A prospective, randomized, intra-patient, comparative, open, multi-center study to evaluate the efficacy of a single use negative pressure wound therapy (NPWT) system* on the prevention of post-surgical incision healing complications in patients undergoing bilateral breast reduction surgery

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Group randomized to the PICO device yielded significant reduc
No significant differences in infection rate: n= 4 v 6 on SC, (p = 0.532, {95% CI = -1.9% to 4.3}).

Overall, there was a subjective feeling that the PICO treated side was
The incidence of delayed healing and dehiscence but not infection appeared to increase with increasing weight of resected tissue.

Within patient difference in POSAS score (PICO/standard care)

Table 1: Summary of data at end assessments

Effect of tissue resection weight on complication rates

Materials and methods

Results

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. Healing complications such as delayed healing and dehiscence appear to be associated with an increased in weight of tissue resected. PICO treatment led to a statistically significant improvement in scar quality within the first 3 months after the procedure.

Clinical case

Patient’s significant history:
15 year old caucasian female

Figure 2. Within patient difference in POSAS score (PICO/standard care)

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Abstract

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 mortality. Applying NPWT to a post-operative dressing for closed incisions has demonstrated a number of benefits.

Methods:
200 patients undergoing bilateral breast reduction surgery and who were suitable for incisional NPWT were recruited. Each patient was treated with both Smith & Nephew’s Single Use NPWT System and standard care for up to 14 days to evaluate within patient comparison. Follow-up assessments were carried out to evaluate the difference in incidence healing complications between PICO and standard care (up to 21 days post-surgery (Primary Endpoint)). Healing complications were defined as delayed healing incision not 100% closed by day 7, 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). Treatment with PICO resulted in significantly fewer incidences of dehiscence compared to standard care (12 patients (6.2%) 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 patients who received the 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. Healing complications such as delayed healing and dehiscence appear to be associated with an increased in weight of tissue resected. PICO treatment led to a statistically significant improvement in scar quality within the first 3 months after the procedure.

Purpose of the study
The purpose of the study was to assess the efficacy of the single use NPWT system (PICO) with regard to reduction of post-surgical incision healing complications during the immediate postoperative treatment phase, and to assess the medium-term aesthetic appearance and quality of the resultant scar, in patients undergoing breast reduction mammoplasty, compared to standard care.

Materials and methods

Group randomized to the PICO device yielded significantly fewer healing complications overall (31% v 50%, p<0.001, 95% CI 3.2% to 13.2%).

Group randomized to the PICO device yielded significantly greater reduction in incidence of dehiscence: 32 patients (16.2%) v 52 patients (26.4%) (p<0.001, effect size=10% {95% CI = 5% to 15%}).

No significant difference in delayed healing at 7 or 10 days: n= 102 v 101. 10 days (p = 0.042, 95% CI = -1% to 2.2%) and n= 64 v 64 (p = 10, 95% CI = -3% to 3.4%).

No significant difference in infection rate: n= 4 v 6 on SC. (p = 0.532, 95% CI = -1.9% to 4.3).