EVALUATION OF NEW AND INNOVATIVE FLUID DELIVERY DEVICE FOR WOUND HEALING

MARC ROBINS, DO, MPH, HYPERBARIC MEDICINE STAFF PHYSICIAN • ANNETTE GWILLIAM, RN, BSN, CWS, ACHRN

Intermountain Healthcare, Utah Valley Wound Care and Hyperbaric Medicine, Provo, UT

No conflicts of interest to disclose.

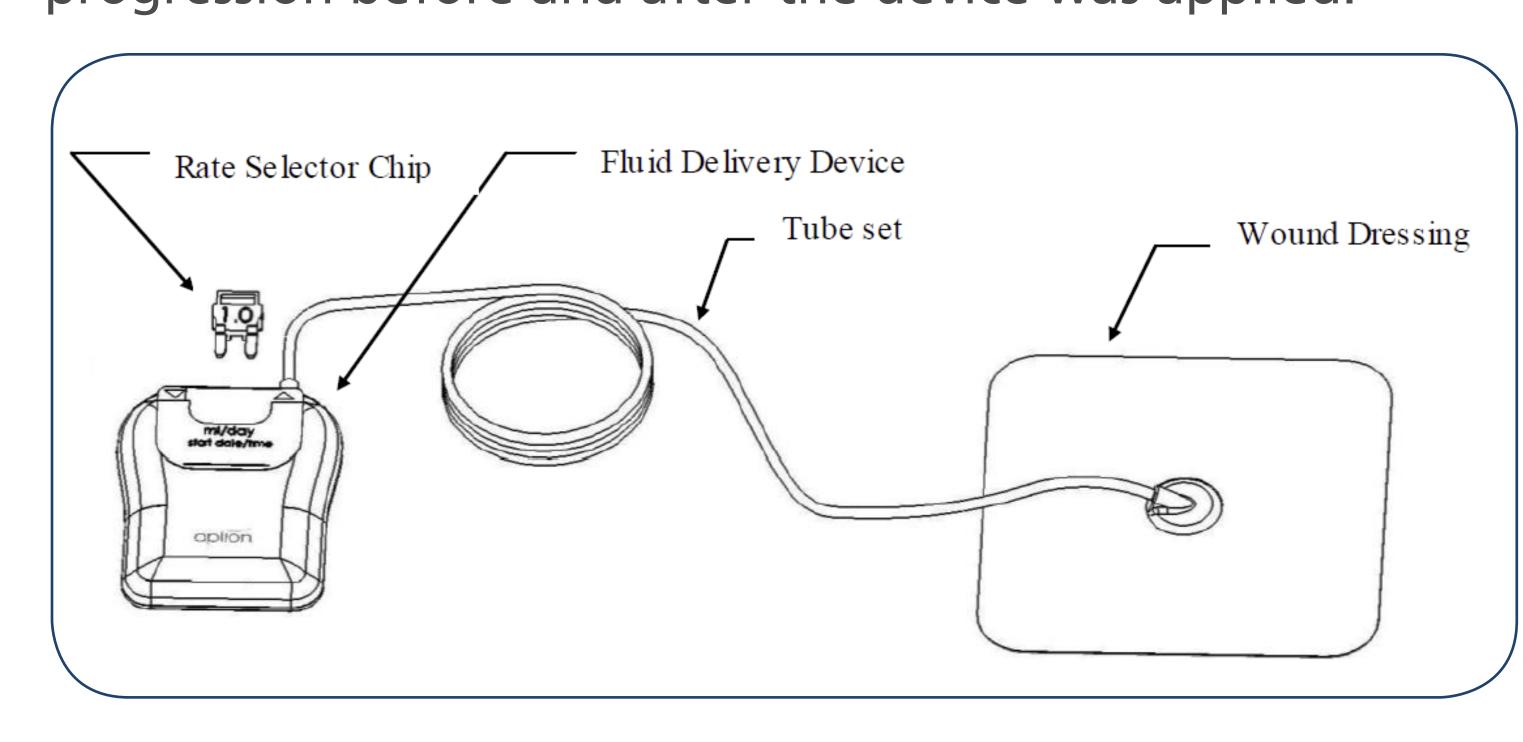
BACKGROUND

Clinical trials are a way to study new products for safety/ effectiveness.¹ Ongoing research on new devices is essential to advance wound care. "New therapies are emerging that involve the use of moist wound healing products to deliver antimicrobials, analgesics and a host of bioactive molecules (i.e., growth factors and micrografts).²

METHOD

We evaluated an innovative fluid delivery device on aspects that are important to patients and providers. Our study consisted of three components: clinical trial, retrospective chart review, and surveys. After receiving IRB approval, 15 patients were enrolled and 57 separate procedures were performed and evaluated.

This non-randomized, unblinded trial involved placement of a novel fluid delivery system instilling small amounts of either a 3% gentamicin solution, sterile water, or normal saline at a constant flow rate to partially saturate a semi-occlusive dressing. The innovative dressing was applied to the wound and the activated device was left in place for up to 5 days. On each visit, the provider completed a survey to analyze application, removal, and device functionality. A patient questionnaire was also administered. This included questions about the ability of the patient to perform activities of daily living (ADLs). A retrospective chart review revealed data on wound progression before and after the device was applied.



RESULTS

Safety: No adverse events were reported during the study and no severe incidents between clinic visits. There were varying degrees of maceration of the periwound skin which may have affected wound healing in only 11% of the cases.



Ease of use: Application time decreased to as little as 10 minutes. The providers deemed the device as "intuitive". Removal of the device received an 89% rating by clinicians as "easy" (Figure 1).

Impact on ADLs: 91% of patients indicated the device posed no limitations on their ADLs; 4% stated the device enhanced their daily activities.

Healing rates: determined to be favorable with 85% of the device applications resulting in wound healing rated "as anticipated" or "better than anticipated"; 14 out of 15 patients (93%) had a reduction in wound surface area.

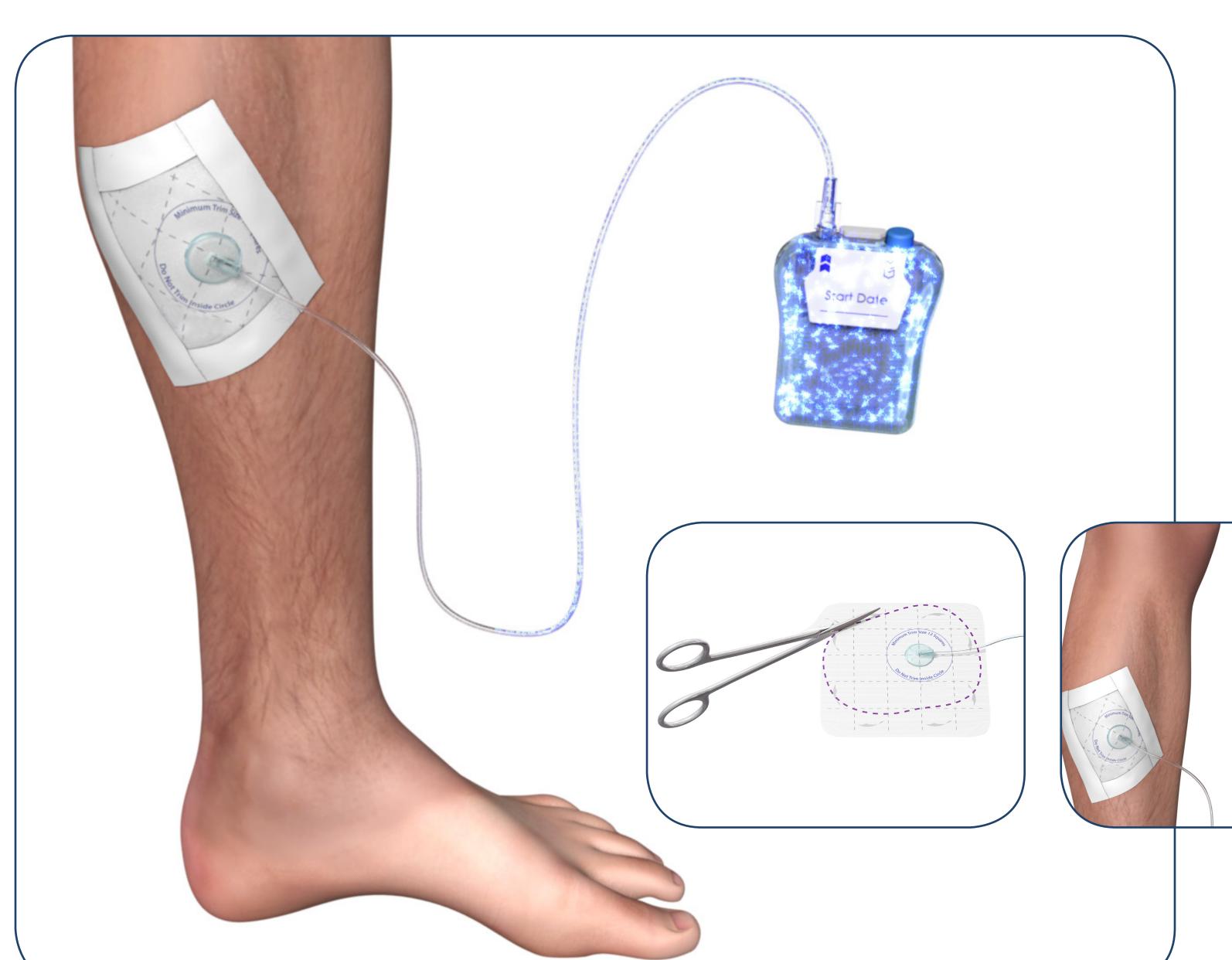


FIGURE 1: CLINICIAN DEVICE RATING FOR EASE OF USE

Table A. Clinician's Perception of Ease of Use $(N = 57*)$						
Rating						
Question	1	2	3	4	5	Rating Scale
Clarity of instructions			28%	28%	44%	1 = Difficult to follow to 5 = easy to follow
Priming pump		5%	11%	28%	56%	1 = Difficult to 5 = easy
Dressing application		2%	34%	28%	36%	1 = Difficult to 5 = easy
Usefulness of kit components		4%	30%	15%	51%	1 = not useful to 5 = useful
Overall packaging		4%	34%	47%	15%	1 = insufficient to 5 = above expectations
Choosing/using beneficial agent		2%	18%	7%	73%	1 = Difficult to 5 = easy
Removing device			4%	7%	89%	1 = Difficult to 5 = easy

All Data presented are percentages of the total for data collected for each category

COMMENTS ABOUT THE PRODUCT: Patient Perception

- "Amazing how much it has healed"
- Wearing it is "like it is not there, just have to watch the tube"
- No irritation from tape while wearing it.
- Dressing stayed on and tube attachment stayed on too.
- "that is healing quick, I can't believe it"

Physician Assessment

- "It's looking good"
- "only a little tiny spot in center looks like it doesn't have epithelialization"
- "the device is easy to apply and the wound is looking good"
- Steroid cream is needed to help with a rash this week

Clinical (RN) Perception

- "I'm amazed that the wound came up because it use to be dented in so deep."
- Wound looks really good, small areas of possible contact dermatitis, however, it may be from a reaction to the barrier wipes.
- "Best I've seen since he came in. Was deep and wound was just sitting there week after week"
- "Best I've seen it look, he's almost done"

REFERENCES

- 1. Beard, S. (2015). What does it mean to participate in a wound care clinical trial? Wound Care Advisor 4(1), 18-21.
- 2. Junker, J. P. E., Kamel, R. A., Caterson, E. J, et al. (2013). Clinical impact upon wound healing and inflammation in moist, wet and dry environments. Advances in Wound Care, 2 (7), 348-356.

CONCLUSION

The moist wound-healing device was favorable with both the provider and patients due to the ease of use and improved healing rates. The patients enjoyed the ability to perform activities of daily living while wearing the device. The results of the research suggest the device may have an application as an advanced wound care resource.

^{*} Data are from 57 treatments received by 15 patients; a small number of individual responses were lacking however, no question has less than 52 responses in total.