Brief Report

Preventing Early Postoperative Arm Swelling and Lymphedema Manifestation by Compression Sleeves After Axillary Lymph Node Interventions in Breast Cancer Patients: A Randomized Controlled Trial

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Abstract

Context. Breast cancer–related lymphedema (LE) remains one of the major long-term complications after surgery. Many reports showed the effectiveness of compression in breast cancer–related LE treatment, but randomized controlled trials evaluating compression garments for postoperative prevention are lacking.

Objectives. The aim of the study was to evaluate the potential role of light arm compression sleeves for reducing the incidence of early postoperative swelling and of breast cancer–related arm LE.

Methods. A total of 45 women were pre-operatively randomly assigned to a group with compression of circular-knit sleeves in compression class I (15–21 mm Hg) for daily wearing (compression group [CG]; $n = 23$) or to a control group without compression (no CG, $n = 22$). Both groups underwent a standardized physical exercise program. Arm volumes were measured before surgery and one, three, six, nine, and 12 months thereafter.

Results. At one month, postoperative swelling was reduced only in CG. After 12 months, the average change of excess volumes (edema) reached −67.6 mL in the CG vs. +114.5 mL in the no CG ($P < 0.001$). Significantly less edema was seen in the CG after three, six, nine, and 12 months. No significant difference between groups in health-related quality of life (measured by EORTC QLQ-C30) was observed.

Conclusion. Fifteen to 21 mm Hg compression sleeves in combination with physical activity may be a safe and efficient option to prevent postsurgical arm swelling and development of LE. J Pain Symptom Manage 2017;54:346–354.

Key Words
BRCL, arm lymphedema, prevention, compression, physical exercises

Introduction

Lymphedema (LE) remains one of major long-term complications of breast cancer treatment. Axillary lymph node dissection, sentinel lymph node biopsy, and radiotherapy are associated with development of LE by damage of the distribution or function in the lymphatic system of the axilla.[1–3] The reported incidence of LE development of the arm is between 5% and 60% of all breast cancer patients depending on the extent of treatment and on the criteria and measurements used.[2,3] LE leads to significant functional, psychological, and social morbidity and decreased health-related quality of life (QoL).[4] In extreme cases, also secondary to LE malignancies like lymphosarcoma, epithelial carcinoma, lymphoma, or melanoma may develop. Older age, higher body mass index (BMI), more extensive surgery, axillary node dissection, radiation therapy, post-operative complications, and decreased range of shoulder motion are important risk factors.[5]

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Many reports showed the effectiveness of compression as a component of decongestive lymphatic therapy (DLT) or complex decongestive physiotherapy at any stage of LE manifestation, requiring lifelong management.[6,7] Preliminary research findings suggest that early diagnosis and initiating compression in the subclinical phase may reduce development of clinical LE,[8,9] but randomized controlled trials evaluating compression garments for LE prevention are lacking. Despite different attempts of prevention, LE still represents a frequent event and remains a major health problem affecting breast cancer survivors. Women undergoing breast surgery are often not provided with sufficient information and counseling before LE development.[10] There is no curative therapy and therefore, there is critical need to improve breast cancer–related LE risk prediction and prevention.

A prospective model of surveillance may reduce the risk of LE. Preoperative baseline arm measurements and monitoring after surgery, education, compression garments, exercise programs, and interdisciplinary collaboration are all interventions to consider in the development of LE surveillance.[11,12]

Based on an expert consensus recommendation,[13] compression garment regime for prophylaxis could be efficient, but this needs to be verified by the principles of evidence-based medicine.

Purpose of the Project

The aim of the study was to evaluate the potential role of light arm compression sleeves in reducing the incidence of early postoperative swelling and of breast cancer–related arm LE up to one year after the intervention. The following thresholds for arm volumes compared with the volume before surgery were defined: relative volume change of ≥10% for clinically significant LE and ≥5% including subclinical LE.[12]

Materials and Methods

Participants

From November 2014 to May 2015, 54 women were pre-operatively randomly assigned to a group with compression (compression group [CG]) or to a control group without compression (no compression group [NCG]). Nine patients (one from CG group and eight from NCG group) resigned at the beginning of this study and 45 women were recruited. The two groups were comparable concerning baseline characteristics, including BMI, type of surgery, and additional onco-therapeutic modalities (Table 1). The exclusion criteria were symptoms and/or signs of infection in the affected limb, signs of heart or renal failure, vein thrombosis, severe pulmonary insufficiency or liver disease, any evidence of active cancer or preoperative LE (≥10% difference in limb volumes), and history of bilateral lymph node dissection.

Interventions

The CG received circular-knit sleeves in compression class I (15–21 mm Hg) for daily wearing in the post-operative period. Compression sleeves (medi Bayreuth, Germany) were fitted to the subjects based on the individual limb measurements (Fig. 1). Standard educational leaflets addressing time wearing, garment washing, and replacement intervals were provided. Arm sleeves were applied in the morning and removed before going to bed (average eight to 10 hours). Both groups received a standardized physical exercise program; active upper limb exercises (flexion and extension, abduction and adduction of the shoulder, shoulder rotations, flexion and extension of the elbow, fist clenching) combined with deep diaphragmatic breathing were performed initially with an instructor, and recommended to perform regularly once daily for 15 minutes.

Table 1
Baseline Characteristics of the Patients Included in the Study

Characteristics	CG ($n = 23$)	NCG ($n = 22$)	*P*
Age, yrs (mean, SD)	52.9 (9.3)	64 (8.6)	0.001[a]
Treatment procedures			
Breast conserving treatment	13	14	0.8[b]
Sentinel node dissection	9	15	0.1[b]
Axillary lymph node dissection	14	7	0.1[b]
Radiotherapy	22	21	1[c]
Chemotherapy	10	3	0.06[b]
Mastectomy	10	8	0.8[b]
Initial limb volumes, mL (median, IQR)			
Affected side	1918 (1780.7–2142.9)	2141.8 (1999.8–2284.5)	0.1
Non-affected, control side	1968 (1739–2227.3)	2094.3 (1933.4–2255.4)	0.4

CG = compression group; NCG = no compression group; IQR = interquartile range (25%–75%).
P-values calculated using Wilcoxon rank sum test.
[a]*t*-Test.
[b]Chi-squared test.
[c]Fisher exact test.

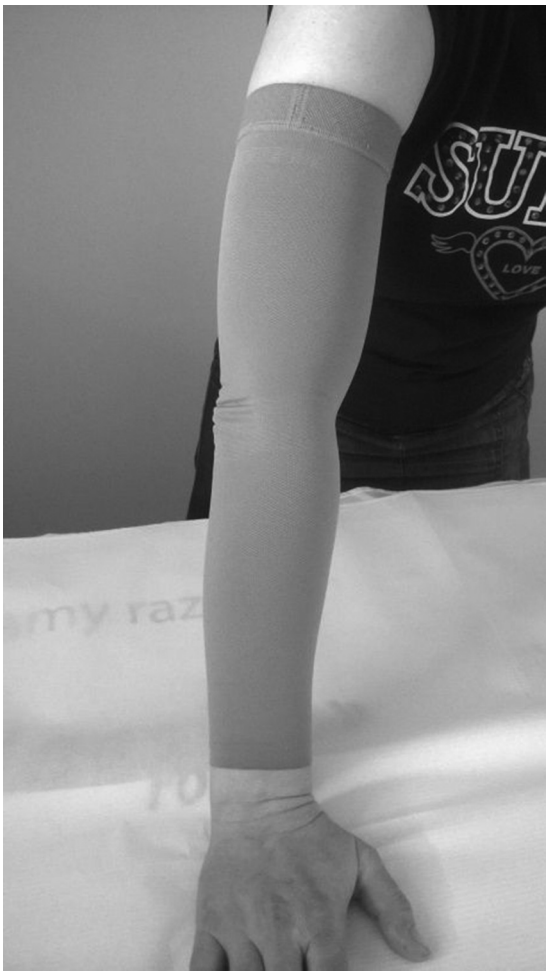

Fig. 1. The arm sleeve.

An increase of the arm volume exceeding 10% compared with the volume before surgery was defined as LE.[12] Difference of more than 5% in the first postoperative month was considered as "sub-clinical lymphoedema."[12]

Measurements and Assessment

Circumferential upper limbs measurements using a tape were taken every 4 cm from the wrist, measurements of the hand which was not covered by the garment were not included. Calculation of limb segment volumes was performed using a simplified frustum formula.[14] Edema volume (mL) was calculated by subtracting the volume of the normal limb from that of the affected limb. In addition, hands circumferences were taken in CG. All measurements were performed preoperatively (one day before surgery) and one, three, six, nine, and 12 months after surgery. The therapists performing the measurements were unaware of the patients group allocation.

At the first sleeve application and six months later, compression interface pressures under the sleeve were recorded using an air-filled pressure transducer (Kikuhime, TT Meditrade, Sorö, Denmark) at the dorsal mid forearm and at the arm over biceps muscle levels, both at rest and on exertion (with fist clenched or elbow flexed). The small probe was placed on the dorsal area of the forearm—the site of the largest increase in the forearm circumference during fist clenching and pressure was recorded. The pressure difference between muscle contraction and relaxation was calculated as a parameter characterizing the stiffness of the textile.[15]

Compliance assessment was based on the declared sleeve wearing hours a day. Health-related QoL was measured in both groups with EORTC QLQ-C30 and QLQ-BR23 questionnaires 12 months after surgery.[16]

Statistics

The sample size calculation was based on our previous pilot study when a power of 80% in a clinically meaningful median limb volume difference of 200 mL was achieved. Actually, the difference of the median volumes was 326 mL and the power reached 95%.

The categorical variable data were presented as proportion and the continuous variables as mean (SD) in normally distributed (according to Shapiro-Wilk test) or median (interquartile range 25%−75%). The associations between categorical variables were analyzed by Chi-squared test or Fisher exact test, whereas continuous variables were compared within one group by paired *t*-test (for normally distributed) or Wilcoxon rank-sum test (non-normally distribution). Means and SDs of normally distributed variables were compared and paired *t*-test was used to examine the differences. Linear regression analysis (analysis of covariance) was identified to control for baseline differences. A *P*-value of <0.05 was regarded as significant.

The research reported in the article was undertaken in accordance with the Helsinki Declaration. Protocol for the research project has been approved by the local ethics committee (No: 63/KBL/OIL/2014).

Results

All 45 patients included (23 within CG) finished the study. BMI has not changed markedly through one year observation, although in NCG, where patients initially were more often overweight, a tendency to losing their weight was more visible (BMI significantly decreased from 30.4 kg/m^2 before surgery to 28.7 kg/m^2; Table 2).

Limb and Edema Volumes

In the first month after the oncology treatment, four patients in the CG and three in the NCG had

Table 2
BMI (kg/m^2) Within the Groups Initially and After One year

BMI	CG, $n = 23$	NCG, $n = 22$	P
Median (IQR) BMI initially	25.6 (22.2–28.5)	28 (25.5–30.7)	0.02
Patients overweight (BMI ≥25)	12	17	
Patients obese (BMI ≥30)	0	6	
Median (IQR) BMI after 1 yr	25.1 (22.4–29.3)	28.7 (25.9–30)	0.2
Patients overweight (BMI ≥25)	13	20	
Patients obese (BMI ≥30)	1	5	

CG = compression group; NCG = no compression group; IQR = interquartile range (25%–75%); BMI = body mass index.
P-values calculated using Wilcoxon rank sum test.

subclinical LE. CG patients showed less frequently excess of ≥2% (the average variation of tape measuring method) volumes (7 of 23 vs. 15 of 22 in NCG, $P < 0.05$). Two of four patients within the CG with LE after one year had subclinical LE before (Fig. 2a); and that in the NCG, none of seven patients with LE after one year was free from any swelling after one month (Fig. 2b).

The CG showed significantly lower mean affected arm volumes after third month and later in comparison with NCG. After one year, four of 23 patients in CG vs. six of 22 in NCG revealed LE. Significantly less edema could be seen in the CG vs. NCG after three months and later (Table 3).

Linear regression analysis for BMI and age at the baseline revealed that patients within CG had less edema after three, six, and 12 months than NCG (mean difference of 114.9 mL $P = 0.03$; 146.3 mL $P = 0.003$, and 171 mL $P = 0.01$, respectively).

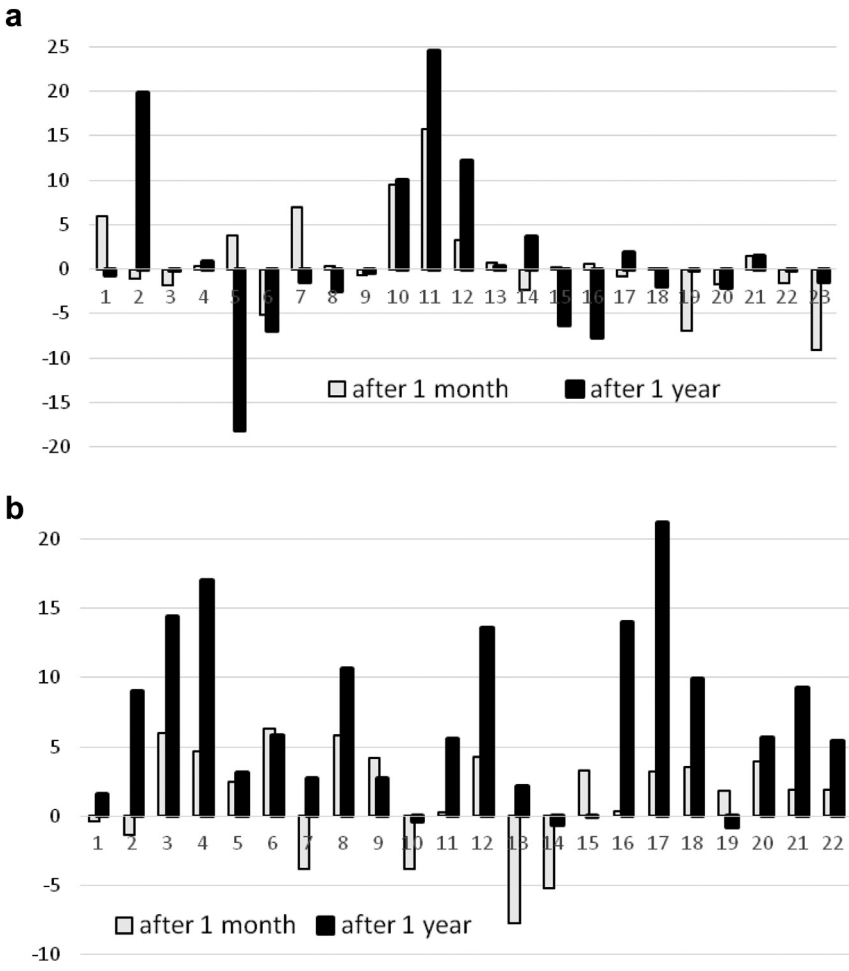

Fig. 2. a) Percentage arm volume after 1 month and 1 year in CG and b) percentage arm volume after 1 month and 1 year in NCG. CG = compression group; NCG = no compression group.

Table 3
Mean (SD) or Median (IQR) Values of the Affected Arm and Edema Volumes (mL) Within the Groups

	CG, $n = 23$		NCG, $n = 22$		P	
Time	Arm Vol.	Edema Vol.	Arm Vol.	Edema Vol.	Arm	Edema
Initially	1918 (1780–2142)	−2.1 (−127.2 to 42.5)	2141 (2000–2285)	35.7 (−31 to 85.8)	0.1	0.1
After one month	1995 (319.5)	−4.2 (131.4)	2207 (507.5)	38.5 (126.3)	0.1[a]	0.3[a]
After three months	1968 (1870–2124)	−23.7 (−83.6 to 33.7)	2207 (2044–2420)	57.2 (−0.3 to 165.3)	0.02	0.02
After six months	1978 (1756–2122)	−43.5 (−113.7 to 23.8)	2272 (2057–2378)	58.2 (0.7–180)	0.009	0.002
After nine months	1925 (1763–2164)	−74.9 (−120 to −6.2)	2179 (2058–2428)	68.6 (−10.1 to 134.4)	0.01	0.004
After 12 months	1969 (1762–2151)	−67.6 (−144.1 to −24.2)	2257 (2032–2420)	114.5 (14.9–166.5)	0.007	<0.001

IQR = interquartile range (25%–75%); CG = compression group; NCG = no compression group.
P-values calculated using Wilcoxon rank sum test.
[a]*t*-Test.

A tendency of decrease in median hand circumferences was observed within CG, which reached significance after 12 months of compression (19.7 cm [interquartile range 18.7–20.15] before the treatment vs. 19.4 cm [18.65–20.05]; $P = 0.03$).

Interface Pressure Under the Sleeves

The mean pressure values under the sleeves measured at forearm were 15.7 mm Hg (SD 3.4) and on the arm level 13 mm Hg (SD 2.5). Some decrease of pressures on the forearm and upper arm and of stiffness after six months was observed ($P = 0.01$; Table 4).

Compliance and Quality of Life

Compliance with the sleeves was very good. The mean time of sleeves wear was 10 hours per day. Only one patient wore the arm sleeve shorter, between six and 10 hours per day. None of the patients reported that the sleeves were uncomfortable to wear and no problems with donning and doffing were noted.

The available data indicated no significant differences between groups at any assessment point (global health status, functional scales, symptom scales) in QLQ-C30. The QLQ-BR23 data revealed better sexual functioning ($P = 0.014$), and greater upset by hair loss in NCG ($P = 0.01$). The remaining functional aspects (body image, sexual enjoyment, future perspective) and symptom items (systemic therapy side effects, breast symptoms, arm symptoms) did not differ significantly between groups (Table 5).

Table 4
Mean (SD) or Median (IQR) Interface Pressures Under the Sleeves Within CG (mm Hg)

Interface Pressure	After One Month	After Six Months	P
Forearm			
At rest	17 (13–18)	15 (13–16)	0.01
Active	23.3 (4.8)	20.3 (4)	0.001[a]
Stiffness index	7.6 (3.7)	6.1 (3.1)	0.03[a]
Arm			
At rest	13 (12–15)	12 (11–14)	0.008
Active	25 (22–27)	18 (16–22)	<0.001
Stiffness index	10 (8–13)	6 (5–10)	<0.001

IQR = interquartile range; CG = compression group.
P-values calculated using Wilcoxon rank sum test.
[a]*t*-Test; Stiffness index = active - resting pressures under the sleeve.

Discussion

Several studies have shown that compression is a very effective treatment modality in patients with arm LE after breast cancer surgery.[17] However, scientific evidence concerning prevention of this frequent event remains poor.[17–20] This is to our knowledge the first randomized prospective study aiming to evaluate the role of light compression sleeves after breast cancer surgery to reduce early postoperative swelling and subsequent LE. It should be underlined that the diagnosis of malignant changes in the lymph nodes was verified by histology in all cases and that nearly all cases in whom only sentinel lymph node surgery was performed had additional axillary radiotherapy, which is more predisposing to LE factor than lymph node dissection. In two patients from the NCG group, sentinel lymph node surgery was combined with mastectomy.

As demonstrated in Figure 2b, postoperative swelling after surgery is a frequent condition. The fact that after one month an arm volume increase of >5% was seen in three patients in the NCG, but also in four patients of the CG (seven of 45 within two groups) demonstrates the problems concerning the relevance of this threshold defining subclinical LE,[8] which does not allow a prognosis for the individual case. Even when this is not a prerequisite for the later development of manifest LE it could be demonstrated that in the NCG all patients developing LE after one year had some degree of swelling after one month.

The reduction of early edema because of trauma and restricted mobility caused by surgery is an important target for immediate postoperative compression. Reducing capillary filtration by external compression will reduce the amount of the lymphatic load and

Table 5
Quality of Life Within Both Groups After One year

QoL Item	CG, $n = 23$ Mean (SD) or Median (IQR)	NCG, $n = 22$ Mean (SD) or Median (IQR)	*P*
EORTC QLQ-C30			
Global health status QoL	67.3 (17.3)	63.5 (23)	0.5[a]
Functional scales			
Physical functioning	60 (50–67)	53.3 (40–60)	0.1
Role functioning	66.7 (58.4–66.7)	66.7 (54.2–66.7)	0.8
Emotional functioning	50 (41.7–66.7)	50 (41.7–58.3)	0.8
Cognitive functioning	66.7 (50–66.7)	58.4 (50–66.7)	0.7
Social functioning	66.7 (66.7–66.7)	66.7 (66.7–66.7)	0.98
Symptom scales			
Fatigue	11.1 (0–33.3)	22.2 (2.8–33.3)	0.3
Nausea and vomiting	0 (0–0)	0 (0–0)	0.3
Pain	16.7 (0–33.3)	8.4 (0–50)	0.9
Dyspnoea	0 (0–33.3)	0 (0–25)	0.8
Insomnia	0 (0–0)	0 (0–0)	0.6
Appetite loss	0 (0–0)	0 (0–0)	0.3
Constipation	0 (0–0)	0 (0–0)	0.8
Diarrhea	0 (0–0)	0 (0–0)	0.1
Financial difficulties	0 (0–0)	0 (0–33.3)	0.058
EORTC QLQ-BR23			
Functional scales			
Body image	100 (83.3–100)	95.8 (77–100)	0.97
Sexual functioning	83.3 (66.6–100)	100 (100–100)	0.01
Sexual enjoyment	100 (50–100)	100 (100–100)	0.09
Future perspective	66.6 (33.3–66.6)	66.6 (33.3–66.6)	0.8
Symptom scales			
Systemic therapy side effects	9.5 (4.7–16.6)	14.2 (9.5–19)	0.3
Breast symptoms	8.3 (0–16.6)	8.3 (8.3–16.6)	0.3
Arm symptoms	11.1 (0–22.2)	0 (0–22.2)	0.9
Upset by hair loss	0 (0–0)	0 (0–33.3)	0.01

CG = compression group; NCG = no compression group; EORTC QLQ-C30 = EORTC quality of life questionnaire; QoL = quality of life; EORTC QLQ-BR23 = EORTC quality of life breast module questionnaire; IQR = interquartile range.
P-values calculated using Wilcoxon rank sum test.
[a]*t*-test; Stiffness index = active - resting pressures under the sleeve.

will therefore inhibit the development of more intense swelling exceeding 10% in the further time course. Our findings regarding prevention of early edema is in agreement with the results of Stout Gergich et al.[8] who were able to alleviate subclinical LE, by using light arm sleeves in a prospective trial. The importance of early intervention counteracting subclinical LE was also demonstrated in a prospective study using bioimpedance.[2]

The question concerning an optimal pressure range of the arm sleeves for preventing edema is still open. Previous studies have shown that already low pressure is able to prevent leg edema in standing professions[21] and that for the treatment of manifest arm LE lower pressures (30 mm Hg) may be even more effective than higher pressure (50 mm Hg).[22] According to the standards of the stocking producer (RAL-GZG standard classification), light sleeves (compression class I) are defined by a pressure range of 18–21 mm Hg. Our arm sleeves exerted a mean resting pressure of 15 mm Hg and could be easily applied by the patients themselves. Our study shows that wearing such sleeves during day time does not only prevent postoperative arm swelling, but also leads to a significant reduction of arm LE between three and 12 months compared with the control group.

Arm volumes may change due to changes of the body weight. This is one reason to calculate the so-called "excess volume" by subtracting the volume of the contralateral arm from that of the affected side. This difference corresponds to "edema." Although there was a continuous increase of edema values in the control group up to one year, a constant decrease of edema was observed in the CG, with significant differences between the two groups starting after three months (Table 3). The increasing tendency of edema in the non-compressed CG raises the suspicion that more patients will develop LE in the future so that after some years the reported incidence of 30%–50% breast cancer–related LE may be reached. In the presented series, six from 22 patients in the control group developed LE after one year. Based on the reported data there is some hope that this high rate can be reduced by early postoperative compression.

Regarding breast cancer–related LE, Zimmermann et al. published beneficial effects of manual lymph drainage (MLD) concerning prevention of arm LE

in patients after breast cancer surgery.[23] In contrast to self-applications of light arm sleeves, MLD is a very demanding and time consuming treatment modality, which needs to be performed by educated staff, as also emphasized in a letter to the editor relating to this article.[24] Controversial information on prophylactic compression comes from studies performed on the lower extremity, where higher pressures would be appropriate. In a randomized controlled pilot study of 22 patients with vulvar cancer, less pronounced increase in leg volume occurred in patients who received prophylactic stockings (15–20 mm Hg) than in those who did not.[25] This contrasts with the results reported in patients after inguinal lymph node dissection because of different cancers (melanoma, urogenital tumors). No evidence of benefit from 23 to 32 stockings was observed up to 12 months after inguinal node surgery.[26]

For the treatment of the manifested LE of the extremities, compression is the basic management.[27–29] Compression bandaging effectively reduces limb volume during the intensive phase of DLT, and compression garments are mainly used to maintain this effect. This treatment requires lifelong management and the effectiveness depends on patient compliance.[29,30] Most studies in LE management are flawed by the fact that in addition to compression, several other components of DLT, especially MLD[31] are used. In our study, both patient groups had the same additional training program shown to be beneficial after lymph node intervention,[31] but no other additional components of DLT. Our study shows that light compression sleeves can prevent secondary LE after lymph node interventions in combination with an exercise program and that low-pressure products providing better compliance are sufficient.

Apart from the pressure, the elasticity of material seems also to be an important feature in selecting suitable arm sleeves. In compression treatment for LE of the arm, flat knitted arm sleeve in compression class (Ccl II; 23–32 mm Hg) with a high stiffness are usually preferred because they exert a massaging effect in combination with exercise.[32] Although systematic *in vivo* data with arm sleeves are still lacking, the measured increase of pressure between seven and 11 mm Hg during fist clenching seems to reflect a high level of stiffness. Significant decrease of sub-garment pressure observed after six months is because of the achieved edema reduction in addition to some fatigue of the material and should lead to the prescription of new sleeves. Because our sleeves were not compressing the hand, some transient swelling in this region toward the end of the day was occasionally seen; but within a year observation, a decrease in edema was noted by measuring hand circumferences.

According to the literature, risk factors for developing LE are extensive surgery (i.e., axillary-lymph-node dissection, greater number of lymph nodes dissected, mastectomy) and being overweight or obese.

In a recent review, patients with breast cancer–related LE reported a lower QoL score compared with those without LE because of resulting decrease in physical functioning and psychological and social well-being.[4] Using the EORTC QLQ C-30 and BR23 as valuable instruments to assess the QoL in breast cancer patients,[16] we did not indicate any significant differences in health-related QoL between the groups with and without compression. Analogue results were also reported in other studies.[25,26] Actually, almost all women planned to continue to use the sleeve after completion of the study. We plan to follow-up the patients for at least five years. Compression was well-tolerated and patients could carry out their jobs, leisure activities, and practice sport. None of the patients reported any complications related to the use of the sleeve. There were no problems with donning and doffing the compression device so that compression sleeves are very easy and safe option in the LE prevention. We believe that low compression sleeves used in this study are acceptable for women at risk. For people who are otherwise healthy, lower pressure would hence be preferable leading to a better compliance.

One major drawback of our study is the low number of patients who agreed to take part in the study, which does not allow to evaluate subgroups concerning the risk for the development of LE. Another weakness of this study was the noticeable number of drop-outs (16.7%; in NCG) and that an intention-to treat analysis could not be performed.

The methodology of calculating arm volumes measuring circumferences is well established.[12,14,25] An important strength of the study is the high level of compliance regarding self-application and wearing of the sleeves and concerning the follow-up visits.

Conclusion

Compression sleeves in a pressure range around 15 mm Hg in combination with physical activity is a safe and efficient option to prevent postsurgical arm swelling and the development of LE between three and 12 months after axillary lymph node interventions.

Disclosures and Acknowledgments

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