# THE EFFICACY

## The POLIT Study

### A Prospective multicenter Observational cohort study of Lymphœdema decongestIve Therapy

I. Quéré, E. Presles, M. Coupé, S. Vignes, L. Vaillant, D. Eveno, S. Laporte, A. Leizorovicz


## Backgrounds

This study aimed to observe volume variation over the intensive phase and 6 months later.

## Objectives

Prospective multicentre observational study of patients with unilateral lymphœdema. Primary objective: to assess lymphœdema volume variation between baseline, the end of intensive phase and 6 months later. Secondary objectives were to assess i) frequency of heaviness limiting limb function and treatments safety ii) predictors for volume reduction.

## Methods

Consecutive adult patients with unilateral limb lymphœdema of any etiology requiring intensive DLT were enrolled in the prospective cohort study. Primary outcome was lymphœdema volume variation, measured after intensive phase and after six-month maintenance treatment. Secondary outcome was heaviness, limb use limits and patient quality of life. Adverse evdents were recorded.

## Results

306 patients (89.9% women; 59.914.3 years old) with upper/lower (n=184/122) limb lymphœdema were included. At the end of intensive phase, median excess lymphœdema volume reduction was 31.0% [41,7-19,9] followed by a 16.5% [5,9-42,3] median increase over the 6 months of maintenance phase. Previous intensive treatment was the only significant predictor of this response. As compared with baseline, heaviness limiting limb use was much less frequently reported at the end of reductive phase (75.5% vs. 42.3% respectively), and was more frequent at the end of maintenance phase (62.6%). The most frequent adverse events reported were skin redness and compression marks (18.4% and 15.7% of patients, respectively). Blisters requiring treatment stoppage were rare (1,4%).

## Conclusions

Intensive phase decreases lymphœdema volume and heaviness limiting limb function. The benefit is partially abolished after the first 6 months of maintenance. There is a need to consider how to provide optimal patient care for the long-term control of lymphœdema.


Full text: I.Quere et al. Journal des Maladies Vasculaires (2014) Vol 39, p. 256-263.

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POLIT results please open

*WITH OUR GRATEFUL THANKS TO ALL POLIT STUDY INVESTIGATORS !*

**Pr I.Quéré,** Hôpital Saint-Eloi, CHU Montpellier, Montpellier, (Coordinateur)
**Dr S. Vignes, Dr M. Arrault,** Hôpital Cognacq-Jay, Paris,
**Dr M. Coupé,** Hôpital Saint-Eloi, CHU Montpellier, Montpellier,
**Pr A. Bura-Rivière, Dr J. Malloizel-Delaunay,** Hôpital Rangueil, CHU Toulouse, Toulouse,
**Dr D. Eveno,** La Tourmaline, Saint Herblain,
**Dr P. Jonas,** CHI des Andaines, La Ferté-Macé,
**Dr P. Brunel,** C3RF, Angers,
**Pr L.Vaillant, Dr V. Tauveron,** Hôpital Trousseau, CHRU Tours, Tours,
**Dr C. Kisterman, Dr A-L. Esquis,** CH Macon, Macon,
**P. Leclercq,** CH Emile Roux, Le Puy en Velay,
**Pr Christian Boissier, Dr S. Feasson,** Hôpital Nord, CHU Saint Etienne, Saint Etienne,
**Dr P. Baudoin,** Polyclinique Bordeaux Nord Aquitaine, Bordeaux,
**Dr F. Poirault,** Therapôle Centre Atlantique, Niort,

**Dr Alain LEIZOROVICZ,** Coordination center, CNRS Villeurbanne / UCBL1, Lyon,
**Dr S.Laporte, Mrs. E.Presles,** Statistical center. URCIP, CHU Saint-Etienne, Saint Etienne

**THUASNE**
CS 10032 - 92309 Levallois-Perret - France
**www.thuasne.biz**

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# MOBIDERM®

## AN INNOVATIVE CONCEPT TO TREAT LYMPHŒDEMA

*Effective* *Innovation* *Concept* *Complete* *Strategy*

**Manufactured by THUASNE**

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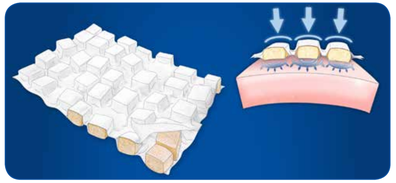
## FROM A SIMPLE SCIENTIFIC CONCEPT

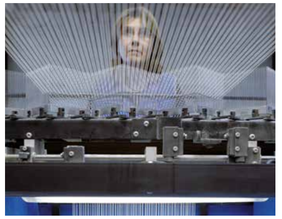
**Mobiderm®** is a medical device composed of foam blocks encased in soft adherent webbing.
It is a system which **can be used under a reducing bandage** (using band or sheet format) **or** incorporated **in ready-to-use contentive garments.**

**Creating zones of differenciated pressure** between the foam blocks and their perimeter, it does **facilitate oedema fluid evacuation** and optimise treatment efficacy.

Having a shear effect on subcutaneous tissues, **Mobiderm® softens indurated areas**.



## TO THE INDUSTRIAL ACHIEVEMENT



Drawing on its initial **expertise in elastic weaving**, and thanks to **flexible and responsive manufacturing tools** controlled by **high skilled emloyees**, Thuasne is able to offer a full range integrating Mobiderm® concept. From mass production to entirely customised made-to-measure solutions.

Born in the middle of the 19th century, **Thuasne group** now operates in over twenty countries around the world and continues to strive towards the same goal: to design products offering efficient therapeutic solutions, enabling mobility and based on clinical tests.

**Mobiderm® is a unique high tech anti-œdema compression device.**

MOBIDERM® range of products please open

# MOBIDERM® : A FULL RANGE OF PRODUCTS

## During the Intensive phase

### In a multi-layer bandage:

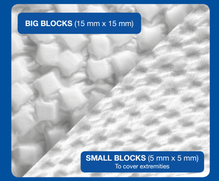
**1 Skin protection**

**SHORT STRETCH COTTON BANDAGE**
11 cm x 4 m

***In direct contact with the skin, this tubular cotton bandage provides tight retention of the limb.***

- **Soft:** it offers a confortable 1st layer to insure skin protection

**2 Mobilisation of the œdema**




**MOBIDERM®**

***Used under a reducing bandage, it does mobilise the œdematous subcutaneous fluids.***

- **Practical:** with its lightness and flexibility, Mobiderm® preserves free movements and hence drainage capacity.
- **Comfortable:** soft skin contact and product conformability for a better anatomical fit.

**BANDS**
to be unrolled along the limb
10 cm x 3 m

**PADS**
adapted to localized zones and to be cut if needed
25 cm x 1 m or 25 cm x 25 cm


**KITS**
for a simple prescription
upper limb or lower limb kit

**3 Retention**

**BIFLEXIDEAL® short stretch**
Width : 3 / 6 / 8 or 10 cm - Length : 5 m

***This short stretch bandage ensures a high working pressure of the limb, in the event of moderate physical activity.***

- **Adjustable:** proposed in four different widths, it is adapted to each operator using habits.

## During the Maintenance phase *(Night treatment)*

### Proposed as ready-to-wear garments:

To strengthen the results obtained during the intensive phase, it is necessary that the patient can pursue a treatment by compression in an autonomous and comfortable way. This to maximise the observance and guarantee the long-term success of the treatment.
Taking over the diurnal orthotics, **Mobiderm® garments have been developed to continue to effectively mobilise the œdema during night**.

- **fast and facilitated threading**
- **comfortable wear**
- **freely move**
- **easy care**

**Upper limbs garments**

**MOBIDERM® ARMSLEEVE**
Big blocks
Standard : 10 sizes - 2 lengths
ambidextrous use
Custom made

**MOBIDERM® MITTEN**
Small blocks
Standard : 6 sizes
ambidextrous use

**MOBIDERM® GLOVE**
Small blocks
Standard : 6 sizes
left / right

**Lower limbs garments**

**MOBIDERM® STOCKINGS**
Big blocks
Custom made

**MOBIDERM® THIGH-HIGH STOCKINGS**
Big blocks
Custom made

Custom made garments are proposed for measures exceeding standards or for specific needs (eg : armsleeve with mitten, special option...).
Standard garments are adapted to regular morphologies after an intensive treatment and can be delivered quicker to the patients.

# MOBIDERM® IN THE POLIT STUDY

## The Intensive phase results *(Duration: 1 to 3 weeks)*

### Treatment components:

**The results of the study show that the major components of the treatment are:**

- Daily Multilayer Bandaging application (observed for 99,7% of patients) with at least:
  - one layer (cotton or jersey) for skin protection, observed for 96,7% of patients
  - one layer of padding, observed for 86,3% of patients (**Mobiderm® for 55,6%**, mousse N/N for 20,1%, others 24,3%)
  - one layer of short stretch material for high pressure, observed for 86,6% of patients




- Manual Lymphatic Drainage (observed for 99,3% of patients)
- Intermittent Pneumatic Compression (observed for 46,5% of patients)

### MOBIDERM®

**In the subgroup of patients (n = 143) treated with daily multilayers bandages including MOBIDERM® padding, it has been observed that:**

- the **median volume reduction** is **-27,4%** (Q1, Q3 : -36.8, -16.1) versus -22,2% (Q1, Q3 : -34.1, -15.1) with others types of padding after the first 5 days of treatment
- the **intensive phase duration** was **5 days** (Q1, Q3 : 5 - 9) versus 10 days (Q1, Q3 : 5 - 11) for others types of padding
- the **safety profile** reports more frequent compression marks on the skin (18% versus 13,5% with other types of padding) and **less common blisters** (2,4% versus 5,6% with other paddings)

### CONCLUSION:

**MOBIDERM®** is largely used as a padding material in the multilayers bandages during the intensive phase of Decongestive Lymphedema Therapy.

It is an option for **short lasting treatment**.

## The Maintenance phase results *(6 month follow-up)*

### Day Treatment

**The results of the study show that the 3 major components of the treatment are:**

- Elastic compression garment (observed for 95,8% of patients)
- Manual Lymphatic Drainage (observed for 76,8% of patients)
- Physical Exercises (observed for 30,5% of patients)

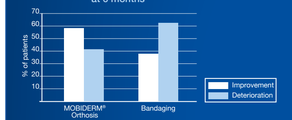
### Night treatment: bandage or garment ?

In the analysed sub-population of 134 women with post cancer upper limb lymphœdema, 58 used the bandaging compression strategy, 47 received the custom made MOBIDERM® garment, and 29 applied no compression system.

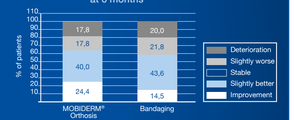
Mean lymphœdema volume evolution, in % (SD)
at 6 months

| MOBIDERM® Armsleeve n = 47 | Self Bandaging n = 58 | No Night Treatment n = 29 |
|---|---|---|
| 14.7% (65.9) | 8.9% (53.6) | 49.0% (167.7) |

Limb function evolution
at 6 months




Patient's quality of life evolution
at 6 months




### CONCLUSION:

Night compression is important to ensure a long term success of the treatment.
**MOBIDERM®** armsleeve is an interesting **alternative to self bandages**, **participating to improve the quality of life of the patients.**