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 breast reduction surgery and who were suitable for inclusion within NPWT were recruited into a prospective, randomised, intra-patient, comparative, 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 within patient comparison. Follow-up assessments were carried out to evaluate the difference in incision healing complications between PICO and standard care up to 21 days post surgery (Primary Endpoint). Healing complications were defined as delayed healing (infection 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% C.I. 2.0% to 9.2%). Treatment with PICO resulted in significantly fewer incidences of dehiscence compared to standard care (13 patients (6.5%) vs 33 patients (16.4%) by day 21 (p=0.001). Scar quality as measured by the Visual 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

Study Design

- Slightly check in the informed consent
- Randomisation
- Dressing application
- Collecting baseline patient data
- Dressing assessment
- Incision closed
- Treatment discontinuation
- Data collection
- Incision assessment
- VAS + POSAS score

Results

Effect of PICO v standard care on post surgical wound related complications

PICO vs. Standard Care (n=199):
- Significantly fewer healing complications overall (5%) p=0.004.
- No significant difference in delayed healing at 7 days or at 90 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

Patient Observer Scar Assessment Scale (POSAS)

Clinical case example

Patient’s significant history
14-year-old female, received bilateral breast reduction and augmentation.

Capsule:

- Cap 1
- Cap 2

CA distance (cm): 31/29
Cup size F
BMI 29.4

Treatment objective:
To treat the patient's wounds with Supersuction Pedicle technique for optimal healing results.

Outcome:
All of the patients were on the Standard Care side. No SD on PICO side. At day 42 follow-up SD did not occur. Overall there was a subjective feeling that the PICO treated side was healing better overall.

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.