

Nipple and Areola Necrosis

The nipple and areola areas were not covered by the PICO™ NPWT or standard-care (SC) dressing as part of the evaluation, but they were all dressed the same with STERI-Strips™ and dry gauze pads, which was essentially the SC dressing regime. Nipple necrosis was very uncommon following surgery (2/200 patients), with no significant difference between SC (n = 1 [0.5%]) or NPWT (n = 2 [1%]) by day 21 (95% CI: -2.8;1.5; $P = 0.530$). One patient developed nipple necrosis on both incisions. Both patients who experienced nipple necrosis within 21 days were in the highest BMI category ≥ 30 kg/m². Within 21 days of surgery, 2 (1.0%) patients developed areola necrosis, and this occurred on both incisions (1 patient also had nipple necrosis). Both patients were in the highest BMI category (≥ 30 kg/m²).

Hematoma

Within 21 days of surgery, 2 (1.0%) NPWT-treated incisions developed a hematoma compared to 3 (1.5%) SC-treated incisions. One (0.5%) patient developed hematoma on both incisions. The difference of one incision (0.5%) was not statistically significant (95% CI: -2.0;3.2; $P = 0.681$). All hematomas were found in the two highest BMI categories.

Seroma

Only one patient developed a seroma in the study. The seroma was present around the incision site treated with SC, while the NPWT-treated incision site was absent of seroma. The patient had a BMI $>30 \text{ kg/m}^2$.

Cellulitis

Within 21 days of surgery, one (0.5%) of the NPWT-treated incisions developed cellulitis compared to two (1.0%) SC-treated incisions. One (0.5%) patient who was also a smoker developed cellulitis on both incisions. The difference of one incision (0.5%) was not statistically significant (95% CI: $-1.5; 2.8$; $P = 0.530$).

Abscess

No patients developed an abscess within 21 days of surgery from either the NPWT or the SC incision.

Suture Abscesses or Extrusions

Suture abscesses or extrusions are small abscess that build up behind the knotted suture and causes them to pop out. They weaken the suture line and are a nidus for a larger infection, and thus may develop into more serious complications. Within 21 days of surgery, 3 (1.5%) NPWT-treated incisions developed a suture abscess or extrusion compared to 4 (2.0%) SC-treated incisions. Three patients developed a suture abscess or extrusion on both their incisions. The difference of 1 (0.5%) was not statistically significant (95% CI: $-1.5; 2.8$; $P = 0.530$).

Other Healing Complications

Within 21 days of surgery, there were 9 (4.6%) NPWT-treated incisions that developed ‘other’ healing complications (e.g. epidermolysis and fat necrosis) compared to 10 (5.1%) treated with SC. The difference of 1 (0.5%) was not statistically significant (95% CI: -3.2;4.3; $P = 0.763$).

Center Effects and Analysis Exclusive of Site 5

When considering the study population excluding site 5, NPWT had a reduced number of incisions that developed a wound dehiscence 21 days post-surgery. Nineteen (14.7%) NPWT-treated incisions experienced dehiscence (partial, superficial, or deep) compared to 31 (24.0%) treated with SC. However, although the difference of 12 (9.3%) was slightly reduced from the complete study population, it remained statistically significant ($P = 0.005$, 95% CI: 3.2;16.4). The treatment effects for this variable at each site are shown in Supplementary Fig. 1 (SDC 3).