

Interim Results of a Pilot Clinical Study: Evaluation of a Novel Active Fluid Management™ Dressing* Incorporating a Silver Ion Antimicrobial

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Introduction

An open-label, eighteen-patient, multi-facility study was conducted to determine the safety and efficacy of a new Active Fluid Management (AFM™) dressing on various wound types. The AFM dressing incorporates safe and effective silver ions to reduce growth of microbial contaminants in the dressing. When the printed side of the dressing is applied away from the wound, the novel construction enables predominantly one-way transport of wound exudate through the AFM dressing into an absorbent secondary dressing.

Study Objectives

- Determine the utility of the AFM silver dressing by wound type and stage.
- Obtain clinician input concerning the AFM dressing's compatibility with wound care practices and adjunct wound care materials such as gauze, tape, secondary dressings and wound cleansers.
- Determine effectiveness and clinical benefit of the dressing's wound exudate transport properties.
- Assess patient comfort and satisfaction with the dressing.

Management and Evaluation Plan

The intent was to qualitatively assess wound responses such as amount of slough, exudate, maceration, malodor, and amount of granulation tissue during several weeks of treatment. Weekly study visits included detailed wound assessments, photography, and tracing for surface area measurements.

During treatment with the AFM silver dressing, the change frequency of the secondary dressing was established based on wound type, location, amount of drainage, and other necessary patient/dressing requirements.

Interim Results

Patient Number	Wound Type	Anatomical Location	Wound Duration Prior to Study	Dimensions (L x W x D, in cm)		Undermining (U) or Tunneling (T) (# or No)	Percent Granulation		Maceration Frequency (# occurrences / # observations)
				Initial	Final		Initial %	Final %	
101	Abscess	Left Breast	< 30 days	0.5 x 0.7 x 1.0	0.3 x 0.4 x 0.0	No	10	26 - 50	0 / 4
102	Venous Ulcer	RLE	> 12 months	Multiple Wounds		No	26 - 50	100	0 / 5
103	Surgical	Abdomen	< 30 days	8.8 x 1.7 x 0.2	4.5 x 1.9 x 0.1	No	26 - 50	100	0 / 4
104	Pressure Ulcer	Sacrum	31 - 60 days	3.0 x 1.8 (irregular)	ND (Patient Expired, W2)	No	25	ND	0 / 2
105	Pressure Ulcer	L. Ischium	> 12 months	0.7 x 0.7 x 0.1 (W1)	0.6 x 0.6 x 0.1	(U) 3 cm	100 (W1)	100 (W2)	1 / 2
106	Surgical Flaps	Sacrum	6 - 12 months	3.0 x 2.1 x 0.2	3.0 x 2.1 x 0.2	(U) 0.5 - 1.5 cm (Max)	51 - 75	100	0 / 7
107	Pressure Ulcer	Sacrum	< 30 days	4.0 x 4.5 x 2.2	0.8 x 1.7 x 4.0	(T) 1 - 2.8 cm	0	76 - 99	0 / 8
108	Pressure Ulcer	Left Hip	61 - 90 days	1.8 x 2.5 x 1.7	0.7 x 1.0 x 0.0	(T) 5 - 7 cm	51 - 75	100	0 / 6
109	Venous Ulcer	RLE	> 10 years	See poster 75 for more details on this patient (Case Study #2)					
110	Surgical Abscess	Right Hip	> 12 months	2.8 x 1.1 x 4.0	0.8 x 2.2 x 3.0	No	100	51 - 75	0 / 8
111	Venous Ulcer	LLE	61 - 90 days	6.2 x 4.0 x 0.2	3.4 x 0.7 x 0.0	No	30	85	0 / 9
112	Surgical	Rt. Posterior Calf	31 - 60 days	3.5 x 7.0 x 0.0	14 x 6.5 x 0.0	No	76 - 99	85	0 / 5
113	Surgical	Chest	< 30 days	0.5 x 1.8 x 0.1	0.2 x 0.5	No	100	100	0 / 2
114	Venous Ulcer	LLE	> 12 months	8.0 x 8.0 x 0.0	9.5 x 7.5 x 0	No	80 (20% dark)	30 (vibrant and healthy)	1 / 3 (Initial Maceration Resolved in W1)
115	Trauma	Rt. Leg Pretibia	31-60 days	1.6 x 0.9 x 0.3	0.9 x 0.3 x 0.1	No	0	0	2 / 5
116	Trauma	Rt. Anterior Leg	< 30 days	9.0 x 2.8 x 0.0	0 (healed, W2)	No	100	100	0 / 3
117	Venous Ulcer	RLE	6 - 12 months	8.5 x 5.5 (irregular)	18.5 x 5.0 (irregular)	No	5	1 - 25	1 / 5 (Initial Maceration Resolved in W1)
118	Pressure Ulcer	Left Heel	6 - 12 months	2.5 x 6.3 x 0.0 2	5 x 6.3 x 0.0 (W1)	No	100	100	0 / 2

Conclusions

Several different types of wounds and stages were treated with the AFM silver dressing. In most cases, wound healing progressed throughout the study period (2-28 weeks) as supported by decreasing wound area measurements and increasing percentages of granulation tissue.

Despite the excessive drainage associated with many of the wounds, observations indicated little to no maceration of the wounds when the AFM dressing was applied as directed. In addition, it was discovered that as exudate levels decreased, the dressing could be applied with the printed side towards the wound to maintain a higher level of moisture at the wound:dressing interface.

