreaticoduodenectomy)	61	✓		
Tan et al (2017)	Vascular peripheral arterial bypass(great saphenous vein harvest site)	42	✓		✓
Irwin et al (2018; published abstract)	Oncological breast surgery (immediate implant reconstruction)	254		✓	
Hackney et al (2017; published abstract)	Laparotomy (mixed abdominal)	71	✓		✓

- SSI in Caesarean Section (RR = 0.53 [95% CI 0.33–0.84] P=0.007)
- SSI in Orthopaedic Surgery (RR = 0.48 [95% CI 0.25-0.93] P=0.03).

Wound dehiscence was measured in six studies representing 1,068 patients. On average, the rate of dehiscence was 17.4% in the standard care group and was reduced by 26% to 12.8% in the PICO sNPWT group [Figure 6] (RR = 0.71 (95% CI 0.54-0.92) P=0.01), which was the first time any NPWT meta-analysis has shown a statistically significant effect on incised wound dehiscence.

Hospital length of stay (LOS) was assessed in eight studies involving 725 patients. As a whole, there was a significant reduction in length of stay by almost half a day when PICO sNPWT was used compared to standard care (mean difference 0.47 days, P<0.001). When the authors stratified data for operative procedures, which have a prolonged baseline length of stay, such as open, elective colorectal surgery, it was observed that PICO sNPWT was able to save just over 5 days in hospital compared to standard care (mean difference 5.14 days, P<0.001) and, thus, the associated cost related to hospital bed use.

Conclusion of meta-analysis

The first meta-analysis is summarised here, which looked solely at a single brand of NPWT device (Strugala and Martin, 2017). By the prophylactic application of the PICO single use NPWT system on closed surgical incisions, when compared to standard care, there was

a clear and significant reduction in surgical site infection by over 50%; wound dehiscence by approximately a third and length of stay by approximately half a day, but by over 5 days after colorectal surgery (Strugala and Martin, 2017).

The meta-analysis is based on a strong evidence base and has shown that PICO sNPWT is effective at reducing surgical site complications and has been demonstrated to have clinical and economic benefit in a wide range of surgical procedures.

Latest evidence

In this fast-moving field there are always new studies being published that could be included in the meta-analysis should it be repeated [Table 1]. Of major note is the recent publication of the largest RCT to date in which PICO sNPWT was compared to standard care. This study by Hyldig et al (2018) was a multi-centre study of 876 obese women undergoing Caesarean section (BMI≥30). The outcome was a significant reduction in SSI rate in the PICO sNPWT group by approximately half, as also highlighted in the meta-analysis (PICO sNPWT 4.6% n=432; Standard Care 9.2% n=444; P=0.007).

Clinical context comment from Professor David Leaper

Surgical site infection (SSI) is becoming the most common of the healthcare associated infections (HAIs), and persists as an expensive complication for healthcare system budgets and patients' postoperative quality of life (WUWHS, 2016). SSI

can be followed by wound dehiscence which adds appreciably to these costs and can involve further prolonged treatment and interventions. SSI is a preventable complication and many guidelines exist, each with an extensive evidence base, to help healthcare clinicians to reduce SSI, but its incidence does not seem to be falling (Kiernan and Leaper, 2014; Leaper and Ousey, 2015; Leaper et al, 2015). This may be partly related to definitions of SSI, adequacy of postoperative surveillance and compliance with recommended SSI care bundles (Tanner et al, 2013; Leaper and Ousey, 2015; Leaper et al, 2015; Tanner et al, 2015; 2016).

Prevention of SSI, and wound dehiscence, involves several prophylactic factors but first, it has to be assumed that all aspects of healthcare facilities, operating theatres, the cleanliness of surgical instruments and dressings comply with national standards and that all surgeons and surgical teams are trained to respect tissues and be competent operators. In addition, every consideration should be given to assuring that patients are subjected to surgical procedures in the best of general health. The use of prophylactic sNPWT as a device/dressing to help prevent SSI or dehiscence is a new option for addition to the SSI care bundle. There have been some good results reported in meta-analyses of the use of NPWT devices for this indication which will support their wider use in clinical practice (Semsarzadeh et al, 2015; Watts et al, 2015; De Vries et al, 2016; Hyldig et al, 2016), but a published systematic review and meta-analysis by Strugala and Martin (2017) presents a wider picture and presents the case for a specific device (PICO single use NPWT system). The conclusions drawn are valid. PICO sNPWT is effective in the reduction of SSI and wound dehiscence, including after three types of 'at risk' surgery:

- After clean-contaminated open colorectal surgery, which has a high incidence of SSI
- After Caesarean section, after which incisional wound dehiscence, probably being related to high BMI, is common, despite being a clean-contaminated operation
- After clean-prosthetic orthopaedic surgery as an SSI, when it occurs, is an expensive disaster for health care and patients.

There other surgical procedures which are 'at risk' of SSI and postoperative wound dehiscence, such as midline sternotomy for cardiac surgery (which carries with it a high risk of associated morbidity and mortality) and breast surgery for cancer (which may delay the start of adjuvant

chemotherapy or radiotherapy). The high risk of SSI and wound dehiscence after breast surgery, and Caesarean section, may relate to procedures undertaken through predominantly fatty tissues or relate to a high BMI.

Evidence-based medicine involves use of the best available scientific data delivered by systematic review and meta-analysis. The scientific evidence that is available, together with clinical expertise, patient choice, health economics and clinical guidance in this heterogeneous field of medicine will continue to grow as further clarification for specific surgical wound types would be welcome. However, the use of PICO single use NPWT system to reduce SSI and postoperative wound dehiscence is clear: Adoption of this specific technology deserves to be routinely considered for inclusion in SSI care bundles for prophylaxis of SSI and dehiscence in at risk incisional wounds. **WINT**

Conflict of interest

Vicki Strugala is an employee of Smith & Nephew plc. David Leaper has no conflict of interest relevant to this article.

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