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Efficacy of gradient compression sleeves in preventing postoperative upper extremity lymphoedema after breast cancer surgery

Submission date
28/01/2026

Recruitment status
No longer recruiting

Registration date
28/02/2026

Overall study status
Completed

Last Edited
27/02/2026

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Plain English summary of protocol not provided at time of registration

Contact information

Type(s)
Principal investigator, Scientific, Public

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Jiangsu Provincial Basic Research Program (Natural Science Foundation) and the Outstanding Youth Fund, Project Number:
BK20230017

Study information

Scientific Title
Efficacy of gradient compression sleeves

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 28/03/2023, Ethics Committee of The First Affiliated Hospital with Nanjing Medical University (No. 368 Jiangdong North Road, Gulou District, Nanjing City, Jiangsu Province, 210036, China; +86 025-86211033; jsphbsh@126.com), ref: 2023-SR-085

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Device feasibility

Study type(s)

Health condition(s) or problem(s) studied
Evaluate the efficacy of gradient compression sleeves in mitigating BCRL-related symptoms, improving limb function and enhancing quality of life in high-risk patients with breast cancer.

Interventions
Eligible patients were randomly assigned in a 1:1 ratio to either the intervention group or the conventional care group. The randomization sequence was generated using a computer-based random number generator by an independent statistician who was not involved in patient recruitment or outcome assessment. The allocation sequence was concealed using sequentially numbered, opaque, sealed envelopes (SNOSE). After a patient provided written informed consent and baseline assessments were completed, the treating therapist opened the next sequentially numbered envelope to reveal the group assignment.

Conventional Post-Breast Cancer Surgery Care for the Conventional Group
(1) Functional exercise of the affected upper limb: Given the surgical resection of chest muscles, fascia and skin, mobility of the affected shoulder joint was significantly restricted. Functional exercises were critical for restoring shoulder joint function and mitigating oedema. To minimise postoperative functional limitations, patients were encouraged and assisted to initiate functional exercises of the affected upper limb early postoperatively. Exercises adhered to the principle of gradual progression to avoid compromising wound healing.

(2) On post-operative day 2, following thrombosis exclusion, air wave limb compression therapy was initiated twice daily, with each session lasting 20–30 min. Patients who underwent ALND were instructed to perform manual lymphatic drainage (MLD) three times daily, with each session lasting 15 min; high-energy narrow-spectrum photon therapy was administered once daily for 20 min when indicated.
(3) Centripetal massage of the affected upper limb was performed under the supervision of healthcare professionals; alternatively, exercises including fist-clenching, elbow flexion, elbow extension and weight training were conducted. Weight training was performed slowly, with gradual increases in load to enhance lymphatic drainage; deep breathing exercises altered intrathoracic pressure, inducing movement of the diaphragm and intercostal muscles, thereby sustaining increased lymphatic drainage in the thoracic and abdominal cavities.
(4) For patients with severe limb swelling, elastic bandages were used for wrapping, or elastic sleeves were worn to promote lymphatic return; for those with local infection, antibiotics were promptly administered.
(5) Preventive education:
(i) Regular assessment of blood perfusion in the affected upper limb was performed, including evaluations of skin colour, temperature and presence of oedema.
(ii) Within 1 year postoperatively, blood pressure measurement, blood drawing and intravenous /subcutaneous injections were prohibited in the affected upper limb.
(iii) Patients were instructed to maintain skin hygiene and use skin moisturisers and cleansers with a neutral-to-weakly acidic pH, avoid all trauma to the affected limb and promptly manage skin lesions on the affected limb; therapeutic procedures on the affected limb were discouraged, and any infectious or allergic symptoms in the affected limb were treated immediately.
(iv) Dietary guidance included maintaining a balanced diet, prioritising foods rich in easily digestible protein (e.g. chicken, fish, tofu) and low in sodium and high in fibre, restricting sodium intake, maintaining ideal body weight and keeping BMI between 18.5 and 23.9.
(v) Patients were instructed to avoid loading the affected limb with >0.5 kg within 2–4 weeks postoperatively and >2.5 kg after 4 weeks; strenuous, repetitive or forceful eccentric movements of the affected limb were avoided. Deep breathing exercises and regular whole-body aerobic exercises were recommended, with caution to avoid excessive fatigue.
(vi) Maintaining unobstructed blood circulation in the affected extremity was emphasised, including avoiding tight clothing, underwire bras, excessively tight jewellery and affected-side lying; frequent movement of the affected extremity was advised to prevent prolonged immobility or dependent positioning of the affected limb, particularly during long-distance travel, air travel or high-altitude exposure – elastic sleeves were recommended during activities in these scenarios; cold exposure, saunas or prolonged hot baths (temperature >41) were avoided, with consistent water temperature maintained during showers or dishwashing; and tobacco use and alcohol consumption were prohibited.
(vii) Patients were instructed to perform early self-monitoring for lymphoedema (e.g. symptoms of dull ache, increased arm circumference) and seek prompt care at the lymphoedema clinic if abnormalities occurred.

Intervention Protocol for the Intervention Group
In addition to conventional care, patients in the intervention group received a 12-month gradient compression sleeve intervention. This study used upper extremity gradient compression sleeves with the specific protocol detailed below:
(1) Compression level selection – per the International Society of Lymphology (ISL) Consensus Guidelines, for preventive use, the selected sleeves delivered Class 1 gradient compression (20–30 mmHg), with the highest pressure intensity distally and a gradual decrease proximally.
(2) Individualised measurement and customisation
Measurements were performed by certified lymphoedema therapists on postoperative day 7.

During measurements, patients were seated with the affected upper limb kept relaxed. Measurement sites – with reference to the manufacturer's size chart, four circumferential measurements were taken precisely: wrist circumference, maximum forearm circumference, elbow circumference and maximum upper extremity circumference.
Size determination – measurement results were cross-referenced with the manufacturer's size chart to select the most appropriate standard size for each patient. For patients whose measurements fell between two standard sizes or with atypical limb morphology, the nearest standard size was chosen, or custom-fitted sleeves were recommended.
(3) Standardised wearing guidance
Therapists provided one-on-one guidance to patients and their primary caregivers per standard operating procedures.
Initiation and timing: The compression sleeve intervention was initiated on postoperative day 7. From this day forward, sleeves were applied each morning before getting out of bed (when limb oedema was minimal) and removed during nighttime rest.
Wearing technique: Therapists demonstrated and had patients practice the 'rolling method' repeatedly to avoid snagging the fabric with nails or accessories. Sleeves were ensured to be smooth and wrinkle-free, with the elbow joint aligned with the sleeve's elbow opening for uniform pressure distribution.
Skin preparation: Before sleeve application, the skin was ensured to be clean and dry. A hypoallergenic, non-irritating moisturiser could be applied and allowed to fully absorb to prevent skin dryness or pruritus.
Fit assessment: After sleeve application, fingers were checked for signs of numbness, tingling, cyanosis or excessive tightness. Patients were also asked about their subjective comfort to ensure sleeves fitted snugly yet comfortably without compromising blood circulation.
(4) Adherence maintenance and sleeve replacement
Adaptation period (days 7–10 post-op) – patients were instructed to wear the sleeves for 2–4 hours daily. Maintenance phase (from day 11 post-op onward) – after the initial adaptation, the wearing duration was gradually increased; the target maintenance dose was 8–12 hours of continuous wear during waking hours. Maintenance – sleeves were hand-washed daily using mild soap and water, then laid flat to air-dry; direct sunlight and machine drying were avoided to preserve compression efficacy and fabric durability. Replacement – patients were informed that compression efficacy would diminish after approximately 3–6 months of use or with a ±5% change in body weight; re-measurement and sleeve replacement were therefore necessary to ensure treatment efficacy.
(5) Adverse event management
Patients were instructed to discontinue use immediately and contact the research team if they experienced adverse reactions, such as skin breakdown, rash, exacerbated pain or swelling in the distal segments of the affected limb.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Gradient compression sleeve

Primary outcome(s)
1. Upper extremity circumference measurement, at the thenar eminence, wrist crease, 5 cm above the wrist crease, 10 cm below the elbow crease, 5 cm below the elbow crease, elbow

crease, 2.5 cm above the elbow crease, 5 cm above the elbow crease, 10 cm above the elbow crease and axillary horizontal line (axilla) measured using a measuring tape (during circumference measurements, marks were made on the arm aligned with the upper edge of the measuring tape to minimise measurement variability) at 90, 180 and 360 days

2. Symptom presence and symptom distress measured using the Breast Cancer Lymphoedema Symptom Experience Index (BCLE-SEI), which is a self-administered questionnaire using a 5-point Likert scale at 90, 180 and 360 days

3. Measurement of Joint Range of Motion (ROM) of the shoulder, elbow, wrist, fingers and the overall joints of the upper limb measured using a standard goniometer by a certified lymphedema therapist at 90, 180 and 360 days

Key secondary outcome(s))

Completion date
30/07/2023

Eligibility

Key inclusion criteria
1. Women aged ≥18 years
2. Histopathological or cytological confirmation of breast cancer
3. Surgical procedures restricted to two types:
3.1. Modified radical mastectomy (i.e. total mastectomy plus ipsilateral axillary lymph node dissection [ALND], using either the Auchincloss or Madden technique)
3.2. Breast-conserving surgery (i.e. segmental mastectomy plus ipsilateral ALND or sentinel lymph node biopsy followed by ALND if indicated)
4. Supraclavicular lymph node dissection was performed at the surgeon's discretion only if axillary lymph node metastases numbered ≥3
5. Classification as high-risk via the Post-Breast Cancer Lymphoedema Risk Assessment Scale (PBCL-RAS), with a threshold score of ≥13 points (consistent with the scale's validated high-risk cutoff); key risk factors assessed included body mass index (BMI) ≥ 25 kg/m², removal of ≥10 axillary lymph nodes, receipt of regional radiotherapy and taxane-based chemotherapy
6. Willingness to participate in the study

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
Female

Total final enrolment
104

Key exclusion criteria
1. History of psychiatric disorders
2. Impaired comprehension or reading ability
3. Severe dysfunction of major organs (e.g. heart, liver, kidneys)
4. Breast cancer being a metastasis from other malignant tumours rather than a primary cancer

Date of first enrolment
01/04/2023

Date of final enrolment
30/07/2023

Locations

Countries of recruitment
China

Sponsor information

Organisation
National Natural Science Foundation of China

ROR
https://ror.org/01h0zpd94

Funder(s)

Funder type

Funder Name
Youth Science Fund Project

Alternative Name(s)
National Outstanding Youth Science Fund Project of NSFC, National Science Fund for Excellent Young Scholars, National Outstanding Youth Science Fund Project of China, Outstanding Youth Science Fund Project of the National Natural Science Foundation of China, National Natural Science Foundation for Excellent Youth Science Fund Project of China, Youth Programs of National Natural Science Foundation of China, , National Outstanding Youth Science Fund Project of National Natural Science Foundation of China, IUSS

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
China

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available