Bringing Certainty to Patient Care Outside the Hosptial

Today, more than ever, your focus is on moving forward to restore healing. In these uncertain times, your patients deserve the certainty of wound care's most trusted portfolio, people, and partnership. For over 25 years, V.A.C.® Therapy has been shown to be an optimal way to manage wounds.

Rely upon 3M NPWT to deliver the clinical and economic outcomes you and your patients depend on to help make up for lost time.

Negative Pressure Wound Therapy vs Conventional Wound Treatment in Subcutaneous Abdominal Wound Healing Impairment (SAWHI)[1]

SAWHI Randomized Clinical Trial Frequently Asked Questions (FAQs):

1. What is this study about?
   - The aim of the SAWHI study was to compare effectiveness and safety of NPWT and conventional wound treatment (CWT) in SAWHI (subcutaneous abdominal wound healing impairment) after surgery in clinical practice to provide sound evidence as a basis for clinical therapy decisions.

2. Where did this study take place?
   - Germany, Belgium, and the Netherlands

3. How many patients were enrolled in this study?
   - 539 consecutive, compliant adult patients were randomized

4. What was the patient population in the SAWHI study?
   - The patient population in the SAWHI study consisted of adult patients (age ≥18 years) diagnosed with spontaneous wound dehiscence after abdominal surgery or active reopening of the suture and patients with open postsurgical abdominal wounds that could not be closed by primary intention. Several patient-related factors, such as morbid obesity or malnutrition, smoking and alcohol abuse, advanced age, or concomitant diseases, promote the development of SAWHI. The baseline characteristics of the Intention to Treat (ITT) population were as follows:

Baseline Parameter	**NPWT (n=256)**	**CWT (n=251)**
Age, median, Y	66	66
Sex, No. (%)		
Male	155 (60.5)	132 (52.6)
Female	101 (39.5)	119 (47.4)
BMI, median	28.7	27.9

Smoking, No./total No. (%)	65/256 (25.4)	55/251 (21.9)
Alcohol use, No./total No. (%)	111/255 (43.5)	114/250 (45.6)

5. How many patients were included in the Intention-To-Treat (ITT) population?
   - 507 patients (NPWT=256; CWT=251) assessed for primary end point in the modified ITT population

6. How many patients were included in the Per-Protocol (PP) population?
   - 331 patients (NPWT=157, CWT=174) successfully complied with the protocol In the PP population (ie. met inclusion criteria, no protocol deviations, received correct treatment, etc.)

7. Which V.A.C.® Dressings were used with NPWT?
   - Mainly V.A.C.® GRANUFOAM™ dressings were used as indicated for dehisced wounds
   - V.A.C. WHITEFOAM™ dressings were used for superficial and sensitive wounds
   - V.A.C. GRANUFOAM™ Silver dressings were used for wounds with need for barrier to bacterial penetration

8. What were the main results of this study?
   - Intention-to-treat (ITT) Population:
     - Wound closure rate within 42 days was significantly higher with NPWT (35.9%) than with CWT (21.5%) (difference, 14.4%; 95%CI, 6.6%-22.2%; P < .001).
     - Mean time to wound closure was significantly shorter for those in the NPWT arm vs. the CWT-arm (36.1 days vs 39.1 days; p<0.001)
     - No recurrences occurred after complete, sustained, and verified wound closure in any of the treatment arms
     - Total reduction of wound surface area within 42 days calculated from width and length was significantly greater in the NPWT arm than in the CWT arm (difference, 253mm^2; 95%CI, −711 to 1217; P = .007)
     - Total reduction of wound volume within 42 days was also significantly greater in the NPWT arm (difference, 395mm^3; 95%CI, −1065 to 1855; P = .002)
   - Per-Protocol (PP) Population:
     - Wound closure rate within 42 days was significantly higher with NPWT (47.8%) than with CWT (27.6%) (p=0.0001)
     - Mean time to wound closure was significantly shorter for those in the NPWT arm vs. the CWT-arm (34.7 days vs 38.6 days; p=0.004).
     - The results for recurrences within 132 days and wound size reduction, quality of life (QoL), pain, and patient satisfaction within 42 days show no relevant deviations from those of the ITT population.

9. What were the conclusions of this study?
   - The SAWHI–V.A.C. ® study is the first randomized controlled trial confirming that NPWT is superior to conventional dressings in achieving complete closure of subcutaneous

abdominal wounds after surgery due to more frequent and faster time to closure than CWT.

10. What were the results of the safety analysis?
    - In the modified ITT population, both treatment arms had approximately the same risk for AEs (RR, 1.04; 95% CI, 0.88- 1.24)
    - After excluding study participants with unauthorized treatment changes, the relative risk for AEs was higher in the NPWT arm (RR, 1.20; 95% CI, 0.97-1.47)
    - It should also be noted that many of the AEs were related to the application of a technical medical device and included issues with the therapy unit, canister, tubing, drape, foam or user error. In contrast, the application of a dressing is a far simpler procedure with less opportunity for error.
    - The most frequently documented wound related AEs were periwound macerations and local infections with signs of inflammation. Maceration is usually caused by a lack of drainage of wound exudate from the wound margin and avoidable with adequate protection. Local infections with signs of inflammation can be quickly eliminated by adequate therapy measures which in case of contaminated abdominal wounds should also be frequently performed when applying NPWT.
    - Most AEs were recovered during the study observation period.
    - None of the deaths was related to the NPWT device, CWT, or the wound.
    - Overall, there were no safety aspects against the use of V.A.C.® Therapy in clinical routine.

11. What were the limitations of the study?
    - Inability to blind study participants due to the nature of NPWT
    - Study treatment and observation time of 42 days was too short: More than 50% of wounds were not closed within 42 days
    - NPWT is an established treatment in clinical practice and affected investigators compliance with randomized treatment arm: Twenty percent of the CWT arm patients were changed from CWT to NPWT
    - Lack of standardization of CWT
    - Lengthy recruitment period with enrollment difficulties at study sites