

# The effects of a single use canister-free Negative Pressure Wound Therapy (NPWT) System\* on the prevention of postsurgical wound complications in patients undergoing bilateral breast reduction surgery

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## Abstract

### Introduction

Post-surgical incision healing complications can vary in severity from mild cases needing local wound care to serious cases with multiple reoperations and a high morbidity. Applying NPWT as a post-operative dressing for closed incisions has demonstrated a number of benefits.

### Method

200 patients undergoing bilateral reduction mammoplasty and who were suitable for incisional NPWT were recruited into a prospective, randomised, intra-patient, comparative, open, multi-centre study (6 centres in USA, South Africa, France and The Netherlands). Each patient was treated with both PICO® and standard care for up to 14 days to enable a within patient comparison. Follow-up assessments were carried out to evaluate the difference in incision healing complications between PICO and std care up to 21 days post surgery (Primary Endpoint). Healing complications were defined as delayed healing (incision not 100% closed by 7 days), or occurrence of dehiscence or infection within 21 days. Differences in scar quality and aesthetic appearance were also assessed using The Patient and Observer Scar Assessment Scale (POSAS) and The Visual Analogue Scale (VAS) at 42 and 90 days.

### Results

Significantly fewer overall healing complications had occurred by 21 days post surgery when treated with PICO compared to Standard Care (5%, p=0.004) (95% CI 2.0% to 9.2%). Treatment with PICO resulted in significantly fewer incidences of dehiscence compared to standard care (32 patients (16.2%) v 52 patients (26.4%) by day 21 (p<0.001). Scar quality as measured by the VAS and POSAS scoring systems was shown to be significantly better on PICO treatment than Standard Care, both at the 42 day and 90 day assessment (p<0.001).

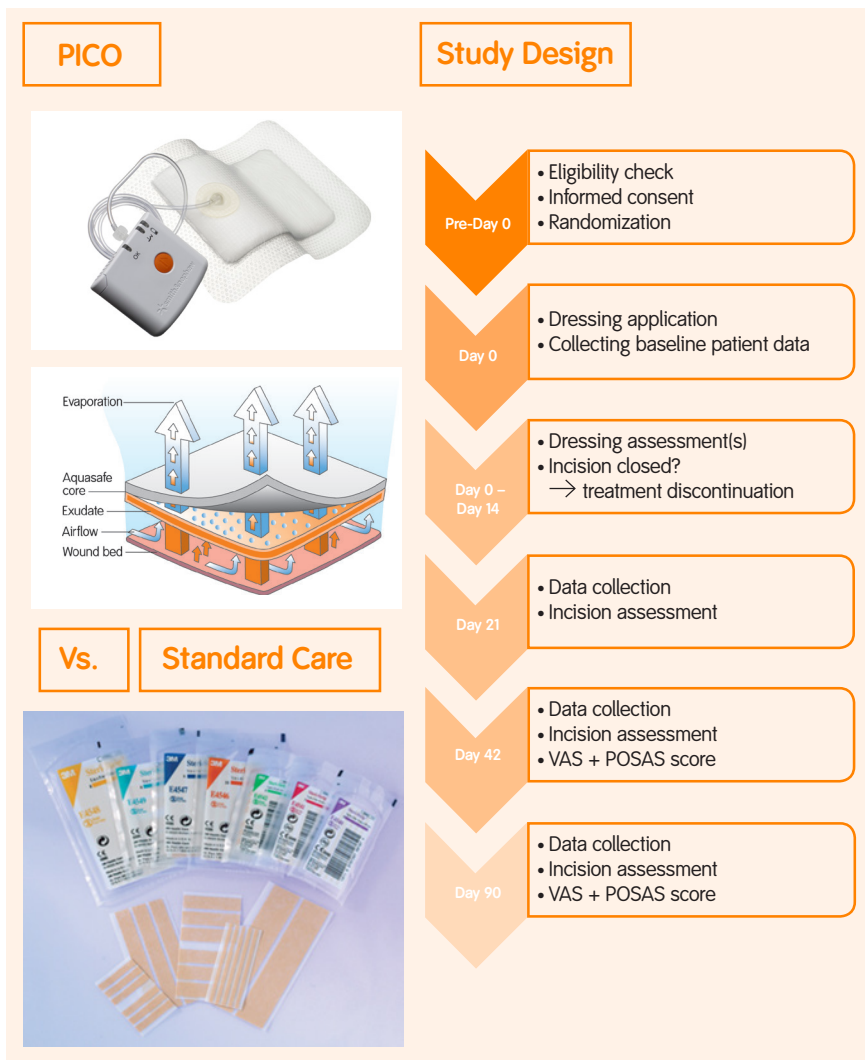
### Conclusion

Treatment of closed surgical incisions with a NPWT system in the form of PICO leads to a statistically significant reduction in incision healing complications, in particular a significant reduction in post-surgical dehiscence and a statistically significant improvement in scar quality within the first 3 months after the procedure.

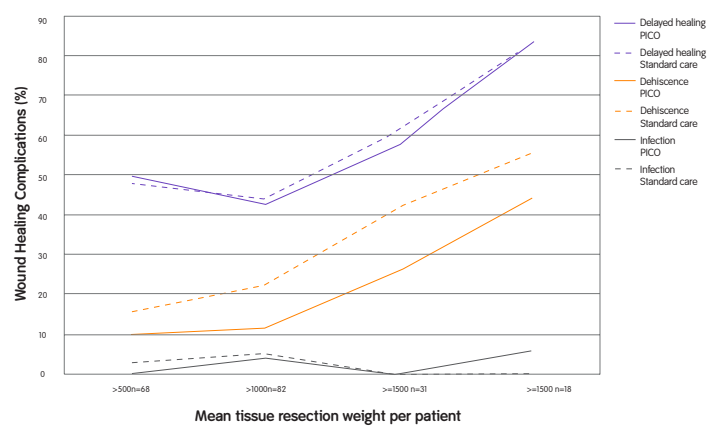
## Purpose of the Study

To assess the efficacy of the Single-Use Negative Pressure Wound Therapy (NPWT) system (PICO) to reduce post-operative complications after reduction mammoplasty and to assess the aesthetic appearance and quality of the resulting scar.

## Materials and Methods



## Effect of tissue resection weight on complication rates



### PICO vs. Standard Care (n=199):

- Significantly fewer healing complications overall (5%) p=0.004.
- Significant reduction in incidence of dehiscence: 32 patients (16.2%) v 52 patients (26.4%) p < 0.001.
- No significant difference in delayed healing at 7 days or 10 days.
- No significant differences in infection rate.
- The incidence of delayed healing and dehiscence but not infection appeared to increase with increasing weight of resected tissue.

## Visual Analog Scale (VAS) Score

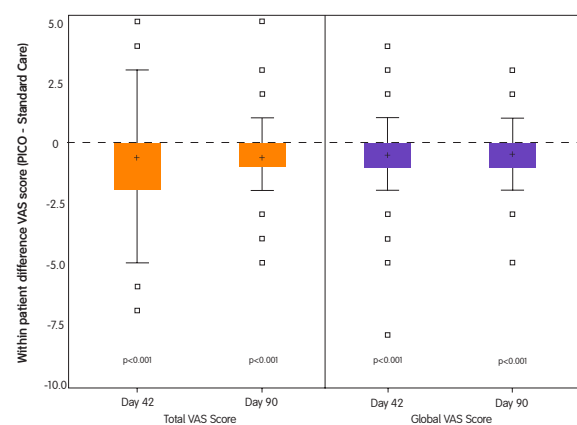


Fig 1. Within patient difference in VAS score (PICO – SC)

## Patient Observer Scar Assessment Scale (POSAS)

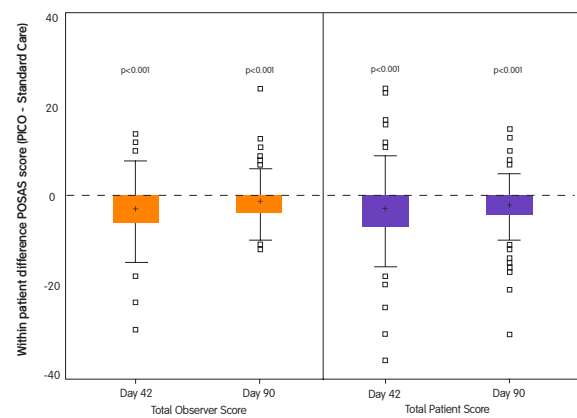


Fig 2. Within patient difference in POSAS score (PICO – SC)

- Significantly better scar quality at 42 day and 90 day assessment (p<0.001).

## Scar Type

	PICO	Std. Care
<b>Day 42</b>		
Immature hypertrophic scar (red)	36 (22.5%)	34 (23.3%)
Linear hypertrophic scar (red raised)	9 (5.6%)	13 (8.9%)
Minor Keloid	1 (0.6%)	2 (1.4%)
Normal (flat/white)	114 (71.3%)	97 (66.4%)
Total	160 (100%)	146 (100%)
<b>Day 90</b>		
Immature hypertrophic scar (red)	32 (18.4%)	38 (22.2%)
Linear hypertrophic scar (red raised)	19 (10.9%)	24 (14.0%)
Minor Keloid	0	3 (1.8%)
Normal (flat/white)	123 (70.7%)	106 (62.0%)
Total	174 (100%)	171 (100%)

Table 1. Scar type at follow up assessments

## Clinical case example

**Patient's significant history:** 58-year-old Caucasian female

**Initial wound assessment:** BMI 29.4

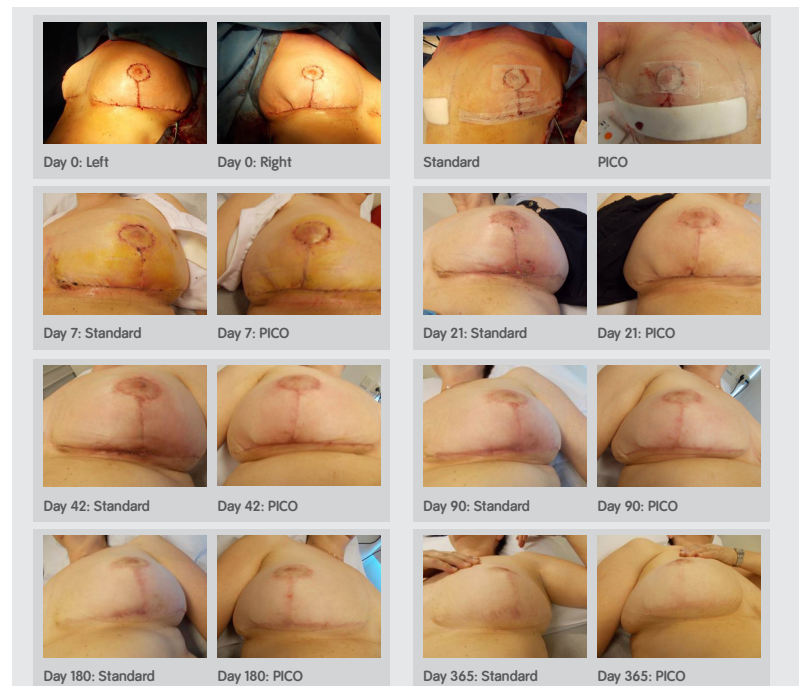
Cup size F  
CA distance (cm): 31/29  
Resection weight (g): 584/615,  
Surgery time: 1h 25min

### Treatment objective:

Bilateral reduction mammoplasty with Superomedial Pedicle technique. Vicryl and Monocryl sutures. PICO (R), Standard Care (L).

### Outcome:

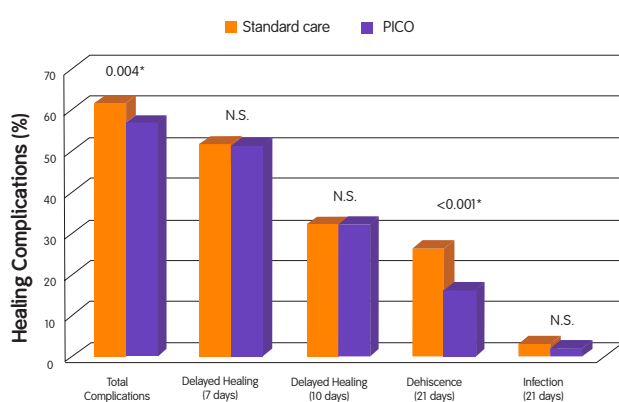
At day 21 there was an SD on the Standard Care side, no SD on PICO side. At day 42 follow-up the SD resolved. Overall, there was a subjective feeling that the PICO treated side was healing better overall.



Images courtesy of Dr Jip Beugel, Dr John H Sawor and Prof. dr. R.R.W.J. van der Hulst, VieCuri Medical Centre Venlo, The Netherlands

## Results

### Effect of PICO v std. care on post surgical wound related complications



\*PICO Single-Use Negative Pressure Wound Therapy System – Smith & Nephew Wound Management, Hull UK. This study was sponsored by Smith & Nephew. NCT01640366 <http://clinicaltrials.gov/ct2/show/NCT01640366>

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## Conclusion

Treatment of closed surgical incisions with a NPWT - system in the form of PICO leads to a statistically significant reduction in incision healing complications (particularly dehiscence) and a significant improvement in scar quality.