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ORIGINAL ARTICLE

Oncoplastic approach to excisional breast biopsies: a randomized controlled, phase 2a trial

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Abstract

Background Oncoplastic surgery has been used in breast cancer patients for better cosmetic outcome over the last decades. The aim of this prospective randomized study is to show its place in excisional breast biopsy.

Methods An oncoplastic approach excision was compared with conventional excisional breast biopsies. The study included 80 patients, of whom half received oncoplastic intervention and half received the conventional. The primary endpoint was the cosmetic result. Patient, surgeon and independent observers rated the results on a four-point scale. Scores other than self-perceived were based on third-month medical photographs.

Results Between May 20, 2015 and April 27, 2016, 40 patients were randomly assigned to oncoplastic biopsy and 40 patients were assigned to conventional excisional biopsy. Median follow-up was 5.6 months (IQR 3.0–6.0). Self-perceived perfect scoring for general cosmetic outcome was found significantly higher after oncoplastic biopsy (73 0.5%) comparing with control group (32.4%) ($p=0.001$). This impact did not change after adjusting patients for potential confounders. Margin clearance rates in malignant cases were comparable in both arms ($p=0.999$); four patients in oncoplastic biopsy group (40%) and three patients in control group (33%) had positive margins.

Conclusions The oncoplastic biopsy achieved better cosmetic results with similar surgical margin positivity rates when compared with conventional breast biopsy. It may be a better biopsy option used for patients requiring excisional breast biopsy.

Keywords Oncoplastic surgery · Excisional breast biopsy · Breast cancer

Introduction

Excisional breast biopsy is selectively tailored either directly or after a core biopsy. A core biopsy for palpable or non-palpable tumors under imaging guidance should be the first choice of tissue sampling method. Alternatively, an excisional breast biopsy may be performed without core biopsy on suspicion of phyllode-like mesenchymal tumors as the sensitivity is superior for a definitive pathologic classification [1]. Despite the tendency for minimally-invasive sampling to replace obsolete surgical excison, lack of hardware and/or other limitations as per the cost-effectiveness strategy especially in resource-limited settings, patient's refusal or inability to tolerate the needle biopsy and technical difficulty with the procedure are other circumstances that would necessitate the excisonal biopsy as a first step in surgical procedure [2, 3].

The excisional breast biopsy has been the traditional diagnostic "gold-standard" for breast cancer [4]. The presence of a discrepancy between radiologic and histopathologic results addressed after a core biopsy is another indication for excisional biopsy [4]. If borderline pathologic findings such as lobular carcinoma in situ (LCIS), atypical ductal hyperplasia (ADH), atypical lobular hyperplasia (ALH) or flat epithelial atypia (FEA) are found after core biopsy, an excisional

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biopsy is necessary [3]. It is often performed under sedation and local anesthesia, and it may be switched to general anesthesia if necessary [5].

Many studies have affirmed the cosmetic-effectiveness and oncologic success of oncoplastic methods [6, 7]. However, these methods were not for diagnostic purposes. We believe the intent of the innovative oncoplastic intervention to the breast is underestimated in terms of providing diagnosis simultaneously constituting the basic component of surgical treatment. This study investigates the outcomes of oncoplastic way of surgical breast biopsy performed by the same primary surgeon; and contribute to the debate as to whether surgeons should place parenchymal sutures to approximate the cut edges of the cavity walls [8].

Patients and methods

The study is officially registered in clinicaltrials.gov (ID: NCT02452333). Eighty female patients presented to the breast unit were included. There were 40 patients in each arm; the oncoplastic approach excisional biopsy (the oncoplastic group) and the conventional excisional biopsy (the control group). A field-specific approach is followed in which the breast tissue is divided into three fields with two sagittal planes; medial, central and lateral fields. All participents randomized to one of two study arms using blocked randomization model with randomly selected block sizes for each field seperately [9]. The sequence (40 patients for each field) was generated by an independent doctor using Excel 2007 (Microsoft, Redmond, WA, USA). The arms were balanced 1:1 separately in 3 fields. All the patients were informed accordingly after they had been allocated to the randomized study arm as the procedure of choice was not masked and was announced to the entire health care team in charge as well. Preoperative needle localization under mammographic or ultrasound guidance was used for localization of non-palpable lesions.

Indications are: (1) lesions where available core biopsy options can not provide sufficient diagnostic efficiency; discretion of the attending radiologist. (2) Presence of radiology–pathology discordance. (3) Cases where core biopsy reveals high-risk pathology such as LCIS, ADH or ALH. (4) Lack of vacuum-assisted sampling device and limited use of stereotactic needle biopsy. (5) Lesions potentially posing a risk of chest wall injury. (6) Small lesions subject to considerable ambiguity in targeting. (7) Physical or mental inability to tolerate the needle biopsy.

Exclusion criteria were: (1) history of previous breast surgery or breast trauma. (2) Patient's refusal to undergo excisional biopsy. (3) Patients feeling reluctant to be photographed; those visiting for follow-up with their minds changed about being photographed were not excluded from other analysis. (4) Patients unable to complete third-month follow-up. (5) Indication for incisional biopsy or mastectomy without biopsy. (6) Indication for secondary breast surgery, not related to the primary lesion during the follow-up. (7) Multicentric lesions. (8) Congenital breast deformity. (9) Any other reason that the patients deem rational to reject or discontinue participation.

Approval was obtained from the institutional ethics committee. All the patients were well-informed about the methods and the potential complications and their written consents were obtained before the operation. The study respects the ethical standards in the Helsinki Declaration of 1975, as revised in 2013, as well as the national law.

Surgical technique

Oncoplastic procedures varying according to the breast size and lesion site, were determined by calculating the anticipated tumor/breast volume ratio (TBVR). Tezel method [10], an Archimedes-based cost-effective procedure was preferred to measure breast volume. The threshold volume rates of 15, 20 and 25% were followed for oncoplastic level shift in medial, central and lateral breast fields, respectively, and limiting rates of 45, 50 and 55% were followed for breast conservation. During calculations, surplus volume was taken into account in lesions expanding the breast (e.g., juvenile fibroadenoma). All procedures were conducted primarily under sedation and local anesthesia and it is switched to general anesthesia if necessary; level II procedures were conducted primarily under general anesthesia.

Periareolar incision for excision and repair with axial volume displacement, PAD (Periareolar Axial Displacement) was applied in cases where the excision was extending underneath the periareolar line (Fig. 1a). Before the displacement, the marginal extraareolar skin on the side of the defect was crescently de-epithelized to supply extra paranchymal support. Periareolar incision for excision and repair with reciprocal rotational volume displacement, PRD (Periareolar Rotational Displacement) was applied for non-retroareolar and non-peripheric lesions (Fig. 1b). A distance threshold of one-areolar-diameter from the periareolar margin was adopted to distinguish lesion peripherality. Periareolar and inframammary videoscopic port incisions for excision and repair with videoscopy-assisted reciprocal rotational volume displacement, VRD (Video-assisted Rotational Displacement) was applied for peripheral lesions (Fig. 1c). Level I oncoplastic procedures are summarized in Fig. 2. Segment-specific delayed oncoplastic reduction (preferentially after 6 months from the radiotherapy) after maintaining clear margins and immediate oncoplastic reduction for cases who would not tolerate re-excision were the procedure of choice when anticipated TBVR fit to level II.

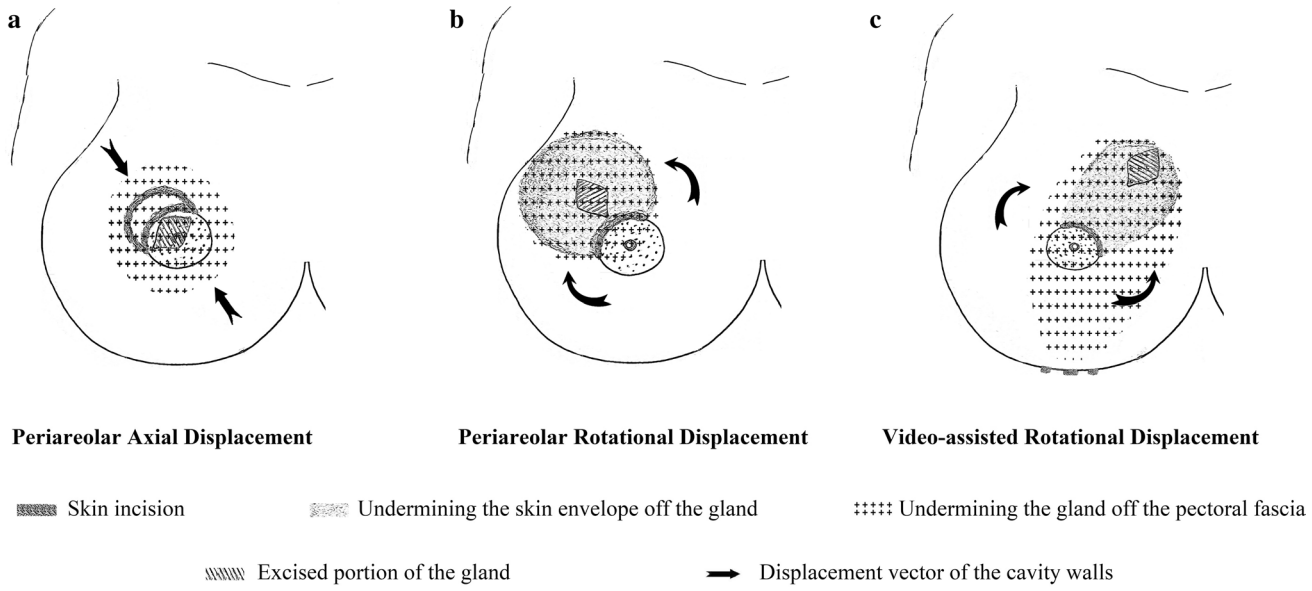

Fig. 1 Level I oncoplastic procedures used in the study. **a** Periareolar rotational displacement. **b** Periareolar axial displacement. **c** Video-assisted rotational displacement

In conventional excisional biopsy, periareolar incisions were used for lesions which are retroareolar or within close proximity of NAC. For other lesions located in the upper half of the breast parenchyma, a paraareolar incision was used. For remaining lesions below, radial incision was preferred. Cavity walls were not shifted nor sutured.

All patients were called in follow-up on 15th day. For malignant cases, isotope mapping and blue dye techniques were used together for sentinel node biopsy. The tracer was injected to peritumoral parenchyma (displaced tissue pillars were taken into consideration in the oncoplastic group) and subdermally to periareloar region.

At the third-month follow-up, patients were invited to participate in an esthetic self-evaluation by grading the similarity between the operated and the untreated side in terms of color, symmetry, contour and general cosmetic outcome separately on a four-level scale, known as the Harris scale [11]. Then, they were offered a professional cosmetic assessment, in which standard medical photographs were taken and graded by the operator (VD) and an independent plastic surgeon. Only the independent rater was blinded to study arm, and did not know what kind of surgery the patient received. Oncoplastic level II patients were not taken into esthetic evaluation because of the contralateral reduction plan. Quality and discordance control and adherence with the protocol were assessed weekly at meetings attended by radiologists and surgeons.

Statistics

For sample size selection, a similar study comparing the oncoplastic surgery and lumpectomy was analyzed [6]. Esthetic outcomes based on a four-point scale scored by specialists were selected where an average score of 2.97 (SD = 0.661) was reported after lumpectomy and 3.40 (SD = 0.704) after oncoplastic surgery [6]. Therefore, sample size of 68 was calculated on the basis of a hypothesis that would yield results sensitive enough to reveal a difference of 15% between the study arms (1:1 enrollment) while the alpha level for rejecting the null hypothesis was set to 0.05.

Depending on the test assumptions Student's t test or Mann–Whitney U test was performed for continuous variables; Pearson's Chi-square test or Fisher's exact test was applied for categorical variables. Inter-rater reliability was assessed using the intraclass correlation coefficient (ICC). Binary logistic regression was used to assess the cosmetic effect of oncoplastic approach after adjustment for potential confounding effects. In all analyses, a p value of 5% or lower is considered to be statistically significant. Data were analyzed using the statistical software SPSS version 20.0 for Windows (IBM Corp., Armonk, NY, USA).

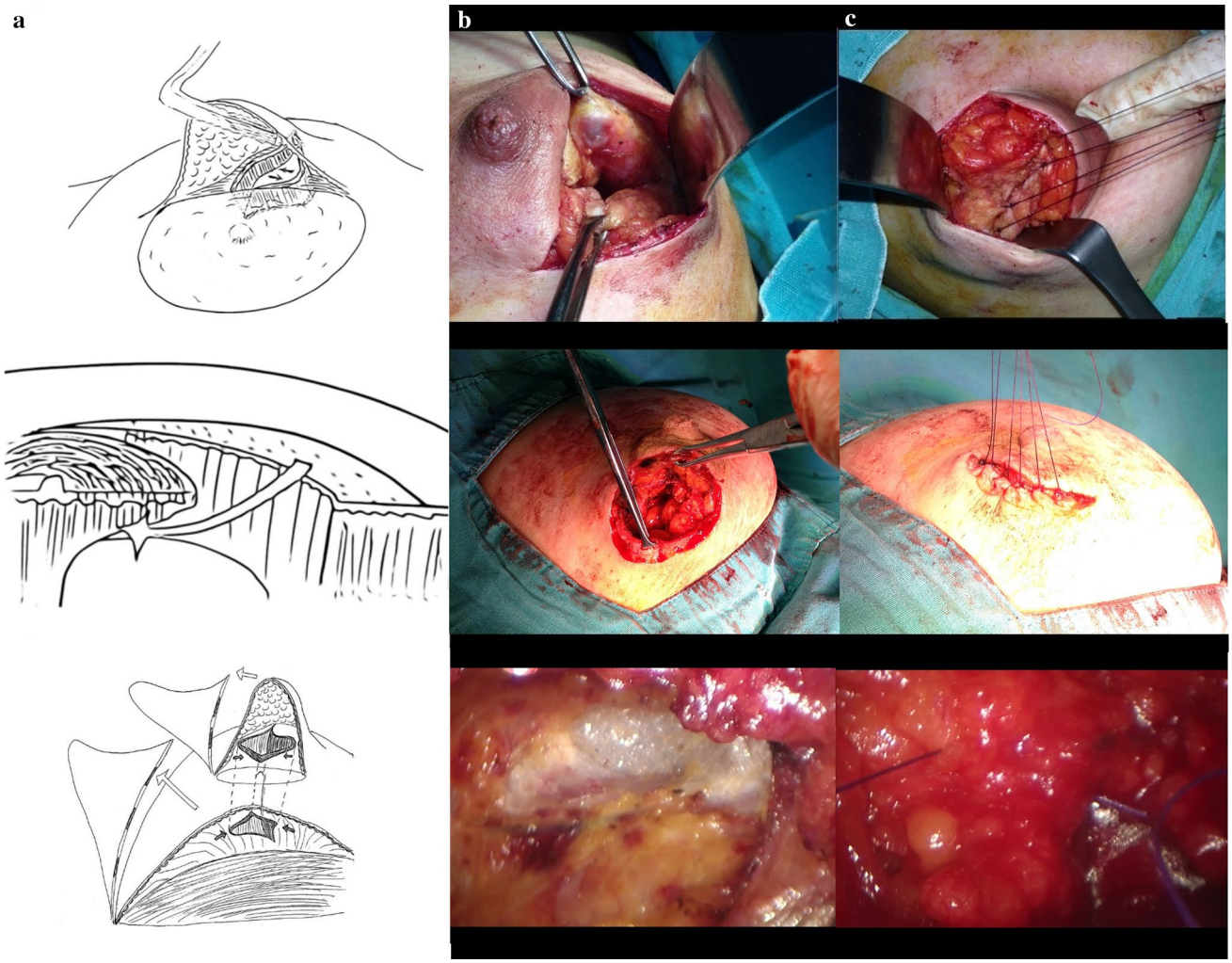

Fig. 2 Summary of the level I oncoplastic procedures. Upper row: periareolar rotational displacement. Middle row: periareolar axial displacement. Bottom row: video-assisted rotational displacement. **a** A schematic diagram of the operation. Black arrows: cavity walls to be displaced. White arrows: parts of the breast have been removed to display underlying subcutaneous (premammary) and retromammary spaces generated after videoscopy-assisted dissection. **b** Preparation of tissue pillars to be displaced. **c** Volume displacement

Results

Excisional breast biopsy was indicated in 118 of the patients admitted to the breast unit between May 20, 2015 and April 27, 2016. Eighty patients were included in the study. Of these patients, 40 underwent conventional and 40 underwent oncoplastic breast biopsy. The groups were well-matched with respect to demographic and clinical characteristics, and oncologic results (Table 1).

The mean age was 45.8 years (± 12.7). On the oncoplastic arm, 13 patients underwent PAD, 21 underwent PRD, 2 underwent VRD and 4 underwent level II procedures. There were two patients for both vertical and wise pattern incisions with pedicular displacement. On the conventional arm 11 patients had periareolar, 26 had paraareolar and three had radial incisions.

Seventeen patients had premalignant (borderline) lesions (10 had FEA, 2 had FEA + ADH, 1 had ADH, 1 had FEA + ADH + ALH, 1 had LCIS, 1 had LCIS + ALH + ADH and 1 had ADH). Nineteen patients had malignancy (13 had invasive carcinoma, 6 had DCIS). Negative surgical margin (no ink on tumor at the fibroglandular boundary of the breast (i.e., skin or chest), and ink ≥ 2 mm from the tumor at other margins) rates for malignant cases were comparable in both arms ($p = 0.999$). Positive surgical margin rates were 3/9 in conventional (2 periareolar and 1 paraareolar) and 4/10 in oncoplastic biopsy arm (1 PAD, 1 VRD, 1 vertical-pattern level-II and 1 wise-pattern level II). 1 patient in the control group (paraareolar) and 2 in the oncoplastic group (level-II) underwent completion mastectomy due to positive margins. There was 1 close margin in each arm (no ink on tumor but ink < 2 mm close to the margin at the fibroglandular

Table 1 Demographic characteristics and clinico-oncologic outcome with respect to the operation type (the conventional excisional biopsy vs. the oncoplastic biopsy)

	Control group	Oncoplastic group	Total	*p* value
Number of patients	40	40	80	N/A
Mean age	48.4 (±13.7)	43.3 (±11.2)	45.8 (±12.7)	0.076
Smoking	8	11	19	0.431
Menopause	22	15	37	0.116
Diabetes	6	5	11	0.745
Obesity	12	12	24	0.999
Family history of breast cancer	5	6	11	0.745
Presence of complaints	7	8	15	0.775
Lateral breast field lesion	20	20	40	0.999
Central breast field lesion	15	15	30	0.999
Medial breast field lesion	5	5	10	0.999
Mean breast volume	721.3 (±386.3)	611.9 (±413.3)	666.6 (±401.3)	0.225
Mean specimen volume rate (%)	9.98 (±8.34)	9.61 (±6.54)	9.80 (±7.45)	0.825
BIRADS 3 and less lesions	6	6	12	0.999
Radiology–pathology discordance	2	3	5	0.999
Clinical multifocality	12	11	23	0.805
MMG indication for excisional bx	17	20	37	0.501
Benign result	6	5	11	0.495
Premalignant result	4	7	11	0.447
Malignant result	7	8	15	0.942
DCIS	2	3	5	0.999
Invasive cancer	5	5	10	0.999
US indication for excisional bx	17	14	31	0.491
Benign result	11	10	21	0.999
Premalignant result	4	2	6	0.664
Malignant result	2	2	4	0.999
DCIS	0	1	1	0.452
Invasive cancer	2	1	3	0.999
Mean size of tumor deposit	8.1 (±3.8)	9.3 (±6.5)	8.8 (±5.3)	0.623
Mean size of invasive tm (mm)	9.0 (±3.7)	12.2 (±7.2)	10.5 (±5.6)	0.327
Mean size of DCIS (mm)	5.0 (±2.8)	5.1 (±0.9)	5.1 (±1.4)	0.960
Margin involvement of tm	3 (out of 9)	4 (out of 10)	7 (out of 19)	0.999

MMG mammography, US ultrasound, DCIS ductal carcinoma in situ, tm tumor, bx biopsy

boundary of the breast). Seven patients with positive surgical margins and two patients with level II oncoplastic excision were excluded from all esthetic evaluations. Of the 71 patients evaluated, 34 (47.9%) underwent oncoplastic and 37 (52.1%) underwent conventional biopsy. Nineteen patients did not allow to take photograph. One patient with antiseptic solution remnants on the breast and one patient with independent skin eruptions was excluded from photographic evaluation but self-scores were taken in. Thus, the photographic evaluations of the esthetic outcomes in the study are based on the scoring of 50 patients; 21 oncoplastic and 29 conventional.

Two sets of results, the comparison of top-half scores (3 and 4) vs. bottom-half (1 and 2) and the comparison of non-full scores (1–3) vs. full (4) are shown in Table 2. Full-score comparison revealed more significant results. Inter-rater agreement for average measures of general cosmetic outcome evaluating full-score was found to be substantial. ICC for single measure was 0.338 (0.163–0.518) and average measure 0.606 (0.369–0.763) ($p < 0.001$). Layered cross-tabulation of full scores according to breast fields revealed significantly better results for central lesions only in self-scoring (15.4 and 71.4%, respectively, for conventional and oncoplastic arm; $p = 0.003$) and for lateral lesions in operator scoring (43.8 and 88.9%, respectively; $p = 0.04$). Binary logistic regression results, examining the factors impacting full scoring for general cosmetic outcome are shown in Table 3.

The number of patients receiving general anesthesia was 22 (55%) in the conventional and 33 (82.5%) in the oncoplastic arm ($p = 0.008$). The mean follow-up time was 5.6 ± 3.0 months (from 3 to 16 months). Early complications were

Table 2 Cross-tabulation analysis: examining the relationship between operation type (the conventional excisional biopsy vs. the oncoplastic biopsy) and esthetic outcome—*n* (%)

Rater	Harris score	Control group				Oncoplastic group			
		Color	Contour	Symmetry	General	Color	Contour	Symmetry	General
Patient	*1–2*	5 (13.5)	6 (16.2)	6 (16.2)	4 (10.8)	1 (2.9)	2 (5.9)	2 (5.9)	1 (2.9)
	3–4	32 (86.5)	31 (83.8)	31 (83.8)	33 (89.2)	33 (97.1)	32 (94.1)	32 (94.1)	33 (97.1)
Rater 1	*1–2*	11 (37.9)*	7 (24.1)	3 (10.3)	6 (20.7)*	1 (4.8)*	1 (4.8)	0 (0)	0 (0)*
	3–4	18 (62.1)*	22 (75.9)	26 (89.7)	23 (79.3)*	20 (95.2)*	20 (95.2)	21 (100)	21 (100)*
Rater 2	*1–2*	20 (69.0)*	19 (65.5)*	18 (62.1)	16 (55.2)	7 (33.3)*	6 (28.6)*	8 (38.1)	8 (38.1)
	3–4	9 (31.0)*	10 (34.5)*	11 (37.9)	13 (44.8)	14 (66.7)*	15 (71.4)*	13 (61.9)	13 (61.9)
Patient	*1–3*	16 (43.2)*	27 (73.0)*	15 (40.5)	25 (67.6)*	7 (20.6)*	10 (29.4)*	10 (29.4)	9 (26.5)*
	4	21 (56.8)*	10 (27.0)*	22 (59.5)	12 (32.4)*	27 (79.4)*	24 (70.6)*	24 (70.6)	25 (73.5)*
Rater 1	*1–3*	24 (82.8)*	14 (48.3)	15 (51.7)*	15 (51.7)*	4 (19.0)*	5 (23.8)	5 (23.8)*	3 (14.3)*
	4	5 (17.2)*	15 (51.7)	14 (48.3)*	14 (48.3)*	17 (81.0)*	16 (76.2)	16 (76.2)*	18 (85.7)*
Rater 2	*1–3*	28 (96.6)*	20 (69.0)	22 (75.9)*	21 (72.4)*	13 (61.9)*	12 (57.1)	9 (42.9)*	9 (42.9)*
	4	1 (3.4)*	9 (31.0)	7 (24.1)*	8 (27.6)*	8 (38.1)*	9 (42.9)	12 (57.1)*	12 (57.1)*

Rater 1 operator, rater 2 independent professional

*p value < 0.05

Table 3 Binary logistic regression results: examining the relationship between operation type and full scoring for general cosmetic outcome—odds ratio (95% CI)

Model	Patient ($n=71$)	Operator ($n=50$)	Independent professional ($n=50$)
Operation type			
Oncoplastic biopsy	4.31 (1.29–14.38)*	5.53 (1.05–29.20)*	1.89 (0.35–10.17)
Age			
40 and older	1.91 (0.38–9.49)	0.29 (0.02–3.99)	3.61 (0.48–27.29)
Breast size			
Medium/large	< 0.001 (0.000-.)	0.39 (0.02–8.84)	0.95 (0.08–10.82)
BMI			
Obese	2.11 (0.52–8.56)	1.00 (0.21–4.69)	1.34 (0.19–9.40)
Menopausal status			
Postmenopausal	0.32 (0.07–1.34)	0.33 (0.07–1.67)	0.02 (0.00–0.18)*
History of diabetes			
Yes	1.59 (0.30–8.54)	0.91 (0.11–7.23)	0.15 (0.01–2.18)
Smoking status			
Smoker	0.43 (0.11–1.65)	0.23 (0.04–1.41)	0.62 (0.09–4.17)

Operation type (referent = conventional excisional biopsy); age (referent = younger than 40); breast size (referent = small breast, i.e., 250 cc and lower); body mass index (referent = non-obese, i.e., BMI less than 30); menopausal status (referent = non-postmenopausal); history of diabetes (referent = no diabetes); smoking status (referent=non-smoker)

Asterisk represents p value < 0.05

transient edema with cellulitis in four patients (two in each arm), seroma in three patients (two conventional and one oncoplastic), breast abscess in two patients (one in each study arm), hematoma in one patient (conventional) and pedicle necrosis treated with debridement, irrigation and reshaping in one patient (level II oncoplastic). Late complications included seroma in 11 patients (seven conventional and four oncoplastic). These complications were not found significantly different between the study arms and did not result in delay of oncologic treatment. Sentinel lymph nodes were successfully identified in every invasive case. There was no recurrence or mortality.

Discussion

This randomized controlled trial is a phase 2a trial according to IDEAL framework and general cosmesis (self-perceived) was found significantly better after oncoplastic approach

excision. The similar impact was confirmed in surgeons' evaluation. However, no difference was identified in scores of independent observer, although this study was underpowered to determine the effect of surgery type on cosmesis based on photographic evaluation.

The idea of developing better breast reshaping tricks in breast-conserving-surgery goes all the way back to 1986 [12]. Several retrospective studies have explained and described their benefit both for improved cosmesis and increased local tumor control in breast cancer [13–16]. Now the challenge is being shifted to biopsy. However, although surgical biopsy is accepted as the gold-standard diagnostic procedure in breast cancer it is becoming more and more obsolete. Yet, the failure of core needle biopsy (CNB) to spare the patient a surgical procedure is notoriously more common for calcifications than for masses [17–19] and harvesting large number of 11-gauge vacuum-assisted CNB specimens ($n > 20$) and strictly following a quality assurance protocol are necessary to achieve excellent results [20]. Besides, stereotactic biopsy methods are more advanced methods requiring maximal level of resources (4/4) according to The Breast Health Global Initiative (BHGI) guidelines and preoperative needle localization under mammographic or ultrasound guidance is suggested as a more cost-effective solution for enhanced level of resources (3/4) [21]. Thus, the time- and cost-effectiveness strategy in our unit was a consequence of our limited-resource settings.

Chagpar et al. [22] reported that the margin involvement was 34–36% after standard lumpectomy. This ratio was 48% in another randomized prospective study, EORTC 10801 [23]. In our study, the positive surgical margin rate was 36.8% (7:19); 40% in the oncoplastic group (4:10), and 33% in the conventional group (3:9) ($p = 0.999$). A reasonable inference to be drawn from these close rates could be that the oncoplastic biopsy is safe and not simply more likely to further escalate the re-excision rate even though this study is a phase 2a trial. We believe phase 2b studies examining learning curve effect will demonstrate the potentially protective function of oncoplastic biopsy over margin control.

Chun et al. [24] in their retrospective study comparing vacuum-assisted stereotactic core biopsy (11-gauge, 3 mm skin incision, 5–9 biopsy specimen), stereotactic-guided excisional biopsy (15 or 20 mm cannula; 1.5–2.5 cm skin incision) and wire-localized excisional biopsy (2–5 cm skin incision) reported that 95% of patients rated perfect score (3/3) for the postoperative second year scar in the first two methods but only 25% in the latter. However, cosmesis after breast surgery is a multifactorial phenomenon and contour integrity is a more decisive factor than the incision scar [25]. Likewise, in our study, rates for patient-perceived perfect color scores were 56.8% in the conventional excisional biopsies and 79.4% in the oncoplastic approach ($p = 0.042$); and same rates for contour integrity were 27.0 and 70.6%,

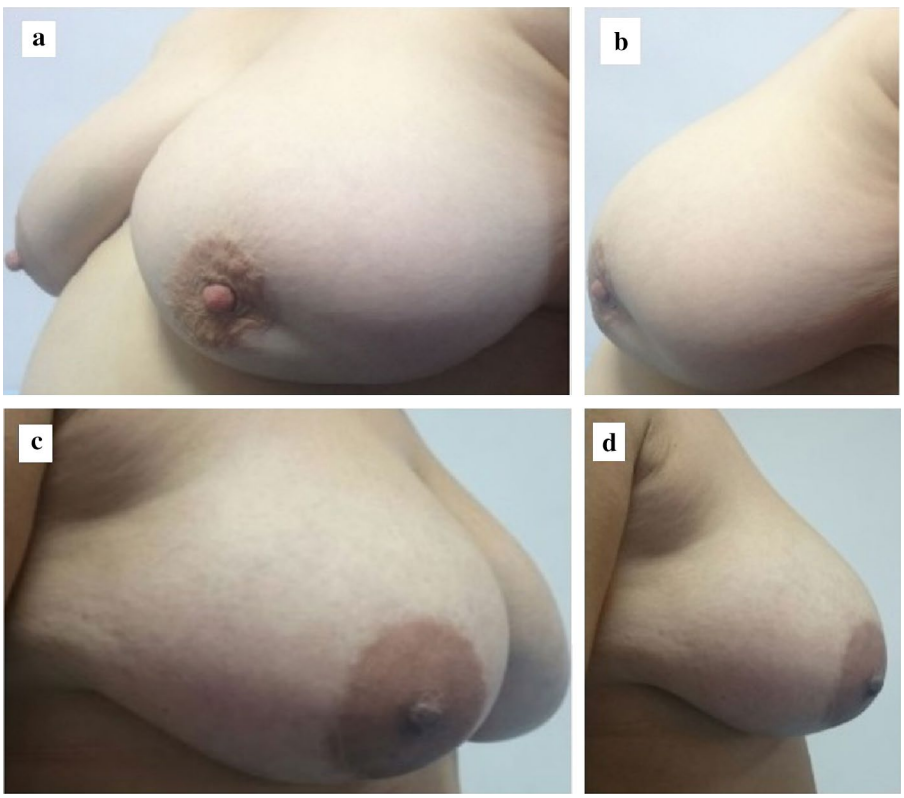

Fig. 3 Three-month esthetic results. Upper: patient in the control group. 40 mL (4.3%) specimen containing a lesion located in the central breast field was excised from 925 mL breast. Lower: patient in the oncoplastic group. 25 mL (3.8%) specimen containing a lesion at the lower part of the central breast field was excised from 650 mL breast. Patient-perceived scores were 4, 3, 4, 3 and 4, 4, 2, 4; operator ranked 4, 3, 3, 3 and 4, 4, 4, 4; independent rater ranked 3, 1, 1, 1 and 3, 4, 4, 4 respectively, for the two patients (Scores are given, respectively, for color, contour, symmetry and general similarity)

respectively ($p < 0.001$). Figure 3 displays the influence of contour integrity over the general esthetic outcome.

It is very likely that the location-specific approach is one of the factors maintaining good cosmetic results. According to Cochrane et al. [26] cosmetic results of breast-conserving surgery differ with regard to the parameters like TBVR and the location of the lesion. In their study, cosmesis and patient satisfaction were shown to be adversely affected when TBVR was greater than 5% for medial tumors, and 15% for laterals. Clough et al. [13] contributed an intriguing analysis of cosmesis by providing a descriptive framework of level II oncoplastic techniques for those a resection of 20–50% is anticipated. The threshold volume rates for oncoplastic level shift and breast conservation limits were arranged according to these two studies.

Mahmoud Bahij El-Tamer [27] reported that patients have rarely had significant tissue and sensation loss with periareolar incisions less than 50% of circumference of the areola irrespective of the location of the tumor. He also warned that when a periareolar incision is planned while the areolar diameter is 2 cm or less, extending the incision laterally, medially or both enhance access to and allow appropriate repair of the defect. According to Alexandre Mendonça Munhoz [28], when making the decision to have a semicircular periareolar incision rather than a round block for a patient with small-to-moderate-sized breast, the diameter of the areola should be greater than 4 cm, the patient should not have a ptosis (Regnault grad 1), and the tumor should be at least 5 cm away from the areola. And, if the diameter of the areola is less than 4 cm and some ptosis is present (grad 2), it is an indication of the round block method [28]. Even though we kept that option in the back of our minds, as a last resort for lesions with a retroareolar component where PAD would fail to prevent conditional skin dimpling and/or wrinkles, none of the patients required this circumferential extension.

Segment-specific level-II volume displacement procedures utilized in this study were in line with the therapeutic mammaplasty techniques reported by Mcculley et al. [14]. These procedures are more time-consuming, costly yet cost-effective procedures as they reduce further admissions [16]. In the comparative analyses of practice models (immediate, staged-immediate or delayed) margin positivity was higher in the immediate fashion, while delayed fashion was reported to have more complications due to radiotherapy-related sequela [29]. For this reason, our strategy was to utilize delayed reduction (preferentially after 6 months from the radiotherapy) after maintaining clear margins and immediate oncoplastic reduction for cases who would not tolerate re-excision. Still, oncoplastic reduction for diagnostic purposes is highly controversial and should be reserved for carefully selected patients only (e.g., multifocal and diffuse radiologic lesions when advanced stereotactic biopsy methods are not available). After a reasonable learning curve in their study, Fitoussi et al. consider 6 months (after the last intervention) to be the ideal time for symmetrization [30]. Thus symmetrization, was not performed simultaneously, but postponed to a later stage in this study. The strategy was to maintain the final look of the diseased breast and to avoid extra wound healing problems ending up with the postponement of adjuvant treatments.

The final maturation phase of wound healing takes several months and many authors wait 6 months before any revision, symmetrization or esthetic evaluation [6, 30]. Although, sooner or later, a better cosmesis will motivate patients, it is acknowledged that picking post-operative third month only for esthetic evaluation may be a confounding factor in the study and it may be a good idea to investigate both 3- and 6-month outcomes in future studies. Additionally, not blinding patients and the operator to study arms put the study at a risk of bias. However, this potential observer bias was examined by independent blinded rating and the substantial inter-rater agreement favors an increased assurance that our findings were not critically biased.

This is the first randomized controlled trial to examine diagnostic capability of oncoplastic methods. Since it is a phase 2a trial, it is of great importance for future studies in terms of research design as this pioneering work represents a priceless source of motivation for oncoplastic surgeons to overcome the difficulties in conducting a randomized controlled trial on oncoplastic breast surgery. The oncoplastic protocol is able to achieve better cosmetic results with comparable margin clearance rates and may take the place of conventional excisional biopsy. Nevertheless, it should not be forgotten that the oncoplastic methods are more invasive procedures resulting in wider incisions, longer operation time and increased likelihood of general anesthesia. They require demanding spatial orientation skills and multidisciplinary collaboration which is indispensable.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no competing interests.

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