

## Original Article



# Fascia Suture Technique Is a Simple Approach to Reduce Postmastectomy Seroma Formation

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## ABSTRACT

**Purpose:** Seroma formation is a common complication in breast cancer patients undergoing mastectomy, and it negatively affects patient recovery after surgery. The present study aimed to evaluate a simple method using fascia suture technique to fix the flap and reduce the incidence of seroma.


**Methods:** A single-center, prospective, randomized controlled trial was carried out among 160 patients who had undergone mastectomy from May 2018 to September 2019. All patients were randomly divided into the fascia suture group (n = 80) or control group (n = 80) and were followed up for at least 3 months for the assessment of immediate and late complications after surgery.

**Results:** No significant differences were observed between the 2 groups with regard to the basic characteristics. Duration of surgery in the fascia suture group was longer by about 6 minutes compared with that in the control group (114.93 ± 13.67 minutes vs. 108.81 ± 15.20 minutes, *p* = 0.008). The fascia suture group had a shorter duration of drain placement (10.99 ± 3.26 days vs. 13.85 ± 5.37 days, *p* < 0.001), a smaller volume of the total drainage (460.95 ± 242.92 mL vs. 574.83 ± 285.23 mL, *p* = 0.007), and the first 3-day drainage (224.96 ± 101.01 mL vs. 272.3 ± 115.47 mL, *p* = 0.006), compared with the control group. The incidence of seroma formation (G2 or G3) was significantly lower in the fascia suture group compared with the control group (28.8% vs. 12.5%, *p* = 0.033). Besides, there was no statistical difference between the 2 groups in the assessment of other complications, including postoperative pain, hematoma, surgical site infections, flap necrosis, and skin dimpling (all *p* > 0.050).

**Conclusion:** The fascia suture technique is a simple and effective method for reducing seroma formation and should be used to prevent seroma formation after mastectomy.

**Trial Registration:** Chinese Clinical Trials Registry Identifier: ChiCTR1800015913

**Keywords:** Breast neoplasms; Mastectomy; Fascia; Suture techniques; Seroma

Shiguang Zhu <https://orcid.org/0000-0003-1741-3090>**Trial Registration**Chinese Clinical Trials Registry Identifier:  
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**Conflict of Interest**

The authors declare that they have no competing interests.

**Author Contributions**

Data curation: Cao J; Formal analysis: Fang X; Investigation: Cong Y; Methodology: Zhang S; Project administration: Qiao G, Zou H; Supervision: Zhu S; Validation: Liu X; Writing - original draft: Cong Y; Writing - review &amp; editing: Zhu S.

## INTRODUCTION

Subcutaneous seroma formation, defined as the collection of serous fluid containing blood plasma or lymph under the flaps or in the axillary dead space, occurs frequently after mastectomy and axillary surgery. It has many adverse effects on patient recovery and subsequent treatment, including local discomfort and anxiety, repeated seroma aspirations, surgical site infection, skin flap necrosis, delay in wound healing and adjuvant therapies [1,2]. The incidence of seroma varies greatly in different studies, ranging from 3% to more than 90% [3,4]. However, the origin of seromas remains uncertain, although it is hypothesized that seromas form as an exudate from an acute inflammatory reaction following surgical trauma leading to increased serous fluid collection in response to increased fibrinolytic activity in serum and lymph [5]. Several risk factors have been extensively analyzed from previous studies, including age, breast size, type of breast surgery, extent of axillary lymph node (LN) involvement, and use of electrocautery [6,7]. However, reducing seroma formation is still a critical problem that is yet to be solved in breast cancer treatment.

In recent years, many studies have tried to find effective techniques for preventing seroma formation. On the whole, nearly all effective techniques have one common denominator: reduction of the dead space [8]. Several methods have been utilized to reduce the dead space, including closed suction drainage, quilting of the skin flaps, and application of adhesive tissue glues [9,10]. Among these techniques, mechanical flap fixation effectively reduces seroma formation and seroma aspiration in patients undergoing mastectomy, based on a systematic review [11,12]. However, in previous studies, nearly all authors fixed the flap by suturing the skin and subcutaneous tissue to the underlying muscles (pectoralis major muscle or pectoral fascia [13], latissimus dorsi muscle, or anterior serratus muscle) with several parallel rows of evenly spaced sutures at about 3–5 cm [14–20]. This continuous multirow fixation of the flap to the chest wall every 3 cm prolongs the duration of surgery and increases the patient's trauma. In our experience, seroma formation often occurred in the skin area of the anterior sheath of the rectus abdominis, the aponeurosis of the obliquus abdominis, and the surface fascia of the serratus anterior, while it rarely occurred in the skin area of the pectoralis major. This might be due to the poor blood supply and smooth contact surface between the subcutaneous fascia and the chest wall fascia, which is easily affected by constant chest wall and shoulder movement. Therefore, we introduced a simple fascia suture technique that involved only suturing the fascia, instead of the muscles, to obliterate the dead space conveniently, with the aim of reducing the duration of surgery. This prospective study aimed to evaluate the effect of fascia suture technique on the incidence of seromas.

## METHODS

### Design

A single-center, prospective, randomized controlled trial was carried out from May 2018 to September 2019 in Yantai Yuhuangding Hospital. The study protocol was approved by the ethical committees of the hospital and registered at ChiCTR (Chinese Clinical Trial Registry, No. ChiCTR1800015913). All participants were recruited and gave written informed consent prior to the surgery. Patients were randomly assigned equally to 2 groups using a computer generated randomizer. In the suture group, the fascia suture technique was used to fix the flaps to the underlying external oblique aponeurosis, together with the obliteration of the axillary space after mastectomy. In the control group, mastectomy was done in the

same way, but without suturing. Six surgeons and patients were all blinded throughout the duration of the trial. During the operation, patients were randomly selected for fascia suture, and the surgeons did not know the specific patient. The doctors who performed dressing change after the operation were also randomized and did not know which patients received a fascia suture.

### Patients

In total, one hundred sixty operable female patients undergoing mastectomy with a sentinel LN biopsy or axillary clearance were enrolled in the study. Patients with a recent history of using anticoagulants, diabetes, previous axillary surgery or bilateral breast cancer surgery, and those who had received neoadjuvant chemotherapy or immediate breast reconstruction were excluded from this study.

### Surgery

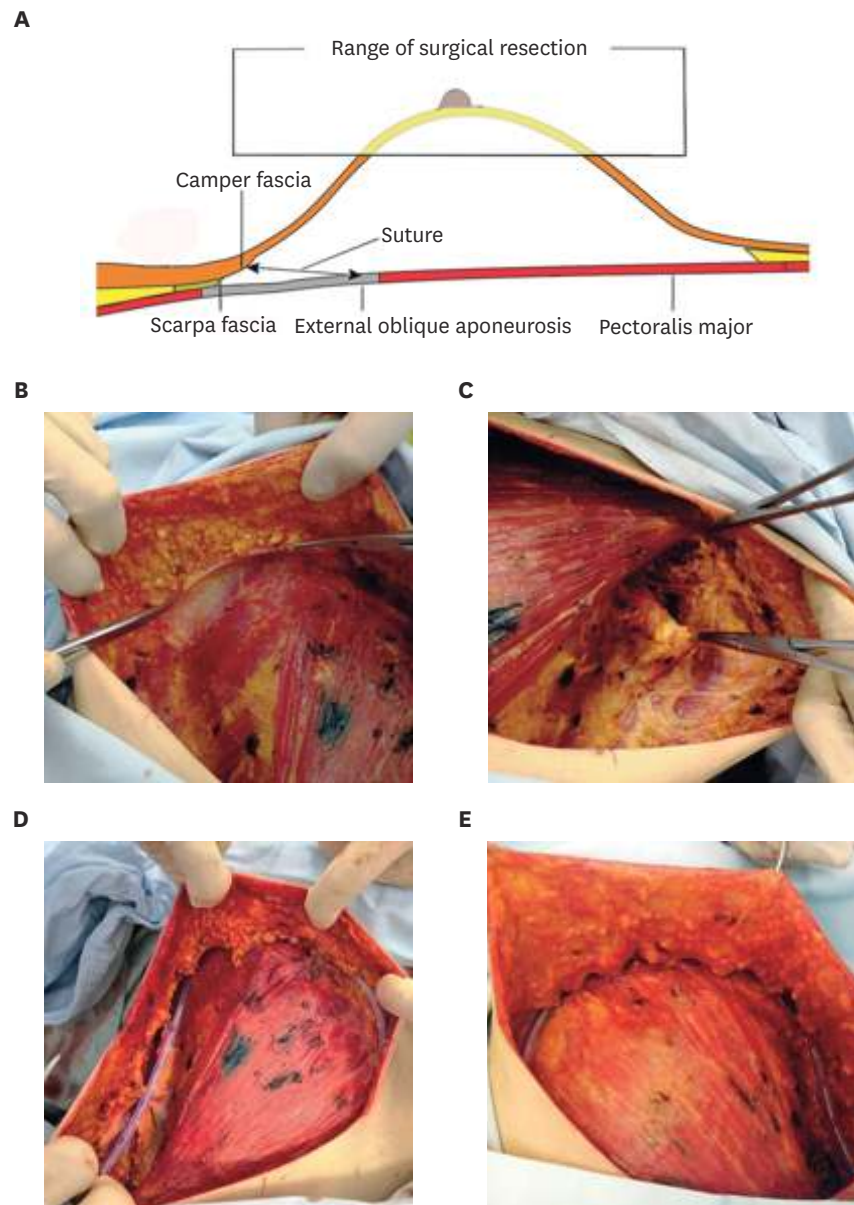
The surgery was performed using electrocautery in all patients, and the fascia of the pectoralis major was removed. Two 18F low-suction drains were placed in the axilla and the lower flap before closure of the skin. For the fascia suture group, a single row of absorbable sutures (Vicryl 4/0) was used to suture the edge of camper (or scarpa) fascia to the external oblique aponeurosis and the anterior serratus fascia to obliterate the smooth contact surfaces. We introduced 2 methods for fascia suture, interrupted and continuous, in order to evaluate which method was more convenient and time-saving. For patients with a clearer fascia, continuous suture was used, otherwise interrupted suture was applied. For patients without axilla clearance, the axilla residual cavity was obliterated by a continuous suture of the clavipectoral fascia (**Figure 1**).

### Follow-up

The 1-10 pain scale was used to evaluate the pain experienced by the patients 3 days after the surgery. Patients were usually discharged on the third postoperative day with instructions for home drain care. The drain was removed when the 24-hour effluent was less than 20 mL for 3 days. The volume of drainage fluid, the duration till the drain removal, and the occurrence of seromas were recorded. The Common Terminology Criteria for Adverse Events Classification 4.0 was used to evaluate the grading scale for seromas, as follows: grade 0: without seroma formation; grade 1: asymptomatic, clinical, or diagnostic observation only, intervention not indicated; grade 2: symptomatic, medical intervention is indicated; and grade 3: severe symptoms, radiological, endoscopic, or elective surgical intervention indicated. All patients were followed up routinely for at least 3 months post-surgery.

### Statistical analysis

Statistical analysis was performed using SPSS 25.0 (IBM Corporation, Armonk, NY, USA). Data are shown as frequencies and percentages for categorical data, and mean  $\pm$  standard deviation for continuous data. Categorical variables were analyzed using the  $\chi^2$  test or Fisher's exact test. Continuous data was examined using independent-samples *t*-tests. Differences were considered significant when *p*-values were less than 0.050.



**Figure 1.** (A) Diagrammatic sketch of the fascia suture technique. (B) Vascular forceps showing camper (or scarpa) fascia. (C) Vascular forceps showing clavipectoral fascia, which will be closed. (D) The fascia interrupted sutured in a left breast. (E) The fascia continuously sutured in a right breast.

## RESULTS

### Basic characteristics of the patients

A total of 160 breast cancer patients were enrolled in this study, with 80 cases assigned to the control group and the other 80 to the fascia suture group. Baseline characteristics of the patients are presented in **Table 1**. There was no significant difference between the 2 groups with respect to age, body mass index (BMI), hypertension, menstrual status, pathology type, tumor size, and histological grade (all  $p > 0.050$ ). Additionally, surgery type, number of resected (LNs), and positive LNs all revealed no significant differences (all  $p > 0.050$ ). Duration of surgery was longer in the fascia suture group by about 6 minutes ( $p = 0.008$ ). When continuous

**Table 1.** Baseline characteristics of breast cancer patients

Characteristics	Control group (n = 80)	Suture group (n = 80)	p-value
Age (yr)	49.34 ± 9.43	50.91 ± 9.78	0.301
BMI (kg/m <sup>2</sup> )	24.47 ± 3.32	25.19 ± 3.09	0.159
Hypertension	10 (12.5)	7 (8.8)	0.442
Menopause	30 (37.5)	28 (35.0)	0.742
Pathologic type			0.650
Ductal	78 (97.5)	77 (96.3)	
Others	2 (2.5)	3 (3.8)	
Tumor size (cm)	2.18 ± 0.79	2.02 ± 0.57	0.143
Grade			0.189
G1	12 (15.4)	21 (27.3)	
G2	53 (68.0)	46 (59.7)	
G3	13 (16.7)	10 (13.0)	
Gx	2	3	
Surgery type			0.495
Mastectomy + ALND	27 (33.8)	23 (28.8)	
Mastectomy + SLNB	53 (66.3)	57 (71.3)	
Number of resected LN	7.61 ± 7.32	6.19 ± 6.03	0.181
Number of positive LN	1.31 ± 2.67	1.19 ± 2.50	0.760
Operative time (min)	108.81 ± 15.20	114.93 ± 13.67	0.008
Interrupted suture (n = 49)	-	116.51 ± 15.21	0.194
Continuous suture (n = 31)	-	112.42 ± 10.56	

Patient characteristics are presented as mean ± standard deviation or frequency (%).

BMI = body mass index; ALND = axillary lymph node dissection; SLNB = sentinel lymph node biopsy; LN = lymph node.

suture was used, the surgery time was reduced by about 4 minutes than in the interrupted group, but this difference did not show any statistically significant difference ( $p = 0.194$ ).

### Risk factors for seroma formation

Clinical data were analyzed to explore the risk factors for seroma formation. As shown in **Table 2**, the total amount of drained fluid, axillary LN dissection, number of resected LNs, and positive LNs were risk factors for seroma formation (all  $p < 0.050$ ). Further, age,

**Table 2.** Clinical factors associated with seroma

Variable	Seroma		p-value
	G0 or G1 (n = 127)	G2 or G3 (n = 33)	
Total amount of drained fluid (mL)	493.25 ± 258.33	612.70 ± 297.13	0.023
Drained fluid in the first 3 days (mL)	239.63 ± 102.39	283.27 ± 134.42	0.089
Days of drain removal	12.09 ± 4.71	13.70 ± 4.28	0.076
Age (yr)	50.40 ± 9.80	49.06 ± 8.86	0.477
BMI (kg/m <sup>2</sup> )	24.75 ± 3.39	25.14 ± 2.46	0.543
Tumor size (cm)	2.05 ± 0.69	2.31 ± 0.64	0.050
Hypertension			0.754
Yes	13 (10.2)	4 (12.1)	
No	114 (89.8)	29 (87.9)	
Menopause			0.673
Yes	45 (35.4)	13 (39.4)	
No	82 (64.6)	20 (60.6)	
Pathologic type			0.972
Ductal	123 (96.9)	32 (97.0)	
Others	4 (3.2)	1 (3.0)	
Surgery type			0.005
Mastectomy + ALND	33 (26.0)	17 (51.5)	
Mastectomy + SLNB	94 (74.0)	16 (48.5)	
Number of resected LN	6.02 ± 6.22	10.30 ± 7.57	0.004
Number of positive LN	0.89 ± 1.97	2.64 ± 3.90	0.017

Variables are presented as mean ± standard deviation or frequency (%).

BMI = body mass index; ALND = axillary lymph node dissection; SLNB = sentinel lymph node biopsy; LN = lymph node.

**Table 3.** Comparison of postoperative outcome

Variable	Control group (n = 80)	Suture group (n = 80)	p-value
Postoperative pain (3 days)	7 (8.8)	5 (6.3)	0.533
Days of drain removal	13.85 ± 5.37	10.99 ± 3.26	< 0.001
Total amount of drained fluid (mL)	574.83 ± 285.23	460.95 ± 242.92	0.007
Drained fluid in the first 3 days (mL)	272.3 ± 115.47	224.96 ± 101.01	0.006
Seroma			
G0 or G1	57 (71.3)	70 (87.5)	
G2 or G3	23 (28.8)	10 (12.5)	0.011
Hematoma	2 (2.5)	1 (1.3)	1.000
Surgical site infections	2 (2.5)	1 (1.3)	1.000
Flap necrosis	4 (5.0)	3 (3.8)	1.000
Skin dimpling (3 mo)	2 (2.5)	5 (6.3)	0.443

Variables are presented as mean ± standard deviation or frequency (%)

hypertension, BMI, and menstrual status had no influence on the development of seromas in the present study (all  $p > 0.050$ ).

### Fascia suture reduces seroma formation

We further explored the effects of the fascia suture technique on seroma formation. The results show that the duration of drain removal was significantly shorter in the fascia suture group than in the control group (10.99 ± 3.26 days vs. 13.85 ± 5.37 days,  $p < 0.001$ ). Similarly, the fascia suture group had less total drainage volume (460.95 ± 242.92 mL vs. 574.83 ± 285.23 mL,  $p = 0.007$ ) and lesser amount of drainage in the first 3 days ( $p = 0.006$ ) than the control group. Additionally, the incidence of seroma (G2 or G3) in the fascia suture group after the drain was removed was significantly lower compared with that of the control group (12.50% vs. 28.75%,  $p = 0.011$ ). There were no significant differences between the 2 groups with regard to postoperative pain (3 days), hematoma, surgical site infection, flap necrosis, and skin dimpling (3 months) (all  $p > 0.050$ ) (**Table 3**).

## DISCUSSION

Seroma formation post-mastectomy has been a concerning complication in breast cancer surgery for many years, due to its many side effects, including patient discomfort, high risk of infections, repeated outpatient clinic visits, and even surgical reinterventions [21]. Considerable research has been undertaken to clarify its pathophysiology, but the exact mechanism remains unclear [10]. Axillary clearance was reported as an important predictive factor for seroma formation [22], which might be explained by the fact that the dead space in the axillary space cannot be closed properly. Our results show that axillary LN dissection and the number of resected LNs were risk factors for seroma formation, which is in accordance with the result of a previous study [22].

Although the application of closed suction drainage has acquired a pivotal position in reducing seroma formation in the last few decades, greater efforts are still needed to reduce it further. In recent years, several studies focusing on reducing dead space by flap fixation have presented some convincing evidence for the prevention of seroma formation [12,14-16,23]. According to previous studies, the incidence of seroma formation decreased from 40%–80.5% to 10%–35.9% when flap fixation was applied [12,14-16,23]. In the present study, the incidence of seroma formation significantly decreased, from 28.8% to 12.5%, which was a little lower than but similar to previous studies. The reason for this difference may be that the criterion

for drain removal in our study was 24-hour effluent being less than 20 mL for 3 days, whereas in most previous studies, it was less than 50 mL. The techniques used for flap fixation in these studies are quilting or tissue glue. Retrospective and prospective studies have demonstrated a lower incidence of seroma formation in patients undergoing mechanical flap fixation. In the retrospective studies published by van Bastelaar et al. [16,17], flap fixation was found to be an effective surgical technique for reducing seroma formation and aspirations in patients undergoing mastectomy. The randomized controlled trial by Khater et al. [13] showed very clear differences in seroma formation aspirations in favor of flap fixation.

Few studies have evaluated the role of tissue glues in preventing seroma formation. In a Cochrane review in 2013 [24], flap fixation using Fibrin Glue (Tisseel) had no influence on incidence of seroma formation, mean volume of seroma, wound infections, complications, and length of hospital stay after mastectomy. In a retrospective study by Eichler et al. [25], seroma formation was nearly significantly higher in the intervention (TissuGlu) group. However, Granzier et al. [18] recently published an interim analysis of a prospective randomized controlled trial (seroma reduction after mastectomy-trial, SAM TRIAL) which revealed that mastectomy followed by flap fixation with either sutures or adhesive tissue glue reduces the number of seroma aspirations. Therefore, the effectiveness of tissue glues in preventing seroma formation is still controversial, and more studies are required to evaluate its effect in relation to flap fixation.

Based on the above studies, mechanical fixation of the flap seems to be an effective approach for reducing seroma formation. However, the duration of surgery in these studies was prolonged significantly, ranging from 7–20 minutes [13,15,19], which is not a small issue for patients and should not be ignored. In order to simplify the process of flap fixation and reduce the duration of surgery, we introduced a simple and effective technique, called fascia suture technique, which involves suturing only the fascia and not the muscle. Simplicity is the greatest advantage of the fascia suture technique, especially with the use of a continuous suture. In contrast to previous studies, our trial was a prospective, randomized controlled study which demonstrated that the duration of surgery in the fascia suture group was longer only by about 6 minutes compared with that of the control group, and if continuous suture was used, the duration of surgery was longer only by about 4 minutes, which is significantly shorter than that reported in most previous studies. Meanwhile, seroma formation was significantly reduced when the flap was fixed or the axillary dead space was closed using the fascia suture technique. Dimpling of the skin has been seen as a disadvantage of using sutures for flap fixation [14]. In our study, all surgeons were trained in placing the sutures in a standard way, and special care was taken to avoid skin dimpling. All doctors participating in this trial were trained through operation skill explanation and operation demonstration. During flap fixation, one doctor pulled the flap upward to bring it closer to the state of the flap suture, and the other doctor fixed the flap. Before suturing the flap, the doctor should pull the 2 sides of the flap together and if there is skin dimpling, then they should remove the fixation from that point and select another fixation point, until there is no obvious dimpling in the flap. The results showed no differences in dimpling of the skin between the 2 groups on follow-up for 3 months. Even if there was skin dimpling, it seemed to decrease over time, when following up for 1 year [18]. Overall, the fascia suture technique did not worsen common complications.

Taken together, compared with the traditional suture method, the fascia suture technique is an effective and simple approach to reduce postoperative seroma formation and duration

of wound drainage. Furthermore, the technique did not increase the duration of surgery significantly. Therefore, the fascia suture technique should be applied as a routine procedure at the end of mastectomy, especially in patients with risk factors for seroma formation.

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