

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

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## 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 (from Technology Lipido Colloid) 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.

## 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 on treatment, the mean surface area was reduced with 37.39%. After completing the 6 weeks of treatment, the investigators considered that the wounds were clinically improved in 74.4%.

Concerning the tolerance of micro-adherence, it can be observed that the condition of the surrounding skin treated is respected. For 24.4% of leg ulcers, the surrounding skin was considered healthy at this end of treatment vs 11% at baseline.

Acceptability was evaluated by the nursing staff at each dressing of removal (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.

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 <sup>2</sup> )	13.15 +/- 10.54 [1.96.45.02]
Local Care documentations	526
Surface area reduction	37.4% +/- 52.2%
Healed ulcer	2
Compression at the inclusion	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 (%)	Minimum/None	97.7 %
Maceration (%)	Moderate/None	87.6 %
Odour (%)	Moderate/None	92.5 %

## CASE 1



## CASE 2



## 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 is highly adapted for the local management of leg ulcers.

\* Brand name: The new micro-adherent absorbent dressing is UrgoCell® Contact from Laboratoires Urgo