

Review

Update on one-stage immediate breast reconstruction with definitive prosthesis after sparing mastectomies

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ABSTRACT

Immediate breast reconstruction after skin and nipple-sparing mastectomies is commonly performed as a two-stage procedure; to overcome the paradox of traditional two-stage tissue expander/implant reconstruction used to create a tight muscular pocket that needs expansion to produce lower pole fullness, while losing the laxity of the mastectomy skin flaps, the authors conceived a subpectoral-subfascial pocket by elevating the major pectoral muscle in continuity with the superficial pectoralis fascia up to the inframammary fold. This alteration allowed for the immediate insertion of the definitive implant.

The authors present their experience in 220 cases of immediate one-stage breast reconstructions with definitive prostheses in sparing mastectomies. Immediate and long-term local complications were evaluated. Immediate breast reconstruction with definitive anatomical silicone-filled implants can produce excellent cosmetic results (78.6%) with a low rate of complications (17.7%); these results allow for agreement between oncologic, aesthetic and economic purposes.

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Introduction

The local management of breast cancer has undergone continuous advances in the last two decades.

Since Toth and Lappert introduced the skin-sparing mastectomy (SSM) in 1991,¹ immediate breast reconstruction has produced better aesthetic results. In addition, preservation of the inframammary fold (IMF) further enhanced the cosmetic results.² More recently, nipple-sparing mastectomies (NSM) have also been proposed in select cases^{3–5} and provide more options for immediate breast reconstruction. Conservation of the skin envelope and the nipple-areola complex has led to improved aesthetic results following both autogenous and prosthetic breast reconstruction.^{6–9}

Focusing on prosthetic breast reconstruction after SSM and NSM, muscle coverage of the implant remains the definitive standard in breast reconstruction.^{10–12} When the pocket is created in the complete submuscular position,^{10,11} its tightness does not allow the prosthesis to fill the skin envelope; therefore, a skin expander has been used by most of the reconstructive surgeons to overcome this problem. It also allows the improvement of the projection of

the lower breast pole by means of progressive post-operative inflation of the tissue expander positioned at the time of mastectomy. At a median interval of six months, it is replaced with a permanent prosthesis.

The authors' main concern has always been the paradox of having redundant mastectomy skin flaps and creating a taut muscle envelope that needs to be expanded. Therefore, to use the redundant skin envelope after sparing mastectomies to obtain a more effective projection of the lower breast, the pocket has been created in a partial submuscular position, and the origin of the major pectoral muscle (PM) is detached from the lower costal arches and the caudal part of the sternum. Different surgical solutions have been proposed as follows:

- the detached part is sutured to the subcutaneous tissues of the caudal mammary skin flap, and a skin expander or a definitive implant is inserted^{12–14};
- the detached part is sutured to an allogenic dermal graft (AlloDerm or DermaMatrix), which is inserted at the IMF to “elongate” the submuscular space inferiorly^{15–21}. Thus, this inferior space becomes large enough to place a fully inflated implant and to supplement the muscle deficit at the lower breast pole;
- a different pocket has been created by the authors to provide better lower pole coverage of the implant: the origins of the PM

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Table 1
Final pathology of 256 mastectomy specimen in 220 patients.

Tumor stage	Number of cases
Precancerous lesions	22
Tumor inferior to 2 cm (T1)	174 (74.5%)
Tumor between 2 and 5 cm (T2)	60 (25.5%)

are dissected downward in continuity with the adipo-fascial layer (i.e., superficial pectoralis fascia (SPF), and overlying subcutis) up to the IMF (“submuscular-subfascial” pocket). This pocket now has a more distensible lower pole compared to the complete submuscular pocket,^{10,11} and permits the insertion of a definitive anatomical prosthesis after skin- and nipple-sparing mastectomies.^{22,23}

In this paper, the authors review a series of prosthetic immediate reconstructions after SSM and NSM; indications, technical aspects, immediate and late complications, cosmetic results, economic implications and patients’ satisfaction are discussed.

Patients and methods

In total, 220 patients with breast cancer underwent to SSM (187 patients) or NSM (33 patients), and their immediate one-stage breast reconstruction with definitive prosthesis during the period from February, 2002 to November, 2009 are reviewed.

A bilateral reconstruction was performed in 36 patients.

The age of the patients was between 25 and 72 years old (mean age 47.5 years).

All patients were evaluated preoperatively by a multidisciplinary team, including the breast surgeon and the plastic surgeon, to define the skin incisions and the skin excision pattern and also to explain to the patient the advantages and possible disadvantages of the selected option.

Anatomically shaped textured silicone-filled implants (Silimed Nuance and Allergan Natrelle—previously Inamed McGhan410) were used.

Patients with small and moderate breast volumes, with or without ptosis, and that had not received or were not expected to receive radiotherapy postoperatively were considered ideal candidates for this procedure. Patients with large breasts who refused autologous reconstruction were also included. The minimum post-operative follow-up time-point was 3 months with an average of 29 months (range, 3 months to 5 years). Oncologic information on tumor size, axillary lymph node surgery, and adjuvant radiotherapy were collected and are reported below. All patients were followed during the post-operative period by the breast surgeon, the plastic surgeon and the oncologist. Immediate local complications, including infections, seromas and hematomas, skin necrosis and wound dehiscence, were evaluated. Long-term complications were evaluated as well. To perform a pre-operative and post-operative comparison, standard anteroposterior and bilateral oblique digital color photographs were taken. Evaluation of the cosmetic results was performed by the attending surgeons, by other plastic surgeons not involved in the surgery and on the basis of the patients’ satisfaction. Cosmetic results were classified by the surgeons based on

Table 2
Axillary lymph node procedures in 234 mastectomies.

Type of axillary lymphnodal procedures	Number of cases
Sentinel lymph node biopsy	94 (40%)
Axillary clearance (level I, II, III)	140 (60%)

Table 3
Axillary access for lymph node procedures in 234 mastectomies.

Type of axillary access for lymphnodal procedures	Number of cases
Axilla dissection performed by the same periareolar incision than mastectomy	173 (74%)
Axilla dissection performed by additional axillary incision	61 (26%)

the shape and volume of the reconstructed breast and the symmetry with the contralateral side. They were scored as very good, good, barely acceptable, or poor, and the overall result was rated from 4 to 1 (4 = very good, 3 = good, 2 = barely acceptable, 1 = poor). The average of each item was used as a final result.

Data were collected from physical examinations, charts, and pictures (pre- and post-operatively).

Oncologic data

Tumor size, stage, and histotype of the 256 mastectomy specimens were as follows:

By histological examination, 22 out of 256 (8.5%) mastectomy specimens were determined as precancerous lesions. Therefore, they were excluded from the following series.

Furthermore, 174 out of 234 mastectomy specimens (74.5%) had tumors measuring 2 cm or less (T1), and 60 out of 234 mastectomy specimens (25.5%) had tumors between 2 and 5 cm (T2) (Table 1).

Axillary lymph node dissection was performed in 234 cases as follows: in 140 cases (60%), a total axillary lymph node dissection (level I, II, III) was performed, and in 94 cases (40%), the axillary region was preserved because of a sentinel lymph node biopsy (Table 2). Axillary dissection was performed using a periareolar incision in 173 cases (74%). In 61 cases (26%), an additional axillary incision was necessary to perform the lymphadenectomy (Table 3).

In 88 out of 220 patients (40%), neo-adjuvant chemotherapy was needed preoperatively.

In 132 out of 220 patients (60%), adjuvant chemotherapy was needed postoperatively.

Surgical technique

Skin-sparing mastectomy (SSM)

SSM was indicated in extensive ductal carcinomas *in situ* (DCIS), in multicentric tumors, in tumors that do not infiltrate the skin, in patients with T1 and T2 tumors and an unfavorable breast to tumor ratio, and in patients who did not respond to chemotherapy. SSM was not indicated in inflammatory tumors or in locally advanced tumors.²

SSM was performed by the breast surgeon through an incision previously planned with the plastic surgeon (Table 4). The periareolar

Table 4
Patterns of SSM and NSM in 220 patients.

Surgical approach in SSM	N°	%
Small horizontal elliptical incision	15	8
Broad horizontal elliptical incision	5	3
Circumareolar incision	132	70
Mammoplasty pattern incision	33	18
Double skin pattern incision	2	1
Surgical approach in NSM	N°	%
Lateral radial incision	12	36
Vertical radial incision	5	15
Hemipiareolar incision	9	27
Through the scar of previous biopsy	4	13
Through the scar of previous mammoplasty	3	9

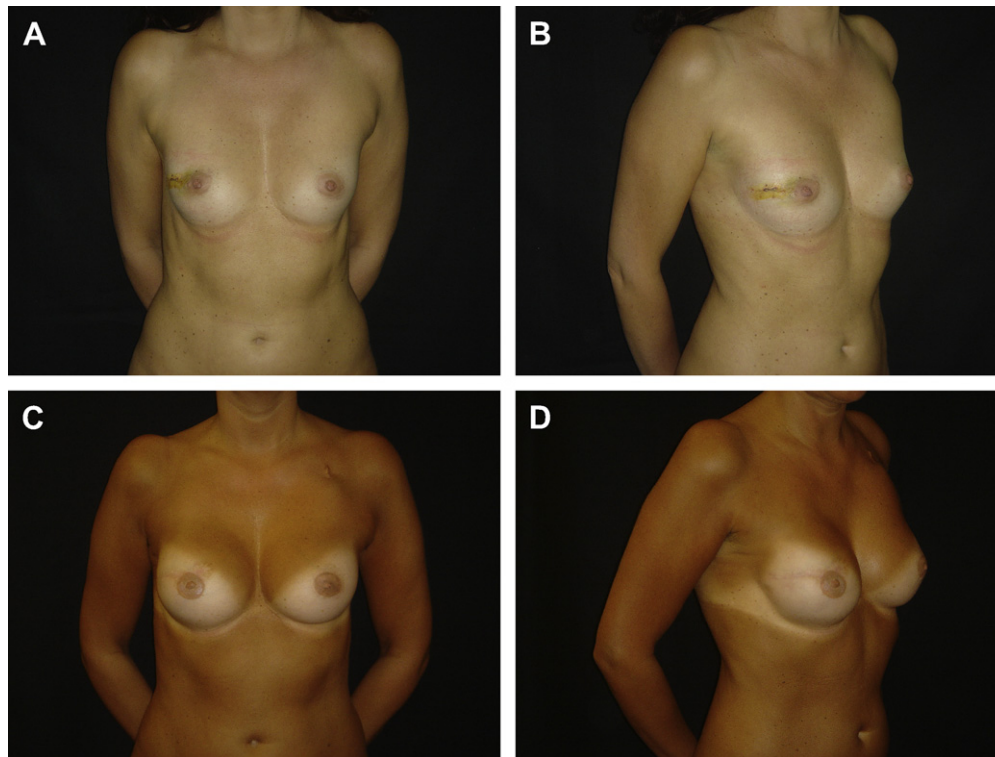


Fig. 1. A, B: pre-operative view; C, D: post-operative view at 24 months after right circumareolar SSM and one-stage immediate reconstruction with a definitive anatomical prosthesis (Silimed Nuance high projection 240 cc) plus a left augmentation mammoplasty. The nipple-areola reconstruction has been performed as a further surgery.

(i.e., circumareolar) approach was more commonly performed because all patients with small/medium breasts and medium/large areolas are potential candidates for periareolar SSM (Fig. 1). In patients with large breasts, skin-reducing mastectomies, which are 13% of the authors' practice, utilize the skin incision of the reduction mammoplasty, i.e., vertical and inverted *T* patterns. Among these mastectomies, the vertical pattern is more frequently used by the authors because it preserves the vascularity of the mastectomy flaps (Fig. 2). For symmetry reasons, the skin-reducing mastectomy should use the same drawing as the contralateral aesthetic procedure.

In all cases, gland excision is performed sparing the SPF.

The axillary dissection could be performed either through a separate axillary incision (more commonly) or through the mastectomy incision based on the laxity of the skin.

Nipple-sparing mastectomy (NSM)

NSM is indicated in prophylactic mastectomies, in patients with precancerous lesions, and in oncologic patients within the following inclusion criteria: *in situ* or infiltrating tumors that do not involve the nipple-areola complex (NAC) during the pre-operative radiologic examinations (possibly small and peripheral tumors or tumors that are at least 2 cm from the NAC) preferably in a small- and medium-sized breast with up to moderate ptosis.²⁴

NSM was performed by the breast surgeon through an incision previously planned with the plastic surgeon. The authors favor the radial incision in the superior-external quadrant (Fig. 3), but they rarely favor periareolar, inframammary, or even incisions from previous biopsy sites or other scars (Table 4). Further surgical steps are the same as for SSM.

Prosthetic breast reconstruction

The peculiarity of this technique is to create a submuscular-subfascial pocket²² that, differently from a complete submuscular pocket, has a more distensible lower pole. This unrestricted lower

pole minimizes the upper pole's push, while providing a better breast shape and also permitting the insertion of a definitive prosthesis at the time of mastectomy. Making the submuscular-subfascial pocket feasible is necessary to spare the SPF during the sparing mastectomy.^{25,26} The SPF covers the PM on its anterior surface. At the inferior border of the PM, the SPF continues until the IMF and lies on the rectus abdominis sheath. At the lateral border of the PM, the SPF fuses with the deep pectoralis fascia (DPF, i.e. the deep layer of the PM fascia that covers the muscle on its posterior surface). At this level, the PM fascia overlies and fuses with the deeper axillary fascia creating a unique fascial structure that overlies the serratus anterior and the oblique external muscles²⁷ (Fig. 4).

The undermining of the PM starts laterally from its lateral edge to preserve the continuity between the PM and the fascial tissues located inferiorly to it. The undermining of the submuscular-subfascial pocket is carried out to the IMF; at this location, the subcutaneous tissue is incised to its superficial layer (areolar fat), which augments the pocket by a few centimeters. The incision of the subcutaneous fat at the level of the IMF is a key of the success of this technique because it also makes the pocket more distensible, thus permitting the placement of the appropriate definitive implant. Thus, the implant is placed in a submuscular position superiorly and a subfascial location inferiorly.

The prosthesis is selected based on the volume of the mastectomy specimen, either with the help of the transverse width and the vertical height of the contralateral breast or with resterilizable sizers. The access to the submuscular-subfascial pocket is sutured to keep the subcutaneous tissue of the mastectomy flaps separated from the implant. Whenever possible, the skin incision is closed with a purse-string suture to keep the final scar short. Usually, the purse-string suture mends as a slough and heals completely in a few weeks without delaying the post-operative chemotherapy. The prostheses used in this study were textured silicone-filled definitive anatomical implants manufactured by Silimed and Allergan as follows:

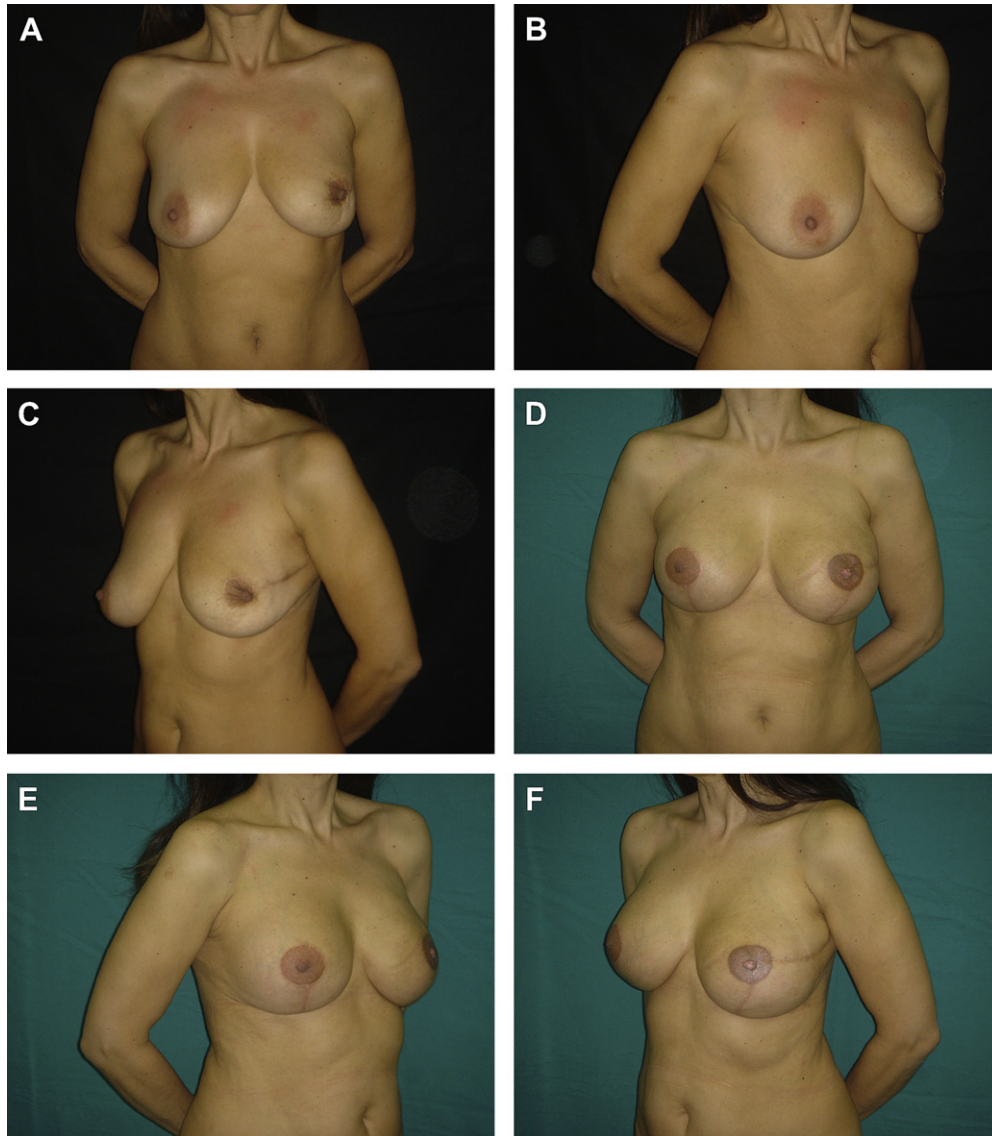


Fig. 2. A, B, C: pre-operative view; D, E, F: post-operative view 10 months after a left skin-reducing mastectomy with a vertical pattern and an one-stage immediate reconstruction with a definitive anatomical prosthesis (Silimed Nuance high projection 470 cc) plus a right augmentation mammoplasty with a vertical mastopexy. The patient shows a scar in the upper lateral quadrant of the left breast from a previous biopsy. The nipple-areola reconstruction was performed after 6 months.

- 167 Nuance implants, i.e., short size anatomical prostheses, manufactured by Silimed, which included 154 high projection and 13 moderate projection ones;
- 89 Natrelle Allergan, previously McGhan, Style 410 implants, which included 8 FX (full height-extra full projection), 35 MX (moderate height-extra full projection), 9 MF (moderate height-full projection), 15 LX (low height-extra full projection), 19 LF (low height-full projection), and 3 LM (low height-moderate projection).

The NAC is usually reconstructed in a second stage a few months after the end of chemotherapy to reconstruct it in the correct position and to optimize the symmetry.

Results

The authors performed immediate breast reconstructions in 220 cases: 187 after SSM (group A, which included 27 bilateral

reconstructions) and 33 after NSM (group B, which included 9 bilateral reconstructions).

All of patients that submitted to SSM or NSM one-stage immediate breast reconstruction were patients who hadn't received radiotherapy yet and weren't expected to receive post-operative radiotherapy.

Nevertheless, in 10 patients treated by SSM one-stage immediate breast reconstruction, the final histology imposed post-operative radiotherapy.

The indication for post-operative radiotherapy was when one or more of the following criteria were present²⁸:

- a) extended multicentric tumor,
- b) peritumoral lymphatic invasion,
- c) more than 4 lymph nodes involved.

After SSM, 2 cases (1.07%) had a local recurrence, and no cases had a recurrence after NSM. These results were obtained after a median follow-up time of 29 months (range, 3 months and 5 years) for SSM and 10 months (range, 3 months and 2 years) for NSM.

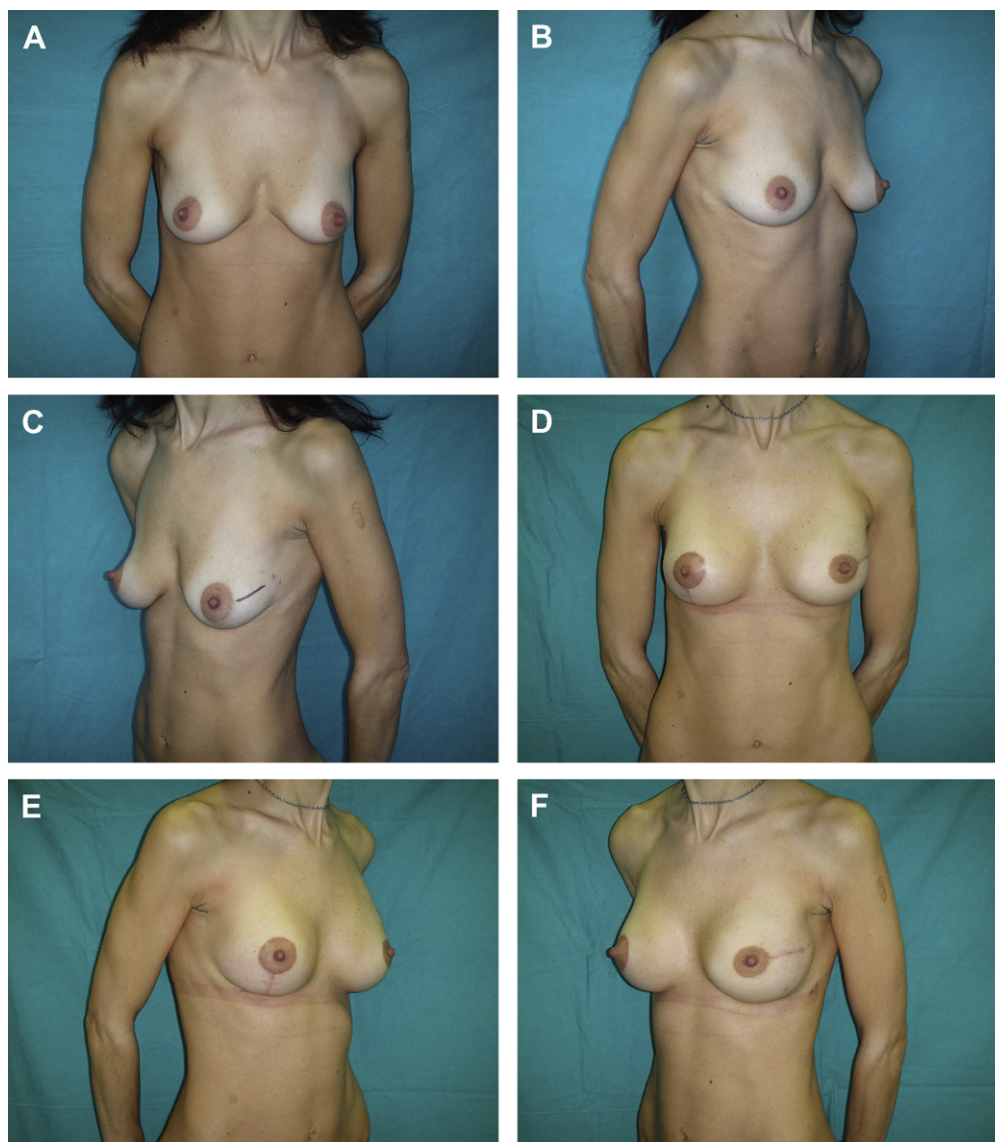


Fig. 3. A, B: pre-operative view; C: pre-operative view, the skin incision of the NSM has been marked; D, E, F: post-operative view 4 months after a left NSM through a radial incision in the upper lateral quadrant and an one-stage immediate reconstruction with a definitive anatomical prosthesis (Allergan Natrelle 410 MX325) and a right augmentation mammoplasty with a vertical mastopexy.

Complications

Among the 220 patients who underwent SSM or NSM and immediate prosthetic breast reconstruction, 39 (17.7%) developed complications in the post-operative time-period; the complications have been collected and are reported in Table 5.

Among the 13 cases of implant infection, 11 were solved with e.v. antibiotics. One patient developed a seroma that became infected, and subsequently, it required the explantation of the implant. Furthermore, one patient experienced an infection 50 days after the surgery during the first cycle of post-operative chemotherapy and required implant explantation. Regarding 11 of the patients who developed an infection and retained their implant, 2 showed severe capsular contractures at the 6 month follow-up time-point.

Furthermore, 6 of 9 patients who developed severe capsular contractions (IV grade) received post-operative radiotherapy.

Among the 70 patients operated on in the last 24 months, 10 (14%) required breast lipofilling for a step-off deformity of the upper pole and/or hypoplasia of the inferior pole of the reconstructed breast.

Post-operative adjuvant chemotherapy was not related with any long-term complications, such as capsular contracture and aesthetic deterioration in this series.

Contralateral breast management

Among 184 unilateral breast reconstructions, 131 patients (71%) had contralateral aesthetic surgery to achieve symmetry. Among these, 28 patients underwent contralateral breast augmentation, 23 patients underwent augmentation mastopexy, 40 patients underwent mastopexy, and 40 patients underwent reduction mammoplasty (with a vertical, J or inverted T pattern).

Cosmetic results and level of satisfaction

The final evaluation was completed by a group of surgeons at a minimum time-point of 6 months in 150 patients. The final aesthetic outcome was judged as very good or good in 118 patients (78.6%), acceptable in 21 patients (14%), and poor in 11 patients

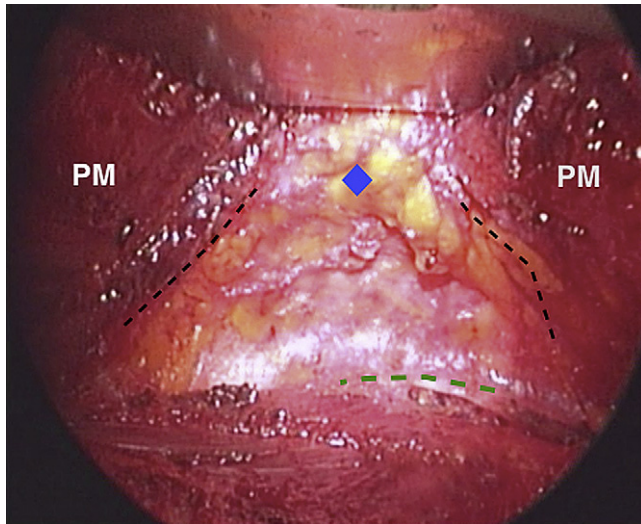


Fig. 4. Intra-operative view of the submuscular-subfascial pocket: the base is the costal cage, the major pectoral muscle (PM) is lifted by the fiber optical elevator (on the top) and the superficial pectoral fascia (SPF) is cut (black dotted line) showing the subcutaneous fat (blue rhombus) at the level of the inframammary fold (IMF), the green dotted line shows the anterior rectus sheath. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article).

(7.3%). Almost all the patients with an unsatisfactory result accepted further surgery.

Discussion

Many studies have shown that immediate breast reconstruction using either implant or autologous techniques is safe and effective in achieving a satisfactory breast mound.^{11–13,29–32}

Immediate prosthetic breast reconstruction after SSM is usually performed by placing a tissue expander or an expandable permanent implant in a complete submuscular pocket at the time of mastectomy.^{10–12,29,33–41}

The main drawback of these procedures is that the total muscle coverage often results in upper-pole hyper-expansion by virtue of decreased resistance to the forces of expansion in this area and a concomitant lower-pole elevation with the raising of the IMF, which often required correction.¹⁸

For these reasons, recently, a subpectoral-subcutaneous pocket has been proposed:

- using the PM as coverage in its upper two thirds and using the mastectomy skin flap as coverage in its lower third. The inferior portion of the PM had been anchored to the skin using a marionette suture^{12,13} or fixed to the lower dermis of the inferior mastectomy flap.¹⁴

Table 5
Complications of this series.

Complications	Cases (%)	Cases requiring further surgeries
Early		
Infections	13 (6.4%)	2
Seroma	3 (1.3%)	1
Haematoma	6 (2.7%)	4
Skin slough/necrosis of mastectomy flaps	17(8%)	2
Delayed		
Severe capsular contracture	9 (4%)	
Implant rotation	1	1
Aesthetic deterioration	12(5.4%)	12

- using an allogenic dermal graft sling sutured superiorly to the detached inferior edge of the PM and inferiorly to the IMF to have a more distensible pocket that is large enough to place a fully inflated implant and to supplement the muscle deficit at the lower breast pole.^{15–21}

In 2001, the authors produced a submuscular-subfascial pocket by elevating the PM off the anterior chest wall, while continuity with the SPF up to the IMF was still maintained.^{22,23} Particular attention was paid to maintain the dissection in the anatomical plane over the anterior fascia of the rectus muscle since it should not be elevated because it is a tough structure that does not allow distention. The elevation of the fascial tissue ends in the subcutaneous fat at the IMF. Here, the fat is opened up to its subdermal layer to gain more space and to allow the distention of the adipo-fascial layer in the lower pole; on the one hand, this permits the creation of a large and distensible pocket to lodge a definitive prosthesis, and on the other hand, it provides better definition of the IMF with a better cosmetic results.

Thus, the skin redundancy can be used immediately after the sparing mastectomies instead of losing it after inserting the tissue expander and then trying to gain it again.

In case the vitality of the skin flap is questionable or extra-skin has been excised because of the fear of positive skin margins, a semi-inflated skin expander is preferred. In the few cases where the SPF is particularly tough and the submuscular-subfascial pocket is not as distensible as usual, which leads to a poor expansion of the lower pole of the breast, the location of an expander is also suggested.

The authors do not have experience using a human acellular dermal matrix because its use is not allowed in Italy. However, about it may not be needed given the presence of SPF. In fact, the SPF reacts well in cases of complications (infections, skin necrosis, and wound slough) because it is vascularized tissue, which allows local wound care in the setting of skin necrosis. Skin necrosis of mastectomy flaps in patients with prosthetic reconstruction using biological material or with partial subcutaneous implant would invariably result in the exposure of the biological material and the implant.

Adipo-fascial tissue is well extendable, and this has been demonstrated in the author's experience with the positioning of the tissue expander in the submuscular-subfascial pocket. At the site of the implant, it was evident that the adipo-fascial layer had been preferentially expanded compared to the muscular layer.

The use of the anatomical hyperprojected prosthesis with a short upper pole improved the final aesthetical outcome of obtaining a reconstructed breast with features similar to the contralateral one. The best aesthetical results are generally achieved in bilateral cases and in small/medium-sized breasts, but the authors' series also included large-sized breast. In these cases, the authors used a "skin-reducing mastectomy" to reduce the abundant skin envelope. The skin-reducing mastectomy can be performed either with the vertical pattern or the inverted T pattern depending on the breast shape. A contralateral breast symmetrization is performed at the same time using the same pattern.

Regarding the recurrence rate, we observed 2 cases (1.07%) of recurrence in SSM and no cases in NSM; this data have been estimated to occur in a percentage ranging from 3 to 10% of SSM and from 5.8 to 11.5% of NSM.^{41–44} However, in our series, few cases of NSM (33 cases) compared to SSM cases (187 cases) were noted. Furthermore, the follow-up time related to NSM (10 months) was shorter than the follow-up time related to SSM (29 months).

Regarding the short-term complications, hematomas and seromas are relatively rare in this series of patients because the authors performed an accurate intra-operative hemostasis and kept the

drains until the daily outcome was under 25 cc. Regarding the occurrence of skin sloughs and/or skin necrosis of the mastectomy flaps, complete healing with dressing changes was achieved on an outpatient basis in most of the cases (92%). In our opinion, the incidence of 8% of delayed healing is negligible compared with the benefit of performing the breast reconstruction in one-stage. Besides, prosthetic extrusion occurred in only one case. Regarding long-term complications, the capsular contracture rate was 4%; furthermore, 8 out of 9 cases (about 90%) occurred in the presence of known predisposing factors (2 cases after infections and 6 cases after post-operative radiotherapy). Among these patients, all but one were treated by explantation of the implant and autologous breast reconstruction (DIEAP flap). The only patient who did not receive radiotherapy but developed capsular contraction was treated by capsulectomy and implant substitution. According to the literature, prosthetic breast reconstruction in patients with previous radiotherapy is relatively contraindicated; patients who submitted to a mastectomy immediate prosthetic breast reconstruction received postoperatively radiotherapy, and subsequently developed capsular contracture, are candidate to delayed autologous breast reconstruction.⁴⁵

A close collaboration between breast surgeons and plastic surgeons is mandatory to thoroughly plan the therapies and the surgical approach needed to optimize the diseases treatment while considering the reconstructive needs.

Furthermore, this unique stage surgery saves time in the surgical theatre and reduces the number of hospitalizations by giving to the patients the chance to complete the reconstruction in one-stage. This opportunity also raises the importance of possible adjuvant therapies that will delay the ending of a breast reconstruction; this may happen in the classical two-stage surgical procedure. In addition, no delays in the start of the post-operative chemotherapy were experienced due to any skin slough of the mastectomy flaps.

Conclusions

Breast reconstruction with a definitive anatomical silicone-filled implant after SSM and NSM can produce excellent cosmetic results in one surgical stage with a low rate of complications. For this purpose, it is crucial that the surgical and oncologic teams coordinate their services and work together to produce optimal care for these patients.

Synergy between the two teams can also be considered as an economical benefit because it reduces the number of hospitalizations, the surgical cost for each patient, and the additional costs of the expander. Furthermore, for the patients also, it represents a good option because a unique one-stage reconstruction reduces the stress related to the surgical operations and the chance to immediately obtain a physical reconstitution. Finally, this technique has been shown to be safe in an oncologic aspect.

Conflict of interest statement

All authors must disclose any financial and personal relationships with other people or organizations that could inappropriately influence (bias) their work.

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