Original Article

A Preliminary Study of the Effectiveness of a Custom-made Compression Garment with Simplified Tailoring for Breast Cancer-related Lymphedema: A Randomized Control Trial

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ABSTRACT

Objectives: To study the changes in arm volume and quality of life of breast cancer-related lymphedema patients after using a custom-made compression garment with simplified tailoring compared with a pressure garment tailoring by a standard method

Study design: A single-blinded randomized controlled trial

Setting: The Outpatient Physical Medicine and Rehabilitation Clinic in Siriraj Hospital, Bangkok, Thailand

Subjects: Females aged 18 years or older diagnosed with breast cancer-related lymphedema

Methods: Forty-three participants were randomly assigned to one of two groups. Both groups received complex decongestive therapy (CDT) over a period of three weeks. The control group was provided custom-made compression garments made using the conventional method, while the experimental group received custom-made compression garments made using a simplified technique of tailoring.

Results: Of the forty-three participants, 22 were in the intervention group and 21 were in the control group. In the control group, the mean arm volume decreased by 77.6 ml (SD = 201.8) after three weeks. The volume in the control group was not statistically significant different from baseline (p = 0.058). During the same period, the mean arm volume reduction in the intervention group was 172.7 ml (SD = 304.3), a statistically significant reduction in the affected arm volume from baseline (p = 0.015). However, no statistically significant difference was observed in other direct comparisons between the two groups, i.e., both groups statistically significantly improved their quality of life as measured by changes in the Lymphedema Functioning, Disability, and Health Questionnaire for Upper Limb Lymphedema (Lymph-ICF-UL). However, there was no statistically significant difference between the two groups regarding quality-of-life improvement.

Conclusions: The data suggests a trend towards a more significant reduction in affected arm volume with the new custom-made tailoring method of making the compression garment over the conventional tailoring technique. These results suggest promising avenues for future larger-scale studies.

Keywords: compression garment, breast cancer-related lymphedema, quality of life, lymphedema, arm volume, functioning, disability and health questionnaire for upper limb lymphedema

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Introduction

Breast cancer was the most commonly diagnosed cancer worldwide in 2020, with 2.3 million women receiving a diagnosis and 685,000 individuals succumbing to breast cancer. Between 2015 and 2020, approximately 7.8 million people were diagnosed with breast cancer. This high prevalence makes breast cancer patients the top-ranked cancer survivors globally in the year 2020.[1]

Although the treatment for breast cancer has made significant progress, patients still have to face numerous side effects that occur after treatment. One of the most common side effects is lymphedema.[2] Lymph is a white milky fluid that all physical activities can influence. The contraction and relaxation of muscles transports lymph. The flow can be affected by the disturbance of lymphatic tissues. Observation of lymphedema subjects in an animal study showed that any method that can change the contour of extremities may increase the lymph flow.[3] Subjects who have lymphedema after mastectomy require special care because subjects with breast cancer usually have reduced physical activity, which may exacerbate the symptoms.[4] Reduced physical activity leads to reduced muscle activity, which secondarily leads to reduced lymph circulation, a cycle which continues repeatedly. Post-mastectomy lymphedema also reduces the subjects' regular physical activity, adversely affecting their quality of life.[5,6] Subjects with post-mastectomy lymphedema commonly complain about pain, discomfort, reduced hand grip strength and joint movements in the related extremities. The "tissue burst" sensation may occasionally lead to secondary edema and increase the limb circumference.[5-7] If left

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untreated, it can lead to various other side effects such as skin infections, infections in the lymphatic vessels, blockage of the blood vessels in the affected area, or severe swelling that compromises normal arm function. Consequences can include a loss of confidence in social situations.[2-8] All these issues contribute to a decreased quality of life for the patients.[9,10]

The standard treatment for lymphedema is complex decongestive therapy (CDT), which is comprised of manual lymphatic drainage, skincare, exercise, and compression garments. Each patient should continue the therapy at home.[11]

The principal objective of decongestive therapy is gradually decreasing the pressure gradient from the highest in the distal wrist area to the lowest toward the arm to facilitate the movement of lymphatic fluid upwards. This therapy helps relieve symptoms, prevents progression and reduces the risk of skin infection. It reduces edema by increasing the interstitial pressure, thus reducing capillary filtration, increasing the lymphatic reabsorption of interstitial fluid, increasing the lymphatic flow, shifting fluid to non-compressed areas, increasing the lympho-venous-muscular pump function, protecting the skin and breaking down fibrosclerotic tissue. In lymphedema, decompressive therapy has been considered the most effective therapeutic procedure.[12]

Compression garments require an appropriate pressure level for each patient; the hospital customizes the pressure for each individual. Pressure garments are tailored specifically for each patient, applying pressure ranging from 20-40 mmHg.[13]

Medical compression garments come in two primary types: circular knit and flat knit. Circular knit garments are seamless, highly elastic and are available as ready-to-wear options, making them suitable for mild lymphedema. In contrast, flat knit garments are made from flat fabric tailored to fit the patient's body measurements. These are constructed from stronger materials, resulting in less stretch, and are designed for moderate to severe lymphedema. Most research on custom-made compression garments has focused on PowerNet fabric,[14] a blend of synthetic fibers like nylon and elastane that provides strength and elasticity.

Studies have shown that compression garments effectively reduce volume and manage early-stage lymphedema.[15] Notably, about 80% of patients following breast cancer surgery were prescribed these garments, yet the guidelines for their use often varied significantly.[16] A randomized controlled trial in 2021 showed that incorporating nighttime compression therapy significantly improved arm lymphedema volume compared to using daytime therapy alone.[17] However, challenges remain: the production of custom-made garments is time-consuming, and some patients choose not to use them or to wear them for shorter periods than recommended, often due to discomfort, unease, and heat.

The research team aimed to develop a new tailoring method for making custom-made compression garments that would save time and reduce the production steps, making them more accessible and practical. The new technique involves measuring the fabric's compression pressure only once when the fabric is initially obtained, then setting the proportion between the width of the fabric and arm circumference, and measuring the pressure to ensure it falls within 25-30 mmHg, a moderate pressure range. Once the proportion of the width of fabrics and arm circumference is determined, sewing the garment must be adjusted to snugly fit the user's arm based on the individual's comfort, eliminating the need for repetitive pressure measurements, thus saving time and reducing complicated methods garment production time.

The key research question is whether this new method for making custom-made compression garments can reduce the volume of lymphedema and improve the quality of life of breast cancer-related lymphedema patients compared to the conventional method.

Material and Methods

Study design

A single-blinded, randomized controlled trial was conducted in a university hospital in Bangkok, Thailand. The study was approved by the Institutional Review Board, Faculty of Medicine, Siriraj Hospital (481/2565). It was registered in the Thai Clinical Trials Registry on September 21, 2022 (ID TCTR20221212005). This study was conducted in accordance with the CONSORT guideline.

Study participants

Inclusion criteria

1. Females age 18 years or older
2. Unilateral upper extremity lymphedema secondary to breast cancer
3. Lymphedema Stage 1 (an early accumulation of the condition which subsides with limb elevation. Pitting may occur) or stage 2 (limb elevation alone rarely reduces tissue swelling and pitting is manifest; the limb may or may not pit) upper extremity lymphedema secondary to breast cancer, as defined by the International Society of Lymphology[13]
4. Having not used a compression garment before

Exclusion criteria

1. Presence of infection in the affected arm
2. Recurrence of breast cancer
3. Unfinished treatment of breast cancer, either surgery, radiation, or chemotherapy
4. Previous treatment of lymphedema, such as surgery
5. Ongoing treatment of lymphedema, such as intermittent pneumatic compression and manual lymphatic drainage by a therapist
6. Bilateral leg edema due to a medical condition

Withdrawal or termination criteria

1. The participant's request to stop participating
2. Complications from using compression garments such as rash or affected arm infection

Sample size calculation

A research study by Vignes et al.[18] investigated the long-term treatment of patients with lymphedema associated with breast cancer using intensive decongestive physiotherapy. The study measured the volume of lymphedema before and after the therapy. The average volume of lymphedema before intensive decongestive physiotherapy was 1,054 ml, while after the therapy, it decreased to an average of 647 ml.

The sample size was calculated using the two independent means formulas, with a specified type I error of 0.05, β (beta) of 0.20, and standard deviations of 633 and 351 before and after therapy. The calculated sample size was 25 individuals per group. Assuming a 10% dropout rate, the sample size for this study was determined to be 28 individuals per group.

Randomization

After taking the patient's medical history, conducting a physical examination, and asking the participants for informed consent, patients with lymphedema were stratified into stages 1 or 2 based on the International Society of Lymphology criteria.[19] Each stage was then randomized using a computer-generated block of four method into 2 groups. The intervention group included 22 patients, and the control group included 21, as shown in Figure 1. The randomization results were placed in sealed envelopes by a third party who was not involved in the study.

Interventions

Both groups received a video teaching exercises to perform at home. The exercises included breathing exercises and neck and shoulder exercises for relaxation and range of motion. They were instructed to have manual lymphatic drainage massage and to use a moisturizer on the affected arm daily. The investigator provided the patient a single custom-made garment made from Powernet fabric.

The control group received a conventional tailoring method custom-made compression garment.19 Arm circumferences were measured at 13 fixed levels. After cutting and sewing to the measured size, adjustment was based on the interface pressure measured by an air-filled pneumatic pressure testing system (PicoPress®, Microlab Elettronica, Ponte San Nicolò, Italy). If the pressure was too high or too low, trained personnel had to remove the stitches before resewing the garment until the interface pressure was in the standard range of 25-30 mmHg. The total time for production was about 2 hours per piece.

The intervention group received garments made using a new tailored custom-made compression technique. Before the therapists began using each roll of fabric, a documented record was made by pulling pieces of the fabric of various widths to determine the percent they could be stretched beyond their original width to provide a pressure between 25-30 mmHg. Patient arm circumferences were measured using the standard method, and the investigator made the compression garment by stretching the fabric to the desired width as planned. There was no pressure measurement after the compression garment was completed; the patients were only asked to test the sensation of tightness to determine if they could tolerate wearing it. The total time for production was about 1.0-1.5 hours per piece.

After the participants received the garment, they were instructed to wear it continuously throughout the day and night, except during bathing (23 hours a day). To measure compliance, participants were asked to record the duration of wearing the compression garment, the frequency and duration of exercise and manual lymphatic drainage, and any adverse events each day for three weeks.

In evaluating the follow-up results at the third week, reference was made to the research conducted by Tantawy Sayed and colleagues[20] comparing the use of Kinesio taping with elastic compression garments in patients with post-mastectomy upper extremity lymphedema. In that study, significant statistical differences in the altered volume of lymphedematous arms were found after three weeks, so the same three-week timeframe was used to assess and monitor the outcomes in the present study.

Outcome measurements

Demographic data, including age, weight, height, body mass index (BMI), dominant hand side, type of breast surgery, duration after surgery, duration of lymphedema, history of chemotherapy, history of radiation therapy, stage of breast cancer and stage of lymphedema were collected at baseline.

Outcome measurements were made at baseline and after three weeks of participating in the rehabilitation program. A physiatrist who performed all measurements was blinded to participant grouping. The outcomes include the following:

1. Arm volume change was the primary outcome. The arm volume was measured using water displacement volumetry following the Archimedes principle. This validated method measures the volume of the whole arm, including the hand. It is an accepted gold standard for measuring limb volume change in a clinical environment.[21] Water displacement volumetry showed good concurrent validity with a high correlation to the cross-sectional area (measured by a computerized tomographic (CT) scan of the affected limb with a correlation coefficient of 0.904, (p < .001).[22] To measure volume while seated, the arm with lymphedema was gradually immersed in a prepared water container until it reached the specified mark. The arm's displaced water volume was then measured by raising the water level. To standardize immersion at the same depth in pre- and post-intervention, the distance from the lateral epicondyle in line with the lateral epicondyle-acromion was recorded in centimeters. This volume was used as the baseline. At the end of the third week, the volume was measured immediately after removing the compression garment. The volume at baseline and the end of the study were calculated to find the volume change.

2. Quality of life change was the secondary outcome. Quality of life was measured using the Thai version of the Lymphedema Functioning, Disability, and Health Questionnaire for Upper Limb Lymphedema (Lymph-ICF-UL).[23,24] The questionnaire consisted of 29 questions: seven questions on pain symptoms, emotions, immune system function, and mobility, four questions on mental well-being, four questions on household functionality, eight questions on mobility capability, and six questions on lifestyle and social participation. The maximum total score is 290 (10 points for each question); a higher score indicates a poorer quality of life. The scores at baseline and at the end of the third week were calculated to determine the change in quality of life.

Statistical analysis

Statistical analysis was performed using IBM SPSS Statistics version 29.0 (IBM Corp, Armonk, NY, USA). Continuous data is shown as mean, standard deviation (SD), and median (IQR 25, 75). The categorical data are shown as numbers and percentages.

Differences between baseline characteristics and continuous outcomes of the two groups were analyzed by Independent T-test or Mann-Whitney U test. Categorical baselines were analyzed by Chi-squared test. A *p*-value less than 0.05 was considered statistically significant.

Results

Characteristics of the participants

Forty-five patients with grade 1-2 breast cancer-related lymphedema from December 2022 to May 2024 were assessed for eligibility. Two patients were excluded because they did not meet the inclusion criteria (Figure 1). The remaining 43 patients participated in this study.

Baseline demographic data

The baseline demographic and clinical characteristics of the participants are presented in Table 1. The mean age in the intervention group was 57.3 (SD = 12.6) years. The control group's mean age was 60 (SD = 11.7) years.

There were no significant differences in any of the baseline data, i.e., age, BMI, stage of breast cancer, stage of lymphedema, median duration after mastectomy, previous treatments, median duration after lymphedema, dominant side effects, baseline arm volume, and quality of life.

Primary and secondary outcomes

The mean arm volume at baseline for the control group was 1,696.2 (SD = 299.1) ml. After three weeks, the mean arm volume in that group had decreased to 1,618.6 (SD = 275.0) ml., a mean arm volume change of 77.6 (SD = 201.8) ml. The volume in the control group after three weeks was not statistically significantly different from the baseline (p = 0.058). In the intervention group, the mean arm volume at baseline was 1,892.7 (SD = 477.7) ml. After three weeks, the mean arm volume had decreased to 1,720.0 (SD = 311.9) ml, a reduction in the mean arm volume of 172.7 ml. (SD = 304.3). The volume in the intervention group after treatment was a statistically significantly lower than the baseline (p = 0.015). However, the between-group analysis did not show a statistically significant difference in arm volume reduction between the different methods of compression garment tailoring (p = 0.216). (Table 2)

Regarding quality of life as measured by the Lymph-ICF-UL, the median of the Lymph-ICF-UL score of the control group at baseline was 38.0 (interquartile range (IQR) = 17.0, 59.5). After three weeks, the median of the Lymph-ICF-UL score was reduced to 12.0 (IQR = 5.5, 37.0). For the intervention group, the median of the Lymph-ICF-UL score at baseline was 40.5 (IQR = 18.5, 69.8). After three weeks,

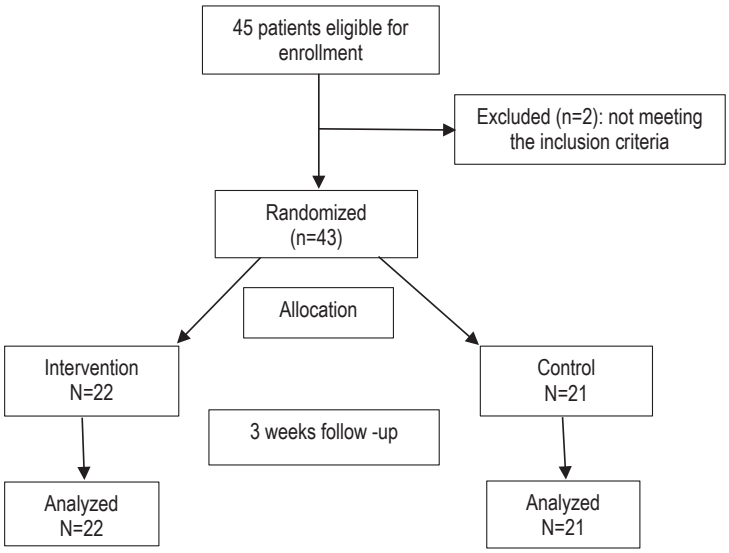

Figure 1. Study flow chart

Table 1. Baseline demographic data

Variables	Intervention	Control	*p*-value
Demographic data			
Age (years)[1]	57.3 (12.6)	60 (11.7)	0.474
BMI (kg/m^2)[1]	24.3 (6.8)	25.9 (4.2)	0.353
Duration after mastectomy (months)[2]	31 (15, 96)	27 (19.5, 72)	0.932
Duration after lymphedema (months)[2]	6 (2, 12)	3 (1, 10)	0.111
Stage of breast cancer[3]			
Stage I	1 (5.6)	1 (5.9)	0.838
Stage II	10 (55.6)	11 (64.7)	0.451
Stage III	7 (38.9)	5 (29.4)	
The dominant side affected[3]	9 (40.9)	11 (52.4)	0.184
Type of surgery[3]			
Total mastectomy	20 (95.2)	16 (76.2)	
Breast-conserving surgery	1 (4.8)	5 (23.8)	1.000
Adjunctive treatment[3]			0.457
Chemotherapy	20 (90.9)	20 (95.2)	
Radiotherapy	19 (86.4)	16 (76.2)	0.607
Lymphedema stage[3]			
Stage I	13 (59.1)	14 (66.7)	0.116
Stage II	9 (40.9)	7 (33.3)	0.644
Arm volume[1]	1692.2 (299.1)	1892.7 (477.7)	
Quality of life (Lymph-ICF-UL)[2]	40.5 (18.5, 69.75)	38 (17, 59.5)	

[1]Mean (SD), [2]median (Q1, Q3), [3]N (%), significant at $p < 0.05$
BMI, body mass index, Lymph-ICF-UL, lymphedema functioning, disability and health questionnaire for upper limb lymphedema;

Table 2. Comparison of arm volume change and quality of life change in the intervention and control groups

	Baseline		Week 3		Change		*p*-value
	Control	Intervention	Control	Intervention	Control	Intervention	
Arm volume mean (SD)	1696.2 (299.1)	1892.7 (477.6)	1618.6 (275.0)	1720.0 (311.9)	77.6 (201.8)	172.7 (304.3)	0.216
Lymph-ICF-UL median (IQR)	38.0 (17.0, 59.5)	40.5 (18.5, 69.8)	12.0 (5.5, 37.0)	13.5 (5.8, 43.0)	15.0 (9.0, 43.0)	16.5 (0.25, 41.8)	0.618

Lymph-ICF-UL, lymphedema functioning, disability and health questionnaire for upper limb lymphedema; SD, standard deviation; IQR, inter-quartile range

the median of the Lymph-ICF-UL score was reduced to 13.5 (IQR = 5.8, 43.0). The changes in both the control group and the intervention group were statistically significant with $p \leq 0.05$, indicating a better quality of life of the participants. Between-group analysis showed that the improvements of the two groups were not statistically significantly different ($p = 0.641$).

Compliance and co-interventions

From the logbook records, the median duration of wearing compression garments in the control group was 13.4 (IQR = 5.0, 20.0) hours per day. In contrast, the median duration in the intervention group was 11.7 hours per day (IQR = 4.7, 19.0). The difference was not statistically significant ($p = 0.641$).

The median duration of neck and arm exercise in the control group was 18.8 minutes per day (IQR = 9.5, 23.5), and in the control group was 14.2 minutes per day (IQR = 6.4, 22.4). There was no statistically significant difference between the two groups ($p = 0.900$). (Table 3)

Regarding decongestive massage, the median duration of massage in the control group's record was 11.7 minutes per day (IQR = 5.0-19.0). The median duration in the intervention group was 8.8 minutes per day (IQR = 4.8-18.3). There was no statistically significant difference between the two groups ($p = 0.641$). No other physical therapy intervention was reported. (Table 3)

Complications

36.4% of the control group reported minor adverse effects, such as discomfort, heat, sweating, and rash, while the percentage was 38.1% in the intervention group. There was no statistically significant difference in the occurrence of adverse effects between the two groups. No severe complications were reported by either group.

Table 3. Comparison of compliance and co-interventions in the intervention and control groups

Median duration (IQR)	Intervention	Control	*p*-value
Wearing compression garment (hours/day)	11.7 (4.7, 19.0)	13.4 (5.0, 20.0)	0.641
Neck and arm exercise (minutes/day)	14.2 (6.4, 22.4)	18.8 (9.5, 23.5)	0.900
Decongestive massage (minutes/day)	8.8 (4.8, 18.3)	11.7 (5.0, 19.0)	0.641

IQR, inter-quartile range

Discussion

The complex decongestive therapy (CDP) used in this study consisted of various techniques, including manual lymphatic drainage, compression garments, exercise, and skincare. This study's outcomes confirm previous studies' results that CDP can reduce arm volume and improve personal quality of life.[25-27]

The only difference in the type of therapy between the two groups was how the compression garment was tailored. Creating compression garments is intricate, involving multiple steps and often taking a significant amount of time. Insufficient pressure will not manage edema, and excessive pressure can be intolerable for the patient, cause pain on pressure points, or making the garment too difficult to wear. Consequently, the research team strived to introduce a new method for making compression garments that streamlines the process, making it efficient and practical.

The trial results indicate that, on average, the conventional technique reduced arm volume by 77.6 ml, while the new technique resulted in a greater reduction of 172.7 ml. However, statistical analysis revealed no significant difference between the two techniques. This lack of statistical significance may be attributed to the sample groups needing to reach the initially calculated statistical power.

However, looking at the tendency of arm volume reduction after three weeks of treatment, the new technique group showed a tendency for a more significant decrease compared to the conventional technique group. This trend might be explained by the longer duration of garment usage in the new technique group, with a median of 13.1 hours, while the conventional technique group had a median garment usage of 12.2 hours.

A review of the literature found that four studies directly evaluated the effectiveness of compression garments for breast cancer-related lymphedema.[17, 20, 28-29] Of the four studies analyzed, three compared Kinesio Taping to compression garments and one looked at nighttime compression. In addition, there was variability in garment pressure (20 to 60 mmHg), usage time (6.7 to 20 hours daily), and duration of the studies (3-24 weeks). McNeely, ML et al. demonstrated that increased wear time was correlated with improved lymphedema outcomes.[17] Due to the variations in pressure applied, usage time, and the duration of the studies, it is difficult to compare the results across these studies.

Regarding the adherence to the use of the compression garment, the lower-than-prescribed garment-wearing compliance may be due to the warm weather in Thailand, leading to sweating, minor skin issues, and discomfort among participants, which likely contributed to the reduced adherence to wearing the garments as recommended. Manufacturers of these garments have made great strides over the years in producing garments that are as lightweight and well-ventilated as possible. The rate of patients wearing compression garments as per recommendation in this study is consistent with a study from Turkey that found the rate of patients wearing compression garments as per recommendation was 51.7%.[30] The most common reasons for not wearing or discontinuing use included functional daily life difficulties (33.0%) and discomfort (28.8%). A Canadian study showed that only 31.0% reported adhering to wearing the garment for more than 12 hours each day because of user discomfort, negative emotions, interference with function, social situations, and visibility.[31]

Although standard information was provided to the patients, adherence to compression garment use was nonoptimal. Obstacles to adherence should be studied in detail to improve adherence to this method as it is the basis for maintaining treatment of lymphedema. A treatment program tailored to individual needs could be useful.

The results of this study demonstrate that the new simplified tailoring technique can reduce arm volume and enhance the quality of life for patients, with no statistically significant differences compared to the traditional technique. The new technique, however, does offer several advantages, including procedural simplicity, time savings for both healthcare providers and patients, and better suitability for implementation in busy hospital settings, making it a strong candidate for consideration. Thus, opting for the new technique for custom-made compression garments is a sensible choice.

However, from the patients' viewpoint, it is vital to account for additional expenses which may include travel costs and transit time to the hospital for measurements. Furthermore, since custom-made compression garments typically last around 4-6 months before requiring replacement, further exploration into the cost-effectiveness of this treatment method is warranted.

Study limitations

Due to time constraints, the number of participants recruited was slightly lower than planned, resulting in a smaller sample size. Therefore, it is important to interpret the results cautiously and to use larger sample sizes to confirm and strengthen the preliminary findings in future studies.

Another limitation of the study is the need for more control over the posture and daily activity of the participants. For posture, the recommendation to intermittently elevate the limbs has been a standard practice for lymphedema for an extended period[32] even though there is no evidence linking the severity of lymphedema to activities of daily living. One study showed that a controlled, short-duration arm exercise program can yield a small but significant increase in lymphoedema arm fluid immediately after exercise which returns to pre-exercise levels within 24 hours.[33] Thus, heavy arm activity similar to strengthening exercises should be considered a confounding factor.

Conclusions

Preliminary analysis showed no statistically significant difference between a custom-made compression garment and a standard garment in terms of arm volume reduction and quality of life improvement. Evaluation of the need for a less time-consuming tailoring method and patients' tendency to wear tailored garments for longer periods each day, suggests that the new simplified tailoring approach offers promising directions for a larger-scale study and in the future could be considered as a standard for producing compression garments.

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Conflicts of interest declaration

None

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Data availability

The data that support the findings of this research article are available from the corresponding author upon reasonable request.

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