

Original article

Skin/nipple sparing mastectomies and implant-based breast reconstruction in patients with large and ptotic breast: Oncological and reconstructive results

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ABSTRACT

In this study we performed 77 procedures on 65 patients fulfilling the oncological criteria for skin-sparing mastectomy and presenting with large or medium size breasts. All the operations were performed as a single-stage procedure with an anatomical prosthesis allocated into a compound pouch, made up of the pectoralis major, serratus anterior fascia, and a lower dermal adipose flap. The medium size of the anatomical implants employed was 444.3 cc. The implant removal rate was 14.2%. At a median follow-up of 36 months we reported a 0.5% local recurrence rate per year. The overall specific survival rate was 98.2%. This study confirms the safety and effectiveness of this technical variation of skin and nipple-sparing mastectomies. All breast, irrespective of mammary shape and size, can be reconstructed with medium size implants and, if required, contralateral adjustments. The overall complication rate is in keeping with previous studies.

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1. Introduction

During the last few years, skin- and nipple-sparing mastectomies have gained widespread acceptance and are currently considered standard treatment in early-stage breast cancer.^{1–3} The preservation of most of the breast envelope has allowed surgeons to reduce the disfiguring impact previously associated with mastectomies. Whereas in the past, reconstruction of large breasts generally demanded the use of myocutaneous flaps, modern implant-based procedures have allowed surgery to become less aggressive in this respect.

In this study, we investigate the outcome of a technical modification of skin- and nipple-sparing mastectomies (skin-reducing mastectomy).⁴

2. Patients and methodology

2.1. Population and statistics

Fifty-eight patients affected by early-stage breast cancer requiring a mastectomy and 17 women selected to undergo a risk-reducing procedure were consecutively enrolled in this study, for a total number of 77 operations in 65 patients.

Statistical comparisons used the χ^2 test and Fisher's exact test. The Kaplan–Meier method was used to calculate the oncological outcome.

2.2. Oncological indications

We offered this technique to women diagnosed with multicentric invasive breast cancer, extensive ductal carcinoma *in situ* (DCIS), or Paget's disease of the nipple (associated with an underlying invasive or *in situ* breast cancer).

We also included patients with a poor response to neo-adjuvant chemotherapy, and those in whom mastectomy was recommended because of positive margins at re-excision.

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Nipple preservation, in neoplastic patients, was used where disease was localised 2 cm (or more) far from the nipple–areola complex. No intra-operative or postoperative radiotherapy was applied to the nipple–areola complex.

All women who underwent a prophylactic procedure received a pre-operative genetic counselling with evaluation of *BRCA-1* and *BRCA-2* mutations in the family history clinic in our institution or elsewhere.

2.3. Reconstructive indications, surgical technique, postoperative evaluation of results

The operations were performed by a team made up of plastic surgeons and surgical oncologists or by a single oncoplastic surgeon at the Istituto Nazionale Tumori, Milano, or at Ospedale Morgagni-Pierantoni in Forlì.

All women in this study presented with large and ptotic breasts. The reconstructive admission criteria also included:

- a. Distance between areola and infra-mammary fold ≥ 8 cm
- b. Distance between sternal notch and nipple > 25 cm.

All reconstructions were accomplished in one-stage using permanent silicone gel implants (ALLERGAN® Style 410-510). A contralateral symmetrisation could also be performed during the same operation, according to patients' and surgical needs.

An accurate survey of morphological characteristics of the breast was performed pre-operatively.

The pre-operative assessment began by marking the position of the new nipple along the mid-clavicular line at a distance of between 19 and 23 cm; further markings followed as for a normal breast reduction or mastopexy with inverted T. We then erased the semicircular drawing of the Wise pattern and extended the two vertical limbs to the new nipple position. (Fig. 1)

The skin was incised in its full thickness along the vertical limbs of the reduction pattern, but in the infra-mammary line the incision did not extend beyond the epidermis. A dermal flap was then created, de-epithelialising the skin between the infra-mammary line and the medial and lateral arms of the reduction pattern. Before starting the mastectomy, the lower flap was sculpted down to the infra-mammary fold; in some cases an axillary dissection or sentinel node biopsy could be performed through the same access.

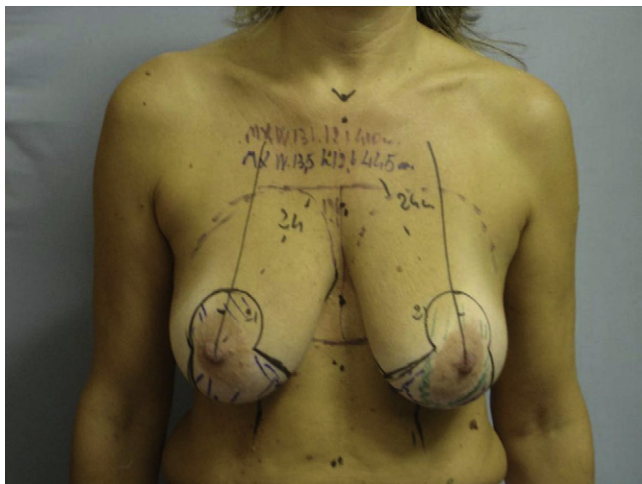


Fig. 1. The pro-operative project of skin-reducing mastectomy and contralateral adjustment.

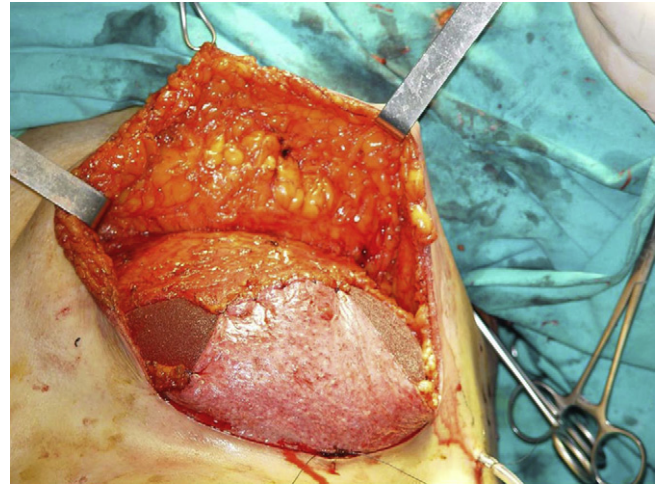


Fig. 2. A permanent implant is allocated in the compound pouch.

The reconstruction was performed dissecting the inferior and lower-medial insertions of the pectoralis major that were sutured to the superior border of the dermal flap and the serratus fascia laterally. An anatomically shaped permanent prosthesis could therefore be located in the pouch (Fig. 2). The nipple was usually reconstructed in a second step under local anaesthesia. In selected cases, a nipple auto-transplantation could be performed with a full-thickness skin graft. In a few cases, we reconstructed the nipple intra-operatively with local skin flaps.

(Fig. 3) Women with small peripherally located or multicentric breast cancers, or who were scheduled for 'risk-reducing' procedures were treated using this technique with preservation of the nipple–areola complex on a superior dermal–adipose flap.

A double intra-operative frozen section (on the mastectomy specimen and on the retro-areolar tissue) was performed to demonstrate absence of disease in the terminal ducts.

2.4. Staging, postoperative treatment and follow-up

All women underwent complete systemic staging with liver ultrasound scan, bone scan, and chest X-rays. Patients with postoperative stage III disease underwent a whole body CT scan.

Post-mastectomy radiotherapy was performed in all patients with 4 or more positive lymph nodes with tumour size > 5 cm.



Fig. 3. Nipple sparing-skin reducing mastectomy.

Adjuvant chemotherapy was prescribed according to internal guidelines in patients with at least one of the following characteristics: positive nodes, tumour size ≥ 1.5 cm (pT1c), pre-menopausal status, Er- and PgR-negative disease and c-erb B2-positive, or triple negative disease.

Hormonal adjuvant treatment was prescribed in accordance with hormone receptors and menopausal status.

The results were evaluated in the out-patient clinic by plastic surgeons at 3, 9 and 12 months, and then yearly after the final surgical stage. Patients' opinions about their reconstruction were rated as 'good', 'medium' or 'bad'. The same scale was used by surgeons to rate breast shape and bilateral symmetry. Results were recorded on a clinical sheet and in the prospective database of our unit. In this publication, we report outcomes at a median observation time of 36 months.

Photographs of patients were taken pre-operatively, post-operatively and at every consultation.

3. Results

3.1. Population

In this consecutive series we performed 77 procedures on 65 women (mean age 48, median follow-up 36 months, range 24–84 months) including 18 prophylactic operations in 17 patients.

In 59 cases the mastectomy was required to treat a breast cancer: 41 patients had invasive ductal cancers, 10 had infiltrating lobular cancers, six had extensive intraductal disease, and two had Paget's disease associated with DCIS. Multicentricity was confirmed in 45 specimens. Sixteen mastectomies were performed for positive margins after re-excision. Eight patients had mastectomy after neo-adjuvant chemotherapy with poor response (two after persistent positive margins on re-excision). We never observed positive margins after mastectomy. Twenty-seven procedures were performed in smokers, 50 in non-smokers.

In 13 cases, nipple preservation was performed after a negative frozen section; permanent histology confirmed absence of disease in the terminal ducts.

3.2. Oncological results

Final staging demonstrated that eight cases were stage 0 (AJCC classification), 24 stage I, 15 stage II A, 3 stage IIB, 6 stage III A, and 3 stage IIIC. Hormonal status was Er+/PgR+ in 38 patients, Er-/PgR- in 10, and Er+/PgR- or Er-/PgR+ in 11 cases.

Adjuvant chemotherapy was prescribed in 26 cases, and hormonal therapy was indicated in 38. Ten patients required post-mastectomy radiotherapy (9 cases in stage III and a single case in stage II, p T3) At a median follow-up of 36 months, one patient had died because of breast cancer, one from pleural mesothelioma and one in an accident (survival rate 98.1%). There was only one case of local recurrence after mastectomy for invasive breast cancer, at 26 months after treatment: this patient underwent re-excision and is still alive without metastatic disease. No patients experienced recurrence in the preserved nipple–areola complex. Two patients who presented with metastatic disease are currently alive but with disease (overall disease-free survival 94.9%; distant disease-free survival 96.6%). Three specimens from contralateral breast reductions revealed an occult breast cancer (intraductal disease in all cases).

One patient who underwent prophylactic treatment for lobular carcinoma *in situ* had a recurrence 8 months after treatment and is currently alive and free of disease. (Table 1)

Table 1
Oncological characteristics.

N Patients/n.cases	58/59
Mean follow-up time (months/years; range)	36/3; 24–84 months
Tumour type	
Invasive ductal carcinoma	41 (69.4%)
Invasive lobular carcinoma	10 (16.9%)
DCIS	6 (10.1%)
Paget + DCIS	2 (3.3%)
Stage 0	
T is, N0, M0	8 (13.5%)
Stage I	
T1, N0, M0	24 (40.6%)
Stage II A	
T1, N1, M0	8 (13.5%)
T2, N0, M0	7 (11.8%)
Stage II B	
T2, N1, M0	2 (3.3%)
T3, N0, M0	1 (1.6%)
Stage III A	
T1, N2, M0	3 (5%)
T2, N2, M0	3 (5%)
Stage III C	
Any T, N3, M0	3(5%)
Multicentricity	45 (76.2%)
Hormone receptors ER/PgR	
+/-	38 (64.4%)
-/-	10 (16.9%)
+/- or -/+	11 (18.3%)
HER2 +	20.3%
Overall specific survival	98.1%
Disease free survival	94.9%
Distant disease free survival	96.6%
Local recurrence rate (per year)	1.6%; (0.5%)

3.3. Complications and reconstructive results

All the reconstructions were accomplished using anatomical permanent implants filled with highly cohesive silicone gel implanted in a single operation. In 70 cases (91%) an extra-projection implant was used. The mean volume of the employed implants was 442 cc. A contralateral adjustment was performed in 41 procedures during a single surgical stage and in 36 (87.8%) cases a symmetrical result was obtained following breast reduction.

In 11 (14.2%) cases the reconstructive process failed with implant extrusion. In four (5.1%) cases a minor complication with partial necrosis of skin flaps was recorded (overall complication rate 20%). In eight cases of severe complication we replaced the exposed implant with a temporary expander, shifting to a two-stage technique. In two cases, a TRAM flap was required. Two cases of partial necrosis were treated with conservative dressing and in two more cases the healing process was supported by fat injection, using the Coleman technique.

Patients' opinions regarding their reconstruction were solicited during out-patient consultations throughout the follow-up period. In 52 (78.7%) cases the cosmetic outcome was rated as 'good', in 13 cases 'medium' and in 1 case 'bad'. The results were also subjectively evaluated by the surgical team (Table 2).

Finally, Baker grade was also assessed and in the great majority was grade 2. Complications were not statistically associated with smoking habit ($p = 0.2$, univariate analysis, Fisher's exact test).

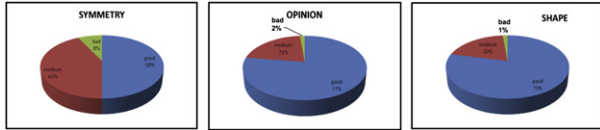
4. Discussion

The concept of conservative breast cancer surgery commonly pertains to the glandular aspects of the operation.^{5,6} However, the new anatomically shaped implants have also allowed surgeons to use less aggressive reconstructive techniques and nowadays complex operations such as myocutaneous pedicled or free flaps may have limited indications.

Table 2

The reconstructive subjective evaluation clearly demonstrated a significantly lower rating for symmetry compared to shape evaluation and patients opinion ($p = 0.02$).

	Shape	Symmetry	Opinion
Good	52	33	51
Medium	13	28	14
Bad	1	5	1



In our previous study on reconstruction with high-projection implants, we introduced a modern reconstructive paradigm that allows reconstruction of all glands, irrespective of shape and volume, with simple prosthetic operations.⁷

The series reported here is part of that project and it demonstrates that even larger breasts can be reconstructed with implants with satisfactory results. Moreover this technique resolves an apparent contradiction of skin-sparing mastectomies for large breasts, in which skin preservation yields a discrepancy between the redundant residual flaps and the small volume of the subpectoral pouch. In our experience, part of the breast envelope can be reshaped using the incisions for breast reductions; the inferior dermal–adipose flap then permits correct positioning of the lower pole of the prosthesis. In this way it is possible to perform a single-stage reconstruction, avoiding a pointless expansion.

4.1. Oncological considerations

The preservation of a large dermal–adipose flap may seem a challenge for the oncological safety of this technique. This is the reason why in this study we also analysed the effectiveness of the technique in local control. We observed only a single case of local recurrence during a median follow-up of 36 months, in a woman with a T1 N0 infiltrating multicentric ductal carcinoma that recurred 26 months after surgery. This patient is currently alive and disease-free. The local recurrence rate reported for the subpopulation affected by invasive cancer was 1.8% (0.5% per year). This is consistent with current international standards and other series on mastectomies with skin preservation.^{1–3,8} Only one woman in this cohort died from breast cancer. These data do not differ from those reported in other series on skin-sparing and nipple-sparing mastectomies and demonstrate the safety of our approach to mastectomies in large and ptotic breasts.

4.2. Reconstructive considerations

With this strategy, the reconstructed breast will have a pleasant medium-sized appearance, owing to the large room provided for the lower pole of the implant by the combined dermal–adipose pouch (Fig. 4).

This is demonstrated by the final average volume of the deployed prosthesis (442 cc) which is nearly equivalent to that reported in our previous study on skin-sparing mastectomies and reconstructions with extra-projection implants.⁷

The reconstructive effectiveness of the technique is confirmed by patients' and surgeons' ratings during out-patient assessment.

A 'good' rating was reported in the large majority of cases, both for surgeons' evaluation of shape and patients' personal opinion on reconstruction. The lower rating in the 'symmetry' parameter may be due to the high number of unilateral operations. To further



Fig. 4. Cosmetic final result.

minimise surgical aggressiveness, we attempted to avoid contralateral operations whenever a reasonable degree of symmetry was expected, operating only on the mastectomy side (Fig. 5).

Wise pattern mastectomies are traditionally challenging in terms of complications.^{9–13} The long and angulated residual flaps can become easily necrotic, especially at the T junction. In the past, this aspect has been evaluated only in very small series on prosthetic and flap based reconstructions, our study is the largest among those in which permanent prostheses were employed to reconstruct large breasts without any other ancillary device. Even in this case the complication rate is quite high with 14.2% total failures requiring implant removal (Table 3).

In the years following the publication of our first report,⁴ several initial studies have discussed possible strategies to reduce the complication rate. One such, developed with our cooperation by Querci della Rovere and colleagues,¹⁴ suggested performing one-stage reconstructions with permanent expanders partially inflated in the first stage. A low extrusion rate was seen in this study, but the Becker's implants did not fulfil patient expectations in terms of cosmetic results (rippling, round shape, one more scar for removal of port); in the long term, a change to permanent anatomical implants was often required and most of the advantages of the one-stage technique were lost.

Another recent work suggested the use of an a-cellular dermal matrix to protect the inferior flap and the T junction.¹⁵ The authors reported a T-point breakdown occurrence in five patients (25%)



Fig. 5. Asymmetric result.

Table 3

Other series on “wise pattern” mastectomies and complication rates reported.

Author	N. cases	Type of reconstruction	Total complication	Minor complication	Implant extrusion
Toth BA, 1991	–	TRAM flaps	4	4	–
Carlson GW et al. 1997	44	Not reported, presumably TRAM flaps	12/44 (27%)	–	–
Hammond DC et al. 2002	12	Two stage implant reconstructions	2/12 (16,6%)	1/12 (8,3%)	1/12 (8,3%)
Hudson DA et al. 2002	19	Single-stage implant reconstructions	3/19 (15,7%)	Not reported	3/19 (15,7%)
Carlson 2004	68	Not reported, presumably TRAM flaps	18 (26,5%)	–	–

who were treated with local wound care and healed with excellent aesthetic results. None of them required implant removal, implant exchange, or operative debridement. The AlloDerm® sheet therefore seems a reliable tool for prevention of skin flaps necrosis in Wise pattern mastectomies. When our series started this device was still at the very beginning of its investigation, and for this reason it was not taken into account in the study design.

Another promising strategy is to use fat injection according to the Coleman technique to improve the vascularity of the T junction and the inferior dermal flap. We are currently testing it on a small number of patients, with promising results that will need to be assessed on larger series.

The dermal–adipose inferior flap can be beneficial in reducing the capsular contracture rate; after three years of observation no Baker grade IV results were seen, and only 6 Baker grade II results were reported out of 66 non-failed reconstructions.

5. Conclusion

In this study, we analyse the outcome of skin- and nipple-sparing mastectomy in large breasts, using a technical variation that has been designated ‘skin-reducing mastectomy’. At 3 years follow-up, we have demonstrated adherence to quality standards for treatment of invasive breast cancer.

The skin-reducing mastectomy can be used to reconstruct large and ptotic breasts without the need to use myocutaneous pedicled or free flaps only for the sake of breast dimensions. A contralateral synchronous adjustment seems advisable to improve the final bilateral symmetry.

The complication rate, although in keeping with other series, is still high. This study did not identify factors associated with skin necrosis and implant extrusion, although as discussed in our previous report, it would be sensible to avoid this technique in heavy smokers or diabetic patients. We are currently investigating the impact of ancillary procedures to improve the reconstructive outcome of the technique.

References

- Carlson GW, Styblo TM, Lyles RH, Jones G, Murray DR, Staley CA, et al. The use of skin sparing mastectomy in the treatment of breast cancer: the Emory experience. *Surg Oncol* 2003;**12**:265–9.
- Carlson GW, Styblo TM, Lyles RH, Bostwick J, Murray DR, Staley CA, et al. Local recurrence after skin-sparing mastectomy: tumor biology or surgical conservatism? *Ann Surg Oncol* 2003;**10**:108–12.
- Gerber B, Krause A, Reimer T, Müller H, Küchenmeister I, Makovitzky J, et al. Skin-sparing mastectomy with conservation of the nipple-areola complex and autologous reconstruction is an oncologically safe procedure. *Ann Surg* 2003 Jul;**238**(1):120–7.
- Nava MB, Cortinovis U, Ottolenghi J, Riggio E, Pennati A, Catanuto G, et al. Skin-reducing mastectomy. *Plast Reconstr Surg* 2006;**118**:603–10.
- Veronesi U, Cascinelli N, Mariani L, Greco M, Saccozzi R, Luini A, et al. Twenty-year follow-up of a randomized study comparing breast-conserving surgery with radical mastectomy for early breast cancer. *N Engl J Med* 2002;**347**:1227–32.
- Fisher B, Anderson S, Bryant J, Margolese RG, Deutsch M, Fisher ER, et al. Twenty-year follow-up of a randomized trial comparing total mastectomy, lumpectomy, and lumpectomy plus irradiation for the treatment of invasive breast cancer. *N Engl J Med* 2002;**347**:1233–41.
- Nava MB, Spano A, Cadenelli P, Colombetti A, Menozzi A, Pennati A, et al. Extra-projected implants as an alternative surgical model for breast reconstruction. Implantation strategy and early results. *Breast* 2008;**17**:361–6.
- Rutgers EJ. Quality control in the locoregional treatment of breast cancer. *Eur J Cancer* 2001 Mar;**37**(4):447–53. Eusoma Consensus Group.
- Toth BA, Lappert P. Modified skin incisions for mastectomy: the need for plastic surgical input in preoperative planning. *Plast Reconstr Surg* 1991 Jun;**87**(6):1048–53.
- Carlson GW, Bostwick 3rd J, Styblo TM, Moore B, Bried JT, Murray DR, et al. Skin-sparing mastectomy. Oncologic and reconstructive considerations. *Ann Surg* 1997;**225**:570–5.
- Hammond DC, Capraro PA, Ozolins EB, Arnold JF. Use of a skin-sparing reduction pattern to create a combination skin-muscle flap pocket in immediate breast reconstruction. *Plast Reconstr Surg* 2002;**110**:206–11.
- Hudson DA, Skoll PJ. Complete one-stage, immediate breast reconstruction with prosthetic material in patients with large or ptotic breasts. *Plast Reconstr Surg* 2002;**110**:487–93.
- Carlson GW. Trends in autologous breast reconstruction. *Semin Plast Surg* 2004;**18**:79–87.
- della Rovere GQ, Nava M, Bonomi R, Catanuto G, Benson JR. Skin-reducing mastectomy with breast reconstruction and sub-pectoral implants. *J Plast Reconstr Aesthet Surg* 2008 Nov;**61**(11):1303–8. Epub 2007 Aug 10.
- Derderian CA, Karp NS, Choi M. Wise-pattern breast reconstruction: modification using AlloDerm and a vascularized dermal-subcutaneous pedicle. *Ann Plast Surg* 2009 May;**62**(5):528–32.