



Minimizing Complications During Dressing Changes of a Bilayer Skin Equivalent in the Treatment of Venous Leg Ulcers

Mark DeCotiis,¹ DPM, FACFAS and Elizabeth C. Konz,² PhD, RD

(1) The Wound Care Center Inc. at Bayshore Hospital, Clinical Instructor, UMDNJ, University Hospital, Newark, NJ

(2) Hollister Incorporated, Libertyville, IL

Purpose:

Venous leg ulcers affect more than 600,000 people in the United States per year.¹ These wounds make up nearly 80% of all leg ulcers and can decrease the quality of life for those affected.² They also pose a challenging problem for the practitioner. Bilayer skin equivalents are a proven and effective treatment for venous ulcers that heal up to 50% more leg ulcers in one-third less time than conventional wound care.³ These skin substitutes require the use of a non-adherent gauze during application. This is a case series of 13 patients undergoing weekly treatment for venous leg ulcers, in which a bilayer skin equivalent was applied and a non-adherent silver contact layer*† was placed over the bilayer skin equivalent.

Methodology:

- Patients with venous leg ulcers were seen in the wound care clinic, at which time a bilayer skin equivalent was applied
- A non-adherent silver contact layer was placed over the skin equivalent and covered with a compression bandage
- Patients were seen in the clinic weekly, at which time the non-adhesive silver contact layer was removed and another one was placed
- Descriptive statistics were used to analyze the data

* Product used was Restore Contact Layer Dressing with Silver and TRIACT Technology by Hollister Wound Care LLC.

Case Study 1:

A 60-year-old female, with no significant past medical history, presented with a venous stasis ulceration of the lower right leg that had been progressively worsening for 14 months. At initial evaluation, the wound measured 6.5 cm x 2.2 cm x 0.1 cm (Figure 1 and Figure 2).



Figure 1

Six weeks post-application of bilayer skin equivalent with silver contact layer. Weekly dressing changes with a non-adherent silver contact layer were performed (Figure 3).



Figure 3

After 18 weeks of treatment, the venous ulcer was healed (Figure 4).



Figure 2



Figure 4

Case Study 2:

An 88-year-old male with a past medical history of hypertension was seen in the wound care clinic with a venous stasis ulceration of the left medial ankle for a duration of 2 months. Upon initial wound examination, the wound measured 2.5 cm x 1.5 cm x 0.2 cm (Figure 5 and Figure 6).



Figure 5



Figure 7

After 10 weeks of treatment, the venous stasis ulcer was healed (Figure 8).



Figure 6



Figure 8

Results:

- Thirteen patients (5 males, 8 females) undergoing treatment with a bilayer skin equivalent for venous ulcers participated in the study
- Age range 52 to 89 years
 - Mean: 73.1 years
- Wound duration range 1 month to 75 months
 - Median: 5 months
- Wound healing range 2 weeks to 36 weeks
 - Median: 8 weeks
- The non-adhesive silver contact layer was easy to apply and remove with minimal to no pain or bleeding upon removal. The bilayer skin substitute remained intact with no signs of local infection
- All the venous ulcers healed during this clinical evaluation

See Instructions for Use for important information regarding the use of this product at www.hollisterwoundcare.com/products/ifus.html.

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

References

1. Bowman PH, Hogan DJ. Leg ulcers: a common problem with sometimes uncommon etiologies. *Geriatrics*. 1999 Mar; 54(3): 43, 47-8, 50 passim.
2. Phillips T, Stanton B, Provan A, Lew R. A study of the impact of leg ulcers on quality of life. Financial, social, and psychological implications. *J Am Acad dermatol* 1994; 31:49-53.
3. Falanga V, Sabolinski ML. A bilayered living skin construct (Apligraf®) accelerates complete closure of hard-to-heal venous ulcers. *Wound Repair Regen*. 1999; 7:201-207.

Hollister WoundCare and logo are trademarks of Hollister Incorporated. Restore and TRIACT are trademarks of Hollister Wound Care LLC. Covered under U.S. Patent No. 6,794,555 and 6,270,792. ©2008 Hollister Wound Care LLC.

910469-1008

Conclusion:

- There are a multitude of products used to cover venous ulcers with the application of a bilayer skin equivalent with very little research to substantiate their use
- The non-adherent silver contact layer was easy to apply, and patients experienced minimal to no pain upon removal
- This clinical evaluation of 13 patients indicated that a non-adhesive silver contact layer dressing is a good option for covering venous ulcers with the application of a bilayer skin equivalent

As Presented at

Clinical Symposium on Advances in Skin & Wound Care

October 26–30, 2008

Las Vegas, NV

FINANCIAL ASSISTANCE/DISCLOSURE

The support of Hollister Incorporated and Hollister Wound Care LLC for this clinical presentation is gratefully acknowledged.



Manufactured for
Hollister Wound Care LLC
1580 South Milwaukee Avenue
Suite 405
Libertyville, Illinois 60048
1.888.740.8999

Distributed in Canada by
Hollister Limited
95 Mary Street
Aurora, Ontario L4G 1G3
1.800.263.7400

www.hollisterwoundcare.com