

Evidence in focus

Compendium of evidence, September 2020

Smith+Nephew

PICO[◇]

Single Use Negative Pressure
Wound Therapy System



Helping you get **CLOSER TO ZERO[◇]** delay in wound healing.

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

Continue to introduction

Abbreviations

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

Introduction

PICO[◇] sNPWT has a strong evidence base

To date, **146*** clinical publications regarding PICO sNPWT have been identified of which this evidence compendium contains a summary of the most relevant. It does not include all publications due to the volume of studies.

Levels of evidence



31

RCTs, meta-analyses,
health economics
evaluations of RCTs

(+12 NPWT meta-analyses
which note PICO sNPWT
studies)



6

Prospective
observational
studies



21

Retrospective
observational
studies



25

Case series



51

Expert opinion,
case studies
or bench research

*To May 1, 2020.

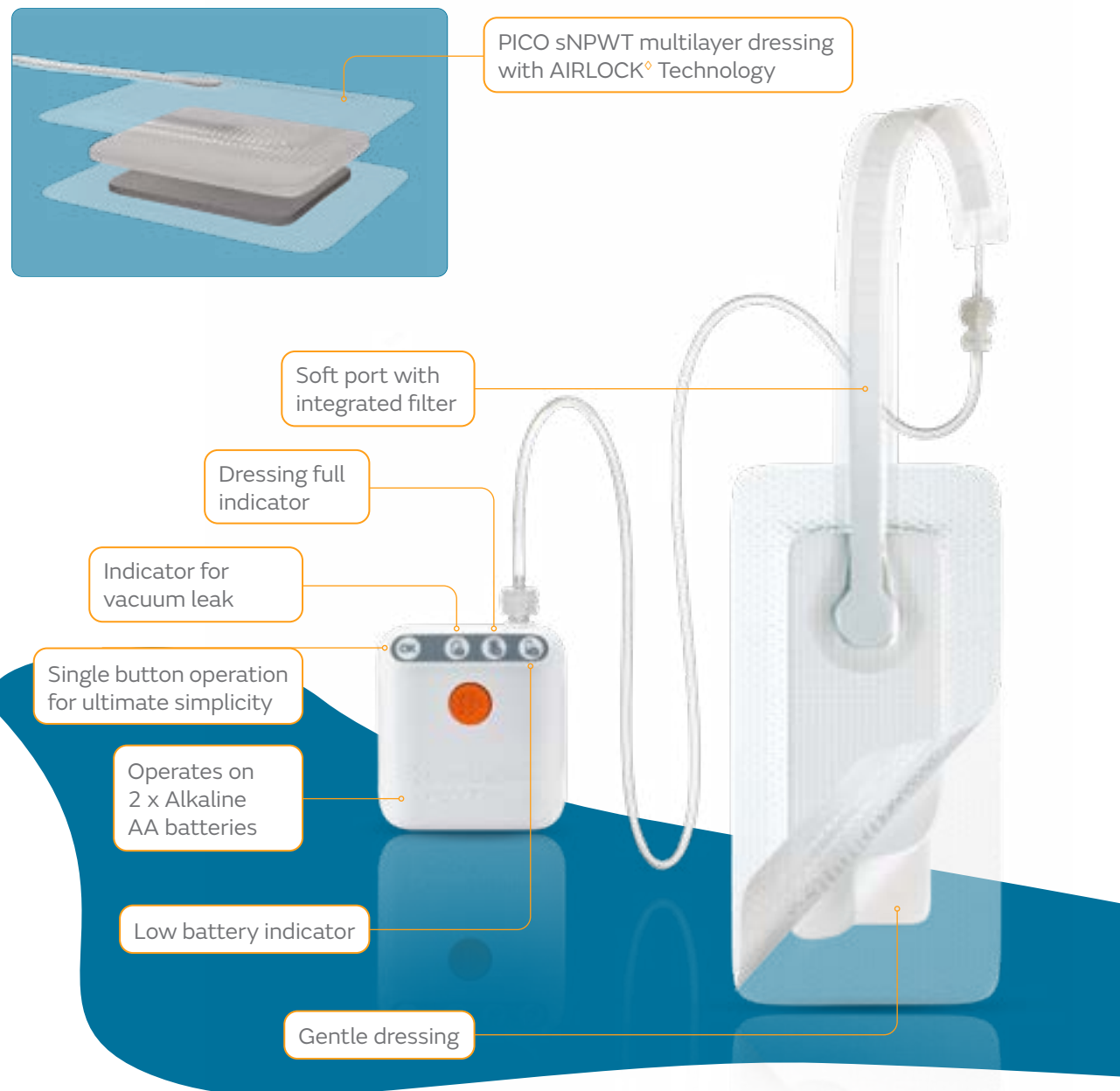
PICO^o sNPWT indication¹

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 exudate⁴
- 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. (2019)
2. Pellino G, et al. (2014)
3. Payne C, et al. (2014)
4. Hudson DA, et al. (2013)

ABDOMINAL

1. O'Leary DP, et al. (2017)
2. Selvaggi F, et al. (2014)
3. Caswell JF, et al. (2015)
4. Gupta R, et al. (2017)

BREAST AND PLASTIC SURGERY

1. Irwin GW, et al. (2020)
2. Galiano RD, et al. (2018)
3. Tanaydin V, et al. (2018)
4. Holt R, et al. (2015)
5. Edwards D, et al. (2018)
6. Sim K, et al. (2018)

CARDIOTHORACIC SURGERY

1. Tabley A, et al. (2020)
2. Witt-Majchrzak A, et al. (2019)
3. Nherera LM, et al. (2018)
4. Rodden D, et al. (2015)

VASCULAR SURGERY

1. Hasselmann J, et al. (2020)
2. Fleming CA, et al. (2018)

OBSTETRICS AND GYNAECOLOGY

1. Hyldig N, et al. (2018)
2. Hyldig N, et al. (2019)
3. Bullough L, et al. (2015)
4. Searle R, et al. (2017)
5. Hickson E, et al. (2015)
6. Lewis LS, et al. (2014)

ORTHOPAEDIC SURGERY

1. Karlakki SL, et al. (2016)
2. Nherera LM, et al. (2017)
3. Dingemans SA, et al. (2018)
4. Matsumoto T, et al. (2015)
5. Adogwa O, et al. (2014)
6. Gillespie BM, et al. (2013)
7. Karlakki S, et al. (2013)
8. Nordmeyer M, et al. (2016)

CHRONIC WOUNDS

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

MODE OF ACTION

1. Brownhill R, et al. (2020)
2. Innocenti M, et al. (2019)
3. Malmjö M, et al. (2014)
4. Loveluck J, et al. (2016)



Click on the author to navigate to study

1. Saunders C, et al.



A single use negative pressure system reduces surgical site complications compared with conventional dressings in closed surgical incisions: a systematic literature review with meta-analysis.

Saunders C, Buzza K, Nherera L. Poster presented at: European Wound Management Association Conference; June 5–7, 2019; Gothenburg, Sweden

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, and the Cochrane Library
 - Final analysis included 29 studies

Results

- PICO sNPWT helped to significantly reduce the odds of SSIs by 63% versus standard care (Figure; $p=0.00001$)
 - Reductions were achieved across several surgical specialties (breast, obstetrics, orthopaedics, and vascular)
- PICO sNPWT helped to significantly reduce the risk of necrosis ($p=0.0007$), seroma ($p<0.00001$) and dehiscence ($p=0.01$) by 89, 77 and 30%, respectively, 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 ($p=0.0002$)

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 by 1.75 days.

SSIs (all surgeries)

↓ 63%
odds reduction
($p=0.00001$)

Necrosis

↓ 89%
odds reduction
($p=0.0007$)

Seroma

↓ 77%
odds reduction
($p<0.00001$)

Dehiscence

↓ 30%
odds reduction
($p=0.01$)

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

2. 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^o 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)

3. Payne C, et al.



Application of the single use negative pressure wound therapy device (PICO) on a heterogeneous group of surgical and traumatic wounds.

Payne C, Edwards D. *ePlasty*. 2014;14:152–166

Overview

- Retrospective and prospective case evaluation designed to observe the efficacy of PICO^o sNPWT within a cost improvement programme
 - PICO sNPWT, n=21 (post-operative complications, n=11; trauma wounds, n=10)

Results

- PICO sNPWT was tolerated well with no dressing failure or failure to comply
- Median time to healing was 16.25 days
- Estimated cost savings in patients with skin grafts versus conventional therapy: 24 bed days (£7,800; n=8)

Conclusions

PICO sNPWT was well tolerated in patients with post-operative complications and trauma wounds, and resulted in a saving of 24 bed days compared with conventional therapy.

4. Hudson DA, et al.



Simplified negative pressure wound therapy: clinical evaluation of an ultraportable, no-canister system.

Hudson DA, Adams KG, Van Huyssteen A, Martin R, Huddleston EM. *Int Wound J*. 2013;12(2):195–201

Overview

- Prospective, open-label, non-comparative study to assess PICO sNPWT functionality and clinical performance on a variety of acute wounds including higher risk closed surgical incisions
 - PICO sNPWT, n=20 (surgical wounds, n=16; traumatic wounds, n=2 and meshed STSGs, n=2)

Results

- All wounds: 55% had closed by day 14 or earlier; further 40% of wounds progressing to closure
- Surgical wounds only: 69% closed by day 14; further 25% (n=4) progressing to closure
- No incidences of wound deterioration or dehiscence

Conclusions

PICO sNPWT helped to close or progress to closure 95% of acute wounds without incidences of wound deterioration or dehiscence.

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^o 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.

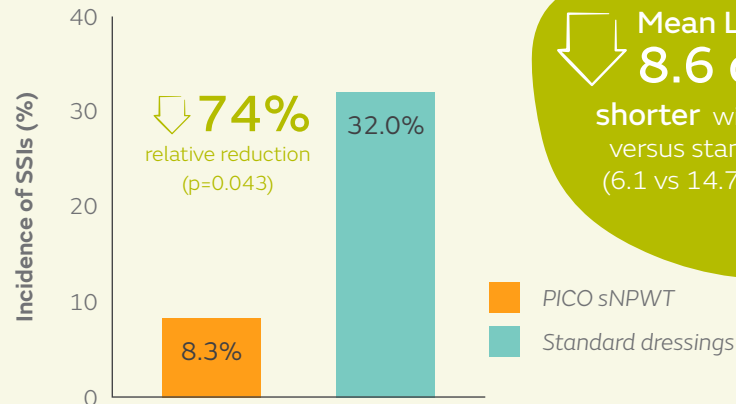


Figure. SSI incidence 30 days postoperatively and mean LoS with PICO sNPWT and standard dressings

2. 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^o sNPWT with conventional gauze dressings in patients undergoing elective surgery for stricturing Crohn's disease
 - PICO sNPWT, n=25
 - Conventional dressings, n=25

Results

- Compared with conventional dressings, PICO sNPWT reduced:
 - SSIs by 83% (8 vs 48%; p=0.004)
 - 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 SSCs resulting in shorter LoS compared with conventional dressings in patients undergoing surgery for stricturing Crohn's disease.

3. Caswell JF, et al.



Prophylactic use of PICO^o negative pressure wound therapy to reduce surgical site infections following large bowel surgery.

Caswell JF, Graham S, Whitehouse PA. Poster presented at: Association of Surgeons of Great Britain and Ireland (ASGBI) conference; April 22–24, 2015; Manchester, UK

Overview

- Open-label, prospective controlled trial to evaluate the impact of PICO sNPWT on SSI rates in high-risk patients following laparotomy. Data were compared with same period the previous year
 - Control period May to November 2013; n=119
 - Study period May to November 2014; n=102 (PICO sNPWT, n=27)

Results

- PICO sNPWT resulted in a 75% reduction in the rate of SSIs compared with the control (1.96 vs 7.69%; p=0.049)
- 27 patients in the study group were treated with PICO sNPWT, with one SSI (3.7%)
- Cost associated with one SSI ≈ 70 PICO sNPWT systems

Conclusions

PICO sNPWT helped to significantly reduce the incidence of SSIs versus control following laparotomy; the cost of one SSI was equivalent to the cost of 70 PICO sNPWTs.

*Defined as need for repeated hospitalisation within 6 months from discharge for wound-related complications.

4. 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^o 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

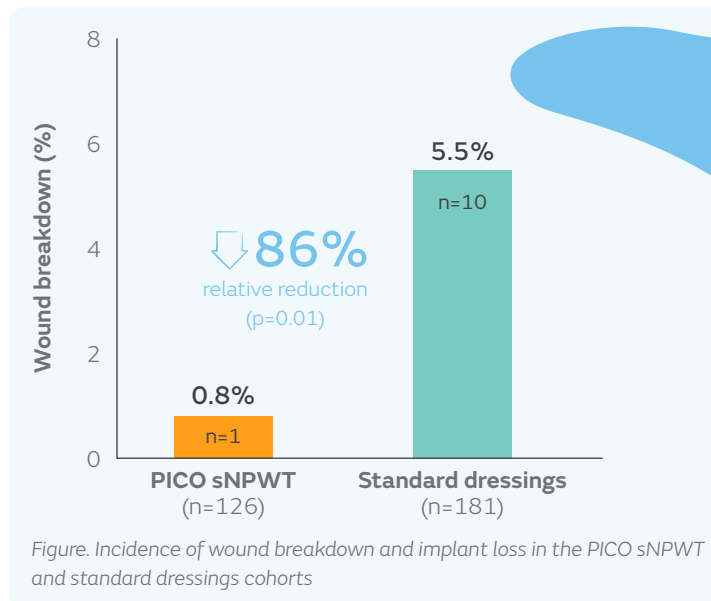
- A prospective cohort study conducted at a single UK centre (N=196) to evaluate wound breakdown and implant loss with use of PICO[®] sNPWT compared with standard dressings in patients undergoing skin-sparing or -reducing mastectomy with immediate prepectoral implant reconstruction
 - PICO sNPWT, 126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



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

2. Galiano RD, et al.



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

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 mammoplasty
- Patients were randomised within-patient (i.e. to right or left breast) to be treated for up to 14 days
 - PICO^o 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/m²

Conclusions

PICO sNPWT helped to reduce wound healing complications, particularly the incidence of wound dehiscence, when applied prophylactically to closed incision reduction mammoplasty surgical wounds compared with standard care. This effect on the incidence of dehiscence was greatest in patients with BMI >25kg/m².

3. 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 mammoplasty 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 significantly 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 mammoplasty surgery.

4. Holt R, et al.



PICO™ incision closure in oncoplastic breast surgery: a case series.

Holt R, Murphy J. *Br J Hosp Med.* 2015;76(4):217–223

Overview

- Prospective, non-randomised, open-label, case control study of consecutive patients undergoing oncoplastic mammoplasty or skin-sparing mastectomy and immediate reconstruction
 - PICO^o sNPWT, n=24 (therapeutic breast)
 - Standard dressings, n=24 (symmetrising breast)

Results

- Incidence of dehiscence was 75% lower with PICO sNPWT compared with standard dressings (4.2 vs 16.7%)
- Mean time to healing was 34% faster with PICO sNPWT compared with standard dressings (10.7 vs 16.1 days)

Conclusions

PICO sNPWT helped to reduce the incidence of dehiscence and decrease the time to heal incision wounds following complex oncoplastic breast surgery compared with standard care.

5. 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.

6. Sim K, et al.



The use of PICO dressing in mastectomy patients: A retrospective analysis.

Sim K, Mackowski A, Bevis H, Hamza S. Poster presented at: 47th World Congress of Surgery; August 13–17, 2017; Basel, Switzerland

Overview

- A retrospective, single-centre study comparing the use of PICO[®] sNPWT with standard dressings in patients post-mastectomy
 - PICO sNPWT, n=50, up to 7 days
 - Standard dressings, n=56

Results

- No significant differences in the incidence of SSIs, wound dehiscence or haematomas
- Number of patients with seroma and seromas requiring aspiration was significantly lower in the PICO sNPWT group than in the standard dressings group
 - 40% relative reduction in seroma (37.9 vs 63.2%; p=0.0071)
 - 55% relative reduction in seromas requiring aspiration (40.9 vs 90.1%; p<0.0001)

Conclusions

PICO sNPWT use may be associated with a reduction in the incidence of seroma and the number of seromas requiring aspiration in mastectomy patients.

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 [Epub ahead of print]

Overview

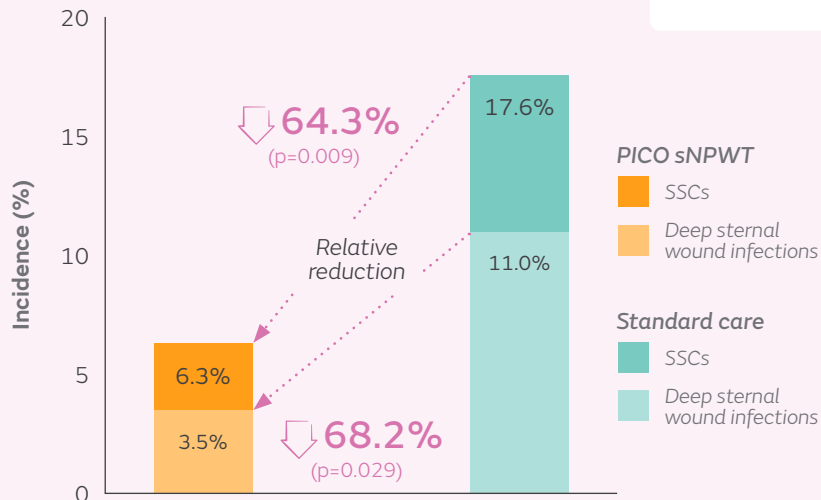
- Review of anonymised records before and after introduction of PICO^o sNPWT for high-risk patients (≥ 2 SSI risk factors) undergoing cardiac surgery at a hospital in France to determine the effect on SSCs
 - PICO sNPWT, n=142
 - Standard care, n=91
- More patients in the PICO group had BMI $\geq 35\text{kg/m}^2$ 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 $\geq 35\text{kg/m}^2$ or who had BIMA surgery ($p < 0.05$ for all)
 - Fewer patients with resultant DSWIs (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 DSWI incidence with PICO sNPWT may be due to preventing spread of superficial infectious material.



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

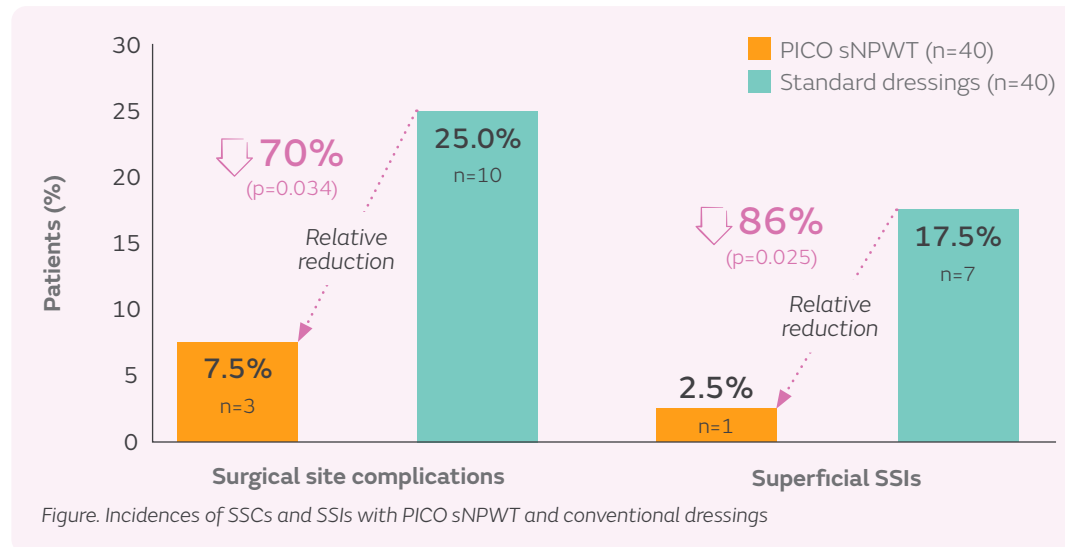
- Prospective, open-label study (6-week follow up) to evaluate wound healing in patients treated with PICO^o sNPWT or conventional dressings immediately after a CABG procedure
 - PICO sNPWT, n=40
 - Conventional dressings, n=40

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.



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/m², 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. Rodden D, et al.



NPWT: Incision management in high risk cardiothoracic patients – reducing surgical site infection and length of stay.

Rodden D, Taylor A. Poster presented at: Wounds UK conference; November 9–11, 2015; Harrogate, UK

Overview

- Single-centre, prospective cohort study to assess the effectiveness of PICO sNPWT in reducing SSCs and LoS in high-risk CABG patients versus low-risk CABG patients with standard dressings
 - PICO sNPWT, n=42
 - Standard film dressings, n=345

Results

- Compared with standard film dressings, PICO sNPWT reduced:
- SSI incidence (3.5 vs 0%)
 - Healing problems (13.9 vs 0%)
 - Mean LoS (11.1 vs 5.2 days)

Conclusions

Use of PICO sNPWT helped to reduce SSIs, healing problems and mean LoS in patients undergoing CABG surgery compared with standard film dressings.

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

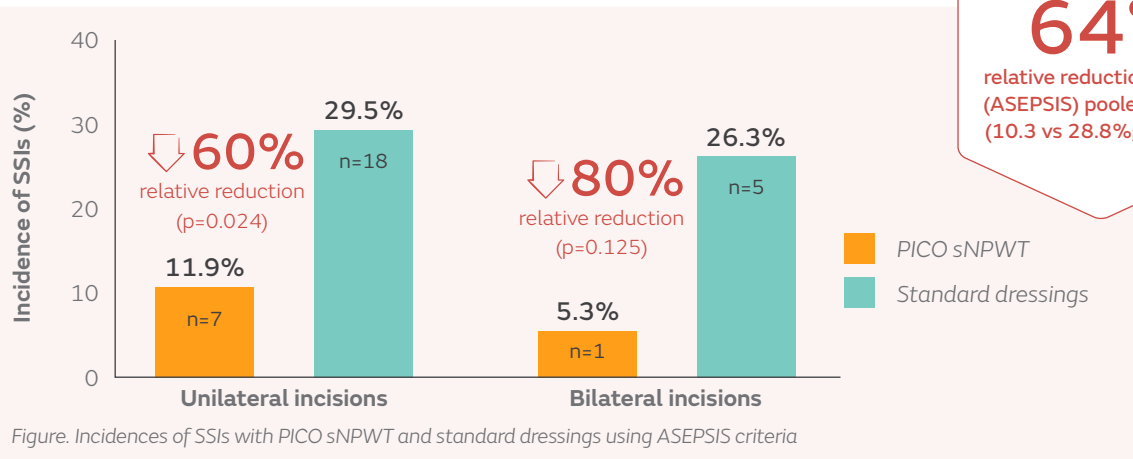
- Single-centre, open-label, RCT comparing the effect of prophylactic PICO sNPWT and standard dressings on the risk of SSIs following groin surgery in patients with both unilateral and bilateral incisions
 - PICO sNPWT (59 unilateral, 19 bilateral)
 - Standard dressings (61 unilateral, 19 bilateral)

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.



2. 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^o 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.



€34,472 lower estimated total cost of treatment with PICO sNPWT versus standard dressings (€34,718 vs €69,190)

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^o sNPWT compared with standard dressings in women undergoing elective or emergency caesarean section with a pre-pregnancy BMI $\geq 30\text{kg/m}^2$
- 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 $\geq 35\text{kg/m}^2$
- 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 $\geq 30\text{kg/m}^2$ undergoing caesarean section.

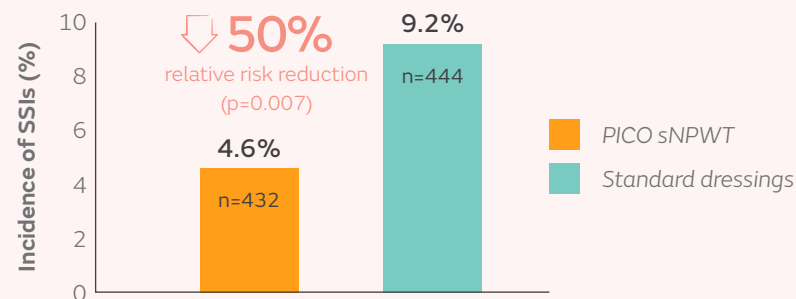


Figure. Incidences of SSIs with PICO sNPWT and standard dressings in obese women undergoing caesarean section

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^o sNPWT compared with standard dressings to help prevent SSIs in obese women after elective or emergency caesarean section (pre-pregnancy BMI $\geq 30\text{kg/m}^2$)
 - PICO sNPWT, n=432
 - Standard dressings, n=444
- Analysis of data from Hyldig, 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 $\geq 35\text{kg/m}^2$ 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 $\geq 30\text{kg/m}^2$ and estimated cost savings for pre-pregnancy BMI $\geq 35\text{kg/m}^2$.

3. 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 $> 35\text{kg/m}^2$) post-caesarean compared with OPSITE^o Post-Op Visible dressing in lower-risk patients (BMI $< 35\text{kg/m}^2$)
 - 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 incidence of SSIs resulting in cost savings.

4. 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^o sNPWT in patients post-caesarean with BMI $\geq 35\text{kg/m}^2$
- 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 $\geq 35\text{kg/m}^2$) caesarean section patients was associated with low incidences of both SSIs and hospital readmission.

Additional supporting studies

5. Hickson E, et al.

A journey to zero: reduction of post-operative cesarean surgical site infections over a five-year period.

Hickson E, Harris J, Brett D. *Surg Infect.* 2015;16(2):174–177

6. Lewis LS, et al.

Cost of care using prophylactic negative pressure wound vacuum on closed laparotomy incisions.

Lewis LS, Convery PA, Bolac CS, Valea FA, Lowery WJ, Havrilesky LJ. *Gynecol Oncol.* 2014;132(3):684–689

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 $\geq 35\text{kg/m}^2$
- 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.

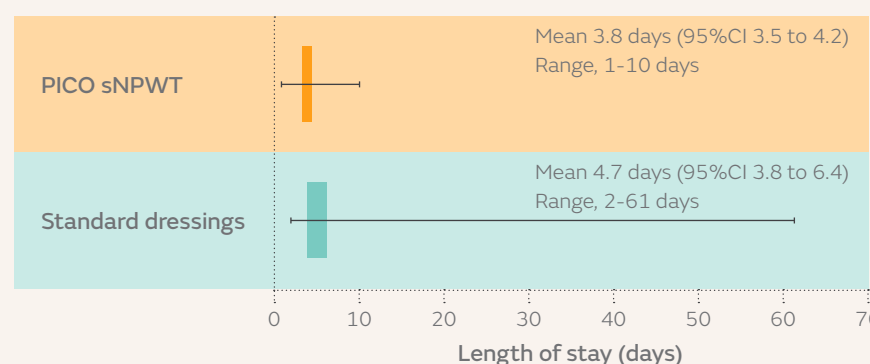


Figure. Mean LoS (and range) with PICO sNPWT and standard dressings

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

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^o 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, 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 $\geq 35\text{kg/mg}^2$
 - £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. 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 $\geq 3\text{cm}$)
 - 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.

4. 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^o 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.

5. 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.

Additional supporting studies

6. Gillespie BM, et al.

End-users' assessment of prophylactic negative pressure wound therapy products.

Gillespie BM, Finigan T, Kerr D, Lonie G, Chaboyer W. *Wound Pract Res.* 2013;21:74–81

7. Karlakki S, et al.

Negative pressure wound therapy for management of the surgical incision in orthopaedic surgery.
A review of evidence and mechanism for an emerging indication.

Karlakki S, Brem M, Giannini S, Khanduja V, Stannard J, Martin R. *Bone Joint Res.* 2013;2(12):276–284

8. Nordmeyer M, et al.

Negative pressure wound therapy for seroma prevention and surgical incision treatment in spinal fracture care.

Nordmeyer M, Pauser J, Biber R, et al. *Int Wound J.* 2016;13(6):1176–1179

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^o 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.

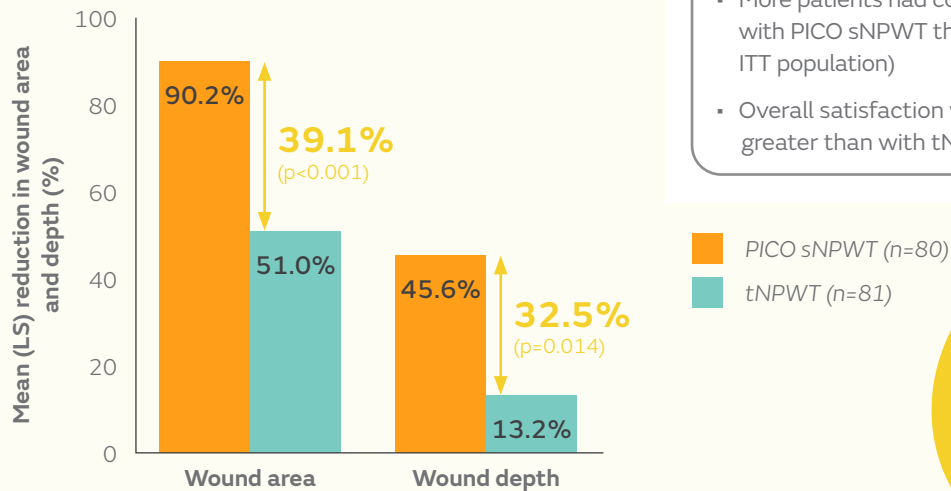


Figure. Percentage reductions from baseline in wound area and depth with PICO sNPWT and tNPWT at 12 weeks (ITT population; LS mean values)

More patients had 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 VLU 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.



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

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

Overview

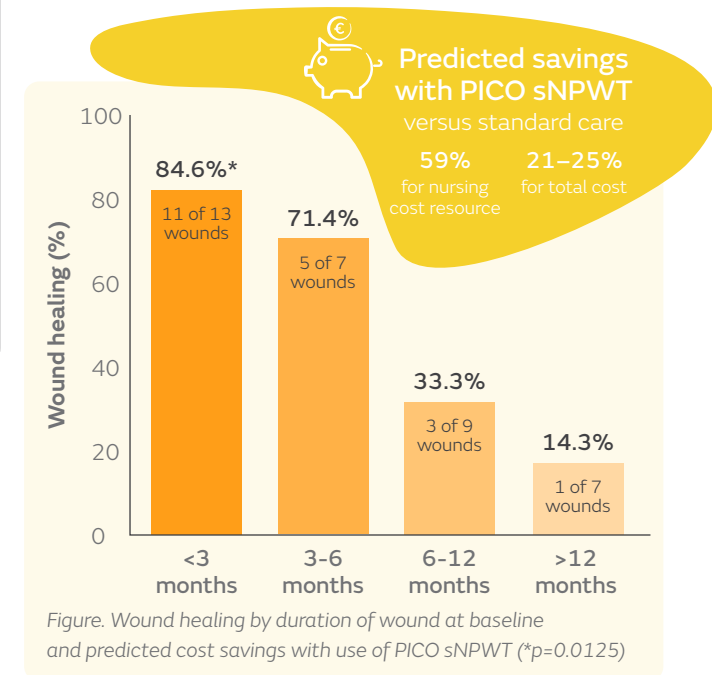
- A service evaluation at seven centres in Northern Ireland and the Republic of Ireland
- Wound healing and health economic impact (in UK sterling and Euros) of using PICO^o sNPWT versus standard care on hard-to-heal wounds over 12 weeks (or until healing) were assessed
- Median wound duration was 3–6 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.



4. 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
 - 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

5. 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^o 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.

6. 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.

7. 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 VLU and PUs treated in the community setting for >6 weeks
- Patients received PICO^o 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.

8. 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

9. 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

10. 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

11. 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

12. 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 R, 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*. 2020 Jul 7. [Epub ahead of print]

Overview

- Using an *in vivo* wound model (12 pigs), contralateral wounds were created (3cm diameter; 24 per group) and treated with either PICO^o 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.

Significantly greater wound area reductions with PICO sNPWT versus tNPWT

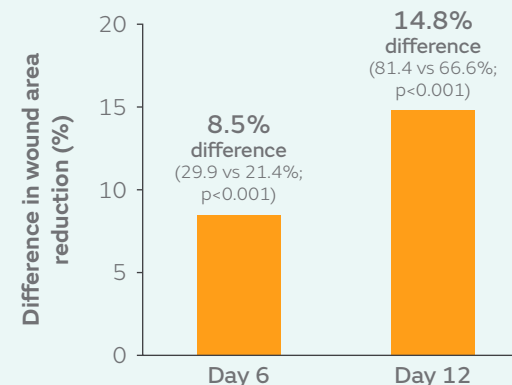


Figure. Difference in percentage change in wound area with PICO sNPWT versus tNPWT at days 6 and 12 post injury

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

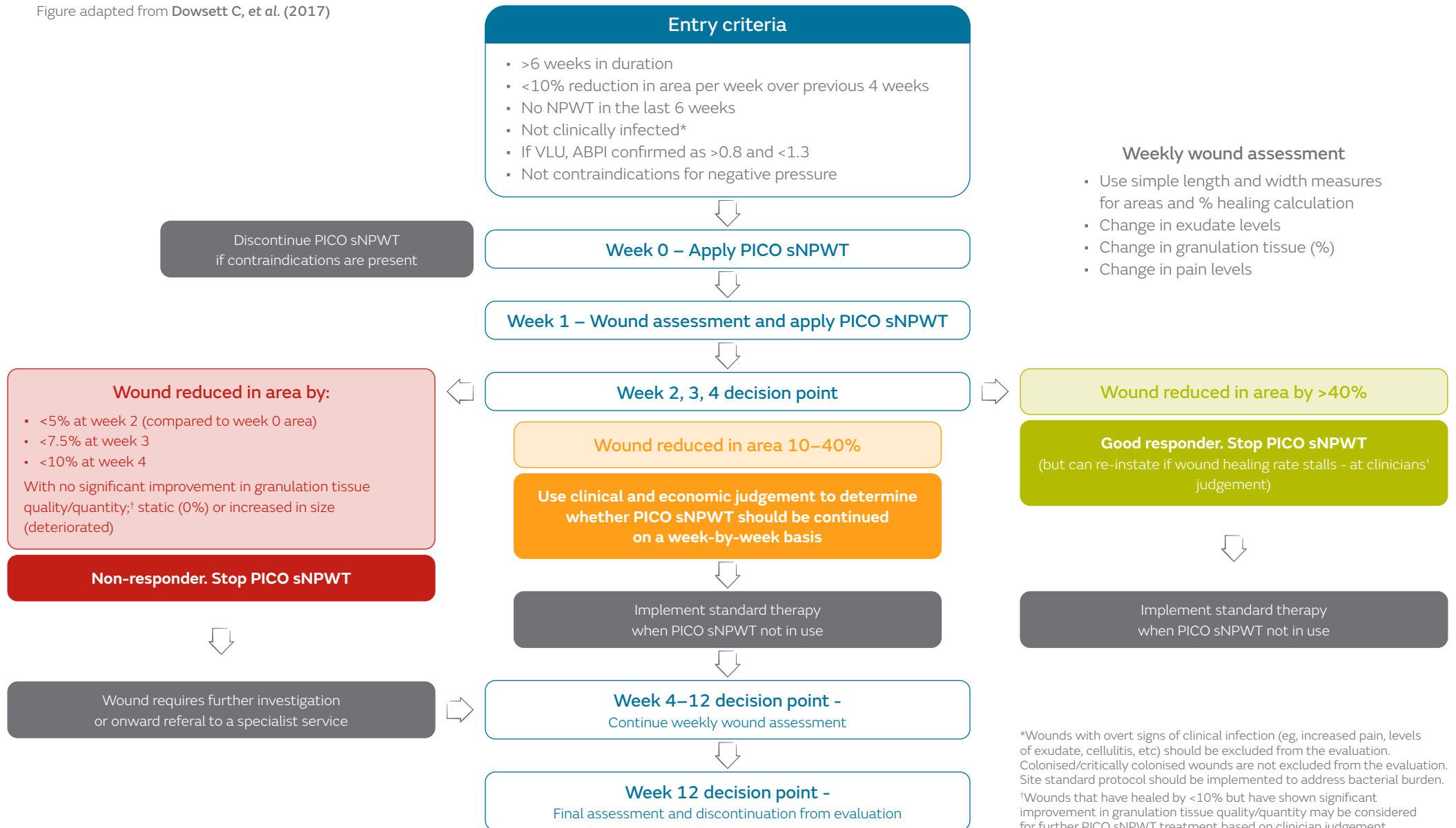
- FEA computer modelling:
 - Application of -80mmHg reduces the lateral tension on an individual suture from 1.31N to 0.4N and exerts a compressive closing force
- Biomechanical testing:
 - At a pressure of -80mmHg, 55% more force is required to disrupt an incision that had PICO sNPWT applied than an 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)





For detailed product information, including indications for use, contraindications, precautions and warnings, please consult the product's applicable Instructions for Use (IFU) prior to use.

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