Embrace the Change: Incorporating Single-Stage Implant Breast Reconstruction into Your Practice

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Background: Multiple studies have reported on the safety of nipple-sparing mastectomy and low complication rates associated with single-stage implant breast reconstruction. Yet many plastic surgeons continue to be resistant to change. This article presents the senior author's (M.A.C.) experience during his transition period from the latissimus dorsi flap with adjustable implants to a "one-and-done" approach using shaped implants and fetal bovine acellular dermal matrix.

Methods: A literature review was performed selecting articles discussing single-stage implant reconstruction, indications, outcomes, technique, and complications. Additional articles were selected after review of the references of identified articles. Clinical pearls discussed include patient selection, implant selection, and mastectomy incision choices, with a detailed description of the senior author's operative technique.

Results: Twenty-seven single-stage implant reconstructions were performed. Average mastectomy weight was 343.82 g. The average implant volume was 367 cc. Shaped implants were most commonly used. Acellular dermal matrix was used in all breasts. Complications included erythema requiring intravenous antibiotics (three patients), skin ischemia caused by methylene blue (one patient), seroma (one patient), unilateral partial nipple necrosis (one patient), mastectomy skin necrosis (one patient), and exposed/infected implants that were salvaged using a sequential irrigation protocol described by Sforza et al. in 2014 (two patients).

Conclusions: Breast reconstruction after mastectomy has evolved toward less invasive, single-stage procedures. Aesthetic refinements include nipple-sparing mastectomy, use of acellular dermal matrix, shaped implants, and fat grafting. Selected patients will benefit from a one-and-done breast implant reconstruction with no additional oncologic risk. Surgeons must embrace the change and provide their patients with a procedure that will offer the best aesthetic outcomes. (*Plast. Reconstr. Surg.* 136: 221, 2015.)

CLINICAL QUESTION/LEVEL OF EVIDENCE: Therapeutic, IV.

One in eight women in the United States will develop invasive breast cancer during their lifetime. An estimated total of 232,670 women will be diagnosed this year (2014) with invasive breast cancer and another 62,570 with carcinoma in situ.[1] Approximately 40 percent of women diagnosed with breast cancer will be treated with mastectomy, with fewer than 25 percent undergoing immediate reconstruction.[2]

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Albornoz et al. reported a 203 percent rise in implant use for immediate reconstruction from 1998 to 2008, making implant-based reconstruction the most common type of reconstruction performed in the United States.[2] In 2013, two-stage reconstructions with tissue expander and implants constituted over 70 percent of all breast reconstructions in the United States.[3] A large multi-institutional study (n = 10,561) showed only 14.5 percent of the women underwent single-stage implant breast reconstruction.[4]

The benefits of a single-stage implant breast reconstruction include the following: obviating the need for recurrent visits for expansion, one operation, and immediate return to normal body image. Multiple studies have reported on the low complication rates associated with single-stage implant breast reconstruction. Delgado et al. reported good short-term outcomes in 400 consecutive patients using direct implant technique with anatomical, gel-cohesive, extra-projection prostheses in Europe.[5] In 2010, Salzberg et al. reported an overall complication rate of 3.9 percent using a direct-to-implant technique with acellular dermal matrix.[6] Two years later, Salzberg reported on his 10-year experience, achieving complication rates less than 2 percent in 439 patients.[7]

Early diagnosis of breast cancer and the acceptance of the oncologic safety of nipple-sparing mastectomy have allowed plastic surgeons to offer a "one-and-done" procedure, simplifying the reconstructive process and improving psychological morbidity.[4]

PATIENTS AND METHODS

A literature search was performed using PubMed and the key words "direct to implant AND breast reconstruction." Articles discussing indications, outcomes, technique, and complications were reviewed. Clinical pearls discussed include patient selection, implant selection, mastectomy incision choices, and a detailed description of the senior author's (M.A.C.) operative technique.

Patient Selection

Patient selection is the most important element to consider to decrease complications and achieve great aesthetic results. Factors taken into consideration include patient comorbidities, body mass index, smoking status, tumor characteristics, radiation therapy, current and desired breast size, degree of breast ptosis, and anticipated mastectomy type.

Hypertension, history of stroke, obesity, diabetes, and active smoking have all been associated with worse outcomes.[8,9] The best outcomes are achieved in thin patients with an athletic body frame, small breast size, minimal ptosis, and low body mass index; nonsmokers; nondiabetics; and patients with no radiation therapy. The ideal candidate will want to be at least the same size or slightly larger, with the average implant size used in our experience being only 367 cc on average. Table 1 summarizes selection criteria associated with good outcomes in single-stage implant reconstruction.[8–12]

Patients with large breasts and significant ptosis will require mastopexy techniques and at times free nipple grafts, which in the senior author's experience has led to an additional vascular insult to the mastectomy flaps, increasing the chances of wound breakdown and implant exposure. Radiation therapy is not an absolute contraindication to single-stage implant reconstruction but is associated with higher complication rates for infection (21.6 percent) and loss of prosthesis (18.75 percent).[13] Irradiation of a permanent implant has been associated with lower total failure rates compared with irradiating a tissue expander (6.4 percent versus 40 percent, respectively).[14]

Clinical assessment of the irradiated skin is the most important factor to consider in this setting. If the skin changes are minimal after radiation therapy, the patient is considered a good candidate for single-stage implant reconstruction.[9] If the patient is known to need adjuvant radiation therapy, the authors prefer an autologous reconstruction with a latissimus dorsi flap, which provides complete muscle coverage of a prepectoral adjustable implant.[15]

Table 1. Factors Associated with Good Outcomes in Single-Stage Implant Breast Reconstruction

Oncologic factors
Tumor size <3 cm; ≥2 cm distance from nipple-areola complex; no clinical involvement of the nipple (criteria for nipple-sparing mastectomy)
Negative intraoperative retroareolar core biopsy
Age older than 45 yr
Presence of estrogen receptors
< Expression of HER-2/neu
< Ki-67
Patient factors
Grade 1 or 2 ptosis
Patient desires equal or smaller breast size
Mastectomy weight <500 g
Nonsmoker
Nonobese
No history of diabetes
Thin, athletic body frame
Professionals/executives with limited time for recovery

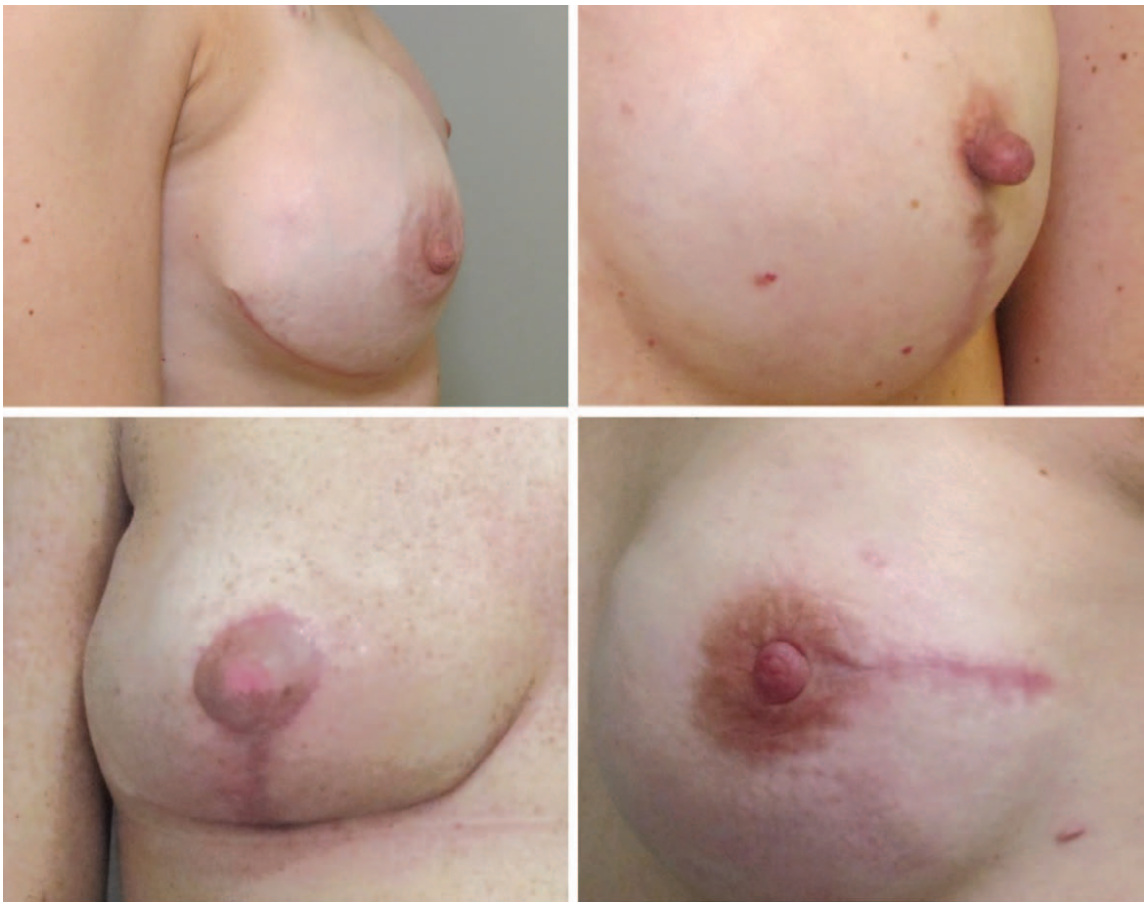

Fig. 1. Mastectomy incision types. (*Above*, *left*) Five to 6 cm in the inferolateral inframammary fold. (*Above*, *right*) Vertical incision. (*Below*, *left*) Inverted-T mastopexy incision with free nipple graft. (*Below*, *right*) Lateral radial incision.

Implant Selection

Important criteria for choosing an implant include the following: breast width; anticipated mastectomy weight; desired postoperative size; and implant characteristics such as texture, shape, height, and projection. Shaped implants were used almost exclusively in all of our reconstructions. If a round implant is selected, a textured implant is preferred, as a textured implant stays in a more medial location when the patient is lying flat, avoiding the characteristic lateral displacement that many reconstructive patients experience.

Women with breasts positioned lower on the chest wall are at an increased risk of having a concave deformity in the upper pole that frequently requires fat grafting. In this scenario, the recently approved tall height shaped implant will improve the aesthetic outcomes and reduce need for further surgery.

Implant sizes are ordered ranging from 50 cc under and 50 cc over the chosen implant size. A back-up tissue expander is always available in the event that single-stage implant reconstruction is not possible.

Mastectomy Incision Type

Mastectomy techniques have evolved from a radical excision to more conservative treatments preserving the skin and nipple-areola complex. Nipple-sparing mastectomy is our preferred technique when oncologic safety allows.

Our preferred incision is at the lateral inframammary fold (Fig. 1, *above*, *left*). This is the least obvious on front view, and it allows good visualization for the oncologic surgeon. This incision has been associated with the lowest rate of nipple necrosis in a nonoperated breast (9.09 percent).[11] A disadvantage is that it could result in greater technical difficulty for the oncologic surgeon when dealing with a large breast. The second choice is a vertical incision from the areola to the inframammary fold (Fig. 1, *above*, *right*). This incision will provide a challenge to get to the axilla, and a separate incision may be needed. The third choice is an inverted-T incision in patients that

also need a mastopexy (Fig. 1, *below, left*). A ptotic nipple will require elevation with a dermal areolar flap or free nipple graft. The additional skin is not removed but is preserved and deepithelialized to maximize implant coverage. The least favorite choice is a lateral radial incision (Fig. 1, *below, right*). This incision is directly visible on the breast, making the final reconstruction more obvious. It also potentially adds retraction ischemia to the mastectomy skin flaps, increasing the chances for wound complications directly over the implant. Periareolar and circumareolar incisions have been associated with the highest nipple necrosis rates (17.81 percent).[11]

Reconstructive Technique

Markings are performed with the patient in the sitting position, in the presence of the oncologic surgeon. For a nipple-sparing mastectomy, a 5- to 6-cm incision is marked in the lateral aspect of the inframammary fold. The midline is marked and a line is drawn 1.5 cm lateral to it as a reminder of the medial origin of the pectoralis major muscle. This area is known as the "no-go zone" and will prevent the implant from displacing medially and causing symmastia.

Adequate tissue handling by the oncologic surgeon is a must, as this will directly influence the skin viability and overall results. Trauma from retraction on the mastectomy flaps plays a significant role in complications.

After the mastectomy is completed, clinical assessment of the mastectomy flaps is performed. Mastectomy flaps should be thick and viable. Intraoperative indocyanine green angiography (Spy Elite System; LifeCell Corp., Branchburg, N.J.) is also used, and it is performed before placement of the acellular dermal matrix and final implant. To mimic the same tension on the mastectomy skin, an implant sizer is used in the prepectoral pocket, and the skin is closed over the sizer with staples. The volume of the sizer is selected based on the mastectomy weight and the desired volume selected by the patient in the office.

A subpectoral pocket is then created. The inferolateral edge of the pectoralis major muscle, which consists of a thin fascia, is excised to allow for a straight and substantial edge on the muscle for suturing the acellular dermal matrix.

Placement of the acellular dermal matrix continues to be the most challenging and time-consuming part of the procedure. Fetal bovine acellular dermis matrix is preferred (SurgiMend; TEI Biosciences, Waltham, Mass.) for various reasons: (1) rapid incorporation and thin periprosthetic capsule because of a higher concentration of type III collagen; (2) decreased drainage and therefore a reported decreased rate of seroma; (3) fenestrations that allow for only one drain to be used, avoiding the need of a drain in the subpectoral pocket in contact with the implant; (4) histologic absence of inflammatory cells in the scaffold because of the product being terminally sterilized and not treated with antibiotics during the processing stage; and (5) decreased cost. The acellular dermal matrix should be hydrated with normal saline and not with an antibiotic solution to prevent the acellular dermal matrix to soak in and retain within the scaffold any antibiotics that could potentially stimulate an inflammatory response as has been reported with other acellular dermal matrices.[16–20] Orientation of the acellular dermal matrix over the sizer allows us to determine how much acellular dermal matrix will be needed (Fig. 2). The acellular dermal matrix is sutured to the pectoralis major muscle first. The anterior axillary line is then transposed and marked into the chest wall to choose the area where the acellular dermal matrix will be sutured on the lateral chest wall. The acellular dermal matrix is then sutured to the inframammary fold under tension. [**See Video, Supplemental Digital Content 1**, which is a surgical video demonstrating the described "tight-pocket" technique (from Codner MA. Surgical tools and techniques: Single-stage direct-to-implant reconstruction. In: Mentor, Part of the Johnson & Johnson Family of Companies, ed. Interactive Surgeon Resource: Mentor MemoryShape Breast Implants, 2015:45–55, available on iTunes), available in the "Related Videos" section of the full-text article on

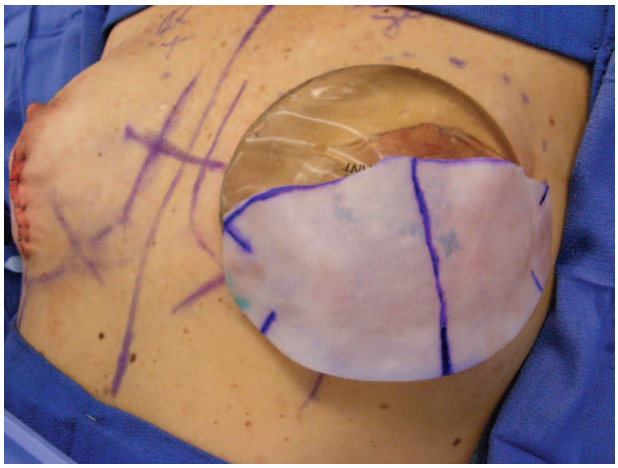

Fig. 2. Acellular dermal matrix over the implant to ensure the chosen size will provide adequate coverage and allow for a more precise trim.

Video. Supplemental Digital Content 1, a surgical video demonstrating the described "tight-pocket" technique (from Codner MA. Surgical tools and techniques: Single-stage direct-to-implant reconstruction. In: Mentor, Part of the Johnson & Johnson Family of Companies, ed. Interactive Surgeon Resource: Mentor MemoryShape Breast Implants, 2015:45–55, available on iTunes), is available in the "Related Videos" section of the full-text article on PRSJournal.com or, for Ovid users, at ***http://links.lww.com/PRS/B345***.

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Insertion of the implant (subpectoral) is performed with a no-touch technique using a Keller Funnel (Keller Medical, Inc., Stuart, Fla.) (Fig. 3). Before insertion, the pocket is irrigated with an antibiotic solution, diluted povidone-iodine, and finally 20 ml of 0.25% plain lidocaine. In a nipple-sparing mastectomy, the nipples are covered with Tegaderm (3M, St. Paul, Minn.) to decrease potential contamination of the implant.[21]

Adequate drainage can be achieved with only one drain under the mastectomy flap. The drain sites are covered with antibiotic-impregnated patches (BioPatch; Ethicon, Inc., Somerville, N.J.). No bra is used in the immediate postoperative period, to prevent additional pressure on the mastectomy flaps and the nipples.

The patient is admitted to the hospital for 24 to 48 hours. The drains are removed when the output is less than 30 ml/day for at least 2 consecutive days. In patients with lymph node dissections, removing the drains earlier than 2 weeks (even if output is low) may result in seroma because of slower reabsorption of interstitial fluid. In this scenario, we wait until the output is less than 20 ml/day. The patient should remain on prophylactic antibiotics for the duration the drain remains in place.

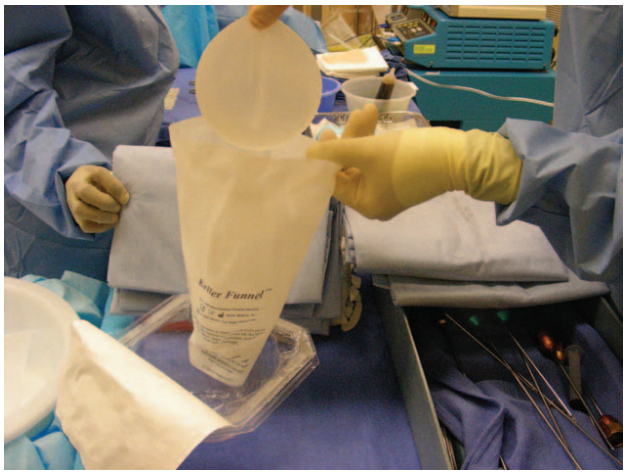

Fig. 3. Proper orientation of the implant is important when delivering a shaped implant using the Keller Funnel.

RESULTS

Twenty-seven single-stage implant breast reconstructions were performed during the senior author's transition period using the described technique (13 bilateral, one unilateral; 24 nipple-sparing mastectomies, and three areola-sparing mastectomies). Average mastectomy weight was 343.82 g (range, 104 to 750 g). Average age was 49 years (range, 34 to 71 years). Average body mass index was 21.35 kg/m^2 (range, 17.11 to 27.46 kg/m^2). Two patients received neoadjuvant radiation therapy (previous lumpectomy); both developed postreconstruction complications (infected seroma/loss of initial implant, capsular contracture). One patient received adjuvant radiation therapy with no short-term implant-related complications reported

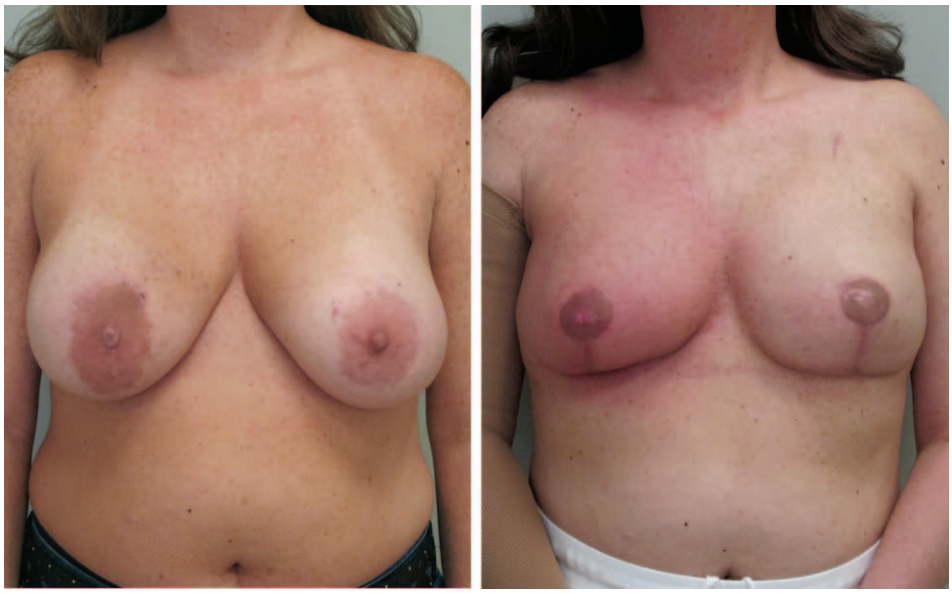

Fig. 4. (*Left*) Preoperative photograph of a 42-year-old woman who underwent bilateral nipple-sparing mastectomy with right axillary lymph node dissection. (*Right*) Seven months postoperatively (adjuvant radiation) after single-stage implant reconstruction with shaped implant (480 cc), inverted-T mastopexy, and free nipple grafts.

at 7-month follow-up (Fig. 4). Acellular dermal matrix was used in all patients. The average implant volume was 367 cc (range, 280 to 480 cc). Shaped implants with moderate height and moderate plus projection were most commonly used (16 of 27). Results of patients who underwent single-stage implant breast reconstruction using the described technique are shown in Figures 5 through 7.

Three patients developed unilateral skin erythema requiring intravenous antibiotics. One patient developed bilateral hypertrophic scars requiring micro-needling treatments (Dermapen; Salt Lake City, Utah). One patient developed unilateral partial nipple necrosis resulting in loss of nipple projection (Fig. 5, *right*). One patient developed skin necrosis at the incision edge after an

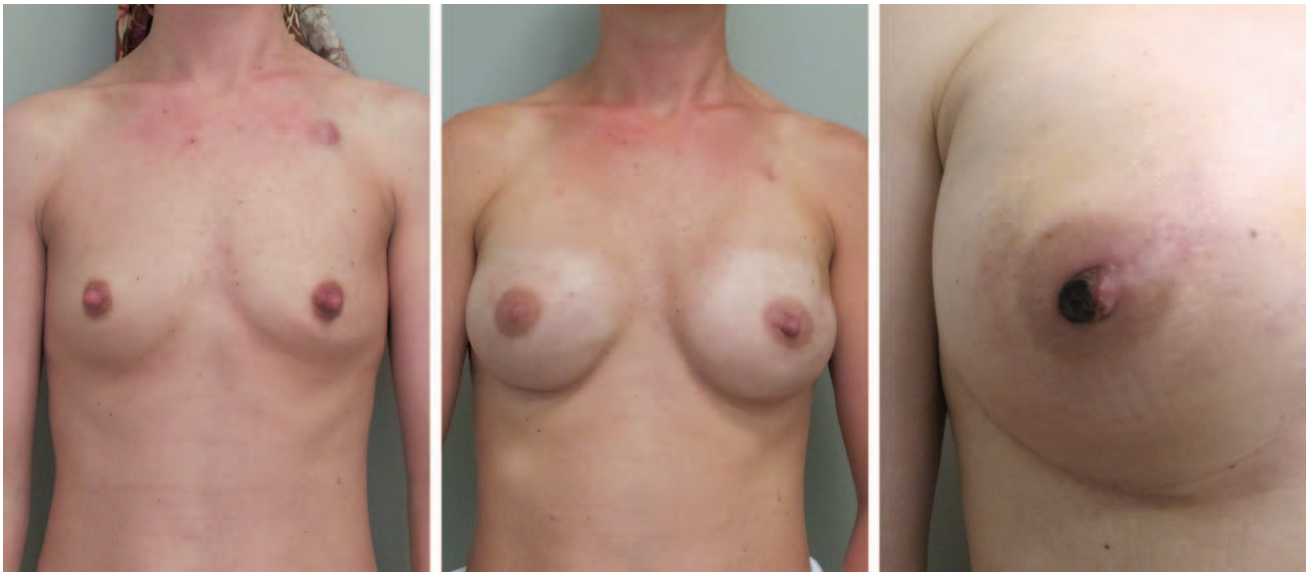

Fig. 5. (*Left*) Preoperative photograph of a 34-year-old woman with right breast cancer. (*Center*) Five months postoperatively after single-stage implant reconstruction through an inferolateral inframammary fold incision, using 395-cc shaped implants and a loose-pocket technique attaching the acellular dermal matrix to the inframammary fold first and then suturing to the pectoralis major over the implant. (*Right*) Partial nipple slough-off resulting in loss of nipple projection on final outcome.

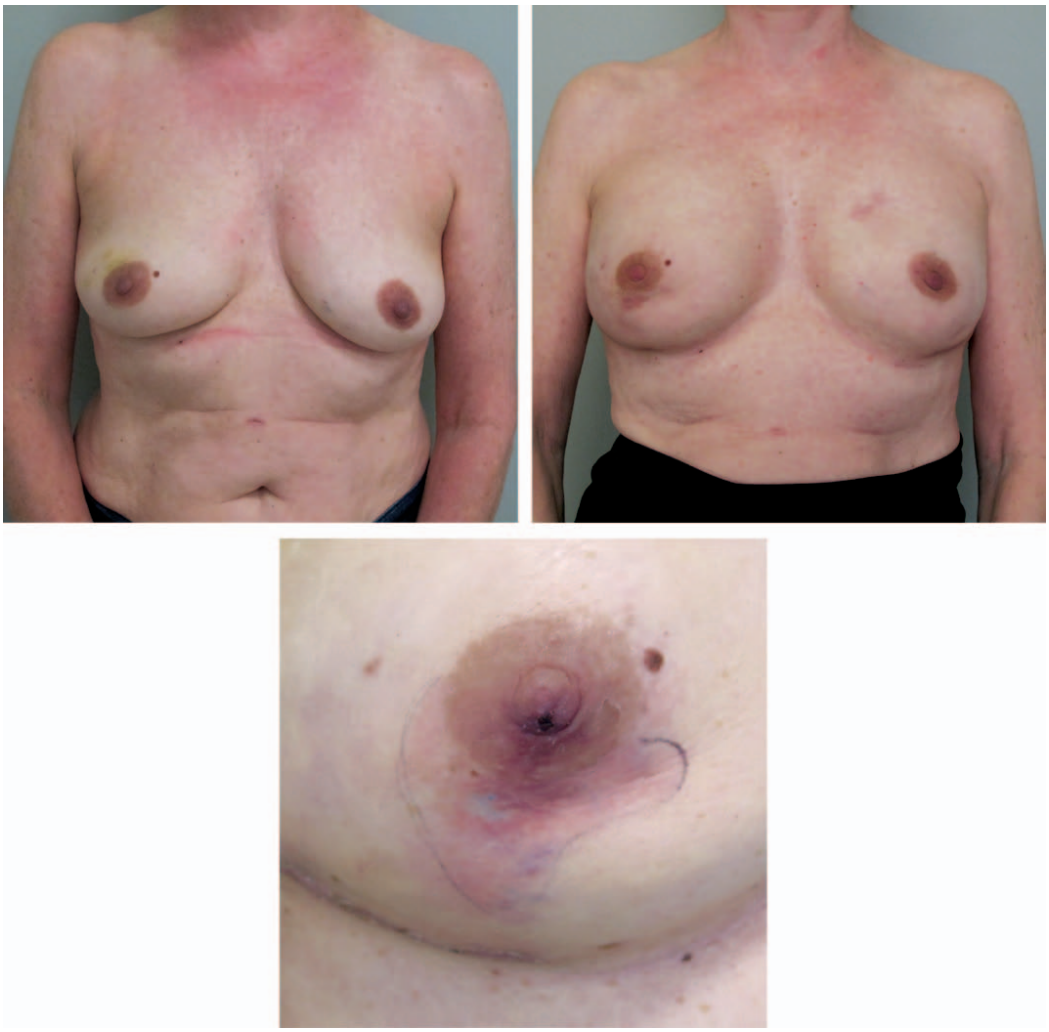

Fig. 6. (*Above, left*) Preoperative photograph of a 65-year-old woman with right breast cancer. (*Above, right*) Six weeks postoperatively after single-stage implant reconstruction with 395-cc tall moderate plus implant using a "tight-pocket" technique with the acellular dermal matrix sutured to the pectoralis muscle first and then to the inframammary fold under tension. (*Below*) Right breast with ischemic changes associated with intradermal injection of methylene blue.

areola-sparing mastectomy. After an attempted salvage of the implant by débridement and layered closure, the patient had exposure/infection of the implant (*Serratia marcescens*) requiring removal and placement of an adjustable saline implant to be used as an expander (Spectrum; Mentor Corp., Santa Barbara, Calif.). One patient developed an infected seroma on her right breast and subsequent bilateral full-thickness skin loss on the free nipple grafts, resulting in exposed and infected implants (*Staphylococcus epidermidis* and *Candida albicans*). This patient also required removal of the initial implant and placement of an adjustable saline implant (Spectrum). Both patients were able to retain a prosthesis at 4 weeks postoperatively using a one-stage salvage irrigation protocol adjusted from a recent report by Sforza et al.[22]

New postoperative asymmetries were found in two of 14 patients: asymmetric nipples as a result of partial nipple loss on one side (one patient), and asymmetric inframammary fold after reoperation for capsular contracture at 9 months postoperatively (one patient). Four additional patients had asymmetries that were present before the reconstruction and they remained present after the reconstruction (upper pole ridge in a woman with a low breast footprint on the chest wall (one patient), asymmetric inframammary fold (two patients), and volume deficiency on the left lower medial quadrant (one patient). All patients were satisfied with skipping the expansion process and the immediate psychological benefits of having addressed a problem (cancer) in most cases with one procedure only.

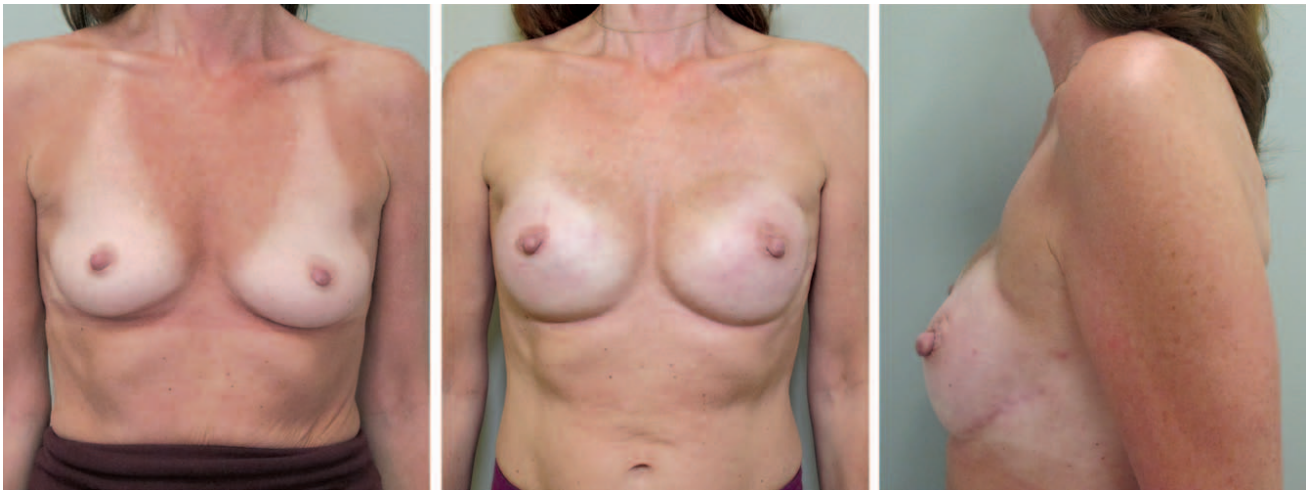

Fig. 7. (*Left*) Preoperative photograph of a 46 year-old woman who underwent bilateral prophylactic nipple-sparing mastectomy. (*Center*) Six-month follow-up after single-stage implant reconstruction with 280-cc moderate height moderate plus shaped implant using a tight-pocket technique. (*Right*) Left breast (lateral view) showing upper pole deformity that will require fat grafting, a corrective procedure that could have been avoided by using a tall height shaped implant.

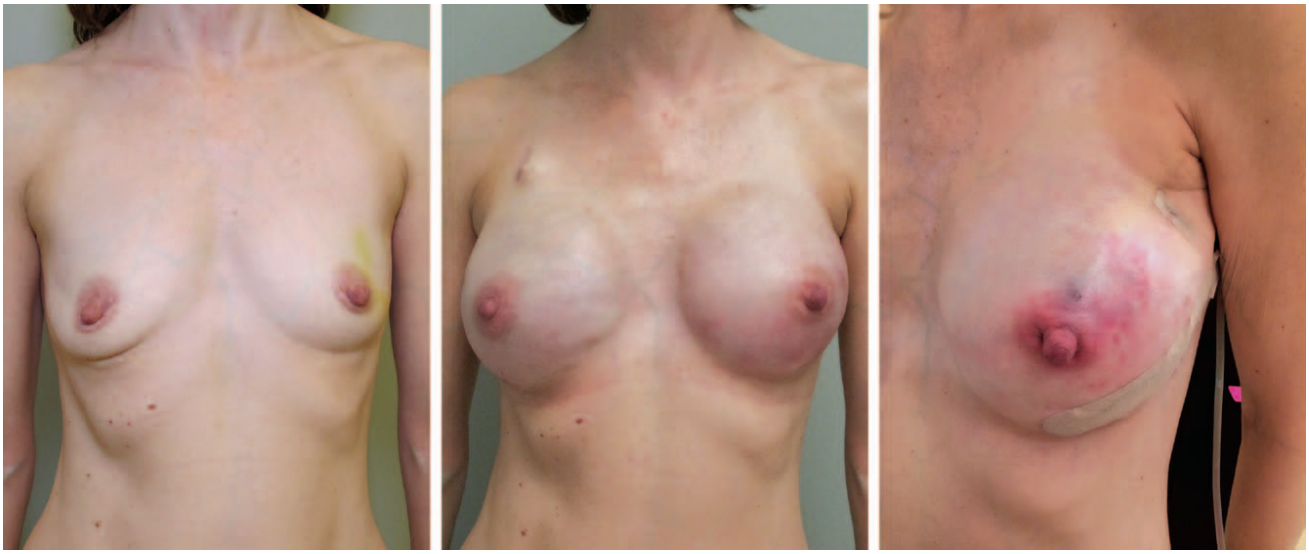

Fig. 8. (*Left*) Preoperative photograph of a 45-year-old woman with left breast cancer. (*Center*) Seven months postoperatively after single-stage implant reconstruction with 355-cc shaped implants and a tight-pocket technique. (*Right*) Left breast erythema at the site of methylene blue injection.

DISCUSSION

Concerns over the oncologic safety and nipple viability have prevented surgeons from accepting the routine use of nipple-sparing mastectomy. The first clinical study evaluating the safety of nipple-sparing mastectomy was performed in 2003. Their protocol included subcutaneous mastectomy, preserving the nipple-areola complex, and leaving a path of glandular tissue measuring 0.5 cm thick and 1 to 2 cm wider than the areola. After confirming intraoperatively that the small amount of glandular tissue left behind was cancer free, 16 Gy of radiation was applied isolated to the nipple-areola complex (ELIOT protocol). The reported nipple necrosis rate was 3.7 percent.[12] In a subsequent study, the same author reported a 0.9 percent rate of cancer recurrence per year, with most recurrences at the tumor bed and not near the nipple-areola complex.[23] Petit et al. reported the local recurrence rate of the breast and nipple-areola complex in 934 nipple-sparing mastectomy patients with invasive breast cancer to be 3.6 percent and 0.8 percent, respectively.[10] With more recent techniques allowing for more aggressive

subcutaneous mastectomies, local recurrence rates are similar to traditional mastectomy at 5 years.[24]

Nipple-sparing mastectomy followed by immediate single-stage implant breast reconstruction is a safe and viable option in a highly selected group of patients. In our experience, patient selection continues to be the most important factor for good outcomes in single-stage implant breast reconstruction. In 2012, Salzberg reported on his 10-year experience demonstrating that, with good patient selection, good surgical technique, and experience, major complications could be kept below 2 percent.[7] Experience and patient selection play a significant role in reducing the complication rates with single-stage implant breast reconstruction. Colwell et al. have reported higher complication rates during the surgeon's first year (21.4 percent) compared with subsequent years (10.9 percent).[25]

Performing indocyanine green angiography before completion of the reconstruction has been found to be an efficient modification to the main author's technique. This will prevent having to change an implant for a tissue expander at the end of the case if it is found that the mastectomy flaps are not viable. Objective perfusion measurements are preferred. In 2013, Munabi et al. showed that an indocyanine green angiography value equal to or less than 7 had an 88 percent sensibility and 83 percent specificity for predicting mastectomy flap necrosis.[26] We have noticed interference of the perfusion map analysis when methylene blue has been used. This has correlated with skin ischemia found at the injection area in the postoperative period. Two patients developed skin changes at the site of methylene blue injection immediately postoperatively (Figs. 6, *below*, and 8, *right*). They received intravenous antibiotics with resolution of the skin erythema. The erythema may not have been related to an infectious process; instead, it may have been a reaction to the methylene blue itself, as shown by previous studies.[27] If skin necrosis occurs in this setting, it would be detrimental for the patient and may result in loss of the implant. The use of methylene blue in this setting should be put in question again.

Most patients will fit the moderate height shaped implants; however, on occasion we have noticed a ridge across the upper pole (Fig. 7, *right*). The anatomical basis of this deformity could be related to the fact that the breast itself is located lower on the chest wall and the pectoralis major muscle will tend to slide over the upper pole of the implant. In the past, we have performed fat grafting to alleviate the deformity. Most recently, we have chosen to use a tall height shaped implant in these patients.

When fat grafting is needed, we favor the use of closed system for harvesting. (Revolve; LifeCell) The most common locations needing fat transfer are the upper pole and the medial breast (rippling).

Salzberg has previously described the tight-pocket technique.[7,9] The reasoning behind the technique has never been reported. We believe that by increasing the muscle-to–acellular dermal matrix coverage ratio over the implant, the chances of postoperative rippling are reduced. Chances of implant rotation are also reduced. The disadvantages with this technique are that projection is compromised temporarily, and might be only acceptable in patients with smaller breast sizes. The implant tends to ride up in the breast for the first 3 to 4 weeks postoperatively.

The potential benefits of a one-stage implant salvage irrigation protocol for infected implants proposed by Sforza et al. must be discussed.[22] Two patients presented with implant exposure/infection and were treated with a sequential irrigation protocol consisting of hydrogen peroxide, normal saline, and full-strength povidone-iodine combined with antibiotic irrigation through the drains at the end of the operation. No signs of infection had been documented by 4 weeks postoperatively. We have found success even in the setting of infection with *Candida* species, which has been known to be associated with failure in implant salvage.[28] Further studies will be required to assess the real implications of our adapted protocol in breast reconstruction patients.

Our study is limited by the number of patients treated and short-term follow-up during the transition period because shaped silicone implants were only recently approved by the U.S. Food and Drug Administration for use in the United States. A statistical analysis of complications is beyond the scope of this study.

CONCLUSIONS

Over the past 20 years, mastectomy and breast reconstruction techniques have co-evolved toward less invasive, single-stage procedures. Aesthetic refinements include nipple-sparing mastectomy, the use of acellular dermal matrix, shaped implants, and fat grafting. Selected patients will benefit from a one-and-done direct-to-implant reconstruction with no additional oncologic risk. We hope that

by sharing the main author's experience and the most recent literature to support it, we can inspire other plastic surgeons to evolve into what we think will be the future of breast reconstruction.

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CODING PERSPECTIVE

This information prepared by Dr. Raymond Janevicius is intended to provide coding guidance.

19340	Immediate breast reconstruction with implant
15777	Implantation of biologic implant

- An immediate breast reconstruction with a permanent implant is reported with code 19340.
- Code 19340 is global and includes creation of a submuscular pocket, placement of the implant, and wound closure.
- Creation of a submuscular pocket is not considered a muscle flap and is not reported separately with code 15734.
- Redraping skin flaps and excisions of dog-ears are included in the wound closure and are not reported separately as complex repairs or adjacent tissue transfers.
- Acellular dermal matrix is a biologic implant and is reported with code 15777.
- Code 15777 is an add-on code and does not take the multiple procedure multiplier, 51.
- If a nonbiologic implant is used instead of acellular dermal matrix, the unlisted procedure code 19499 is reported. Code 15777 is to be used only for biologic implants.
- Contralateral breast surgery is reported separately.
- Always preauthorize all breast procedures **in writing** prior to performing surgery. Coverage and coding preferences vary by payer.

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