Evidence-Based Medicine: Alloplastic Breast Reconstruction

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Learning Objectives: After studying this article, the participant should be able to: 1. Understand the different advances that have resulted in improved outcomes in implant-based reconstruction. 2. Gain knowledge about specific techniques that have evolved rapidly in recent years and how to implement these. 3. Gain an understanding of controversies associated with alloplastic reconstruction. 4. Recognize undesirable outcomes in implant-based breast reconstruction and understand strategies for correction.

Summary: There have been multiple advances in implant-based breast reconstruction. Many of these have resulted in improvements in patient outcomes and care. Understanding new techniques and technologies ensures competence in providing care for the alloplastic breast reconstruction patient. This article was prepared to accompany practice-based assessment with ongoing surgical education for the Maintenance of Certification for the American Board of Plastic Surgery. It is structured to outline the care of the patient with the postmastectomy breast deformity. (*Plast. Reconstr. Surg.* 140: 94e, 2017.)

The popularity of implant-based breast reconstruction continues to increase, and it now constitutes the majority of reconstructions.[1] This may reflect the increasing number of bilateral reconstructions, the greater resource requirements in autologous (especially microsurgical) reconstruction, and financial implications.[2] Furthermore, the evolution of multiple new techniques and devices over the past decade, including acellular dermal matrices, autologous fat grafting, and nipple-sparing mastectomy, has contributed to better outcomes in implant-based breast reconstruction.

TIMING OF RECONSTRUCTION

The understanding that breast reconstruction does not have a negative impact on outcomes has resulted in immediate reconstruction becoming the standard of care in most breast reconstruction centers.[3,4] This allows preservation of the skin envelope, and minimization of the number of operations. Several studies have shown that immediate reconstruction can delay the onset of adjuvant therapy,[5,6] although this was recently refuted by Eck et al.[7] Meta-analysis has demonstrated that despite the possibility of increased time to adjuvant treatment, immediate reconstruction has no impact on outcomes.[8] The advantages of delayed reconstruction include a stable soft-tissue envelope, completion of all adjuvant therapies, and realistic patient expectations; delay may thus be used in centers where autologous reconstruction for patients known to require adjuvant radiotherapy is preferred.[9]

Delayed immediate reconstruction has been popularized as an alternative for patients with indeterminate need for adjuvant radiotherapy.[10] A tissue expander is placed at the time of mastectomy and potentially deflated if the patient requires adjuvant radiotherapy. The goal is to maintain as much breast skin as possible and minimize the

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Received for publication February 12, 2016; accepted October 24, 2016.

DOI: 10.1097/PRS.0000000000003472

Disclosure: *Dr. Macadam and Dr. Bovill have no financial interest in any of the products or devices mentioned in this article. Dr. Lennox is a consultant for LifeCell and Allergan and a shareholder in Strathspey Crown.*

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impact on the delivery of radiation. Patients then undergo conversion to autologous reconstruction after their radiotherapy. A criticism of the technique is the high (14 percent) tissue expander loss rate as a result of skin breakdown and tissue expander exposure during radiotherapy.[10]

Staged immediate reconstruction involves skin-sparing or nipple-sparing mastectomy with closure of skin over drains. Drains are removed at 1 week, and reconstruction is undertaken, either with direct-to-implant reconstruction with acellular dermal matrices, or tissue expander and acellular dermal matrices, at 2 weeks. The mastectomy flaps are effectively delayed and therefore may have a lower complication rate related to flap vascularity. In addition, the final pathologic condition is known and adjuvant therapies can be appropriately planned.[11]

ONCOLOGIC CONSIDERATIONS

Mastectomy Incision

Over the past two decades, there has been a gradual change from traditional modified radical mastectomy to skin-sparing mastectomy and nipple-sparing mastectomy in the setting of immediate reconstruction. Nipple-sparing mastectomy has the advantages of maintaining the entire breast skin envelope, the conical shape of the breast, and the patient's native nipple-areola complex. Patient selection is based on oncologic factors at presentation, with earlier guidelines based on known risk factors associated with nipple-areola complex involvement in total mastectomy specimens (Table 1).[12,13] Recently, the indications for nipple-sparing mastectomy have expanded, with many surgical oncologists feeling that the majority of mastectomy patients are candidates for nipple-sparing mastectomy.[14] To date, oncologic safety has been confirmed, with recurrence rates comparable to other types of mastectomy,[15] and with appropriate patient selection, complication rates for nipple-sparing mastectomy are comparable to those in skin-sparing mastectomy.[16] Multiple incision types have been described (Fig. 1). Lower rates of nipple-areola complex necrosis have been reported with inframammary fold and lateral breast incisions.[17]

An alternative mastectomy pattern for large-breasted women is reduction pattern mastectomy[18] with or without free nipple grafting. (**See Video, Supplemental Digital Content 1**, which displays a technique for reduction pattern mastectomy. This video is available in the "Related Videos" section of the full-text article on PRSJournal.com or available at ***http://links.lww.com/PRS/C204***.) This allows reduction of the skin envelope with maintenance of breast shape and acceptable scars. Reduction pattern mastectomy can be combined with a deepithelialized lower pole dermal flap (Figs. 2 and 3), to allow release of the lower pectoralis major muscle, at a cost saving over acellular dermal matrices. Reduction pattern mastectomy does have a higher complication rate, particularly of mastectomy flap necrosis.[19] Addition of a lower pole dermal flap, however, adds another layer of vascularized tissue in the lower pole. The vascularity of this tissue has been demonstrated clinically and by use of indocyanine green perfusion assessment[20] (Figs. 4 and 5). (**See Video, Supplemental Digital Content 2**, which displays intraoperative SPY (Novadaq, Toronto, Ontario, Canada) imaging of an inferior

Table 1. Selection Criteria for Nipple-Sparing Mastectomy

Criteria	Suitable NSM Candidate	Nonsuitable Candidate
Strong		
Tumor size	<2 cm	>2 cm
Lymph node involvement	No positive nodes	Positive nodes
Lymphovascular invasion	None	Positive
Tumor location	>2 cm from NAC Peripheral	<2 cm from NAC Central
Her 2	Negative	Positive
Grade	1–2	3
Weak		
ER/PR status	Positive	Negative
DCIS	No DCIS	DCIS

NSM, nipple-sparing mastectomy; NAC, nipple-areola complex; ER, estrogen receptor; PR, progesterone receptor; DCIS, ductal carcinoma in situ.

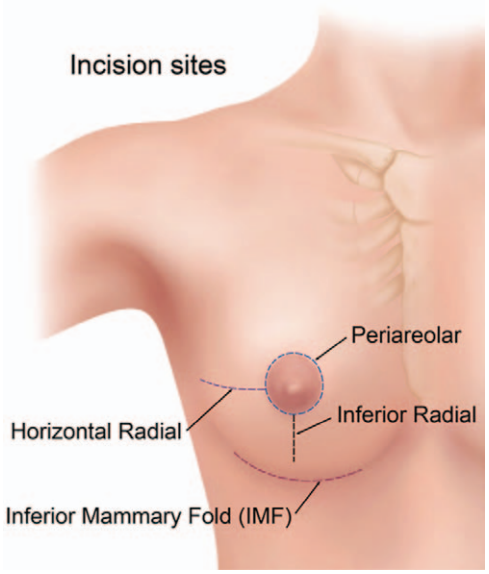
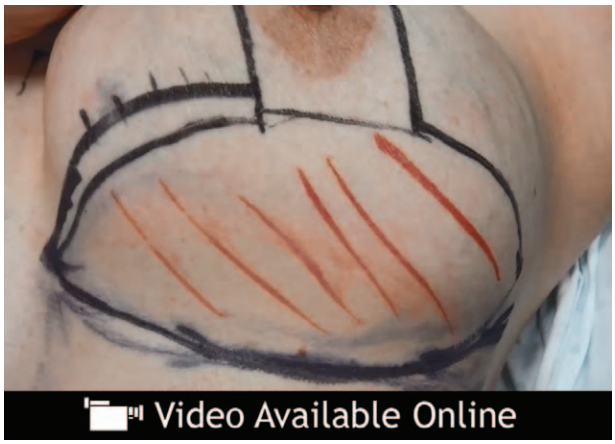


Fig. 1. Possible incision patterns for nipple-sparing mastectomy.



Video 1. Supplemental Digital Content 1, which displays a technique for reduction pattern mastectomy, is available in the "Related Videos" section of the full-text article on PRSJournal.com or at ***http://links.lww.com/PRS/C204***.

dermal flap. This video is available in the "Related Videos" section of the full-text article on PRSJournal.com or at ***http://links.lww.com/PRS/C205***.)

Radiation Therapy

Indications for adjuvant radiotherapy have expanded over recent years. In many centers, patients with one or more positive lymph nodes will have a recommendation for adjuvant radiotherapy.[21] Recently, there has also been a suggestion that node-negative patients with medial tumors will also benefit from adjuvant radiotherapy.[22] As a result, the number of patients undergoing immediate breast reconstruction who subsequently require radiotherapy has increased significantly. Alloplastic reconstruction in the setting of adjuvant radiotherapy remains controversial. There is a large body of evidence that these patients have higher complication rates, poorer outcomes, and increased failure rates compared with their nonirradiated counterparts.[23,24] Reported recommendations range from different protocols for alloplastic reconstruction with radiation therapy, to the suggestion that only autologous reconstruction should be performed in the setting of adjuvant radiotherapy.[9]

Large-scale trials are required to confirm optimal timing of radiation with alloplastic reconstruction, with radiation therapy to either the tissue expander or the final implant. The University of British Columbia model, in which radiation is given to the tissue expander before final implant placement, has demonstrated lower capsular contracture rates and similar complication rates compared with the Sloan Kettering model described by Cordeiro et al., in which the radiation is delivered to the final implant.[25]

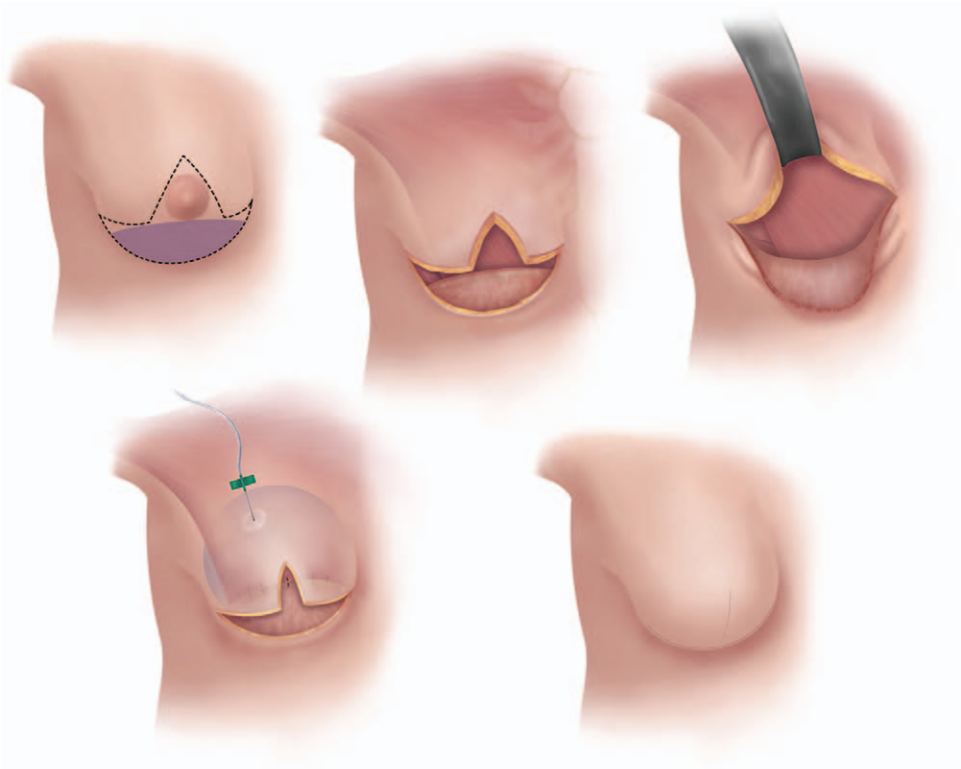


Fig. 2. Surgical sequence for reduction pattern mastectomy.

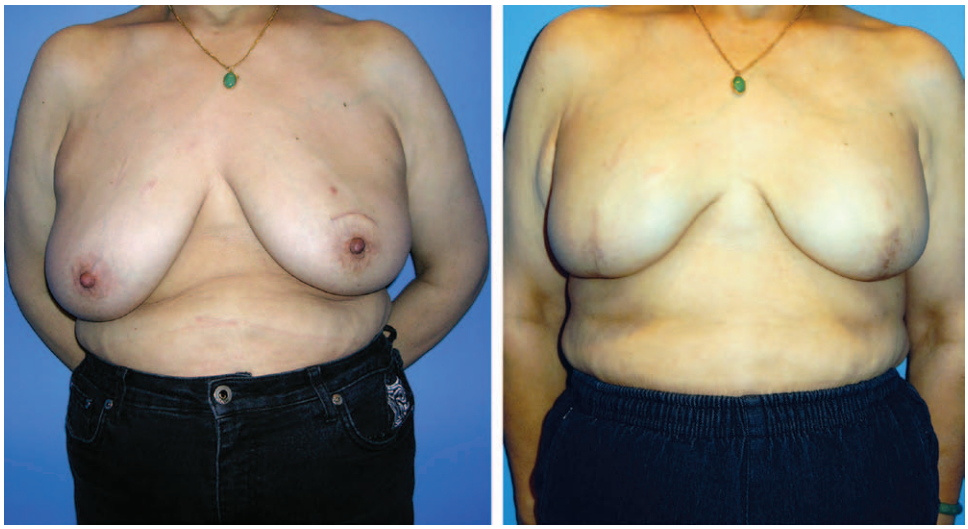


Fig. 3. (*Left*) A 61-year-old woman with invasive left breast reconstruction who underwent bilateral reduction pattern mastectomies and two-stage tissue expander/implant reconstruction with a deepithelialized dermal flap and no acellular dermal matrix. (*Right*) After second-stage reconstruction with fat grafting and smooth silicone (Inspira SSF 540 g; Allergan, Inc., Dublin, Ireland) implants.

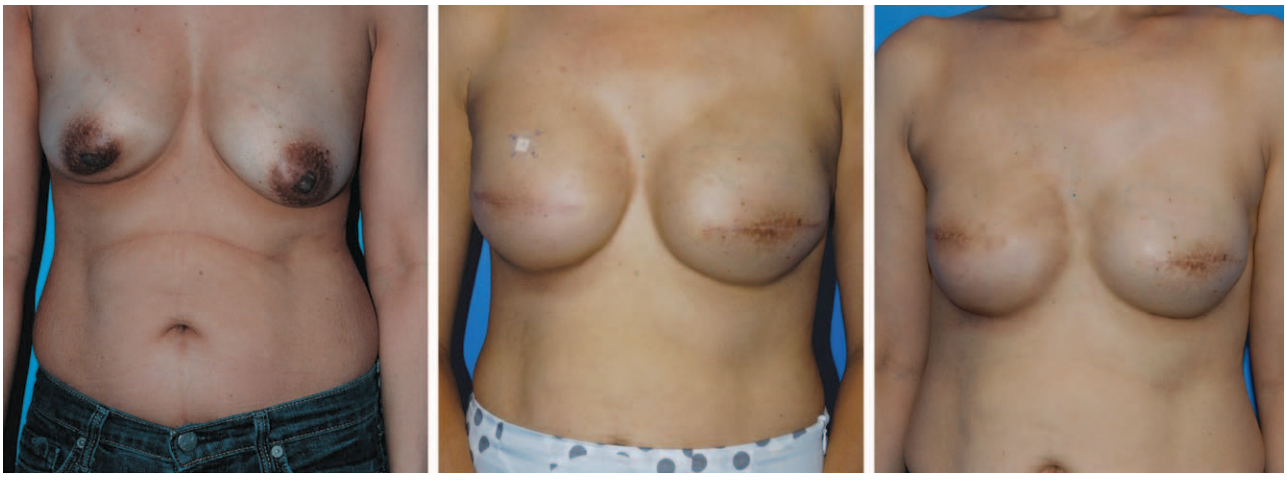
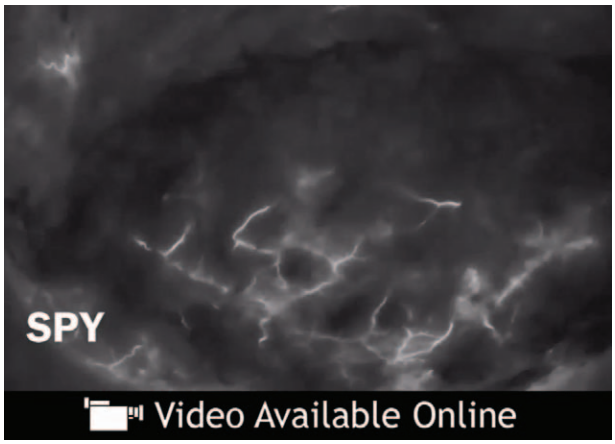


Fig. 4. (*Left*) A 51-year-old woman who underwent bilateral skin-sparing mastectomy and tissue expander reconstruction with acellular dermal matrix for invasive right breast carcinoma. (*Center*) Tissue expanders in place after completion of right adjuvant radiotherapy. Mastectomy weights were approximately 420 g per side, and she has MV-13 tissue expanders with 380 cc on the left and 430 cc on the right. (*Right*) After second-stage reconstruction with fat grafting and form-stable implants [right, MX 130-410; left, MX 125-370 (Allergan)].

EVOLUTION OF ALLOPLASTIC RECONSTRUCTION

Breast implant technology has developed and evolved, resulting in improvements in outcomes in breast reconstruction.[26] During the silicone implant moratorium in North America (1992 to 2006), silicone implants were available for breast reconstruction, but many practitioners used saline over silicone. Since 2006, silicone implants constituted the majority of implants used in reconstruction. Implants are classified by fill (saline versus silicone), shape (round versus shaped), and surface (smooth versus textured). Silicone implants can also further be described by the degree of cross-linking of the silicone gel, or the degree of cohesivity. Increasing cohesivity is associated with less postoperative rippling but a more firm feeling breast. It has been shown using the BREAST-Q that patients prefer silicone over saline implants.[27] Furthermore, patients report a feeling of firmness with highly cohesive implants, but no preference of round over shaped implants.[28] To date, there



Video 2. Supplemental Digital Content 2, which displays intraoperative SPY (Novadaq, Toronto, Ontario, Canada) imaging of an inferior dermal flap, is available in the "Related Videos" section of the full-text article on PRSJournal.com or at ***http://links.lww.com/PRS/C205***.

is no clear evidence to support the choice of one specific implant type over another.

ANAPLASTIC LARGE-CELL LYMPHOMA

Breast implant–associated anaplastic large-cell lymphoma was first described in 1997 by Keech and Creech (Table 2).[29] Arising first in the implant capsule, it often presents with only free floating tumor cells in the space between the implant and the capsule.[30] It has then been shown to develop into a solid tumor of the capsule, with the potential to metastasize to regional lymph nodes. There have been 173 cases reported in the literature to date.[28] The only epidemiologic study available suggests an incidence of one in 300,000,[31] but recent data suggest that this is changing as reporting improves.

Table 2. Criteria for Diagnosis of Breast Implant–Associated Anaplastic Large-Cell Lymphoma*

Description
A tumor with adequate pathologic specimen for analysis either involving an effusion surrounding a breast implant or in continuity with a breast implant capsule
Neoplasm with large lymphoid cells with abundant cytoplasm and pleomorphic nuclei
Tumor demonstrates T-cell markers with uniform expression of CD30 on immunohistochemistry
Negative for anaplastic lymphoma kinase (ALK) protein or translocations involving the *ALK* gene at chromosome 2q23

*Data from Miranda RN, Lin L, Talwalkar SS, Manning T, Medeiros LJ. Anaplastic large cell lymphoma involving the breast: A clinicopathologic study of 6 cases and review of the literature. *Arch Pathol Lab Med.* 2009;133:1383–1390; and Clemens MW, Miranda RN. Commentary on: Lymphomas associated with breast implants: A review of the literature. *Aesthet Surg J.* 2015;35:545–547.

The clinical presentation may include an effusion with swelling of the breast or a mass associated with the capsule. Mean time from implantation to detection is 9.3 years in the most recent review.[28] The recommendation is that breast implant–associated anaplastic large-cell lymphoma be discussed with all patients for whom a breast implant is part of their treatment.[32] If a patient presents with a delayed seroma (defined as a seroma 1 year after implantation), the initial workup is ultrasound evaluation. If a mass is identified, oncologic evaluation is mandated. If a seroma is present, ultrasound-guided aspiration with cytology and culture of the fluid is performed. Fluid is sent for cytology and labeled "suspicious for breast implant–associated anaplastic large-cell lymphoma." Flow cytometry and CD30 immunohistochemistry is then carried out. If disease is confined to the effusion, surgery includes total capsulectomy and explantation. If the patient responds, she is observed for recurrence with ultrasound with or without computed tomography (or positron emission tomography) evaluation every 6 months for 2 years and then annually. If there is no response, the patient is diagnosed as having refractory disease and treated with chemotherapy (cyclophosphamide, doxorubicin, vincristine, and prednisone) or a clinical trial with brentuximab vedotin versus cyclophosphamide, doxorubicin, vincristine, and prednisone. If the patient presents with advanced disease including an unresectable mass or lymph node involvement, total capsulectomy and explantation are combined with chemotherapy or a clinical trial with brentuximab vedotin versus cyclophosphamide, doxorubicin, vincristine, and prednisone. In this case, if there is no response, an autologous stem cell transplant may be considered.

ACELLULAR DERMAL MATRICES AND SCAFFOLDS

Acellular dermal matrices and soft-tissue scaffolds have significantly changed the environment in alloplastic breast reconstruction. The use of acellular dermal matrices was first described in the breast literature in 2007[33,34] for direct-to-implant reconstruction. Subsequently, the use of acellular dermal matrices and scaffolds has expanded to include tissue expander reconstruction and revision reconstruction. Soft-tissue scaffolds can be divided into either biological or synthetic, with biological further divided into allogenic or xenogenic (Table 3). The most recent American Society of Plastic Surgeons (2015) data estimate that acellular dermal matrices

Table 3. Acellular Dermal Matrices and Scaffolds

Product	Type	Manufacturer/ Distributor	Source
AlloMax (Neoform)	Biologic	Bard/Davol, Warwick, R.I.	Human
AlloDerm	Biologic	LifeCell Corp., Branchburg, N.J.	Human
Strattice	Biologic	LifeCell Corp.	Porcine
DermACELL	Biologic	LifeNet/Novadaq, Toronto, Ontario, Canada	Human
Veritas	Biologic	Baxter	Bovine fetal pericardium
Flex HD	Biologic	MTF/Ethicon, Somerville, N.J.	Human
DermMatrix	Biologic	MTF/Synthes, West Chester, Pa.	Human
Seri Scaffold	Synthetic Bioresorbable	Allergan, Dublin, Ireland	Purified Silk
Vicryl mesh	Synthetic	Ethicon	Synthetic (polyglactin 910)

MTF, Musculoskeletal Transplant Foundation.

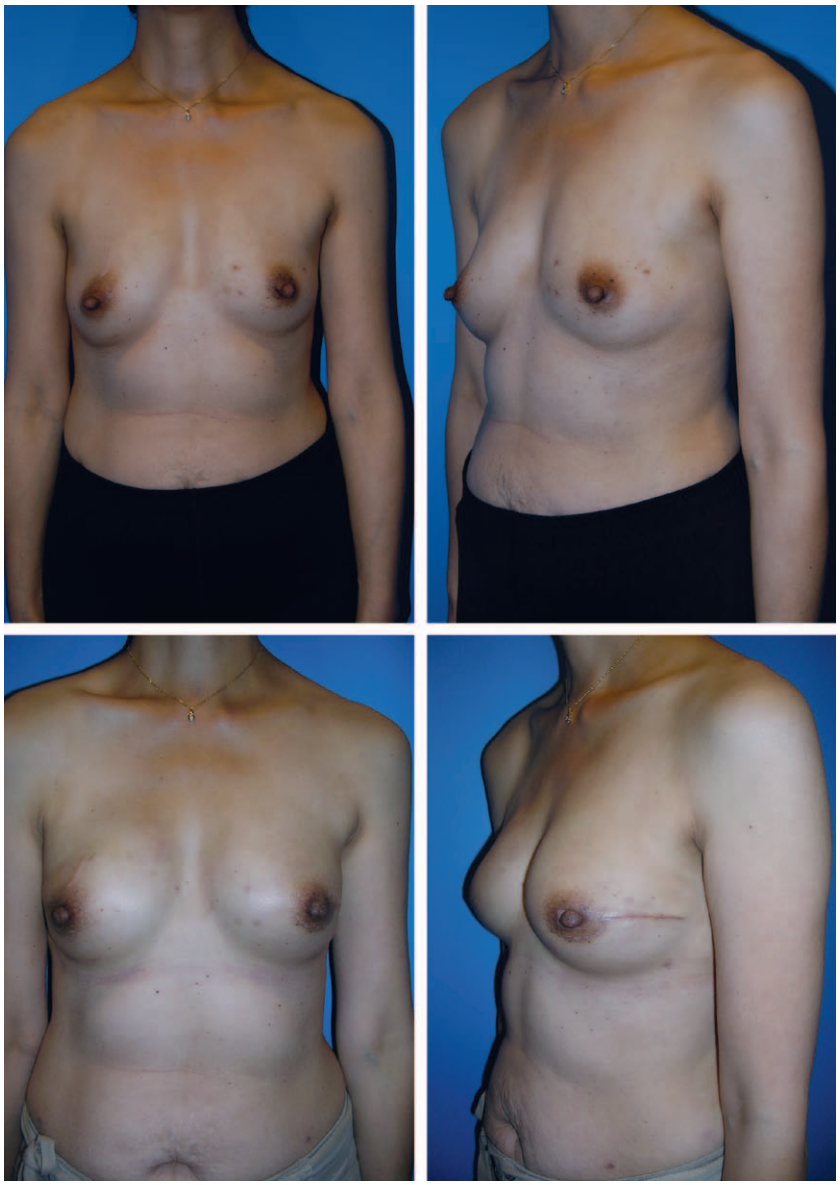


Fig. 5. (*Above*) Preoperative anteroposterior and oblique images of a 49-year-old woman with invasive left breast carcinoma. (*Below*) Postoperative views after bilateral nipple-areola complex–sparing mastectomies and tissue expander reconstruction with second-stage reconstruction with form-stable shaped implants.

were used in 65 percent of nonautologous breast reconstructions in the United States.[35]

Acellular dermal matrices and scaffolds have allowed significant improvements in outcomes in direct-to-implant reconstruction,[36] particularly when combined with nipple-sparing mastectomy. The majority of their use, however, continues to be in conjunction with tissue expanders, first described by Bindingnavele et al.[37] There is a large body of evidence that supports the safety of acellular dermal matrices and scaffolds. The subjective advantages of acellular dermal matrices and scaffolds over traditional two-stage reconstruction are well documented, with better control of the inframammary fold, better lower pole projection, less pain with expansion, better aesthetic outcomes, and reduced capsular contracture.[38] McCarthy et al.,[39] however, have demonstrated that use of acellular dermal matrices with two-stage tissue expander reconstruction was not associated with reduction in pain or decreased fill times.

Meta-analyses offer conflicting data, with some finding increased risks of overall complications, infection, and hematoma/seroma and reconstructive failure rates compared with total submuscular coverage,[40,41] whereas the most recent meta-analysis demonstrated higher infection, mastectomy flap necrosis, and seroma, but no difference in total complication rates or implant loss. Furthermore, long-term complications of capsular contracture and implant malposition were statistically lower in the acellular dermal matrix group.[42] Data analysis from the American College of Surgeons National Surgical Quality Improvement Program identified smoking and body mass index as independent risk factors for short-term complications, but found no statistically significant risk differences between immediate acellular dermal matrix–assisted (n = 1717) and submuscular (n = 7442) tissue expander reconstruction.[43] Other scaffolds have also been described, with polyglactin 910 (Vicryl; Ethicon, Inc., Somerville, N.J.) mesh perhaps the best known. A recent systematic review of polyglactin 910 mesh revealed low complication rates and significant cost savings over acellular dermal matrices, but only included 112 patients.[38] There are no trials in the literature comparing acellular dermal matrices to other scaffolds directly, and these would be beneficial in answering the questions of cost and benefit.

PERFUSION ASSESSMENT

Mastectomy flap vascularity has been a long-standing issue in breast reconstruction. The advent of nipple-sparing mastectomy, reduction pattern mastectomy, and direct-to-implant reconstruction have all further increased the relevance of the vascularity of mastectomy flaps.[44] Mastectomy flap necrosis in the setting of reconstruction is potentially the most significant variable affecting timing of adjuvant therapy for breast cancer patients. Historically, options for assessment of mastectomy skin were limited to clinical assessment. Use of fluorescein and UV light have been described, but are criticized for lack of quantitative assessment and because of the long half-life of fluorescein, which decreases the frequency with which it can be used.

Indocyanine green dye combined with laser angiography is a technique that allows real-time assessment of perfusion. Indocyanine green has a short half-life, which allows multiple assessments. The most commonly available indocyanine green/laser angiography device is reported to have a sensitivity of 83 percent and a specificity of 97 percent in predicting full-thickness mastectomy flap necrosis.[45] Cost analysis has suggested that indocyanine green/laser angiography be reserved for smokers, patients with a body mass index greater than 30 kg/m^2, and patients with large (>800 g) breasts.[46] It may also prove helpful in ptotic breasts and patients undergoing nipple-sparing mastectomies and for assessing doubtful perfusion in patients with preexisting scars. Despite the criticism of fluorescein, a recent study indicated it was at least as effective as, and is certainly much less costly than, indocyanine green/laser angiography.[47]

SURGICAL TECHNIQUES FOR ALLOPLASTIC RECONSTRUCTION

Two-Stage Reconstruction

Two-stage tissue expander reconstruction (with or without acellular dermal matrices) accounts for 73 percent of breast reconstruction in the United States (American Society of Plastic Surgeons 2014 data). Traditional immediate two-stage reconstruction usually involves initial placement of a tissue expander in a total submuscular pocket. The largest series of traditional two-stage tissue expander reconstruction[48] revealed tissue expander reconstruction to be safe and reproducible (Figs. 6 and 7). Advantages of total submuscular coverage include vascularized tissue between the tissue expander and the mastectomy flap in the case of mastectomy flap necrosis. Criticisms of total submuscular coverage include the following:

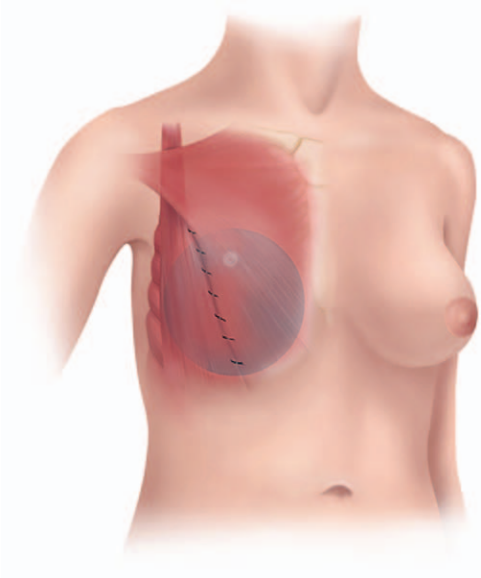


Fig. 6. Total submuscular coverage of tissue expander, including serratus laterally.

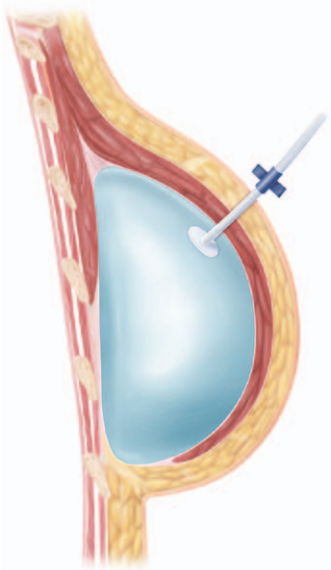


Fig. 7. Cross-section of total submuscular tissue expander coverage.

(1) lack of lower pole and inferolateral breast expansion; (2) increased time for expansion; (3) pain with expansion; and (4) requirement for increased pocket modification at a second stage.

Acellular Dermal Matrix–Assisted Reconstruction

Acellular dermal matrices or tissue scaffolds are now used in the majority of two-stage reconstructions in the United States. Techniques for their use as a lower pole sling have been well described. (**See Video, Supplemental Digital Content 3**, which displays a tissue expander technique plus acellular dermal matrix reconstruction. This video is available in the "Related Videos" section of the full-text article on PRSJournal.com or at ***http://links.lww.com/PRS/C206***.) It is in the use of single-stage reconstruction, however, that the acellular dermal matrix is particularly convincing for reducing costs and procedures.

Video 3. Supplemental Digital Content 3, which displays a tissue expander technique plus acellular dermal matrix reconstruction, is available in the "Related Videos" section of the full-text article on PRSJournal.com or at ***http://links.lww.com/PRS/C206***.

Direct-to-Implant Reconstruction

Direct-to-implant breast reconstruction can be performed in three ways: adjustable implant, partial submuscular coverage, and use of a scaffold or acellular dermal matrix.

Adjustable Implant

Several implants exist that combine the benefits of a permanent silicone implant with the adjustability of a tissue expander. In North America, the Becker implant (Mentor) is the most widely known. This part-silicone device has a central saline component that is adjustable. The ratio of saline fill to silicone fill is either 35 percent or 50 percent silicone. This technique was first described by Becker in 1984, with the first large series reported by Camilleri et al. in 1997.[49] In 2012, Eriksen et al.[50] reported a prospective randomized trial of one-stage (Becker) versus traditional two-stage reconstruction, with both arms having total submuscular pockets. They demonstrated a 70 percent revision rate, lower patient satisfaction rates, and poorer aesthetics in the one-stage group compared with the two-stage group. Sindali et al.[51] demonstrated similar findings, with a low rate of retention (25 percent) of Becker devices over the long term in breast reconstruction patients.

Partial Submuscular Coverage

In this technique, a subpectoral pocket is created and the inferior border of the pectoralis major is released. The implant is placed into the pocket, and the inferior border of the muscle is sutured to the mastectomy flap directly or with marionette sutures. The implant is only covered by the mastectomy flap in the lower pole.

Use of a Scaffold or Acellular Dermal Matrix

In this technique, the acellular dermal matrix is sutured to the inferior border of the released pectoralis major muscle to provide support and coverage to the implant in the lower pole. Direct-to-implant reconstruction with a scaffold has been shown to be cost effective in appropriate patients,[52,53] and good outcomes with comparable complication rates to two-stage reconstruction have been reported.[36,54] Appropriate patient selection is key to good outcomes, with the procedure best suited to smaller nonptotic breasts, low–body mass index patients, nonsmokers, and nonirradiated patients[55,56] (Figs. 8 through 10).

AUTOLOGOUS FAT GRAFTING

Fat grafting is commonly used at second-stage surgery to improve contour deformities and implant rippling and to thicken the soft-tissue envelope.[57,58] Hammond et al. have recently reported on their experience with total envelope fat grafting in addition to "spot grafting" for contour deformities.[59]

The presence of mesenchymal stem cells in autologous fat has been well documented, as has the potential to improve the quality of the soft-tissue envelope, including irradiated tissue.[60] This has expanded the potential use of nonautologous reconstruction in previously irradiated patients. Fat graft can be processed in a variety of ways, and the process may affect the number of adipose-derived stem cells and graft take (Table 4).[61]

Cleveland et al.[62] recently reviewed techniques for processing of fat, noting some differences in outcomes (Table 4). These were not shown to translate to clinical improvement, however, and they concluded that there is no clear superior method. Autologous fat can be enriched with either stromal vascular fraction or platelet-rich plasma. Enrichment of the graft is termed cell-assisted lipotransfer. The data on outcomes are again conflicting. Peltoniemi et al. found that stromal vascular fraction enrichment did not have a positive impact on in vivo graft survival,[63] whereas Domenis et al. have demonstrated improved graft take long term.[64] In a blinded randomized controlled trial, Kølle et al. also reported that expanded stromal vascular fraction cell–assisted lipotransfer resulted in significantly higher residual take in the study group.[65]

Similarly, use of platelet-rich plasma remains controversial. Salgarello et al. failed to demonstrate a difference in patients treated with breast fat grafting with or without platelet-rich plasma.[66] Serra-Mestre et al., in a review, however, conclude that the literature indicated a dose-dependent positive effect of the addition of platelet-rich plasma to fat grafting techniques.[67]

Many authors have presented concerns about autologous fat grafting to the breast.[68] Particularly

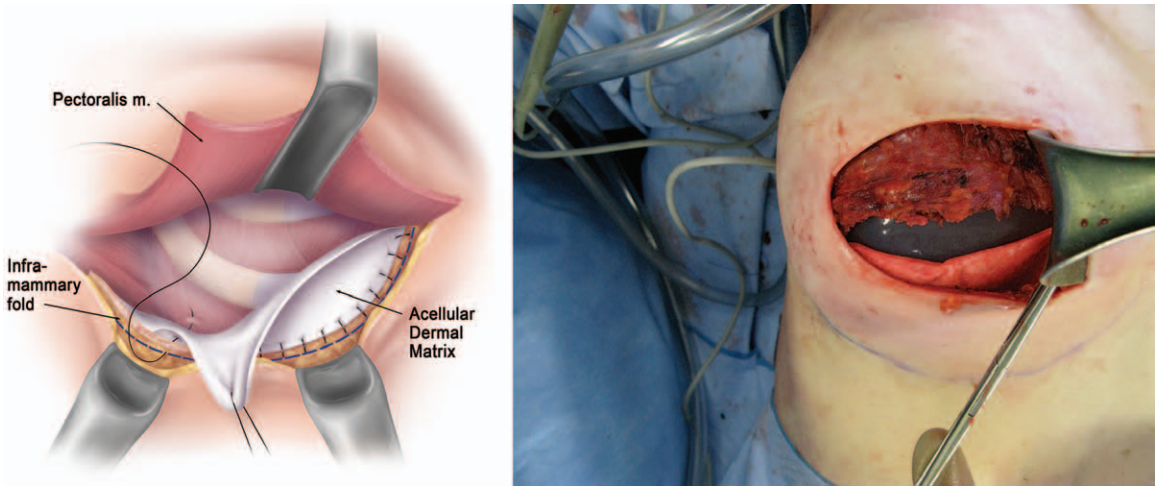


Fig. 8. (*Left*) Illustration of elevated subpectoral pocket and acellular dermal matrix sutured into the inframammary fold. (*Right*) Intraoperative photograph of acellular dermal matrix sutured in place and implant in subpectoral pocket before suturing acellular dermal matrix to inferior border pectoralis muscle.

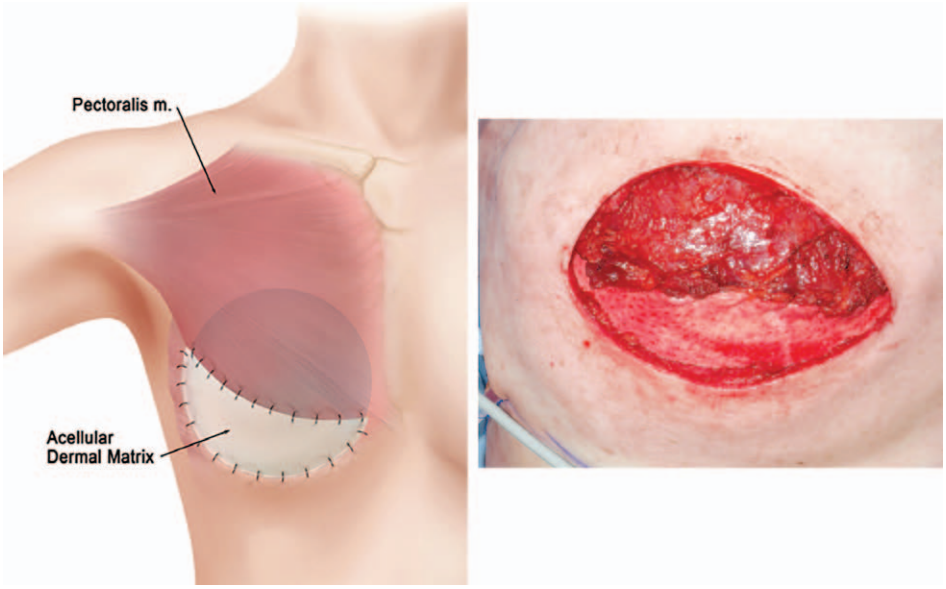


Fig. 9. (*Left*) Schematic of acellular dermal matrix/pectoralis construct over implant. (*Right*) Intraoperative photograph of acellular dermal matrix/pectoralis junction covering the implant.

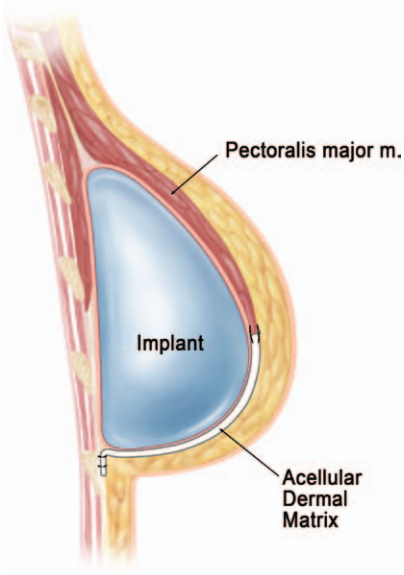


Fig. 10. Lateral diagram of reconstructive model of acellular dermal matrix/pectoralis coverage over the implant.

pertinent in patients with a history of breast cancer, the concern is that adipose-derived stem cells may stimulate remaining cancer cells or conversion of normal breast cells into malignant cells. There are a number of in vitro studies that demonstrate the stimulatory effect that stromal vascular fraction (presumably adipocyte-derived stem cells) have on breast cancer cells.[69] However, in one review, with the exception of intraepithelial neoplasms, the recurrence rate after fat grafting in 2100 patients in 16 clinical trials was 2.2 percent, which compares favorably to recurrence rates reported in the literature of 5.2 to 10.6 percent in patients treated for breast cancer without fat grafting. The recurrence rate for patients with either ductal or lobular intraepithelial neoplasia treated with fat grafting, however, was 18.2 percent, which was statistically significantly higher (Figs. 11 and 12).

In December of 2014, the U.S. Food and Drug Administration published draft guidelines for human tissue derived from adipose tissue, referred to as 21 CFR.[39] According to this publication, adipose tissue must meet the following requirements for clinical use: (1) minimal manipulation; (2) homologous use only; (3) no combination of the cells or tissues with another article, except for water, crystalloids, or a sterilizing, preserving, or storage agent; and (4) adipose tissue cannot have a systemic effect and be dependent on the metabolic activity of living cells for its primary function, unless for autologous use, allogeneic use in a first- degree or second-degree blood relative, or reproductive use.[70] These requirements would suggest that cell-assisted lipotransfer is not approved by the U.S. Food and Drug Administration currently. Furthermore, the joint American Society of Plastic Surgeons/American Society for Aesthetic Plastic Surgery task force on stem cell therapies has recommended that any stem cell–based therapies only be performed under institutional review board approval.[71]

REVISION RECONSTRUCTION

One of the criticisms of nonautologous breast reconstruction is the higher revision rate and associated costs when compared to

Table 4. Fat Graft Processing Techniques

	Time	Cost	Device-Dependent	Comments
Decanting	+	Min	Min	Higher numbers of proinflammatory contaminants that may be harmful to engraftment
Centrifugation	++	+	+	High centrifugation speeds associated with poorer cell viability
Puregraft	++	++	++	High number of viable cells; in vivo outcome unknown
Revolve	++	++	++	Viable cells and low free oil; in vivo outcome difference unclear
Rolling (Telfa*/gauze)	++	Min	Min	Very good viability and graft survival; labor-intensive

Min, minimal.
*Covidien, Mansfield, Mass.

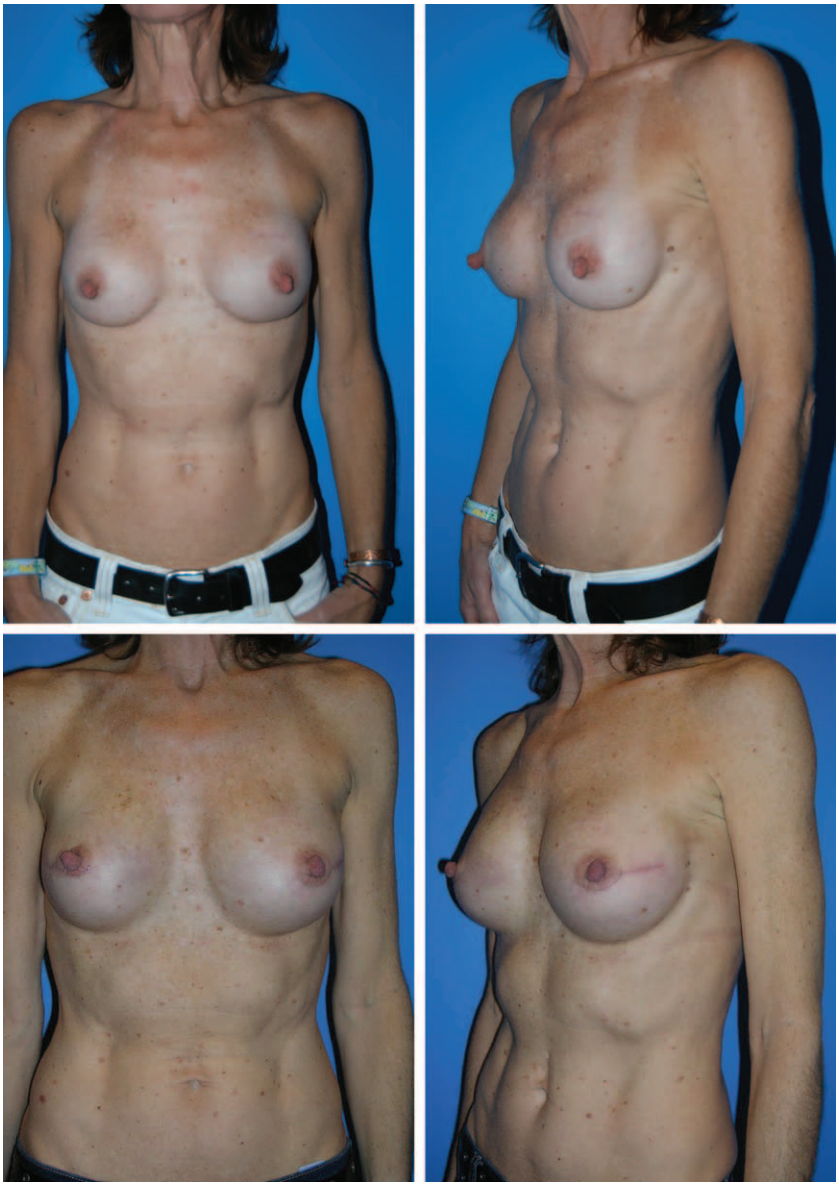


Fig. 11. (*Above, left*) Preoperative anteroposterior view of 52-year-old woman with left ductal carcinoma in situ and previous saline (200 cc) subpectoral saline implants. (*Above, right*) Preoperative oblique view. (*Below, left*) Postoperative anteroposterial bilateral nipple-sparing mastectomies and direct-to-implant reconstruction with acellular dermal matrix and form-stable implants (FX 120 to 360 g). (*Below, right*) Postoperative oblique view.

autologous reconstruction.[72] Review of the Allergan and Mentor Core data reveals overall reoperation rates of up to 71.5 percent at 10 years (Table 5).[73–76] In general, indications for

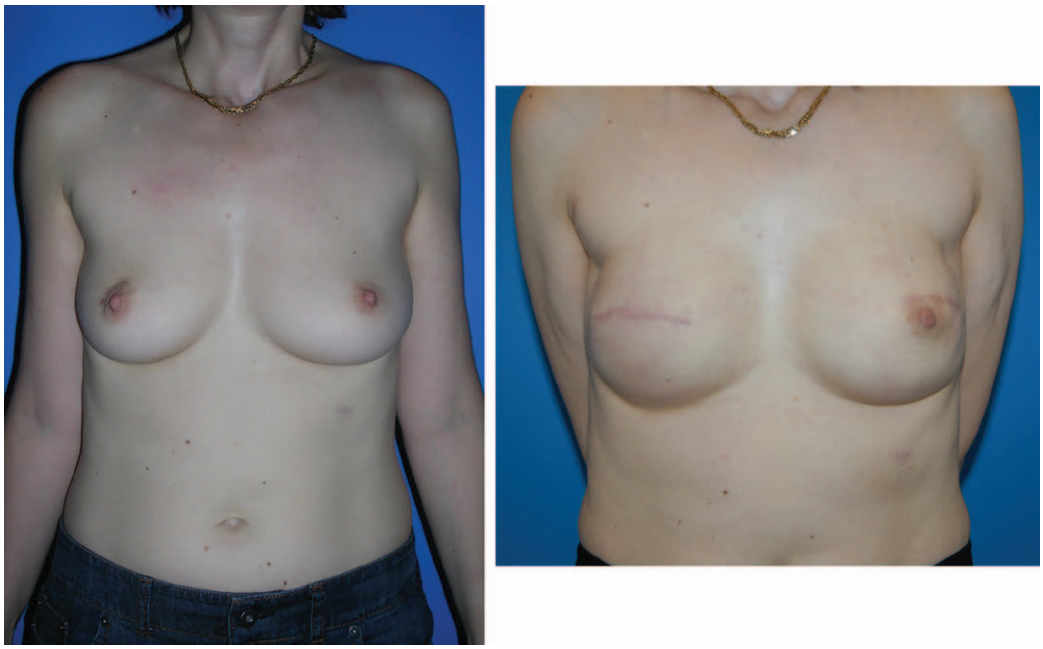


Fig. 12. (*Left*) Preoperative anteroposterior image of a 44-year-old woman with invasive right breast carcinoma. (*Right*) Postoperative anteroposterior image following right skin-sparing mastectomy and left nipple-sparing mastectomy and bilateral direct-to-implant reconstruction Allergan Style 15 371 g implant with acellular dermal matrix.

Table 5. Primary Reconstruction Revision and Complication Rates from Core Studies*

	Mentor CPG, 6 Yr	Allergan 410, 10 Yr	Mentor Smooth, 3 Yr	Allergan Smooth, 10 Yr
Reoperation	44.5	54.6	27	71.5
Baker grade III/IV capsular contracture	10.1	14.5	8.3	24.6
Rippling/wrinkling	4.0	6.2	2.6	10.2
Implant malposition	7.4	5.7	1.7	2.3
Rupture (MRI)	1.5	12.4	0.9	35.5
Asymmetry	10.6	12.4	6.7	23.2

MRI, magnetic resonance imaging.
*Kaplan-Meier estimated risks (%).

revision can be classified into two main categories: implant-related (implant failure or significant rippling), and soft tissue-related (implant malposition and capsular contracture).

Rippling can be addressed in several ways, often using a combination of techniques. Autologous fat grafting can be used to improve the soft-tissue envelope and thickness of mastectomy flaps. Changing to a more cohesive implant can reduce rippling, although this can be at the expense of the softness of the breast. Finally, using acellular dermal matrix, especially for the superomedial aspect of the breast, has been described to improve the coverage of the device.[77,78]

Common implant malpositions include bottoming-out with loss of the inframammary fold delineation, inferolateral displacement, and medial displacement or symmastia. Similar to aesthetic augmentation, submuscular device placement may predispose to lateral displacement, especially with smooth implants. A variety of techniques using capsular flaps have been described to correct implant malposition.[79,80] More recently, acellular dermal matrices have been described for correction of implant malposition, using techniques similar to those used for aesthetic surgery[78] (Fig. 13).

CAPSULAR CONTRACTURE

Capsular contracture represents the most significant long-term complication of implant-based reconstruction. Evidence from aesthetic breast surgery that infection and early hematoma may be largely responsible has translated to reconstruction, and as such, management of encapsulation begins with surgical technique.

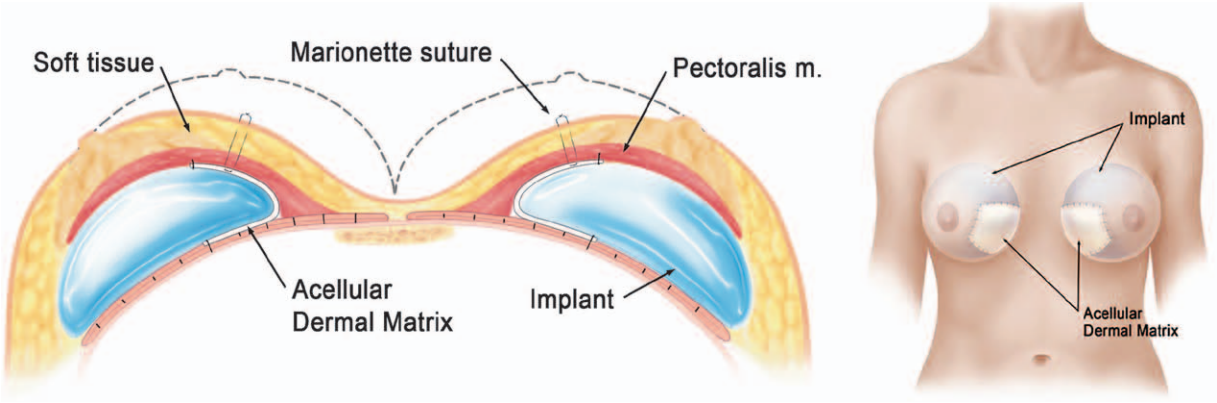


Fig. 13. Illustrations of acellular dermal matrix placed medially in the subpectoral pocket to correct symmastia.

Options for treatment of capsular contracture include implant exchange with capsulotomy or capsulectomy, change of implant type, and change of plane if possible. Recently, acellular dermal matrix has also been used in revision capsular contracture surgery in reconstructive patients and aesthetic patients. Most descriptions involve use of the "reconstructive model," with partial coverage of the implant in the lower pole.[77,81] It is not yet clear whether the acellular dermal matrix simply forms an elastic firebreak in the capsule or inherently inhibits capsule formation at the biocellular level. Cheng et al. recently described a 0 percent recurrence rate of capsular contracture in 11 patients treated with completely wrapping an implant with acellular dermal matrix.[82]

CONCLUSIONS

Alloplastic breast reconstruction accounts for the majority of reconstructions performed in North America, and this trend continues to increase. There are limitations to implant-based reconstruction, particularly related to body habitus and adjuvant radiotherapy. Recent advances including different mastectomy patterns, use of acellular dermal matrices, intraoperative assessment of flap vascularity, and fat grafting have all led to improved outcomes in nonautologous reconstruction. Knowledge of newer techniques and technologies allows plastic surgeons to deliver the best possible results.

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