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Results obtained with level II oncoplastic surgery spanning 20 years of breast cancer treatment: Do we really need further demonstration of reliability?

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Abstract

Oncoplastic surgery (OPS) has demonstrated its superiority above traditional breast conserving surgery, but is still struggling to consolidate its role in breast cancer therapeutic protocols mainly because of contrasting scientific evidences and reduced follow-up results available. The objective of our contribution is to analyze results obtained with 381 patients consecutively treated in our Multidisciplinary Breast Center by means of level II OPS between January 1998 and January 2018 for unilateral, primary breast cancer. Surgical endpoints were mean specimen weight and volume, mean diameter of main lesion (MLD), rates of positive margins (PMR), re-excision (RR), conversion to mastectomy (CMR), complications (CR) and oncological endpoints as overall survival (OS), disease-free survival (DFS), and local recurrence rate (LR). About 29.1% were treated for multifocal/multicentric disease, and 29.1% previously underwent neo-adjuvant chemotherapy (NACT). Regarding surgical techniques, 53.0% of patients received "inverted T" and 30.1% "J" mammoplasties, whereas 13.6% underwent "round block," 2.3% "Grisotti," and 1% "batwing" techniques. Regarding surgical outcomes, mean specimen weight was 215 g (50-2157) and volume 345 mm^3 (21-7980). MLD 23 mm, PMR 7.6%, RR 3.6%, CMR 1.6%, and CR 5.8%. With a mean follow-up of 118 months, oncological outcomes were: OS 93.7%, DFS 82.3%, LR 4.4%. In conclusion, our analysis confirmed level II OPS reliability even for longer follow-up timing and in difficult situations as multifocal disease or after NACT.

KEYWORDS

breast cancer, breast cancer treatment, breast surgery, breast-conserving surgery, mastectomy, oncoplastic surgery

1 | INTRODUCTION

Breast cancer treatment has gone through a dramatic shift over the past three decades, trending away from radical procedures toward breast-conserving techniques that provide patients with greater esthetic satisfaction.

As a result, breast-conserving surgery (BCS) combined with adjuvant radiotherapy is now considered the "gold standard" for early breast cancer treatment, having confirmed same oncological outcomes of mastectomy.[1,2]

In addition to offering overlapping rates of overall/disease-free survival (DFS) and local recurrence, the aim of BCS is to reach a

higher level in preservation of glandular contour and breast symmetry, ensuring a more natural result and, compared to prosthetic surgery, lower complication rates and a better quality of life.[3,4]

These targets are easy to obtain when lesions to be treated are under 2 cm, in medium-large breasts or if the rate of gland to be removed does not exceed 20% of the whole breast.[5,6]

Nevertheless, in routine clinical practice, these conditions do not always occur and up to 85% of BCS patients are reported to suffer from physical imperfections that frequently result in considerable psychological repercussions.[5,7-9]

In order to broaden the possibilities of conservative surgery and reduce these risks, our group was among the first to introduce and develop techniques that were named "Oncoplastic Surgery" (OPS)[10,11] masterfully codified by Dr. Clough and the Paris Breast Center.[12]

These techniques include oncological excisions followed by extensive glandular remodeling, combining oncological resections and plastic surgery solutions.

Oncoplastic surgery, in addition to having demonstrated its superiority in the esthetic field, has further expanded the possibilities of conservative surgery, allowing wider resections (with a lower margin infiltration rates) and lower rates of local recurrence.[13]

Despite its unquestionable potential and the considerable interest aroused among breast cancer specialists, OPS is still struggling to consolidate its role in therapeutic protocols worldwide.

This phenomenon correlates mainly to the absence of training programs of modern Breast Units in OPS,[14-16] but also to the low level of scientific evidences available, as OPS literature offers only retrospective results of small and heterogeneous observational studies, with reduced follow-up timing.[13,17]

A clear consequence of this phenomenon is reflected in recently published Anglo-American statistics, still reporting a 90% rate of mastectomies proposed as primary treatment for early breast tumors[18,19] and the extreme variability to which OPS is adopted in Europe[20,21] especially in the treatment of complex cases, such as tumors after neo-adjuvant chemotherapy (NACT) or multifocal/multicentric neoplasms.[22,23]

The objective of our study is to retrospectively analyze 20 years of results obtained in a high volume Multidisciplinary Breast Unit, from patients undergoing level II OPS.

Our results could offer a starting point both for prospective trials and for the consolidation of these techniques as a valuable alternative to mastectomy.

2 | MATERIALS AND METHODS

At the Multidisciplinary Breast Center of the Fondazione Policlinico A. Gemelli IRCCS in Rome, between January 1998 and January 2018, 9874 patients were treated for breast cancer, among which 9217 surgical procedures were performed for unilateral primary malignant neoplasms.

The most appropriate surgical treatment was decided in a multidisciplinary meeting, considering the overall conditions of the patient, breast volume and grade of ptosis, the quadrant of the onset and extension of the neoplasm.

In 7925 cases (86.0%), the proposed treatment was a conservative technique, while in 1292 cases (14.0%), a mastectomy was preferred over breast conservation.

In the vast majority of cases subjected to conservative treatments (7544 cases—95.1%) traditional BCS or level I OPS techniques were used.

In 381 cases (4.9%), patients were surgically treated with level II OPS techniques and their prospectively collected reports are analyzed in our study.

2.1 | Preoperative planning

The preoperative workout included a physical examination, breast ultrasound, mammography, core biopsy, standardized photographic record.

Magnetic resonance (MRI) was multi-disciplinary discussed in cases of suspected multifocality/multicentricity, in patients eligible for NACT and in cases of discrepancy between first level radiological examinations.

In case of non-palpable lesions, patients underwent preoperative radioguided (ROLL) or radiological localization (by means of wire positioning or ultrasound-guided tattooing) according to breast and neoplasm characteristics.

2.2 | Selection of level II oncoplastic techniques

For resections of 20%-50% of the breast volume, level II OPS techniques were adopted including "inverted T" or "J" mammoplasty, "Round Block," central quadrantectomy with the "Grisotti" approach and quadrantectomies with the "Batwing" techniques, according to as previously described.[10,11]

In all patients, a contralateral breast symmetrization was also performed, in order to optimize the esthetic result. The technique used was always the same as the side of the tumor affected breast, except for the Grisotti, in which a J-mastoplasty was preferred for symmetry of scars.

2.3 | Intraoperative evaluation

The removed specimen was always weighed, oriented with sutures and clips, and sent for an intraoperative mammographic margin assessment. In case of involved or close margins, a cavity shaving was performed.

2.4 | Endpoints and purpose of our study

The purpose of this retrospective analysis is to present our results of 20 years of experience in level II OPS. The endpoints under analysis are defined as follows:

2.4.1 | Surgical endpoints

- Estimates of mean "overall radiological diameter" (ORD) intended as maximum extension of neoplastic foci (monocentric, multifocal/multicentric) measured at the preoperative radiological workout.
- Estimates of OPS effectiveness indicators measured during surgical procedure, intended as mean specimen weight and volume.
- Estimates of mean "overall pathologic diameter" (OPD), intended as maximum extension of neoplastic foci (monocentric, multifocal/multicentric) measured at pathologic exam.
- Estimates of mean diameter of main lesion (indicator of "T" score at pathologic exam).
- Positive Margin Rate (PMR): Defined, for invasive carcinomas, as the presence of tumor in ink, in accordance with the ASCO guidelines.[22] For cases treated until 2015 for ductal in situ ductal carcinomas, an involved margin was defined as ink on tumor. From 2015, an involved margin is defined as a distance lower of 2 mm from the tumor cells to the inked margins, as assessed by the European Society for Medical Oncology (ESMO), and National Comprehensive Cancer Network (NCCN) guidelines.[24,25]
- Re-excision Rate (RR): Percentage of patients undergoing conservative surgical enlargement of margins following proven margin involvement at pathology report.
- Conversion to Mastectomy Rate (CMR): Percentage of patients who required mastectomy as the only treatment possible to obtain a margin widening following margin involvement at pathology report.
- Complications Rate (CR): Percentage of complications related to surgical treatment occurred during the postoperative period (within 30 days from surgical procedure) including seroma, liponecrosis, hematomas, surgical site infections (including clinical signs and microbiological evidences), and wound dehiscence.

2.4.2 | Oncological endpoints

- Overall Survival (OS): Patients in the study who were alive from the time of surgery to date of last follow-up
- Disease-Free Survival (DFS): Patients in the study who were alive from the time of surgery to date of last follow-up without relapsing breast cancer (locoregional, contralateral, or distant).
- Local Recurrence (LR): Patients that developed an ipsilateral locoregional recurrence of disease (chest wall, residual gland, skin, and axillary lymph nodes) following surgical treatment and prior to date of last follow-up.

2.4.3 | Esthetic endpoints

The esthetic result was assessed every six months starting from the end of the adjuvant treatments by means of photographic records and an internal questionnaire headed for attending surgeons and for patients.

2.5 | Statistical analysis

Results are expressed as means with associated median and range. Statistical analysis was performed using the SPSS (version 24.0 for Windows). Fisher exact test was used for comparison of categorical variables. A *P*-value equal to or less than .05 was considered statistically significant. Estimates of OS, DFS, and LR were produced by cumulative incidence, using the Kaplan–Meier method. The oncological results of the global sample were calculated at 240 months (20 years). Patients were considered censored when lost after last registered contact, or, for the purposes of LR and DFS, at the time of death.

3 | RESULTS

Between January 1998 and January 2018, a total of 381 consecutive patients surgically treated with level II OPS techniques were included in the study (patient and tumor characteristics are summarized in Table 1).

The average age of the patients was 49 years (49, 24-79); breast volume was classified as medium or large in 282 patients (74.0%) with moderate or severe ptosis in 287 patients (75.3%).

The 381 patients were all affected by unilateral neoplasms. Mainly unifocal (270 cases—70.9%), but in 111 cases (29.1%), patients received level II OPS for the treatment of a multifocal/multicentric disease.

With reference to the location of the lesions, 231 aroused in the upper quadrants (60.6%), 32 in the central quadrants (8.4%), 73 in the lower quadrants (19.2%), and 45 with mixed localizations (11.8%).

In relation to the initial size of the tumor, the axillary lymph node involvement and the biological characteristics of the neoplasms, 111 patients (29.1%) underwent NACT, obtaining a complete pathological response in 19 tumors (17.1%), a greater response (reduction of more than 50% of the diameter) in 38 cases (34.2%), a partial response in 43 (38.8%), and no response in 11 cases (9.9%).

Among level II OPS techniques, 202 cases were treated with the inverted T mammoplasty (160 with an inferior and 42 with a superior pedicle); 118 cases with the J mammoplasty; 48 cases using the "round block" technique; 9 cases of central quadrantectomies implementing the "Grisotti" technique and 4 with the "batwing" technique (Table 2).

Final pathology report revealed 59 cases (15.5%) of ductal carcinoma in situ and 259 cases (68%) of invasive carcinoma, of which 207 cases were ductal (54.3%), 52 were lobular (13.7%) and 63 showed to be of mixed ductal and lobular histotypes or mucinous neoplasm variants (16.5%).

Regarding the adjuvant treatments performed after the histopathological analysis and the instrumental investigations of systemic staging, all the patients underwent complementary radiotherapy, except 6 with positive margins treated with rescue mastectomy.

TABLE 1 Patient and tumor characteristics

Mean age	49 (49, 24-79)
Menopause	
Yes	171 (44.9%)
No	210 (55.1%)
BMI	
16-20	26 (6.8%)
20-25	163 (42.8%)
25-30	165 (43.3%)
>30	27 (7.1%)
Breast size	
3°	99 (26%)
4°	203 (53.3%)
5°	72 (18.9%)
>5°	7 (1.8%)
Tumor location	
Upper quadrants	231 (60.6%)
Central quadrants	32 (8.4%)
Lower quadrants	73 (19.2%)
Mixed	45 (11.8%)
Focality	
Unifocal	270 (70.9%)
Multifocal	74 (19.4%)
Multicentric	9 (2.4%)
Multifocal/multicentric	28 (7.3%)
Neo-adjuvant chemotherapy	
Yes	111 (29.1%)
No	270 (70.9%)
Pathological T stage	
0 (after NAC)	12 (3.2%)
Is	59 (15.5%)
1	147 (38.6%)
2	156 (40.9%)
3	5 (1.3%)
4b	2 (0.5%)
Pathological N stage	
0 – not removed (DCIS)	225 (59%)
1	107 (28.1%)
2	43 (11.3%)
3	6 (1.6%)
Histopathological Examination	
Pure DCIS	59 (15.5%)
Invasive ductal carcinoma	207 (54.3%)
Invasive lobular carcinoma	52 (13.7%)
Mixed/other	63 (16.5%)
Histologic subtype (invasive)	
Luminal A	149 (46.3%)
Luminal B (HER2 negative)	68 (21.1%)
Luminal B (HER 2 positive)	47 (14.6%)
HER2 non luminal	24 (7.5%)
Triple negative	31 (9.6%)
Missing	3 (0.9%)
Adjuvant therapy	
Radiotherapy	72 (18.9%)
Radiotherapy + hormone therapy	228 (59.8%)
Hormone therapy	6 (1.6%)
Chemotherapy + radiotherapy + hormone therapy	75 (19.7%)

3.1 | Surgical outcomes

Surgical outcomes are summarized in Table 3.

According to preoperative radiological workout, mean ORD was 33 mm (30, 8-150).

The average volume of the surgical specimen was 345 mm^3 (227, 21-7980) with an average weight of 215 g (235, 50-2157).

Specimen macroscopic examination confirmed an average OPD of 31 mm (25, 7-120) and a mean diameter of main lesion of 23 mm (20, 0-120).

Resection margins were negative in 352 cases (92.4%). In 29 cases, however, margins were considered positive (PMR—7.6%). In these patients, after multi-disciplinary discussion we proceeded to

TABLE 2 Level II OPS techniques according to quadrant of breast cancer onset

Upper quadrants	231 (60.6%)
Inverted T mammoplasty with inferior pedicle	140 (60.6%)
J mammoplasty	63 (27.3%)
Round block technique	24 (10.4%)
Batwing mastopexy	4 (1.7%)
Central quadrants	32 (8.4%)
Round block technique	11 (34.3%)
J mammoplasty	8 (25%)
Inverted T mammoplasty with inferior pedicle	7 (21.9%)
Grisotti technique	6 (18.8%)
Lower quadrants	73 (19.2%)
Inverted T mammoplasty with superior pedicle	39 (53.4%)
J mammoplasty	25 (34.3%)
Round block technique	9 (12.3%)
Mixed	45 (11.8%)
J mammoplasty	22 (48.9%)
Inverted T mammoplasty with inferior pedicle	13 (29%)
Round block technique	4 (8.9%)
Inverted T mammoplasty with superior pedicle	3 (6.6%)
Grisotti technique	3 (6.6%)

TABLE 3 Surgical outcomes

Overall radiological diameter – ORD (mm)	33 (30, 8-150)
Specimen volume (mm^3)	345 (227, 21-7980)
Specimen weight (g)	215 (235, 50-2157)
Overall pathologic diameter—OPD (mm)	31 (25, 7-120)
Main lesion diameter (mm)	23 (20, 0-120)
Positive Margin Rate—PMR	29 cases—7.6%
Re-excision Rate—RR	14 cases—3.6%
Conversion to Mastectomy Rate—CMR	6 cases—1.6%
Complications Rate	22 cases—5.8%
Wound dehiscence	7 cases—1.8%
Seroma	5 cases—1.3%
Hematoma	5 cases—1.3%
Skin necrosis	3 cases—0.8%
Infection	2 cases—0.6%

perform conservative re-excision in 14 cases (RR—3.6%), completion mastectomy in 6 cases (CMR—1.6%) and adjuvant radiotherapy with additional Boost in 9 cases (2.3%).

Postoperative complication rate was 5.8% (22 cases recorded) with a complication-related reintervention rate of 0.7% (3 cases of hematomas that required a surgical revision of hemostasis).

The remaining 19 postoperative complications were managed on an outpatient basis: 11 with conservative treatments (57.9%) and 8 with the use of minor surgery (42.1%).

No perioperative mortality was observed, and postoperative complications did not delay adjuvant therapies.

3.2 | Oncological outcomes

Overall 20-year survival (OS) with mean follow-up of 118 months (range 12-160 months) was 93.7% and DFS was 82.3%.

The total local recurrence rate (LR) was 4.4%, with an average recurrence period of 87.3 months after surgery (Figure 1).

3.3 | Esthetic outcomes

In the evaluation by the attending physician, the esthetic result was judged as excellent/good in 358 patients (94.8%). Excellent esthetic results were even obtained for patients with multifocal and multicentric neoplasia who therefore were at greater risk of imperfections, esthetic results that were not affected by the adjuvant radiotherapy treatment.

As for the self-evaluation questionnaire of the esthetic result, 349 patients (92.1%) declared themselves extremely satisfied with the result. In 248 cases (65.1%), the perception of an improvement of the breast from before diagnosis was reported, this was especially true in patients who had previously large breasts and/or a moderate or severe degree of ptosis (this analysis excludes the 6 patients who underwent a complete mastectomy).

4 | DISCUSSION

As OPS boasts to offer the best combination of oncological radicality and good esthetic results after conservative surgery, scientific research in this field has increased by 500% in the last 5 years, demonstrating how these techniques aroused considerable interest, both for oncological and cosmetic potential.

Nevertheless, the reluctance of Breast Units to be conceived as multi-disciplinary centers dedicated to the treatment of breast cancer, combined with the absence of training programs in OPS, have both contributed to the disorderly diffusion of these techniques, generating inhomogeneous scientific evidence, with contrasting results and reduced follow–up periods.

Looking forward, current absence of standardized guidelines for OPS adoption shall not be overcome until strong evidence will be produced. This change of pace can only be reached via prospective data collection, and in the meantime, by means of long-term, high–quality, retrospective series.

Our study traced 20 years of surgical activity carried out within a high-volume Breast Unit, where the proposed treatments have

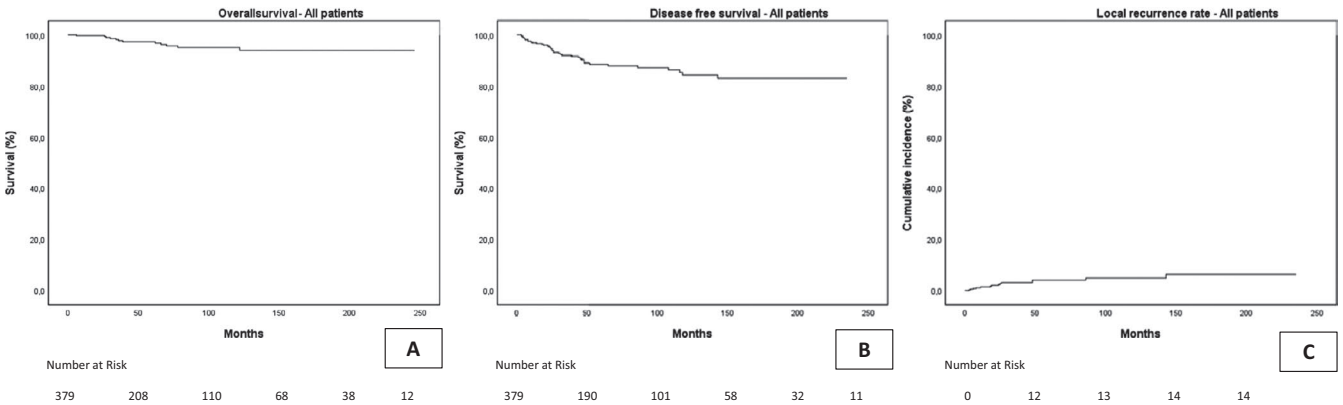

FIGURE 1 Oncological outcomes. A, Overall survival. B, Disease-free survival. C, Local recurrence rate

always been the result of multi-disciplinary sharing of diagnostic and therapeutic protocols.

This analysis of such a vast sample confirms our position as the most numerous study focused on level II OPS and with one of the longest follow-up periods ever reported in literature.

Surgical results obtained (7.6% of PMR, RR of 3.6%, and CMR of 1.6%) confirmed to the trends which emerged in the Losken meta-analysis of 2014, that includes 1773 treated with oncoplastic reduction techniques,[13] and de La Cruz 2016, including 6011 patients[17] (Table 4).

Regarding tumoral diameter, we set OPS strategies basing on preoperative workout and we consider that OPS radicality should be valued not only on main lesion diameter. Nearly one-third of our sample is constituted by multifocal/multicentric disease. Therefore, it would be more appropriate to analyze ORD and ultimately, OPD (especially for multifocal/multicentric disease).

Our mean OPD is 31 mm, a condition that has been directly related to higher rates of PMR, RR and CMR[25-30] but conversely, our rates are in line with reported results for lesions smaller than 15 mm.[31,32]

Furthermore, despite several experiences reporting higher rates of PMR, RR, and CMR for DCIS[33,34] or tumors previously treated with NACT[35,36] our study refutes these data.

As a matter of fact, with rates of patients with multifocal/multicentric or following NACT tumors that are among the highest ever reported, we did not observe any significant difference in PMR, RR, or CMR between invasive/in situ disease, patients receiving NACT or uni/multifocal/multicentric disease (Table 5).

In regards of postoperative complications, OPS has been often associated with a higher risk of early and late postoperative issues that can reach 20%, mainly due to a higher risk of fat necrosis.[37,38]

In our experience, level II OPS does not seem to expose patients to a such high level of postoperative complications (our complications rate is 5.8%) also considering that every patient underwent a bilateral surgical procedure.

Concerning oncologic outcomes, our 20-year collected data overlap with those previously reported in literature in over 100 articles with an overall average follow-up that did not exceed 5 years[13,17] confirming OPS efficacy even in longer periods of observation (Table 4).

The Emiroglu study of 2017[39] reports results obtained from a sample of 82 patients with macromastia undergoing OPS II level intervention over a 15-year period (1996-2011) and is currently the study with the median major follow-up (10 years). Our surgical evaluations performed on a sample of 381 patients treated consecutively over a period of 20 years (1998-2018), demonstrate a

TABLE 4 Comparison of main surgical and oncologic outcomes

Study	No. of patients	OPD	Mean main lesion diameter	Mean weight (g)	PMR	RR	CMR	Complications (%)	Mean follow-up (mo)	OS	DFS	LR
Meta-analysis												
Losken 2014	1773	–	25.1 (15-40)	249	12.4	2.9	7.8	16.5	37.1 (12-74)	–	–	4.7
De La Cruz 2016	6011	–	23	167	10.8	6.0	6.2	14.3	50.5 (12-121)	95	90	3.2
Retrospective studies (FU ≥ 10 y)												
Emiroglu 2017	82	–	26 (4-47)	679	3.7	–	–	12.2	121	82.2	73.2	8.7
Our study (at 20 y)												
Masetti 2018	381	31	23	215	7.6	3.6	1.6	5.8	118	93.7	82.3	4.4

TABLE 5 Correlation between focality, histotype, neo-adjuvant therapy and PMR, RR, CMR

	N of patients	PMR	RR	CMR
Focality				
Unifocal	270 (70.9%)	22	13	4
Multifocal/multicentric	111	7	1	2
P value		.672	.075	1.000
Histotype				
In situ	59 (15.5%)	3	1	1
Invasive	322	26	13	5
P value		.595	.705	1.000
Neo-adjuvant chemotherapy				
Yes	111 (29.1%)	25	13	1
No	270 (70.9%)	4	1	5
P value		.087	.075	.676

higher PMR (7.6 vs 3.7), but lower than reported by Losken and De La Cruz.[13,17]

Moreover, from the comparison of oncological outcomes, this difference in PMR does not have a negative prognostic impact, shown in the higher rates of OS during our study (93.7% vs 82.2%) DFS (82.3% vs 73.2%), and LR (4.4% vs 8.7%) compared to those of Emiroglu.

5 | CONCLUSION

Although the limitations of a retrospective study, the analysis of our results, together with the review of the most significant data reported in recent literature, allows for the following conclusions:

- Optimal use of OPS cannot be separated from a multi-disciplinary collaboration between various specialists. Therefore, the effective implementation of these techniques can only take place in Multidisciplinary Breast Units where personalized diagnostic protocols and treatment plans are wisely combined with education and training programs.
- Surgical and long-term oncological good results of level II OPS are confirmed, even for multifocal/multicentric breast cancers or patients who were previously treated with NACT.
- Level II OPS techniques must be a part of the "tool kit" of the breast surgeon, that has to be fully trained in this field, in order to guarantee every patient the possibility to receive the most natural and reliable treatment available in every situation.

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