Prospective Cohort Study

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Nipple-areolar complex sensory recovery based on incision placement after nipple-sparing mastectomy: a prospective nonrandomized controlled trial

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Introduction: Nipple-sparing mastectomy (NSM) aims to improve patient satisfaction by preserving the nipple-areola complex (NAC) while ensuring oncologic safety. Different surgical incisions, such as inframammary fold (IMF) and periareolar/radial incisions, are used in NSM; however, their impact on NAC sensory loss remains unclear. In this study, the authors aimed to assess NAC sensation after NSM and compare the results of different incisional approaches, specifically IMF versus periareolar/radial.

Methods: In this prospective, single-center, nonrandomized controlled trial, 105 post-NSM patients were recruited from October 2019 to November 2021 and followed up at 24–48 months postsurgery. Of these, 97 (IMF: 65; periareolar/radial: 32) were analyzed for sensory assessment. NAC sensation was measured using the pin-prick test, with scores ranging from 0 (no sensation) to 2 (sharp sensation) across five NAC areas. Sensory loss was defined as a total score below 3.

Results: The median total score on the pin-prick test for NAC sensation was significantly higher in the IMF incision group than in the periareolar/radial incision group (3.77 ± 3.11 vs. 2.47 ± 2.51; $P = 0.043$). The rate of NAC sensory loss was significantly lower in the IMF group than in the periareolar/radial group (36.9% vs. 62.5%; $P = 0.017$). Multivariable analysis revealed that the incisional approach (95% CI: 0.14–0.97; $P = 0.044$) and radiotherapy (95% CI: 0.05–0.36; $P < 0.01$) were independent determinants of NAC sensory loss.

Conclusion: Our study emphasized the importance of incision placement during NSM in preserving NAC sensation and may provide a valuable perspective for clinicians and patients considering this surgical approach.

Keywords: incision placement, nipple-sparing mastectomy, nipple sensory

Introduction

Breast cancer is one of the most prevalent types of cancer among women worldwide, and mastectomy is a common treatment for early-stage breast cancer[1–4]. Compared to skin-sparing mastectomy or conventional total mastectomy, nipple-sparing mastectomy (NSM) involves removing the breast tissue while preserving the nipple-areolar complex (NAC)[5]. The primary goal of NSM is to maintain the natural appearance of the breast and improve the patient's quality of life and satisfaction without sacrificing oncologic outcomes[6,7].

NSM is performed using various incision types, including the inframammary fold (IMF) and radial or periareolar incisions[5,8]. An IMF incision is placed under the breast fold, whereas a radial/

HIGHLIGHTS

- Nipple-sparing mastectomy (NSM) focuses on esthetic and functional preservation of the nipple-areola complex (NAC) in breast cancer surgery. This study compares the impact of inframammary fold (IMF) versus periareolar/radial incisions on NAC sensory recovery post-NSM.
- A total of 97 patients undergoing NSM were assessed for NAC sensation using the pin-prick test at 24–48 months postoperation.
- Findings indicate significantly better NAC sensory recovery with IMF incisions compared to periareolar/radial incisions. The rate of sensory loss was lower in the IMF group than in the periareolar/radial group, highlighting the importance of incision placement.
- The study emphasizes the role of surgical technique in optimizing NAC sensation preservation, influencing clinical decision-making and patient satisfaction.

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periareolar incision is placed from the NAC to the lateral breast periphery with or without a circumferential incision around the areola. Incision selection is based on several factors, including the location and size of the tumor, patient body type, and surgeon preference, each having both advantages and disadvantages[5,9].

Different incision approaches may influence complication rates after NSM, such as ischemia or secondary surgeries[10–12]. However, their impact on NAC sensation remains understudied. The breast skin is innervated by the anterior and lateral cutaneous branches of the second to sixth intercostal nerves, while the NAC is innervated by the third to fifth intercostal nerves[13]. This indicates that the surgical incision used during NSM can cause nerve injury and altered approaches to the incision may reduce sensory loss.

Therefore, our study aimed to investigate the effects of different incision placements on NAC sensation. We hypothesized that NSM with an IMF incision enhances recovery of NAC sensation compared with a periareolar/radial incision, based on the idea that an IMF incision may minimize nerve injury and sensory changes to the NAC.

Methods

Study participants

This was a single-center prospective nonrandomized controlled trial study on NAC sensation. The study protocol was reviewed and approved by the Institutional Review Board of the center (IRB no. 3-2019-0235), prior to patient enrollment. The study was performed in accordance with Good Clinical Practice guidelines and the principles of the Declaration of Helsinki. Written informed consent was obtained from all patients at the time of enrollment.

Altogether, 105 post-NSM patients were prospectively recruited between October 2019 and November 2021. The inclusion criterion was having undergone NSM at our institution within 2–4 years before NAC sensory evaluation in this study. They were classified into two groups, IMF and periareolar/radial, depending on the incision type during surgery (Figs 1A and B), regardless of molecular subtype or adjuvant treatment. Patients with loss or excision of the NAC owing to postsurgical necrosis and/or diagnosis of other conditions that may interfere with cutaneous sensation were excluded.

Surgical procedure

NSM was performed by two surgeons, using IMF or periareolar/radial incisions. Incision types were decided upon considering factors such as tumor location, breast volume, and shape.

For the IMF incision, the natural skin crease under the breastfold was used along the lower outer curve. The radial incision was made from the midpoint of the lateral border of the areolar and extended towards the axilla. The periareolar incision was made starting from the upper or lower segment of the areolar depending on the location of the cancer and extended towards the axilla, similar to the radial incision. Radial/Periareolar incisions were preferred if the patient had a tumor close to the NAC (within 2 cm from the nipple) or if the patient had breasts with ptosis.

Skin flap was formed along the superficial mammary fascia maintaining a thickness ranging from 7 to 15 mm. The extent of the flap was made to the lower clavicle border superiorly, the upper portion of the rectus sheath inferiorly, the parasternal border medially, and the anterior border of the latissimus dorsi laterally. Breast parenchyme was detached from the chest wall by the deep fascia and NAC cancer invasion was evaluated intraoperatively through the frozen section. Axillary surgery, either sentinel lymph node biopsy or axillary lymph node dissection, was performed depending on the patient's nodal status using the same incision as the mastectomy incision.

Immediate reconstruction was performed by two plastic surgeons after mastectomy in a direct-to-implant (DTI), tissue expander, or autologous manner. For implant-based reconstruction, allogenic dermal matric slings were used to cover the implant.

Outcomes

The primary outcome was the difference in NAC sensory loss between patients who underwent two different incisions. NAC sensory evaluation was performed 24–48 months after surgery. NAC sensation was scored using the pin-prick test on a scale from 0 to 2 (0: no sensation, 1: dull sensation, 2: sharp sensation) in five areas (Fig. 2) and was summed up to 10. NAC sensation loss was defined as a total score < 3. The secondary outcome was to explore factors that were associated with NAC sensory loss.

Study design and statistical analyses

Based on a review of previous studies[14,15], we assumed that 30% of patients who underwent an IMF incision and 60% of patients who underwent periareolar/radial incision would lose NAC sensation. Considering that more patients underwent NSM with an IMF incision in our institution, the ratio of patients with IMF and periareolar/radial incisions was set at 2:1. The sample size was calculated using G*Power (version 3.1.9.2, Germany) with $\alpha = 0.05$ and $\beta = 0.2$, revealing that 93 patients would be an appropriate accrual number. Considering a 10% dropout rate, at least 69 patients who underwent IMF incision and 35 who underwent periareolar/radial incision were recruited. The study has been reported in line with the Strengthening the reporting of cohort, cross-sectional, and case–control studies in surgery (STROCSS) criteria[16].

The χ^2 test was used to evaluate whether the incisional approach affected NAC sensory loss, and the Mann–Whitney-*U* test was used to compare the NAC sensory score as a continuous variable. Analysis of variance and the χ^2 test were used to compare the continuous and categorical variables, respectively, for the baseline characteristics. A few of the variables were tested using Fisher's exact test owing to the sample size. Finally, logistic binary regression was performed for univariate and multivariate analyses to identify independent determinants of NAC sensory loss. All the tests were performed using IBM SPSS Statistics for Windows, version 26. Two-sided *P*-values < 0.05 were considered statistically significant.

Results

Patient baseline characteristics

A total of 105 patients (IMF, 69; radial/periareolar, 36) were recruited, and among them, 97 (IMF, 65; radial/periareolar, 32) were included in the analyses. Eight patients were excluded from the analysis because they did not undergo surgery between 24 and

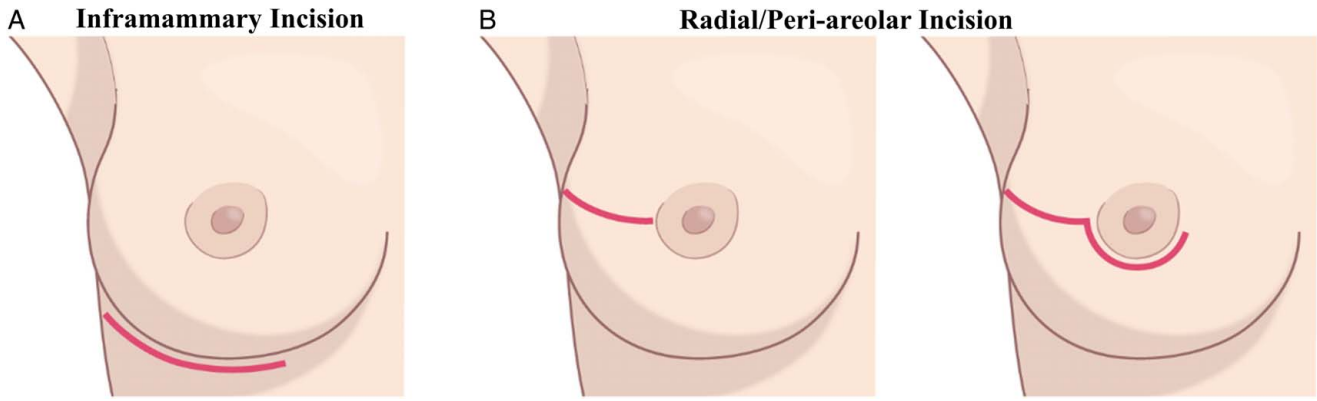

Figure 1. Incision placement of NSM (Illustration based on the right breast). NSM; nipple sparing mastectomy. (A) Inframammary incision. (B) Radial/Periareolar incision.

48 months prior to the evaluation. A CONSORT diagram of patient inclusion is shown in Figure 3.

The baseline characteristics of the study participants are presented in Table 1. The median age among patients who underwent NSM with IMF was 47, while those with radial/periareolar incisions were 44 ($P = 0.191$). There were no significant differences in terms of social history (i.e. smoking) or medical history (i.e. diabetes or hypertension) between the two groups. The median operation time, including reconstruction, was 285 min for IMF incisions and 305 min for radial/periareolar incisions ($P = 0.638$). Preoperative clinical factors, such as tumor-to-nipple distance ($P = 0.747$) and tumor location ($P = 0.180$), were also evenly distributed between both cohorts.

No statistically significant difference was noted concerning prior surgery on the ipsilateral breast ($P = 0.157$). Similarly, there were no notable distinctions in adjuvant treatments, including radiotherapy ($P = 0.119$), chemotherapy ($P = 0.724$), or endocrine therapy ($P = 0.778$). Moreover, complication rates did not exhibit a difference ($P = 0.103$).

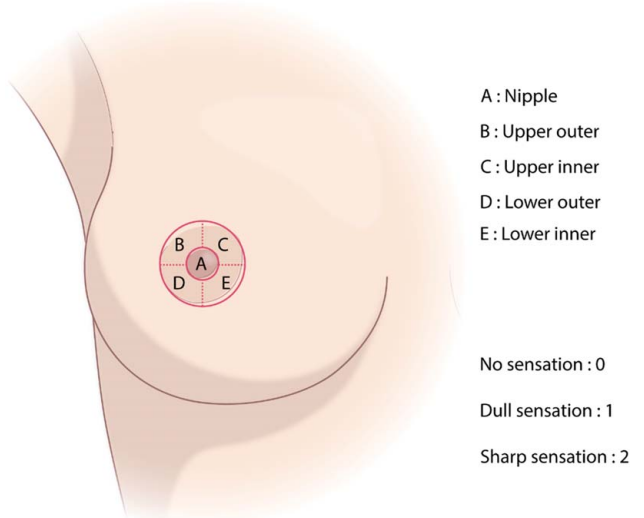

Figure 2. Pin-prick test sections of NAC (Illustration based on the right breast NAC). NAC; nipple-areolar complex.

Pin-Prick test of the nipple-areolar complex

The median total score on the NAC pin-prick test for all patients was 3; the median score for patients who underwent IMF incision was 3, whereas that for patients who underwent periareolar/radial incision was 2. A significantly higher sensory score was observed in patients with IMF than in patients with periareolar/radial incision (Fig. 4A, 3.77 ± 3.11 vs. 2.47 ± 2.51; $P = 0.043$). Additionally, the rate of NAC sensory loss (total score < 3) was significantly higher in the periareolar/radial group than in the IMF group (Fig. 4B, 62.5% vs. 36.9%; $P = 0.017$).

Factors associated with nipple-areolar complex sensory score

We conducted logistic binary regression analyses to examine the factors associated with NAC sensory loss and the results are shown in Table 2. Univariate analysis revealed that incisional approach and history of ipsilateral breast radiotherapy (before or after surgery) and history of previous surgery may contribute to NAC sensory loss ($P < 0.2$). However, other factors such as patient medical history, chemotherapy, endocrine therapy, and clinical characteristics did not show any significant correlation. In the multivariable analysis, incisional approach (95% CI: 0.14–0.97; $P = 0.044$) and radiotherapy

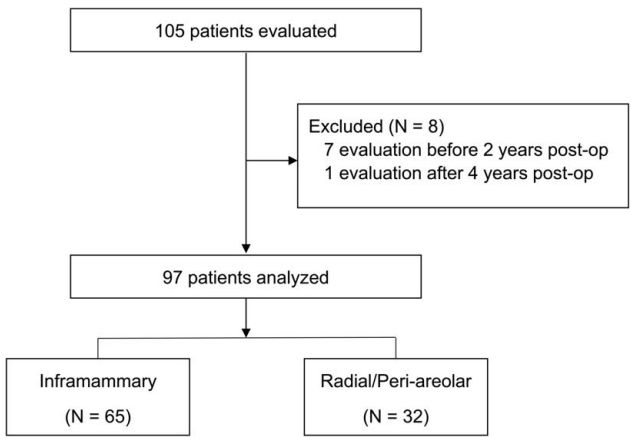

Figure 3. STROBE diagram of patient inclusion.

Table 1

Baseline characteristics of patients.

Characteristics	IMF ($N=65$)	Radial/Periareolar ($N=32$)	P
Age (median, years)	47	44	0.191
Interval from operation to pin-prick test (median, days)	951	796	0.056
NAC sensory total score (mean)	3	2	0.043
BMI (mean, kg/m^2)	22.03	21.54	0.520
Smoking history	1 (1.5%)	1 (3%)	1.00
Diabetes mellitus[a]	2 (3%)	0 (0%)	0.316
Hypertension[a]	3 (4.6%)	1 (3%)	0.729
Previous breast surgery	12 (19.3%)	10 (31.2%)	0.157
Radiotherapy history	18 (27.7%)	13 (40.6%)	0.119
Previous radiotherapy	6	6	
Postoperative radiotherapy	12	7	
Chemotherapy history	38 (58.5%)	21 (65.6%)	0.724
Previous chemotherapy	4	2	
Neoadjuvant chemotherapy	10	5	
Adjuvant chemotherapy	24	14	
Endocrine therapy	47 (72.3%)	24 (75%)	0.778
Operation time (median, min)	285	305	0.638
Tumor-to-nipple distance (median, mm)	23	27	0.747
Tumor location[a]			0.180
Upper outer	31	21	
Upper inner	15	4	
Lower outer	12	7	
Lower inner	6	0	
Center or whole breast	1	0	
Complication[a]	7 (10.8%)	9 (28%)	0.103
Infection	0	3	
Skin necrosis	0	4	
Nipple necrosis	7	2	

IMF, inframammary fold; NAC, nipple-areolar complex.

Unless otherwise noted, the values represent the number of patients with percentages in parentheses.

[a]Fisher's exact test.

(95% CI: 0.05–0.36; $P<0.01$) remained independent determinants of NAC sensory loss.

In our study, 12 patients underwent radiotherapy for prior ductal carcinoma *in situ* or invasive breast cancer of the ipsilateral breast, whereas 19 patients underwent radiotherapy post-NSM. Excluding one patient with unavailable radiotherapy details, those receiving radiotherapy before NSM received doses between 50 and 66 Gy in 23–28 fractions over 37–172 months (median, 66 months) after NAC sensory evaluation. Only one patient had preserved NAC sensation. Among those who received radiotherapy after NSM, doses ranged from 40.5 to 50.4 Gy in 15–28 fractions, and six patients retained NAC sensation. In exploratory multivariable analysis, statistically significant associations were observed between sensory recovery and radiotherapy administered before and after NSM, respectively (data not shown).

Discussion

Preserving the appearance and sensory function of the NAC has gained significant importance in breast surgery, specifically in cases of NSM for breast cancer treatment or sex affirmation surgery. Meta-analyses[17–20] have demonstrated that preserving NAC enhances patient satisfaction by maintaining nipple appearance and sensation while ensuring good oncologic outcomes.

This study aimed to compare NAC sensory loss based on various surgical incisions. To our knowledge, this is the first prospective cohort study evaluating post-NSM NAC sensory based on incisional approach. Our study met its primary endpoint that IMF incision would result in superior sensory recovery compared to periareolar/radial incision.

The recovery of NAC sensory function following NSM poses a considerable challenge. Chirappapha *et al*.[21] revealed that of 35 patients, only 1 experienced complete sensory recovery, whereas

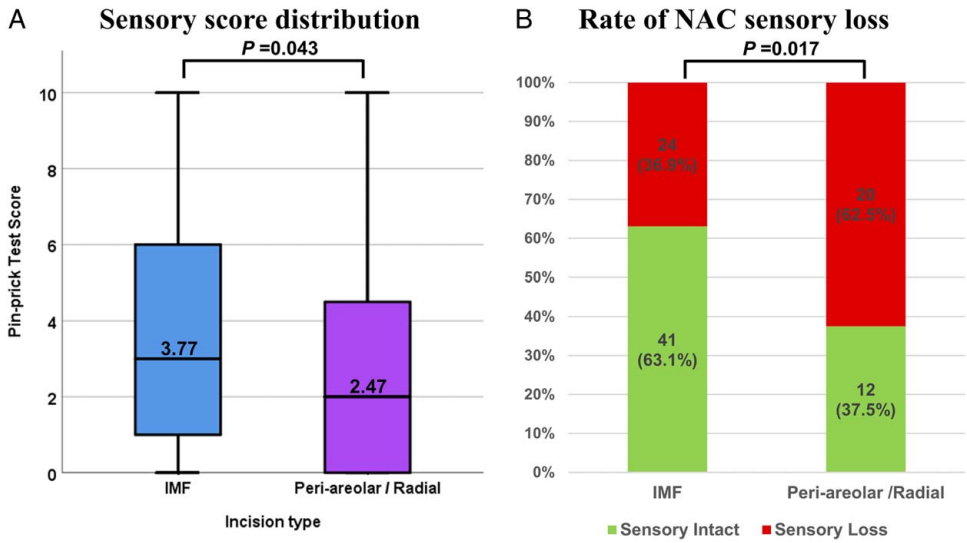

Figure 4. Pin-prick test results. IMF, inframammary fold, NAC; nipple-areolar complex. (A) Distribution of pin-prick test scores is illustrated in a box-and-whisker plot. The mean score was significantly higher in the IMF group than in the periareolar/radial group (3.77 ± 3.11 vs. 2.47 ± 2.51; $P=0.043$). (B) Rate of NAC sensory loss by the incision is illustrated by a bar graph. NAC sensory loss was significantly higher in the periareolar/radial group (36.9% vs. 62.5%; $P=0.017$).

Table 2

Binary regression analysis for factors affecting NAC sensory loss.

Determinants	Univariate analysis*	Logistic binary regression		
	P	Odds ratio	95% CI	*P*
Incision approach	0.018	2.70 (Ref. IMF incision)	1.03–7.09	0.044
BMI ≥23	0.733			
Smoking	0.273			
Diabetes mellitus	0.119			
Hypertension	0.858			
Previous breast surgery	0.050	1.16 (Ref. no previous surgery)	0.36–3.78	0.806
Radiotherapy history	< 0.001	7.66 (Ref. no RT Hx.)	2.78–21.12	< 0.01
Chemotherapy history	0.782			
Adjuvant endocrine therapy	0.983			
Tumor-to-nipple distance	0.094			
Unilateral vs. bilateral	0.107			
Breast volume	0.534			
Complication	0.521			

NAC, nipple-areolar complex.

21 had partial recovery 1 year postsurgery. Although no prior study has directly compared post-NSM sensory outcomes between two different incisions, Gahm *et al*.[14] and Yueh *et al*.[15] reported sensory loss rates of 62 and 25% for radial and IMF incisions, respectively. Considering these results, our study was designed to demonstrate that 30% of patients who underwent an IMF incision and 60% of patients who underwent a radial incision experienced NAC sensory loss.

Herein, we demonstrated the direct correlation between the choice of incision and its impact on the NAC sensation postsurgery. The NAC receives innervation from the anterior and lateral cutaneous branches of the third to fifth intercostal nerves. A periareolar/radial incision, running transversely on the breast skin, presents a higher risk of transecting these nerve branches, potentially causing nerve injury and subsequent sensory loss. Conversely, an IMF incision, placed beneath the breast along its fold, is positioned distantly from these nerve pathways, reducing the likelihood of direct interference with the nerves governing NAC sensation.

In our study, we opted for a sensory evaluation period of 2–4 years after the surgical procedure. This selection aimed for a more complete sensory recovery than that typically observed at 1-year mark[21]. This study design rationale finds support in research like Lai *et al*.[22]'s retrospective study of 460 NSM patients, which highlighted factors associated with better nipple sensation recovery. They found that a longer time gap between surgery and sensory evaluation (11.6% for ≤12 months vs. 38.5% for >60 months) correlated with improved recovery, validating our decision for an extended recovery evaluation timeframe.

In this study, it was found that the loss of NAC sensation was independently influenced by ipsilateral breast radiotherapy. Consequently, the observed changes in sensory perception may, in part, be attributable to well-documented complications associated with radiotherapy, such as radiotherapy-induced dermatitis or neuropathy, as reported in previous studies[23–26]. The occurrence of neuropathy and sensory dysfunction appears to persist across a spectrum of variations in both the total amount of radiation administered and the fractionated doses[23]. This suggests that a complex interplay of factors is responsible for these sensory alterations. Among these potential contributing factors are nerve compression resulting from radiation-induced fibrosis, direct nerve injury caused by axonal damage or demyelination, and the possibility of ischemic events arising from injury to blood vessels.

A relatively new surgical technique could serve as an option for patients experiencing reduced NAC sensation after NSM. NAC reinnervation has emerged as a strategy to reinstate NAC sensory perception[25,27]. This technique involves the dissection and preservation of the fourth lateral cutaneous intercostal nerve, followed by a neurotinization technique via neurorrhaphy of the nerve into the nerve stump of the NAC base, with or without using a nerve allograft. Preliminary studies have shown encouraging results with a higher likelihood of sensory recovery[25,27]. Therefore, NAC reinnervation may be beneficial, especially for individuals with risk factors associated with diminished NAC sensory function, such as a history of radiotherapy or having undergone NSM with periareolar/radial incision.

Limitations

This study offers valuable insights into the sensory recovery of the NAC following NSM; however, it has several limitations. As this was a single-center study, the applicability of our findings to other institutions may require additional investigation and validation. Nevertheless, it is worth highlighting that the rate of sensory recovery observed in our study either surpasses or falls within the range reported in previous research conducted across multiple centers (ranging from 10 to 68%)[8,18,28]. This consistency with existing data indirectly supports the proficiency of our surgical techniques.

Additionally, owing to the limited number of patients with specific medical conditions such as diabetes that may influence peripheral sensory function, the impact of these factors on NAC sensation might not have been fully accounted for. A larger study cohort could yield different results and enhance our understanding of the relationship between medical history and NAC sensory recovery.

Another limitation was that we were unable to use a validated tool for the evaluation or expand the scope of sensory sensations into different types. Our study focused on pain assessment using a subjective scale via the pin-prick test, omitting other sensory stimulation tests such as numbness, pressure, dysesthesia, thermal sensation, and arousal. Thus, although this study provides a valuable foundation for understanding pain sensitivity after NSM, further research is needed to evaluate the various qualities of sensation. As the demand for NAC sensory preservation extends beyond pain perception, future studies should expand the scope of sensory evaluation to comprehensively capture the diverse sensory experiences of patients after NSM.

Conclusions

This study highlighted the crucial role of different surgical incisions in NAC sensory loss and revealed that radiotherapy may also play a role in this regard. Using modifiable factors such as IMF incisions for NSM may mitigate the risk of NAC sensory loss

and enhance recovery. However, further research is necessary to improve the techniques for NAC sensory restoration and optimize patient outcomes and satisfaction, particularly when predisposing factors such as radiotherapy are present. Overall, our study underscores the importance of considering incision placement as a crucial factor in preserving NAC sensation during NSM and may provide valuable insights for clinicians and patients considering this surgical approach.

Ethical approval

This research has been reviewed and approved by the Institutional Review Board of Gangnam Severance Hospital, Yonsei University, Seoul, South Korea (IRB no. 3-2019-0235).

Consent

We obtained a fully informed written consent from all the study participants.

Source of funding

No funding was received.

Author contribution

J.J.: concept and design; Y.K., D.K., S.P., C.C., J.S.J., and S.H.B.: data curation; Y.K., D.K., S.P., and S.J.B.: acquisition, analysis, or interpretation of data; Y.K.: drafting of the manuscript; S.G.A. and J.J.: critical revision of the manuscript for important intellectual content; Y.K.: statistical analysis; J.J.: supervision.

Conflicts of interest disclosure

The authors no conflicts of interest.

Research registration unique identifying number (UIN)

This research was registered at clinicaltrials.gov, NCT05917834.

Guarantor

Jeong had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Data availability statement

Joon Jeong, corresponding author, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. The data that support the findings of this study are available from the corresponding author, upon reasonable request.

Provenance and peer review

Not commissioned, externally peer-reviewed.

Access to data and data analysis

Joon Jeong, the corresponding author, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. The datasets used and/or analyzed during the current study available from the corresponding author on reasonable request.

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