

Use of PICO^o Single Use Negative Pressure Wound Therapy System (sNPWT) reduced wound area, depth and volume compared with traditional negative pressure wound therapy (tNPWT) in patients with venous leg ulcers (VLUs) and diabetic foot ulcers (DFUs)

Complete wound closure was more frequent at 12 weeks with PICO sNPWT than with tNPWT



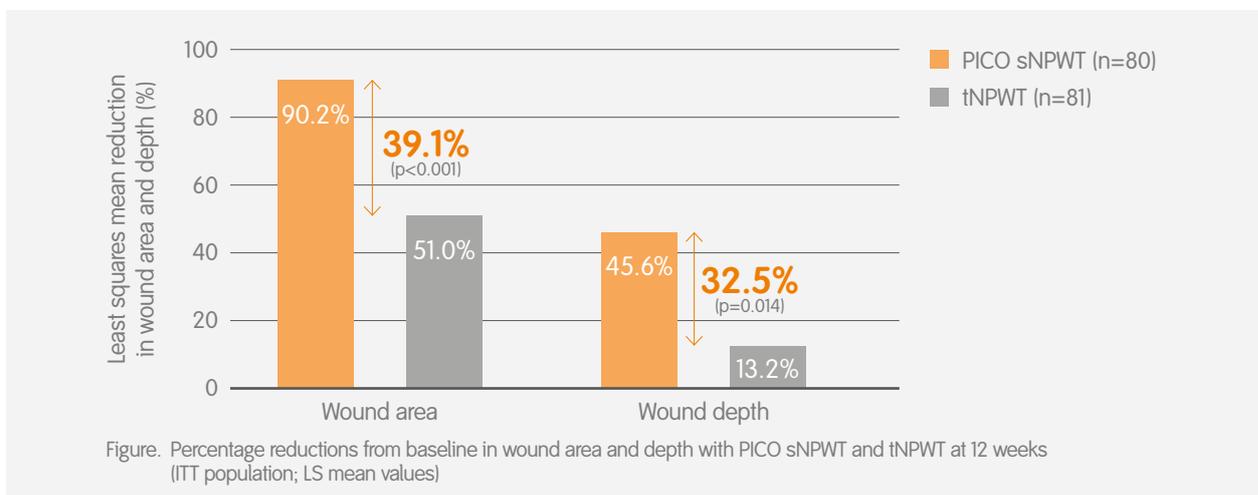
Study overview

- A randomised, controlled, multicentre study conducted at 16 centres in the USA and two centres in Canada to compare the efficacy and safety of PICO sNPWT with tNPWT in the management of patients with lower extremity ulcers (>4 weeks duration; VLUs and DFUs) over 12 weeks
- In total, 164 patients (VLUs, 104; DFUs, 60) were randomised to receive either PICO sNPWT (n=80) or tNPWT (n=84); mean patient age was 61.5 years and 63.4% were male
- Non-inferiority analysis was performed on the Per Protocol (PP) population (n=115) and superiority analysis was performed on the intention-to-treat (ITT) population (n=161)



Key results

- Least squares (LS) mean reduction in wound area was significantly greater with PICO sNPWT than with tNPWT in the PP population (88.7 vs 58.6%; p=0.003) and in the ITT population (p<0.001; Figure)
- Significant LS mean reductions in wound area were achieved with PICO sNPWT versus tNPWT in VLU (36.2%; p=0.007) and DFU (38.8%; p=0.031) patient subgroups
- Use of PICO sNPWT also achieved significant reductions versus tNPWT in wound depth (Figure) and volume in the PP and ITT populations (p<0.02, all comparisons)
- More patients had complete wound closure at 12 weeks with PICO sNPWT than with tNPWT (45 vs 22%; p=0.002; ITT population)
- Overall satisfaction with PICO sNPWT was greater than with tNPWT and quality of life was similar for both treatments
- Device-related adverse events were less frequent with PICO sNPWT than tNPWT (16 vs 41 events)



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Evidence in focus (continued)



Conclusion

In patients with VLU and DFUs, PICO[®] sNPWT significantly reduced wound area, depth and volume compared with tNPWT when used over a 12-week period. In addition, complete closure of lower extremity ulcers was more frequent with PICO sNPWT than with tNPWT.



Considerations

- Filler was used for all patients receiving tNPWT, but only for a minority of PICO sNPWT patients (<20%), which may have affected the results



Study citation

*Kirsner R, Dove C, Reyzelman A, Vayser D, Jaimes H. A prospective, randomized, controlled clinical trial on the efficacy of a single-use negative pressure wound therapy system, compared to traditional negative pressure therapy in the treatment of chronic ulcers of the lower extremities. *Wound Rep Regen*. 2019. May 14 [Epub ahead of print].

Available at: [Wound Repair Regeneration](#)