INTRODUCTION

Nipple-sparing mastectomy (NSM) is a valid option for carefully selected patients with breast cancer and for healthy, high-risk patients undergoing risk-reducing surgery. The uptake of NSM has been facilitated by advances in surgical and reconstructive techniques, as well as recognition that improved systemic therapies have markedly diminished locoregional recurrence rates.1–3 Breast reconstruction after NSM yields a superior aesthetic result compared with skin-sparing mastectomy (SSM). NSM is considered feasible both for risk reduction and for treatment of breast cancer4,5; however, the indications for NSM for breast cancer are still being debated.

The American Society of Breast Surgeons maintains an ongoing registry of NSM, and in a recent publication, they reported no recurrences in the nipple areola complex (NAC) among 833 cancer cases. In 2009, Spear et al7 had debated the controversy related to NSM and concluded that provided that certain oncologic and practical criteria are applied, it has the potential to allow less invasive surgery and improve cosmetic outcomes without increased oncologic risk in appropriately selected patients.

Two years later, he published a landmark article,8 which has since outlined the indications and contraindications for NSM.

Method: All NSM procedures performed at our institution between 2014 and 2018 were reviewed. The tumor-to-nipple distance was measured for each patient using mammography, ultrasound, or magnetic resonance imaging. All patients underwent a frozen section (FS) biopsy of the base of the nipple during surgery, and if cancer was detected, the procedure was converted to a skin-sparing mastectomy. Patients were followed for postoperative complications and cancer recurrence.

Results: Sixty-eight patients (98 breasts) underwent NSM with immediate reconstruction. Fifty-three patients (78%) underwent the procedure for breast cancer. Nipple involvement was detected on FS in 1 patient and on permanent pathology after a negative FS in 1 patient. Forty-three percent of our patients had a tumor-to-nipple distance of ≤2 cm. During a mean follow-up of 32.5 months (±19.4 months), no locoregional recurrences were observed; however, distant metastasis occurred in 3 patients.

Conclusions: When histologic examination from the base of the nipple is negative (either by FS or permanent pathology), NSM can be considered oncologically safe. Lack of nipple involvement by preoperative clinical and imaging assessment and intraoperative FS is sufficient to classify patients as suitable for NSM. (Plast Reconstr Surg Glob Open 2020;8:e2963; doi: 10.1097/GOX.0000000000002963; Published online 21 July 2020.)
for NSM. He retrospectively reviewed 162 cases of NSM: 49 for therapeutic indications and 113 for risk reduction. The majority had subareolar biopsies during surgery. In that article, the authors proposed major criteria for NSM. Oncologic criteria included tumor size <3 cm, tumor distance >2 cm from the nipple, clinically negative axillary nodes, and no skin involvement or evidence of inflammatory carcinoma or Paget’s disease. Anatomic criteria excluded very large or ptotic breasts and operative criteria included a negative intraoperative frozen section (FS) from the nipple base.

We decided to reexamine the oncologic criteria. The aim of our study was to describe our experience with NSM outside the proposed guidelines.

**PATIENTS AND METHODS**

All NSM procedures for breast cancer performed between the years 2014 and 2018 at our institution were included in this retrospective study. Patients were offered NSM if the nipple was free of tumors, determined by clinical examination and imaging. Patients with large and ptotic breasts who were not candidates for NSM based on anatomical features were not offered NSM; however, lymph node involvement or planned postmastectomy radiation therapy was not considered a contraindication for NSM. The NSM was carried out by 5 different breast surgeons.

FS biopsy of the tissue at the base of the nipple was performed in all cases, and if cancer was detected, the procedure was converted to SSM. All patients underwent immediate implant-based or autologous reconstruction.

For the purpose of this study, we defined a new parameter: “tumor-to-nipple distance” (TND). TND was determined after reviewing all available preoperative imaging studies by a radiologist and double checked and confirmed by a breast radiologist. The distance was defined as the shortest distance from the mass, calcifications, or enhancement to the base of the nipple as seen on any of the imaging studies (Fig. 1). The imaging modalities used were mammography, ultrasound (US), and magnetic resonance imaging (MRI). We divided the TND into 4 major groups: <1, 1–2, 2–3, and >3 cm.

If neoadjuvant therapy (NAT) was given, image analysis was conducted before and after treatment. Reasons for NAT included large tumors, lymph node involvement, Human Epidermal Growth Factor Receptor 2/Neu (HER2/Neu) positive or triple negative breast cancer, and in cases where the tumor-to-breast size ratio might dictate a large excision with a poor aesthetic result.

Data extracted from medical records included patient demographics, tumor characteristics, lymph node status, surgical risk factors (prior radiation treatment, smoking status, and diabetes), type of NAT, the surgical and reconstructive procedures performed, adjuvant treatment, and postoperative outcomes and complications. Postoperative complications recorded included: infection, wound dehiscence, seroma, skin flap necrosis, nipple–areola complex necrosis, and explantation. Reconstruction was mostly direct to implant with acellular dermal matrix. In selected cases, we performed free flap reconstruction with the deep inferior epigastric perforator flap. Two-staged breast reconstruction was conducted less frequently with insertion of a tissue expander. Follow-up was from the date of surgery to the date of last clinical follow-up. Patients were followed for locoregional recurrence, distant metastases, and death from the disease.

**RESULTS**

**Patient Characteristics**

We performed 98 nipple-sparing mastectomies in 68 patients over the study period (2014–2018): 43% (42 breasts) for risk reduction and 57% (56 breasts) for breast cancer. Fifty-three patients (78%) underwent the procedure for breast cancer and 15 (22%) for risk reduction. Only the therapeutic cases were analyzed for this report. All patients underwent immediate reconstruction (Table 1). The mean age was 47.6 (±10). Five patients (7%) were known breast cancer gene (BRACA) mutation carriers. Eleven patients (16%) were active smokers (all smokers were requested to stop smoking at least 2 weeks before surgery). Two patients (3%) had diabetes. Six patients (9%) received prior radiation to the operated breast. Twenty-three patients (43%) received NAT. NAT converted 10 patients (43%) to NSM who would otherwise not be considered appropriate. The mean follow-up was 32.5 months (±19.4 months).

**Surgical and Reconstructive Procedures**

The incisions used for NSM were inframammary fold (N = 23/56 breasts, 41%), lateral radial (N = 29/56 breasts, 52%), and periareolar (N = 4/56 breasts, 7%). Average specimen weight was 412 g (110–1160 g). The majority of the patients (N = 54/53, 64%) had direct to implant reconstruction. Fifteen patients (28%) had deep inferior epigastric perforator flap reconstruction. Four patients...
had cancer detected on FS from the nipple base, and the characteristics are summarized in Table 1. One patient cases (28%), there was lymph node involvement. Tumor in 26 patients (49%), had multicentric disease. In 15 according to the pathology report. Twenty-six breasts, presented and the mean size after treatment was 1 cm (±0.5) accord-
The mean tumor size before therapy was 4 cm (1.8–9 cm), data regarding tumor size of before and after treatment. Twenty patients who received neoadjuvant treatment had (tumor size of 0–1.9 cm), 10 patients had T2 (tumor size to 7 cm). For the non-neoadjuvant population, mean tumor size was divided into 3 groups: 15 patients had T1 (tumor size of 2.1–5 cm), and 5 patients had T3 (tumor size of >5 cm).

**Pathologic Characteristics**

Tumor size was extracted from the final pathologic report. In cases of multicentric involvement, the largest dimension of the largest tumor was used. If a patient had both invasive and in situ masses, the size of the invasive tumor was used. The mean tumor size was 1.6 cm (1 mm to 7 cm). For the non-neoadjuvant population, mean tumor size was divided into 3 groups: 15 patients had T1 (tumor size of 0–1.9 cm), 10 patients had T2 (tumor size of 2.1–5 cm), and 5 patients had T3 (tumor size of >5 cm). Twenty patients who received neoadjuvant treatment had data regarding tumor size of before and after treatment. The mean tumor size before therapy was 4 cm (1.8–9 cm), and the mean size after treatment was 1 cm (±0.5) according to the pathology report. Twenty-six breasts, presented in 26 patients (49%), had multicentric disease. In 15 cases (28%), there was lymph node involvement. Tumor characteristics are summarized in Table 1. One patient had cancer detected on FS from the nipple base, and the

**Tumor-to-nipple Distance**

Of the 53 who were included in this study, 50 patients had imaging studies available for review. Thirty patients had mammography images available. TN1 was measured on both the mediolateral and the craniocaudal views, and the shorter distance was recorded. Thirty-one patients had MRI and US imaging. Only 12 patients had all the 3 modalities available for review. The mean TN1 was first calculated per modality (Table 2). TN1 was divided into 4 groups (Table 3); 6 patients had a TN1 of <1 cm, and 14 patients had a TN1 between 1 and 2 cm. Of the 24 patients who received NAT, 7 patients had a complete clinical response and 3 patients showed no response to treatment. The mean TN1 at the group of <1 cm was 6 mm; the shortest distance documented was 4.3 mm.

**Postoperative Complications**

Overall, 19 patients (35%) had any postoperative complication. Infection rate was 11%. Nipple-areola complex necrosis occurred in 5 patients (9%) (Table 4).

**DISCUSSION**

The use of NSM has expanded from risk reducing to therapeutic indications; however, the question whether and when this procedure is oncologically safe is still

| Table 1. Patient Characteristics and Risk Factors, Tumor Characteristics, and Treatments |
|---------------------------------|---------------------------------|
| Patient Characteristics, N = 53 Patients (%) |
| Age at diagnosis                | 47.6 (20-68) |
| Smoking                         | 11 (20%)    |
| Diabetes mellitus               | 2 (4%)     |
| BRCA positive, N = 53 patients  | 5 (9%)      |
| Tumor characteristics, N = 56 Breasts (%) |
| Size                            | 1.6 cm (1 mm to 7 cm) |
| Multifocal                      | 26 (46%)   |
| ER positive                     | 36 (65%)   |
| PR positive                     | 19 (35%)   |
| HER2/Neu positive               | 7 (12.5%)  |
| Triple negative                 | 6 (10.5%)  |
| Axillary node involvement       | 15/53 (28%) |
| Positive FS converted to SSM    | 2/53 (3.7%) |
| Treatment, N = 53 (%)           |
| Prior radiation                 | 6 (11%)    |
| Neoadjuvant chemotherapy        | 23 (43%)   |
| Adjuvant radiation              | 23 (43%)   |
| Adjuvant chemotherapy           | 4 (8%)     |
| Antihermoral therapy            | 28 (53%)   |
| Biologic treatment              | 5 (9%)     |
| BRCA, breast cancer gene; ER, estrogen receptor; HER2/Neu, human epidermal growth factor receptor/Neu; PR, progesterone receptor. |

| Table 2. Mean TN1 per Modality |
|--------------------------------|
| Imaging Modality              | TN1 (mm) |
| MMG-CC                        | 38.8 ± 21.3 |
| MMG-MLO                       | 42.7 ± 21.2 |
| MRI                           | 32 ± 21.5  |
| US                            | 35.8 ± 17.7 |
| CC, craniocaudal; MLO, mediolateral; MMG, mammography. |

| Table 3. TN1 of 50 Patients Categorized into 4 Groups |
|-------------------------------------------------------|
| TN1                                                    |
| <1 cm                                                  |
| 1–2 cm                                                 |
| 2–3 cm                                                 |
| >3 cm                                                  |
| 6/50 (12%)                                             |
| 14/50 (28%)                                            |
| 9/50 (18%)                                             |
| 21/50 (42%)                                            |

| Table 4. Surgical Approach and Complications |
|----------------------------------------------|
| Incision type N = 56 Breasts (%)             |
| Inframammary fold                            | 23 (41%) |
| Radial                                       | 29 (52%) |
| Periareolar                                  | 4 (7%)  |
| Method of reconstruction N = 53 patients (%) |
| Tissue expander                              | 4 (7%)  |
| Implant                                      | 34 (63%) |
| Free flap (DIEP)                             | 15 (28%) |
| Complications N = 53 patients (%)            |
| Total complication rate                      | 19 (35%) |
| Infection                                    | 6 (11%)  |
| Dehiscence                                   | 3 (5.5%) |
| Skin flap necrosis                           | 6 (11%)  |
| Seroma                                       | 1 (1.8%) |
| Explantation                                 | 4 (7.4%) |
| Nipple areola complex necrosis               | 5 (9%)   |
| DIEP, deep inferior epigastric perforator flap. |
| Note: some patients had more than one complication. Overall 19 patients had any complication. Some had more than one. |
debated. Initial guidelines for NSM were outlined based on the prospective experience of a single institution.9

There is an increasing interest in this technique because there is evidence that it provides a better cosmetic outcome and improved quality of life.9 Our aim in this study is to outline new guidelines for NSM that are being currently used in our institution, mainly based on the TND. We measured the TND on all available imaging modalities and found that 39% of our patients had a TND of <2cm. According to our institutional practice, we include patients with tumor that is as close as <1 cm to the nipple as long as the nipple is not involved with tumor on FS. We performed intraoperative FS of the nipple base in all cases; however, as long as the nipple base is evaluated separately, it may be done on permanent pathology as well, if FS is not available for any reason.

Overall NAC involvement in this study was 3.5% (2/56 breasts). One patient had her nipple removed within the surgery and the second due to final pathologic diagnosis. Moreover, almost half of our patients had multicentric cancer (49%), and third had lymph node involvement (28%). The overall complication rate in this series was 35%; however, the infection rate was low (11%). NAC complication rate was 9%, and surgical intervention was indicated in all cases for salvage.

Only 3 patients (6%) had any recurrence, and all recurrences were systemic only. There were no local recurrences in this series.

The safety and practicality of NSM were examined by Jensen et al.10 who followed 99 patients for 5 years. They observed 3 recurrences with no deaths and therefore concluded that the 5-year recurrence for the procedure is low when NSM margins (both frozen and permanent) are included that the 5-year recurrence for the procedure is low. According to our institutional practice, we include patients with tumor that is as close as <1 cm to the nipple as long as the nipple is not involved with tumor on FS. We performed intraoperative FS of the nipple base in all cases; however, as long as the nipple base is evaluated separately, it may be done on permanent pathology as well, if FS is not available for any reason.

Overall NAC involvement in this study was 3.5% (2/56 breasts). One patient had her nipple removed within the surgery and the second due to final pathologic diagnosis of ductal carcinoma in situ within the nipple base after a negative FS at the time of surgery.

Mean overall tumor size was 1.6 cm (1 mm to 7 cm). Half of our non-NAT patients had a tumor size of <2 cm (50%), a third of them had tumor size of 2.1–5 cm (33%), and in 17%, tumors were larger than 5 cm at the time of diagnosis. Moreover, almost half of our patients had multicentric cancer (49%), and third had lymph node involvement (28%). The overall complication rate in this series was 35%; however, the infection rate was low (11%). NAC complication rate was 9%, and surgical intervention was indicated in all cases for salvage.

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prior radiation treatment (XRT) (11%), and alloplastic reconstruction (70%). In a previous publication based on an overlapping dataset, we found that alloplastic reconstruction had a higher complication rate compared with autologous reconstruction.

We included even minor events that were treated conservatively as complications. Moreover, our inclusion criteria for breast reconstruction were very liberal and we tend to operate on obese patients, smokers, and patients who received prior XRT.

In a systematic review by Piper et al., a 9.1% rate of NAC complications was reported, which is similar to the rate in this series (9%). Most of our NAC complications were treated conservatively and did not require surgical intervention.

Nipple ischemia and necrosis may be minimized by preserving major perforating vessels, elevating skin flaps in the plane between the subcutaneous fat and the breast glandular tissue, and the use of incisions that do not devascularize the NAC.

To summarize, literature review suggests strong support of the TND factor, with the minimal favorable distance ranging from 1 to 4 cm. We propose first to exclude nipple involvement by any imaging modality, and performance of a FS biopsy of the nipple base (followed by permanent pathologic evaluation) as the final determinant for nipple preservation, rather than relying on the TND alone. With this approach, the indications for NSM can be expanded to tumors that are located <2 cm from the nipple and even as close as 5 mm. The limitations of this study are its small size and retrospective nature.

**CONCLUSIONS**

Our results suggest that when clinical examination and preoperative studies do not suggest nipple involvement, and pathologic examination of tissue from the base of the nipple is negative (on FS or permanent histology), NSM can be considered oncologically safe. TND of <2 cm, multicentric cancer, lymph node involvement, or tumor size >3 cm should not be absolute contraindications for NSM. Larger studies and longer follow-up are needed to establish the safety of this approach.

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