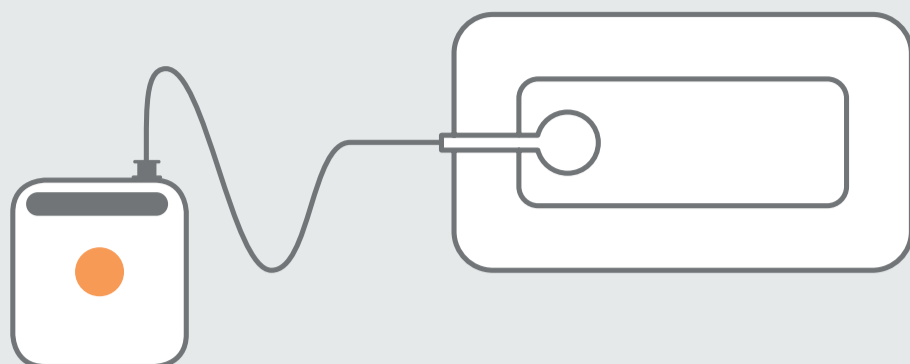


Significant reductions in wound area, depth and volume with use of PICO[®] Single Use Negative Pressure Wound Therapy System (sNPWT) versus traditional negative pressure wound therapy (tNPWT) in patients with venous leg ulcers (VLUs) and diabetic foot ulcers (DFUs)

Kirsner R, et al. *Wound Rep Regen.* (2019)¹



Why was the study performed?

This study evaluated whether PICO sNPWT was as effective as tNPWT at managing VLUs and DFUs¹

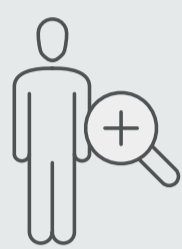


>6 million people affected by chronic wounds in USA²

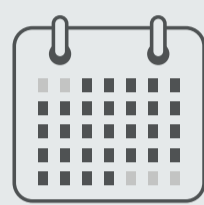


VLUs and DFUs are common chronic wounds³

What was done?



A randomised, controlled study was performed at 18 centres in the USA and Canada¹



For 12 weeks or until closure of the target ulcer, patients were treated with either PICO sNPWT or tNPWT (one of four similar devices)¹



A filler was used for all wounds treated with tNPWT, but the investigator could choose whether to use a filler with PICO sNPWT¹

Which patients were included?



164 patients enrolled¹ with lower extremity ulcers (>4 weeks duration)



- **104 with VLUs** (2–36cm²)
- **60 with DFUs** (0.5–10cm²)



- **Males** (63.4%)
- **Females** (36.6%)



61.5 years mean age



How the populations were analysed



Safety¹

- **80 PICO sNPWT**
 - **84 tNPWT**
- Evaluate **safety** in all patients enrolled who received either treatment¹



Per protocol (PP)¹

- **64 PICO sNPWT**
 - **51 tNPWT**
- Show **non-inferiority** versus tNPWT in all patients treated as planned¹



Intention to treat (ITT)¹

- **80 PICO sNPWT**
 - **81 tNPWT**
- Confirm **superiority** versus tNPWT in all patients who attended a follow up visit¹

What were the main results?

Wound area



39.1% reduction¹ for PICO sNPWT versus tNPWT

(mean* reductions of 90.2 vs 51.0%; p<0.001; ITT population)¹

Significant differences remained when analysed by wound type (VLUs, p=0.007; DFUs, p=0.031)¹

Wound depth



32.5% reduction¹ with PICO sNPWT versus tNPWT

(mean* reductions of 45.6 vs 13.2%; p=0.014; ITT population)¹

Wound volume



91.1% reduction¹ with PICO sNPWT versus tNPWT

(mean* reduction of 48.6% vs mean* increase of 42.5%; p=0.013; ITT population)¹

Significant reductions in wound area (p=0.003), wound depth (p=0.018) and wound volume (p=0.01) were also achieved with PICO sNPWT versus tNPWT in the PP population¹

Wound closure

51% more closed wounds¹

at 12 weeks with PICO sNPWT than tNPWT

(45 vs 22%; p=0.002; ITT population)¹

*Mean = least squares mean values

Device satisfaction



Overall satisfaction

with PICO sNPWT was significantly better than with tNPWT (p=0.006; ITT population)^{1,4}

- Willingness to use again (p=0.003)⁴
- Comfort of use (p<0.001)⁴
- Impact on mobility (p<0.001)⁴
- Impact on activity levels (p=0.017)⁴
- Impact on sleep (p=0.017)⁴

Wear time



more wear time with PICO sNPWT versus tNPWT

(6.5 vs 3.1 days)¹

Adverse events

12 vs 29

patients (16 vs 41 events)¹

Fewer patients had device-related adverse events with PICO sNPWT than with tNPWT (Safety population)¹

What did it demonstrate?



Use of PICO sNPWT helped to significantly reduce wound area, volume and depth compared with tNPWT in patients with VLUs and DFUs over 12 weeks.¹ More patients achieved wound closure¹ and overall satisfaction was greater⁴ with PICO sNPWT than with tNPWT in this randomised controlled study.