

Mobiderm® Autofit Garments for Reducing Lower Limb Lymphedema: A Single-Arm Study

Exploring Underlying Mechanisms: ACTIODERM study

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METHODS

- This monocentric, exploratory, open-label, single-armed study was performed in France between 2020 and 2022.
- 9 patients with primary (N=6) or secondary (N=3) lower limb lymphedema, who were about to begin five days of intensive phase treatment at the hospital, were included in the study.
- The patients wore Mobiderm® Autofit for the first 48 hours of their intensive phase treatment.
- The main outcomes were the following :
 - **Lower limb volume**, calculated using the mathematical formula for the volume of a truncated cone ;
 - **Lymphoscintigraphy**, measuring the lymphatic system activity, and visualizing lymph nodes and deep lymphatic vessels ;
 - **High-frequency ultrasonography**, measuring the dermal thickness and echogenicity, the edema distribution
 - **Cutometer**, assessing the patients' skin elasticity and viscoelasticity ;
 - **Patient's satisfaction, compliance and safety.**

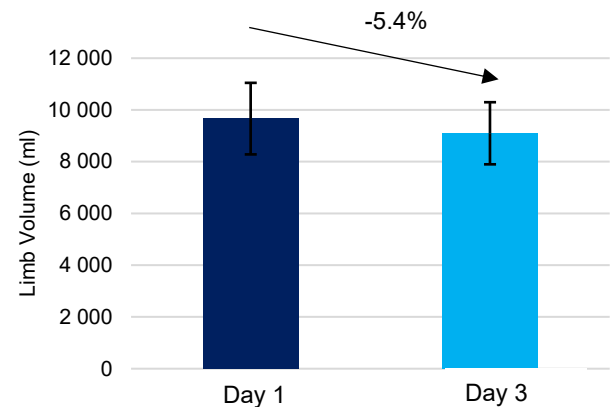
RESULTS

1

A lymphedema volume reduction

There was a mean 5.4% significant reduction in the volume of the affected lower limb ($p=0.0039$), and a 15.8% reduction in the excess volume after 48H of treatment. **Mobiderm® Autofit successfully reduced limb volume in patients with lymphedema within a short period of time, without any other treatment.**

The pressure applied by the device was assessed at the ankle, and the mean (SD) values were between 34.9 (21.7) and 55 (22.9) mm Hg, according to the day of measure.



2

An improvement in lymph circulation

Lymph speed: After 48 hours of wearing the Mobiderm® Autofit device, the radiotracer used for lymphoscintigraphy migrated up the leg to the knee in a shorter space of time. Although this difference was not statistically significant, the pattern of results indicates that **Mobiderm® Autofit led to an increase in the speed of the radiotracer propagation and its movement through the lymphatic vascular system, thus improving the circulation of lymph.**

Lymph nodes: The lymph nodes collect lymph from multiple afferent vessels. When they are visible, this indicates that the radiotracer has been successfully transported along the lymphatic vessels as far as the node. The number of patients with visible lymph nodes increased when the device was put on. Moreover, for patients with visible lymph nodes at baseline, the number of nodes was seen to increase when they wore the device, even if these differences were not statistically significant ($p>0.1$ for all comparisons with baseline). Nevertheless, these results indicate that **Mobiderm® Autofit device facilitates the flow of lymph along the vessels towards the lymph nodes.**

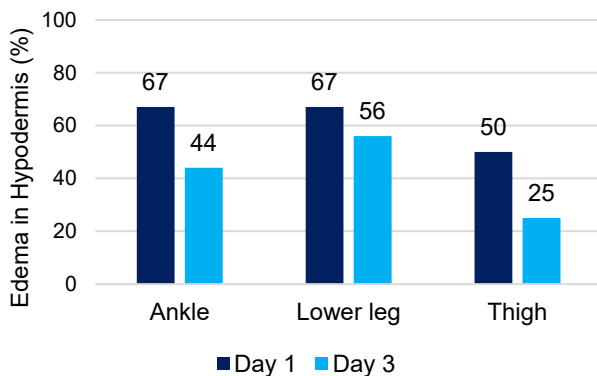
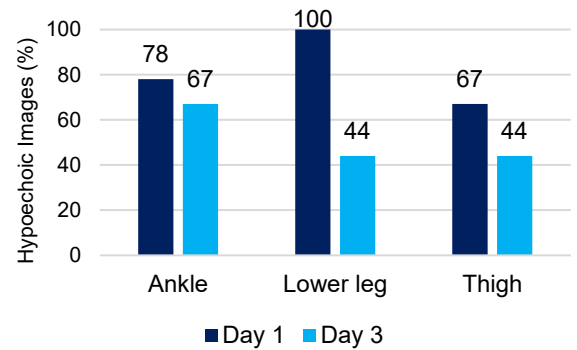
Tortuous vessels and collaterals: Tortuous vessels were seen for most of the patients (83%) and are in line with the dysfunctional lymphatic system. Collaterals were also seen for over half of the patients (57%), which indicate that alternative lymphatic pathways were being used. These features did not change for any of the patients over the course of the study, which suggests that the device did not affect these features over the short term.

A reduction of edema within the dermis and hypodermis

Dermal thickness: Previous studies showed that patients with lymphedema have increased dermal thickness. After 48H of treatment with Mobiderm® Autofit, the mean dermal thickness slightly decreased at the ankle (-0.24 mm), but it increased slightly at the lower leg (+0.29 mm) and remained unchanged at the thigh (p values>0.1). **The patients with a larger reduction in limb volume all showed decreased dermal thickness at the ankle after wearing Mobiderm® Autofit.** This therefore suggests that improvements in dermal thickness may begin at the level of the ankle when patients are treated for lower limb lymphedema.

Dermal echogenicity: Echogenicity of the skin has been shown to be low (hypoechoic) in patients with lymphedema. In line with this, all the patients of the study had hypoechoic images at the lower leg, and most also had hypoechoic images at the thigh and ankle.

Following the 48H of treatment, fewer hypoechoic images were found at all tested locations, particularly the lower leg, where the proportion of hypoechoic images fell down from 100% to just 44%. These findings are in line with the reduction in limb volume following the Mobiderm® Autofit treatment.



Edema distribution: Most patients had edema within the hypodermis as well as the dermis at baseline. This is in line with previous work, which has shown that most excess lymph is located within the subcutaneous tissues (hypodermis).

After 48H of treatment with Mobiderm® Autofit, the edema was no longer seen within the hypodermis for several patients. This result indicates that the excess fluid had been drained away from these tissues in these patients, implying that the device can improve the drainage of lymph from the hypodermis, at least in certain patients.

Skin elasticity: Previous studies have shown that patients with lymphedema have low skin elasticity, and that this worsens with the progression of the disease. **The study did not show an improvement of skin elasticity after 48H of treatment with Mobiderm® Autofit. It is possible that the results relate to the short duration of the study.**

A high satisfaction with the device

Patient satisfaction: All patients reported that the device was comfortable both day and night, and the pressure was bearable, which is in line with their full compliance over the 48 hours. The patients all felt that their lymphedema had improved following the treatment, and that their skin had become more supple. Two out of three patients also reported that the discomfort caused by the lymphedema (e.g., heaviness, numbness) had improved. **At the end of the study, all patients decided to keep the device for the maintenance phase of their treatment, and five of them used the device for the rest of the intensive phase (the others used classical bandages).**

Safety: No adverse events were reported, and the device was found to be **well tolerated by all patients.**

KEY MESSAGES

- ✓ Mobiderm® Autofit device is effective for reducing limb volume in patients with lymphedema.
- ✓ The imaging results indicate that Mobiderm® Autofit improves the drainage of edema from the subcutaneous tissue and facilitates the flow of lymph towards the lymph nodes.
- ✓ The reduction of edema within the dermis and hypodermis (reflected by less hypoechoogenicity) mainly results from the passage of lymph through the superficial lymphatic.
- ✓ Mobiderm® Autofit promotes the movement of lymph through the usual lymphatic pathways.
- ✓ Further studies are required to confirm these results.