Leg ulcers and a new micro-adherent absorbent dressing* Results of the clinical qualification study

J.-L. Schmutz (1), J.-P. Gobin (2), H. Cartier (3), B. Labeille (4), V. Brayer (5) and S. Bohbot (5)
(1) Head of Dermatology Department, CHU Nancy. (2) Vascular Medicine Doctor, Lyon. (3) Dermatologist, Arras Hospital.
(4) Dermatologist, CHU Saint Etienne. (5) Urgo Laboratories Chenôve, France.

INTRODUCTION

The therapeutic strategy of venous leg ulcers is based on two complimentary elements: compression therapy and topical care with dressings that promote the healing process. One prospective multicenter phase III clinical trial was conducted to assess the performance (efficacy, tolerance and acceptability) of a new type of micro-adherent absorbent dressing in the treatment of leg ulcers.

MATERIAL AND METHOD

A non comparative open label clinical trial was conducted in 17 investigating centers that included Hospital Dermatology, Vascular Medicine Departments and private physicians. The *new micro-adherent absorbent dressing** is composed of a non-occlusive micro-adherent mass (Lipido Colloid Technology) used in contact with the wound and the surrounding skin, associated with an absorbent foam and a protective polyurethane backing. The dressing had a useful surface area of 100% meaning that it may be cut according to the wound surface. This clinical trial included patients presenting venous or mixed leg ulcers. Subjects were treated for 6 weeks with the study dressing, and were evaluated weekly (clinical evaluation, planimetric and photographic records). 45 patients were enrolled in the trial. The first endpoint was the efficacy judged by the reduction of the wound surface area after the 6 week treatment.

* Restore® Foam Dressing with TRIACT ADVANCED® Technology from Hollister Wound Care.

Table I: Baseline ulcer's characteristics

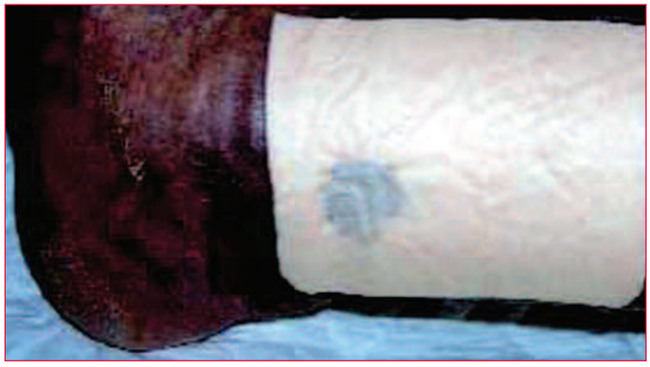
Ulcer Duration (month)	9.2 +/- 6.9 months [0.5; 24.0]
Recurrent nature of ulcers	71.1%
Initial surface area (cm^2)	13.15 +/- 10.54 [1.96.45.02]
Local Care documentations	526
Surface area reduction	37.4% +/- 52.2%
Healed ulcer	2
Compression used	84.4 %
• Monolayer	81.6 %
• Multilayer	18.4 %

Table II: Dressing acceptability

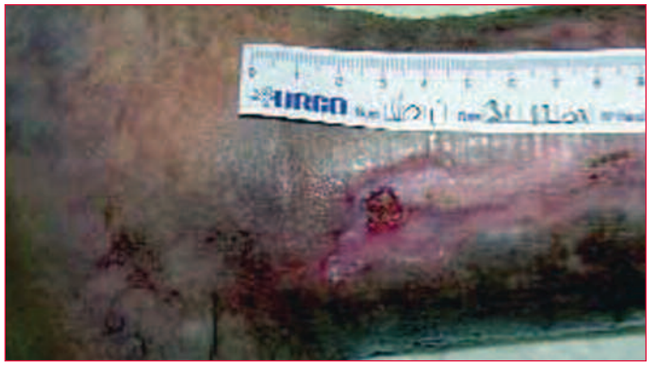
Ease of application (%)	Very easy/ Easy	98.6 %
Conformability to the wound bed (%)	Very good/ Good	97.1 %
Micro-adherence to the wound (%)	Very good/Good	95.1 %
Ease of removal (%)	Very easy/ Easy	99.6 %
Pain during removal (%)	Minimal/None	97.7 %
Maceration (%)	Moderate/None	87.6 %
Odour (%)	Moderate/None	92.5 %

CASE 1

Surface area at inclusion: 4.92 cm^2

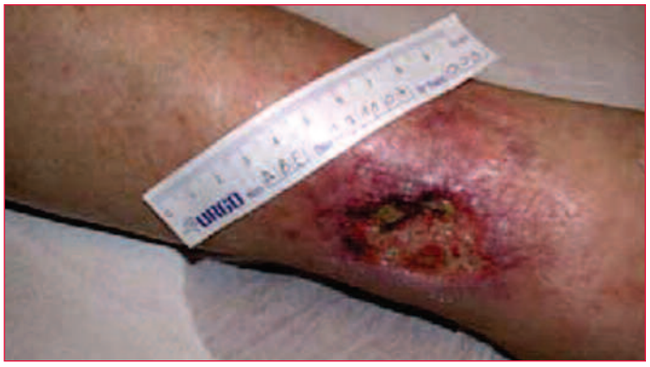


Dressing in place



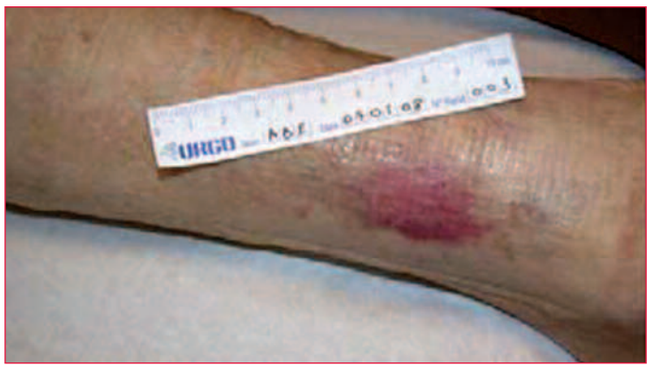
Surface area at week 6: 0.98 cm^2
Reduction in surface area: 80.08%

CASE 2



Surface area at inclusion: 6.47 cm²

W1



W6: completed healed

RESULTS

The baseline characteristics of the treated leg ulcers and type of compression from the study is documented in **Table I**. The dressings were removed on average every 3 days. After 6 weeks of treatment, the mean surface area was reduced by 37.39%. After completing the 6 weeks of treatment, the investigators considered that the wounds were clinically improved in 74.4% of the cases. Concerning the tolerance of micro-adherence, it was observed that the condition of the surrounding skin was maintained or improved. Acceptability was evaluated by the nursing staff at each dressing change (**Table II**). The ***new micro-adherent dressing**** was noted easy to use by the nursing staff (dressing application and removal) and the patients particularly appreciated the pain free removal.

CONCLUSION

This clinical trial has demonstrated the good efficacy, tolerance and acceptability of this ***new micro-adherent absorbent dressing**** for the treatment of venous leg ulcers. This dressing appears to be a good choice for the local management of leg ulcers.

As presented at

WOCN/WCET Joint Conference

June 12–16, 2010

Phoenix, AZ

The Symposium on Advanced Wound Care

April 17–20, 2010

Orlando, Florida

hollisterwoundcare

Complex Problems. Innovative Solutions.

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

911075-610