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A Technique of Endoscopic Nipple-Sparing Mastectomy for Breast Cancer

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ABSTRACT

Background and Objectives: Nipple-sparing mastectomy (NSM) is a widely accepted surgical technique for patients with early breast cancer. The technique improves cosmetic outcomes, but a decrease in nipple sensitivity has been observed with NSM because of the incision into the nipple–areola complex (NAC). Endoscopic nipple-sparing mastectomy with skin lifting system (ENSMSLS) removes all breast tissue through the axillary incision used for the sentinel lymph node biopsy, to avoid incision around the NAC area. With only one incision, NAC sensitivity is less likely to be affected by this technique. We sought to investigate the effect of ENSMSLS on sensation in the NAC, compared with NSM.

Methods: A single-institution retrospective review was performed from August 2014 through August 2015. Thirty patients who underwent NSM in the past 6 years were frequency matched for age and cancer stage with those who underwent ENSMSLS between 2014 and 2015. All patients were recalled and re-examined for the study. Patients from the ENSMSLS group were recalled twice at both 3 and 6 months after surgery. Matched control subjects who underwent NSM were examined when they were recalled. The sensations of pressure, temperature, and vibration were measured.

Results: Patients who underwent ENSMSLS were significantly less likely to have decreased or impaired sensations of pressure, temperature, and vibration compared those who had NSM. The improvement in preservation of sensations by the use of ENSMSLS was very impressive.

Conclusions: ENSMSLS, which avoids incision around the NAC, significantly decreases the possibility of decline in NAC sensation.

Key Words: Breast reconstruction, Endoscopic nipple-sparing mastectomy with skin lifting system, Nipple–areola complex sensitivity, Nipple-sparing mastectomy.

INTRODUCTION

Breast cancer is the most common cancer in women worldwide.[1] The age of development and diagnosis of breast cancer is much younger in China than in the United States and the European Union.[2] Mastectomy is associated with psychological trauma for many patients.[3] Surgical therapy for breast cancer has evolved from radical mastectomy to breast-conserving techniques.[4,5] Breast-conserving surgery (BCS) is considered a safe technique with good aesthetic results for breast cancer,[6] but may result in obvious breast asymmetry in women with small breasts. Nipple-sparing mastectomy (NSM) with reconstruction technology offers the opportunity to preserve the shape of both the breast and the nipple–areola complex (NAC). It has been shown to be oncologically safe in selected cases.[6–8] A more extensive incision is required in mastectomy involving all the breast tissue in NSM cases, which is detrimental to cosmetic appearance and may decrease nipple sensitivity, especially the incision in the NAC. There is increasing concern over postsurgical nipple–areola sensitivity, as nipple sensation plays an integral part in women's psychological and sexual health.[9] Endoscopic subcutaneous mastectomy (ESM) without an incision on the surface of the breast gives the best preservation of anatomical structures and results in high trophism and vitality of the NAC. Endoscopic nipple-sparing mastectomy with skin-lifting system (ENSMSLS) creates operation space without liposuction and CO_2 and preserves the subcutaneous fat tissue, which is important in reconstruction. Such a technique avoids placing the incision on the breast surface. It could reduce other complications, such

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as skin necrosis, nipple necrosis, and infection.[10,11] The ENSMSLS procedure could reduce the possibility of damaging the anterior cutaneous branches of the intercostal nerves, which are equally important in NAC sensitivity. However, there is a lack of evidence in the literature to support the hypothesis that ENSMSLS (in avoiding the incision on the breast) could reduce the probability of decline of sensation on the NAC. It is important to provide enough scientific evidence to prove the effectiveness of ENSMSLS in preserving NAC sensitivity.

In the current study, we compared the efficacy of ENSMSLS and NSM in maintaining NAC sensitivity.

METHODS

Selection of Patients

Primary breast cancer was histopathologically diagnosed in 30 patients, and they underwent ENSMSLS at our hospital from August 2014 through August 2015. Patients who underwent NSM without the endoscopic technique and skin-lifting system at our hospital since late 2008 were randomly selected and frequency matched with patients who underwent ENSMSLS by age (7-year group), stage of cancer, and reconstruction method.

Patients were included if they (1) met the criteria for BCS but refused BCS or radiotherapy after surgery; (2) did not meet the criteria for BCS (e.g., extensive intraductal cancer or presence of multicentric tumors) and had no indication of skin, NAC, or pectoralis muscle infiltration; and (3) had no indication of axillary lymph node metastasis.

Exclusion criteria were (1) nipple discharge or nipple Paget's disease; (2) distant metastasis; and (3) positive surgical margins below the NAC identified through intraoperative frozen section analysis.

The study was approved by the Ethics Committee of Beijing Tongren Hospital affiliated with Capital Medical University. Informed consent was obtained from all patients.

MRI was performed in all patients before the operation to ensure that there was no indication of infiltration of the breast skin, the NAC, or the pectoralis muscle. A biopsy was performed before surgery to diagnose breast cancer, and multiple departments discussed the therapeutic plan.

All patients were recalled for the assessment of NAC sensation. Patients who had undergone ENSMSLS surgery were examined 3 and 6 months after surgery for NAC sensitivity. Since sensation status tends to be stable shortly after surgery, all patients from the NSM group were at least at postsurgical month 6 when they were recalled. The matched controls who underwent NSM were examined only once when they were recalled.

ENSMSLS Surgical Technique

Under general anesthesia, patients were placed in a sitting position to mark the inframammary fold (**Figure 1**). Patients were then placed supine with the ipsilateral arm fixed at 90°. An incision along the line of the axillary skin (6–8 cm) was made to perform the sentinel lymph node biopsy under direct vision (**Figure 2**). An axillary lymph node dissection (ALND) was added if necessary. A skin flap around the incision was created by dissecting the subcutaneous tissue with an electrosurgical device under direct vision, creating a space in the axilla and lateral breast. Three wires (20 × 0.2 cm) were placed between the subcutaneous layer and the gland at intervals that separated the breast skin surface about equally. The depth of wire penetration was ?0.5 cm, guided by ultrasound. The wires were fixed with a frame and lifted to the support structure, which easily adjusts the location during the operation, and is good for manipulation. With an operation space created by the skin-lift system (including wires, frames, and support structure; Mizuho, Tokyo, Japan), a skin flap was created from the incision to the whole breast under endoscopic vision. The cavity was observed

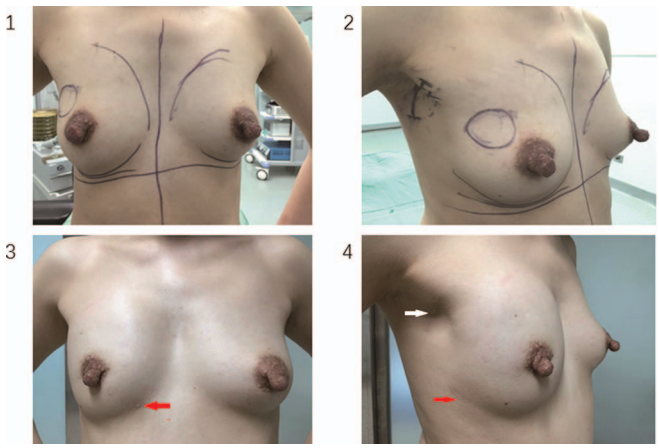

Figure 1. A 32-year-old woman with right breast cancer in the upper outer quadrant. The operation method was ENSMSLS. (1, 2) She was placed in a sitting position and preoperative marking of the mammary fold was made. (3, 4) Postoperative appearance at 3 months is shown. The white arrow shows the location of the incision at the axilla. The red arrows show the scars of drain placements.

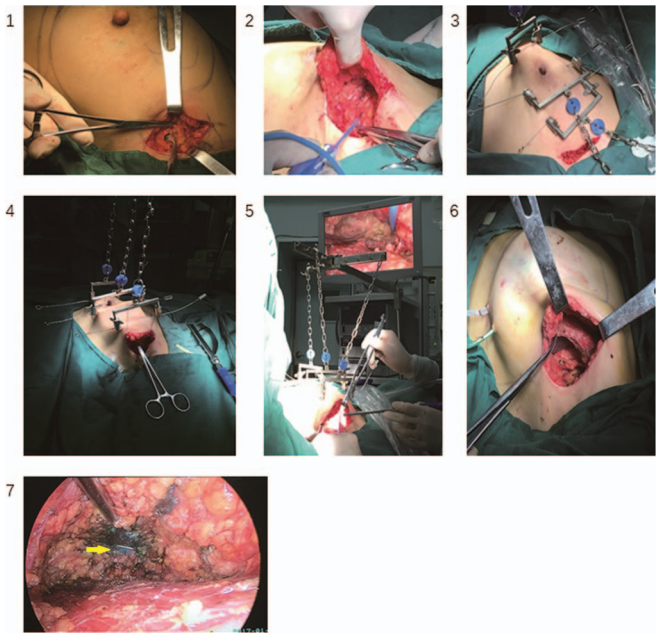

Figure 2. A 42-year-old woman with left breast cancer in the upper outer quadrant. The operation method was ENSMSLS. (1) The incision was made along the line of the axillary skin, through which the sentinel lymph node biopsy (SLNB) was performed under direct vision. (2) A skin flap was created under direct vision. (3) Needles were placed through the breast skin and connected to the lifting system. (4) The skin-lift system created operation space. (5) Under endoscopic vision, a skin flap was created from the incision to access the whole breast. (6) The pocket for the mammary prosthesis was created beneath the pectoralis major. The arrow shows the pectoralis major. (7) The endoscopic view is demonstrated. The blue shows the location of the nipple. The arrow shows a portion of one of the needles of the lifting system that had been placed under the breast skin.

through a 30°, 10-mm-diameter camera (Storz, Tuttlingen, Germany), stabilized by the assistant without a port. Through the incision, the whole mammary gland and pectoralis major fascial were excised with an electrosurgical device. Surgical margins below the NAC were identified through intraoperative frozen section analysis. Methylene blue was injected at the NAC before the operation, and the location of the NAC was identified by endoscope (**Figure 2**). The scar created by the previous core needle biopsy for the diagnosis of breast cancer was excised as per our routine practice. The same reconstruction procedures were performed as usual (**Figure 2**). The NSM procedure was similar to ENSMSLS. However, an additional incision was made on the surface of the breast (ie, around the NAC), and no skin-lift system or endoscopic technique was used.

For immediate implant reconstruction, the pocket for the mammary implant was created beneath the pectoralis major muscle. An implant was inserted into the pocket to reconstruct the breast after the patient was placed back in the sitting position (**Figure 2**). Two to 3 drains were placed subcutaneously.

Data were extracted from patient charts, including patient characteristics, stage of cancer, medical examinations, type of operation, methods of treatment before and after operation, and postoperative complications.

The Measures of NAC Sensation

The test sites were the nipple, the areola, and 4 quadrants of the breast skin (superior, inferior, medial, and lateral). These sites were measured for both the surgical breast and the normal one, which provided a comparison.

Pressure sensation was tested by applying a neuropathy testing pen (Huatai Healthcare Technology Co. Ltd, Beijing, China) with 40 g pressure. The pen is like a needle that produces a pressure stab on the surface of the breast, to test whether the patient felt the pain. Such a threshold was found to cause a pain sensation on the NAC on the patients' normal breast in all of the patients. Loss of pressure sensation was identified if no feeling of pain was found in the tested sites.

Tip-Therm (Huatai Healthcare Technology Co. Ltd, Beijing, China) was used to assess the temperature sensation. This equipment is made of special polymer and metal alloys. The polymer side feels warm and the alloy side feels cold. The clinician placed the 2 surfaces on patients' test sites at irregular intervals. Patients were queried to see whether they could correctly identify the temperature difference with their eyes closed. Loss of temperature sensation was identified if the patient was unable to distinguish the difference in feeling in the tested sites.

Both the Neuropathy Testing Pen and Tip-Therm are commonly used to test pressure and temperature perceptions in diabetic feet, which are similar in potential nerve injury.

Vibration sensation was tested by the Bio-Thesiometer diagnostic apparatus [Vibration Perception Threshold Monitor (VPT)-1; Huata, Beijing Huatai Healthcare Technology Co. Ltd., Beijing, China). This device, used to test vibration of the skin, has been found to be useful for testing vibration sensation among diabetic patients with peripheral neuropathy.[12] Three points adjacent to the areola incision were selected and tested for vibration sensation. The same points of both the surgical side and the normal side were assessed. The mean of the 3 points was

used to compare vibration sensations between patients who underwent ENSMSLS and those who had NSM. Loss of vibration sensation was identified if there was no feeling of vibration in the tested sites.

Statistical Analysis

The χ^2 test or Fisher's exact test was performed for categorical data. Student's *t* test was used to compare the mean differences in continuous variables between different surgical procedures. Multiple logistic regression was applied to determine the association between dichotomous outcomes and the types of surgery, with adjustments made for potential confounders. Multiple linear regression was used to assess the impact of operation types on the changes of vibration sensation while controlling for confounding. All statistical analyses were performed with SAS 9.3 (Cary, North Carolina, USA).

The covariate risk factors included in the multivariate analyses are breast size, chemotherapy, radiotherapy, and endocrine therapy. Age and stage of cancer were not included in the analysis, because they were matched at the research design stage.

Table 1.
Patients' Characteristics

Characteristic	NSM (n = 30)	ENSMSLS (n = 30)	*P*
Age, years	43.87 ± 8.27	44.57 ± 8.84	.75
Follow-up, months	43.22 ± 19.80	27.77 ± 20.43	<.05*
Lymph node metastasis, n	20/30	24/30	.24
Axillary dissection (ALND)	11 (36.67)	11 (36.67)	.99
Multiple foci	11 (36.67)	13 (43.33)	.60
Chemotherapy	26 (86.67)	24 (80.00)	.49
Radiotherapy	14 (46.67)	13 (43.33)	.80
Endocrine therapy	23 (76.67)	24 (80.00)	.75
Reconstruction method			.96
Implant	18 (60.00)	19 (63.33)	
Skin flap	10 (33.33)	9 (30.00)	
None	2 (6.67)	2 (6.67)	
Breast volume			.15
A (<150 cc)	6 (20.00)	13 (43.33)	
B (150–250 cc)	20 (66.67)	14 (46.67)	
C and above (>250 cc)	4 (13.33)	3 (10.00)	
Breast-ptosis	10 (33.33)	5 (16.67)	.14
SLN	20 (66.67)	25 (83.33)	.14
Stage			.87
None	5 (16.67)	5 (16.67)	
I	4 (13.33)	4 (13.33)	
IIA	13 (43.33)	14 (46.67)	
IIB	1 (3.33)	3 (10.00)	
IIIA	7 (23.33)	4 (13.33)	
Physician satisfied	22 (73.33)	23 (76.67)	.77
Patient satisfied	29 (96.67)	29 (96.67)	.99

Stage: 2 patients of 11 with stage III cancer, who were T2N2M0. both had lymphatic metastasis. Unless otherwise indicated, the data are expressed as the number (% of the total group). ALND, axillary lymph node dissection. *Significantly different.

RESULTS

Patients' characteristics are showed in **Table 1**. The mean ages were 44.57± 8.84 and 43.87± 8.27 years for patients who underwent ENSMSLS and NSM, respectively. There was no significant difference between the ENSMSLS and NSM groups in patients' ages, clinical stages, and histopathologic types. All patients accepted immediate reconstruction, and most chose implant reconstruction. Almost all the patients had a breast volume of less than 250 cc and only a quarter of them showed breast ptosis.

Most patients' cancer was less than stage IIA; others were stage III because of lymphatic metastasis. No patients had a local recurrence. Three patients died of distant metastasis: including 2 who underwent NSM and 1 who underwent ENSMSLS. All patients were nonsmokers, and none of them had diabetes (data not shown).

At 3 months after surgery, patients who underwent ENSMSLS were significantly less likely to have decreases in pressure sensation (OR = 21.00; 95% CI = 4.20–105.04) and temperature sensation (OR = 13.16; 95% CI = 0.69–249.48), compared with patients who underwent NSM. Similar results were observed at 6 months after surgery (**Table 2**). Almost all the patients in the NSM group had decreased pressure sensation. The outcomes observed in the ENSMSLS group were much better; about two-thirds of them did not have decreased pressure sensation. The status of pressure sensation for both groups at 6 months was almost the same as that observed for each of them at the 3-month time point.

All the patients in the NSM group had decreased temperature sensation. Therefore, the OR cannot be calculated normally, and SAS calculated these ORs with a correction of 0.5 instead of zero in the corresponding contingent tables. The risk difference between the ENSMSLS group and the NSM group was 16.67% at 3 months and 23.33% at 6 months. Although the OR seems high, the status of temperature sensation stayed almost the same at the 3-month and the 6-month follow-ups after the surgery.

Vibration sensation loss is defined as the patient's inability to feel vibration on the breast when the maximum vibration force is applied by the VPT-1. Because no patients in the ENSMSLS group had lost their vibration sensation, the

Table 2.
Comparison of 3 and 6-Month Postsurgery Sensation Status of ENSMSLS Patients With That of NSM Patients

Parameter	NSM (n = 30)	ENSMSLS (n = 30)	OR*	95% CI of OR	*P*
Pressure sensation decrease (3 months)	28/30	12/30	21.00	4.20, 105.04	<.0001
Pressure sensation decrease (6 months)		11/30	24.18	4.82, 121.61	<.0001
Temperature sensation decrease (3 months)†	30/30	25/30	13.16‡	0.69, 249.48‡	.02
Temperature sensation decrease (6 months)†		23/30	19.47‡	1.06, 358.38‡	.005
Vibration sensation loss (3 month)§	10/30	0/30	31.24‡	1.73, 563.16‡	.0006
Vibration sensation loss (6 month)§		0/30	31.24‡	1.73, 563.16‡	.0006
Nipple transposition	16/30	12/30	1.71	0.62, 4.77	.30

Sensation status in the matched NSM group was conducted only once, on the day when they were called back for re-examination. *Odds ratio of patients in the NSM surgical group compared with patients in the ENSMSLS group. †Because all the patients in the NSM group had a drop in sensitivity to temperature, the OR cannot be calculated normally. The risk decrease for the ENSMSLS group vs the NSM group was 16.67% in 3 months and 23.33% in 6 months. ‡All logit estimators with this marker use a correction of 0.5 in every cell of those tables that contain a zero. §For vibration sensation change; because no patients in the ENSMSLS group had lost their vibration sensation, the OR cannot be calculated normally. There was a 33.33% risk decrease for ENSMSLS group compare to NSM group at both the 3 and 6 month follow-ups.

ORs are calculated the same way by SAS as for the change in temperature feeling. There was a 33.33% decrease in risk for the ENSMSLS group compared with the NSM group, at both the 3- and 6-month follow-up.

Because of the limited number of patients, the OR did not provide a good estimate of the difference between the 2 types of surgery. We therefore estimated the difference in the vibration force level that was felt during the vibration testing for each group. All patients performed normally when their vibration sensation was tested on the nonsurgical side. The force level needed to feel the vibration on the normal side was ?5–7 in both groups, and the difference between the 2 groups was not significant, which means both groups had no substantive underlying difference in their vibration sensation states before surgery. However, patients in the NSM group actually needed a bigger shaking force to feel the vibration on the surgical side, and the difference was statistically significant ($P <$ .0001).

DISCUSSION

Maintaining a natural breast appearance including preservation of the NAC has been shown to improve the physical and mental quality of life of patients, especially that of young women with breast cancer. However, the incisions around the NAC, similar to other incisions on the skin in Asian patients, are more likely to leave dark pigment and scars.[13] The incision commonly causes NAC sensory decrease by disturbing the vascular supply and the innervation.

An anatomical study of breast specimens showed that both the anterior and the lateral cutaneous branches of the intercostal nerves are equally important for NAC sensitivity.[14] The anterior cutaneous branches which take a superficial course is thought to be origin of the cutaneous innervation of the breast, whereas the lateral cutaneous branches take a deep course[15] and could be easily damaged by removing all breast tissue in ENSMSLS and NSM procedures. The integrity of the anterior cutaneous branches which take a superficial course therefore becomes very important for maintaining NAC sensitivity.

The routine incisions on the lateral or inframammary regions of the breast may cause damage to the nerves. The placement of incisions around the NAC harm the blood supply and nerves to the NAC. The ideal operation creates a breast skin cover without incisions on the breast surface. The use of endoscopic technology avoids the need for large incisions, but it is difficult to use the technique in the solid-organ breasts. The lifting system creates an operative space without the need for liposuction or CO_2. It also preserves the subcutaneous fat tissue, which is important for reconstruction. The ENSMSLS applies endoscopic technology to remove all breast tissue through only one axillary incision and avoids placing an incision on the breast surface. The whole procedure took ~3 hours for all our patients, and the estimated blood loss (EBL) during the procedure was between 60 and 130 mL. The duration of drainage was about 7 days, the amount of drainage was ~240 mL. There was no significant difference in operative time, EBL, and drainage between patients in the different groups. The operation data (length of operation, EBL, and drainage) were the same as reported by Guan et al.[16] This procedure could avoid damaging the anterior cutaneous branches and reduces the possibility of decreased sensation of the NAC. It is unknown whether

Table 3.
Comparison of Detailed Vibration Sensation Status at 3 and 6 Months After Surgery in the ENSMSLS Group versus the NSM Group

	NSM (Mean ± SD)	ENSMSLS (Mean ± SD)	Difference	Paired *t* Test	*P*
Surgical shake					
3 Months postop	43.96 ± 98	26.66 ± 10.27	17.30 ± 12.24	7.74	<.0001
6 Months postop		24.89 ± 10.69	19.07 ± 11.87	8.80	<.0001
Normal shake					
3 Months postop	5.58 ± 4.09	6.93 ± 6.34	−1.36 ± 7.76	−0.96	.3468
6 Months postop		6.77 ± 5.95	−1.19 ± 7.35	−0.89	.3831

Shake: force testing in the matched NSM group patients was conducted only once, on the day when the patient was called back for re-examination. Surgical shake, the vibration sensation was tested in the surgical breast at the test points. Normal shake, the vibration sensation was tested in the normal, nonsurgical breast at the test points.

the anterior cutaneous branches alone are capable of maintaining the NAC sensation.

Pressure, temperature, and vibration sensation decreases were observed in all patients, but more obviously in the NSM group. Our findings cannot be explained by age or stage of cancer because we matched the 2 groups for these factors. There similarly was no significant difference relative to breast size, radiotherapy, chemotherapy, and endocrine therapy between the 2 groups. Most of the patients lost temperature sensation and did not recover it after 6 months. Only a few patients in the ENSMSLS group maintained temperature sensation, but due to the small number of cases, the significance level for this difference is not reliable. A larger sample and a longer observation time is needed to validate this conclusion. Pressure sensation was significantly different in the 2 groups. Almost all the patients in the NSM group experienced decreased pressure sensation, as compared to less than half of the patients in the ENSMSLS group. Vibration sensation was tested by determining the vibration thresholds at the test points. Our results demonstrated that all patients lost vibration sensation on the surgical side, and the sensation decreased significantly more in the NSM group. This result implies that temperature sensation is more related to the lateral cutaneous branches, which are damaged by removing all the breast tissue, whereas pressure and vibration sensations are more connected to the anterior cutaneous branches.

The results imply that 3 months after the operation is the appropriate time point to evaluate the degree of NAC sensation loss. Although sensation change progresses with time, even after 6 months, evaluation at 3 months is a reasonable observation time point, because the major changes have already happened. Our matched group data, implies that the sensation loss will not recover, even a long time after surgery.

Multiple studies in patients who have undergone NSM have shown recurrence rates comparable to traditional and skin-sparing mastectomies. As a result, more surgeons are starting to perform NSM on patients who had been excluded. More than 70% of patients in our study had lymphatic metastasis and accepted ALND. There were no local recurrences in the axilla. Breast sensation may be more adversely affected by ALND in these patients than in those without it.

ENSMSLS is the application of an endoscopic technique in breast surgery. It has some advantages: the stability of the scope during the operation and the development of special endoscopic instruments for the breast. Endoscopic mastectomy combined with immediate breast reconstruction can be completed, with all procedures occurring through only one incision hidden in the axilla. Vision is better with this technique. The cost of devices and the learning curve of the surgeries limits the popularity of these approaches.

CONCLUSIONS

ENSMSLS not only provides an optimal aesthetic outcome; it also reduces the possibility of decreased NAC sensation. (**Table 3**).

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