Use of the PICO™ single use NPWT system in the prevention of surgical site infections

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Surgical site infection is a common complication following surgery and is associated with high morbidity and healthcare costs. The chance of infection can be considerably reduced, however, by assessing patient and surgical risk factors, giving patients prophylactic antibiotics and applying negative pressure wound therapy (NPWT). Evidence has demonstrated that the use of NPWT reduces surgical site complications. The National Institute for Health and Care Excellence has recently recommended the use of the PICO single use NPWT system for closed surgical incisions as it reduces the risks of surgical site infection and seroma.

Surgical site infection (SSI) is the second most common type of healthcare-associated infection in Europe and the US (World Health Organization [WHO], 2018). As SSI has significant social, healthcare and economic impacts, clinical practice should focus on prevention rather than cure (World Union of Wound Healing Societies [WUWHS], 2016). A range of preventative measures need to be implemented to optimise outcomes (WHO, 2018). Numerous studies demonstrate that negative pressure wound therapy (NPWT) reduces surgical site complications (SSCs), including SSI, seroma/haematoma and dehiscence, and is associated with cost savings (WUWHS, 2016). This article reviews the role of the PICO NPWT system in SSI prevention following its recommendation by the National Institute for Health and Care Excellence (NICE).

Surgical site complications and infections

SSCs lead to increased length of hospital stay, morbidity and mortality (WUWHS, 2016; NICE, 2019a). Various factors impact a patient's risk of developing SSCs *[Table 1]*. The most important patient factors are a very high or low BMI, uncontrolled diabetes and renal dialysis. Extended or emergency surgery and hypothermia pose the greatest procedure-related risks.

The number of people at risk of SSI is rising due to population ageing, increasing multimorbidity and the rising number and complexity of surgical procedures (WUWHS, 2016). SSIs are also increasing pressure on clinicians and healthcare budgets. Annually, SSI management costs around $7bn in the US and £758m in the UK (WUWHS, 2016).

Up to 60% of SSIs are preventable (Anderson et al, 2014; WUWHS, 2016). The complexity of factors contributing to SSI risk means that prophylactic antibiotics, antiseptic use during surgery and the application of NPWT to closed surgical incisions is advised in high-risk patients (WUWHS, 2016; WHO, 2018; NICE, 2019b). NICE (2019a) recommends the use of PICO as it is associated with fewer SSIs and seromas compared with standard wound dressings.

The PICO single use NPWT system

PICO is a single use NPWT system indicated for use in surgical incisions with low or moderate exudate levels. Unlike conventional NPWT systems, it is portable, disposable and has no canister for exudate. The battery-operated pump and multilayer dressings deliver –80 mmHg of continuous negative pressure across the surgical incision and surrounding zone of injury for up to 7 days (Malmsjö et al, 2014; Strugagla and Martin, 2017; Ambler and Casey, 2018).

The four layers within each dressing *[Figure 1]*, produce the properties unique to this product. Negative pressure is distributed evenly across the tissue contact area, decreasing lateral tension across closed surgical incisions and reducing the risk of dehiscence (Loveluck et al, 2016) as well as stimulating exudate drainage (Malmsjö et al, 2014). This negative pressure is maintained under high compressive force (Data on file, 2017).

Exudate as demonstrated *in vitro/vivo* is drawn into the absorbent layer and approximately 80% evaporates through the top film, giving the

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Table 1. Risk factors for surgical site complications (WUWHS, 2016).

Risk factor category	Patient-related factors	Procedure-related factors
Major (1+ = high SSI risk)	■ BMI ≥40 or ≤18 ■ Uncontrolled insulin- dependent diabetes ■ Renal dialysis	■ Extended duration of surgery ■ Emergency surgery ■ Hypothermia
Moderate (≥2 = high SSI risk)	■ Poor physical status (ASA >II) ■ Age <1 year or >75 years ■ BMI 30–39.9 ■ Diabetes ■ COPD Gold class ≥2 ■ Renal insufficiency/chronic kidney disease ■ Immunosuppression ■ Steroids for a chronic condition ■ Chemotherapy ■ Pre-existing infection ■ Serum albumin <2.5g/dl ■ Current smoker	■ Anaemia/blood transfusion ■ High wound tension after closure ■ Dual antiplatelet treatment ■ Suboptimal timing or omission of prophylactic antibiotics ■ Tissue trauma/large area of dissection/large area of undermining

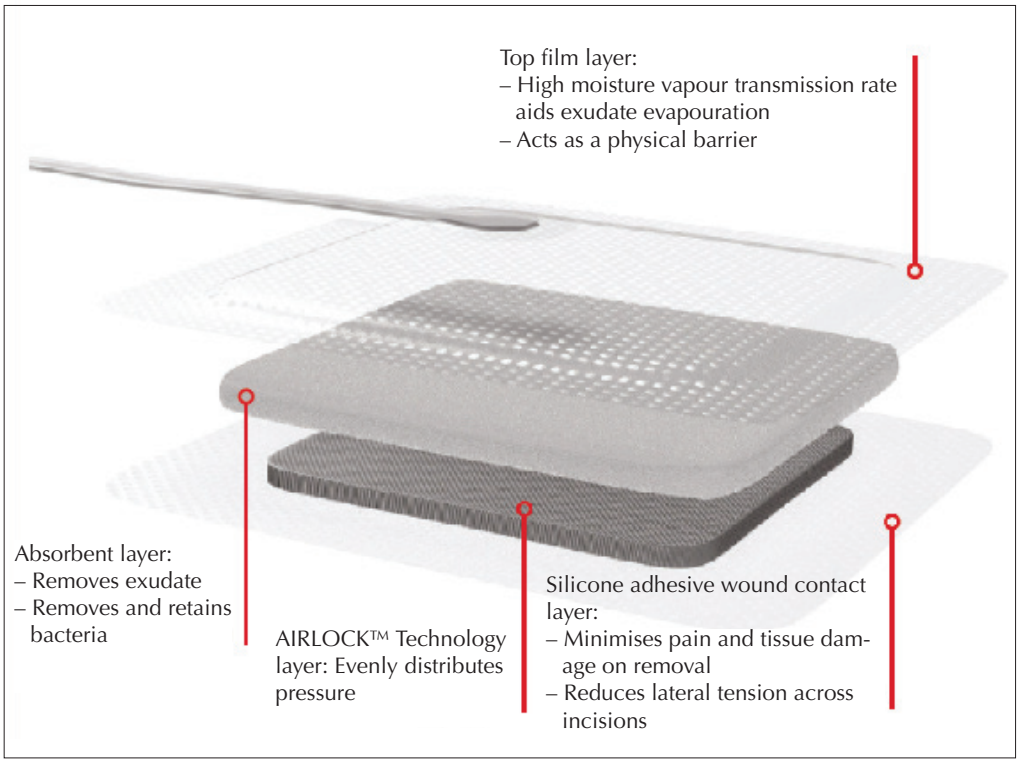

Figure 1. *Actions of the layers within the PICO dressing.*

dressing good fluid- handling capacity (Malmsjö et al, 2014; Ambler and Casey, 2018). Over 99% of bacteria are captured and retained within the absorbent and AIRLOCK™ Technology layers, reducing bioburden at the wound bed as tested *in vitro* (McManus and Woodmansey, 2018). The slight decrease in local blood flow following application may stimulate angiogenesis and granulation tissue formation (Malmsjö et al, 2014). Its small size, portability and length of time in situ minimise the impact treatment has on patient quality of life. Adverse events are rare, but skin blisters and maceration may occur if PICO is incorrectly applied (NICE, 2019a).

When to use PICO

PICO can be used for any of its licensed indications. There are strong data to show it

Box 1. Surgeries where PICO use may be appropriate (Karlakki et al, 2013; Beecher et al, 2016; Karlakki et al, 2016; Strugala and Martin, 2017; Galiano et al, 2018; Hyldig et al, 2018).

- Colorectal
- Vascular
- Abdominal
- Orthopaedic
- Caesarean section
- Breast

Table 2. Reduction in the odds of developing surgical site complications with PICO versus standard dressings (Smith & Nephew, 2019).

Surgical site complication	Number of studies	Total number of patients	Odds reduction
Seroma	6	771	77% (p<0.00001)
Skin necrosis	2	474	89% (p=0.0007)
Dehiscence	9	1,790	30% (p=0.01)

Table 3. Reduction in the risk of surgical site infection with PICO versus standard dressings (Smith & Nephew, 2019).

Type of surgery	Number of studies	Total number of patients	Risk reduction
All types	19	4,530	63% (p<0.00001)
Breast	2	420	64% (p=0.04)
Obstetrics	3	2,911	51% (p=0.003)
Orthopaedics	5	607	57% (p=0.02)
Vascular	2	193	78% (p=0.03)

should be considered in patients at high risk of SSI *[Box 1]*. When compared to standard care, significant reductions in SSI risk have been found in orthopaedic surgical procedures (*P*=0.03), Caesarean section (*P*=0.007), colorectal surgical procedures (*P*=0.0004) and abdominal operations (*P*<0.0001) (Strugala and Martin, 2017). It reduces SSI rates in breast and colorectal cancer patients (Strugala and Martin, 2017; Galiano et al, 2018), which has important implications as evidence suggests infection negatively impacts survival (Artinyan et al, 2015; Beecher et al, 2016).

The evidence

Prophylactic use of PICO reduces SSCs in various closed incisional wounds when compared to standard dressings *[Tables 2 and 3]*. A meta-analysis of 16 studies involving 1,863 patients with 2,202 incisions found PICO reduced SSIs by 51%, dehiscence by 26.4% and length of stay by 0.47 days (Strugala and Martin, 2017). These improved outcomes were seen irrespective of the type of surgery. A systematic review and meta-analysis of 10 randomised controlled trials (RCTs) including a total of 1,311 closed surgical incisions in 1,089 patients found significant relative reductions in the risk of SSI (44.4%) and seroma formation (51.8%) and a reduction in dehiscence (30.0%) compared to standard care (Hyldig et al, 2016).

There are several groups in which RCTs have demonstrated PICO to be particularly effective. A large RCT found prophylactic PICO significantly reduced SSI risk in obese women after caesarean section (*P*=0.0007) (Hyldig et al, 2018). Of the 876 women with a BMI ≥30 who underwent elective or emergency caesarean section, 9.5% of those that received a standard dressing developed a SSI compared to 4.6% of women treated with PICO. This effect remained significant after adjusting for BMI and other risk factors (Hyldig et al, 2018). A multicentre RCT of 200 patients undergoing reduction mammoplasty reported a 5% absolute reduction in complications (SSI, dehiscence or delayed healing) by 21 days post surgery with PICO versus standard care (*P*=0.004) (Galiano et al, 2018). A third RCT including 220 patients undergoing routine primary hip and knee arthroplasty found a four-fold reduction in SSCs (SSI, prolonged discharge, delayed healing and haematoma) and significant reduction in extreme lengths of say when PICO was compared to standard care (*P*=0003) (Karlakki et al, 2016).

NICE recommendations and rationale

NICE Medical Technologies Guidance MTG43 recommends adopting PICO for closed surgical incisions, particularly in high-risk patients, as it is associated with fewer SSIs and seromas and provides additional clinical benefits when compared to standard wound dressings (NICE, 2019a).

Following a comprehensive literature search, 31 studies were initially submitted for review by NICE, see *Figure 2*. A total of 15 RCTs and 16 observational studies were included in the final clinical and cost-effectiveness analysis. The RCTs covered a wide range of surgeries and included patients from seven countries.

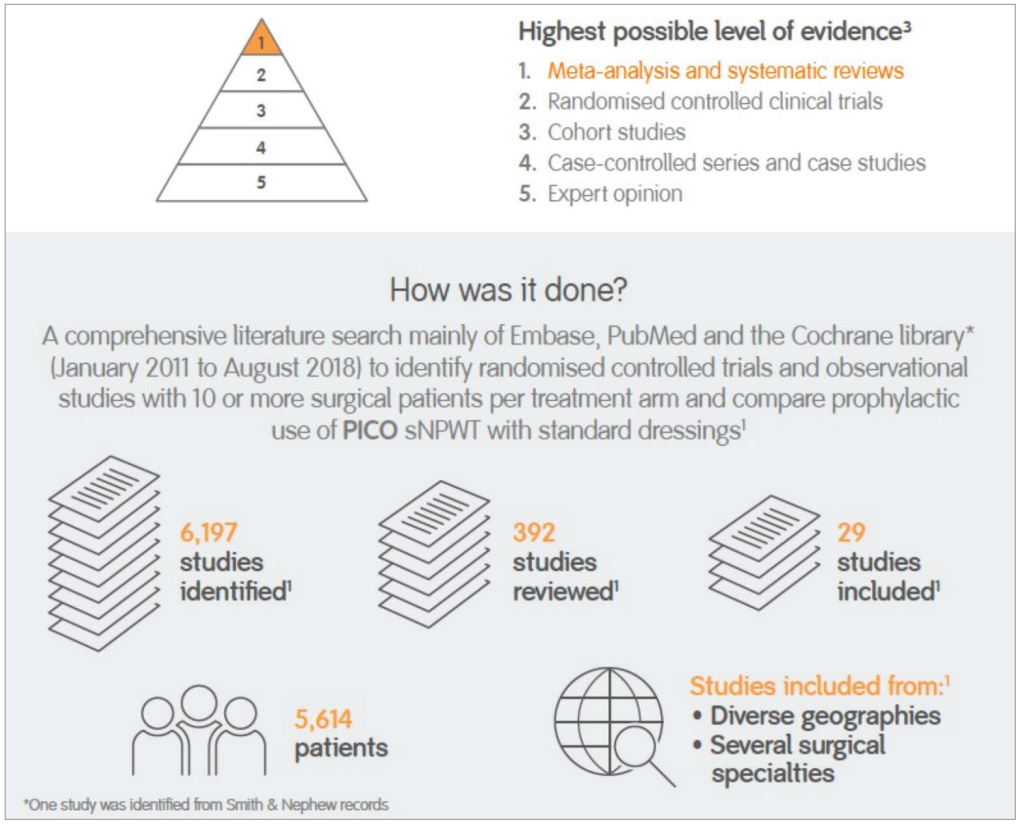

Figure 2. *Evidence submitted to NICE.*

NICE performed a meta-analysis of eight RCTs comparing PICO with standard wound dressings in people with closed surgical incisions and found a significant reduction in SSI rates with PICO (P=0.006). Evidence from a meta-analysis of 10 observational studies supported this finding (P=0.001). Analysis of two RCTs and five observational studies showed a significant reduction in the incidence of seroma (P=0.0003).

NICE concluded that the cost of PICO dressings is offset by the reduction in SSIs and that use of this NPWT may provide additional benefits at no additional cost to the NHS.

Use in practice

PICO is being successfully applied to closed surgical incisions in a number of settings. Here, we focus on two high-risk groups: obese women undergoing Caesarean section and breast cancer surgery.

Miss Darly Mathew, Consultant Obstetrician and Gynaecologist at Chesterfield Royal Hospitals NHS Trust, devised a PICO pathway after a 2012 audit found local infection rates of 10–15%. PICO is applied following caesarean section in patients with a BMI >35 or <35 with an additional risk factor — such as diabetes, a previous SSI or a compromised immune system — and is left in place for 7 days. Miss Mathew and her team find PICO easy to apply in practice and advise patients on what to expect from the treatment *[Box 2]*. SSI is now rare and patient feedback has been extremely positive, particularly from those who have experienced a previous SSI.

Mr John Murphy, Consultant Breast Surgeon at the Nightingale and Genesis Breast Cancer Prevention Centre, uses PICO in patients with one or more risk factors for SSI or at a high risk of losing a breast reconstruction. In the UK, 25% of breast reconstruction patients develop an infection following surgery, 18% require hospital readmission and 9% of implants are lost (Potter et al, 2019). Complication rates increase with the complexity of surgery and may result in the delay or omission of adjuvant chemotherapy or radiotherapy, adversely affecting outcomes such as recurrence and survival (Dave et al, 2016). Since its introduction in Mr Murphy's practice 8 years ago, SSI rates have fallen from 10% to 1%, resulting in an average cost saving of £426 per patient. No collapsible damage has been reported and levels of hypertrophic, red or keloid scarring have dropped from 30% to 4%. He reported that patients have found PICO comfortable to wear, experiencing lower levels of pain than other treatments.

These examples indicate that PICO has the potential to improve clinical outcomes and reduce NHS costs.

Box 2. Practice tips.

- Carefully assess the patient's risk of surgical site infection to maximise treatment and cost benefits
- Ensure staff members have received training in how to correctly apply PICO
- Select a dressing large enough to cover the incision while keeping the port away from the injured area
- Advise patients that PICO:
  - Is portable and can fit in a pocket
  - Is safe
  - May cause a slight pulling or drawing sensation when first turned on
  - Can be left in place for up to 7 days
  - Can be paused to enable showering

Conclusion

SSIs can be reduced by identifying at-risk patients and using NPWT. Evidence shows that PICO NPWT reduces SSIs in breast, obstetric, orthopaedic and vascular surgery in addition to reducing SSCs. NICE recommends PICO over the current standard of care for closed surgical incisions, as treatment results in improved outcomes and additional benefits, as well as potential cost savings. WINT

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