INTRODUCTION

Direct to implant (DTI) immediate breast reconstruction following nipple sparing mastectomy (NSM) represents a reliable therapeutic option. However, 3–15.3% of patients undergoing this procedure could experience flap necrosis that may involve the nipple areola complex (NAC) as an immediate complication.1–6

Several recommendations have been proposed to avoid necrosis of the mastectomy flaps and/or the NAC.7,8 Preservation of adequate flap thickness during mastectomy significantly reduces skin necrosis. However, this is not always possible, depending on the breast characteristics of each patient.9 Performing an oncologically safe mastectomy requires dissection below the superficial layer of the fascia superficialis.10 The distance between the skin and the gland determines the subcutaneous tissue or “gland envelope” thickness (Fig. 1).

Larson et al.11 reported differences in the thickness of the subcutaneous breast tissue not related to breast

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Therefore, it could be advantageous to know the thickness of the subcutaneous breast tissue before considering a DTI reconstruction following an NSM.

Preoperative digital mammogram allows an accurate evaluation of the breast coverage and a preview of the resulting flap thickness, with a consequent possible prevision of flap quality and vascularization.

A more comprehensive indication for a reconstructive method could be evaluated considering this preoperative information over the possible resulting flap thickness after mastectomy.

We reported that the thickness of the breast subcutaneous tissue can be determined preoperatively by digital mammogram and proposed a breast tissue coverage classification (Table 1) according to the mammographic evidences.¹²

We hypothesized that the selection of patients with breast subcutaneous tissue coverage above 2 cm, as an evidence at preoperative digital mammography, would determine an adequate flap after NSM, directly representing the distance between the superficial layer of the fascia superficialis (the mastectomy “safe” surgical plane) and the skin: immediate DTI reconstruction could be safely indicated in these cases.

The purpose of this study was to describe the incidence of skin flap/NAC necrotic complications in patients eligible for NSM and immediate DTI reconstruction with type 3 tissue coverage according to the preoperative digital mammogram.
MATERIALS AND METHODS

This prospective study was performed at the University Hospital, between May 2011 and December 2015. The study protocol was approved by the institution’s ethical committee, and patients provided written informed consent.

Patients were screened for eligibility according to the results of a preoperative digital mammogram. The mammography was performed using a 3D Selenia Dimensions Full Field Digital Mammograph (Hologic, Bedford, Mass.). Breast tissue coverage measurements were reported in centimeter and millimeter. A single operator evaluated all mammograms, and measurements were obtained with OSIRIX Software (available at www.osirix-viewer.com) from digital imaging and communications in medicine format. The patients have been classified as type 1 to type 3 tissue coverage according to the thickness of the breast subcutaneous tissues. Only type 3 patients (subcutaneous tissue thickness of >2 cm or more) with small-to-moderate sized breasts (cup size A–B, 200–500 g) have been included.

The inclusion criteria were as follows: large or multicentric ductal carcinoma in situ (DCIS), invasive carcinoma 2 cm from the nipple without skin involvement, multifocal or multicentric invasive carcinoma, BRCA 1–2 mutated patients, medium or small breast with < 8 cm of NAC-inframammary fold distance, patients’ preference for contralateral risk reducing mastectomy, no more than grade 1 ptosis according to the Regnault classification,13 patients’ desire of breast reconstruction with a volume no larger than the preoperative one, and a type 3 preoperative tissue coverage at digital mammogram. The exclusion criteria were as follows: inflammatory carcinoma, skin involvement, pathologic NAC secretion, previous radiotherapy, hypertrophic and ptotic breasts, and recent (last 12 months) peri- or subareolar surgery.

Surgical Procedure and Implant Selection

The same surgical team operated on all the patients. A 10-cm radial lateral incision was performed without reaching the areola, over the pectoralis major border. The skin incision lasted few millimeters from the areolar margin to preserve the aesthetics of the NAC without scar retraction of the areola. This lateral incision allowed complete access to the whole breast. A separate axillary incision was performed for the sentinel lymph node biopsy or axillary lymph node dissection (ALND). The internal mammary fat and perforators have been carefully preserved. Intraoperative frozen section pathology of the remaining chest wall was performed, and the subpectoral plane was approached by the lateral pectoral border and dissected following the dual plane technique.14 A 2-mm skin resection of the incision borders was always performed. No acellular dermal matrices have been used in this series.

Three types of silicone implants have been used: Allergan Anatomical FX (full height, extra-full projection; Allergan Inc., Santa Barbara, Calif.), Mentor Anatomical CPG (medium height, maximum projection 323 - maximum height, maximum projection 333; Mentor Inc., Tx.), and Mentor round high projection (Mentor Inc.). Implants have been chosen on the basis of preoperative assessment of breast width and height. Chosen devices were 0.5 cm shorter than the breast measurements in each of these dimensions. Implant projection was selected according to skin stretch and patients’ desire, varying only between medium and maximum projections.

A drain was placed in the mastectomy pocket and another one in the axilla when ALND was performed. The drains were removed when less than 30 cc of drainage fluid per day was obtained.

Follow-Up Evaluation

All the patients were evaluated immediately after the surgery and scheduled for a monthly follow-up clinical examination every 30 days up to 6 months. After this period, they were followed up every 6 months to evaluate complications. The follow-up period ranged from 6 to 42 months (mean, 18 months).

Patient Satisfaction and Quality of Life

The 36-item short-form health survey (SF-36) questionnaire was administered 3 months after surgery for quality of life assessment.15 The SF-36 evaluates health status with 2 separate components: mental health and physical health. The physical health component includes 4 scales comprising 10 questions about physical functioning, 4 questions about role limitation due to physical problems, 2 questions about body pain, and 5 questions about general health. The mental health component also includes 4 scales. These comprise 4 questions about vitality, 2 questions about social functioning, 3 questions about role limitation due to emotional problems, 5 questions about mental health, and 1 question about general health perception. Each of these 8 subscales is scored separately, from 0 to 100. A higher score in each subscale indicates a better condition.

Patient satisfaction was assessed at 6 months after surgery. Patients were asked to rate 4 domains based on their perceptions of several aesthetic aspects as follows: (1) satisfaction in unclothed appearance, (2) satisfaction in clothed appearance, (3) body image appearance, and (4) overall satisfaction with surgery (Table 2). A 5-point Likert scale was used to rate satisfaction.

Table 2. Breast Reconstruction Satisfaction Questionnaire

| Satisfaction in unclothed appearance | 1 2 3 4 5 |
|-------------------------------------|----------|
| Satisfaction in clothed appearance  | 1 2 3 4 5 |
| Body image appearance               | 1 2 3 4 5 |
| Overall satisfaction with surgery   | 1 2 3 4 5 |

1, Not at all satisfied; 5, very satisfied.

Table 1. Breast Tissue Coverage Classification According to Digital Mammogram

| Type 1 | Up to 1 cm | Poor coverage |
|--------|------------|---------------|
| Type 2 | Between 1 and 2 cm | Medium coverage |
| Type 3 | More than 2 cm | Good coverage |

Intraoperative frozen section pathology of the remaining breast was performed. Based on the result of the frozen section, the NSM procedure was continued or changed to a skin sparing mastectomy with an elliptical resection of the NAC in continuity with the original incision. Careful he-
Table 3. Preoperative and Postoperative Patients’ Characteristics

| Patient No. | Age (y) | Implant Characteristics | Mastectomy | Axilla | Drains | Disease | Complications | Previous Implants | Postoperative Radiotherapy | Capsular Contracture | Patient Complaints |
|-------------|---------|-------------------------|------------|--------|--------|---------|----------------|--------------------------|-----------------------------|------------------------|---------------------|
| 1           | 43      | Mentor CPG 333 320 cc   | Unilateral | ALND   | Axilla/breast 1/1 | Invasive carcinoma |               | Yes                       |                           |                         |                     |
| 2           | 36      | Allergan 410 FX 300 g   | Bilateral  | No     | Breast 2       | BRCA +             |               |                           |                           |                         |                     |
| 3           | 41      | Mentor CPG 325 255 cc   | Unilateral | No     | Breast 1       | DCIS               |               |                           |                           |                         |                     |
| 4           | 49      | Mentor CPG 333 320 cc   | Unilateral | ALND   | Axilla/breast 1/1 | Multifocal        |               |                           |                           |                         |                     |
| 5           | 51      | Mentor CPG 333 350 cc   | Unilateral | No     | Breast 1       | DCIS               |               |                           |                           |                         |                     |
| 6           | 44      | Mentor CPG 325 300 cc   | Bilateral  | No     | Breast 2       | Multifocal 2 breast |               |                           |                           | Yes                     |                     |
| 7           | 20      | Mentor CPG 325 350 cc   | Unilateral | ALND   | Axilla/breast 1/1 | Invasive carcinoma |               |                           |                           |                         |                     |
| 8           | 33      | Mentor Round HP 400 cc  | Bilateral  | ALND   | Axilla/breast 1/2 | BRCA +            |               | Bilateral hypertrophic scar |                     | Yes                     | Yes                 |
| 9           | 53      | Mentor Round HP 400 cc  | Bilateral  | ALND   | Axilla/breast 2/2 | Invasive carcinoma bilateral |               |                           |                           |                         |                     |
| 10          | 54      | Mentor CPG 333 360 cc   | Unilateral | No     | Breast 1       | DCIS               |               |                           |                           |                         |                     |
| 11          | 58      | Mentor CPG 325 350 cc   | Unilateral | ALND   | Axilla/breast 1/1 | Invasive carcinoma |               |                           |                           | Yes                     | Yes                 |
| 12          | 53      | Mentor CPG 333 320 cc   | Unilateral | No     | Breast 1       | Multifocal        |               |                           |                           |                         |                     |
| 13          | 42      | Mentor CPG 333 360 cc   | Unilateral | ALND   | Axilla/breast 1/1 | Invasive carcinoma |               |                           |                           |                         |                     |
| 14          | 55      | Mentor CPG 333 360 cc   | Unilateral | ALND   | Axilla/breast 1/1 | Invasive carcinoma |               |                           |                           |                         |                     |
| 15          | 42      | Mentor CPG 323 345 cc   | Bilateral  | No     | Breast 2       | BRCA +            |               | Incision accidentally reached nipple on left breast |                     |                         |                     |
| 16          | 41      | Mentor Round HP 460 cc  | Unilateral | ALND   | Axilla/breast 1/1 | Multifocal        |               |                           |                           |                         |                     |
| 17          | 40      | Mentor CPG 325 320 cc   | Unilateral | No     | Breast 1       | Invasive carcinoma |               |                           |                           |                         |                     |
| 18          | 48      | Mentor Round HP 460 cc  | Unilateral | No     | Breast 2       | BRCA +            |               |                           |                           |                         |                     |
| 19          | 36      | Allergan 410 FX 300 g   | Unilateral | ALND   | Axilla/breast 1/1 | Invasive carcinoma |               |                           |                           | Yes                     |                     |
| 20          | 56      | Mentor Round HP 360 cc  | Bilateral  | No     | Breast 2       | Multifocal 2 breast |               |                           |                           | Yes                     |                     |
| 21          | 47      | Mentor CPG 333 350 cc   | Unilateral | No     | Breast 1       | Invasive carcinoma |               |                           |                           |                         |                     |
| 22          | 45      | Mentor CPG 323 195 cc   | Unilateral | No     | Breast 1       | Invasive carcinoma |               |                           |                           |                         |                     |

ALND, axillary lymph node dissection.
scale was used (5, excellent; 4, very good; 3, good; 2, fair; and 1, bad) to rate each domain.

RESULTS
Twenty-two consecutive female patients who underwent 30 NSMs with immediate DTI reconstruction with silicone implants were included (Table 3). In this series, 8 patients received NSM as risk-reducing surgery. We performed 8 bilateral and 14 unilateral mastectomies. The mean patient age was 44.1 years (range, 20–56). The preoperative diagnosis was unifocal invasive carcinoma in 9, multifocal invasive carcinoma in 5, DCIS in 4, and BRCA 1/2 mutation in 4 patients.

Short-Term Complications
We experienced no wound healing problems or skin flap/NAC ischemic complications immediately after surgery. We only observed 1 seroma. Clinical outcomes are presented in Figures 2 and 3.

Patients’ Satisfaction and Quality of Life
Quality of life was optimal at 3 months after surgery (Table 4). Patient satisfaction was optimal at 6 months after surgery, the aesthetic results being evaluated as good to excellent in all 22 cases. General patient satisfaction while dressed was either “very good” or “excellent” in all 22 cases. One patient rated her unclothed appearance as “mildly dissatisfied,” whereas 21 of the 22 patients were either “satisfied” or “very satisfied” with their unclothed appearance. The patient complaint was due to lack of fullness of the upper pole.

Long-Term Complications
At a mean follow-up of 18 months, 2 patients who underwent postmastectomy radiotherapy experienced a Baker 2 capsular contracture. One patient experienced bilateral scar hypertrophy and 1 scar retraction. No anatomical implant rotation was observed.

DISCUSSION
Several studies demonstrated 2 main sources of neurovascular supply to the nipple: a central and a superficial network.

The central supply travels in a ligamentous septum originating from pectoralis fascia at the level of the 5th rib and inferior border of pectoralis major. Branches of the thoracoacromial, lateral thoracic, and intercostal arteries and the deep branch of the fourth intercostal nerve passed within this septum. Würinger also described a medial ligament arising from the sternum and guiding blood vessels of the internal thoracic artery and anterior cutaneous intercostal nerve branches. A lateral ligament attached to the lateral border of pectoralis minor guides branches of the lateral thoracic and lateral cutaneous intercostal nerves. These ligaments merge and carry a blood supply to the superficial layer of the fascia superficialis.

O’Dey et al. found that the lateral thoracic artery supplies up to 3 separate branches to the nipple-areola complex during its descending course. These branches pass through deep breast tissue before ascending toward the nipple-areola complex to reach the superolateral edge. These branches are obviously divided during a mastectomy.

The superficial supply consists in a sparse dermal and subdermal plexuses around the nipple-areolar complex and 1 or 2 perforating vessels deriving from the internal thoracic artery (usually emerging in second or fourth intercostal spaces) that have a curved course with superior
convexity and arrive at the supero-medial border of the NAC at a depth of 1.5 ± 0.4 cm.17

According to these anatomical considerations, the skin flap thickness remains relevant to prevent and reduce necrotic complications, as preserving a flap thickness of more than 1.5 cm (when oncologically safe according to the information deriving from the preoperative digital mammography and the direct confirmation of the surgical mastectomy plane during the procedure) allows the NAC to base its vascular supply not only on the dermal and subdermal plexus but on the subcutaneous plexus as well.

Several publications noted the relationship between NAC vascularization and subcutaneous tissue preservation. Salgarello et al.19 and Spear et al.20 concluded that it is critically important to find and follow the plane between the breast gland and subcutaneous fat, to maximize the blood supply to the mastectomy flaps and NAC.

Our extensive survey of 253 digital mammograms revealed that the variation of the thickness of the subcutaneous layer is not related to the body mass index, breast size, or age,12 in accordance with the conclusions of Larson et al.11 and Beer et al.21

To the best of our knowledge, this is the first study to evaluate the usefulness of digital mammograms to choose the best reconstructive option in patients undergoing mastectomy.

In type 3 patients (those with breast subcutaneous tissue thickness of 2 cm or more) with small-to-moderate size breasts, the patients experienced no necrotic complications when undergoing NAC-sparing mastectomy and immediate DTI reconstruction, with high patient satisfaction levels.

Preoperative information about the thickness of the subcutaneous tissues could provide valuable data to foresee the postmastectomy flap viability and therefore to choose the best reconstructive technique. Thin flaps may implicate a high risk of tissue suffering, and immediate reconstruction might not be safe. Otherwise, a flap thickness of 2 cm or more provides a reliable coverage. In these cases, DTI reconstruction could represent a good option.

Immediate DTI breast reconstruction represents the best option in patients with small or medium breasts (200–600 g) with minimal or no ptosis, who desire minimal or no change in breast volume.22 Immediate DTI breast reconstruction requires meticulous planning, accurate marking, and accurate implant selection.23 The use of sizers and the weight of the resected gland could also be helpful. The preservation of the new inframammary fold

| Subscale                              | Median | Range  |
|---------------------------------------|--------|--------|
| Physical health                       | 84     | 82–87  |
| Physical functioning                  | 78     | 75–81  |
| Body pain                             | 75     | 73–82  |
| Role limitation due to physical problems | 74    | 71–76  |
| General health                        | 74     | 70–78  |
| Mental health                         | 85.5   | 83–88  |
| Social functioning                    | 77     | 72–80  |
| Role limitation due to emotional problems | 74    | 70–78  |
| Mental health                         | 60     | 57–63  |

SF-36, 36-item short-form health survey.

Fig. 3. A 42-year-old patient with DCIS on her left breast, with previous biopsy (BRCA+). Bilateral NSM; immediate bilateral DTI reconstruction was performed with Mentor CPG shaped 323 345cc. A, Preoperative digital mammogram showing a type 3 breast. B–D, Frontal and oblique preoperative views. E–F, Frontal and oblique 10-month postoperative views. The scar running through the NAC was due to a surgical accident by excessive tension with the retractors during surgery (described as a complication in Table 3, patient 15).
is essential for an optimal aesthetic result and should be symmetrical with the contralateral one.24

Implant selection remains a key element with this technique: the operator must match the implant base and height with the breast measurements. This is done simply with a caliper and a measuring tape.

Preoperative evaluation of breast tissue coverage by digital mammogram could provide important information for DTI reconstruction in NSM patient selection. Preoperative communication between the oncoplasty breast surgeon and the patient, based on digital mammogram findings, may improve decision-making concerning the selection of the best reconstructive method.

The present study is limited by the small sample size and relatively short follow-up period. Evaluation of larger population with a longer follow-up will demonstrate whether the information deriving from the preoperative digital mammography could be the driver for choosing an immediate DTI reconstruction following NSM.

CONCLUSIONS

Our findings suggest that NSM and immediate DTI reconstruction in patients with type 3 coverage, according to preoperative digital mammogram, minimizes the risk of skin flap and NAC necrotic complications, achieving high levels of patients’ satisfaction.

Alberto O. Rancati, MD, PhD
Instituto Oncologico Henry Moore
Avenida Callao 1046, PB “A”
Buenos Aires, (1425), Argentina
E-mail: rancati@gmail.com

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