

Randomized Clinical Study Comparing NPWT Devices

Title: A Randomized Clinical Study to Compare Negative Pressure Wound Therapy with Saline Irrigation and Traditional Negative Pressure Wound Therapy for Complex Foot Infections

Authors: Lawrence A. Lavery, DPM, MPH; Kathryn E. Davis, PhD; Javier La Fontaine, DPM, MS; David Farrar, PhD; Orhan Oz, PhD, MD; Peter A. Crisologo, DPM; Sandra Berriman, PhD

Objective

To compare the efficacy of different Negative Pressure Wound Therapy (NPWT) devices and NPWT with and without simultaneous irrigation in patients admitted to the hospital with moderate and severe foot infections.

Methods

Design: Prospective, randomized non-inferiority trial.

Study population: Patients admitted with a moderate or severe foot infection that required incision and drainage, parenteral antibiotics, and NPWT was indicated.

Intervention: NPWT delivered at 125 mmHg continuous pressure. Simultaneous saline irrigation, when delivered, at 15 mL/hr.

Primary outcome: Proportion of healed wounds at 12 weeks.

Secondary outcomes: Surgical wound closure, number of surgeries, length of stay, and time to wound healing.

Device used	Group	Therapy	Number of patients
Cardinal Heath, PRO with Simultaneous Irrigation™	NPWT-I	NPWT with Irrigation	30
Cardinal Health, PRO	NPWT-C	Traditional NPWT	30
KCI, V.A.C. Ulta	NPWT-K	Traditional NPWT	30

Results

Device used	Cardinal Health™ PRO (NPWT-I)	Cardinal Health™ PRO (NPWT-C)	KCI V.A.C. Ulta (NPWT-K)	p-value
Irrigation type	Saline	None	None	n/a
Healed wounds	63.3%	50%	43.3%	0.29
Surgical wound closure	83.3%	80%	63.3%	0.15
Length of stay (days)	16.3 ± 15.7	14.7 ± 7.4	15.3 ± 10.5	0.87
Time to wound healing (days)	46.2 ± 22.8	40.9 ± 18.8	45.5 ± 29.5	0.80

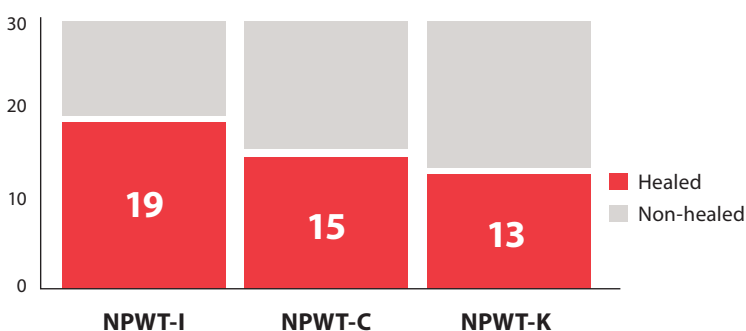
Conclusion

There were **no differences in clinical outcomes or adverse events identified between patients treated within the three treatment arms using different NPWT devices**, including:

- Proportion of Healed Wounds
- Surgical Wound Closure
- Length of Stay (days)
- Time to wound healing (days)

While the proportion of wounds that healed in the NPWT-I groups was higher, the difference was not statistically significant.

Healed wounds at 12 weeks (p = 0.29)



Presented at the Symposium of Advanced Wound Care May 8, 2019, San Antonio Texas. Pending peer reviewed publication.

© 2019 Cardinal Health. All Rights Reserved. CARDINAL HEALTH, the Cardinal Health LOGO and ESSENTIAL TO CARE are trademarks of Cardinal Health and may be registered in the US and/or in other countries. Lit. No. 2MP19-945138 (4/2019)