

Positive impact of a new compressive garment in patients with genital lymphedema: OLYMPY STUDY

Sandrine Mestre, Stéphane Vignes, Julie Malloizel-Delaunay, Sarah Abba, Stéphanie Villet, Astrid Picolet, Éric Vicaut, and Isabelle Quéré. (2024). *Lymphatic Research and Biology*.

METHODS

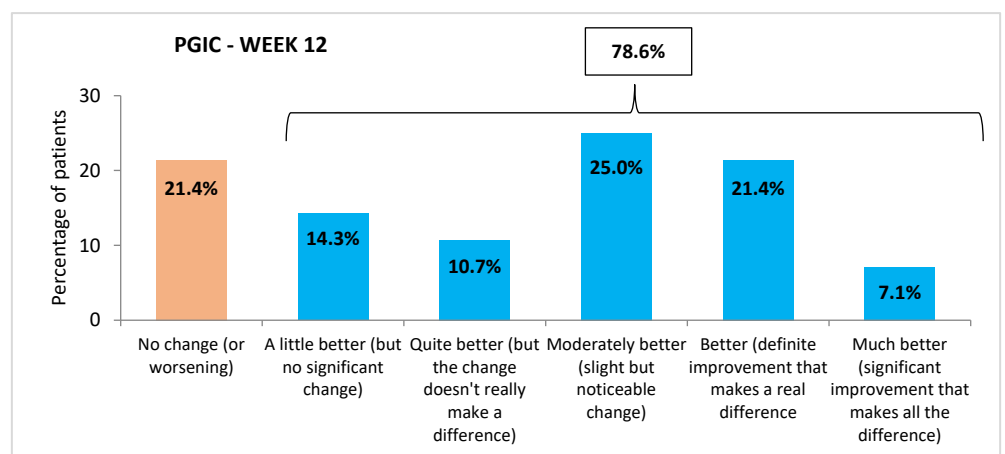
- This multicenter, prospective, open-label, single-armed study was performed in France within three specialist centers for vascular medicine between 2020 and 2021.
- 32 patients with primary (N=13) or secondary (N=19) genital lymphedema were advised to wear the new compressive garment, MOBIDERM Intimate Shorts, for 12 weeks, during day and nighttime in addition to conventional management of lower limb lymphedema.
- The primary endpoint was the evolution of patient's clinical condition** after 12 weeks using the Patient Global Impression of Change (PGI-C) questionnaire.
- Secondary endpoints** included:
 - Clinical improvement of the patient's pathology perceived by physicians, using the Clinical Global Impression-Improvement (CGI-I).
 - Evolution in lymphedema severity using the Genital Lymphedema Score (GLS), measuring the **scrotal perimeter** for men (Whitaker tool), and evaluating patient skin condition.
 - Evolution in Quality of Life (QoL) via **LyQLI** and **EQ-5D-5L** self-questionnaires, and lymphedema-associated symptoms using Visual Analog Scales (VAS).

RESULTS

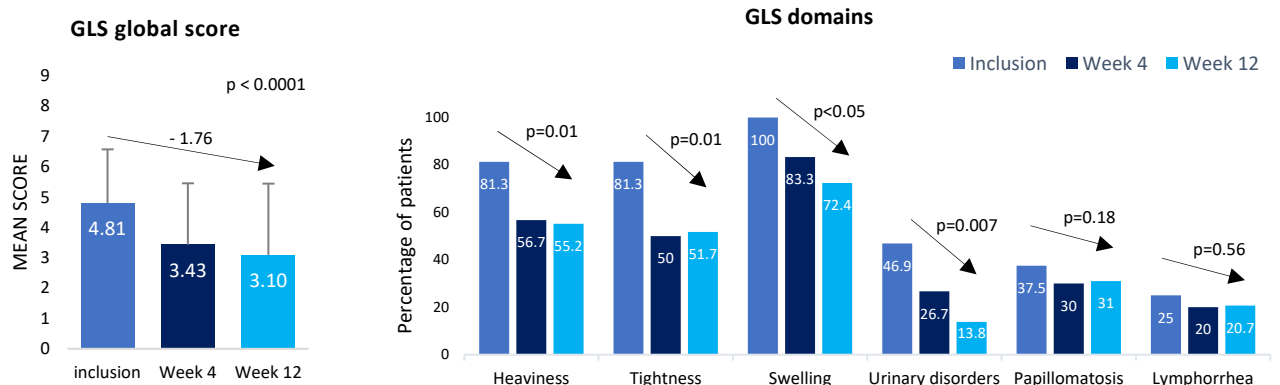
1 An improvement in the patient's clinical condition

After 12 weeks, **78.6%** of patients reported some improvement of their condition according to the **PGI-C**, with **28.5%** reaching a strong improvement with a real relevant change.

This positive evolution was confirmed by physicians using the **CGI-I**, indicating a clinical improvement in **82.8%** of patients after 12 weeks. Among them, 27.6% showed strong improvement, while 20.7% exhibited very strong improvement.



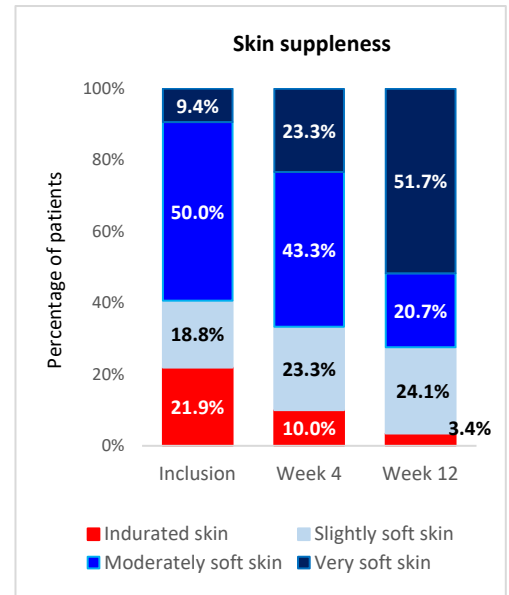
2 A significant reduction in genital lymphedema severity



GLS: The mean global GLS score significantly decreased throughout the study period, from 4.81 at baseline to 3.43 at week 4, and 3.10 at week 12, indicating a significant decrease in genital lymphedema severity ($p < 0.0001$). The proportion of patients reporting heaviness, tightness, swelling or urinary disorders significantly decreased after 12 weeks.

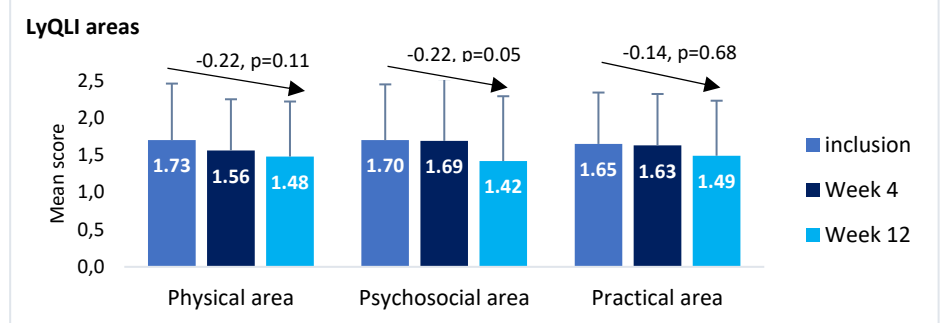
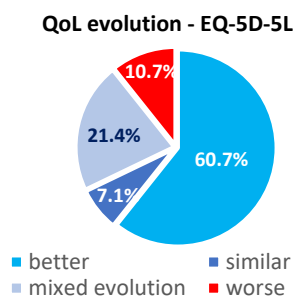
Scrotum perimetry: In men, a 2.7 cm reduction in one of the 3 scrotal perimetric measurements (middle-scrotal circumference), was observed after 12 weeks ($p = 0.001$), with 65% of clinicians indicating improved scrotal anatomy.

Skin suppleness: After 12 weeks, skin condition improved in 65.5% of patients ($p = 0.009$). The proportion of patients with indurated skin was divided by 7 after these 12 weeks (from 21.9% at inclusion to 3.4% at 12 weeks), with a notable increase in the proportion of patients with very soft skin from 9.4% at inclusion to 51.7% at 12 weeks.



3 An improvement in quality of life and lymphedema-associated symptoms

QoL: After 12 weeks, 60.7% of patients reported a better quality of life via the EQ-5D-5L questionnaire. An improvement in the 3 domains, physical (-0.22, $p = 0.11$), psychosocial (-0.22, $p = 0.05$) and practical (-0.14, $p = 0.68$) was also observed via the LyQLI questionnaire, specifically related to lymphedema.



VAS: Swelling and global discomfort related to lymphedema significantly improved after 12 weeks, with over 1.5 points decrease in VAS scores ($p = 0.01$ and $p = 0.02$ respectively). Patients also reported lower VAS ratings for feeling of heaviness and pain (not significant).

4 A high satisfaction with the device

Patient satisfaction was high, with more than 80% of patients rating the compressive garment as easy to put on and take off and 86% expressing overall satisfaction. At the end of the study, most patients (96%) indicated their choice to continue with use.

Patient compliance with garment wear was relatively high throughout the study, with 69% of patients wearing the compression shorts for 5 days or more each week.

Safety: Adverse events related to the device were observed in 12 patients, and mainly corresponded to skin complaints (pruritus, irritation, skin marks) or swelling of the lower limb or knee

KEY MESSAGES

- ✓ This is the first study to evaluate a compression device specifically for genital lymphedema.
- ✓ The use of MOBIDERM Intimate Shorts provides clinical benefits to patients with genital lymphedema, with a significant improvement in genital lymphedema severity, associated symptoms and quality of life.
- ✓ The MOBIDERM Intimate Shorts may present potential benefits in routine use, with a favorable benefit–risk balance.
- ✓ Further studies are required to confirm these results.