The Use of Acellular Dermal Matrices in Implant-Based Breast Reconstruction

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Glyn Jones

Implant-based techniques are the most widely used approaches to breast reconstruction of the world today. In the United States alone, they account for six times the number of reconstructions compared with all autologous reconstructive techniques combined. Two-stage expander-implant reconstruction is one of the most widely used forms of breast reconstruction, although single-stage direct-to-implant reconstruction is becoming increasingly popular. Despite the popularity of implant-based techniques, they have been fraught with the problems of capsular contracture, rippling of implants beneath the overlying thin skin envelope, and pseudoptosis of the device as the lower pole skin attenuates with time. Numerous solutions to these issues have been tried often with little success. During the past 14 years, acellular dermal matrices have been increasingly incorporated into implant-based reconstructions and appear to offer a degree of resolution to many of these troublesome issues.

Additionally in recent years, there has been renewed interest in the pre-pectoral approach to breast reconstruction. This has included both two-stage and single-stage reconstructions, and both techniques have relied heavily on the use of ADM for their success. The results achieved with the pre-pectoral approach have been exceptionally good in terms of both form and function.

While autologous techniques remain the gold standard of breast reconstruction, for many surgeons, time constraints, resource allocation, availability of operating time, and decreasing reimbursement have all contributed to the ongoing popularity of prosthetic device-based techniques despite their problems. Many patients are also concerned about the magnitude of some of the autologous approaches, including free tissue transfer, and see implant reconstruction as a quick and relatively easy answer to their reconstructive needs. In the United States in 2015, implant-based reconstruction was performed six times more commonly than all autologous techniques combined.

Surgeons familiar with all of these approaches are only too painfully aware of some of the major negatives associated with implant reconstructions.

Problems with implant-based reconstruction:

- Window shading of the pectoralis muscle release
- Difficulty controlling the expander or implant pocket size and location
- Visible implant ripples
- Visible animation deformity
- Tightness and functional upper extremity limitation
- Postoperative infection
- Inadequate lower pole expansion
- Capsular contracture rates in the long term
- The negative impact of radiation on implant-based reconstruction

At the time of surgery, coverage of the device with pectoralis major provides upper pole cover which can reduce long-term visible rippling of an underlying implant. Unfortunately inferomedial pectoralis major muscle release is complicated by window shade retraction of the muscle in a cephalad direction. Traditionally this has been countered by placing percutaneous sutures to anchor the muscle to the mastectomy skin envelope, an approach complicated by necrosis of marginally vascularized skin. The technique only provides cover to the upper pole, leaving the lower pole devoid of anything but thin skin coverage. Attempts at raising rectus muscle or fascia and the serratus fascia laterally can aid in resolving this dilemma but come at the expense of creating tight banding across the bottom of the reconstruction right where fullness and suppleness are most

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necessary. Having a biologic material to bridge the gap between the caudal edge of pectoralis major and the inframammary crease provides reliable, supple cover which can stretch with time or expansion.

In addition to the dilemma of providing cover, surgeons are faced intraoperatively with the difficulty of maintaining an expander or implant in its exact location within a larger mastectomy pocket than the device requires. Without the ability to control pocket size, particularly laterally, a device can shift or even rotate, creating major problems later. Having a biologic mesh to help shape and control pocket size is a desirable advantage in achieving excellent outcomes, particularly when one-stage direct-to-implant reconstructions are attempted. Tabbed expanders have made a significant difference in this regard, but the use of some form of mesh further enhances the surgeon's ability to control pocket size and shape.

With the acute intraoperative issues dealt with, we face the task of achieving successful expansion with subsequent expander-implant exchange. Isolating a prosthetic device from the mastectomy space could potentially reduce infection and device loss.

Once exchanged for a permanent implant, we encounter the problem of visible rippling and wrinkling of the implant beneath the skin. While cohesive gel implants have reduced this issue substantially, it remains a cause for concern. Any biologic material that places more thickness between the skin and the implant can only serve to improve this troublesome problem and enhance esthetic outcomes.

Another significant issue encountered following implant reconstruction in the subpectoral plane is that of animation deformity. It can be found in almost all patients having a subpectoral implant-based reconstruction. Patients find this condition troubling, and its association with decreased pectoral muscle thickness and reduction in pectoral muscle power combines to make this a very distressing problem impacting patients' lives on a daily basis. The use of a prepectoral approach to breast reconstruction has almost eliminated these two issues.

Probably the most troubling complication of all remains that of capsular contracture.

With all of these complications in mind, acellular dermal matrices have become a useful and simple adjunct to our surgical armamentarium, providing significant improvement in clinical outcomes. The last 15 years have seen a dramatic increase in the number of patients receiving postoperative radiation as radiation criteria have expanded to include earlier forms of breast cancer. Radiation exerts a negative influence on implant reconstruction by tightening the overlying skin envelope and increasing the incidence of capsular contracture, resulting in deteriorating symmetry and increasing deformity with time. Acellular dermal matrices appear to be a valuable adjunct to improving the outcomes of implant-based reconstruction.

In addition, the author has moved from two-stage expander-based subpectoral reconstruction to single-stage direct implant pre-pectoral reconstruction, which is greatly facilitated by the use of ADMs.

In the past 14 years, numerous biologic materials have been introduced for use in reconstructive breast surgical procedures. Theoretically biologically derived materials should allow a surgeon to achieve a better, more natural clinical outcome than by using synthetic materials. However, along with the many choices in biologic materials available to plastic surgeons comes very little published data on most of these materials and considerable confusion as to the differences between them. Surgeons must be equipped with a fundamental understanding of these materials and how they work so they can make educated choices when developing a reconstructive strategy.

38.1 Currently Available Biologic Materials

Numerous allogeneic and xenogeneic tissue scaffolds have been introduced commercially, and a table indicating the nature and source of some of the most widely marketed is shown in Table 38.1.

The goal of using regenerative tissue matrices in reconstructive surgery is to establish an environment that enables the patient to "regenerate" tissue other than scar or foreign-body capsule that mimics the autologous tissue and allows the surgeon to achieve an excellent outcome with durable esthetics and function.

38.2 Biologic Matrix Applications in Breast Reconstruction

Reconstructive options for using biologic matrices in breast reconstruction include the following:

- Implant reconstruction
- Expander reconstruction

Table 38.1 Biologic materials available for breast reconstruction

Name	Company	Source tissue	Alpha-gal removed
DermaMatrix	MTF (Synthes)	Human dermis	N/A
Flex HD	MTF (Ethicon)	Human dermis	N/A
Neoform/ AlloMax	Tutogen (Mentor)	Human dermis	N/A
AlloDerm	LifeCell	Human dermis	N/A
Strattice/Artia	LifeCell	Porcine dermis	Yes
SurgiMend	TEI Biosciences	Fetal bovine dermis	No
Veritas	Synovis	Bovine pericardium	No

- Augmentation of the reconstructed nipple
- Abdominal wall reinforcement
- Reducing capsular contracture after radiation therapy

The aim of this chapter is to discuss the use of ADM in expander-implant reconstructions.

38.2.1 Subpectoral Implant Reconstruction

Patients undergoing skin-sparing mastectomy for breast cancer may be candidates for either immediate implant or expander insertion. Direct-to-implant insertion is becoming an increasingly attractive proposition as methods to assess skin viability become more available. Prerequisites for successful direct-to-implant insertion include a well-vascularized skin envelope and adequate skin surface area. The use of indocyanine green-based fluorescence imaging has revolutionized our ability to assess skin vascularity at the time of mastectomy. If the skin envelope is viable, an implant of similar size to the original breast volume may be inserted without fear of postoperative necrosis. Unfortunately, such implant placement requires accuracy of implant positioning and maintenance of that position if the esthetic outcome is to be acceptable to both patient and surgeon. The mastectomy pocket is, by definition, larger than the space occupied by the implant. The tendency for the implant is to fall laterally and inferiorly as well as to slide out from beneath the pectoralis major into a subcutaneous plane. To correct both of these issues, a sheet of acellular dermal matrix can be used to reduce both pectoralis major window shading and controlling the implant pocket dimensions and location. The larger the implant and the greater the degree of ptosis required, the larger this sheet of matrix should be. My personal preference for a sheet 8 × 16 cm in size for most subpectoral is expander reconstructions, while an additional 6 × 16 cm sheet may be necessary for large (700–800 cc) implant reconstructions. In addition, the surgeon can use AlloDerm as a lower pole reinforcement to reduce both lower pole implant rippling and long-term capsular contracture.

38.2.1.1 Operative Technique

The perfusion and viability of the mastectomy skin envelope should be carefully assessed prior to committing to a direct-to-implant approach. It is the author's preference to use indocyanine green laser fluorescence for this assessment as it is quick, easy, and exceptionally accurate. The inferolateral border of pectoralis major is grasped with Alice tissue forceps (Fig. 38.1), and the subpectoral plane is entered (Fig. 38.2). Pectoralis major is released from 6 to 3 o'clock on the right and 6 to 9 o'clock on the left (Fig. 38.2a) producing a release that gives rise to the window shade effect of the muscle. A sheet of AlloDerm or

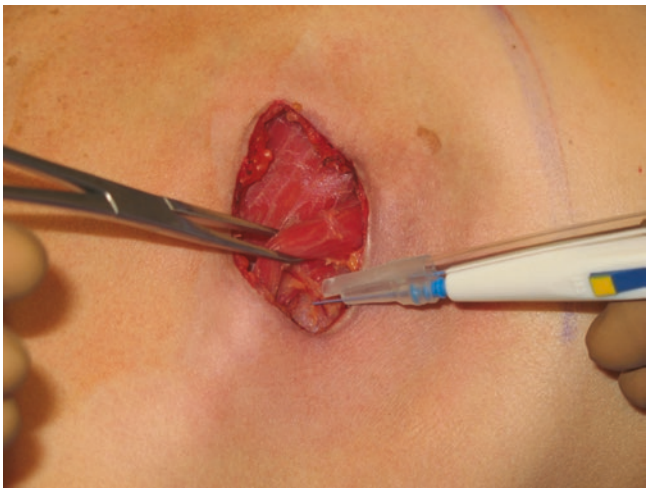

Fig. 38.1 The inferolateral border of pectoralis major is elevated with cautery

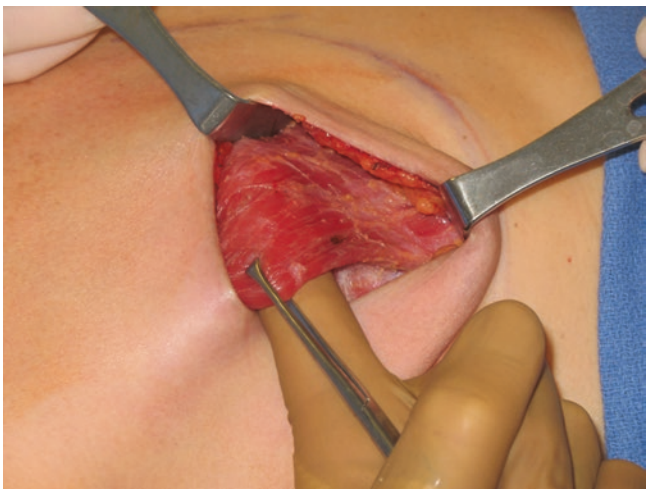

Fig. 38.2 The subpectoral plane is elevated

Strattice (LifeCell Corp., Branchburg, New Jersey) is washed for 2 min in saline to rinse off preservatives (Fig. 38.3). The superomedial corner of the matrix is sutured to the inferomedial cut edge of the pectoralis major muscle with running 2-0 polydioxanone suture (Fig. 38.4). The suture is run along the medial breast border (Fig. 38.5) and then across the curve of the inframammary crease and can be sutured to a raised cuff of serratus anterior fascia laterally which provides additional domain for an implant if required. This creates an inferior sling of AlloDerm into which an implant or expander can be placed (Fig. 38.6). The device is placed beneath the AlloDerm inferiorly and the Strattice superiorly, following which the caudal edge of pectoralis major is sewn to the cephalad edge of the AlloDerm with running 2-0 PDS suture (Fig. 38.7). This creates complete coverage of the implant with the mesh. It is essential that a drain be placed

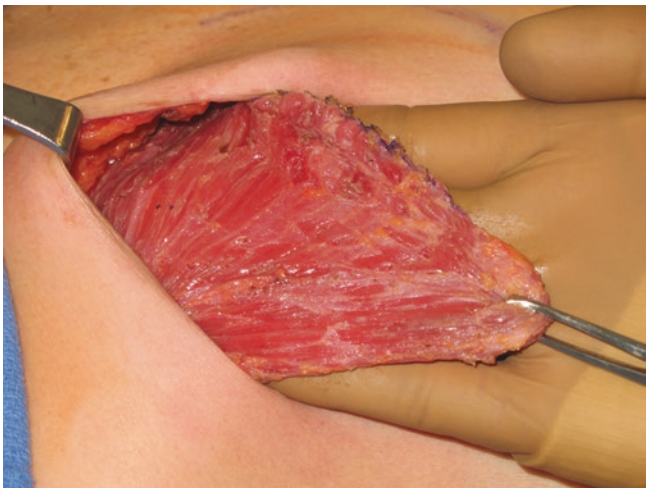

Fig. 38.3 The pectoralis major muscle is elevated after incising the origin inferomedially

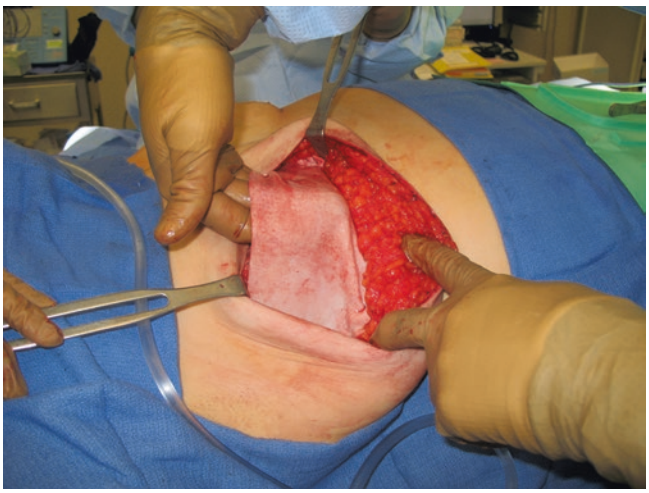

Fig. 38.6 The completed sling is shown

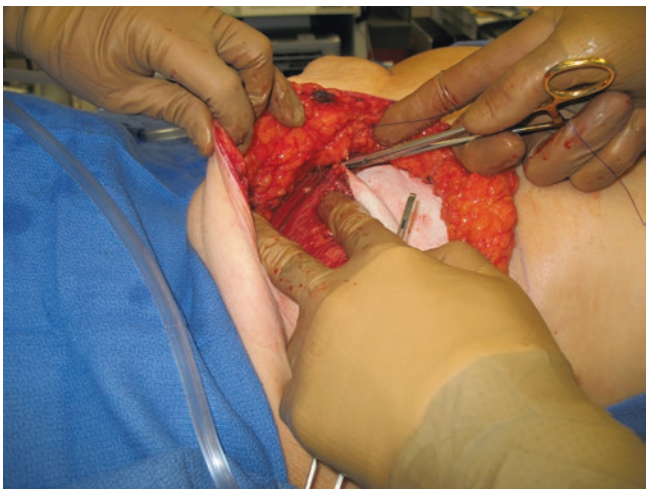

Fig. 38.4 The sheet of acellular dermal matrix is sutured to the cut origin of pectoralis major medially

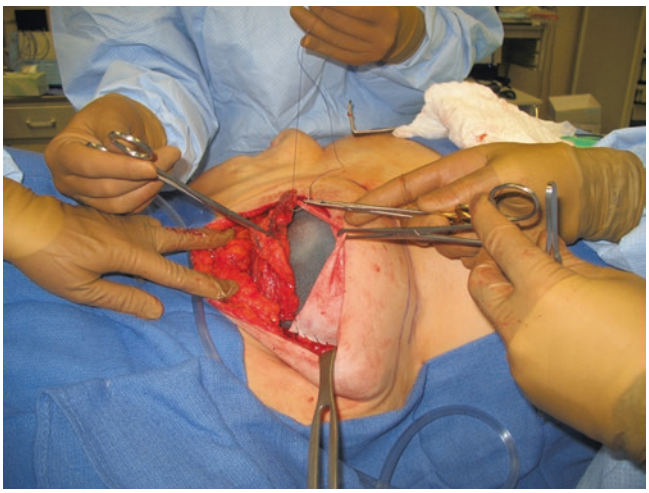

Fig. 38.7 The prosthetic device (expander or implant) is placed beneath the acellular dermal matrix inferiorly, and the matrix is sutured to the caudal border of pectoralis major muscle superiorly

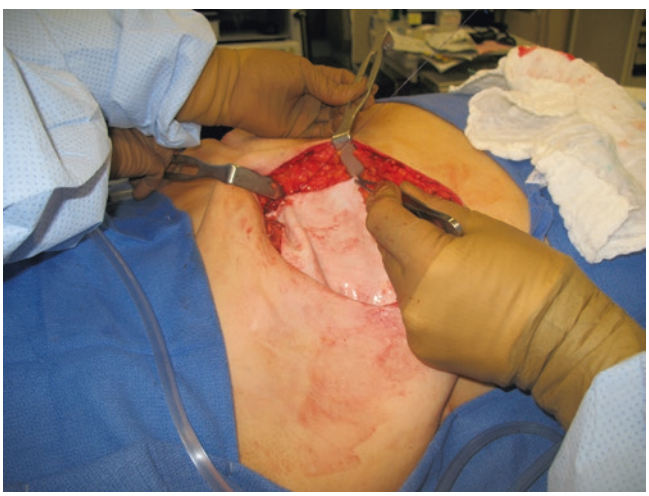

Fig. 38.5 Suturing is continued inferiorly along the inframammary crease and laterally to serratus anterior fascia to complete the creation of an inferior sling of acellular dermal matrix

between the AlloDerm and the overlying skin in order to minimize seroma formation which could inhibit contact between the mesh and the skin, thereby reducing vascular ingrowth and incorporation. The skin is then closed with absorbable subcutaneous and subcuticular sutures in a two-layer closure sealed with cyanoacrylate cement, Steri-Strips, and an occlusive waterproof dressing such as Tegaderm (Fig. 38.8).

38.2.1.2 Direct-to-Implant Reconstruction

This 55-year-old woman with cancer of the left breast and cancer phobia requested bilateral mastectomies with immediate implant reconstruction. She was a nonsmoker and had well-perfused skin flaps. AlloDerm was placed in the lower poles of both breasts, and high-profile 650 cc gel implants were placed subpectorally. She is shown 9 months after nipple reconstruction; the result is soft and stable, with good symmetry (Fig. 38.9).

38.2.2 Expander Reconstruction

Tissue expander insertion after mastectomy is subject to the potential problems of poor lower pole coverage, expander migration, and capsular contracture. The use of ADM provides thicker lower pole coverage and support and may reduce capsular contracture. In addition, the complete coverage of an expander by the muscle and ADM compartmentalizes the device from a potentially more contaminated mastectomy pocket. This may reduce acute infection rates associated with expanders and could increase expander salvage in the presence of cellulitis of the mastectomy skin postoperatively. The technique of insertion is identical to that used with implant insertion. The expander should be inflated to the maximum intraoperative volume permissible that would allow adequate skin perfusion as it is preferable to have the matrix compressed up against the overlying mastectomy skin to encourage vascular ingrowth into the matrix as rapidly as possible. Drain insertion is mandatory to prevent seroma formation between the matrix and the skin (Fig. 38.10).

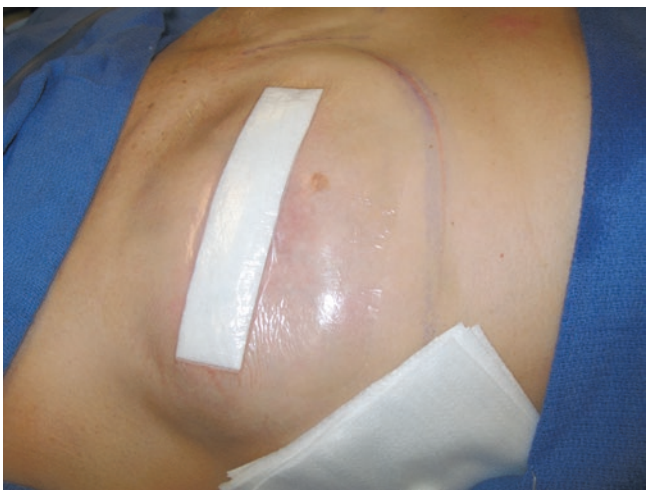

Fig. 38.8 The completed closure with dressings applied

38.2.3 Pre-pectoral Direct-to-Implant Reconstruction

This technique has become my procedure choice for almost all implant-based breast reconstruction at this time. I no longer perform expander-implant two-stage reconstruction unless the patient has a dramatic lack of skin availability at the initial operation or if delayed reconstruction is planned. In the immediate sitting, the only time I will perform a subpectoral implant-based direct implant reconstruction arises in the situation of a patient with an extremely close posterior tumor margin which threatens invasion of the pectoralis major muscle. Under such circumstances, traditional subpectoral reconstruction can be performed so as to allow the anterior border of the pectoralis major muscle to lie immediately beneath the skin flap for long-term tumor recurrence monitoring.

For all other clinical scenarios, I use pre-pectoral implant placement in a direct-to-implant fashion. This technique has revolutionized my breast reconstruction results, creating much more natural breast contours as well as reducing the need for fat grafting and almost completely eliminating the problem of animation deformity. Postoperative recovery is much more comfortable given that the pectoralis major muscle does not have to be divided at any point and our motion at the shoulder is regained much more rapidly. There is absolutely no negative impact on upper extremity power.

38.2.3.1 Operative Technique

Once the mastectomy has been completed, skin viability is assessed with ICG perfusion techniques. This is invaluable

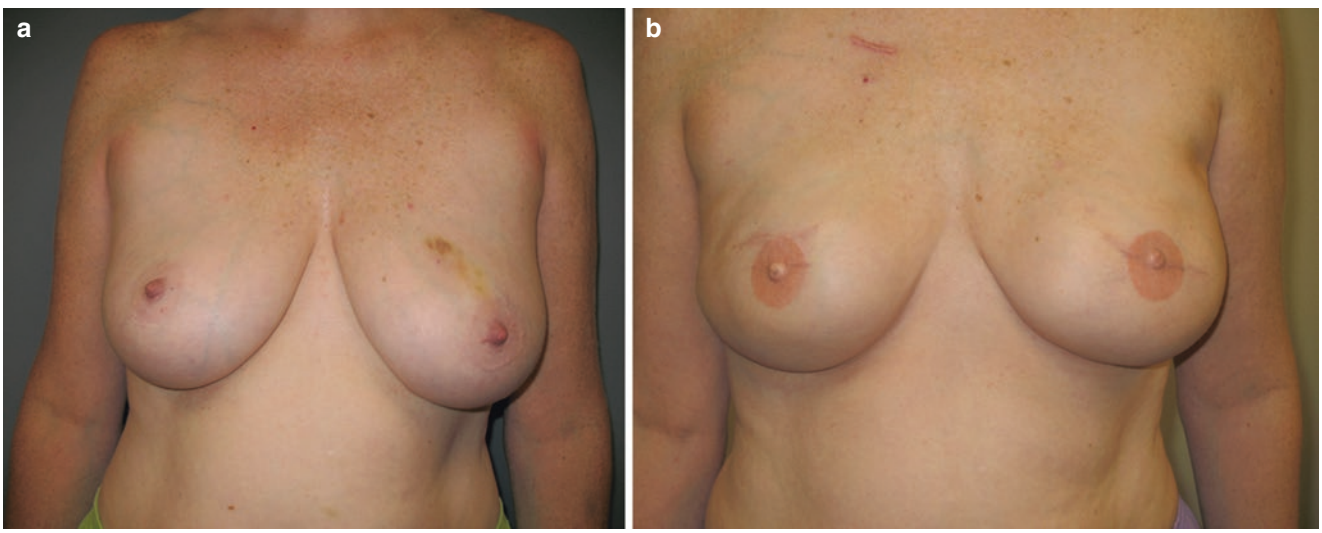

Fig. 38.9 Pre and post operatory view 55y bilateral mastectomy with immediate implant reconstruction associate with AlloDerm placed in the lower poles of both breasts

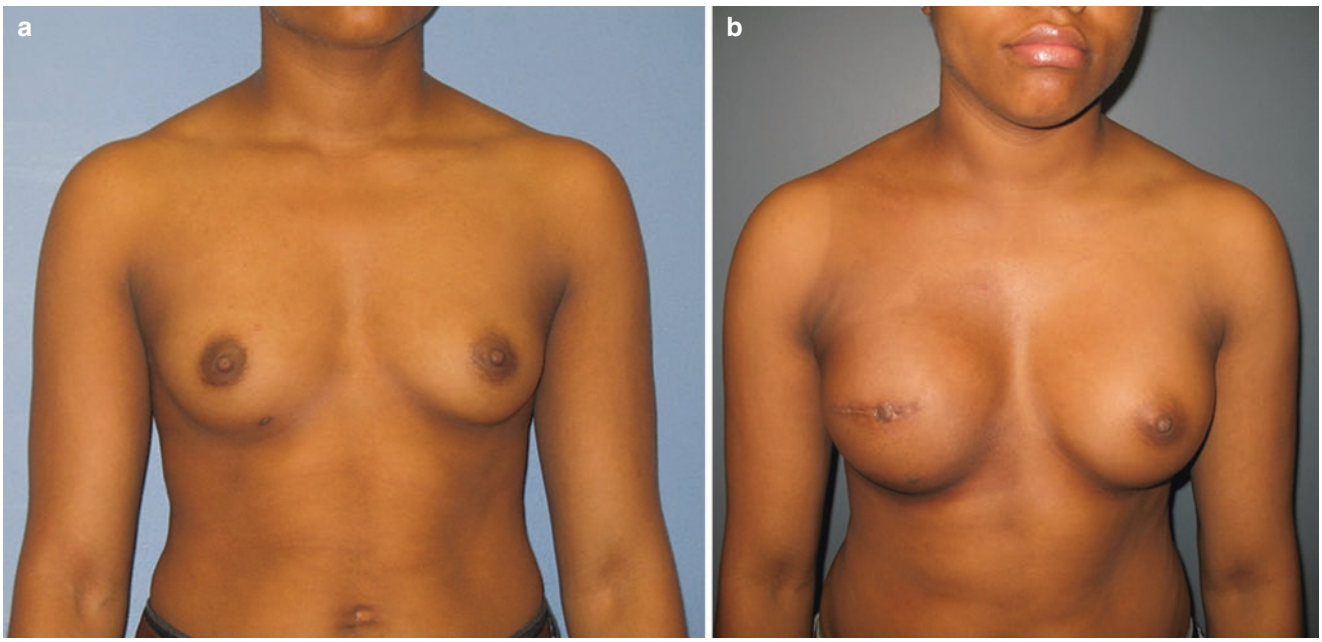

Fig. 38.10 This patient underwent expander insertion after right mastectomy for breast cancer. She had an implant exchange followed by radiation therapy and nipple reconstruction. No tattoo was performed. She is shown 1 year after treatment (**a**) Her breast remains soft and symmetry (**b**), with excellent shape and maintenance of symmetry despite radiation therapy

for determining whether or not the overlying mastectomy skin envelope will be able to tolerate the volume of the reconstruction without impacting skin viability negatively. I will typically insert a temporary breast size based on the mastectomy volume and staple the skin closed over the device. ICG perfusion is then performed, and if the skin appears healthy and well perfused, I proceed with direct implant reconstruction.

A sheet of 16 × 20 cm ADM (AlloDerm, Strattice, or Artia—LifeCell Corp., Branchburg, NJ) is rinsed for 2 min to remove any preservative solution. The material can be perforated with a 3 mm dermatology punch unless the pre-perforated version is available. Once washed, I cut off the upper edges of the ADM to create a teardrop-shaped sheet of matrix which will aid in reducing the risk of implant rotation in the long term. Using this approach I have seen only 1 implant rotation in over 150 patients operated on using pre-pectoral techniques.

The ADM is then placed into the pre-pectoral pocket and suited to the anterior aspect of the pectoralis major muscle using 2-0 PDS. Suturing is performed from 12 to 7 o'clock and 12–5 o'clock, leaving an inferior access window open for implant insertion. Next, the implant pocket is copiously localized with a liter of irrigation. I always start with a 50–50 dilution of Betadine solution, followed by a triple antibiotic solution containing 1 g of cefazolin, 80 mg of gentamicin, and 50,000 units of bacitracin. I have added Betadine wash in recent months based on discussions with Clemens at MD Anderson Cancer Center, regarding the potential for development of breast implant-associated anaplastic large-cell lymphoma. While there is no certainty regarding the etiology of this extremely rare condition, there is some data suggesting that an association with bacterial contamination from *Ralstonia pickettii* may be an inducing agent. This organism is sensitive to Betadine but not chlorhexidine and can be further reduced by treating the patient with doxycycline postoperatively. It is now my preference to use doxycycline as my preferred postoperative antibiotic.

Having selected the appropriate implant size, I change my gloves, and I am the only person on the operative team to handle the implant. I always insert the device using a Keller Funnel, which allows for no contact with the skin insertion technique. The implant is carefully oriented within the pre-pectoral space. The ADM is then pulled taut over the surface of the implant and is sutured to the inframammary crease with the remaining tails of running 2-0 PDS.

A 15 French fully fluted round hubless channel drain is inserted between the skin and the ADM. If the mastectomy is particularly large, or an axillary dissection has been performed, I insert a second drain to this area (Figs. 38.11 and 38.12).

38.2.4 Augmentation of the Reconstructed Nipple

Nipple reconstructions undergo a degree of atrophy over time. Nipples reconstructed from expanded mastectomy skin are most prone to this phenomenon because of the thin dermis

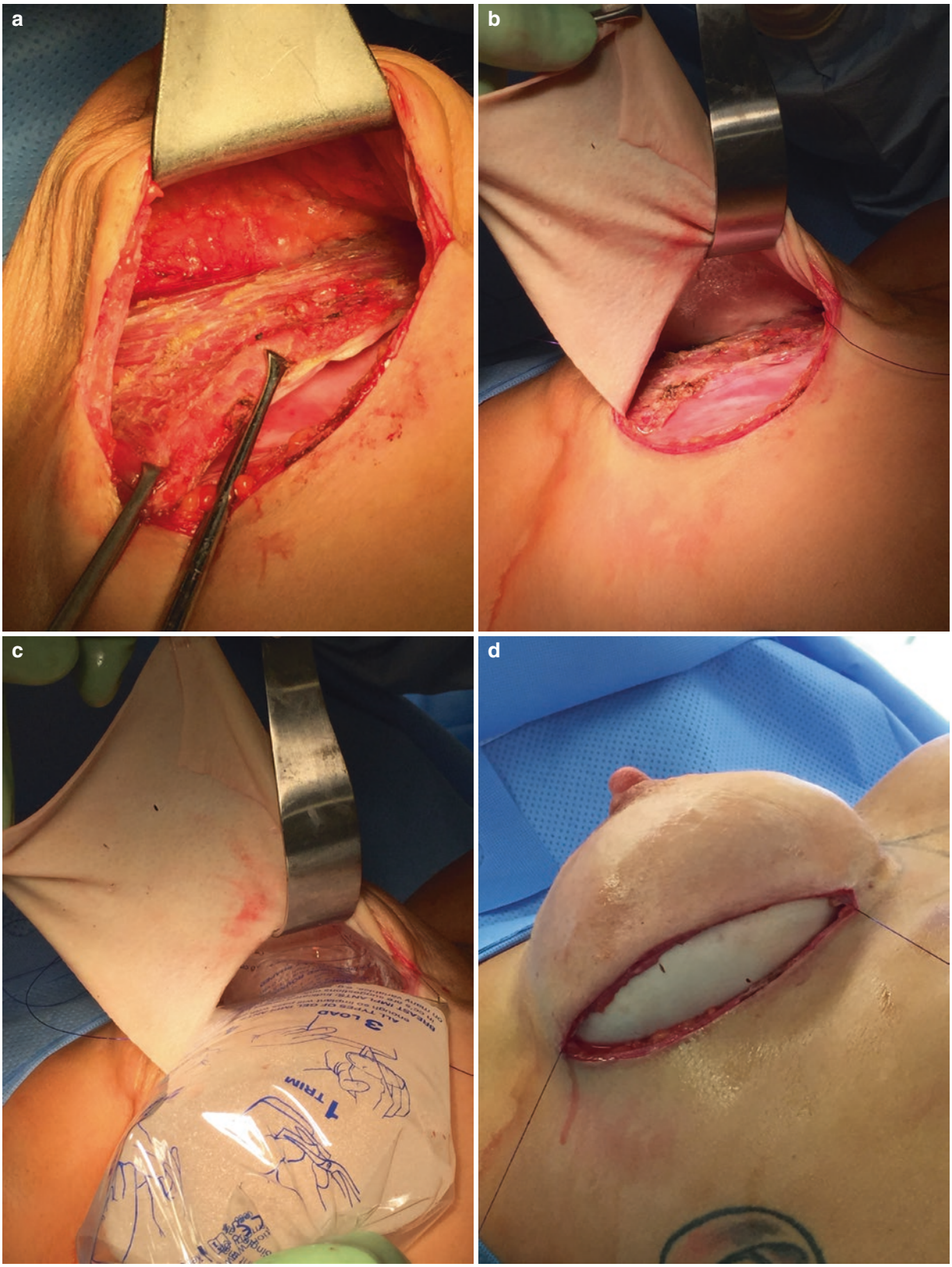

Fig. 38.11 (**a**) The pre-pectoral pocket showing the skin elevated on the retractor and the pectoralis major muscle held in Allis tissue clamps. (**b**) The ADM sutured from 12 to 7 o'clock and 12–5 o'clock with running 2-0 PDS sutures, showing the ADM elevated with the skin flap and the pectoralis major muscle below. (**c**) The anatomic textured cohesive gel implant being inserted using a Keller Funnel, ensuring no contact between the implant and the skin. (**d**) The ADM draped over the lower pole of the implant and sutured to the inframammary crease with the remaining tails of 2-0 PDS

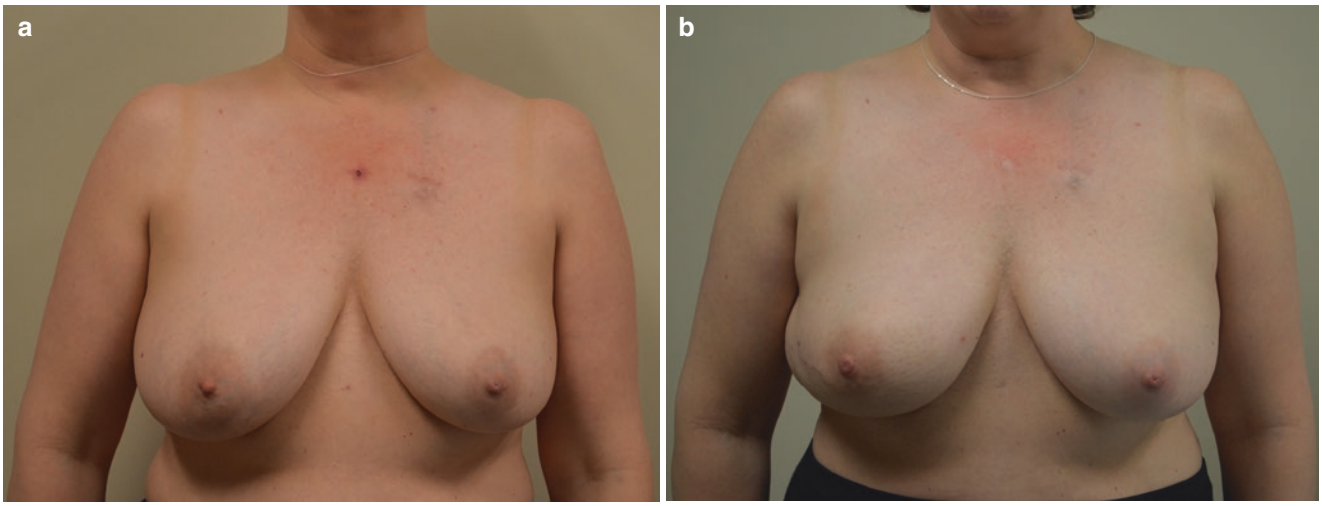

Fig. 38.12 (**a**) Preoperative view of patient with right breast carcinoma. (**b**) Same patient shown 1 year after right immediate single-stage pre-pectoral direct-to-implant reconstruction with ADM coverage over a cohesive gel anatomic implant. No symmetry surgery has been required for the contralateral normal breast

present in breast skin and the lack of subcutaneous tissue following skin-sparing mastectomy. Several techniques have been used as possible solutions to this problem. These include staged autologous fat injection before elevation of the nipple-skin flaps, implantation of additional autologous dermal grafts, or the use of commercially available ADMs. The latter technique obviates the need for a donor site.

Nahabedian and others have described the use of AlloDerm in secondary nipple reconstruction using C-V flaps, with satisfactory maintenance of projection over time. Although histologic evaluation of mature AlloDerm in the nipple has not been reported, Silverman conducted an animal study analyzing the cell repopulation and vascularization of AlloDerm sutured into a roll and implanted within a subcutaneous flap in rabbits. Results demonstrated revascularization of all layers of the matrix, with maintenance of projection.

38.2.4.1 Data Regarding Capsular Contracture in Non-radiated Patients

While numerous ADMs exist on the market today, many of them are products formerly used with varying degrees of success or failure in the hernia market, and few have undergone rigorous pre-market testing and clinical trials in breast surgery. Currently the most widely tested and used products are AlloDerm and Strattice, both developed and marketed by the LifeCell Corporation. This chapter is not intended to be an endorsement of any product or company but reflects the author's experience with this particular product series as well as the fact that the literature is replete with hundreds of articles on the successful use of AlloDerm and Strattice in breast reconstruction, while there are few if any papers attesting to the long-term success of most of the other products. This data may, however, be forthcoming in the future, and comparisons will be interesting to observe.

Experience with AlloDerm in breast reconstruction goes back approximately 14 years. Capsular contracture data is steadily emerging, and more and more papers are attesting to the fact that ADM incorporation in immediate or delayed breast reconstruction appears to be associated with significant decreases in capsular contracture. Breuing reported a zero contracture rate at 3 years in non-radiated breast in a series of 97 immediate and 4 delayed reconstructions with either implants or expanders, while Salzburg has reported 0.5% contracture rates at 14 years for subpectoral direct-to-implant reconstruction. Most recently Sigalove and Maxwell reported 0% contracture in a multicenter series of over 300 patients treated with two-stage expander-implant pre-pectoral reconstruction.

Although data to support this contention are still emerging, we are beginning to see an encouraging trend in this direction. Research in my own subpectoral patient population has demonstrated grades II–III capsular contracture occurring in 22 of 79 breasts treated without ADM but only grade II contracture in 14 of 109 patients treated with ADM, the remainder being grade I. Infection rates between the two groups were similar, but expander salvage was significantly higher in the ADM-treated patients than in those without ADM insertion. In our immediate pre-pectoral series of 70 direct-to-implant reconstructions, capsular contracture at 2.5 years has been 0% in non-irradiated breasts with a 3% periprosthetic infection rate requiring explantation.

Jansen reviewed the recent literature and found a spread of capsular contracture rates of 0–8% with AlloDerm usage,

all of which were well below reported averages for non-AlloDerm-based capsular contracture rates historically. Basu et al. demonstrated a highly statistically significant difference in capsular structure histologically between conventional fibrous capsules and the more elastic AlloDerm-based capsules seen with ADM usage resulting in more supple, soft clinical outcomes. In our own experience, we have seen a reduction in capsular contracture based on AlloDerm usage when compared with our historic controls of non-AlloDerm patients.

Capsular contracture grade	No AlloDerm used (%)	AlloDerm used (%)
I	72	87.1
II	21.5	1.6
III	6.3	0
IV	0	0

38.2.4.2 Data Regarding Reduction of Capsular Contracture After Radiation Therapy

Expander-implant reconstruction in the face of prior or subsequent radiation therapy has been associated with worse clinical outcomes than in the non-radiated patient population. Spear demonstrated dramatically increased complication rates, including capsular contracture, distortion, increased infection rates, and loss of the reconstruction. He reported an 84% complication rate, with 39% of patients requiring conversion to an autologous technique. The incorporation of ADMs into expander-implant reconstruction appears to be helpful in reducing these complications based on 5-year observations in our practice.

The stimulus for their use was triggered by some of the earlier animal studies suggesting that subcutaneous AlloDerm insertion followed by radiation therapy did not appear to adversely affect vascularization, cell density, or graft thickness. In our own early data in patients undergoing adjuvant radiation therapy, only two of eight breasts (25%) treated with ADM developed grade II capsular contracture, whereas six of seven breasts (85%) without ADM developed grade II to III capsular contracture ($p < 0.05$). Of these non-AlloDerm-radiated patients, 14% were grade II, while 71% were grade III capsules, a highly significant difference between the two groups. This trend has been borne out over a 5-year period. We have been so impressed by these sustained outcomes that conversion to autologous reconstruction after radiated implant reconstruction has decreased by at least 50% in our practice. Furthermore, the patients who have maintained an implant-based reconstruction in the face of radiation have maintained at most a grade II capsule without progression to grade III or IV capsules as was so common in the past. The trend has saved both patient morbidity and health-care costs in this important patient subset.

38.2.4.3 Data on Cost Analysis

An additional cause of concern about the use of ADMs in breast reconstruction has been the issue of cost. Jansen et al. reviewed cost outcome analyses of AlloDerm usage based on the Canadian health-care system and found that AlloDerm usage reduced operative times and postoperative complications resulting in less take backs, greater usage of direct-to-implant reconstruction, and less re-operative events for capsular contracture. Based on their estimates, direct-to-implant reconstruction with AlloDerm was particularly cost-effective.

38.2.4.4 Data on Infection Rates

Infection following expander-implant reconstruction is a major cause of postoperative morbidity. This is exacerbated by radiation therapy as evidenced by Spear's data. While user experience and familiarity with the product may affect infection rates, the use of ADMs certainly does not seem to increase infection rates and may even decrease them due to separation of the mastectomy pocket from the implant pocket by both the pectoralis major muscle and the ADM. Nahabedian found that in their series, the use of ADM neither increased nor decreased infection rates in expander-implant reconstruction, a conclusion which is similar to our own experience. In our current series of 70 patients treated with pre-pectoral direct-to-implant reconstruction and 49 patients treated with pre-pectoral conversions for animation deformity, infection rates have been 3% and 0%, respectively.

38.3 Conclusion

Acellular dermal matrices have assumed a pivotal role in the prevention of complications of expander-implant-based breast reconstruction. An increasing body of data from multiple centers confirms this trend. While costly at the outset, the short-, medium-, and long-term benefits of these materials far outweigh the negatives associated with their use, and it is likely that they will become a standard of care in the management of expander-implant-based breast reconstruction in the future.

Pre-pectoral reconstruction as a single-stage immediate direct-to-implant approach has become the author's preferred technique for immediate reconstruction in 95% of implant-based reconstructions. Traditional two-stage expander-implant reconstruction is now reserved only for patients who have too little skin available at the time of mastectomy or who require delayed reconstruction in my practice.

Suggested Reading

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