Supportive Care in Cancer (2026) 34:512
https://doi.org/10.1007/s00520-026-10735-6

RESEARCH

Night-time compression with a Mobiderm® auto-adjustable arm-sleeve in addition to daytime compression was superior to daytime compression alone for maintenance therapy of upper limb lymphedema in breast cancer patients in a randomized controlled trial: LYMphoNIGHT study

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Received: 13 October 2025 / Accepted: 28 April 2026

Abstract

Purpose To assess the benefit of night-time compression in addition to daytime compression on arm excess volume after 3 months of maintenance treatment in patients with secondary upper limb breast cancer-related lymphedema (BCRL).

Methods This multicenter, controlled, randomized study was carried out in six centers in France and Turkey. Women with upper limb BCRL who had undergone the intensive phase of decongestive lymphedema therapy (DLT) were randomized into two groups: the Control group wore a daytime compression sleeve without any night compression for 3 months and the MOBIDERM Autofit (MobA) group used a night-time compression sleeve in addition to the daytime compression. The primary outcome was the change in arm excess volume between day 0 (D0) and D90. The main secondary endpoints were: quality of life (QoL), sleep quality, skin thickness and suppleness, satisfaction, compliance, and safety.

Results Fifty-six patients were recruited (mean (±SD) age: 61.4 ± 12.3 years). Between D0 and D90, the mean excess volume decreased by 29.2% in the MobA group and increased by 10.7% in the Control group ($p = 0.001$). Only 3.6% of patients in the MobA group presented with treatment failure vs. 23.1% in the Control group. At D90, patients in the MobA group had a significantly greater improvement in QoL ($p < 0.05$), sleep quality ($p = 0.018$), skin suppleness ($p = 0.01$) reduced skin thickness ($p = 0.025$) compared with the Control group.

Conclusion MOBIDERM Autofit used in addition to daytime compression for 3 months during the maintenance phase after DLT was superior to daytime compression alone for the reduction of arm excess volume.
Registered on ClinicalTrials.gov (NCT04203069; 17/12/2019).

Keywords Breast cancer · Lymphedema · Treatment · Compression garment

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Published online: 07 May 2026

Introduction

Breast cancer-related lymphedema (BCRL) is a serious, life-long complication of breast cancer surgery, causing arm swelling, pain, reduced upper limb function, hardening or thickening of the skin, and fibrosis, and severely affecting a patient's quality of life (QoL), personal and societal interactions, and emotional wellbeing [1–3]. Risk factors for BCRL include axillary lymph node dissection, total mastectomy, radiotherapy, taxane use, and being overweight or obese [1–3]. It has been estimated that up to 20% of breast cancer survivors will develop BCRL [3], with 87–89% being diagnosed within 2–3 years post-surgery [4–6].

Non-surgical treatment for BCRL consists of skin care, physical exercises, and decongestive lymphedema therapy (DLT), administered as an initial intensive volume reduction phase involving low-stretch bandages and manual lymph drainage, followed by a long-term maintenance phase, usually including daytime and sometimes night-time compression, to maintain the optimal decongested state [1–3, 7].

The recommended first-line maintenance treatment for upper limb lymphedema involves a daytime compressive arm-sleeve that should apply a pressure of 15 mmHg or more depending on the patient's tolerance. Low stretch, multilayer bandages are an alternative to elasticated arm-sleeves [8–12], but the amount of pressure provided by bandaging is hard to control. Current arm-sleeves are non-adjustable, cannot adapt to changes in limb volume long-term, and are uncomfortable to wear at night, resulting in decreased compliance with maintenance therapy.

Previous studies have provided data on compression garments using a patient-centered approach. This began with the POLIT study, which showed that the benefit obtained during intensive DLT is partially lost over a 6-month maintenance phase, with a median excess limb volume increase of 16.5% [11]. Therefore, 24 h compression using garments or bandages seems to be crucial for long-term management of BCRL.

To understand this pathology and provide solutions adapted to the patients' needs, a standard auto-adjustable arm-sleeve (MOBIDERM Autofit®; Thuasne, France) was developed and evaluated in a pilot study (MARILYN study) as adjuvant night-time treatment to a daily compressive garment. Mean lymphedema volume increase doubled between Day (D)0 and D30 in the no night-time use group [13]. Furthermore, in high-responder patients who used night-time MOBIDERM Autofit, 89% of the initial volume reduction achieved was conserved vs. only 54% in the no-night user group [14]. The absence of a rebound effect in night-use patients focused our efforts on optimizing 24 h compression within the first few months after intensive DLT. This approach is supported by a recent study, which showed that the addition of night-time compression was more beneficial than daytime compression alone in patients with BCRL [15].

Our aim was to confirm the potential benefits of using MOBIDERM Autofit for night-time compression on arm excess volume after 3 months of maintenance treatment in patients with secondary upper limb BCRL.

Methods

Study design and ethics

This prospective, international, multicenter, open-label, randomized, parallel group study (LYMphoNIGHT) was carried out in four centers in France and two centers in Turkey, between October 2020 and September 2023. The Clinical Investigation Protocol was the subject of a compliance agreement with the Commission Nationale de l'Informatique et des Libertés (CNIL), in accordance with French law "Informatique et Libertés" and European Regulation 2016/679. It was approved by local ethics committees (West V, Rennes, France; and Etik Kurul, Ankara, Turkey).

The study was registered on clinicalTrials.gov (ID: NCT04203069) and was conducted according to ICH standards of Good Clinical Practice and the Declaration of Helsinki, as well as applicable European and/or local laws and regulations. All patients gave their written, informed consent before taking part.

Study population

Women with secondary upper limb BCRL were enrolled. The main inclusion criteria were: age ≥ 18-years; a positive response to intensive DLT, defined by a ≥ 20% decrease in lymphedema volume at DLT end; unilateral secondary upper limb lymphedema stage II or III according to International Society of Lymphology criteria; an affected arm that fit one of the six standard sizes of MOBIDERM Autofit.

Exclusion criteria were: multiple location lymphedema; active cellulitis/infectious dermo-hypodermatitis; lymphedema associated with active cancer requiring acute chemotherapy; motor and sensory neurological deficits/psychiatric or addictive disorders; post-operative edema; contraindications for compression, including skin lesions at the device placement site.

Study intervention and randomization

Consecutive women with BCRL were enrolled at the end of intensive phase DLT and randomized in blocks of four in a

1:1 ratio into two groups: Group 1 (MobA group) consisted of patients wearing a daytime compression sleeve ± mitten and a night-time compression Mobiderm® auto-adjustable arm-sleeve (Thuasne, France); and Group 2 (Control group) consisted of patients wearing only the daytime compression sleeve ± mitten. Randomization was stratified by center using an Interactive Web Response System, and centralized. All patients were required to wear compression sleeves for 3 months. Follow-up visits were performed after 30 days (D30) and 90 days (D90).

Compression garments

Night-time compression

Night-time compression was provided by MOBIDERM Autofit, a standard, self-adjustable, compression arm-sleeve with a mitten. Arm insertion is facilitated by several small rigid straps, which help adjust the garment to the patient's morphology and allow it to be tightened securely (Supplementary Fig. 1a). The garment incorporates MOBIDERM technology, to help mobilize the lymph fluid.

Daytime compression

Daytime compression was provided by a Lymphatrex® Expert Arm-sleeve, a custom-made flat-knitted garment, which covers the arm from the wrist to the armpit (Supplementary Fig. 1b). Each garment is manufactured according to patient's individual measurements, guaranteeing pressure adapted to their morphology (French class II/III arm-sleeve according to doctor's advice).

Outcomes

The primary aim was to compare arm excess volume evolution in the two groups between D0 and D90. Excess volume was defined as the difference in volume between the affected arm and the contralateral arm, calculated using the truncated cone formula [16]. The calculation used the circumference of the limb every 5 cm between the metacarpal head of the thumb and 20 cm above the elbow.

The secondary objectives were to evaluate the impact of MOBIDERM Autofit at D30 and D90 by comparing the following parameters between the two groups:

Limb volume evolution The affected limb volume was assessed at D0, D30, and D90. The percentage of patients presenting with maintenance failure, defined by a ≥ 30% increase in volume reduction observed during intensive phase DLT, was assessed.

Quality of life The evolution of lymphedema-related QoL (LYMQOL-Arm), global EQ-5D-5L QoL, and a specific question relating to QoL evolution according to the patient, were determined. The LYMQOL-ARM questionnaire [17] consists of two parts. The 20 questions of the first part cover four sub-domains (function, appearance, symptoms, mood). The second part consists of VAS scoring regarding general QoL.

EQ-5D-5L [18] was chosen as a generic QoL instrument and comprises five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression, each with five levels (ranging from "no problems" to "extreme problems"). Patient scores were also assessed using the allied EQ-VAS.

Sleep quality evolution was assessed between D0, D30, and D90 using the Jenkins Sleep Scale [19]. This comprises four items measuring different aspects of sleep quality and disturbances.

Clinicians' and patients' perception of the improvement in the patients' health condition The Patient Global Impression of Change (PGI-C) [20] measures the change in a patient's overall status on a 7-point verbal rating scale, ranging from ''no change or condition has become worse'' (1) to ''a great deal better and a considerable improvement" (7). As well as indicating any improvement, patients also rated any change in their status on a −5 to + 5 scale at D30 and D90.

Physician assessment of clinical improvement was evaluated using the Clinical Global Impression-Improvement (CGI-I) [20]. The CGI-I is a 7-point scale that asks clinicians to assess the extent to which a patient's illness has improved or worsened at D30 and D90 as compared with the baseline condition (D0) (from "very greatly improved" to "very greatly worsened"). Physicians' opinion on lymphedema severity was measured using the Clinical Global Impression-Severity (CGI-S) [20] questionnaire at D0, D30, and D90. This scale has 7 levels from "normal, not sick at all" (best outcome) to "among the most severely ill patients"(worst outcome).

Range of motion Arm range of motion (RoM) evolution between D0 and D30 or D90 was assessed by measuring different joint amplitudes with a goniometer.

Skin parameters The thickness of three skin tissue layers (subcutaneous, dermo-hypodermis, and epidermis) was assessed by ultrasound using a 5–12-MHz linear probe and SL10-2 linear probe (Logiq P5; GE Medical Systems, Milwaukee, WI, USA, and Ultimate ultrasound system; Aixplorer, Aix-en-Provence). All measurements were performed by operators with > 10 years expertise in musculoskeletal ultrasound. Measurements were performed 10 cm above and 10 cm below the bend of the elbow. The patients also reported any changes in arm skin suppleness at D30 and D90.

Patient Satisfaction was assessed using two self-questionnaires, which were administered at D90. The

questionnaires mainly included an assessment of ease of use, tightness, comfort and aesthetics.

Compliance was recorded from the patient's diary. Good compliance was defined by wearing MOBIDERM Autofit for at least 5 nights/week, for a minimum of 50% of each night.

Safety Number and type of serious and non-serious device-related adverse events were collected.

Sample size estimation

Our hypothesis was that night-time compression in addition to daytime compression is superior to daytime compression alone for the reduction of arm excess volume after 3 months maintenance phase treatment in patients with secondary upper limb BCRL. Based on a difference between the two groups of 120 cm^3 in excess volume variation from D0 to D90 and a standard deviation of 154.34, type I error $\alpha = 5\%$ (two-sided), $\beta = 10\%$ (statistical power = 90%) [13, 14], the sample size estimation using the classical formula of comparison of two means yields n = 39 valid patients/treatment group, including 10% to account for the multicenter study design. Allowing for a 10% rate of non-evaluable patients, it was aimed to recruit 88 patients (44 patients/group).

Statistical analysis

Quantitative data are summarized as number of documented/missing data, mean, standard deviation (SD), median (range: min–max), and quartiles when appropriate. Wald two-sided 95% confidence intervals [95%CI] are shown for the primary analysis. Categorical data are described as frequency and percentage of non-missing data.

Normality of quantitative variables was analyzed using the Shapiro–Wilk test. Normally distributed quantitative variables were compared using the Student's t-test with Satterwhaite's correction in the case of unequal variance. Non-normally distributed quantitative endpoints were compared using the Wilcoxon non-parametric exact rank test.

For the comparison of categorical data, the Chi^2 test or Fisher's exact test were used. In the case of ordinal variable with < 5 modalities, the Cochran-Mantel–Haenszel test was used. In the case of ordinal variable with ≥ 5 modalities, the non-parametric Wilcoxon rank test was used.

All between-group comparisons were performed using SAS® version 9.4 or higher (SAS Institute, North Carolina, USA). The level of significance was set at $p < 0.05$. Statistical analyses were carried out by an external company (ICTA PM).

Results

Study population

Out of 88 patients planned for the study, 63 (71.6%) were screened and 58 (92.1%) were randomized. The intent-to-treat (ITT) population used for the statistical analysis of efficacy consisted of 56 patients (MobA group, n = 30; Control group, n = 26). The flowchart of the study population is shown in Fig. 1.

Mean (± SD) age of the patients was 61.4 ± 12.3 years and median BMI was 29.2 kg/m^2 (range: 20.8–38.2). Mean time (± SD) since breast cancer diagnosis was 10.8 ± 9.4 years. The majority of patients (n = 35; 62.5%) had invasive ductal carcinoma of intermediate SBR grade (n = 27; 67.5%). Mean time since lymphedema diagnosis was 5.5 ± 5.4 years and most patients (n = 53; 94.6%) had stage 2 lymphedema (mainly stage 2b). Many patients (80.3%) were overweight or obese (Table 1).

Regarding the current intensive phase of DLT before inclusion, the mean duration in both groups was similar, with an overall average of 12.4 days. The excess volume decrease was also similar in the two groups (MobA group 37.3% ± 11.6; Control group 40.7% ± 25.2) (Table 2). In addition to the study compression used during the maintenance phase, the majority of patients (n = 53; 98.1%) also used manual lymphatic drainage (n = 41; 77.4% self-administered) and 33 (62.3%) used adapted physical exercises routinely (Table 2).

Primary endpoint: evolution of arm excess volume

Between D0 and D90, mean (± SD) excess volume decreased from 684.9 ± 394.0 to 574.1 ± 466.0 ml in the MobA group, but increased from 666.1 ± 377.6 to 745.2 ± 440.9 ml in the Control group (p = 0.001) (Fig. 2). This corresponds to a mean relative decrease in excess volume of 29.2% vs. a

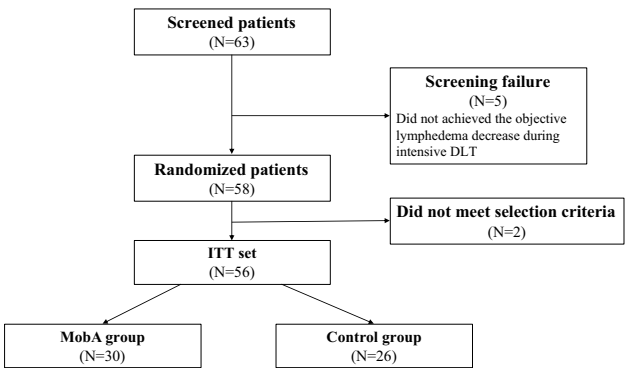


Fig. 1 Flowchart of the LYMphoNIGHT study population

Table 1 Demographic and lymphedema characteristics of the study population at inclusion

	Treatment group		
	MobA group (N = 30)	Control group (N = 26)	Total (N = 56)
Age (years) [a], mean ± SD	61.9 ± 12.9	60.9 ± 11.9	61.4 ± 12.3
BMI (kg/m^2), median Range (min–max)	29.7 (20.8–38.2)	26.8 (21.9–36.5)	29.2 (20.8–38.2)
BMI class (kg/m^2)			
18.5–25, n (%)	5 (16.7)	6 (23.1)	11 (19.6)
25–30, n (%)	12 (40.0)	9 (34.6)	21 (37.5)
30–35, n (%)	9 (30.0)	9 (34.6)	18 (32.1)
≥ 35, n (%)	4 (13.3)	2 (7.7)	6 (10.7)
Time since breast cancer diagnosis (years) [b]	12.9 ± 10.7	8.5 ± 7.1	10.8 ± 9.4
Time since lymphedema diagnosis (years) [c]	6.1 ± 5.4	4.8 ± 5.3	5.5 ± 5.4
Anatomopathologic and immunohistochemical results, n (%)			
Invasive ductal adenocarcinoma	19 (63.3)	16 (61.5)	35 (62.5)
Invasive lobular adenocarcinoma	1 (3.3)	6 (23.1)	7 (12.5)
Mucinous carcinoma or mucous colloid	2 (6.7)	0 (0.0)	2 (3.6)
Apocrine carcinoma	1 (3.3)	0 (0.0)	1 (1.8)
Unknown	5 (16.7)	3 (11.5)	8 (14.3)
Other	2 (6.7)	1 (3.8)	3 (5.4)
Histological grade, SBR	20 (66.7)	20 (76.9)	40 (71.4)
I	3 (15.0)	0 (0.0)	3 (7.5)
II	12 (60.0)	15 (75.0)	27 (67.5)
III	5 (25.0)	5 (25.0)	10 (25.0)
Dominant arm, n (%)			
Right-handed	27 (90.0)	24 (92.3)	51 (91.1)
Left-handed	2 (6.7)	2 (7.7)	4 (7.1)
Ambidextrous	1 (3.3)	0 (0.0)	1 (1.8)
Lymphedema stage, n (%)	28 (93.3)	25 (96.2)	53 (94.6)
Stage 2	13 (46.4)	7 (28.0)	20 (37.7)
Stage 2a	15 (53.6)	18 (72.0)	33 (62.3)
Stage 2b	2 (6.7)	1 (3.8)	3 (5.4)
Stage 3			
Limb concerned, n (%)	13 (43.3)	13 (50.0)	26 (46.4)
Right upper	17 (56.7)	13 (50.0)	30 (53.6)
Left upper			
One or more DLTs prior to the DLT for which the patient was hospitalized: yes	13 (43.3)	7 (26.9)	20 (35.7)
Duration since last DLT (days) [d]	817.4 ± 642.6	820.4 ± 345.1	818.5 ± 546.3

All data shown are n (%), mean ± standard deviation, or range (min–max)

MobA: MOBIDERM Autofit; DLT: decongestive lymphedema therapy

[a] Age = (date of inclusion visit – date of birth)/12

[b] Time since breast cancer diagnosis = (date of inclusion visit – date of breast cancer diagnosis + 1)/365.25

[c] Time since lymphedema diagnosis = (date of inclusion visit – date of lymphedema diagnosis + 1)/365.25

[d] Duration since last DLT = start date of hospitalization for this DLT – end date of the last DLT

mean increase in excess volume of 10.7% in the Control group. Overall, there was a significantly greater improvement (p = 0.001) in the MobA group vs. Control group.

Among the patients with an excess volume decrease between D0 and D90 (67.9% (n = 19/28) in the MobA group vs. 23.1% (n = 6/26) in the Control group), 52.6% of patients in the MobA group had a > 30% excess volume decrease vs. 16.7% in the Control group.

Only 3.6% (n = 1/28) of patients in the MobA group had treatment failure vs. 23.1% (n = 6/26) in the Control group (p = 0.001).

Table 2 Characteristics of current DLT (intensive phase) at inclusion

	Treatment group		
	MobA group (N = 30)	Control group (N = 26)	Total (N = 56)
Current DLT			
Duration of intensive phase (days)	11.5 ± 8.7	13.4 ± 9.2	12.4 ± 8.9
0–5	15 (50.0)	11 (42.3)	26 (46.4)
11–15	4 (13.3)	1 (3.8)	5 (8.9)
> 15	11 (36.7)	14 (53.8)	25 (44.6)
Lymphedema during intensive phase			
Mean excess volume of affected arm before intensive phase DLT (ml) (%)	1045.1 ± 564.5 (37.0 ± 23.6)	1059.4 ± 562.0 (39.2 ± 21.1)	1051.8 ± 558.2 (38.0 ± 22.3)
Mean excess volume of affected arm after intensive phase DLT (ml) (%)	663.0 ± 385.2 (23.5 ± 15.0)	665.1 ± 384.2 (24.7 ± 14.8)	664 ± 381.3 (24.1 ± 14.8)
Excess volume decrease during DLT (%)	37.3 ± 11.6	40.7 ± 25.2	38.9 ± 19.0
Current maintenance phase treatments			
Manual lymphatic drainage	28 (100.0)	25 (96.2)	53 (98.1)
Self-drainage	20 (71.4)	21 (84.0)	41 (77.4)
Adapted personal physical exercises	16 (57.1)	17 (68.0)	33 (62.3)

Data shown are mean ± standard deviation, or n (%)

MobA: MOBIDERM Autofit; DLT: decongestive lymphedema therapy

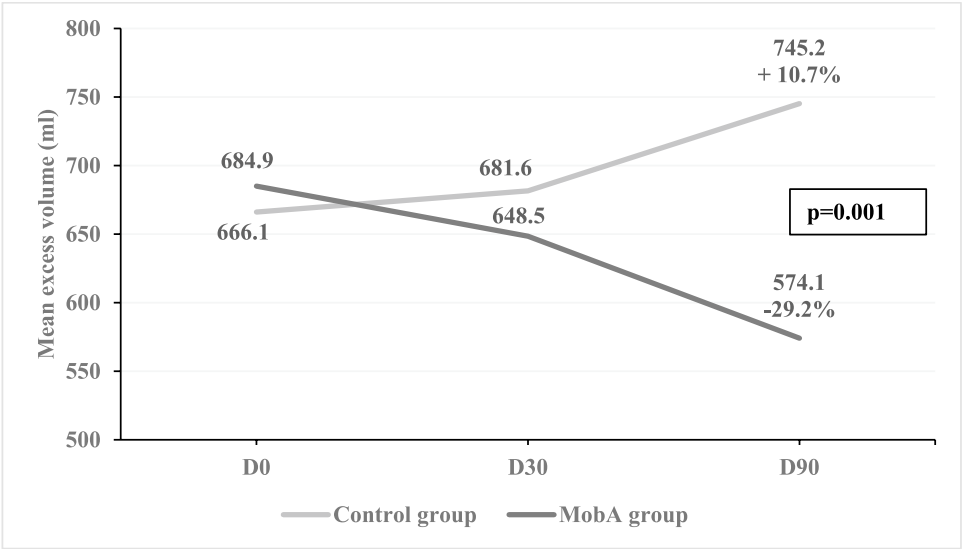


Fig. 2 Excess volume variation in the MobA and Control groups between D0 and D90 (ITT, N = 54). Excess volume was defined as the difference in volume between the affected and the contralateral arms, calculated using the truncated cone formula. Data represents the mean excess volume in mL at Day 0 (D0), Day 30 (D30) and Day 90 (D90) for Control and MobA groups

Secondary endpoints

Quality of life

LYMQOL-Arm. Overall, QoL improved continuously in both groups between D0 and D90. However, patients in the MobA group showed a significantly greater improvement in their overall QoL (p = 0.02) (Fig. 3a). There was a trend towards a greater increase in scores for the four subdomains in the MobA group at D90, although this was not statistically significant.

EQ-5D-5L Between D0 and D90, more patients reported a "better health state" in the MobA group (63.3%) (n = 19) vs. 53.8% (n = 14) in the Control group. For EQ-5D-3L VAS, there was a significantly greater improvement in score at D90 in the MobA group (+ 18.3%) vs. Control group (+ 1.3%) (p = 0.001) (Fig. 3b). However, for the four subscores (mobility, self-care, pain, anxiety), this was only statistically significant for mobility at D90 (p = 0.048).

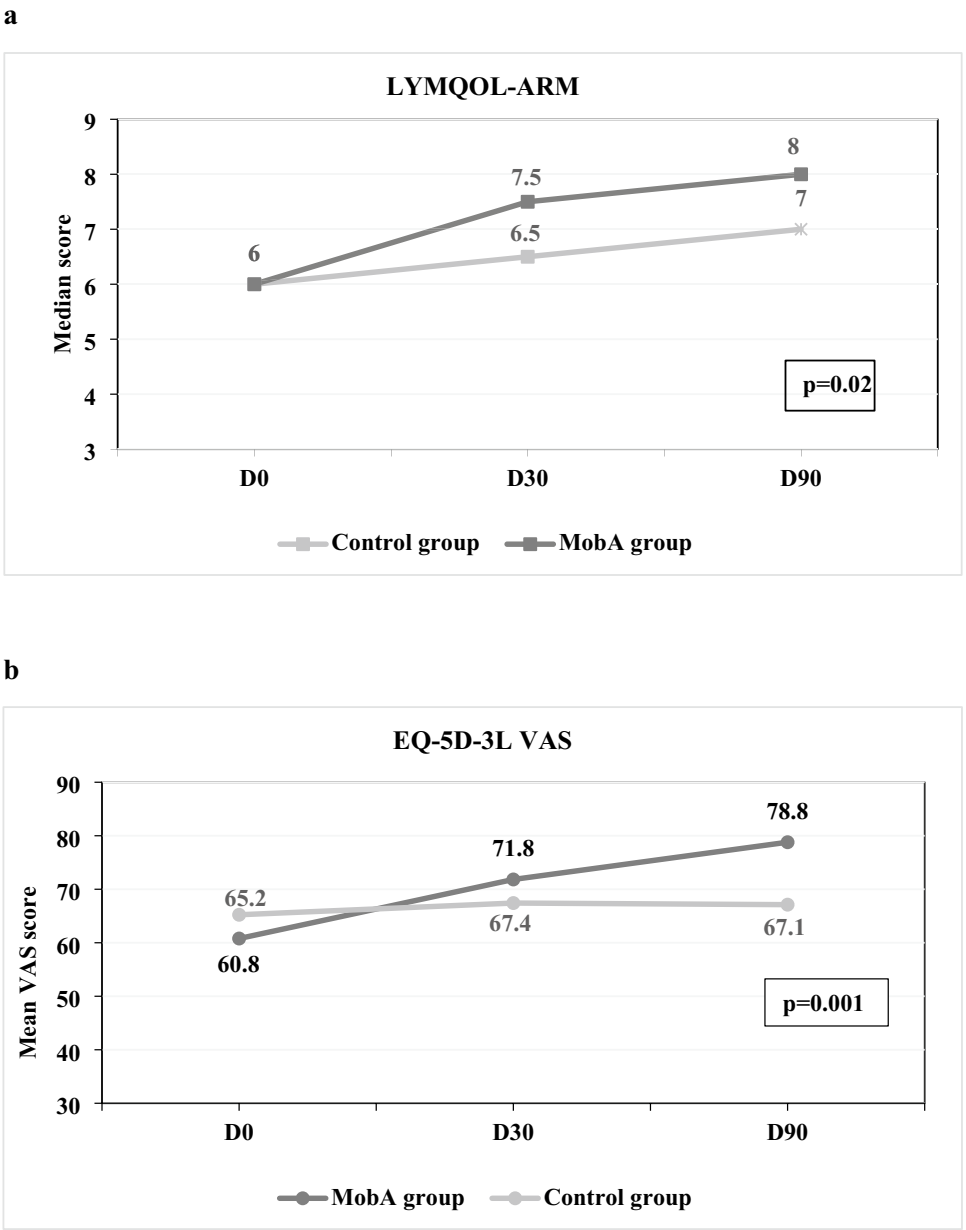


Fig. 3 Evolution of patient's quality of life and sleep quality between D0 and D90. a. Evolution of the median score calculated from the lymphedema related quality of life questionnaire (LYMQOL ARM, question n° 21) at Day 0 (D0), Day 30 (D30) and Day 90 (D90) for Control and MobA groups (ITT, N = 54). b. Evolution of the mean score related to the 100-point visual analog scale (VAS) from the quality of life EQ-5D-3L questionnaire at Day 0 (D0), Day 30 (D30) and Day 90 (D90) for Control and MobA groups (ITT, N = 54). c. Evolution of the mean patient's quality of life perception of change via a specific question at D90 for Control and MobA groups (ITT, N = 55). d. Evolution of the mean score calculated from the quality of sleep Jenkins questionnaire at Day 0 (D0), Day 30 (D30) and Day 90 (D90) for Control and MobA groups (ITT, N = 54)

Specific question Overall, 69% of patients in the MobA group vs. 34.6% in the Control group (p = 0.013) had a greater improvement in general QoL between D0 and D90 (Fig. 3c).

Sleep quality

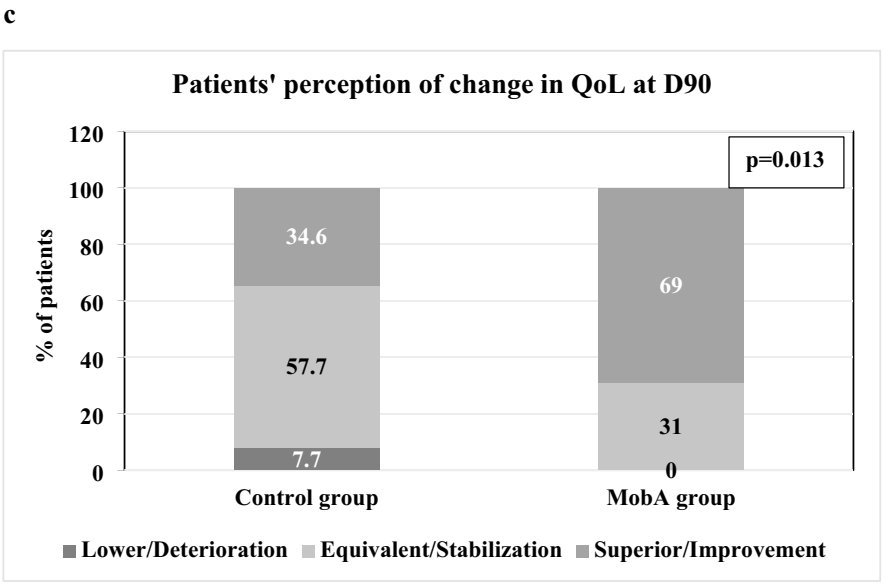
Sleep improvement was significantly greater in MobA patients (52.7% score reduction) vs. Control group (7.1% score reduction) (p = 0.018) (Fig. 3d).

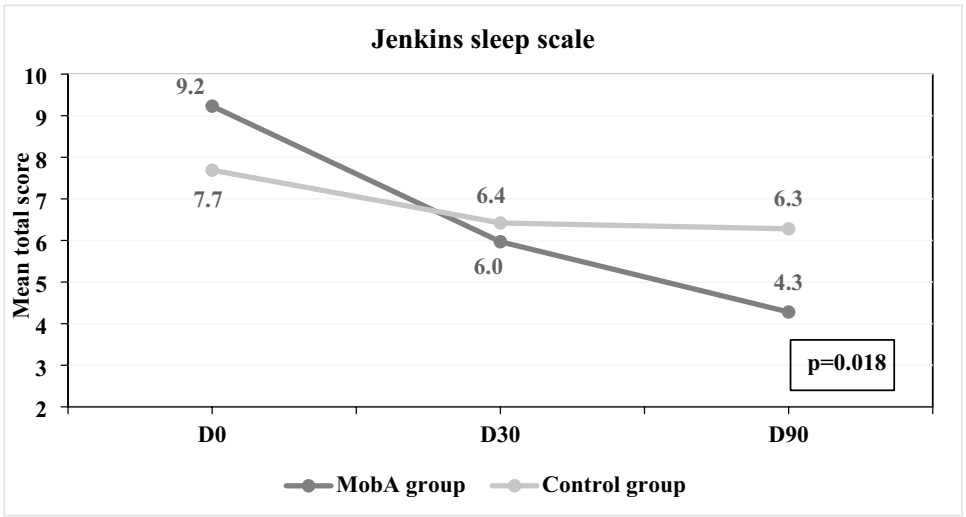
Patients' health condition

Patients' health condition was assessed by the clinicians using the modified CGI-S and CGI-I questionnaires. With the CGI-S at D90, there was an improvement in 73.3% of patients in the MobA group vs. 34.6% in the Control group (p = 0.009).

With the CGI-I at D90, 93.1% of patients in the MobA group had an improvement in their condition (very much improved for 48.3% of patients) vs. 65.4% in the Control

Fig. 3 (continued)





group (very much improved for 0% of patients) (p = 0.025) (Supplementary Fig. 2a and 2b).

Using the PGI-C scale, there was a statistically greater mean improvement in health condition of patients in the MobA group at D90 vs. the Control group (+3.7 vs. +2.0; p = 0.002). This improvement was strong (better/great deal better) for 65.5% of patients in the MobA group vs. 20.0% in the Control group (p = 0.006) (Supplementary Fig. 3).

Skin suppleness and thickness

Skin measurements at D90 were available for 24 patients in each group. There was a greater reduction in subcutaneous tissue thickness above and below the elbow in MobA patients, but the difference between the two groups was only significant for thickness measured 10 cm below the elbow (MobA group −3.23 mm vs. Control group + 0.78 mm; p = 0.025) (Fig. 4a and 4b). There was no significant difference in measurements taken at the other locations (dermo-hypodermis or epidermis).

A significatively greater number of patients also reported an improvement in skin suppleness with a strong improvement for 48.3% in the MobA group vs. 15.4% in the Control group (p = 0.01) (Supplementary Fig. 4).

Range of motion

Arm RoM remained similar in both groups, with no clear impact of the intervention in either group.

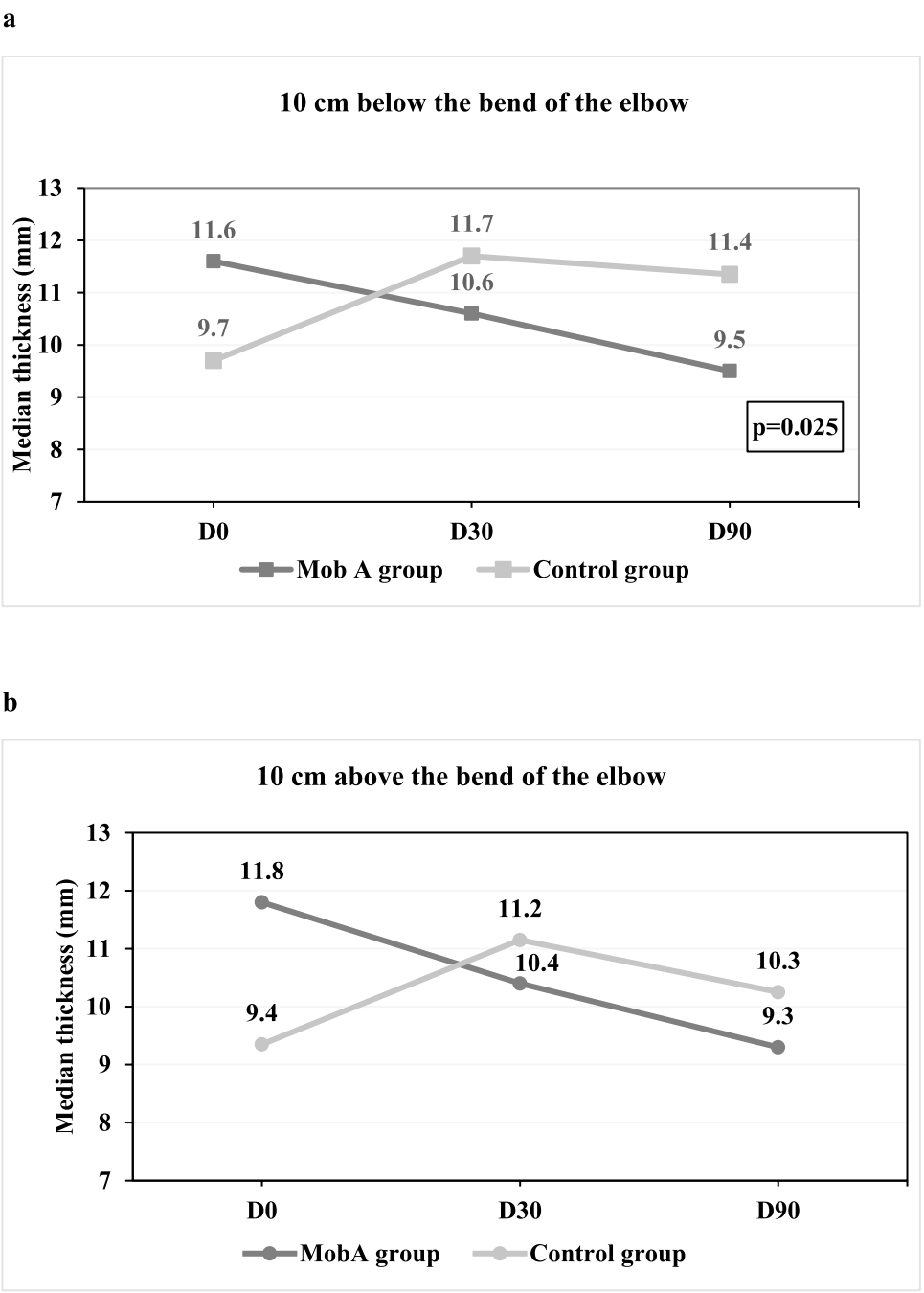


Fig. 4 Evolution of subcutaneous tissue median thickness 10 cm below (a) and above (b) the elbow (ITT, N = 48). Subcutaneous tissue thickness was measured in mm via the high sensitivity Ultrasound at Day 0 (D0), Day 30 (D30) and Day 90 (D90) for Control and MobA groups

Patient satisfaction

Satisfaction with MOBIDERM Autofit was high, with 89.7% of patients rating the compression sleeve as comfortable/very comfortable, 82.7% as easy/very easy to fit, and 60.7% reported the adjustment easy/very easy. The mean time to setting up the device was only 3.2 ± 3.4 min.

Patient compliance

Compliance with MOBIDERM Autofit was very high, with 96.7% of patients wearing the device on > 5 nights/week.

Safety

Only one device-related event was reported with MOBIDERM Autofit, corresponding to slight redness on the affected arm.

Discussion

This study demonstrates the efficacy of night-time compression with MOBIDERM Autofit in combination with daytime compression for the maintenance treatment of BCRL. MOBIDERM Autofit used at night for 90 days in combination with daytime compression consistently out-performed daytime compression alone for lymphedema volume evolution and all secondary endpoints except arm RoM. The latter finding could be because the patients were included immediately after intensive phase DLT and did not present a significant RoM deficit at inclusion.

The 3-month study period appeared to be relevant to achieve and maintain a continuous decrease in lymphedema volume. Adjuvant night-time compression with MOBIDERM Autofit prevented a rebound in volume during the first months of maintenance treatment and also made it possible to continue the reduction in limb volume after the intensive phase. QoL and sleep also improved significantly in the MobA group, likely due to the maintenance of reduced arm volume during the night and the associated decrease in nocturnal pain or discomfort related to lymphedema. This is supported by the high rate of compliance with MOBIDERM Autofit (96.7% of patients for ≥ 5 nights/week). Patient tolerance and satisfaction with MOBIDERM Autofit were very high suggesting that this auto-adjustable sleeve is well suited for managing the maintenance phase in BCRL.

Optimizing compression therapy and compliance during the maintenance phase of DLT are key to long-term lymphedema control. The most common approach to night-time compression to date has involved compression bandages. A recent randomized, controlled trial in 120 Canadian women receiving maintenance treatment for BCRL reported a significant improvement in arm excess volume after the addition of night-time compression with bandages or compression garments [15]. As in our study, these authors observed that the addition of night-time compression was significantly superior to standard care daytime compression alone in terms of absolute milliliter ($p = 0.006$) and percentage ($p = 0.002$) reductions in arm excess volume [15]. However, bandaging as a type of night-time compression is limited by the amount of time taken to apply the bandages (~20 min), and the difficulties in applying bandages consistently and effectively [21], resulting in poor compliance [22].

In the current study, MOBIDERM Autofit was quick/very quick to set up for 89.6% of patients, with a mean application time of 3.2 ± 3.4 min. Furthermore, 89.7% of patients said that MOBIDERM Autofit was comfortable/very comfortable to wear.

Several subgroup analyses were carried out in an attempt to define the patient populations who will benefit the most from night-time compression. Although the study was not powered to draw definite conclusions on this subject due to the small number of patients in each subgroup, our results suggest that MOBIDERM Autofit achieved a significantly better response than no night-time compression in women with a BMI ≥ 30 kg/m^2 and a time since lymphedema diagnosis of < 5 years. The latter result is consistent with the progressive tissue damage caused by lymphedema that becomes irreversible over time [23]. A better result with night-time compression was also found in patients with a $> 40\%$ volume reduction following intensive DLT. This is likely because patients with a high-volume reduction during intensive DLT are at greater risk of rebound during the maintenance phase and night-time compression will therefore have a greater impact in this group. This was highlighted in the MARILYN study in the subgroup of high responders (patients with a $> 35\%$ reduction during intensive DLT) [14]. Altogether, this profile of best respondents to night-time compression is in line with trends emerging from the POLIT study [11].

Our study has several limitations. First, we intended to recruit a minimum of 78 participants (out of 88 randomized). However, it was only possible to include 63 patients and to randomize 58. A conservative approach was used to calculate the sample size, anticipating a smaller difference (in terms of excess volume reduction) than that actually observed. The effect on the primary endpoint was sufficiently robust to be detected, even though the target sample size of assessable participants was not reached. Moreover, the fact that the standard deviation was similar in the two groups (198.1 ml MobA vs. 189.7 ml Control group) and compliance was high, strengthens our conclusions on MOBIDERM Autofit efficiency.

The clinical trial was performed in both Turkey and France, but a sensitivity analysis showed no impact of the country on the significance of the results.

Due to the nature of the intervention, a blinded clinical investigation was not feasible. However, the main evaluation criterion (arm volume measurement), associated with an investigator blinded to the results, limited any potential bias related to the open-label nature of the study. Furthermore, several tools were used to ensure the relevance of the clinicians' and patients' opinions. The consistency of the results between patients and clinicians, and the fact that all main outcomes converge towards superiority in the MobA group strengthen the significance of the results. Because skin thickness in secondary lymphedema has been poorly studied, future research should also consider standardized tools such as the Lymph Vessel Failure measurement system described by Kasseroller

[24], as well as systematic assessment of skin layer thickness and stiffness using shear wave elastography [25].

Conclusion

MOBIDERM Autofit used for 3 months in addition to daytime compression during the DLT maintenance phase was superior to daytime compression alone for the reduction and maintenance of arm excess volume, and to avoid the rebound effect.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s00520-026-10735-6.

Acknowledgements The authors would like to thank all patients and the specialized lymphedema health care teams who participated in the study. The authors thank Newmed Publishing Ltd for their help in writing and editing this manuscript, as well as ICTA, the contract research organization (CRO) for supporting in study management and statistical analyses.

Author Contributions Conception and design: SM, IQ.
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Funding This study was funded by THUASNE.

Data Availability No datasets were generated or analysed during the current study.

Declarations

Ethic approval The study was registered on clinicalTrials.gov (ID: NCT04203069) and was conducted according to ICH standards of Good Clinical Practice. All procedures performed in studies involving human participants were in accordance with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards, as well as applicable European and/or local laws and regulations.

The study was approved by local ethics committees (West V, Rennes, France; and Etik Kurul, Ankara, Turkey).

Consent to participate Informed consent was obtained from all patients included in the study.

Competing interests The authors have no competing interests to declare that are relevant to the content of this article.

References

1. Donahue PMC, MacKenzie A, Filipovic A, Koelmeyer L (2023) Advances in the prevention and treatment of breast cancer-related lymphedema. Breast Cancer Res Treat 200:1–14
2. Aguilera-Eguía RA, Seron P, Gutiérrez-Arias R, Zaror C (2022) Which physical therapy intervention is most effective in reducing secondary lymphoedema associated with breast cancer? Protocol for a systematic review and network meta-analysis. BMJ Open 12:e065045
3. DiSipio T, Rye S, Newman B, Hayes S (2013) Incidence of unilateral arm lymphoedema after breast cancer: a systematic review and meta-analysis. Lancet Oncol 14:500–515
4. Rupp J, Hadamitzky C, Henkenberens C, Christiansen H, Steinmann D, Bruns F (2019) Frequency and risk factors for arm lymphedema after multimodal breast-conserving treatment of nodal positive breast cancer–a long-term observation. Radiat Oncol 14:1–8
5. Norman SA, Localio AR, Potashnik SL, Simoes Torpey HA, Kallan MJ, Weber AL et al (2009) Lymphedema in breast cancer survivors: incidence, degree, time course, treatment, and symptoms. J Clin Oncol 27:390–397
6. Davies C, Levenhagen K, Ryans K, Perdomo M, Gilchrist L (2020) Interventions for breast cancer-related lymphedema: clinical practice guideline from the Academy of Oncologic Physical Therapy of APTA. Phys Ther 100:1163–1179
7. Schaverien MV, Moeller JA, Cleveland SD (2018) Nonoperative treatment of lymphedema. Semin Plast Surg 32:17–21
8. Haute Autorité de Santé. Dispositifs de compression médicale à usage individuel. Utilisation en pathologies vasculaires. 2010. Availabale at: https://www.has-sante.fr/upload/docs/application/pdf/2010-12/rapport_compression_medical_1276_vf.pdf (Accessed August 1, 2024).
9. Vignes S, Porcher R, Arrault M, Dupuy A (2007) Long-term management of breast cancer-related lymphedema after intensive decongestive physiotherapy. Breast Cancer Res Treat 101:285–290
10. European Wound Management Association (EWMA). Caine S, editor. Focus document: lymphedema bandaging in practice. London: Medical Education Partnerships, Ltd; 2005.
11. Quéré I, Presles E, Coupé M, Vignes S, Vaillant L, Eveno D et al (2014) Prospective multicentre observational study of lymphedema therapy: POLIT study. J Mal Vasc 39:256–263
12. The Lymphedema International Framework. Best practice for the management of lymphedema - Second edition. 2012
13. Mestre S, Calais C, Gaillard G, Nou M, Pasqualini M, Ben Amor C et al (2017) Interest of an auto-adjustable nighttime compression sleeve (MOBIDERM Autofit) in maintenance phase of upper limb lymphedema: the MARILYN pilot RCT. Support Care Cancer 25:2455–2462
14. Mestre S, Gaillard G, Benhamou M, Soulier-Sotto V, Nou M, Pasqualini M et al (2017) An auto-adjustable night garment to control early rebound effect of edema volume after intensive phase of decongestive lymphedema therapy. Lymphat Res Biol 15:364–370
15. McNeely ML, Dolgoy ND, Rafn BS, Ghosh S, Ospina PA, Al Onazi MM et al (2022) Nighttime compression supports improved

self-management of breast cancer-related lymphedema: a multicenter randomized controlled trial. Cancer 128:587–596
16. Breast Cancer Arm Volume Calculator. Available at: https://riskcalc.org/BreastCancerArmLympedemaArmVolume/ (Accessed August 1, 2024)
17. Keeley V, Crooks S, Locke J, Veigas G, Riches K, Hilliam R (2010) A quality of life measure for limb lymphoedema (LYMQOL). J Lymphoedema 5:26–37
18. EUROQOL. EQ-5D-3L. Available at : https://euroqol.org/information-and-support/euroqol-instruments/eq-5d-3l/ (Accessed August 1, 2024).
19. Jenkins CD, Stanton B-A, Niemcryk SJ, Rose RM (1988) A scale for the estimation of sleep problems in clinical research. J Clin Epidemiol 41:313–321
20. Busner J, Targum SD (2007) The clinical global impressions scale. Psychiatry (Edgmont) 4:28–37
21. Ridner SH, Dietrich MS, Kidd N (2011) Breast cancer treatment-related lymphedema self-care: education, practices, symptoms, and quality of life. Support Care Cancer 19:631–637
22. Brown JC, Cheville AL, Tchou JC, Harris SR, Schmitz KH (2014) Prescription and adherence to lymphedema self-care modalities among women with breast cancer-related lymphedema. Support Care Cancer 22:135–143
23. Rucigaj TP, Leskovec NK, Zunter VT (2010) Lymphedema following cancer therapy in Slovenia: a frequently overlooked condition? Radiol Oncol 44:244–248
24. Kasseroller R (1999) Das LVF-Messsystem - Eine Möglichkeit der Klassifizierung der Lymphödeme. Lymphol Forsch Prax 3:11–16
25. Zarrad M, Duflos C, Marin G, Benhamou M, Laroche JP, Dauzat M, Quéré I, Mestre-Godin S (2022) Skin layer thickness and shear wave elastography changes induced by intensive decongestive treatment of lower limb lymphedema. Lymphat Res Biol 20(1):17–25