✚ Evidence in focus

PICO◊ sNPWT clinical compendium

PICO◊
Single Use Negative Pressure
Wound Therapy System

November 2021

Smith+Nephew

Key for icons

Closed incisions

Chronic/open/ hard-to-heal wounds

Health economics

Link to full **Evidence in focus** summary

Link to open access reference

Evidence pyramid

Level 1

Level 2

Level 3

Level 4

Level 5

Abbreviations

ABPI	Ankle-brachial pressure index
ASA	American Society of Anaesthesiologists
ASEPSIS	A quantitative scoring system used to identify and classify SSIs
BIMA	Bilateral internal mammary artery
BMI	Body mass index
CABG	Coronary artery bypass graft
CDC	Centers for Disease Control and Prevention
DFU	Diabetic foot ulcer
DSWI	Deep sternal wound infection
FEA	Finite element analysis
ITT	Intention-to-treat
LoS	Length of hospital stay
LS	Least squares
MTG	Medical technologies guidance
NICE	National Institute for Health and Care Excellence
NNT	Number needed to treat
NPWT	Negative pressure wound therapy
POSAS	Patient Observer Scar Assessment Scale
PP	Per-protocol
PU	Pressure ulcer
QALY	Quality adjusted life years
RCT	Randomised controlled trial
RRR	Relative risk reduction
sNPWT	Single use negative pressure wound therapy
SSC	Surgical site complication
SSI	Surgical site infection
TAA	Total ankle arthroplasty
TKA	Total knee arthroplasty
TEWL	Transepidermal water loss
tNPWT	Traditional negative pressure wound therapy
VAS	Visual analogue scale
VLU	Venous leg ulcer
WUWHS	World Union of Wound Healing Societies

Introduction

PICO◊ sNPWT has a strong evidence base

To date, **228*** clinical publications (peer-reviewed manuscripts and conference abstracts) regarding PICO sNPWT have been identified (122 unique clinical studies). This evidence compendium contains summaries of the most relevant publications; it does not include all the publications due to the volume of studies.

Levels of evidence

46

RCTs, meta-analyses, health economics evaluations of RCTs

(**+30** NPWT meta-analyses that note PICO sNPWT studies)

14

Prospective comparative observational studies

25

Retrospective comparative observational studies

47

Case series and case studies

66

Expert opinion, case studies or bench research

*Up to October 13, 2021.

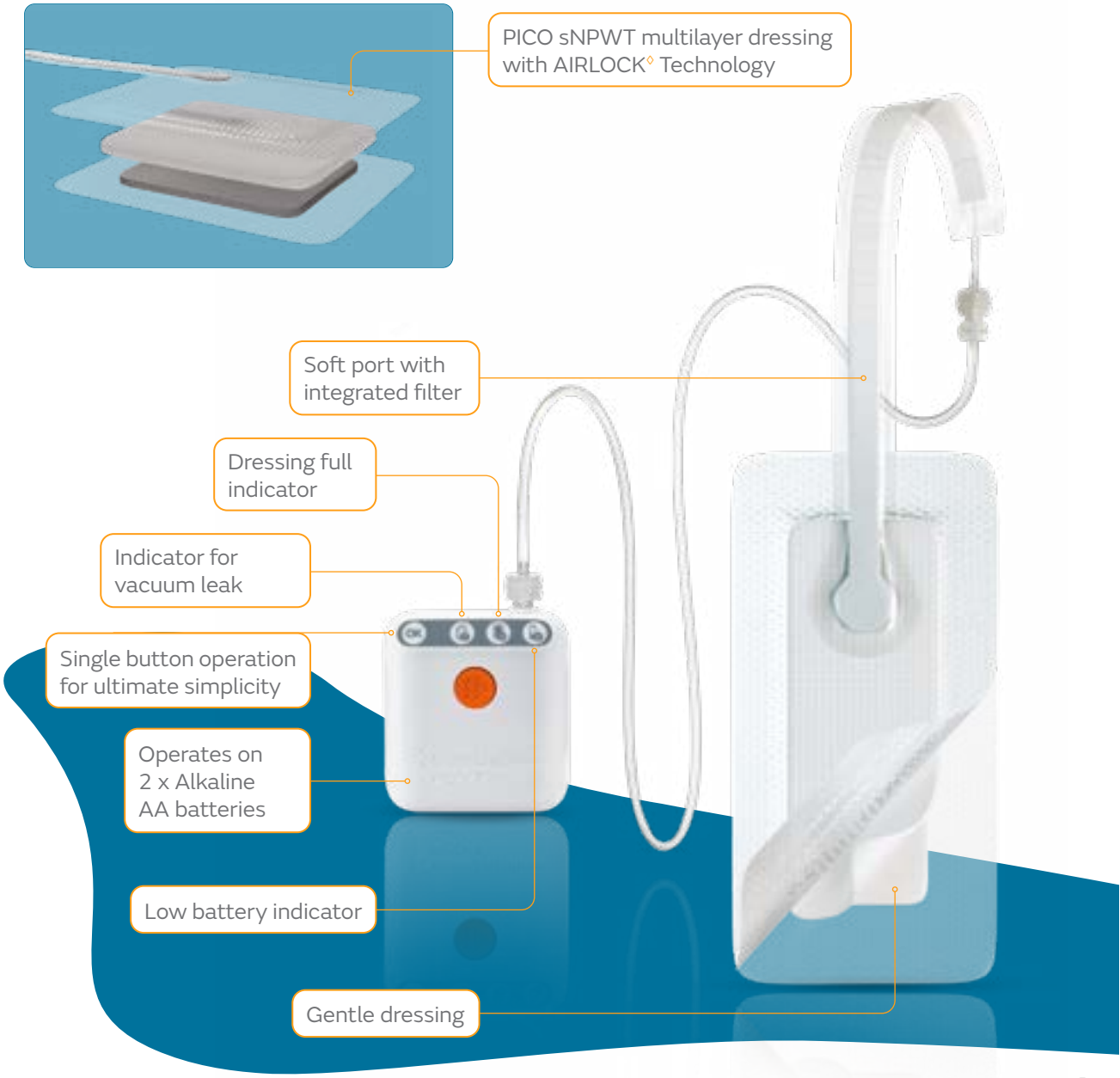
PICO◊ sNPWT indication[1]

PICO sNPWT is indicated for patients who would benefit from a suction device (NPWT) as it may promote wound healing via removal of low to moderate levels of exudate and infectious materials.

Appropriate wound types include:

- Closed surgical incisions
- Chronic
- Acute
- Traumatic
- Subacute and dehisced wounds
- Partial-thickness burns
- Ulcers (such as diabetic or pressure)
- Flaps and grafts

PICO sNPWT systems are suitable for use both in a hospital and homecare setting.



Consensus document/guidelines about prophylactic NPWT and PICO◊ sNPWT for closed surgical incisions

World Health Organization

The World Health Organization recommends the use of prophylactic NPWT "in adult patients on primarily closed surgical incisions in high-risk wounds, for the purpose of the prevention of SSI, while taking resources into account."[2]

World Union of Wound Healing Societies

WUWHS proposes NPWT is used in patients with closed surgical incisions who have intrinsic risk factors for SSCs or who have had a surgical procedure associated with higher incidence and/or higher consequence of SSCs.[3]

The 2019 *WUWHS Consensus Document on Wound Exudate: effective assessment and management*, recognises the benefits of sNPWT in the management of closed surgical incisions:[4]

- Provides a barrier to external contamination[3,4]
- Removes excess wound exudate[4]
- May aid healing by:[3,4]
  - Reducing lateral tension across the closed incision
  - Improving lymphatic drainage
  - Reducing the risk of wound infection and separation (dehiscence)

National Institute for Health and Care Excellence (NICE)

NICE Medical technologies guidance: *PICO negative pressure wound dressings for closed surgical incisions* (MTG43)

NICE aims to improve health and social care in England through evidence-based guidance. NICE guidance helps people make efficient, cost-effective and consistent decisions about adopting new medical technologies. NICE guidance is internationally recognised.

NICE recommends that PICO sNPWT should be considered as an option for closed surgical incisions in patients who are at high risk of SSIs.[5]

In a review of data from 31 clinical studies (15 randomised controlled trials and 16 non-randomised comparative observational studies), NICE concluded that PICO sNPWT is associated with fewer SSIs and seromas compared with standard wound dressings. Cost modelling suggests that compared with standard wound dressings, PICO sNPWT provides extra clinical benefits at a similar overall cost with standard wound dressings.[5]

Key evidence

MULTIDISCIPLINE

1. Saunders C, *et al.* (2021)
2. Nherera L, *et al.* (2021)
3. Pellino G, *et al.* (2014)

ABDOMINAL

1. O'Leary DP, *et al.* (2017)
2. Bueno-Lledó J, *et al.* (2021)
3. Abadía P, *et al.* (2021)
4. Obeid N, *et al.* (2021)
5. Selvaggi F, *et al.* (2014)
6. Gupta R, *et al.* (2017)

BREAST AND PLASTIC SURGERY

1. Irwin GW, *et al.* (2020)
2. Murphy JA, *et al.* (2021)
3. Galiano RD, *et al.* (2018)
4. Tanaydin V, *et al.* (2018)
5. Ryu JY, *et al.* (2021)
6. Edwards D, *et al.* (2018)

CARDIOTHORACIC SURGERY

1. Tabley A, *et al.* (2020)
2. Witt-Majchrzak A, *et al.* (2014)
3. Nherera LM, *et al.* (2018)
4. Battaglia S, *et al.* (2018)

VASCULAR SURGERY

1. Hasselmann J, *et al.* (2020)
2. Svensson-Björk R, *et al.* (2020)
3. Fleming CA, *et al.* (2018)

OBSTETRICS AND GYNAECOLOGY

1. Hyldig N, *et al.* (2018)
2. Hyldig N, *et al.* (2019)
3. Hyldig N, *et al.* (2020)
4. Bullough L, *et al.* (2015)
5. Ascuitto KC, *et al.* (2020)
6. Searle R, *et al.* (2017)

ORTHOPAEDIC SURGERY

1. Karlakki SL, *et al.* (2016)
2. Nherera LM, *et al.* (2017)
3. Masters J, *et al.* (2021)
4. Dingemans SA, *et al.* (2018)
5. Matsumoto T, *et al.* (2015)
6. Adogwa O, *et al.* (2014)
7. Helito CP, *et al.* (2020)

HARD-TO-HEAL WOUNDS

1. Kirsner R, *et al.* (2019)
2. Kirsner RS, *et al.* (2020)
3. McCluskey P, *et al.* (2020)
4. Hughes J, *et al.* (2020)
5. Dowsett C, *et al.* (2017)
6. Patel A, *et al.* (2019)
7. Hurd T, *et al.* (2020)
8. Hampton J. (2015)
9. Sharpe A, *et al.* (2018)
10. Dowsett C, *et al.* (2013)
11. Schwartz JA, *et al.* (2015)
12. Hurd T, *et al.* (2014)
13. Hurd T. (2013)

MODE OF ACTION

1. Brownhill RV, *et al.* (2020)
2. Innocenti M, *et al.* (2019)
3. Malmsjö M, *et al.* (2014)
4. Loveluck J, *et al.* (2016)

Click on the author to navigate to study

1. Saunders C, *et al.*

Single-use negative-pressure wound therapy versus conventional dressings for closed surgical incisions: systematic literature review and meta-analysis

Saunders C, Nherera LM, Horner A, Trueman P. *BJS Open*. 2021;5(1):1–8.

Overview

- Systematic review and meta-analysis of RCTs and observational studies with ≥10 surgical patients to assess the effect of prophylactic PICO◊ sNPWT on the incidence of SSCs compared with standard care
- Articles published January 2011 to August 2018 identified from Embase, PubMed, the Cochrane Library, and other sources
  - Final analysis included 29 studies (5,614 patients)

Results

- PICO sNPWT helped to significantly reduce the odds of SSIs by 63% versus standard care (Figure; p<0.001)
  - Significant reductions were achieved across several surgical specialties: breast (p=0.04), obstetric (p=0.003), orthopaedic (p=0.02) and vascular (p=0.03) surgery
- PICO sNPWT helped to significantly reduce the risk of necrosis (p<0.001), seroma (p<0.001) and dehiscence (p=0.01), compared with standard care (Figure)
  - Results for other SSCs (haematoma, abnormal scarring, delayed healing) were similar in both groups
- Mean LoS was 1.75 days shorter with PICO sNPWT than with standard care (p<0.001)
  - Rates of re-admission and re-operations were similar in both groups

Conclusions

Compared with standard care, PICO sNPWT helped to significantly reduce the odds of SSIs, necrosis, seroma and dehiscence in patients with closed surgical incisions, and reduced hospital LoS.

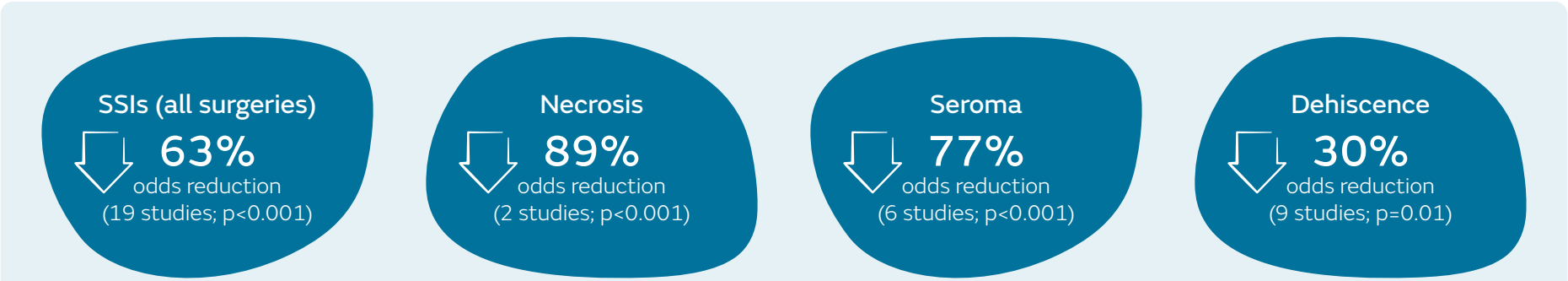


Figure. Odds reductions (%) with PICO sNPWT compared with standard care for SSIs, necrosis, seroma and dehiscence

2. Nherera L, *et al.*

Single-use negative pressure wound therapy reduces costs in closed surgical incisions: UK and US economic evaluation

Nherera LM, Saunders C, Verma S, Trueman P, Fatoye F. *J Wound Care*. 2021;30(Sup5):S23–S31.

Overview

- Cost effectiveness evaluation of PICO◊ sNPWT versus standard care to prevent a complication (SSIs or dehiscence) in patients with closed surgical incisions
- Analysis of data from Saunders C, *et al.* 2020 in 1,000 patients over 12 weeks

Results

- Use of PICO sNPWT improved health outcomes and was considered to be less costly for all types of surgery combined versus standard care
  - £105 per patient cost saving from a UK payer perspective
  - $637 per patient cost saving from a US payer perspective
  - Greatest savings observed in high-risk patients (diabetes, BMI ≥30kg/m^2, ASA ≥3)

Conclusions

Use of PICO sNPWT was less costly and resulted in improved health outcomes compared with standard care for combined surgical specialties.

£105
saving per patient
from the UK payer perspective
($637 per patient
from a US payer perspective)

Greatest savings
in **high-risk patients**

3. Pellino G, *et al.*

Preventive NPWT over closed incisions in general surgery: does age matter?

Pellino G, Sciaudone G, Candilio G, et al. *Int J Surg.* 2014;12(suppl 2):S64–S68.

Overview

- Open-label, prospective controlled trial to assess the efficacy of PICO◊ sNPWT in preventing SSCs compared with conventional dressings in patients undergoing surgery for breast or colorectal diseases
  - Breast and colorectal: PICO sNPWT, both n=25; standard dressings, both n=25
- 40% (n=10) of each treatment group were aged >65 years

Results

- SSIs in patients aged >65 years were significantly lower with PICO sNPWT, versus standard dressings regardless of surgery type (p=0.003)
- SSCs were significantly lower in all patients receiving PICO sNPWT (breast, p=0.04; colorectal, p=0.008)
- Rates of seroma were similar between both breast groups, while in colorectal patients these were higher in controls (8 vs 40%, p=0.02)
- ASEPSIS scores were significantly lower with PICO sNPWT (breast, p=0.03; colorectal, p=0.01)

Conclusions

PICO sNPWT helped to significantly reduce the incidence of SSIs and SSCs compared with standard dressings in patients undergoing breast and colorectal surgery. The effect of PICO sNPWT on SSIs was greatest in patients aged >65 years.

50% reduction in SSIs in patients >65 years with PICO sNPWT versus standard dressings in both **breast** and **colorectal surgery** (both p=0.003)

1. O'Leary DP, *et al.*

Prophylactic negative pressure dressing use in closed laparotomy wounds following abdominal operations. A randomised controlled open-label trial: The P.I.C.O. Trial

O'Leary DP, Peirce C, Anglim B, et al. *Ann Surg*. 2017;265(6):1082–1086.

Overview

- A single-centre, randomised controlled trial comparing SSI incidence with prophylactic use of PICO◊ sNPWT and standard dressings in patients undergoing laparotomy surgery
- Median ASA score was 2 in both groups; 35% (17 of 49) of patients were obese
  - PICO sNPWT, n=24; worn for four days post-operatively
  - Standard dressings, n=25

Results

- SSI incidence was significantly reduced with PICO sNPWT compared with standard dressings 30 days postoperatively (74% relative reduction; p=0.043; Figure)
  - SSI incidence on Day 4 was lower with PICO sNPWT (4.1 vs 8.0%; p=0.516)
- Mean LoS was significantly shorter with PICO sNPWT compared with standard dressings (6.1 vs 14.7 days, p=0.019; Figure)
- Cosmetic outcome and patient satisfaction were similar in both groups

Conclusions

Prophylactic use of PICO sNPWT in patients undergoing laparotomy surgery significantly reduced the incidence of SSIs and mean LoS compared with standard dressings.

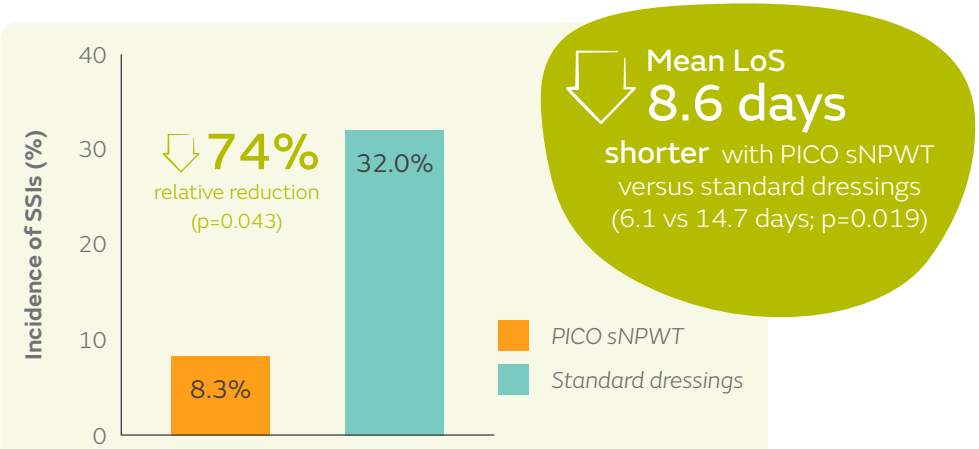


Figure. SSI incidence 30 days postoperatively and mean LoS with PICO sNPWT and standard dressings

2. Bueno-Lledó J, *et al.*

Prophylactic single-use negative pressure dressing in closed surgical wounds after incisional hernia repair

Bueno-Lledó J, Franco-Bernal A, Garcia-Voz-Mediano MT, Torregrosa-Gallud A, Bonafé S. *Ann Surg.* 2021;273(6):1081–1086.

Overview

- Independent, single-centre RCT to compare the incidence of SSCs in midline elective incisional hernia repair via laparotomy
  - PICO◊ sNPWT, n=72
  - Standard dressings, n=74

Results

- PICO sNPWT resulted in a 44% significant relative reduction in SSC incidence versus standard dressings (16.6 vs 29.8%; p=0.042)
- There were no incidences of SSIs in the PICO sNPWT group compared with six cases with standard dressings (p=0.002)
- No significant differences were observed in dehiscence, seroma or hospital LoS (p=ns)

Conclusions

Use of PICO sNPWT helped to significantly reduce the incidences of SSCs and SSIs compared with standard dressings in patients undergoing elective midline incisional hernia repair via laparotomy 30 days post surgery.

3. Abadía P, *et al.*

Prophylactic use of negative pressure wound therapy reduces surgical site infections in elective colorectal surgery: A prospective cohort study

Abadía P, Ocaña J, Ramos D, et al. *Surg Infect.* 2021;22(2):234–239.

Overview

- Independent, prospective, non-randomised, single-centre cohort study in patients undergoing elective open and laparoscopic open-assisted colorectal surgery
- Patients were treated for 7 days and followed up weekly after discharge for up to 30 days post surgery
  - PICO sNPWT, n=100
  - Surgical dressings, n=100

Results

- Significant 53% relative reduction in incidence of SSIs with PICO sNPWT versus surgical dressings (9 vs 19%; p=0.02)
- Length of hospital stay:
  - Similar with PICO sNPWT versus surgical dressings (p=ns)
  - 4.5 days longer in patients with SSIs versus those without (16.2 vs 11.7 days; p<0.01)

Conclusions

In patients undergoing elective colorectal surgery, PICO sNPWT helped reduce the incidence of SSIs compared with surgical dressings.

4. Obeid N, *et al.*

Negative pressure therapy for stoma closure sites – a nonrandomised case control study

Obeid N, Sharma E, Dunstan M, et al. *Int J Colorectal Dis*. 2021;36:161–167.

Overview

- Retrospective analysis of patients undergoing stoma closure surgery
  - Wounds covered with a PICO◊ sNPWT dressing, n=17
  - Wounds packed with non-absorbable dressings, n=15

Results

With PICO sNPWT versus standard care:

- 10 fewer community dressing clinic visits (1.9 vs 11.9 visits)
- More patients were able to return to work within 2 weeks of surgery (100 vs 66%)
- Shorter mean hospital LoS (5 vs 6 days)

Conclusions

PICO sNPWT applied following stoma closure surgery helped to reduce the number of community dressing clinic visits and hospital LoS compared with traditional wound packing. PICO sNPWT also enabled all patients to resume work/daily activities within 2 weeks.

5. Selvaggi F, *et al.*

New advances in negative pressure wound therapy (NPWT) for surgical wounds of patients affected with Crohn's disease

Selvaggi F, Pellino G, Sciaudone G, et al. *Surg Technol Int*. 2014;24:83–89.

Overview

- Prospective, open-label, controlled study to compare PICO sNPWT with conventional gauze dressings in patients undergoing elective surgery for stricturing Crohn's disease
  - PICO sNPWT, n=25
  - Conventional dressings, n=25
- Several patients (38%) were taking ≥20mg of corticosteroids at baseline, which increase the risk of developing SSIs

Results

- Compared with conventional dressings, PICO sNPWT helped to reduce:
  - The incidence of SSIs by 83% (8 vs 48%; p=0.004) overall and by 89% in patients receiving corticosteroids at baseline (8 vs 75%; p=0.001)
  - LoS (7 vs 12 days; p=0.0001)
  - Seroma by 82% (8 vs 44%; p=0.008)
  - Early readmission rate* by 100% (0 vs 24%; p=0.02)

Conclusions

PICO sNPWT helped to reduce the incidence of SSIs and seroma resulting in shorter LoS compared with conventional dressings in patients undergoing surgery for stricturing Crohn's disease.

*Repeat hospitalisation within 6 months from discharge for wound-related complications

6. Gupta R, *et al.*

Efficacy of negative pressure wound treatment in preventing surgical site infections after Whipple procedures

Gupta R, Darby GC, Imagawa DK. *Am Surg.* 2017;83(10):1166–1169.

Overview

- Retrospective study evaluating the incidence of SSIs in patients following pancreaticoduodenectomy (Whipple procedure), performed by one surgeon at a single centre in the USA
  - PICO◊ sNPWT, n=25
  - Traditional dressings, n=36

Results

- PICO sNPWT resulted in a 71% relative reduction in SSIs versus traditional dressings (12 vs 41%; p=0.01; NNT: 3.4)
- Pancreatic fistulas were less frequent with PICO sNPWT than with traditional dressings
  - All grades: RRR, 53% (8 vs 17%; p=0.33)
  - Grade B: RRR, 27% (8 vs 11%; p=0.69)
- PICO sNPWT reduced the incidence of deep SSIs by 6x compared with traditional dressings (4 vs 25%)

Conclusions

Use of PICO sNPWT helped to significantly reduce the number of SSIs in patients undergoing pancreaticoduodenectomy compared with traditional dressings.

PICO sNPWT reduced the incidence of **deep SSIs** by **6x** compared with traditional dressings (4 vs 25%)

1. Irwin GW, *et al.*

Negative pressure wound therapy reduces wound breakdown and implant loss in prepectoral breast reconstruction

Irwin GW, Boundouki G, Fakim B, et al. *Plast Reconstr Surg Glob Open*. 2020;8:e2667.

Overview

- A prospective cohort study conducted at a single UK centre (N=196) to evaluate wound breakdown and implant loss with use of PICO◊ sNPWT compared with standard dressings in patients undergoing skin-sparing or -reducing mastectomy with immediate prepectoral implant reconstruction
  - PICO sNPWT, 126 breasts
  - Standard dressings, 181 breasts

Results

- Wound breakdown was less frequent with PICO sNPWT than standard dressings (0.8 vs 5.5%; p=0.01; Figure)
- No implants were lost in the PICO sNPWT cohort; 7 were lost in the standard dressings cohort (p<0.05; Figure)
- Estimated cost savings per patient were £426 from using PICO sNPWT versus standard dressings
- Allowing for reconstruction failure and PICO sNPWT costs, mean cost per patient was £147.60 for the PICO sNPWT cohort and £573.14 for the standard dressings cohort

Conclusions

Use of PICO sNPWT helped to significantly reduce wound breakdown, which resulted in fewer implant losses, compared with standard dressings in patients undergoing mastectomy and was estimated to provide cost savings.

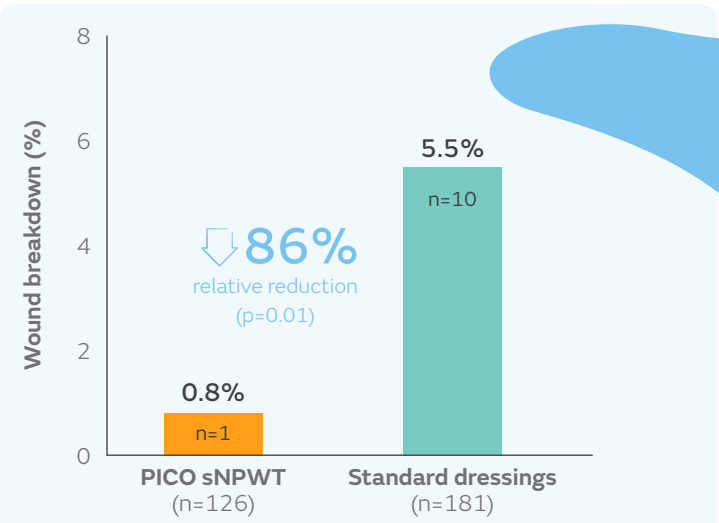


Figure. Incidence of wound breakdown and implant loss in the PICO sNPWT and standard dressings cohorts

0 vs 7 implant loss
with PICO sNPWT compared with traditional dressings (0.0 vs 3.9%; p<0.05)

2. Murphy JA, *et al.*

Cost-effectiveness of single-use negative-pressure therapy compared with standard care for prevention of reconstruction failure in prepectoral breast reconstruction

Murphy JA, Myers D, Trueman P, Searle R. *BJS Open*. 2021;5(2):zraa042.

Overview

- A cost-effectiveness evaluation of PICO◊ sNPWT versus standard care for prevention of wound breakdown leading to reconstruction failure following prepectoral breast reconstruction in the UK
- Data from Irwin GW, *et al.* 2020 was included and analysed over a 48 month time horizon

Results

- £1,706 estimated mean per patient cost saving with PICO sNPWT versus standard care (£230 vs £1,937)
- Use of PICO sNPWT was estimated to reduce reconstruction failure rate resulting from wound breakdown compared with standard care (0 vs 8.3%)

Conclusions

PICO sNPWT was estimated to be cost saving and helped to decrease reconstruction failures resulting from wound breakdown when compared with standard care in patients undergoing prepectoral breast reconstruction.

£1,706
estimated cost savings per patient
with PICO sNPWT versus standard care

Reduced incidence of reconstruction failure
due to wound breakdown with PICO sNPWT versus standard care (0 vs 8.3%)

3. Galiano RD, *et al.*

Incisional negative pressure wound therapy for prevention of wound healing complications following reduction mammaplasty

Galiano RD, Hudson D, Shin J, et al. *Plast Reconstr Surg Glob Open*. 2018;6(1):e1560.

Overview

- Prospective, within-patient, randomised controlled, open-label, multicentre study assessing the prevalence and type of healing complications in patients who had elective bilateral reduction mammaplasty
- Patients were randomised within-patient (i.e. to right or left breast) to be treated for up to 14 days
  - PICO sNPWT, n=200
  - Standard care, n=200

Results

- PICO sNPWT significantly reduced incidence of wound healing complications within 21 days post-operatively compared with standard care (56.8 vs 61.8%; p=0.004)
- Incidence of dehiscence within 21 days of surgery was significantly reduced with PICO sNPWT versus standard care (16.2 vs 26.4%; p<0.001)
  - This effect was greatest in patients with BMI >25kg/m^2

Conclusions

PICO sNPWT helped to reduce wound healing complications, particularly the incidence of wound dehiscence, when applied prophylactically to closed incision reduction mammaplasty surgical wounds compared with standard care. This effect on the incidence of dehiscence was greatest in patients with BMI >25kg/m^2.

4. Tanaydin V, *et al.*

Randomized controlled study comparing disposable negative-pressure wound therapy with standard care in bilateral breast reduction mammoplasty evaluating surgical site complications and scar quality

Tanaydin V, Beugels J, Andriessen A, Sawor JH, van der Hulst RRWJ. *Aesthetic Plast Surg*. 2018;42(4):927–935.

Overview

- A single-centre, prospective, RCT of patients undergoing bilateral breast reduction mammaplasty who received PICO sNPWT or standard care (fixation strips) on either the left or right breast
  - PICO◊ sNPWT, n=32
  - Standard care, n=32

Results

- PICO sNPWT resulted in a significant 50% relative reduction in SSCs (incision not completely closed at 7 days, dehiscence or infection) compared with standard care (15.6 vs 31.3%; p<0.004)
- Scar quality (POSAS and VAS scores) was signficantly better with PICO sNPWT versus standard care at 42 and 90 days (p<0.05)

Conclusions

PICO sNPWT use significantly reduced the number of SSCs, including dehiscence, and significantly improved the quality of scarring compared with standard care in patients undergoing mammaplasty surgery.

5. Ryu JY, *et al.*

Usefulness of incisional negative pressure wound therapy for decreasing wound complication rates and seroma formation following prepectoral breast reconstruction

Ryu JY, Lee JH, Kim JS, et al. *Aesthetic Plast Surg*. 2021 Jan 20; [Epub ahead of print].

Overview

- Retrospective, single-centre cohort study in patients undergoing prepectoral breast reconstruction
  - PICO sNPWT, n=37
  - Standard dressings (foam dressing plus ointment), n=23

Results

With PICO sNPWT versus standard dressings, there were significant reductions in:

- SSC incidence (7 vs 12; p=0.007)
- Major seroma incidence (6 vs 10; p=0.02)
- Mean duration of seroma (21.9 vs 61.7 days; p=0.018)
- Mean volume of seroma (53.9 vs 189.7cm^3; p=0.019)
- Patients requiring an unplanned re-operation (1 vs 6; p=0.01)

Conclusions

When used immediately after prepectoral breast reconstruction, PICO sNPWT helped to significantly reduce the incidences of SSCs and major seroma, and fewer patients required re-operation, compared with standard dressings.

6. Edwards D, *et al.*

Using portable, single-use, canister-free, negative-pressure wound therapy for plastic surgery wounds

Edwards D, Bourke N, Murdoch J, Verma S. *Wounds UK*. 2018;14(3):56–62.

Overview

- Retrospective, single-centre data review evaluating the pathway used to treat complex plastic surgery wounds using PICO sNPWT in an outpatient setting
  - PICO◊ sNPWT, n=213

Results

- Use of PICO sNPWT within this pathway facilitated the management of complex wounds in an outpatient setting and facilitated early patient discharge, enabling 367 bed days to be released over 5 years
- A total of £76,592 was saved in the plastic surgery department due to bed management efficiencies, after deducting device and nursing resource costs

Conclusions

Use of PICO sNPWT facilitated the management of complex wounds in an outpatient setting and early patient discharge, which resulted in a total saving of £76,592 over a five-year period due to bed management efficiencies.

1. Tabley A, *et al.*

A survey of cardiac surgery infections with PICO™ Negative Pressure Therapy in high-risk patients: survey of surgical site complications

Tabley A, Aludaat C, Le Guillou V, et al. *Ann Thorac Surg.* 2020;110(6):2034–2040.

Overview

- Review of anonymised records before and after introduction of PICO◊ sNPWT for high-risk patients (≥2 SSI risk factors) undergoing cardiac surgery at a hospital in France to determine the effect on SSCs
  - PICO sNPWT, n=142
  - Standard care, n=91
- More patients in the PICO group had BMI ≥35kg/m² or underwent BIMA (p<0.05 for both)

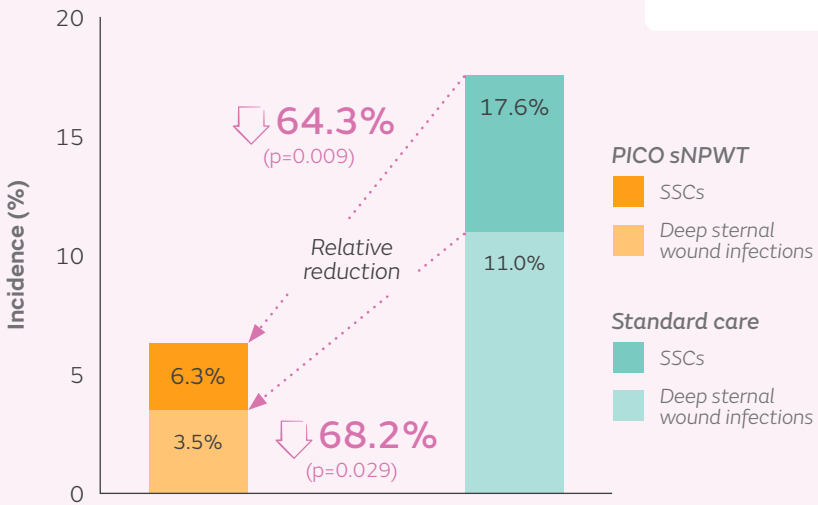
Results

Compared with standard care, prophylactic use of PICO sNPWT resulted in:

- A significant reduction in the incidence of SSCs (6.3 vs 17.6%; p=0.009; Figure)
  - Particularly those with diabetes, BMI ≥35kg/m² or who had BIMA surgery (p<0.05 for all)
- Fewer patients with resultant deep sternal wound infection (3.5 vs 11.0%; p=0.029; Figure)
- An estimated saving of €1,295 per patient, releasing capacity to treat 10 extra patients

Conclusions

Use of PICO sNPWT in high-risk cardiac surgery patients significantly reduced the incidence of SSCs compared with standard care; it also reduced costs by an estimated €1,295 per patient. The authors suggest that the reduction in deep sternal wound infection incidence with PICO sNPWT may be due to preventing spread of superficial infectious material.



~10 days — Shorter length of hospital stay for patients without SSCs (11.5 vs 21.4 days)

€1,295 per patient estimated savings

Figure. Incidence of SSCs with PICO sNPWT and standard care, as well as cost reductions and effect of SSCs on length of hospital stay

2. Witt-Majchrzak A, *et al.*

Preliminary outcome of treatment of postoperative primarily closed sternotomy wounds treated using negative pressure wound therapy

Witt-Majchrzak A, Żelazny P, Snarska J. *Pol Przegl Chir.* 2014;86(10):456–465.

Overview

- Prospective, open-label study (6-week follow up) to evaluate wound healing in patients treated with PICO◊ sNPWT or conventional dressings immediately after a CABG procedure
  - PICO sNPWT, n=40
  - Conventional dressings, n=40

Results

- Compared with conventional dressings, PICO sNPWT resulted in:
  - 70% relative reduction in incidences of SSCs (7.5 vs 25.0%; p=0.034; Figure) and 86% relative reduction in superficial SSIs (2.5 vs 17.5%; p=0.025; Figure)
  - No cases of skin necrosis versus 12 cases with conventional dressings (p=0.0002)

Conclusions

Prophylactic use of PICO sNPWT significantly reduced the incidences of SSCs and superficial SSIs compared with conventional dressings in patients with closed sternotomy wounds.

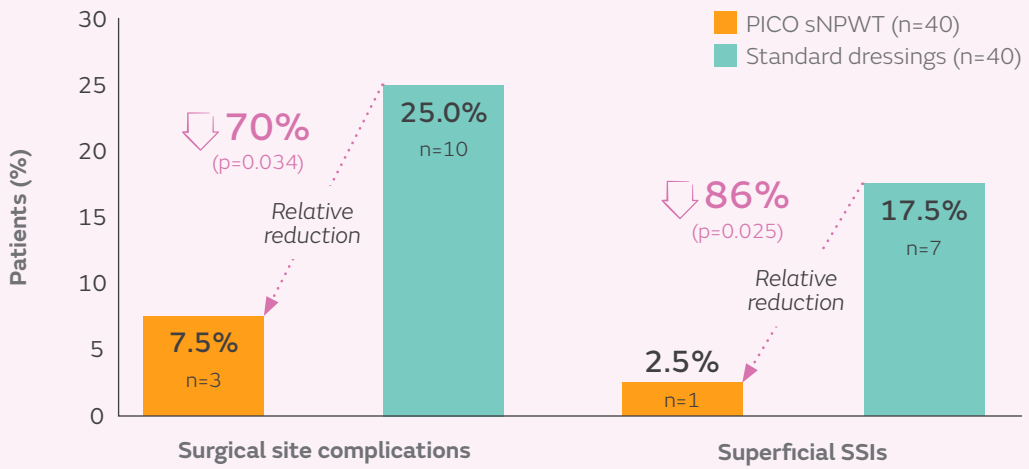


Figure. Incidences of SSCs and SSIs with PICO sNPWT and conventional dressings

3. Nherera LM, *et al.*

Cost-effectiveness analysis of single use negative pressure wound therapy dressings (sNPWT) compared to standard of care in reducing surgical site complications (SSC) in patients undergoing coronary artery bypass grafting surgery

Nherera LM, Trueman P, Schmoeckel M, Fatoye FA. *J Cardiothorac Surg*. 2018;13:103.

Overview

- A cost-effectiveness evaluation of PICO◊ sNPWT and standard care in reducing the incidence of SSCs (superficial and deep infections or dehiscence) in sternotomy wounds in patients undergoing CABG surgery (Germany Insurance payer perspective)

Results

Compared with standard care, PICO sNPWT was estimated to:

- Reduce total mean treatment costs per patient (€20,572 vs €19,986) with a cost-saving of €586
- Avoid more wound-related complications (0.989 vs 0.952) and provide more QALYs (0.8904 vs 0.8593)
- Provide greater savings in high-risk patients (BMI ≥30kg/m^2, patients with diabetes and smokers)

Conclusions

Prophylactic use of PICO sNPWT was estimated to be less costly and more effective than standard care for sternotomy wounds in patients undergoing CABG when analysed from a German payer perspective; the magnitude of savings increased in high-risk patients.

4. Battaglia S, *et al.*

Implementation of the Brompton and Harefield Infection Score (BHIS) and PICO Single-Use Negative Pressure WoundTherapy (sNPWT) pathway at the Bristol Heart Institute

Battaglia S, et al. Poster presented at the Wounds UK Annual Conference, 5–7 November 2018; Harrogate, UK.

Overview

- A quality improvement audit conducted at a major UK cardiac centre to compare standard dressings with PICO sNPWT in medium and high-risk patients undergoing CABG and non-CABG procedures
- A new pathway was introduced using the Brompton and Harefield Infection Score to decide which patients to treat with PICO sNPWT instead of standard post-operative dressings

Results

Compared with baseline, utilising this pathway resulted in:

- 50% reduction in the incidence of SSIs in 148 CABG patients (17.6 vs 8.8%)
- A slight increase in SSI incidence in 153 non-CABG patients (3.1 vs 5.2%)
- 31% reduction in estimated total cost of SSIs versus baseline (£83,271)

Conclusions

Accurate identification of appropriate patients, based upon a pre-operative risk assessment, can drive best practice with PICO sNPWT, help to reduce the incidence of SSIs and reduce costs.

1. Hasselmann J, *et al.*

Inguinal vascular surgical wound protection by incisional negative pressure wound therapy. A randomized controlled trial – INVIPS trial

Hasselmann J, Björk J, Svensson-Björk R, Acosta S. *Ann Surg.* 2020;271(1):48–53.

Overview

- Single-centre, open-label, RCT comparing the effect of prophylactic PICO◊ sNPWT and standard dressings on the risk of SSIs following groin surgery in patients with both unilateral and bilateral incisions
  - PICO sNPWT (59 unilateral, 19 bilateral)
  - Standard dressings (61 unilateral, 19 bilateral)

Results

- At 90 days follow up, SSI incidences were lower with PICO sNPWT than with standard dressings by ASEPSIS criteria for both unilateral and bilateral incisions (Figure)
  - SSI incidences were also lower with PICO sNPWT than with standard dressings by CDC criteria, in both the unilateral (11.9 vs 27.9%; p=0.039) and bilateral (5.3 vs 26.3%; p=0.125) groups
- After pooling unilateral and bilateral results, SSI incidences were significantly lower for PICO sNPWT versus standard dressings by both ASEPSIS (10.3 vs 28.8%; p=0.02; Figure) and CDC (10.3 vs 27.5%; p=0.03) criteria
- No differences in other surgical site complications were noted between groups

Conclusions

Prophylactic use of PICO sNPWT significantly reduced the incidence of SSIs in patients undergoing groin surgery compared with standard dressings when assessed using ASEPSIS and CDC criteria.

64%
relative reduction in SSIs (ASEPSIS) pooled results (10.3 vs 28.8%; p=0.02)

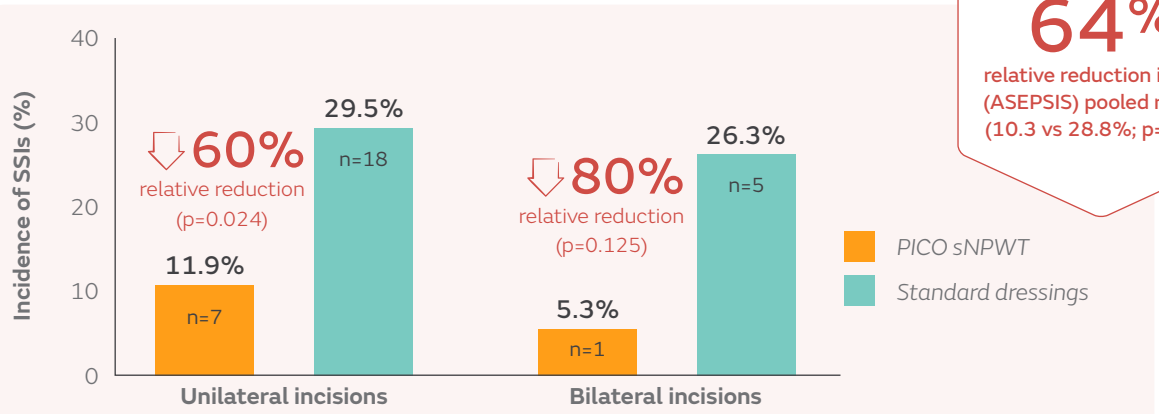


Figure. Incidences of SSIs with PICO sNPWT and standard dressings using ASEPSIS criteria

2. Svensson-Björk R, *et al.*

Cost-effectiveness analysis of negative pressure wound therapy dressings after open inguinal vascular surgery – The randomised INVIPS-Trial

Svensson-Björk R, Saha S, Acosta S, et al. *J Tissue Viability*. 2021;30(1):95–101.

Overview

- Cost-effectiveness evaluation of PICO◊ sNPWT versus standard dressings in reducing the incidence of SSIs in patients undergoing inguinal vascular surgery (healthcare payers perspective)
- Analysis of data from Hasselman J, *et al.* 2020
  - PICO sNPWT, n=59
  - Standard dressings, n=60

Results

- Estimated mean procedure-related costs at 90 days were similar with PICO sNPWT compared with standard dressings (€16,621 vs €16,285; p=ns)
- PICO sNPWT helped to significantly reduce the incidence of SSIs by 60% compared with standard dressings (11.9 vs 30.0%; p=0.015)
- When all costs were considered, PICO sNPWT was determined to be cost effective for reducing SSI incidence

Conclusions

Use of PICO sNPWT after open inguinal vascular surgery was considered to be cost effective compared with standard dressings due to reduced SSI incidence with similar procedure-related costs.

60% relative reduction
in SSI incidence with PICO sNPWT versus standard dressings (p=0.015)

Similar costs
for PICO sNPWT versus standard care

3. Fleming CA, *et al.*

Routine use of PICO Dressings may reduce overall groin wound complication rates following peripheral vascular surgery

Fleming CA, Kuteva M, O'Hanlon K, O'Brien G, McGreal G. *J Hosp Infect*. 2018;99:75–80.

Overview

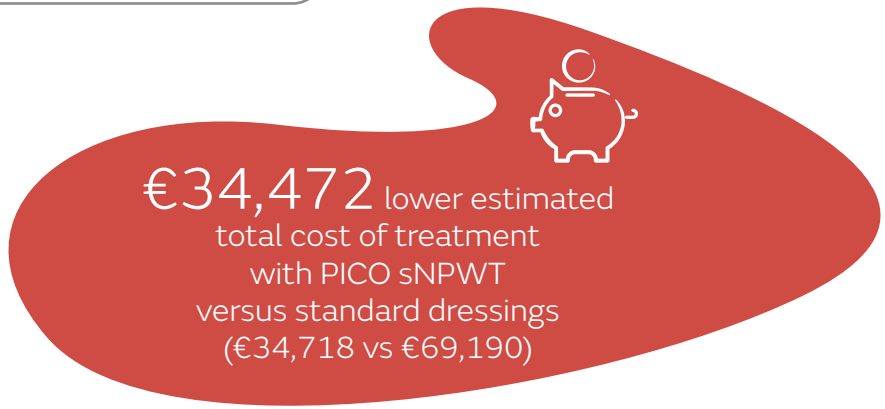
- Single-centre, retrospective analysis of wound complications that occurred up to six weeks postoperatively in patients who underwent peripheral vascular surgery of the lower limb
  - PICO◊ sNPWT, n=73
  - Standard dressings, n=78

Results

- Compared with standard dressings, patients treated with PICO sNPWT had:
  - Significantly fewer wound complications (8.2 vs 19.2%; p=0.042)
  - Substantially lower seroma incidence (1.4 vs 7.7%; p=0.069)
  - Shorter mean hospital LoS for readmissions (3 patients, 2.83 days versus 6 patients, 5.67 days)
  - Reduced mean time to resolution of wound complications (53 vs 96 days; p=0.015)
  - Reduced estimated total cost of treatment (€34,718 vs €69,190)

Conclusions

PICO sNPWT helped to significantly reduce the incidence of groin wound complications in patients undergoing vascular surgery. Mean hospital LoS and time to resolution of wound complications were shorter with PICO sNPWT than with standard dressings for readmitted patients, which contributed to cost savings.



1. Hyldig N, *et al.*

Prophylactic incisional negative pressure wound therapy reduces the risk of surgical site infection after caesarean section in obese women: a pragmatic randomised clinical trial

Hyldig N, Vinter CA, Kruse M, et al. *BJOG*. 2018;126(5):628–635.

Overview

- An open-label, pragmatic, randomised study to assess PICO◊ sNPWT compared with standard dressings in women undergoing elective or emergency caesarean section with a pre-pregnancy BMI ≥30kg/m²
- Dressings were left in place for approximately five days with PICO sNPWT and at least 24 hours with standard dressings
  - PICO sNPWT, n=432
  - Standard dressings, n=444

Results

- Use of PICO sNPWT significantly reduced the incidence of SSIs compared with standard dressings (p=0.007; Figure)
  - NNT: 22
- Results were similar after adjustment for risk factors including pre-pregnancy BMI ≥35kg/m²
- Significantly fewer women experienced wound exudate as a complication with PICO sNPWT than those using standard dressings (22.4 vs 32.9%; p=0.001)
  - RRR with PICO sNPWT versus standard dressings was 31.0%
  - NNT: 10
- Deep SSIs, dehiscence and self-rated health status were similar in both groups

Conclusions

Use of PICO sNPWT helped to significantly reduce the incidences of SSIs and wound exudate compared with standard dressings in high-risk, obese women with pre-pregnancy BMI ≥30kg/m² undergoing caesarean section.

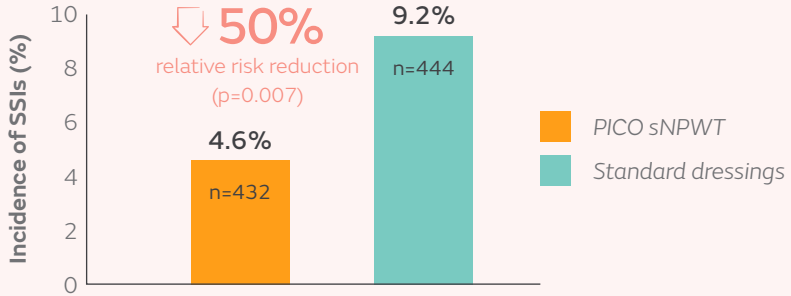


Figure. Incidences of SSIs with PICO sNPWT and standard dressings in obese women undergoing caesarean section

2. Hyldig N, *et al.*

Cost-effectiveness of incisional negative pressure wound therapy compared with standard care after caesarean section in obese women: a trial-based economic evaluation

Hyldig N, Joergensen JS, Wu C, et al. *BJOG*. 2019;126(5):619–627.

Overview

- Cost-effectiveness evaluation of using PICO◊ sNPWT compared with standard dressings to help prevent SSIs in obese women after elective or emergency caesarean section (pre-pregnancy BMI ≥30kg/m²)
  - PICO sNPWT, n=432
  - Standard dressings, n=444
- Analysis of data from Hyldig N, *et al.* 2018

Results

- Estimated total healthcare costs per patient were similar with PICO sNPWT and standard dressings (€5,794 vs €5,841; p=0.81)
  - PICO sNPWT was the dominant strategy as it was more effective than standard dressings at helping to reduce SSIs
- Estimated costs per patient with pre-pregnancy BMI ≥35kg/m² were lower with PICO sNPWT than with standard dressings

Conclusions

Use of PICO sNPWT in obese women after caesarean section helped to reduce the incidence of SSIs versus standard dressings with similar estimated costs per patient for pre-pregnancy BMI ≥30kg/m² and estimated cost savings for pre-pregnancy BMI ≥35kg/m².

3. Hyldig N, *et al.*

Clinical evaluation of scar quality following the use of prophylactic negative pressure wound therapy in obese women undergoing cesarean delivery: a trial-based scar evaluation

Hyldig N, Möller S, Joergensen JS, Bille C. *Ann Plast Surg.* 2020;85(6):e59–e65.

Overview

- Substudy of cosmetic outcomes for patients undergoing elective or emergency caesarean section with a pre-pregnancy BMI ≥30kg/m^2 who were involved in the study by Hyldig N, *et al.* 2018
  - PICO sNPWT, n=105
  - Standard dressings, n=101

Results

With PICO sNPWT versus standard dressings:

- The incidence of SSIs was reduced (4.7 vs 9.9%; 52.5% relative reduction)
- Significantly more patients were satisfied with overall scar appearance at 30 days (72.4 vs 53.1%; p=0.018) and 6 months (75.3 vs 58.2%; p=0.043)
  - Results were similar at 12 months (75.0 vs 60.7%; p=0.170)
- Significantly fewer women had hatch marks at 6 months (20 vs 43%; p=0.002) and 12 months (19 vs 36%; p=0.037)

Conclusions

Obese women undergoing caesarean section were significantly more satisfied with the appearance of scars within 6 months of surgery using PICO sNPWT than using standard dressings and fewer patients had hatch marks at 6 and 12 months post surgery.

4. Bullough L, *et al.*

Reducing C-section wound complications

Bullough L, Burns S, Timmons J, Truman P, Megginson S. *Clin Serv J.* 2015;2–6.

Overview

- Thirty-month audit study (UK) reporting 2-year experience with PICO◊ sNPWT in high-risk patients (BMI >35kg/m²) post-caesarean compared with OPSITE◊ Post-Op Visible dressing in lower-risk patients (BMI <35kg/m²)
  - PICO sNPWT, n=239
  - OPSITE Post-Op Visible dressing, n=1,405

Results

- SSI rate:
  - Baseline: 12.0% (prior to audit study)
  - PICO sNPWT: 0.4% (patient had gestational diabetes)
  - OPSITE Post-Op Visible dressing: 3.6%
- No readmission for infection or wound dehiscence
- PICO sNPWT in high-risk patients was cost effective

Conclusions

Inclusion of PICO sNPWT in the strategy for treatment of post-operative wounds following caesarean helped to reduce the incidene of SSIs resulting in cost savings.

5. Ascuitto KC, *et al.*

Negative pressure wound therapy (NPWT) in groin wounds after lymphadenectomy in vulvar cancer patients

Ascuitto KC, Acosta S, Borgfeldt C. *In Vivo.* 2020;34:3511–3517.

Overview

- Prospective, single-centre case series of patients (n=20) undergoing lymphadenectomy for vulval cancer whose wounds were managed with PICO sNPWT
- Patients were followed up for ≥3 months

Results

- 55% of patients developed an SSC; 82% of these were mild
- Readmission was required for 3 patients
- After continued used of PICO sNPWT for 7–10 days there were no longer signs of accumulated lymphatic fluid in patients with lymphocele
- During follow up 4 patients developed an SSI, all were classified as superficial

Conclusions

Use of PICO sNPWT may help to reduce the severity of SSCs in the groin after lymphadenectomy in vulval cancer patients.

6. Searle R, *et al.*

A survey of caesarean section surgical site infections with PICO™ single use negative pressure wound therapy system in high-risk patients in England and Ireland

Searle R, Myers D. *J Hosp Infect*. 2017;97(2):122–124.

Overview

- Audit study (four sites in England and Ireland) of PICO sNPWT in patients post-caesarean with BMI ≥35kg/m^2
- PICO◊ sNPWT was applied after surgery and left for 7 days in accordance with the instructions for use
  - PICO sNPWT, n=399

Results

- Low incidences of SSIs and hospital readmission:
  - SSI incidence, 9.0% (vs 19.3% previously published data)
  - Readmission incidence, 0.8%

Conclusions

PICO sNPWT use in high-risk (BMI ≥35kg/m^2) caesarean section patients was associated with low incidences of both SSIs and hospital readmission.

1. Karlakki SL, *et al.*

Incisional negative pressure wound therapy dressings (iNPWTd) in routine primary hip and knee arthroplasties: a randomised controlled trial

Karlakki SL, Hamad AK, Whittall C, Graham NM, Banerjee RD, Kuiper JH. *Bone Joint Res.* 2016;5:328–337.

Overview

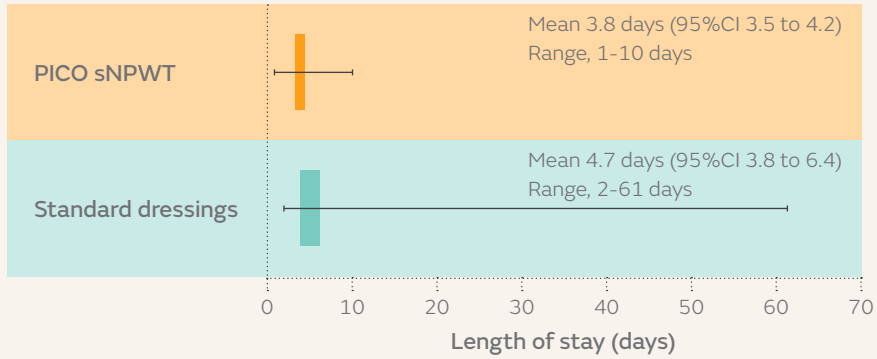
- A single-centre, open-label, randomised, parallel-group, controlled trial to assess the effect of prophylactic PICO◊ sNPWT compared with standard dressings on wound exudate, LoS, wound complications, dressing changes and cost-effectiveness in patients undergoing elective primary total hip or knee arthroplasty in the UK
  - PICO sNPWT, n=102
  - Standard dressings, n=107

Results

- SSC incidence was reduced more with PICO sNPWT than with standard dressings at 6 weeks follow-up (2.0 vs 8.4%; p=0.06)
- Compared with standard dressings, PICO sNPWT redistributed grades of peak post-surgical wound exudate (p=0.007) with more patients in low grades and fewer in high grades, and required significantly fewer dressing changes (2.5 vs 4.2; p=0.002)
- Use of PICO sNPWT benefited high-risk patients with ASA score ≥3 and BMI ≥35kg/m^2
- Mean LoS was reduced by 0.9 days with sNPWT compared with standard dressings (Figure)
  - PICO sNPWT also helped to significantly reduce extreme LoS (≥13 days; 0 vs 2%; p=0.003)

Conclusions

PICO sNPWT helped to reduce the incidence of wound complications and reduce LoS (including extreme LoS) compared with standard dressings in primary hip and knee arthroplasty. The authors suggest that reductions in the incidence of wound complications are a result of reducing oedema and stabilising wound edges.



0.9 days
(95%CI -0.2 to 2.5; p=0.07)

Figure. Mean LoS (and range) with PICO sNPWT and standard dressings

2. Nherera LM, *et al.*

Cost-effectiveness analysis of single-use negative pressure wound therapy dressings (sNPWT) to reduce surgical site complications (SSC) in routine primary hip and knee replacements

Nherera LM, Trueman P, Karlakki SL. *Wound Repair Regen.* 2017;25(3):474–482.

Overview

- An economic analysis comparing the expected costs and benefits of PICO◊ sNPWT with standard dressings from the UK healthcare payer perspective in high-risk patients undergoing elective primary hip and knee replacement
- Analysis of data from Karlakki SL, *et al.* 2016
  - PICO sNPWT, n=102
  - Standard care, n=107

Results

- Estimated cost/patient was £5,692 and £6,740 for PICO sNPWT and standard care respectively, resulting in an estimated cost-saving of £1,049 in favour of PICO sNPWT
- Greater cost savings were observed in subgroups of high-risk patients, compared with standard dressings
  - £7,955 per patient with a BMI ≥35kg/mg^2
  - £7,248 per patient with an ASA score ≥3

Conclusions

PICO sNPWT is estimated to be a cost-effective intervention for helping to reduce SSCs following primary total hip and knee replacements. Estimated savings of £1,049 per patient were associated with using PICO sNPWT compared with standard care, with greater savings in high-risk patients.

3. Masters J, *et al.*

A feasibility study of standard dressings versus negative-pressure wound therapy in the treatment of adult patients having surgical incisions for hip fractures: the WHISH randomized controlled trial

Masters J, Cook J, Achten J, Costa ML. *Bone Joint J.* 2021;103-B(4):755–761.

Overview

- A multicentre, randomised, controlled feasibility trial conducted in patients aged >65 years undergoing hip fracture surgery
  - PICO sNPWT, n=214
  - Standard dressings, n=218

Results

- SSI incidence was lower with PICO sNPWT than with standard dressings at 30 (1.9 vs 6.4%) and 90 days (2.3 vs 6.4%) post surgery
- Nine patients with deep SSIs underwent re-operation during the study period
- Health-related quality of life scores were similar with PICO sNPWT and standard dressings 120 days post surgery

Conclusions

Patients undergoing hip fracture surgery had a lower incidence of SSIs with prophylactic use of PICO sNPWT than with standard dressings at 30 and 90 days post surgery.

70% relative reduction in SSIs incidence with PICO sNPWT versus standard dressings 30 days after surgery (1.9 vs 6.4%)

Similar SSIs incidence with PICO sNPWT versus standard dressings at 90 days after surgery (versus 30 days after surgery)

4. Dingemans SA, *et al.*

Prophylactic negative pressure wound therapy after lower extremity fracture surgery: a pilot study

Dingemans SA, Birnie MFN, Backes M, et al. *Int Orthop*. 2018;42(4):747–753.

Overview

- Single-centre, prospective pilot study assessing the feasibility of using PICO◊ sNPWT to help reduce the incidence of SSIs in adult patients undergoing major foot and ankle surgery (incision length ≥3cm)
  - PICO sNPWT, n=53; 47 of which were case-match to the historical cohort

Results

- PICO sNPWT resulted in a 71% relative reduction in SSIs (total, superficial and deep) compared with controls (4.3 vs 14.9%; p=0.29) , and a total incidence of SSIs of 7.5%
- Patient satisfaction with PICO sNPWT was high

Conclusions

Prophylactic use of PICO sNPWT resulted in an SSI incidence of 7.5% in patients undergoing major foot and ankle surgery. Patient satisfaction with PICO sNPWT was high in this pilot study.

5. Matsumoto T, *et al.*

Use of negative pressure wound therapy on closed surgical incision after total ankle arthroplasty

Matsumoto T, Parekh SG. *Foot Ankle Int*. 2015;36:787–794.

Overview

- Single-centre, retrospective cohort study to investigate the role of PICO sNPWT in decreasing the rate of wound healing problems after TAA
  - PICO sNPWT, n=37
  - Standard care (historic cohort), n=37

Results

- PICO sNPWT resulted in an 88% reduction in SSCs compared with standard care (3 vs 24%; p=0.014)
- Differences in SSIs were not significant; 3% PICO sNPWT versus 8% with standard care (p=0.615)

Conclusions

PICO sNPWT helped to reduce the incidence of SSCs compared with standard care in patients undergoing TAA.

6. Adogwa O, *et al.*

Negative pressure wound therapy reduces incidence of post-operative wound infection and dehiscence after long-segment thoracolumbar spinal fusion: a single institutional experience

Adogwa O, Fatemi P, Perez E, et al. *Spine J.* 2014;14(12):2911–2917.

Overview

- Retrospective study to assess the incidence of wound infection and dehiscence in patients undergoing long-segment thoracolumbar fusion with routine use of PICO◊ sNPWT compared with a historic cohort
  - PICO sNPWT, n=46
  - Standard care (historic cohort), n=114

Results

- Versus standard care, PICO sNPWT resulted in:
  - A 29% relative reduction in SSIs (10.6 vs 14.9%; p=0.04)
  - A 48% relative reduction in wound dehiscence (6.4 vs 12.3%; p=0.02)

Conclusions

PICO sNPWT helped to significantly reduce the incidence of SSIs and dehiscence compared with standard care in patients undergoing long-segment thoracolumbar fusion.

7. Helito CP, *et al.*

The use of negative-pressure wound therapy after total knee arthroplasty is effective for reducing complications and the need for reintervention

Helito CP, Sobrado MF, Giglio PN, et al. *BMC Musculoskelet Disord.* 2020;21(1):490.

Overview

- Consecutive, nonrandomised case series of patients with primary or secondary knee osteoarthritis who underwent elective unilateral TKA
  - PICO sNPWT for 7 days, n=97
  - Historical controls receiving conventional dressings, n=199

Results

Compared with conventional dressings, use of PICO sNPWT significantly reduced:

- Relative incidence of SSCs by 38% (45.7 vs 28.5%; p=0.001)
  - Including skin necrosis (8.5 vs 2.1%; p=0.04), wound dehiscence (10.1 vs 3.1%; p=0.03) and hyperaemia (40.2 vs 14.7%; p=0.01)
- Need for surgical reintervention (8.5 vs 2.0%; p=0.001)

Conclusions

Use of PICO sNPWT helped to significantly reduce SSCs, including necrosis and dehiscence, and the need for surgical reintervention compared with conventional dressings in patients undergoing TKA.

1. Kirsner R, *et al.*

A prospective, randomized, controlled clinical trial on the efficacy of a single-use negative pressure wound therapy system, compared to traditional negative pressure wound therapy in the treatment of chronic ulcers of the lower extremities

Kirsner R, Dove C, Reyzelman A, Vayser D, Jaimes H. *Wound Repair Regen.* 2019;27(5):519–529.

Overview

- A randomised, controlled, multicentre study conducted at 16 centres in the USA and two centres in Canada to evaluate efficacy and safety of PICO◊ sNPWT or tNPWT to manage lower extremity ulcers (>4 weeks in duration)
- In total, 161 patients were included in the ITT population (101 VLUs; 60 DFUs) and were randomised to receive either PICO sNPWT (n=80) or tNPWT (n=81)
  - The PP population (non-inferiority analysis) included 115 patients (PICO sNPWT, n=64; tNPWT, n=51)

Results

- Reduction in wound area was significantly greater with PICO sNPWT than tNPWT in the PP population (88.7 vs 58.6% mean reduction; p=0.003) and the ITT population (p<0.001; Figure)
  - Significant LS mean reductions in wound area were also achieved with PICO sNPWT versus tNPWT in VLU (36.2%; p=0.007) and DFU (38.8%; p=0.031) subgroups
- Reductions in wound depth and volume in the PP and ITT populations (Figure) were also significantly greater with PICO sNPWT versus tNPWT (p<0.02, all comparisons)
- More patients had complete wound closure at 12 weeks with PICO sNPWT than with tNPWT (45 vs 22%; p=0.002; ITT population)
- Overall satisfaction with PICO sNPWT was significantly greater than with tNPWT

Conclusions

In patients with VLUs and DFUs, PICO sNPWT significantly reduced wound area, depth and volume compared with tNPWT; complete closure of lower extremity ulcers at 12 weeks was more frequent with PICO sNPWT than with tNPWT.

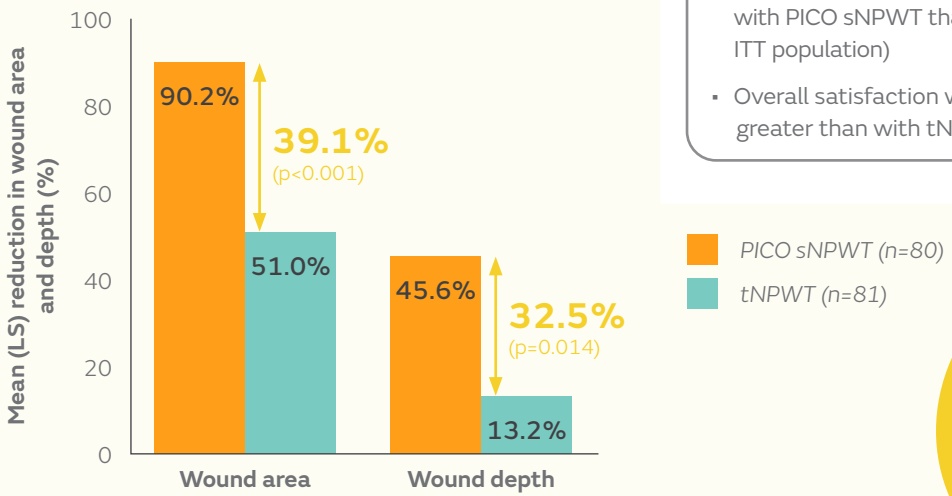


Figure. Percentage reductions from baseline in wound area and depth with PICO sNPWT and tNPWT at 12 weeks (ITT population; LS mean values)

51%
relative increase in patients with complete wound closure
at 12 weeks with PICO sNPWT versus tNPWT (p=0.002)

2. Kirsner RS, *et al.*

A cost-effectiveness analysis comparing single-use and traditional negative pressure wound therapy to treat chronic venous and diabetic foot ulcers

Kirsner RS, Delhougne G, Searle RJ. *Wound Manag Prev*. 2020;66(3):30–38.

Overview

- A cost-effectiveness evaluation of PICO◊ sNPWT and tNPWT in treating lower extremity ulcers (US payer perspective)
  - Time horizons of 12 and 26 weeks were used to show the effect on wound closure
- Analysis of data from Kirsner, *et al.*, 2019 and US National 2016 Medicare claims

Results

- For both ulcer types combined, switching from tNPWT to PICO sNPWT resulted in an estimated:
  - Expected cost saving per patient of $7,756 at Week 12 and $15,749 at Week 26
  - Decrease in total expected open ulcer weeks of 1.67 at Week 12 and 5.31 at Week 26
  - Increase in percentage of expected closed ulcers of 22.6% at Week 12 and 31.0% at Week 26
- Similar results were observed for VLUs and DFUs when analysed separately

Conclusions

PICO sNPWT was estimated to be highly cost saving and reduced expected weeks to ulcer closure compared with tNPWT in patients with VLUs and DFUs, when analysed from a US payer perspective.

$15,749 estimated cost saving per patient with PICO sNPWT versus tNPWT at Week 26

3. McCluskey P, *et al.*

Impact of a single-use negative pressure wound therapy system on healing

McCluskey P, Brennan K, Mullan J, et al. *JCN*. 2020;34:36–43.

Overview

- A service evaluation at seven centres in Northern Ireland and the Republic of Ireland
- Wound healing and health economic impact (in UK sterling and Euros) of using PICO◊ sNPWT versus standard care on hard-to-heal wounds over 12 weeks (or until healing) were assessed
- Median wound duration was 3–6 months; 36 wounds were included
- Eligible patients had:
  - Wounds >6 weeks in duration with no signs of clinical infection
  - <10% per week wound area reduction over 4 weeks
  - No NPWT in the last 6 weeks or contraindications for NPWT
  - ABPI >0.8 and <1.3 for VLUs

Results

- Using PICO sNPWT, 20 of 36 wounds healed within 12 weeks (55.6%)
  - Mean healing time was 6.95 weeks
- Wound healing rate was greater for wounds with <3 months duration than those with ≥3 months duration (84.6 vs 71.4%; p=0.0125; Figure)
- Improvements in mean wound area per week with PICO sNPWT (-16.8%) continued after use (-18.9%)
- Dressing changes per week were less frequent with PICO sNPWT versus standard care (1.75 vs 3.56 changes; p<0.001)
  - They were also less frequent in the post PICO sNPWT phase (1.95 vs 3.56 changes per week; p<0.001)
- Use of PICO sNPWT was predicted to reduce costs versus standard care (Figure):
  - Total costs by 25% (£15,467) and 21% (€12,001)
  - Nursing resource costs by 59% (£31,494 and €27,517)

Conclusions

In patients with hard-to-heal wounds, PICO sNPWT was most effective for wounds of <3 months in duration. It helped to reduce dressing change frequency and was predicted to reduce nursing resource costs compared with standard care.

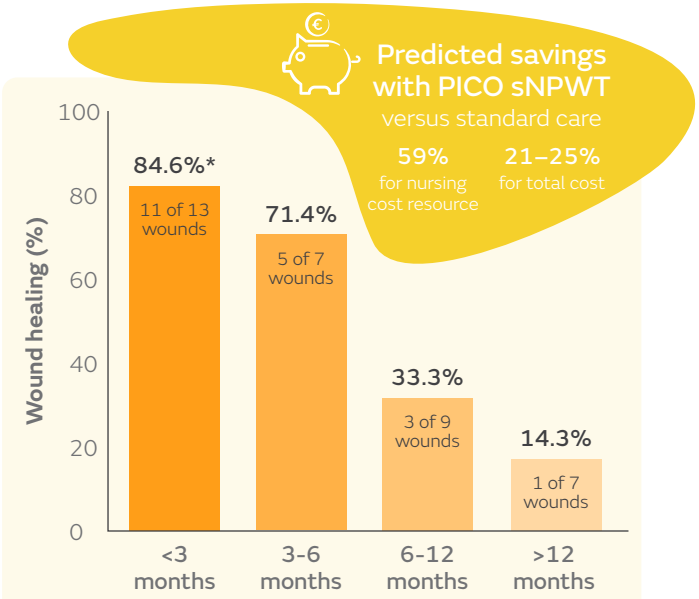


*Figure. Wound healing by duration of wound at baseline and predicted cost savings with use of PICO sNPWT (*p=0.0125)*

4. Hughes J, *et al.*

The burden of dehisced wounds in the community: using early results from a multi-centre service evaluation to propose a standard of care to improve patient outcomes and safeguard woundcare budgets

Hughes J, Costello M, Belshaw M, Horton H, Styche T. *Br J Health Care Manag.* 2020;27:16–25.

Overview

- Analysis of a subset of 34 dehisced surgical wounds from a service evaluation of PICO◊ sNPWT
- The service evaluation adopted a previously published pathway for hard-to-heal wounds (*go to PICO sNPWT pathway*)

Results

- After implementation of the PICO sNPWT pathway, 18 of 34 wounds (53%) healed within 12 weeks
  - Mean time to healing was 6.1 weeks
- Mean dressing change frequency reduced with use of PICO sNPWT from 4.7 to 3.2 times per week and remained at 3.3 times per week after returning to standard care
- Estimated savings of £16,577 for total wound care treatment over 12 weeks with PICO sNPWT versus standard care
  - Nursing time was reduced by 513 hours using PICO sNPWT compared with standard care

Conclusions

Use of PICO sNPWT as part of a pathway for hard-to-heal wounds helped to support healing of dehisced surgical wounds, as well as reduce estimated total costs and release nursing time compared with prior standard care in this service evaluation.

53%
of dehisced wounds healed within 12 weeks

513
nursing hours
saved with PICO sNPWT versus standard care

21.6%
estimated cost reduction
with PICO sNPWT use versus standard care (from £76,828 to 60,251)

5. Dowsett C, *et al.*

Use of PICO™ to improve clinical and economic outcomes in hard-to-heal wounds

Dowsett C, Hampton J, Myers D, Styche T. *Wounds International.* 2017;8(2):52–58.

Overview

- A prospective cohort study of 52 hard-to-heal wounds of varied aetiology and duration treated according to the PICO◊ sNPWT pathway (*go to PICO sNPWT pathway*)
  - Patients were switched from standard care to treatment with PICO sNPWT at Week 0 for at least two weeks

Results

- During PICO sNPWT treatment, wound area reduced by 13.4% more per week than pre-PICO sNPWT (p=0.006)
- After the PICO sNPWT phase, wound area reduced by 9.6% more per week than pre-PICO sNPWT (p=0.001)
- PICO improved the trajectory of wounds of over 1 year, and healing rates were almost three times greater in wounds of <3 months duration (94.1 vs 33.3%)
- Implementing the PICO sNPWT pathway was estimated to reduce total costs by 33.1% (£50,000) and release 119 nursing days over 26 weeks compared with predictions for standard care

Conclusions

PICO sNPWT helped to significantly improve the healing trajectory of hard-to-heal wounds, resulting in reduced estimated costs and nursing time compared with previous standard care.

119 days Estimated released nursing days with PICO sNPWT compared with predictions for standard care

33.1% estimated cost reduction with PICO sNPWT compared with predictions for standard care

6. Patel A, *et al.*

Comparison of wound closure in chronic lower extremity ulcers between single use negative pressure wound therapy and traditional negative pressure wound therapy: a real-world analysis

Patel A, Delhougne G, Nherera L. Poster presented at: Wild on Wounds National Conference. September 11–14, 2019. Las Vegas, NV, USA.

Overview

- Retrospective cohort study to assess wound closure rates with PICO◊ sNPWT and tNPWT in a real-world setting in patients with DFUs and VLUs
  - PICO sNPWT: DFUs, n=84; VLUs, n=62
  - tNPWT: DFUs, n=86; VLUs, n=60

Results

- Compared with tNPWT, wound closure rates with PICO sNPWT were greater for all lower extremity ulcers (46.6 vs 34.9%; p=0.043)
  - Rates were also greater for DFUs and VLUs when analysed alone
- Compared with tNPWT, wounds treated with PICO sNPWT were 89% more likely to achieve closure (p=0.042)

Conclusions

Lower extremity ulcers (DFUs and VLUs) of patients treated with PICO sNPWT were more likely to achieve wound closure than those treated with tNPWT in this retrospective analysis of real-world outpatient wound clinic data.

7. Hurd T, *et al.*

Single use negative pressure wound therapy (sNPWT) in the community management of chronic open wounds deeper than 2cm

Hurd T, Gilchrist B. Poster presented at: Symposium on Advanced Wound Care/WHS Annual Meeting. July 24–26, 2020; virtual conference.

Overview

- Retrospective two-year analysis of the healing of chronic open wounds >2cm deep (DFUs, VLUs, PUs and dehisced surgical wounds) in the home or community care setting following introduction of an integrated care bundle including PICO sNPWT compared with standard care
  - PICO sNPWT, 409 wounds (patients were significantly older with higher comorbidity score, both p<0.001)
  - Standard care, 2,242 wounds

Results

- Use of PICO sNPWT to manage chronic open wounds >2cm compared with standard care resulted in:
  - Shorter mean healing times (46% relative reduction; 11.5 days)
  - Longer mean time between dressing changes (3.23 days)

Conclusions

PICO sNPWT may help reduce healing times and frequency of dressing changes in chronic open wounds >2cm deep compared with standard care.

8. Hampton J.

Providing cost-effective treatment of hard-to-heal wounds in the community through use of NPWT

Hampton J. *Br J Community Nurs*. 2015;S14 (Suppl Community Wound Care): S16–S20.

Overview

- Cohort case study involving patients with hard-to-heal VLUs and PUs treated in the community setting for >6 weeks
- Patients received PICO◊ sNPWT for 2 weeks followed by standard treatment appropriate for each wound
  - PICO sNPWT, n=9

Results

- Average weekly reduction in wound size was 21%
- With PICO sNPWT target wound size was achieved on average 10 weeks earlier than predicted with standard treatment
- In wounds that responded, wound size reduction was 6 times faster than predicted with standard treatment
- Mean savings of DKK 6,670 (€895)* per patient using PICO sNPWT compared with prior standard treatment

Conclusions

Use of PICO sNPWT for 2 weeks helped to kick start the healing of chronic hard-to-heal wounds, which resulted in faster overall rates of healing and reduced costs compared with previous standard treatment.

9. Sharpe A, *et al.*

Using single use negative pressure wound therapy for patients with complicated diabetic foot ulcers: an economic perspective

Sharpe A, Myers D, Searle R. *Wounds UK*. 2018;14(4):89–93.

Overview

- UK case series of four patients using PICO 7 sNPWT to help manage complicated DFUs
- Patients and carers self-assessed the dressing status using the dressing-full indicator
  - PICO 7 sNPWT, n=4

Results

- All four DFUs improved (mean ulcer area reduction, 49%), exudate levels were managed effectively and the frequency of dressing changes was reduced
- Total combined weekly clinician time saving using PICO 7 sNPWT was 279min (4hr 39min) for four patients
- Use of PICO sNPWT was estimated to release 13.5 clinician hours per patient on average over 12 weeks

Conclusions

Frequency of clinician visits and dressing changes were reduced by using PICO 7 sNPWT to help manage DFUs, improving service delivery with potential efficiency savings compared with prior practice.

*Exchange rate 1 EUR = 7.45550 DKK as of May 19 2020.

Additional supporting studies

10. Dowsett C, *et al.*

Venous leg ulcer management: single use negative pressure wound therapy

Dowsett C, Grothier L, Henderson V, et al. *Br J Community Nurs*. 2013;(Suppl.S6):S8–S10, S12–S15.

11. Schwartz JA, *et al.*

Single-use negative pressure wound therapy for the treatment of chronic lower leg wounds

Schwartz JA, Goss SG, Facchin F, Gendics C, Lantis JC. *J Wound Care*. 2015;24:S4–S9.

12. Hurd T, *et al.*

Use of a portable, single-use negative pressure wound therapy device in home care patients with low to moderately exuding wounds: a case series

Hurd T, Trueman P, Rossington A. *Ostomy Wound Manage*. 2014;60(3):30–36.

13. Hurd T.

Evaluating the costs and benefits of innovations in chronic wound care products and practices

Hurd T. *Ostomy Wound Manage*. 2013;Supplement:1–16.

1. Brownhill RV, *et al.*

Pre-clinical assessment of single-use negative pressure wound therapy during *in vivo* porcine wound healing

Brownhill RV, Huddleston E, Bell A, et al. *Adv Wound Care*. 2021;10(7):345–356.

Overview

- Using an *in vivo* wound model (12 pigs), contralateral wounds were created (3cm diameter; 24 per group) and treated with either PICO◊ sNPWT (no filler) or tNPWT (foam filler)
- PICO sNPWT was changed every 6 days and tNPWT was changed every 3 days
- Comparative assessments of wound area, re-epithelialisation and contraction were made at days 6 and 12
- Wound granulation, surface damage and peri-wound skin health were also assessed

Results

- Compared with tNPWT, PICO sNPWT had:
  - Significantly greater reductions in wound area at days 6 and 12 (Figure)
  - Increased re-epithelialisation at days 6 ($p<0.01$) and 12 ($p<0.001$)
  - Less wound edge hyperproliferation
  - Improved quality and maturity of granulation tissue (increased collagen deposition and matrix components)
  - Reduced wound surface damage with less noticeable bleeding upon dressing removal
- Wound bed inflammation was reduced with PICO sNPWT versus tNPWT
  - Trapped foam filler particles caused foreign body reactions (increased neutrophils, inflammatory cytokines and matrix metalloproteinases)
- With use of PICO sNPWT there was less disruption to skin around the wound, less peri-wound erythema and skin barrier function was less compromised than with tNPWT
- Peri-wound skin had less inflammation with use of PICO sNPWT than with tNPWT, which may help support a prohealing wound edge environment

Conclusions

Use of PICO sNPWT increased wound closure compared with tNPWT in this porcine model of wound healing; re-epithelialisation was faster, granulation tissue was more mature and peri-wound skin was less compromised.

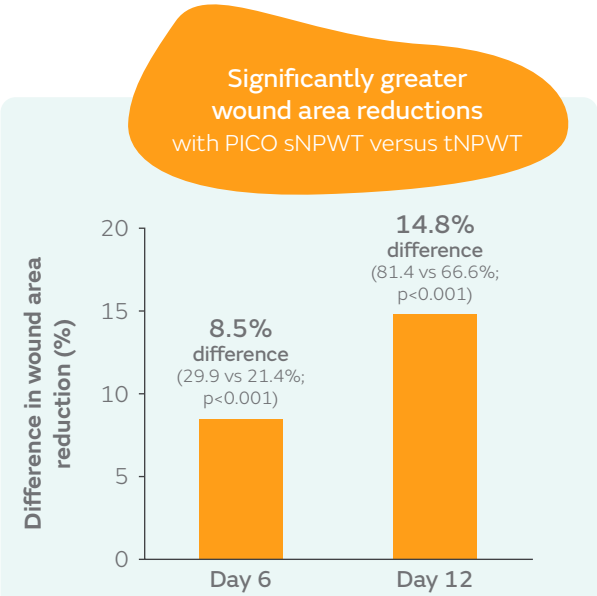


Figure. Difference in percentage change in wound area with PICO sNPWT versus tNPWT at days 6 and 12 post injury

2. Innocenti M, *et al.*

Effects of cutaneous negative pressure application on perforator artery flow in healthy volunteers: a preliminary study

Innocenti M, Santini M, Dreassi E, et al. J *Reconstr Microsurg*. 2019;35(3):189–193.

Overview

- A single-centre study to evaluate the effects of PICO◊ sNPWT on blood flow in cutaneous perforator arteries in 10 volunteers compared with controls

Results

- Mean flow velocity increased from 19.870 to 28.618cm/sec (↑8.748cm/sec) with PICO sNPWT and from 28.635 to 31.370cm/sec (↑2.735cm/sec) with controls
- PICO sNPWT increased mean flow in perforator vessels by 8.765cm/sec versus controls (p<0.0001)
- Application of PICO sNPWT to just one perforator vessel increased the relative flowmetry in both perforator vessels by 2.74cm/sec (p<0.0001)

Conclusions

In this preliminary study, PICO sNPWT significantly increased flowmetry in perforator vessels compared with controls, which if confirmed in a subsequent study, could be clinically relevant in microsurgical procedures.

3. Malmsjö M, *et al.*

Biological effects of a disposable, canisterless negative pressure wound therapy system

Malmsjö M, Huddleston E, Martin R. *ePlasty*. 2014;14:e15.

Overview

- Preclinical assessment of the biological effect of PICO sNPWT compared with tNPWT in a porcine full thickness defect wound model and sutured incisional wound model
- Fluid handling was assessed in this *in vitro* wound model

Results

- PICO sNPWT delivers therapeutic levels of NPWT, with similar effects to tNPWT on:
  - Wound edge contraction
  - Microvascular blood flow
  - Pressure transmission
  - Effective exudate handling

Conclusions

PICO sNPWT functioned in a similar manner to tNPWT with regard to exudate handling, pressure transmission to the wound bed, wound edge contraction and changes in microvascular blood flow.

4. Loveluck J, *et al.*

Biomechanical modeling of the forces applied to closed incisions during single-use negative pressure wound therapy

Loveluck J, Copeland T, Hill J, Hunt A, Martin R. *ePlasty*. 2016;16:e20.

Overview

- Finite element analysis computer modelling and biomechanical testing with Syndaver SynTissue™ synthetic skin were used to explore the resulting biomechanical forces from the application of PICO◊ sNPWT on a sutured incision

Results

- FEA computer modelling:
  - Application of -80mmHg reduces the lateral tension on an individual suture from 1.31N to 0.4N and exerts a compressive closing force
- Biomechanical testing:
  - At a pressure of -80mmHg, 55% more force is required to disrupt an incision that had PICO sNPWT applied than an incision closed with sutures or staples with no NPWT applied

Conclusions

PICO sNPWT was able to reduce lateral tension across a closed incision wound, which may explain reductions observed in SSCs.

Hard-to-heal pathway: when to use PICO◊ sNPWT

Figure adapted from **Dowsett C, *et al.* (2017)**

Back to Dowsett C, *et al.*

Entry criteria

- >6 weeks in duration
- <10% reduction in area per week over previous 4 weeks
- No NPWT in the last 6 weeks
- Not clinically infected*
- If VLU, ABPI confirmed as >0.8 and <1.3
- Not contraindications for negative pressure

Discontinue PICO sNPWT if contraindications are present

Week 0 – Apply PICO sNPWT

Week 1 – Wound assessment and apply PICO sNPWT

Week 2, 3, 4 decision point

Wound reduced in area by:

- <5% at week 2 (compared to week 0 area)
- <7.5% at week 3
- <10% at week 4

With no significant improvement in granulation tissue quality/quantity;† static (0%) or increased in size (deteriorated)

Non-responder. Stop PICO sNPWT

Wound requires further investigation or onward referal to a specialist service

Wound reduced in area 10–40%

Use clinical and economic judgement to determine whether PICO sNPWT should be continued on a week-by-week basis

Implement standard therapy when PICO sNPWT not in use

Week 4–12 decision point -
Continue weekly wound assessment

Week 12 decision point -
Final assessment and discontinuation from evaluation

Wound reduced in area by >40%

Good responder. Stop PICO sNPWT
(but can re-instate if wound healing rate stalls - at clinicians' judgement)

Implement standard therapy when PICO sNPWT not in use

Weekly wound assessment

- Use simple length and width measures for areas and % healing calculation
- Change in exudate levels
- Change in granulation tissue (%)
- Change in pain levels

*Wounds with overt signs of clinical infection (eg, increased pain, levels of exudate, cellulitis, etc) should be excluded from the evaluation. Colonised/critically colonised wounds are not excluded from the evaluation. Site standard protocol should be implemented to address bacterial burden.

†Wounds that have healed by <10% but have shown significant improvement in granulation tissue quality/quantity may be considered for further PICO sNPWT treatment based on clinician judgement.

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