Materials and methods

**PICO**

- **Pre-operative phase**
  - A prospective, randomized, intra-patient, comparative, open, multi-center study to evaluate the efficacy of a single-use negative pressure wound therapy (NPWT) system.*
  - **Purpose of the study**
    - The purpose of the study was to assess the efficacy of the single-use NPWT system in patients undergoing bilateral breast reduction surgery in preventing post-surgical incision healing complications.
  - **Methods**
    - 200 patients undergoing bilateral reduction mammoplasty and who were suitable for inclusion in the study were enrolled.
    - Each patient was treated with one of the PICO™ Single Use NPWT System or standard care for up to 14 days to evaluate within a 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 incision not 100% closed by 7 days, occurrence of dehiscence or infection within 21 days.
    - Differences in scar appearance and photographic appearance were also assessed using the Patient and Observer Scar Assessment Scale (POSAS) and The Visual Analogue Scale (VAS). (Primary Endpoint) 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.
- **The incidence of delayed healing and dehiscence but not infection appeared to increase with increasing weight of resected tissue.**
- **Group randomized to the PICO device showed significantly** lower healing complications over all (31% vs 40%, 15% vs 30%, 13% vs 21%).
- **Group randomized to the PICO device showed significantly** reduced incidence of dehiscence (32% patients 16% vs 32 patients 21% (p<0.001), effect size=10% (95% CI 4.9% to 15.9%).
- **No significant difference in delayed healing of 7 days or 10 days: n= 102 vs 103 at 11 days, n= 64 vs 64 at 28 days, n= 108 vs 108 (p=0.682, 95% CI -1.9% to 3.2%) and n= 64 vs 64 (p=0.18, 95% CI -3.4% to 3.4%).
- **No significant differences in infection rate: n= 4 vs 6 on SC, (p=0.532, 95% CI -1.6% to 1.4% to).**
- **Significantly fewer overall healing complications had occurred by 21 days** post-surgery when treated with PICO compared to standard care.
- **Fewer hypertrophic scars (immature and linear) at day 90 on patients treated** with PICO compared with standard care.
- **There were no healed scars at day 90 on patients treated with PICO and 3 healed scars on patients treated with standard care.**
- **Difference in scar appearance** within the first 3 months after the procedure.
- **Clinical case**
  - **Patient's significant history:** 58 year-old caucasian female with a history of smoking.
  - **Bilateral reduction mammoplasty with Superomedial Pedicle technique** performed.
  - **Treatment objective:** Bilateral reduction mammoplasty using Superomedial Pedicle technique and to assess the medium-term aesthetic appearance and quality of the resultant scar in patients undergoing reduction mammoplasty, compared to standard care.

**Conclusion**

Treatment of delayed 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 increase in weight of tissue resected. PICO treatment led to a statistically significant improvement in scar quality within the first 3 months after the procedure.