



Research Paper

Total Sealing Technique (TST) with a bipolar vessel sealing system reduces lymphorrhea and seroma formation for axillary lymph node dissection in primary breast cancer

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HIGHLIGHTS

- Mastectomy & axillary lymph node dissection complications include seroma formation.
- Seroma occurs from inadequate lymphatic vessel closure & excess drainage.
- Novel total sealing technique (TST) significantly reduced lymphatic drainage volume.
- TST shortens interval to chemotherapy initiation and hospital stay.
- Overall, TST effectively reduces complications in ALND & relieves economic burden.

ARTICLE INFO

Keywords:

Axillary lymph node dissection
Lymphorrhea
Seroma
Total Sealing Technique
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ABSTRACT

Background: The purpose of this study is to evaluate the potential of a novel surgical procedure, the Total Sealing Technique (TST), using the latest bipolar vessel sealing system (BVSS; LigaSure™ Exact Dissector) to reduce lymphatic leakage and seroma formation after electrocautery axillary lymph node dissection (ALND) in breast cancer surgery. Prolonged drainage is a common occurrence after ALND, primarily due to lymphatic leakage. In addition, the presence of seroma often leads to delays in the administration of postoperative adjuvant chemotherapy even after drain removal.

Methods: We conducted a comparative analysis of 36 patients who underwent total mastectomy with ALND using conventional electrocautery technique (CONV) during the first 3 years, and 35 patients who underwent the same procedure using TST during the subsequent 3 years. The following factors were compared to assess the impact of TST: operation time, blood loss, total drainage volume, mean time to drain removal, postoperative hospital stay, mean time to initiation of postoperative chemotherapy, and postoperative complications in each group.

Results: TST significantly reduced drainage volume (360.5 vs. 820.6 mL, $p < 0.001$), days to drain removal (4.8 vs. 6.8 days, $p < 0.001$), postoperative hospital stay (5.9 vs. 9.6 days, $p < 0.001$), the incidence of seroma (28.6 % vs. 65.9 %, $p = 0.001$), and time to chemotherapy initiation (33.1 vs. 61.4 days, $p < 0.001$) compared to CONV.

Conclusions: TST in total mastectomy with ALND effectively decreases the incidence of lymphorrhea and seroma formation; thus, it can be recommended for total mastectomy with ALND.

Introduction

Over the past few decades, the surgical management of breast cancer has evolved substantially in response to the growing demand for conservative approaches and improved early diagnosis. However, despite

the trends toward breast-conserving treatment and sentinel node biopsy, axillary lymph node dissection (ALND) still plays a crucial role in the surgical management of breast cancer [1,2]. Electrocautery, a conventional method introduced in the 1970s, has been widely used for tissue dissection and hemostasis in breast cancer surgery. However, this

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technique has been associated with an increased risk of surgical complications [3]. These complications, particularly seroma formation, may arise after ALND in mastectomy due to two reasons predominantly: (1) the temporary and inadequate sealing of lymphatic channels by electrocautery, which subsequently reopen to allow fluid drainage, and (2) thermal trauma due to extensive fat necrosis and lymphatic vessel damage resulting from tissue burn [4,5]. Current evidence has indicated a strong correlation between the increased incidence of postoperative seroma and electrocautery [5,6]. Furthermore, previous studies have reported significant drainage volumes (3300–4500 mL) after total mastectomy with ALND using electrocautery [7,8]. Therefore, ALND should be modified to prevent prolonged fluid drainage, by incorporating alternative methods such as ligation or complete occlusion of lymphatic vessels.

We have developed a novel technique called total sealing technique (TST) using the latest bipolar vessel sealing system (BVSS; LigaSure™ Exact Dissector) to effectively reduce lymphatic leakage and seroma formation during total mastectomy with ALND. Instead of beginning the procedure with electrocautery excision of the axillary fat pad, TST uses the LigaSure™ Exact Dissector (LGSED) (Medtronic plc. Dublin, Ireland) to identify and dissect the natural tissue layers while completely sealing all dissected tissue prior to resection (Video 1). It is important to note that these dissected and sealed tissues contain microvessels and microlymphatics. LGSED, the latest addition to the LigaSure™ family of BVSS, features a small, curved, thin jaw design that presents with a low temperature profile, minimal thermal spread, and multifunctionality. Moreover, its incorporation of FT10 technology prevents thermal damage to the surrounding unsealed tissue, unlike electrocautery, which further reduces lymphatic leakage. The introduction of the LGSED, with its dissecting forceps design, is critical to the success of TST. Its unique concept eliminates the need for instrument exchange, suturing, or electrocautery; thus, in the present study, TST was performed with the LGSED alone.

While there have been previous reports on axillary dissection with LigaSure™, it should be noted that these reports did not pertain to TST; instead, the procedures involved limited dissection with a monopolar electrocautery scalpel or a scalpel to the greatest extent possible [9,10]. This discrepancy is due to the fact that prior to LGSED introduction, the LigaSure™ device had a thick and short tip shape that was not conducive to delicate dissection. Although there have been several reports of the use of LGSED in thyroid and vascular surgery [11–13], this is the first report of the use of LGSED in breast cancer surgery. Additionally, Novitsky et al. demonstrated the efficacy of electrothermal bipolar devices, including LigaSure™, for sealing large porcine lymphatic vessels [14]. However, our study is the first to provide microscopic evidence of complete lymphatic vessel sealing with LGSED in human surgical specimens. The aim of this study was to compare the surgical outcomes of ALND performed with TST using LGSED to those of conventional electrocautery (CONV) and to confirm TST efficacy.

Patients and methods

Study population

Among 644 patients who underwent breast surgery at Nara Medical University between December 1, 2015, and November 30, 2021, 165 patients underwent ALND. Of these, 71 consecutive patients who underwent total mastectomy with ALND, excluding partial mastectomy, were included. In the first 3 years, 36 patients underwent conventional ALND, and in the following 3 years, ALND was performed with TST. We included only consecutive patients who underwent total mastectomy and ALND, and excluded patients who underwent partial mastectomy, because TST is beneficial in reducing lymphatic leakage and seroma formation even in total mastectomy procedures without ALND. The patients were divided into two groups based on the technique: CONV and TST. We compared several factors between the two groups,

including intraoperative blood loss, operative time, total drainage volume, mean days to drain removal, postoperative hospital stay, mean time to induction of postoperative chemotherapy, postoperative complications, and baseline variables (age, body mass index (BMI), neo-adjuvant chemotherapy, total number of lymph nodes removed, and stage). We also evaluated the clinical utility of TST according to BMI. BMI was calculated as body weight (kg)/height² (m²), and patients were divided into two groups according to the cut-off value set by the Japan Society for the Study of Obesity (BMI = 25 kg/m²). All patients had confirmed axillary metastases prior to ALND as determined by sentinel node biopsy or cytopathology evaluation. Exclusion criteria included concurrent malignancy, prior axillary surgery or radiation, severe diabetes, infection, bleeding diathesis, or anticoagulant use. Preoperative, intraoperative, and postoperative data were collected from medical records, and written preoperative informed consent was obtained from all participants.

Surgical technique and axillary drain management

In total mastectomy, skin flaps were created with an electrocautery scalpel and extended 2–3 cm below the subclavian bone on the cephalic side, beyond the inferior breast margin on the caudal side. The flaps were then inscribed at the sternal margin and circumscribed to the anterior margin of the vastus lateralis muscle in both the groups. Simple closure was performed without grafting or additional procedures. With regard to ALND, in both groups, ALND was performed in the same wound as the mastectomy. In the TST group, all tissues dissected with LGSED were subsequently sealed with LGSED prior to resection, without instrument exchange, sutures, or electrocautery in ALND. It is important to note that these dissected and sealed tissues contain microvessels and microlymphatics. In the CONV group, electrocautery or suture ligation was used to control hemostasis in both total mastectomy and ALND.

There are multiple lymphatic pathways from the breasts to the axillary lymph nodes, with a substantial amount of lymphatic fluid draining into the anterior axillary region [15,16]. For total mastectomy in the TST group, to prevent lymphatic leakage from these microlymphatic vessels, the breast margin near the axilla was resected after sealing using the same procedure as for ALND (Video 2). ALND involved the dissection of level I and II lymph nodes and was performed through the same incision as the mastectomy using a unique dissection technique for microlymphatic vessel closure. At this time, the remaining side is essentially double-sealed and resected. At the end of the ALND procedure, a closed suction drain (size: 3.5 mm) was placed in the axilla and a closed suction drain (size: 3.5 mm) was also placed in the anterior chest. The wound was sutured in the subdermal layer with absorbable monofilament suture (4–0 PDS®). In all cases, axillary dissection was performed after total mastectomy, and the duration of surgery was documented from skin incision to completion of the procedure. A standard non-compressive dressing was applied in all patients after closure of the surgical incision. There were no planned restrictions on arm movement.

The axillary drain was removed if the daily output was <50 mL within the previous 24 h. In general, patients were discharged from the hospital the day after drain removal. However, discharge was delayed in cases of seroma formation or uncontrolled drainage. Even if the total drainage volume did not fall below 50 mL/24 h, drain removal was scheduled within 14 days to reduce the risk of retrograde infection. Nurses measured the total drainage volume daily during hospitalization, and any complications were recorded daily in the patients' medical records. After hospital discharge, patients were scheduled for outpatient follow-up visits every 1 to 2 weeks for a minimum of 30 days. Any complications were documented during these visits. Seroma was defined as the presence of fluid collection under the skin flaps in an amount sufficient to cause patient discomfort within 30 days of surgery after drain removal. Puncture drainage with a 21G needle under ultrasound guidance was used to detect and treat seroma; the number of seroma

punctures and the volume of fluid aspirated were recorded.

Verification of lymphatic vessel occlusion

To evaluate the extent of lymphatic sealing achieved by LGSED in TST, we performed an additional experiment in patients undergoing sentinel lymph node biopsy. During the procedure, which involved the use of indocyanine green and indigocarmine, a blue lymphatic collecting vessel adjacent to the sentinel lymph node was sealed with the LGSED and subsequently harvested for analysis. The sealed area was subjected to histologic examination after staining with hematoxylin-eosin and elastic Verhoeff-van Gieson (EVG).

Statistical analysis

Categorical variables were compared using the Chi-squared test or Fisher's exact test, while continuous variables were analyzed using Student's *t*-test. Statistical significance was set at $p < 0.05$. The statistical analysis was performed using the JMP software package (SAS, Tokyo, Japan).

Results

Patient characteristics

Table 1 shows the patient characteristics. No significant differences were observed between the two groups in terms of age, BMI, neo-adjuvant chemotherapy, postoperative chemotherapy, number of dissected lymph nodes, and stage.

Intraoperative data

Table 2 summarizes the intraoperative data. No significant differences were observed between the TST and CONV groups in terms of total operative time (149.5 vs. 146.0 min, $p = 0.931$) and mean blood loss (31.3 ± 43.6 vs. 42.6 ± 45.7 mL, $p = 0.153$).

Postoperative data

Postoperative data are shown in Table 2 and Figs. 1 and 2. As shown in Fig. 1A, the TST group had a significantly lower total drainage volume compared to the CONV group (360.5 ± 187.9 vs. 820.6 ± 661.6 mL, $p < 0.001$). Furthermore, the TST group had a significantly shorter time for drain removal (4.8 ± 1.3 vs. 6.8 ± 2.1 days, $p < 0.001$) (Fig. 1B). In addition, the TST group had a significantly shorter postoperative

Table 1
Clinicopathologic characteristics of the study population.

	Total Sealing Technique (TST)	Conventional method (CONV)	P value
Number of patients	35	36	
Age	60.6 ± 14.1	66.2 ± 13.0	0.114
BMI (kg/m ²)	24.4 ± 4.4	23.2 ± 4.1	0.337
Neoadjuvant chemotherapy	18 (51.4 %)	11 (30.6 %)	0.074
Postoperative chemotherapy	10 (28.6 %)	14 (38.9 %)	0.454
Total number of removed lymph nodes	17.3 (14.5–20.1)	15.3 (13.7–16.9)	0.119
Stage			0.015
0	0	2	
IA	1	4	
IIA	10	10	
IIB	5	9	
IIIA	6	7	
IIIB	3	2	
IIIC	5	1	
IV	5	1	

Table 2

Clinical results of the Total Sealing Technique (TST) and conventional method (CONV) groups.

Variables	Total Sealing Technique (TST)	Conventional method (CONV)	p value
Total operating times (min)	149.5 ± 30.7	146.0 ± 22.0	0.931
Estimated blood loss (mL)	31.3 ± 43.6	42.6 ± 45.7	0.153
Total drain volume (mL)	360.5 ± 187.9	820.6 ± 661.6	<0.001
Days until drain removal (days)	4.8 ± 1.3	6.8 ± 2.1	<0.001
Postoperative hospital stay (days)	5.9 ± 1.3	9.6 ± 3.4	<0.001
Time to induction of postoperative chemotherapy (days)	33.1 ± 8.7	61.4 ± 14.9	<0.001

hospital stay compared to the CONV group (5.9 ± 1.3 vs. 9.6 ± 3.4 days, $p < 0.001$) (Fig. 2A). Finally, the mean time for initiation of post-operative chemotherapy was significantly shorter in the TST group compared to the CONV group (33.1 ± 8.7 vs. 61.4 ± 14.9 days, $p < 0.001$) (Fig. 2B).

We performed a subgroup analysis according to BMI. Compared to the group with BMI < 25 kg/m², the use of TST in those with BMI ≥ 25 kg/m² was more effective in terms of drainage volume ($p < 0.001$ vs. $p = 0.001$) and intraoperative blood loss ($p = 0.098$ vs. $p = 0.312$) (Table 3).

Complications

Table 4 shows the short-term postoperative complications observed in the present study. In the CONV group, three patients (7.3 %) experienced complications such as bleeding and hematoma. In addition, two cases (5.6 %) of wound infection were also reported in the CONV group. In contrast, no cases of bleeding, infection, skin burns, or necrosis were observed in the TST group. Furthermore, the incidence of seroma was significantly lower in the TST group compared to the CONV group (28.6 % vs. 65.9 %, $p = 0.001$). The TST group also had a significantly lower number of seroma punctures (1.8 vs. 4.6, $p = 0.022$) and a significantly lower total seroma drainage volume (171.5 vs. 656.8 mL, $p = 0.013$) compared to the CONV group.

Verification of lymphatic occlusion results

During the microscopic observation, the lymphatic vessels experimentally sealed with LGSED adjacent to the sentinel node showed complete fusion and integration with no evidence of necrosis, secondary bleeding, and thrombus formation. Histological evaluation of the sealed vessels revealed the presence of an adherent fibro-inflammatory pseudomembrane layer. Notably, EVG staining showed preservation of the internal elastic lamina and formation of collagen bundles across the obliterated vessel lumen. The highlighted square in Fig. 3 represents the specific area that was successfully sealed using the LGSED (EVG staining, original magnification ×100) (Fig. 3).

Discussion

Seroma formation is a well-known and important complication following breast cancer surgery [17]. It is associated with several problems, including delayed wound healing, which can further delay the initiation of adjuvant chemotherapy or radiotherapy [18,19]. As a result, preventing seroma formation is critical for reducing post-operative complications in the surgical management of breast cancer. Although several hypotheses have been proposed to explain the etiology and pathophysiology of seroma formation, such as acute inflammatory responses, increased fibrinolytic activity, and decreased fibrinogen levels, a clear understanding of the underlying mechanisms remains

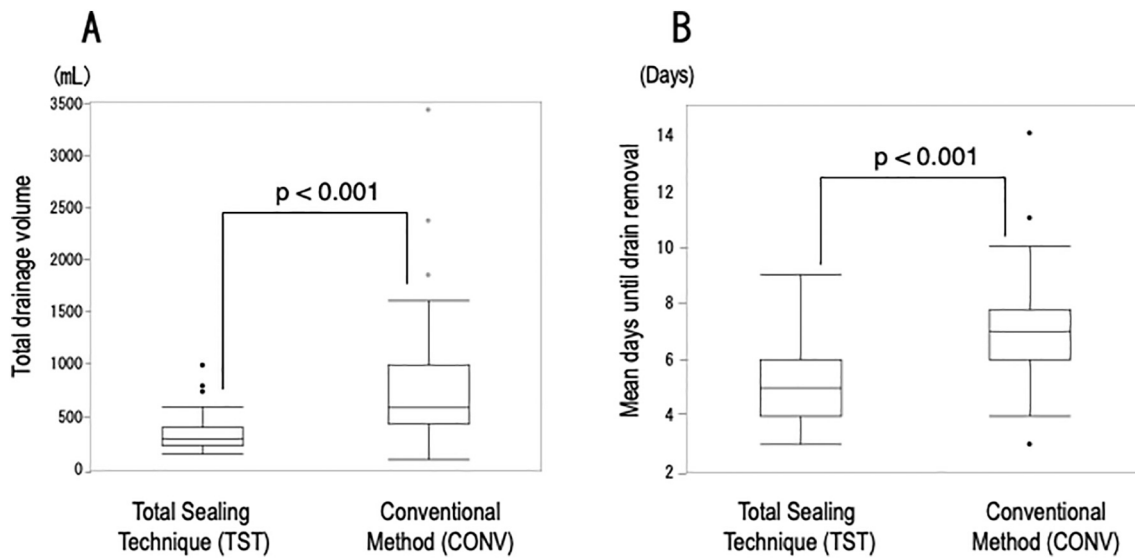


Fig. 1. Total drainage volume and mean days to drain removal were significantly reduced in the TST group compared to the CONV group. (A) Total drainage volume (360.5 ± 187.9 vs. 820.6 ± 661.6 mL; $p < 0.001$). (B) Mean days to drain removal (4.8 ± 1.3 vs. 6.8 ± 2.1 days; $p < 0.001$).

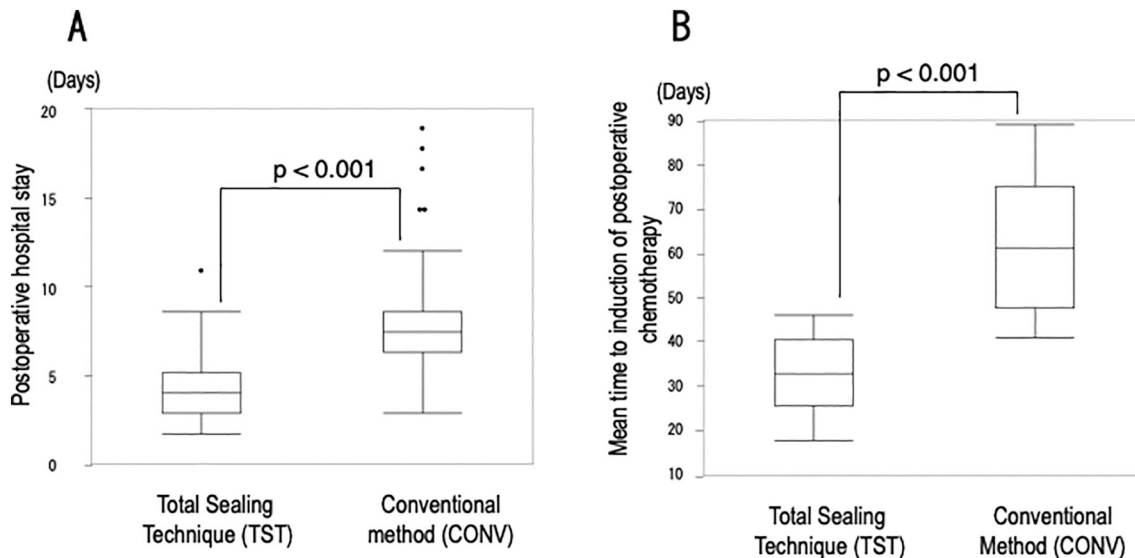


Fig. 2. Postoperative hospital stay and time to postoperative chemotherapy initiation were significantly shorter in the TST group than in the CONV group. (A) The mean number of days of postoperative hospital stay (5.9 ± 1.3 vs. 9.6 ± 3.4 days; $p < 0.001$). (B) The time to postoperative chemotherapy initiation (33.1 ± 8.7 vs. 61.4 ± 14.9 days; $p < 0.001$).

Table 3

Clinical results of the Total Sealing Technique (TST) and conventional method (CONV) groups according to body mass index (BMI).

Variables	BMI < 25			BMI ≥ 25		
	Total Sealing Technique (TST)	Conventional method (CONV)	p value	Total Sealing Technique (TST)	Conventional method (CONV)	p value
Total operating times (min)	141.4 ± 25.9	141.2 ± 23.8	0.815	164.8 ± 34.3	155.9 ± 14.6	0.623
Estimated blood loss (mL)	30.9 ± 51.5	30.2 ± 27.1	0.312	32.1 ± 23.9	67.3 ± 64.0	0.098
Total drain volume (mL)	309.5 ± 144.2	562.2 ± 344.4	0.001	458.4 ± 227.3	1337.5 ± 841.1	<0.001
Days until drain removal (days)	4.6 ± 1.1	6.0 ± 1.3	0.001	5.3 ± 1.5	8.4 ± 2.4	0.001
Postoperative hospital stay (days)	6.0 ± 1.7	8.8 ± 3.0	<0.001	6.4 ± 1.4	11.3 ± 3.7	0.001
Time to induction of postoperative chemotherapy (days)	30.2 ± 9.6	60.7 ± 16.8	0.002	37.5 ± 5.8	62.6 ± 12.5	0.014

elusive [8,16,20–22]. Nevertheless, it is widely acknowledged that lymphatic leakage is a central component in seroma formation [23,24]. Therefore, our proposed technique, TST, has significant potential to

reduce seroma formation through the effective closure of lymphatic vessels, including microlymphatic vessels.

The LGSED plays a critical role in the performance of TST. The

Table 4
Postoperative complications.

Variables	Total Sealing Technique (TST)	Conventional method (CONV)	p value
Number of patients	35	36	
Postoperative bleeding	0	3 (7.3 %)	
Hematoma	0	3 (7.3 %)	
Seroma	10 (28.6 %)	27 (65.9 %)	0.001
Number of aspirations for axilla seroma	1.8 (1.1–2.5)	4.6 (3.1–6.1)	0.022
Total seroma volume (mL)	171.5 (33.8–309.2)	656.8 (307.3–1006.3)	0.013
Wound infection	0	2	
Flap necrosis	0	0	

bipolar coagulation devices of the LigaSure™ family permanently seal blood vessels, lymphatic vessels, and tissue bundles by denaturing collagen and elastin in the vessel wall, enabling a thread ligation-free surgery. Introduced in 2018, LGSED is the latest generation of these devices and possesses several remarkable capabilities. First, the LGSED has a narrow tip that is only 2 mm wide, surpassing the width of the previous generation LigaSure™ Small Jaw, and also has a longer sealing length (20.6 mm vs. 16.5 mm). The narrower jaw width and longer sealing length of the LGSED allow for more precise and controlled dissection maneuvers, allowing for meticulous dissection of lymph nodes from blood vessels and nerves. Second, although the LGSED has evolved into a structure with thinner and longer jaws that are well suited to the dissection procedure, it is capable of effectively sealing blood vessels up to 7 mm in diameter, including the surrounding connective tissue. This study is the first comparison of the LGSED with conventional devices in total mastectomy with axillary dissection.

A notable aspect of our study is the original demonstration of complete lymphatic sealing, specifically with LGSED, via lymphatic staining of sentinel lymph node biopsies. This major and valuable finding represents a significant contribution to the field of breast cancer surgical management, as previous research has not demonstrated this level of efficacy in achieving lymphatic vessel occlusion. Thus, our result further supports the efficacy of TST in achieving complete lymphatic closure (Fig. 3).

In the present study, only patients who underwent total mastectomy with ALND were included; the rationale behind this selection was to

highlight and recognize that TST is beneficial in reducing lymphatic leakage and seroma formation even in total mastectomy procedures without ALND. The efficacy of TST using LGSED use in total mastectomy may be anatomically attributed to the flowing of lymphatic vessels from the breast to the axilla [15,16]; thus, if the lymphatic-vascularized tissue is roughly resected with an electrocautery scalpel during total mastectomy, it may lead to lymphorrhea and seroma formation. In support of this hypothesis, Manouras et al. reported historical data showing a drainage volume range of 213–320 mL for mastectomy alone, which was significantly reduced to a mean volume of 20 mL with the use of a bipolar vessel sealing system [25]. Our study results were consistent with this finding and demonstrated significant benefits with the use of LGSED in total mastectomy with ALND in terms of reduced drainage volume, drainage duration, and postoperative hospital stay (Table 2). While our results clearly showed the notable benefits of TST in total mastectomy with ALND, the utility of TST can also be extrapolated to axillary dissection with partial mastectomy.

To the best of our knowledge, there have been eight reports between 2007 and 2022 comparing LigaSure™ with conventional methods for axillary dissection in breast surgery; six of these were randomized controlled trials (RCTs) (Table 5) [9,10,26–31]. Among these reports, a meta-analysis conducted by Pergialiotis et al. based on three studies reported between 2007 and 2012 showed no significant difference in the overall effect between LigaSure™ and the conventional method in terms of total discharge and duration [32]. Even in previous models, LigaSure™ is designed to completely seal lymphatic vessels and therefore, when used appropriately, should result in less lymphatic leakage and drainage volume compared to the conventional method. Thus, the above finding may be due to the relatively low percentage of total mastectomies (34.8 %) in the included studies; additionally, the full sealing effect of LigaSure™ may have not been fully realized. Four of eight studies reported significantly lower mean total drainage volume in the LigaSure™ group while six studies reported significantly shorter drainage time in the LigaSure™ group. Regarding total drainage volume, Nespoli reported a mean volume of 265 mL in the LigaSure™ group [9], which is lower than our findings (Table 5). Again, this discrepancy may be due to the significantly lower percentage of total mastectomies (15.5 %) included in their study. In the three RCTs conducted since 2014, both drainage volume and drainage duration were significantly lower in the LigaSure™ group compared to the conventional approach (Table 5). Regarding the mean total drainage volume in the LigaSure™

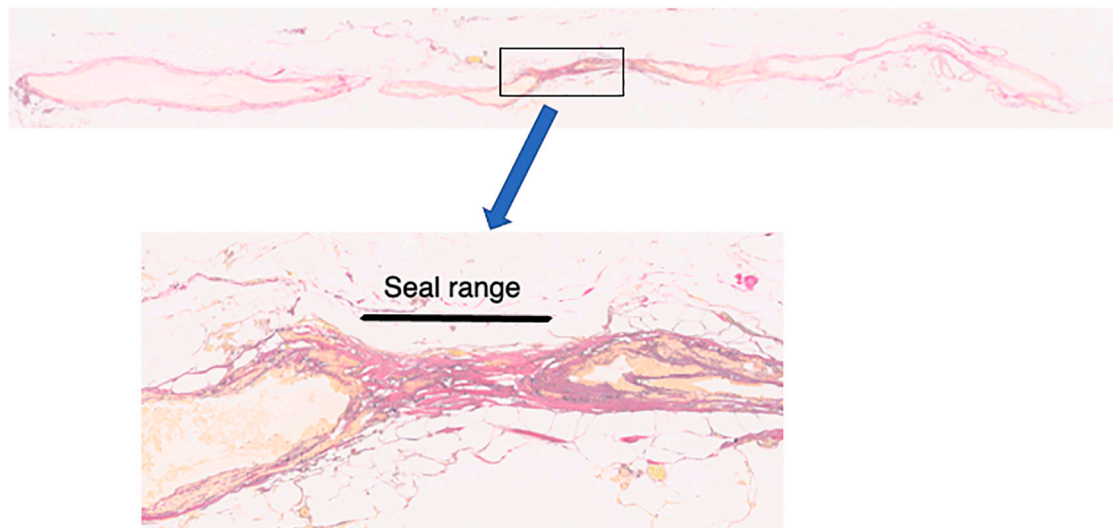


Fig. 3. Microscopical observation revealed that the lymphatic vessels experimentally sealed by the LGSED adjacent to the sentinel node were completely fused and integrated without necrosis, secondary hemorrhage, and thrombus. Histologic examination of the sealed vessels revealed a layer of adherent fibro-inflammatory pseudomembrane. EVG staining showed preservation of the internal elastic lamina and formation of collagen bundles across the obliterated vessel lumen. The square area is the area sealed with the LGSED (EVG staining, original magnification $\times 100$).

Table 5
8 reports previously reported comparing LigaSure™ with conventional methods for axillary lymph node dissection between 2007 and 2022.

Year	Author	Type of study	Type of LigaSure	Number of the total mastectomies	Axillary drainage (mL)	P value	Duration of drainage (days)	P value	Hospitalization (days)	p value	Seroma	P value	Number of punctures	p value	Fluid drained by punctures (mL)	P value
2007	Antonio M	RCT	LigaSure™	18/50 vs 28/50	624.5 vs 793.0	0.090	4.6 vs 5.0	0.150	N/A	0.005	22/50 vs 9/50	0.070	1.1 vs 0.6	0.070	149.2 vs 88.8	0.290
2011	Cortadellas T	RCT	LigaSure™	24/50 vs 23/50	366.2 vs 422.9	0.325	4.3 vs 5.7	0.012	5.1 vs 6.5	0.021	N/A	0.098	0.6 vs 1.1	0.098	140.9 vs 261.2	0.092
2012	Nespoli L	RCT	LigaSure™ Precise	13/58 vs 24/58	265 vs 260	0.500	N/A	0.039	4.0 vs 4.0	0.189	18/58 vs 15/58	0.767	N/A	0.767	275 vs 505	0.226
2014	Tukenmez M	RCT	LigaSure™ Precise	N/A	620 vs 809	0.047	7.6 vs 10.0	0.044	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
2016	Tomoko Seki	RCT	LigaSure™ Small Jaw	18/31 vs 18/30	365.3 vs 625.1	0.009	6.4 vs 8.2	0.033	8.8 vs 10.1	0.077	13/31 vs 11/30	N/A	N/A	N/A	N/A	N/A
2018	Yuka Inoue	Non RCT	LigaSure™ Small Jaw	43/43 vs 49/49	478 vs 614	0.007	7.0 vs 10.0	0.001	8.0 vs 11.0	<0.001	N/A	N/A	N/A	N/A	N/A	N/A
2019	Gambardella C	Non RCT	LigaSure	9/25 vs 8/25	600 vs 640	N/A	6.0 vs 5.6	N/A	6.3 vs 6.0	N/A	11/25 vs 14/25	N/A	N/A	N/A	N/A	N/A
2022	Park HS	RCT	LigaSure™ Maryland23NC	24/41 vs 23/41	756.3 vs 1167.7	0.010	13.9 vs 17.1	0.010	5.3 vs 5.4	0.930	N/A	>0.990	N/A	>0.990	13.3 vs 35.6	0.360

group, Tukenmez et al. reported 620 mL in 2014 and Park et al. reported 756.3 mL in 2022 (Table 5), whereas our data showed a notably lower mean volume of 360.5 mL (Table 2). The use or non-use of our proposed TST may have contributed to this difference. Contrastingly, in 2016, Seki et al. reported a mean total drainage volume of 365.3 mL in the LigaSure™ Small Jaw group [10], which is similar to our findings; however, 38.7 % of their study included breast-conserving procedures.

The introduced TST is based on a novel concept in which there is the sealing of all dissected tissue, including microlymphatics, without damaging the lymphatics, thus, resulting in the sealing of the majority of lymphatics and reduction of lymphatic leakage. The reduced lymphatic leakage subsequently leads to a reduction in drainage volume, allowing for earlier drain removal and shorter hospital stays. Our data show that TST with LGSED significantly reduced the length of hospital stay by an average of 3.7 days compared with the CONV group (TST group vs. CONV group, 5.9 ± 1.3 vs. 9.6 ± 3.4 days, $p < 0.001$) (Table 2, Fig. 2A). This reduction in hospitalization duration is not only indicative of improved patient outcomes but also holds considerable economic implications. By implementing TST with LGSED, an average cost savings of approximately 92,500 yen per case can be achieved. This estimation takes into account the daily hospitalization cost of 25,000 yen, which is based on the National Health Insurance System in Japan. In addition, the reduction in hospital stay duration contributes to increased bed availability, allowing surgeons to perform more surgeries and providing additional economic benefits. Most importantly, minimizing the delay in starting postoperative chemotherapy is crucial. In our study, although the sample size was small, the TST group had a significantly shorter time to initiation of postoperative chemotherapy compared to the CONV group (TST group vs. CONV group, 33.1 ± 8.7 vs. 61.4 ± 14.9 days, $p < 0.001$) (Fig. 2B). This finding can be attributed to the significantly lower incidence of seroma in the TST group (Table 4). While none of the eight previously published reports (Table 5) demonstrated significant results when evaluating the frequency of seroma occurrence, the number of aspirations for seroma, and the total seroma volume (mL), our data demonstrate a significant superiority of the TST group over the CONV group in all categories. More interestingly, subgroup analysis by BMI showed that ALND with TST was more effective in obese patients (Table 3).

This study had certain limitations, including its single-center design, limited sample size, and lack of randomization. However, the authors mitigated these biases by selecting consecutive clinical cases.

Conclusion

In conclusion, our study demonstrates that TST with LGSED leads to improved surgical outcomes, particularly in terms of reduced postoperative drainage volume, shorter hospital stay, and lower incidence of seroma in breast cancer surgery with ALND, and thus we recommend the use of this technique in this study population. These findings may serve as a basis for future prospective studies investigating the use of advanced energy devices in breast cancer surgery.

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.sopen.2024.01.011>.

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Ethical approval statement

This study was conducted at Nara Medical University, Nara, Japan. After explaining the study protocol, written informed consent was obtained from all patients for their participation in this study and for the storage and use of their data. The study protocol was approved by the Ethics Committee of Nara Medical University (No. 2427) in accordance

with the Declaration of Helsinki.

CRediT authorship contribution statement

Naoya Ikeda: Conceptualization, Writing – original draft, Writing – review & editing. **Takahiro Akahori:** Formal analysis, Investigation. **Tomoyo Yokotani:** Data curation, Validation. **Tomomi Fujii:** Data curation, Software. **Masayuki Sho:** Supervision.

Declaration of competing interest

All the authors declare no potential conflict of interest.

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