Clinical evidence supporting use of PICO◊ Single Use Negative Pressure Wound Therapy System (sNPWT) in patients with chronic, hard-to-heal venous leg ulcers (VLUs) receiving compression therapy

Key points

Use of PICO sNPWT in patients with VLUs has been evaluated in several clinical studies, which show:

36.2%

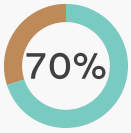
Significantly greater reduction in mean wound area with PICO sNPWT versus traditional NPWT both with compression therapy (p=0.007)[1]

Significant reductions from baseline in median wound area, depth, length and width, with use of PICO sNPWT and compression therapy (p≤0.05)[2]

High clinician and patient satisfaction with use of PICO sNPWT to help manage VLUs[1,3–5]

The burden of VLUs

Chronic, non-healing wounds, such as VLUs, are a substantial burden to healthcare systems;[6] VLUs can also have a negative impact on patient wellbeing by contributing to depression, anxiety and social isolation.[7–9] Some key statistics about VLUs are summarised in Figure 1.[10–13]



Most chronic leg ulcers are VLUs[10]

50–55% of VLUs are likely to **recur** within 1 year[11]

On average, time to heal a VLU is **~6 months**[12]

x4.5 more expensive to manage VLUs than patients with healed wounds[13]

Figure 1. Key statistics about VLUs and their management

A publication in 2014 estimated that the total cost of managing VLUs in the USA was $14.9 billion based on Medicare and healthcare claims databases.[14] In the UK, the estimated costs associated with VLUs amount to £1.98 billion, most of which are attributable to nurse visits, dressings and compression bandages.[15] Furthermore, approximately 40% of VLUs have underlying deep venous disease; conservative estimates of the total annual economic burden for these VLUs is $10.73 billion in seven countries or $5,527 per person per year (Figure 2).[13]

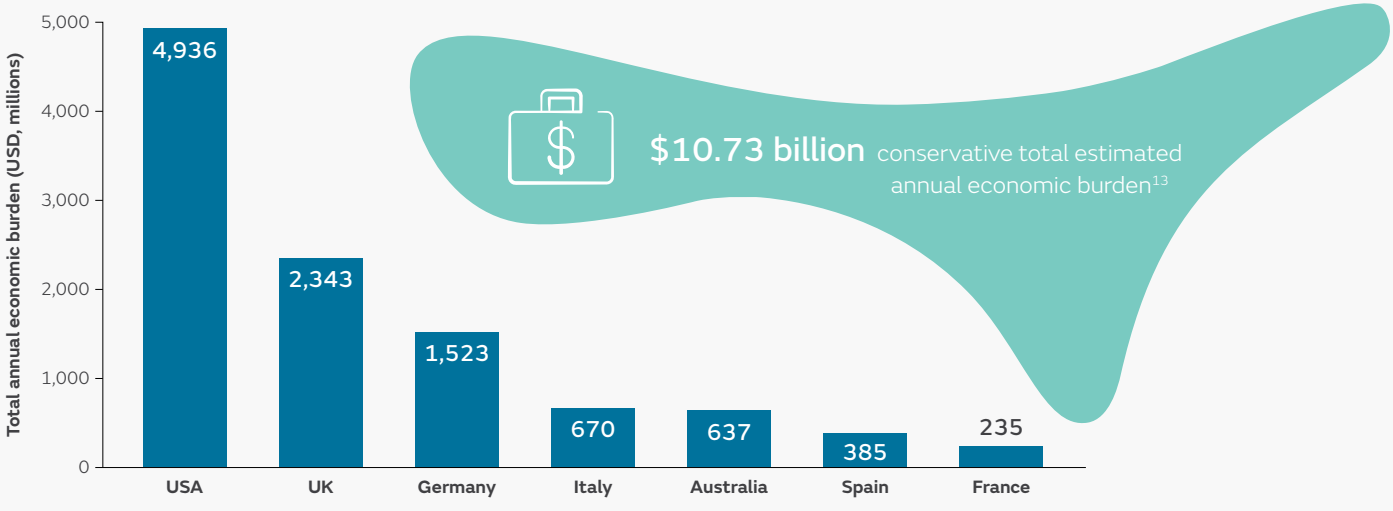


Figure 2. Total annual economic burden of deep-venous disease-related VLUs in seven countries[13]

The role of negative pressure wound therapy (NPWT) in managing VLUs

Compression therapy is widely recognised as the most effective treatment strategy for managing VLUs. However, complex VLUs that are hard to heal, despite optimal local wound management and compression therapy, may require use of other therapies, such as negative pressure wound therapy (NPWT).[7] Both traditional NPWT (tNPWT) and single-use NPWT (sNPWT) can be used as an adjunct to compression therapy in patients with complex VLUs.

In 2021, a consensus panel supported use of tNPWT and sNPWT in patients with acute and chronic wounds, including VLUs.[16] The panel proposed that sNPWT should be the first-line treatment choice for all wounds where use of NPWT is appropriate, to help increase patient satisfaction and quality of life.[16] Preferential use of sNPWT over tNPWT to manage acute and chronic wounds was also proposed by the panel to help reduce healthcare costs – a recommendation that is supported by a cost-effectiveness analysis conducted in the USA.[17]

Use of PICO◊ sNPWT with compression to help manage VLUs

Four clinical studies[1–3,5] and seven case series/reports[18–21] have evaluated use of PICO sNPWT and compression therapy in patients with VLUs.

Clinical studies and case series in patients with VLUs

The largest and most recent study of PICO sNPWT with compression therapy was a multicentre, randomised, controlled study of 161 patients VLUs and diabetic foot ulcers (DFUs).[1] They received either PICO sNPWT or tNPWT with multilayer compression bandaging for patients with VLUs over a 12-week period.[1] A subanalysis of 101 patients with VLUs showed that the mean change in wound area (improvement) from baseline was greater with PICO sNPWT than with tNPWT (Figure 3).[1] Furthermore, the number of patients with confirmed closure of VLUs was greater in the PICO sNPWT group than in the tNPWT group (Figure 4).[1]

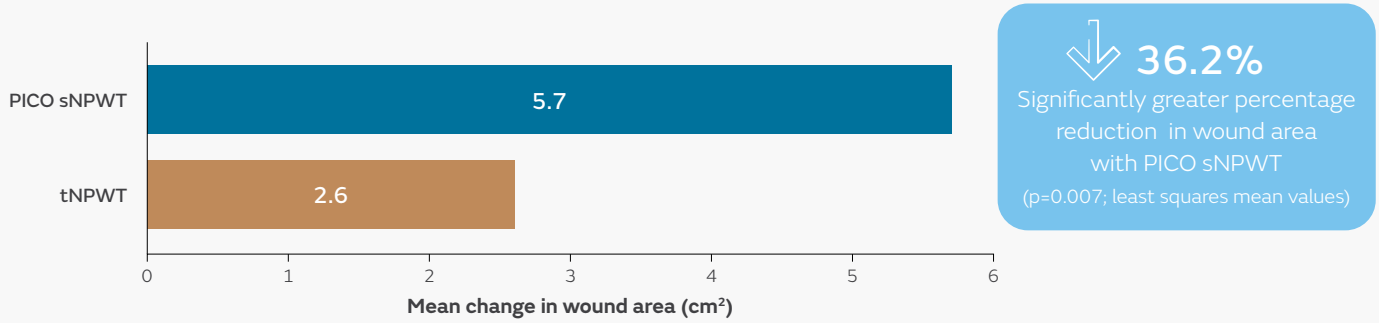


Figure 3. Mean change in wound area from baseline (cm²) and least squares mean percentage difference in reduction in wound area over 12 weeks with PICO sNPWT and tNPWT with compression in patients with VLUs (n=101)[1]

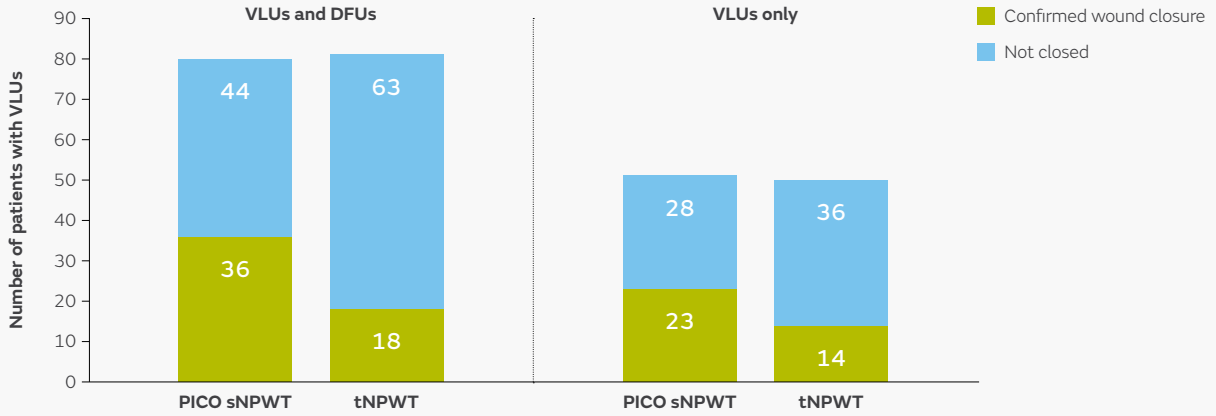


Figure 4. Number of patients with VLUs (with or without concomitant DFUs) and confirmed wound closure at week 12[1]

In 2017, a prospective case series investigated the effects of using PICO◊ sNPWT as an adjunct to compression therapy in patients with VLUs.[2] The study included 12 patients with 15 VLUs who received a combination of PICO sNPWT and compression therapy for a median of 20 days (range: 8 to 42 days).[2] Type of compression therapy (four-layer, three-layer or class II compression stockings) was determined by patients' tolerability.[2]

Median surface area of VLUs reduced significantly from 2.1cm^2 at baseline to 0.8cm^2 with use of PICO sNPWT and compression therapy (p=0.022).[2] Median VLU depth also significantly improved from 3.0mm at baseline to 0.0mm at the end of the study (p=0.005), accompanied by significant reductions in VLU length (p=0.021) and width (p=0.003; Figure 5).[2] Mean time to granulation in all VLUs was 2.8 weeks with a mean linear healing rate of 1.03cm^2/week. After 12 weeks, most VLUs (73%) had healed with an estimated mean time to healing of 4.3 weeks.[2]

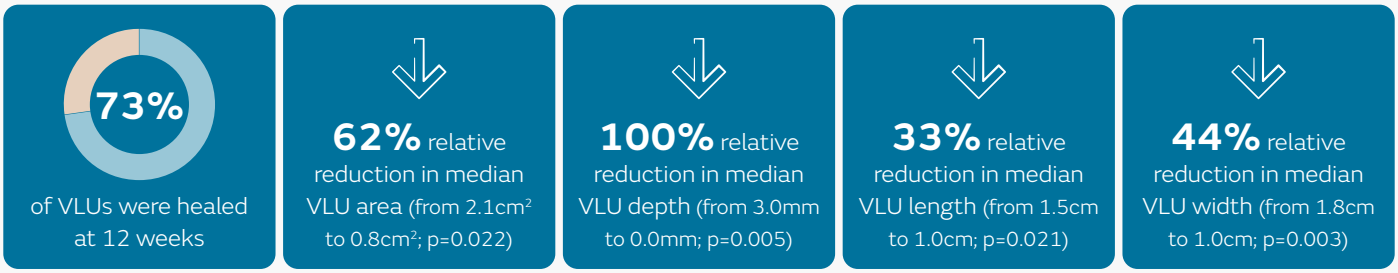


Figure 5. Proportion of wounds healed at 12 weeks and median changes in VLU dimensions from baseline with use of PICO sNPWT and compression therapy[2]

Positive wound healing outcomes, as well as favourable clinician and patient experiences, were also reported for individual cases using PICO sNPWT as an adjunct to compression therapy for VLUs.[19–21]

PICO sNPWT studies with subgroups of VLU patients

Two clinical studies investigating PICO sNPWT have included subgroups of patients with VLUs. One small prospective trial of 12 patients with lower extremity ulcers, which included patients with nine VLUs, demonstrated that use of PICO sNPWT with compression therapy reduced mean surface area by 32% over a 4-week period (Figure 6).[3] Mean wound depth also improved from baseline for all wound types during the study.[3] Overall, PICO sNPWT managed exudate well, adequately protected the periwound skin and had high patient satisfaction.[3]

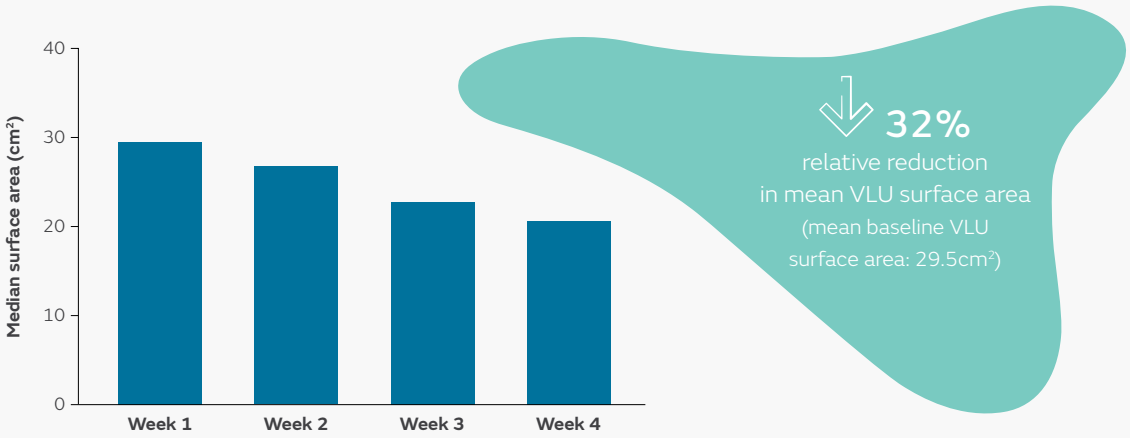


Figure 6. Change in mean VLU surface area from baseline (cm^2) over 4 weeks (n=9)[3]

A publication by Canonico *et al.* reporting results from several case series included use of PICO sNPWT under compression in 6 patients with VLUs.[18] PICO sNPWT was used under two-layer compression bandaging for VLUs that had not progressed for more than 4 weeks and had low to moderate exudate levels.[18] Formation of granulation tissue was reported for all patients and use of PICO sNPWT did not compromise perilesional skin.[18] Use of PICO sNPWT was well tolerated by patients and the use of compression bandaging did not affect functionality of the device.[18]

Other PICO sNPWT studies including patients with VLUs

Clinical evaluations of PICO sNPWT in patients with VLUs who had received compression therapy separately, or where details of how compression therapy was used were not provided, have also been published. In a study by Hurd *et al.* evaluating use of PICO sNPWT in patients with 326 mixed aetiology wounds, 21 VLUs were included.[4] Analysis of the 104 non-surgical wounds, which included the

21 VLUs, showed that 49% had completely healed within the 8-week study period.[4] Across all wound types, patient satisfaction with use of PICO◊ sNPWT was high (80%), and most patients (94%) were able to perform their everyday activities.[4] In addition, patients found that PICO sNPWT was comfortable during wear.[4] Satisfaction ratings for PICO sNPWT were also high for nurses.[4]

An evaluation of a pathway for implementation of PICO sNPWT use in hard-to-heal wounds (>6 weeks in duration) also included a subset of patients with 12 VLUs after unsuccessful use of compression therapy.[5] Although results for VLUs were not analysed separately, the study highlighted the importance of early intervention with PICO sNPWT to change the healing trajectory of stalled wounds.[5] Its use for a minimum of 2 weeks improved patient outcomes, lowered the cost of treatment and reduced overall cost burden to the healthcare system compared with prior practice, with high clinician satisfaction ratings for use of the device.[5]

Summary

- Addition of NPWT to compression therapy may be required to help manage patients with complex, hard-to-heal VLUs;[7] use of sNPWT is recommended, over tNPWT, to help increase patient satisfaction and quality of life,[16] as well as reduce healthcare costs
- Use of PICO sNPWT to help manage VLUs has been evaluated in several clinical studies demonstrating:
  - Greater reductions in mean wound area, and more wounds that were confirmed as closed, than with use of tNPWT, when both types of NPWT were used with compression therapy over 12 weeks[1]
  - Significant reductions from baseline in median surface area, depth, length and width of VLUs over 12 weeks when used in addition to compression therapy[2]
  - High clinician satisfaction with exudate management and protection of the periwound skin, as well as positive experiences in patients with VLUs[3,18]
  - Improved wound healing outcomes with reductions in overall cost burden for stalled VLUs compared with prior practice where use of compression therapy alone was unsuccessful[5]

For detailed product information, including indications for use, contraindications, precautions and warnings, please consult the product's applicable Instructions for Use (IFU) prior to use.

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