

## The PICO<sup>o</sup> system significantly reduced the rate of Surgical Site Infections compared to Standard Care in patients undergoing laparotomy incisions

Results of a randomised controlled trial (RCT) using PICO single use Negative Pressure Wound Therapy (NPWT) for closed surgical incision management following abdominal laparotomy surgery, including colorectal and gynaecological procedures



### Evidence

- Level 1 evidence: an adequately powered RCT
- Could be considered Level 2 (lesser quality RCT) due to statistical flaws
- NPWT (PICO) for up to 4 days versus Standard Care which recruited 50 patients



### Surgical site infections (SSI) were significantly reduced by PICO compared to standard care

- PICO 2 /24 = 8.3% ; Standard care 8/25 = 32.0%  
*statistically significant p=0.043*  
*PICO n=1 treatment discontinued early and excluded*



### Length of stay (LOS) was significantly reduced by PICO compared to standard care

- PICO 6.1 days ; Standard care 14.7 days  
*statistically significant p=0.019*



### There was no difference in cosmetic outcome or patient satisfaction

- VAS and POSAS wound assessment scale
- Patient and clinical assessment

### S.M.A.\* COMMENTS:

This RCT included patients undergoing elective or emergency abdominal surgery via a laparotomy for either colorectal or gynaecological reasons. The study excluded very high risk patients with morbid obesity (BMI $\geq$ 40), high co-morbidities (ASA $>$ 3) or dirty wounds (according to Surgical Wound Classification).

This is a small study (50 patients recruited) but the high baseline SSI rate seen in laparotomy surgery (35% in the power calculation) and the expected reduction with PICO (10% in power calculation) suggests that this study with 50 patients was properly powered. It may be considered level 2 rather than level 1 evidence as per protocol analysis was performed (as opposed to Intention to Treat) and statistical significance was obtained by 1-tailed test rather than 2-tailed test. The actual result was a significant reduction in SSI rate from 32% to 8.3% which equates to a 74% reduction in SSI rate.

There was also a significant impact on hospital length of stay relating to an average of 8.6 days. Most patients with an SSI were successfully treated with antibiotics – one patient needed a wash out and another needed intravenous antibiotics along with NPWT to close the resulting wound. PICO seemed to reduce the number of patients with extreme LOS.

The use of standard dressings was the only predictive factor for SSI that was identified from univariate analysis.

The results of this RCT are comparable to those reported in the same sized, but none randomised, studies by Italian colorectal surgeons who reported 44% reduced to 8%<sup>1</sup> and 48% reduced to 8%<sup>2</sup>.

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Title:	Prophylactic negative pressure dressing use in closed laparotomy wounds following abdominal operations. A randomized, controlled, open-label trial: The P.I.C.O. Trial
Aim of the study:	To investigate the prophylactic approach to using single use NPWT (PICO) on postoperative surgical site infection rates in closed surgical incisions and resulting length of stay
Study Type:	RCT
Wound Type:	Laparotomy - Closed surgical incision
Speciality/Indication:	Colorectal, Gastrointestinal, Gynaecology
Products:	PICO
Number of patients	50 patients in the RCT: (PICO 24; Standard care 25)
Reference:	Annals of Surgery (2016) published ahead of print DOI: 10.1097/SLA.0000000000002098 Published online 06 December 2016
Details:	Peer Reviewed Journal   PubMed Listed   Impact Factor 8.569

1. Pellino, G. *et al.* (2014) Preventive NPWT over closed incisions in general surgery: does age matter? *Int. J. Surg.* 12 Suppl 2, S64-S68; 2. Selvaggi, F. *et al.* (2014) New advances in negative pressure wound therapy (NPWT) for surgical wounds of patients affected with Crohn's disease. *Surg. Technol. Int.* 24, 83-89.

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