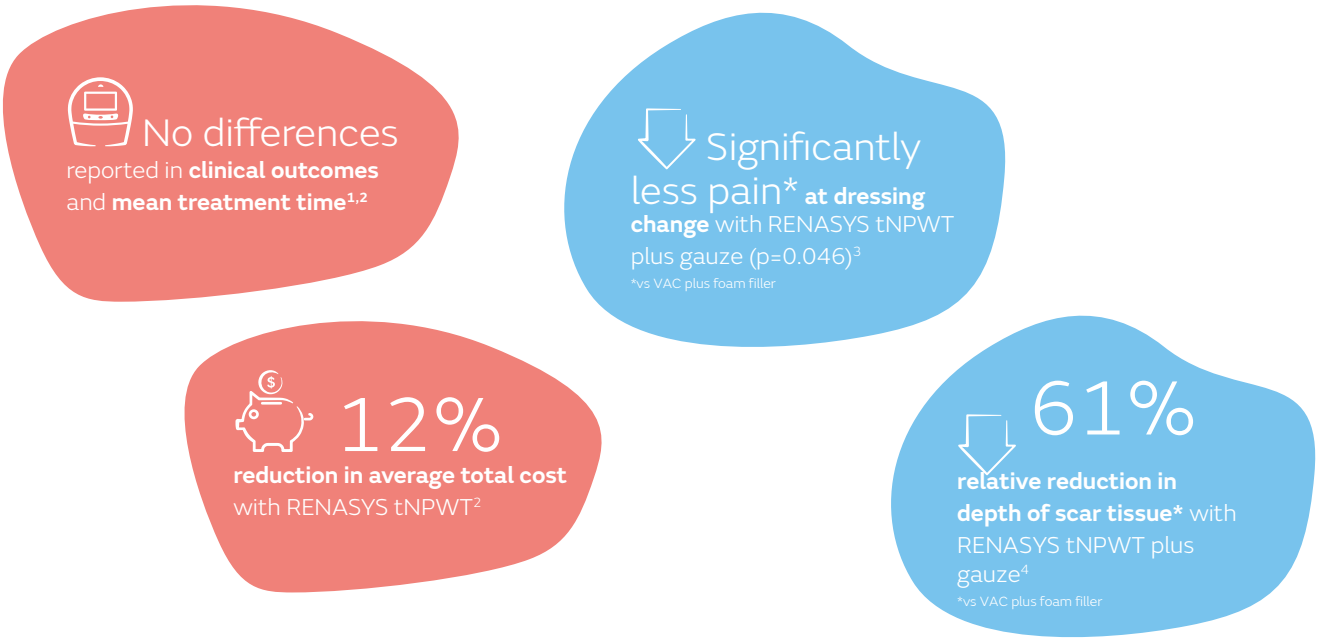
Smith+Nephew

RENASYS◊ Negative Pressure Wound Therapy System (tNPWT) versus V.A.C.™ NPWT: results of head-to-head studies

✚ Plus points

In four studies comparing use of RENASYS tNPWT with V.A.C.™ NPWT in patients with wounds of mixed etiology:[1–4]



What is the background?

- Negative pressure wound therapy (NPWT) is an established wound care method with a substantial body of evidence supporting its use in a range of wound types.[5]
- Several studies have evaluated the effects of different treatment variables on clinical outcomes (eg, pressure level, vacuum source, type of filler and continuous versus intermittent therapy) using individual systems.[5]
  - However, few studies have directly compared clinical outcomes using different NPWT systems.

What was done?

- A systematic literature review of all studies directly comparing RENASYS tNPWT (Smith+Nephew, Hull, UK) with V.A.C.™ Therapy (Acelity, San Antonio, Texas, USA), two widely used NPWT systems, was therefore conducted to determine any differences in clinical outcomes.[6]
- In total, 344 studies were identified; only four studies with a minimum of 10 patients and that had results available in English were included.[6]

Which studies were included?

- The first study was a large retrospective analysis of real-world NPWT use in Canada.[1]
- The second study, conducted in Germany, although quite small, was a randomized controlled trial comparing prospectively defined clinical endpoints.[2]
- The aim of the other two studies, both conducted in Italy, was to compare outcomes with the choice of filler, using RENASYS tNPWT to assess outcomes with gauze and V.A.C.™ NPWT for foam filler.[3,4]

What were the key findings?

Similar clinical outcomes

In this retrospective study by Hurd T, *et al.*, in patients with wounds of mixed etiology, choice of NPWT system and filler was determined by the healthcare professional.[1]

- There were **no significant differences in key outcome measures** for RENASYS◊ tNPWT (n=808) and V.A.C.™ NPWT (n=299), including:[1]
  - Proportion of patients achieving treatment goal at 8 weeks (Figure 1)
  - Median time to achieve treatment goal (8 weeks for both groups)
  - Total reduction in wound area (~65% in both groups)
  - Weekly reduction in wound area (~9.5% in both groups)

*"The results of this study demonstrate that there are **no clinically significant differences in outcomes** that can be observed between the two different commercial NPWT systems. **The choice** of which system to use is then no longer dependent on clinical efficacy or the size of the body of evidence but can **become dependent on other factors such as cost, availability, and personal choice**."*[1]

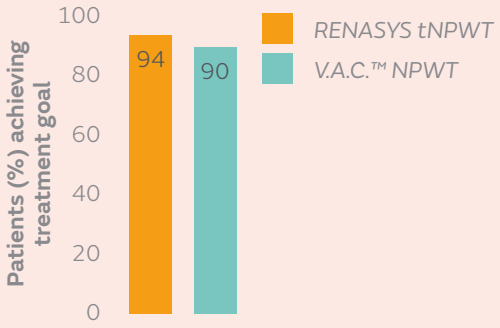


Figure 1. Proportion of patients achieving their goal after 8 weeks of treatment with RENASYS tNPWT (n=808) and V.A.C.™ NPWT (n=299)[1]

Impact on cost

The randomized controlled trial conducted by Rahmanian-Schwarz A, *et al.*, evaluated use of RENASYS GO NPWT (n=20) and V.A.C.™ NPWT (n=22), using foam filler for both systems, in patients with acute or chronic wounds to prepare the wound bed for skin grafting.[2]

- **No significant differences in clinical outcomes** (median values) were noted between respective systems and there were no reported complications with either treatment:[2]
  - Healing time (35.2 vs 37.2 days)
  - Duration of NPWT application (15.0 vs 13.5 days)
  - Number of total and partial dressing changes (3.0 vs 4.2)
- **Average total cost, and cost per day, were both reduced** with RENASYS GO tNPWT compared with V.A.C.™ NPWT (Figure 2).[2]

*"Since there are **no significant differences** in our results for the V.A.C.™ system and RENASYS GO system we believe that the **cost factor should be one of the determining criteria** for the selection of a foam-based NPWT system."*[2]
Cost analysis has been conducted in Germany based on NPWT systems costs in 2008-2010

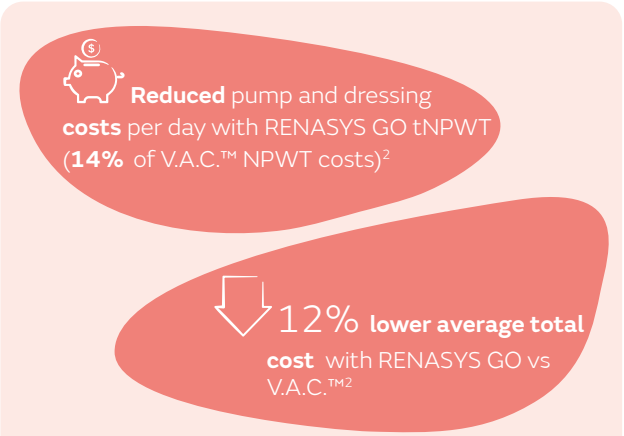


Figure 2. Differences in total and daily costs using RENASYS GO tNPWT and V.A.C. NPWT (both with foam filler)[2]

For RENASYS tNPWT: Foam should be changed every 48–72hr, but ≥3 times per week.[7] Gauze should be changed 48hr after initial application, then 2–3 times per week.[7]
For V.A.C.™ NPWT: Dressings should be changed every 48–72hr, but ≥3 times per week. Dressings of infected wounds may need to be changed more frequently.[8]

Differences in pain

The Italian researchers compared pain levels with different fillers in patients with post-trauma wounds using RENASYS tNPWT with gauze (n=13) and V.A.C.™ NPWT with foam (n=18).

The prospective comparative study by Fraccalvieri M, *et al.*, showed a **statistically significant reduction in pain levels at dressing change** in the group receiving gauze filler with RENASYS tNPWT compared with foam and V.A.C.™ NPWT (Figure 3).[3]

*"The finding of this study suggest that the patients treated with **NPWT with gauze** have **less pain at dressing change** compared with the patients treated with NPWT with foam."*[3]

Differences in pain levels during treatment and at dressing change for foam and gauze treated wounds can be caused by difference in pain level before treatment, different levels of pressure (80 mmHg for gauze and 125 mmHg for foam), and be a result of ingrowth of granulation tissue into the micropores of the foam.

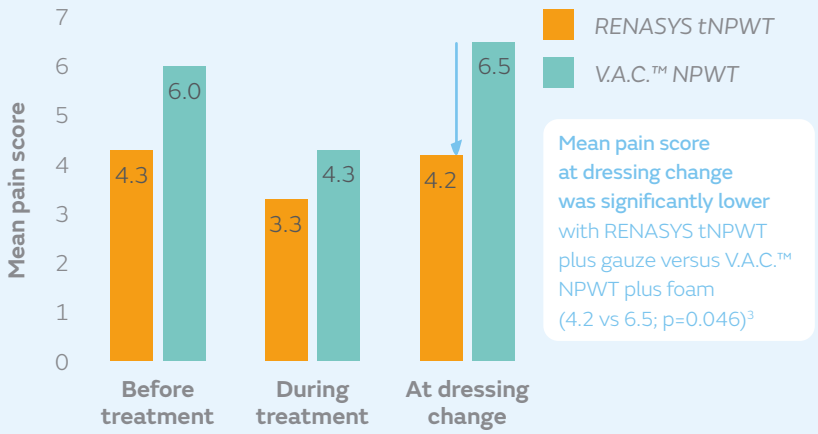


Figure 3. Reduction in pain with use of RENASYS tNPWT + gauze vs V.A.C.™ NPWT + foam[3]

What were the key findings? (cont)

Effects on scarring

The same group conducted another study evaluating the effects of gauze and foam fillers using RENASYS◊ tNPWT (n=13) and V.A.C.™ NPWT (n=16), respectively, on granulation and scar tissue in patients with post-trauma wounds.[4]

After 20–25 days of treatment, biopsies of granulation tissue were taken from a subgroup of patients.[4] The scars of patients treated with gauze filler using RENASYS tNPWT prior to skin grafting were not as deep as those treated using foam filler with V.A.C.™ NPWT (Figure 4).

Using gauze with RENASYS tNPWT compared with foam and V.A.C.™ NPWT, wound healing markers increased:

- Vascular endothelial growth factor (mean levels: 2.0 vs 0.8; p=0.0165)
- Matrix metalloproteases (mean levels: 2.5 vs 0.7)
- Formation of new blood vessels (neovascularisation)

*"The presence of **less scar tissue after NPWT with gauze** is accompanied by an increased formation of **new mini-vessels.** The presence of this blood supply leads to the **restoration of the physiological condition.**"*[4]

NPWT was used to prepare post-trauma wounds, all wounds were closed via skin grafting. NPWT was applied at the level of 80 mmHg for gauze and 125 mmHg for foam fillers. Scar depth was measured between 6 and 15 months after healing

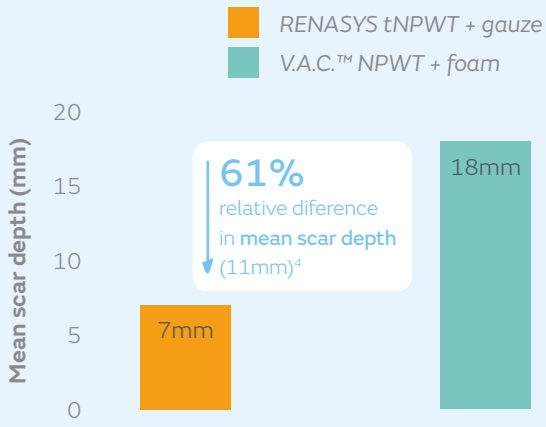


Figure 4. Mean scar depth (mm) with RENASYS tNPWT (n=12) + gauze versus V.A.C.™ NPWT + foam (n=11)[4]

Summary

This systematic literature review identified four studies that compare patients treated with RENASYS tNPWT and V.A.C.™ NPWT using gauze and foam fillers. The results show no differences in clinical outcomes and treatment time between the two systems,[1,2] and highlight potential benefits for RENASYS tNPWT versus V.A.C.™ NPWT:

- Lower average total and daily costs for treatment with Renasys using foam filler[2]
- Less pain at dressing changes using gauze filler[3]
- Reduced scar depth post skin grafting for wounds treated with gauze filler[4]

The information herein is intended for healthcare professionals. RENASYS is contraindicated in the presence of untreated osteomyelitis, exposed arteries/ veins/organs/nerves, necrotic tissue with eschar present, malignancy in the wound, non-enteric and unexplored fi stulas, and exposed anastomotic sites. Excessive bleeding is a serious risk associated with the application of suction to wounds, which may result in death or serious injury. For full product and safety information, please see the Instructions for Use.

References

1. Hurd T, Rossington A, Trueman P, Smith J. A retrospective comparison of the performance of two negative pressure wound therapy systems in the management of wounds of mixed etiology. *Adv Wound Care*. 2017;6(1):33-37. **2.** Rahmanian-Schwarz A, Willkomm LM, Gonser P, Hirt B, Schaller HE. A novel option in negative pressure wound therapy (NPWT) for chronic and acute wound care. *Burns*. 2012;38(4):573-577. **3.** Fraccalvieri M, Ruka E, Bocchiotti MA, Zingarelli E, Bruschi S. Patient's pain feedback using negative pressure wound therapy with foam and gauze. *Int Wound J*. 2011;8(5):492-499. **4.** Fraccalvieri M, Zingarelli E, Ruka E, Antoniotti U, Coda R, Sarno A, Bocchiotti MA, Bruschi S. Negative pressure wound therapy using gauze and foam: histological, immunohistochemical and ultrasonography morphological analysis of granulation and scar tissues. Second phase of a clinical study. *Eur J Plast Surg*. 2014;37:411-416. **5.** Apelqvist J, Willy C, Fagerdahl AM, *et al*. Negative Pressure Wound Therapy – overview, challenges and perspectives. *J Wound Care*. 2017;26(Suppl 3):S1-S113. **6.** Ebohon S. A systematic literature review to identify comparative studies comparing RENASYS vs VAC. Evidence Outcomes report. EO/AWM/RENASYS004/v2. 10 Sep 2019. **7.** RENASYS GO Negative Pressure Wound Therapy User Clinician Manual. Ref 66801244, 66801496. July 2015. **8.** Acelity. VAC™ Therapy system safety information (2017). Available at: https://www.acelity.com/-/media/Project/Acelity/Acelity-Base-Sites/shared/PDF/v-a-c--granufoam-application-ifu.pdf/#EN. Accessed 26 November 2019.