Clinical Evaluation of Non-adherent Contact Layer and Foam Dressings with and without Silver for the Local Management of Acute and Chronic Wounds

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STUDY OBJECTIVES

- The primary objective of this product evaluation was to obtain the perception of the user characteristics of a non-adherent contact layer and foam dressing with and without silver,*† specifically with the following parameters
  - Ease of application of the dressing
  - Adherence of the dressing to the wound
  - Pain during removal of the dressing
- The secondary objective was to obtain an overall impression of time and resources required to use the non-adherent dressings

* Dressings used were Restore Dressings with TRIACT Technology: Restore Contact Layer; Restore Contact Layer, Silver; Restore Foam, Adhesive; Restore Foam, Non-Adhesive; and Restore Foam, Silver, Non-Adhesive.

STUDY DESIGN

- Open-label, non-randomized, uncontrolled product evaluation
- 8 sites treated, between 3 and 26 wounds each
- Eligible subjects with acute or chronic wounds had the contact layer or foam dressings with or without silver applied following the institution's practice and product instructions
- Subjects were followed until
  - Use of either a contact layer or foam dressing was no longer appropriate
  - Wound healed
  - 4 weeks (or longer at the discretion of the clinician)

- Specific questions were asked in order to obtain the clinician's perception of the performance characteristics of the contact layer and foam dressings with and without silver

RESULTS

A total of ninety-four (94) wounds had the non-adherent dressings applied.

Table 1 Subject Demographics

	N	Age, yrs (SD)	Chronic Wounds	Acute Wounds
Total	94	67.4 (14.5)	75	19
Female	51	67.7 (14.9)	41	10
Male	43	67.1 (14.2)	34	9

Type of Wounds Applied with Contact Layer or Foam Dressing with or without Silver

- 54 Venous Ulcers
  - 17 in conjunction with a bilayer skin equivalent
  - 1 in conjunction with a skin graft
  - 7 in conjunction with a Unna boot
- 10 Diabetic Foot Ulcers
- 8 Split-thickness Skin Graft Donor Sites
- 5 Traumatic
  - 3 acute
  - 2 chronic
- 8 Post-operative
  - 4 acute
  - 4 chronic
  - 5 in conjunction with negative pressure wound therapy
- 2 Pressure Ulcers
  - 1 stage 4
  - 1 stage 3
- 2 Arterial Ulcers
- 1 Skin Tear
- 1 Burn
- 1 Soft Tissue Radiation Necrosis of Right Heel
- 1 Neuropathic Foot Ulcer Secondary to Spina Bifida
- 1 IV Extravasation with Tissue Necrosis

Type of Dressing Chosen

- 7 Contact Layer
- 41 Contact Layer Silver
- 5 Foam with Adhesive Tape
- 5 Foam without Adhesive Tape
- 21 Foam Silver
- 15 Combination Contact Layer with or without Silver and Foam with or without Silver

Figure 1 Clinician perception of the ease of application of the non-adherent dressings with and without silver.

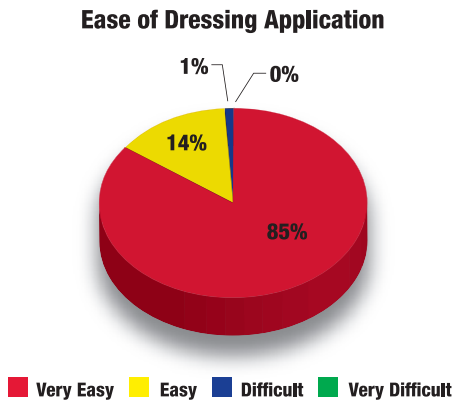


Figure 2 Clinician perception of the conformability of the non-adherent dressings with and without silver to the wound.

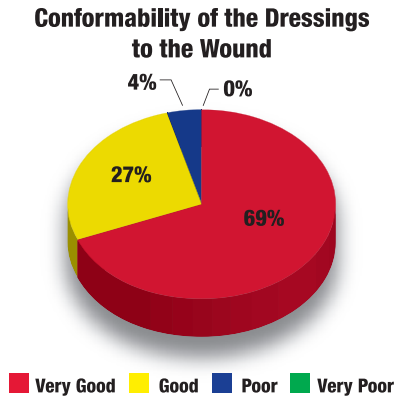


Figure 3 Clinician perception on the amount of bleeding present with the removal of the non-adherent dressings with and without silver.

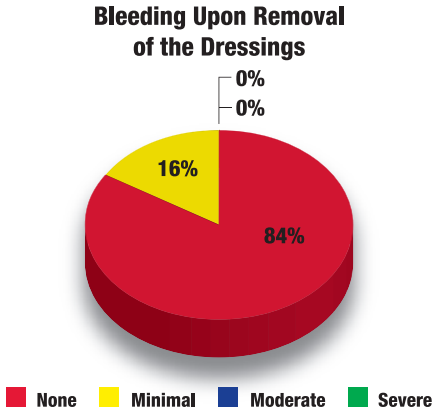


Figure 4 Clinician perception on the adherence of the non-adherent dressings with and without silver to the wound.

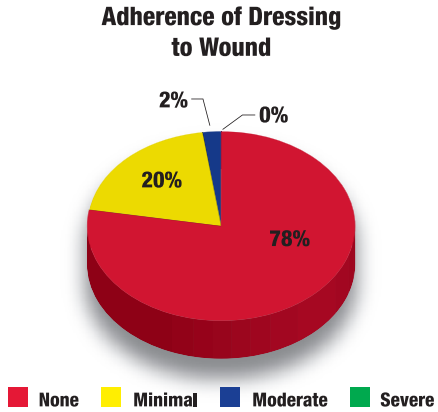


Figure 5 Clinician assessment of maceration present associated with use of the non-adherent dressings with and without silver.

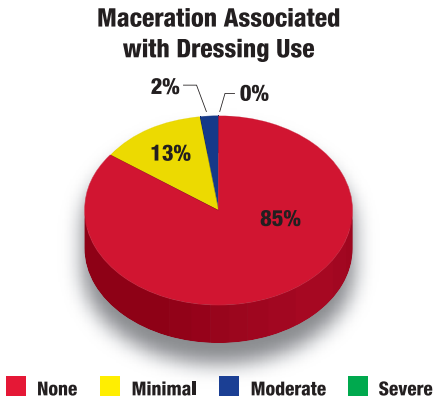


Figure 6 Clinician perception of the ease of removal of the non-adherent dressings with or without silver.

Figure 7 Perceived pain associated with the removal of the non-adherent dressings with and without silver.

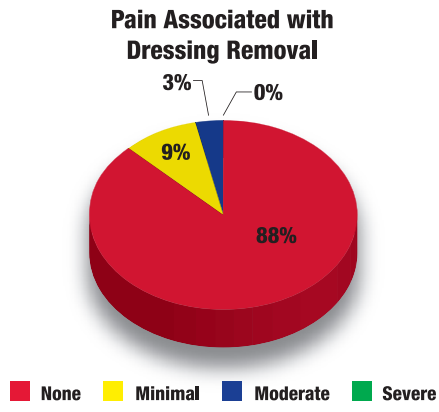
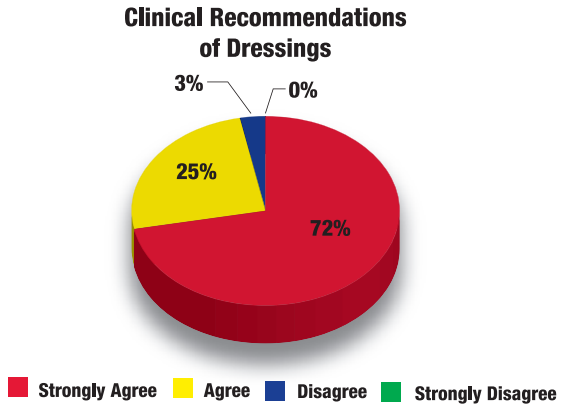


Figure 8 Clinician overall recommendation to use the non-adherent dressings with and without silver.



CONCLUSION

The non-adherent contact layer and foam dressings with and without silver conformed well and were easily applied. Removal was performed with minimal to no bleeding to the wound bed. These attributes are thought to decrease patient pain during dressing removal and may help to promote the healing process in the chronic and acute wounds observed in this evaluation of this product.

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† **Caution:** Federal law restricts this device to sale by or on the order of a physician or licensed healthcare professional.

FINANCIAL ASSISTANCE/DISCLOSURE

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