EVALUATION OF NEW AND INNOVATIVE FLUID DELIVERY DEVICE FOR WOUND HEALING

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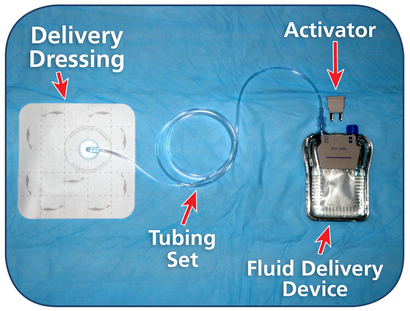
BACKGROUND

Clinical trials are a way to study new products for safety and 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.[2]

METHOD

We evaluated an innovative Fluid Delivery System 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 Device instilling small amounts of either a 0.3% gentamicin solution, sterile water, or normal saline at a constant flow to a semi-occlusive Delivery Dressing. The innovative dressing was applied to the wound and the activated System 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 System was applied.



RESULTS

Safety: No adverse events were reported during the study. In a small number of cases some slight maceration was observed.

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

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

Healing rates: Determined to be favorable, with 85% of the System 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.

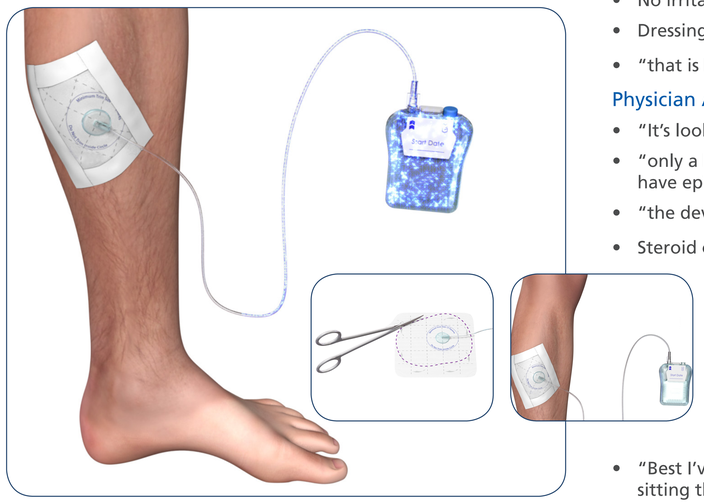


FIGURE 1: CLINICIAN DEVICE RATING FOR EASE OF USE

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 fluid delivery device	--	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

* 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.

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

- "Best I've seen it look, he's almost done"
- "I'm amazed that the wound has healed in because it used to be 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"

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.

Product: The Acton Topical Delivery System is a patented product of Aplion Medical Corporation. Salt Lake City, Utah.