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ORIGINAL ARTICLE

Effect of Quilting Technique versus Fibrin Glue on Post Mastectomy Seroma

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ABSTRACT

Background: Breast cancer ranks as the second most common cancer worldwide and by far the most prevalent cancer among women. A common side effect following a modified radical mastectomy or wide local excision with lymph node dissection is the buildup of fluid and Seroma.

Methods: This study included 150 female patients who underwent mastectomy due to cancer. It was a prospective, randomized, and controlled study where they were divided into three groups at random: group I consisted of fifty women who had fibrin glue sprayed on their axilla and mastectomy bed and had suction drains placed. In group II, fifty women had flap fixation using sutures with low vacuum drainage. In group III, fifty women had traditional closure with low vacuum drainage.

Results: With a mean of 489±188.7 ml , patients with quilted flaps in our study showed the lowest seroma volumes with a statistical significance (p value < 0.001). Quilting sutures reduced the frequency of aspiration, with a lowest median of 2.0 (0-3) (P = 0.046). It also had the lowest number of drain reinsertion, with a statistically significant difference (P = 0.029). The mean drainage periods for Group I and Group II were found to be 9 and 5 days, respectively (P = 0.03). **Conclusion:** Our research led us to conclude that quilting flaps following mastectomy is a useful strategy for significantly cutting down on the amount of time and volume of wound drainage and reducing postoperative seroma.

Keywords: Quilting Technique, Fibrin Glue, Post mastectomy seroma, Breast cancer

INTRODUCTION

Breast cancer ranks as the second most common cancer worldwide. Globally, it has an incidence that ranges from 27 per 100,000 in Middle Africa and Eastern Asia to 96 in west of Europe with a roughly fourfold variation [1].

In the United States, women between the ages of 30 and 49 account for around 19% of all breast cancer diagnoses, while women 65 and older account for 44%. Due to the low median age of the African population, which is typically 20 years or younger, breast cancer diagnoses in young women account for a higher attribution of cases than amongst older women in most African nations [2].

Compared to women in the US and Europe, Arab women present with breast cancer on average ten years sooner. In Arab communities, 48 years was the median age when first diagnosed, and nearly two thirds of patients are less than 50 years of age. In Egypt, there were around 22,700 breast cancer cases in 2020, and that figure is expected to rise to about 46,000 by 2050 [3].

The standard of care for early breast cancer is surgery, either with or without radiation. In cases where there are poor prognostic indicators, such as nodal affection, suggesting a high risk of metastatic recurrence, systemic medication, such as hormone therapy or chemotherapy, is added [4].

A common side effect following a modified radical mastectomy (MRM) or wide local excision with axillary lymph node dissection is buildup of fluid and seroma. Seroma raises risk of wound infection and delays the initiation of chemotherapy since it slows down healing. A great deal of study has been

done on postoperative seroma reduction [5].

The most frequent early consequence, seroma, is the accumulation of fluid in the dead space of the breast, axilla, or under skin flap after MRM or breast conserving surgery (BCS). Nonetheless, the definition of seroma varies throughout published studies. This suspected issue might lengthen hospital stays, slow down healing, and put a strain on the health system's finances. There is a large range in the reported incidence of seroma development, from 15 to 81% [2].

Three risk factors raise the chance of seroma production include obesity, diabetes mellitus, and hypertension. Though opinions regarding their respective roles in its pathogenesis vary, iatrogenic post mastectomy seroma may result from extensive dissection and axillary lymphadenectomy, high number of positive nodes, adjuvant radiation, and whether or not intraoperative lymphatic channel ligation was performed. The primary pathophysiology of seroma is currently unclear and up for debate [6].

Seroma's low fibrinogen levels throughout the postoperative period, when compared to plasma levels, lend credence to the theory that seroma most likely originates from lymph. Based on the theory that fluid buildup may be facilitated by fibrinolytic activity in serum and lymph, a fibrinolysis inhibitor was used. A combination of materials known as "human fibrin glue" (HFG) has sealing and hemostatic qualities. By aiding in hemostasis and healing, HFG can stop leaking via lymphatics and blood arteries, reducing the risk of seroma development, allowing for early drain removal and a shorter hospital stay [7].

The goal of quilting suture is to preserve the tissue planes' integrity. The anatomical dead space left over after a mastectomy is eliminated by quilting. Before the incision is closed, it entails inserting interrupted absorbable sutures between the pectoral muscle and the mastectomy flap [8].

This study aimed to improve mastectomy outcome through the assessment and comparison of the efficacy of fibrin glue versus flap fixation using sutures in reducing post mastectomy seroma.

METHODS

This is a prospective randomized controlled study that was carried out at **s**urgery department, outpatient's clinics, at Suez Canal University hospital in Ismailia city during the period between 2022 and 2024. After ethical approval, this study included female patients diagnosed with operable breast cancer and scheduled for mastectomy based on the following criteria:

Inclusion Criteria:

Female patients who were above the age of eighteen and whose breast cancer stage was I, II, or III were scheduled for a modified radical mastectomy along with axillary clearance surgery. They also had to have no prior history of steroid use, chest radiation, or chemotherapy (neoadjuvant).

Exclusion criteria

Patients with an abnormal coagulation (platelets count <99,000/mL), bleeding disorder, or a history of anticoagulant treatment were excluded. Also patients scheduled for BCS, immediate reconstruction, or sentinel lymph node biopsy (SLNB) were excluded. All women who are nursing or pregnant, and those with recurrent breast cancer were excluded as well.

Sampling:

Sample size calculation was performed using G*Power version 3.1.9.2, Faul et al, (2007 & 2013) Kiel University, Germany. (c) 1992-2014.

Using a computer-generated random number, 150 female were randomly split into three equally sized groups. Group I (Fibrin Glue Group): 50 women undergoing suction drain implantation and fibrin glue sprayed on their axillary and mastectomy beds. Fifty women in Group II (Quilting Group) had flap fixation to underlying muscles with low vacuum drainage. Group III (Control Group): Fifty women had low vacuum drainage and traditional closure.

A) ***Pre-operative assessment:***

● Demographic data were documented followed by careful history of the current condition and past history including previous surgeries as well as any postoperative or anesthetic complications.

● Clinical assessment including general and breasts examination were carried out and other systems related to fitness for surgery and anesthesia. Also co-morbidities, serum albumin level and breast mass size were recorded.

B) ***Operative Technique:***

All patients had MRM using same technique minimizing the use of cautery as much as possible with meticulous hemostasis.

1. **Group I (Fibrin glue)**

The fibrin sealant was prepared at the blood bank of Suez Canal University just before the operation.

1. Human thrombin, 10 ml of patient blood in plain tubes, the tubes are left for 30 minutes till clotting then centrifuged at 3600 rpm for 12 minutes, collect supernatant as autologous thrombin.

2. Human fibrinogen 10 ml cryoprecipitate the same

blood group of the patient.
3. 2 ml calcium gluconate.
Adding thrombin to fibrinogen resulted in fibrin formation and coagulum occurs.

Intervention methods:

Study uses the (fibrin glue of Suez Canal University Blood Bank). The mixture would be sprayed, after complete drying of the field, 8 ml for potential dead space under the mastectomy flaps and the 16ml to the axillary bed. After the mixture being sprayed, gentle pressure applied for not less than 5 minutes over the flaps and the wound is closed in layers as rapid as possible.
Lastly, drains were put and postoperative data were recorded.

2. Group II (Quilting flap)

In the quilting group multiple interrupted absorbable sutures were taken between the flaps and the underlying pectoralis muscle using 2/0 vicryl obliterating the potential dead space underneath the mastectomy flap. Distance between sutures was placed to be 4-5cm with care to avoid skin dimpling. No sutures were used in the axilla.

3. Group III (conventional closure)

C) ***Post-operative follow up:***

Drained fluid was recorded daily till drain removal. Hospital stay, Length of drain placement, wound infection or need for drain reinsertion was recorded. Drain usually removed when its output below 50 ml per day or maximum period of 14 days .

Statistical analysis

Data analysis was done using Statistical Package for Social Science version 26 (SPSS Inc., Chicago, IL, USA). Quantitative variables expressed in means and standard deviation while qualitative variables expressed in numbers and percent. Parametric quantitative variables between groups were compared using Kruskal Wallis test while for qualitative variables chi-square (X_2) test was used or Fisher's exact test when frequencies were below five. A P value < 0.05 is considered significant.

RESULTS

This prospective randomized controlled study was meant to involve 150 female patients with operable breast cancer. They were splitted into three groups:

- Group I (Fibrin Glue Group): 50 women having mastectomy bed and axilla sprayed by fibrin glue and suction drain placement.
- Group II (Quilting Group): 50 women had mastectomy flaps fixed but quilting to underlying muscles with low suction drainage.
- Group III (Control Group): 50 women conventional closure after mastectomy with low suction drainage.

Patients' characteristics including demographic data, BMI, and co-morbidities is shown in table 1. Which were evenly distributed between the three groups without any statistical difference.
There were no statistically significant difference between the three groups in regard to breast size or weight of resected specimen where most of the patients had a weight between 1000 to 3000 gm distributed throughout the comparison groups. (Table 2) Also seen in the same table that most of our Patients had invasive duct carcinoma with no difference between groups in distribution. Most of the patients had stage II disease with 92, 90, 96% distributed across groups I, II, and III. Also tumor sizes and number of retrieved lymph nodes were shown in table 2 without any substantial difference that could affect results between groups statistically.
The results showed that the seroma volumes were lowest with quilting sutures with mean of 489±188.7 mL with statistical significant difference (P<0.001). Quilting technique reduced the number of aspirations with lowest median of 2.0 (0-3) (P = 0.046). Also, quilting sutures had the lowest rate of drainage reinsertion with statistical significant difference (P = 0.029). (Table 3)
The mean period till drain removal was nine days in group 1 and five days in group II, and eleven days in group III that revealed a statistically significant difference (P = 0.03) between the groups in favour to the quilting group.. However, hospital visits periods showed no statistically significant difference between tween groups (P = 0.109). (Table 4) & (Fig. 1)

In view of the retrieved number of axillary lymph nodes, there was a significant correlation (p < 0.001) between the number of removed nodes and the seroma volume. Using a post hoc test, it was discovered that when more than 25 nodes were removed, a more seroma volume was accumulated in comparison other groups (p < 0.001), and that when removed nodes were between 15 and 25 the seroma volume was more than with fewer than 15 nodes (p < 0.001). (Fig. 2)

Table 1: Baseline characteristic of the study groups.

Variables	Group I (n=50)	Group II (n=50)	Group III (n=50)	P-value
Age (Years)	**44.25 ± 1.37**	**46.4 ± 1.57**	**45.4 ± 1.57**	**0.375[1]**
BMI (kg/m2)	**26.5 ± 3.46**	**25.45 ± 2.52**	**26.82 ± 3.33**	**0.432[1]**
Comorbidities				
✓ **CVD**	18(36%)	10(20%)	19(38%)	**0.241[2]**
✓ **HTN**	10(20%)	16(32%)	7(14%)	
✓ **DM**	12(24%)	15(30%)	17(34%)	
✓ **Others**	8(16%)	10(20%)	8(16%)	

1: Student t test used. 2: Chi square test used. *Statistically significant as p<0.05.

Abbreviations: BMI; body mass index, CVD; cardiovascular disease, HTN; hypertension, DM; diabetes mellitus.

Table 2: Clinicopathologic data of the study groups:

Variables	Group I (n=50)	Group II (n=50)	Group III (n=50)	P-value
Breast size				
✓ **500-1000g**	8(16%)	6(12%)	5(10%)	
✓ **>1000-<3000g**	39(78%)	40(80%)	43(86%)	**0.360[1]**
✓ **>3000g**	3(6%)	4(8%)	2(4%)	
Pathology				
✓ **IDC**	44(88%)	46(92%)	48(96%)	
✓ **ILC**	3(6%)	1(2%)	1(2%)	**0.155[1]**
✓ **Others**	3(6%)	3(6%)	1(2%)	
TNM Stage				**0.969[1]**
✓ **II**	46(92%)	45(90%)	48(96%)	
✓ **III**	4(8%)	5(10%)	2(4%)	
Number of lymph nodes				**0.302[1]**
≤15	10(20%)	11(22%)	9(18%)	
15-25	28(56%)	25(50%)	30(60%)	
>25	12(24%)	14(28%)	11(22%)	
Tumor size				
≤3cm	14(28%)	16(32%)	14(28%)	
3-5cm	30(60%)	32(64%)	29(58%)	**0.572[1]**
>5cm	6(12%)	2(4%)	7(14%)	

1: Fisher exact test used. *Statistically significant as p<0.05.

Abbreviations: IDC; invasive ductal carcinoma, TNM; Classification of Malignant Tumors, ILC; invasive lobular carcinoma.

Table 3: Primary outcome results of the study groups.

	Group I (n=50)	Group II (n=50)	Group III (n=50)	P-value
Volume of seroma (mL)	578±210.8	489±188.7	1180±382.5	**<0.001*[1]**
Frequency of aspiration	4(1-6)	2(0-3)	6(3-8)	**0.046*[2]**
Hemo VAC reinsertion (%)	5(10%)	2(4%)	7(14%)	**0.029*[3]**

*1: ANOVA test used. 2: Kruskal Walli's test used. 3: Fisher exact test used. *Statistically significant as p<0.0*

Table 4: Secondary outcome results of the study groups.

	Group I (n=50)	Group II (n=50)	Group III (n=50)	P-value
Post-operative infection	6(12%)	4(8%)	8(16%)	**0.342**[1]
Hospital visits periods (day)	14(13-15)	11(10-14)	17(14-21)	**0.109**[1]
Period till drain removal (day)	9(8-10)	7(5-9)	11(9-14)	**0.030**[1]

*1: Fisher exact test used. 2: Kruskal–Walli's test used. *Statistically significant as p<0.05.*

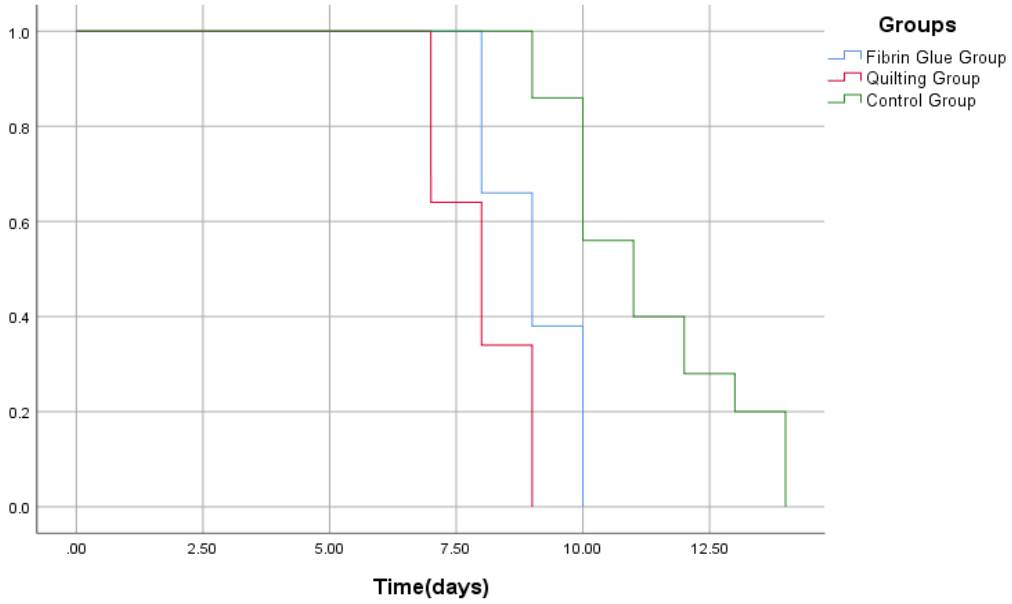

Figure 1: Time to drain removal among the study groups.

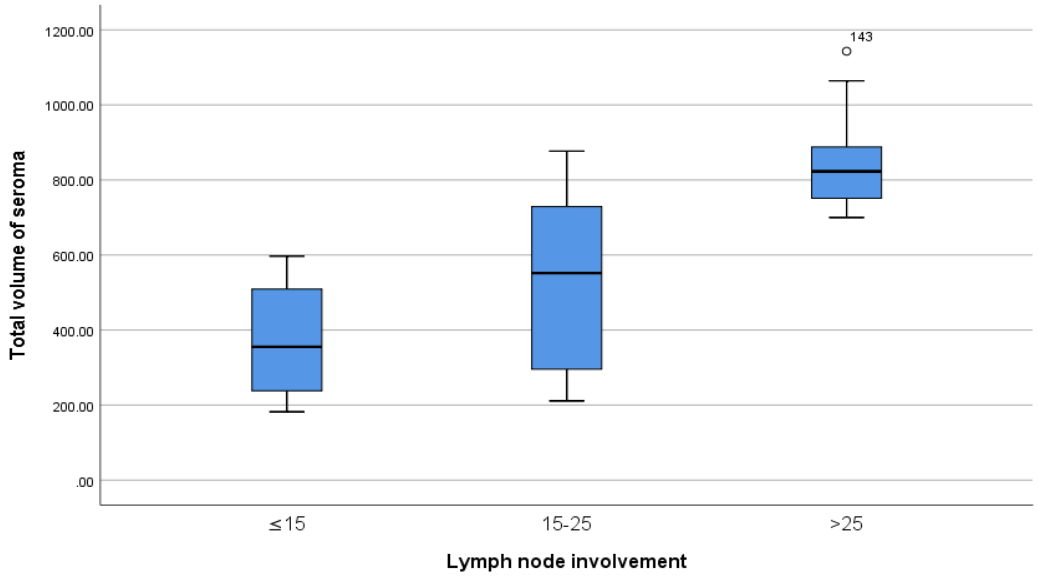

Figure 2: Association between total volume of seroma and lymph node involvement.

DISCUSSION

Sequential aspiration is necessary for patients who experienced seroma in a postoperative clinical assessment. Sometimes aspiration is insufficient to remove seromas; in such cases, reoperation is necessary to enable fibrinous loculations to be debrided. Patient morbidity and extra treatment costs are reduced when seromas are prevented. Additionally, postponing adjuvant chemotherapy and radiation therapy is prevented by reducing seroma. Although the exact etiology of seroma production is yet unclear, the cause of seroma appears to be complex [5].

According to Schwabegger et al., thermal injury to tissue raises the incidence of seroma fluid accumulation, and electrocautery usage is a key contributing agent in seroma production following MRM [10].

According to Jain et al., seroma may be lymphatic leaks or transudates low in protein. These might be plasma filtrates. On the other hand, they suggested that it may be due to enhanced capillary permeability, leading to exudates that are rich in protein and frequently seen in inflammatory stage of healing process. It's interesting to note that a number of studies have demonstrated how drains can aggravate the inflammatory phase by extending it, which in turn promotes seroma production [12].

After mastectomy and axillary clearance, there is a significant surgical dissection and tissue disruption that causes a potential dead space leading to seroma production [9].

Restoring integrity and probity of tissue planes and eliminating resultant dead space are two goals shared by quilting technique and fibrin glue. Fibrin sealant was found by Saltz et al. to decrease seroma development under different surgical conditions [13].

Quilting sutures alone did not minimize seroma development, aspiration frequency, or drainage period duration as well as fibrin sealant and quilting sutures together did, according to Ebner et al. Furthermore, it is priceless when a patient has less difficulty and suffering [2].

Consequently, the goal of this study was to enhance mastectomy outcomes. In this prospective, randomized, controlled research, 150 individuals with operable breast cancer were examined. Three patient groups were created: group I (Fibrin Glue Group) involved fifty women who had suction drain placement and fibrin glue sprayed on their axillary and mastectomy beds; group II (Quilting Group) consisted of fifty women mastectomy flaps fixed by sutures to underlying muscles with low suction drainage; and group III (Control Group) consisted of fifty women who had conventional wound closure.

The quilted sutures in the current investigation had the lowest seroma volumes, with a mean of 489±188.7 mL with a difference that is statistically significant (P<0.001). The frequency of aspiration was decreased with quilting sutures, with the lowest median of 2.0 (0-3) (P = 0.046).

The least amount of drainage reinsertion was also seen with quilting sutures, showing a statistically significant difference (P = 0.029).

This is consistent with a previous study of two breast cancer hospitals conducted a combined prospective and retrospective analysis to examine the impact of quilting after mastectomy. Both prospective cohort and combined cohort showed a substantial decrease in the incidence of Cancer Specific Survival (CSS), despite the quilting approach requiring an extra 10 minutes of surgery time. After quilting, there was a significant decrease in non-aspirated seroma, bleeding problems from surgical site infections (SSI), and other wound complications. Shorter hospital stays and fewer postoperative trips to the outpatient clinic were the outcomes of quilting. Analgesic usage and postoperative shoulder function did not substantially differ between the two cohorts in a prospectively examined group of patients [8].

Ten patients who had mastectomy procedures were given a quilting method, according to Titley et al. Using interrupted polydioxanone sutures spaced 3–4 cm apart, they quilted the mastectomy flaps to underlying tissues in numerous layers. Following the application of the quilting technique, seroma rates decreased from 56% to 0% [14].

In order to completely eliminate dead space following a mastectomy, Coveney et al. stated using quilting technique. They discovered that seroma occurrences were 25% in quilted group and 85% in non-quilted group ($p < 0.001$). The current study's findings are consistent with this where the quilted cohort's CSS incidence was 12.9%, and in the non-quilted was 62.3% ($p<0.001$) [16].

Similar findings were reported by Ouldamer et al., who found that quilting reduced seroma from 21.7% to 6.8% ($p = 0.03$). After the presence of CSS, there was no much difference observed in term of volume or number of aspirations per patient among the cohorts in this investigation [17].

One known risk factor for SSI is CSS. The results of this study indicate a correlation between quilting and SSI, with the quilted group experiencing SSI at a considerably lower rate in comparison to non-quilted group (5.0% vs. 14.0%; $p = 0.013$) [18].

An analogous decline in seroma and problems related to seroma was previously shown [19]. The CDC standards state that SSI must happen no later than 30 days following a surgical procedure. It's possible that the number of wound infections that follow mastectomy is underreported in the literature since wound infections induced by seroma might happen both within the first 30 days or beyond. According to the current study, quilting reduces the incidence of wound healing issues and bleeding complications [20].

There are established risk factors that preclude ailments to function of both shoulder and arm, including mastectomy and ALND. The shoulder girdle's range of motion and muscular strength are adversely affected by the discomfort, sensory abnormalities, and scar contraction that are related to it. Due to the skin flap's strong fixation on the pectoralis muscle, quilting may have an impact on shoulder function that is still unknown [21].

Comparable to Granzier et al., who discovered a slight and transient reduction in shoulder function affecting both groups post operatively by two weeks. Disabilities of Arm, Shoulder, and Hand (DASH) scores six months after surgery were 14 in the quilted group and 22 in the non-quilted one ($p = 0.127$) [5].

Our results ran in line with those of Granzier et al., who found no negative effects on self-reported shoulder function after flap fixation, including wound drainage, after mastectomy. Quilting did not limit shoulder mobility, according to Myint et al. [5,21].

There's also the worry that quilting might cause further pain and discomfort. The Visual Analog Scale (VAS) was used by Ouldamer et al. to assess patient self-reported discomfort 15–21 days following quilting technique and traditional closure. In comparison to the non-quilted group, the quilted cohort had a larger percentage of pain-free patients (61% versus 30%, $p < 0.001$) [22].

According to Myint et al., there was no difference in the quantity of analgesic usage between the cohorts with and without quilts. Between the cohorts, there was no change in the kind of analgesics used (paracetamol, nonsteroidal anti-inflammatory medications (NSAIDs), or opioids) or increase in their usage, neither two weeks postoperatively nor six months postoperatively as compared to preoperative use [21].

Dead space and shearing pressures are eliminated by quilting sutures, which decreased seroma in our sample from 76% to 42.9%. The first trial was conducted by Abu Qasida A et al. and compared a

group that received just fibrin sealant to a group that received both fibrin sealant and quilting suture. They have demonstrated that for lowering the seroma rate and volume, total quantity of drainage, and duration of drain placement time with consistently less aspirations, the use of fibrin sealant In addition to quilting is much better than fibrin sealant alone. Additionally, it resulted in fewer aspiration-related postoperative visits, which lessened the discomfort and inconvenience for the patients. It had no effect on of hospital stay length, though. Depending on the underlying risk factors, multidisciplinary preventive methods for minimizing seroma should be developed and put into practice [23].

In relation to the variables linked to the seroma's volume, we discovered that smaller tumor sizes, fewer removed lymph nodes, lower tumor stages, and lower pretreatment breast weight were all connected to reduce fluid levels. This is in line with a prior research [21], but it contradicts findings from other studies [8–10] that showed no correlation between increased seroma production and tumor size, histology, location, or resected specimen weight.

Conclusion:

This study shown that, besides the greatly lowered amount and length of wound drainage, mastectomy combined with quilting of flaps is an effective way to significantly minimize postoperative seroma.

As a result, we advise quilting the flaps as a standard procedure following any mastectomy. Depending on the underlying risk factors, handy methods for minimizing seroma ought to be developed and put into practice. More research with a bigger sample size is needed to support our findings.

Ethical Approval:

Approval of the research ethics committee was obtained from Faculty of medicine Suez Canal University under No. 5162.

All procedures and management of data ran in according to the Declaration of Helsinki and the code of ethics of the World Medical Association.

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Citation

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