

Optimizing Safety, Predictability, and Aesthetics in Direct to Implant Immediate Breast Reconstruction: Evolution of Surgical Technique

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Background: Although immediate breast reconstruction with the insertion of a permanent prosthesis rather than a tissue expander (direct to implant [DTI]) has become gradually more preferred and requested by patients, the technique has yet to be fully embraced by most plastic surgeons, presumably due to concerns of patient safety and perceived higher complication and revision rates, despite not being supported by the literature.

Objectives: The authors review the senior author's protocol for patient selection and surgical technique in DTI reconstructions. A simple device is introduced which adds predictability and control in determining the inset suture line for the acellular dermal matrix and thus the position of the inframammary fold and lateral mammary fold, resulting in improved aesthetic outcomes, reduced complications, and reduced reoperation rates.

Methods: A retrospective review of our one surgeon experience with 134 DTI breast reconstructions in 77 patients between 2006 and 2015 is presented. The series is further subdivided into 74 reconstructions in 43 patients in whom their reconstruction was performed before the use of a patented 2-dimensional (2-D) template, and 60 reconstructions in 34 patients in whom the template was used.

Results: The overall complication rate requiring reoperation in the first 54 reconstructions was 50% versus 15% in the last 84. Failure of the reconstruction, defined by explantation, occurred in 11 of 74 reconstructions (14.9%) before the use of 2-D templates, and in 5 of 60 reconstructions (8.3%) in which templates were used, representing a 44% reduction. The revision rate specifically for implant malposition dropped from 18.6% before the use of templates to 2.9% after the incorporation of templates. Fifty-three reconstructions in 33 patients (40%) had no complications and no reoperations, correctly described as "one and done."

Conclusions: Direct to implant reconstruction can be technically more demanding and exacting than 2-stage expander/implant reconstructions. A review of this single surgeon series confirms that despite a learning curve with a higher complication rate early in the series, in the setting of proper patient selection DTI immediate reconstruction is both safe and reliable, and can potentially have clinical, psychological, and aesthetic advantages for patients when compared with a 2-stage expander/implant reconstruction, with 40% of patients having 1 operation only. The use of a patented 2-D template has reduced complications and the rate of reoperation.

Key Words: Immediate single stage breast reconstruction, Direct to implant immediate breast reconstruction, Final implant immediate breast reconstruction, aesthetics in breast reconstruction, safety in immediate breast reconstruction, acellular dermal matrix

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Since the original publication by Salzberg¹ in 2006 introducing the concept of incorporating the use of acellular dermal matrix (ADM) in immediate breast reconstruction allowing for the insertion of a permanent prosthesis rather than a tissue expander, multiple series reporting complication rates have been reported in the literature^{2–4} (Table 1) with differing conclusions as to which is the preferred method, a traditional 2-stage expander/implant versus the insertion of the permanent prosthesis, commonly referred to as "direct to implant" (DTI),^{5–14} often making this a lively controversy within our specialty. Less than 8% of breast reconstructions in 2014 were DTI compared with a 2-stage expander/implant,¹⁵ suggesting that the majority of plastic surgeons still seem to prefer 2-stage expander/implant reconstruction over DTI reconstruction, citing concerns of safety and predictability.¹⁶ Salzberg et al's⁸ complication rate in their 8-year retrospective review has yet to be replicated by other authors yet complication rates in these other series prove to be comparable to or better than expander/implant reconstructions.^{5,6,10–14,16–19}

Complication rates for DTI reported in the literature, including reoperation and complete failure requiring explantation, vary^{20–25} and are summarized in Table 1. Late revisions are most often performed for asymmetry. Of those with asymmetry, the majority of revisions are for malposition necessitating correction of the inframammary fold (IMF) and/or lateral mammary folds (LMF). Despite meticulous attention to preoperative marking and proper surgical planning, it is often challenging to precisely determine the proper inset for the ADM in the operating room, and it has been emphasized by Salzberg et al^{1,8} and other authors subsequently^{9–11} that one of the critical steps in reducing complications including malposition, rotation, seroma formation, and infection, is the creation of a snug subpectoral/ADM pocket for the implant to minimize the risk for movement or rotation.

Creation of the IMF and LMF landmarks when using ADM is determined by the inset of the suture line for the ADM. This suture line, in turn must be determined based on the size of the implant selected for insertion. Because it is virtually impossible to draw an accurate line along the edge of a soft breast implant or gel sizer, a 2-dimensional (2-D) template has been designed to correspond to the circumferential foot print of the implant to be inserted²⁶ (Figs. 1A, B). Once the mastectomy is completed, and proper vascularity of the breast flaps (and the nipple/areola, in the case of nipple sparing mastectomy) have been confirmed, and the decision to proceed with a DTI reconstruction has been made, the templates are then used intraoperatively to precisely mark the IMF and LMF suture lines for the ADM (see Surgical Technique below). Use of the templates has reduced operative time, as well as complications and revision rates, particularly for asymmetry due to malposition (Table 2).

PREOPERATIVE SELECTION

The factors critical in determining whether or not a patient is suitable for DTI reconstruction include a proper history and physical examination, and an understanding from the patient as to what she desires as her final breast size, shape, and feel. In the senior author's experience, the overwhelming majority of patients prefer the DTI option over a 2-stage expander/implant if it can achieve their desired goal. This is also the finding of several other authors.^{8–10,16,18} Preoperative breast size, degree of ptosis, and postoperative desired breast size are critical

TABLE 1. Current Literature Regarding Complications

Publication	Seroma	Hematoma	Skin Necrosis	Infection	Failed Expansion	Late Revision
Tissue Expander/Implant						
Spear et al. 1998	-	1%	8.1%	4.7%	7.0%	
Cordeiro et al. 2006	0.2%	0.4%	2.0%	2.5%	0.1%	
McCarthy et al. 2008	-	-	8.7%	4.9%	0.2%	
Nguyen et al. 2009	-	-	-	8.0%	-	
Colwell et al. 2014	1.7%	1.7%	5.2%	3.3%	-	
Colwell et al. 2015	-	-	-	-	-	19.9%
	Seroma	Hematoma	Skin Necrosis	Infection	Explantation	Late Revision
Direct to Implant						
Salzberg 2006	0%	0%	2.0%	0%	0%	2%
Topol BM et al. 2008	-	-	-	8.6%	8.6%	0%
Colwell et al. 2011	1.5%	1.2%	9.1%	3.0%	1.5%	-
Salzberg et al. 2011	-	1.1%	1.1%	0.2%	1.3%	0.4%*
Susarla et al. 2015	5%	2%	14%	4%	-	32.3%
Colwell et al. 2015	-	-	-	-	-	21%

-; not reported.
*: revision surgery for capsular contracture within 12 months of initial surgery.

determinants of who is a good candidate. In general, patients who wish to be the same size, slightly smaller, or even slightly bigger might be suitable candidates. Patients with grade 0-III ptosis are also potential candidates, because in the moderately ptotic patient, the nipple areola position in nipple sparing mastectomies can be modified and fixated internally with sutures to the pectoralis muscle and/or ADM intraoperatively from the underside of the mastectomy skin flap.

The critical and necessary steps for a successful DTI reconstruction include:

1. Precise preoperative biodimensional analysis;
2. Coordination with a skilled oncologic breast surgeon with a commitment to breast reconstruction;
3. Intraoperative assessment of skin flap perfusion and nipple areolar vascularity following mastectomy; and
4. Control of the subpectoral/ADM implant pocket, including the creation of precise IMF and LMF.

Patients should always be educated to several important facts regarding DTI reconstruction:

1. It may *not* be a “one and done” operation, because revisions might be required, be they for malposition, size modification, contour enhancement with fat grafting, and so on. Instead, it is more

proper to regard DTI as a “skip the expander” procedure. The insertion of a permanent implant does not and should not necessarily imply that this will be their only operation, nor their “final” implant.

2. There is always the possibility that an intraoperative decision will be made to insert a breast implant that is smaller than originally planned, for reasons of skin flap perfusion. Once the reconstruction has matured, should the patient elect to be revised with a larger implant, this can be done electively and more safely at a future date.
3. Similarly, there is also the possibility that an intraoperative decision will be made to insert a tissue expander instead of a permanent prosthesis if it is felt that the skin flap perfusion would not support the insertion of a permanent prosthesis. Again, this would be at the discretion of the plastic surgeon, and the patient should always be made aware of that possibility.

A decision regarding insertion of a smaller implant versus a tissue expander should occur during the preoperative consultation with the patient as to her preference. In the senior author's experience, patients will often articulate a preference for avoiding tissue expanders, even if it means a revision of her reconstruction for a size change at some future date, but it is the senior author's policy to always remind the patient that

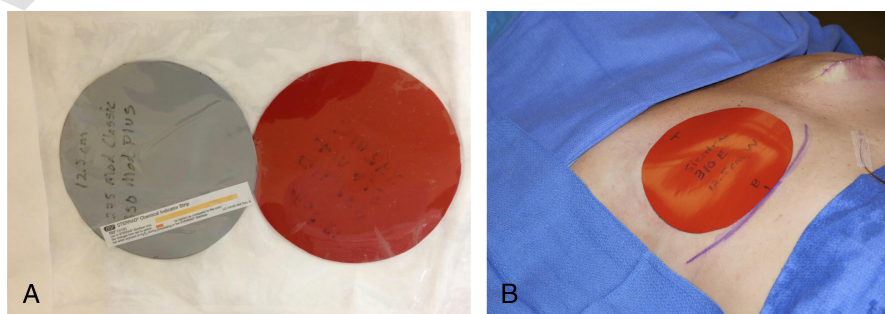


FIGURE 1. A, (above left) Sterile 2-D templates, in their sterile peel pack. B, (above right) Template before insertion into the right mastectomy defect intraoperatively, the left breast reconstruction has been completed.

TABLE 2. DTI Study Series

	All DTI		
	Reconstructions	Pre-Template	Post-Template
No. patients	77	43	34
No. breast reconstructions	134	74	60
Patient age, y			
Range	27–81	30–79	27–81
Average	54.2	54.6	53.9
BMI			
Range	19.4–47.8	19.4–37.3	19.5–47.8
Average	26.0	26.8	25.0
XRT			
Preoperative	13	9	4
Postoperative	8	5	3
Diagnosis (per breast)			
Cancer or DCIS	72	36	36
Prophylactic	62	38	24

the decision to insert an expander rather than a final implant always needs to be considered an option.

SURGICAL TECHNIQUE

Preoperative markings are made with the patient sitting or standing up right. The IMF's are marked bilaterally, along with a vertical mid line from the sternal notch to just below the xyphoid, making note of any asymmetries in the chest wall, IMF, or nipple positions so that this can be accounted for with incision planning for the mastectomy and during the reconstruction. (Fig. 2). The LMF and the palpable perimeter of each breast is also marked. The mastectomy incision is then planned and marked in coordination with the oncologic breast surgeon. If oncologically feasible, either nipple-sparing or skin-sparing incisions should be selected for optimal aesthetic results. Direct to implant reconstruction is achievable via most nipple-sparing and skin-sparing incisions, including inframammary, radial, vertical, or hockey stick ("J" or "L" shaped). We rarely opt for a vertical inverted "T" because this tends to be riskier in the setting of DTI, more so than with an expander reconstruction.

In the case of bilateral mastectomies, the reconstruction is generally performed in the same sequence as the mastectomies, usually with the prophylactic side being completed before the breast in which the cancer is located.

Once the mastectomy is completed, the first step is to transpose the IMF marking on to the chest wall. In the case of IMF asymmetry, the desired IMF marking is made accordingly. Because the

implant selection has been made preoperatively, a sizer is first used to assess skin flap tension in the subcutaneous pocket. If the implant is accepted easily and without tension, a temporary suture is placed, and vascular skin flap perfusion is assessed with intravenous injection of indocyanine green fluorescence angiography using the SPY Elite protocol (Novadaq Technologies, Inc, Mississauga, ON), as previously reported by several authors.^{27–30}

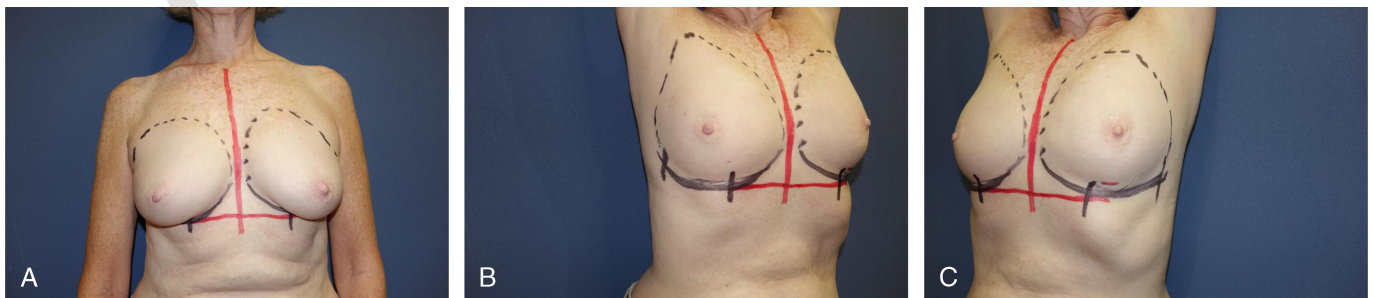
If vascular perfusion is deemed adequate using accepted criteria,^{28,29} the lateral pectoralis major muscle is reflected and a subpectoral cautery dissection performed with the inferior and inferomedial attachments of the pectoralis major (PM) to the ribs and sternum is released. It is critical to elevate the PM sufficiently in a cephalad direction to allow for adequate mobilization and proper redraping and inset of the pectoralis/ADM composite with undue tension once constructed.

A sheet of thick or thick or extra thick ADM is then brought to the field and tailored by trimming the medial and lateral corners converting the rectangular sheet into a contoured shape which will correspond to the desired rounded inferomedial and inferolateral breast contour. A contoured sheet can also be used, with or without fenestrations. In most cases, an 8 × 16 cm rectangular sheet suffices. The ADM is then sutured basal membrane side up to the free border of the PM using 3-0 Vicril on a tapered needle (Ethicon US, LLC, Johnson & Johnson) which is less traumatic to the muscle than a cutting needle. In thin flaps, Vicril™ also tends to be less visible or palpable than PDS™, which can be bothersome to patients before it resorbs. The running suture is not pulled tightly, so as to avoid shearing or strangulation of the muscle. For ease of suturing, usually 2 running sutures are used, one from medially to about the midclavicular line, and the second from the superolateral aspect of the pectoralis major muscle to the midclavicular line where the 2 running suture ends are tied to each other. This essentially creates the familiar pectoralis major/ADM composite which will allow for complete implant coverage once the inset of the ADM at the desired IMF, MMF, and LMF is completed.

At this point, a preoperatively selected prefabricated sterile silicone 2-D template²⁶ corresponding to the exact circumference of the intended implant is brought to the field and used to draw the inset suture line on the chest wall for the ADM (Fig. 3).

Interrupted sutures of 2-0 Vicril on a tapered needle (CT-1 pop-off) are used from the medial border of the ADM to the breast meridian and from the superior lateral edge of the ADM at the axillary tale to the breast meridian. These sutures are left untied and controlled individually with hemostats, which are sequentially held in place on a sponge stick to preserve their sequence and avoid entanglement. Usually, 2 sponge sticks are used, 1 for the medial set of untied sutures and 1 for the lateral set, respectively (Fig. 4).

The preselected sterile implant is then brought to the field, Bacitracin/Gentamycin irrigation solution added to its packet, surgeon's gloves either changed or thoroughly cleansed, and the implant inserted. In the case of a form-stable highly cohesive anatomic-shaped implant, proper orientation is confirmed using the orientation line or

**FIGURE 2.** Preoperative DTI markings.

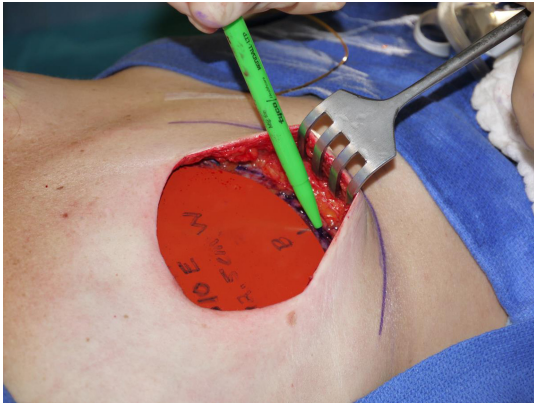


FIGURE 3. Two-dimensional template being used intraoperatively to delineate MMF, IMF, and LMF suture lines for inseting ADM.

bumps, at which point the Vicril sutures are tied, first laterally then centrally and finally medially, until the ADM completely covers the implant (Fig. 5).

At this point, a closed single suction drain is placed and positioned to drain the lateral gutter and axilla, as well as the lower pole of the breast. Occasionally, in larger pockets, a second drain is inserted to adequately drain the medial or superior subcutaneous pocket. The subpectoral space is not routinely drained, and there is therefore no contact between the surgical drain and the breast prosthesis.

Before incision closure, a temporary suture is placed, and the patient is assessed from the foot of the operating table with her back elevated to 90 degrees. Once IMF and implant position symmetry is confirmed, the incisions are closed in 3 layers with interrupted 3-0 Vicril sutures approximating Scarpa fascia, followed by a running dermal suture of 3-0 Monocril on an SH tapered needle, followed by a 3-0 Monocril on a cutting PS-2 needle for intradermal closure, followed by skin adhesive. It is critical to avoid tension in the running suture line to avoid strangulation of the mastectomy skin flaps.

Occlusive dressings with Biopatch are used to dress the drain exit points, and Bacitracin ointment and Tegaderm dressings are used over both breast mounds, creating a sealed occlusive dressing that requires no dressing changes by the patient for at least 4 to 5 days. A noncompressive tube top garment which was worn by the patient and placed around her lower abdomen preoperatively is adjusted upward over the surgical site upon completion of surgery purely for modesty (Figs. 6A, B). To avoid compression and the risk of vascular compromise and skin flap necrosis, a brassiere is never used in the

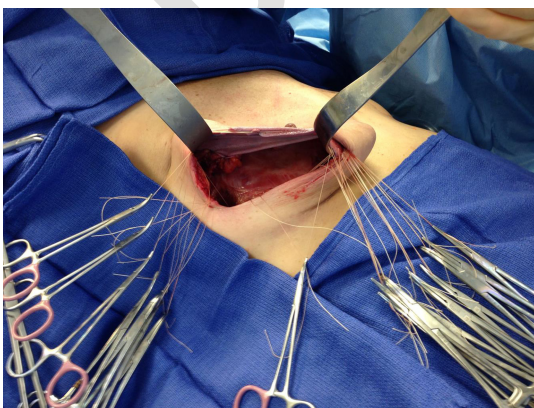


FIGURE 4. Untied Vicril sutures between ADM and chest wall in place along IMF and LMF before insertion of prosthesis.

immediate postoperative setting. The vast majority of DTI patients are observed for 23 hours in the hospital and are discharged on the first postoperative morning.

RESULTS

During the study period between 2006 and 2015, a total of 134 DTI reconstructions in 77 patients were performed by the senior author, along with 143 expander/implant reconstructions in 93 patients during the same period. The demographics of the patients in this retrospective series appear in Table 2. The total number of oncologic surgeons was 13, but the majority of immediate reconstructions were performed in coordination with 3 oncologic breast surgeons.

Forty-three patients underwent 74 breast reconstructions before the use of templates. Thirty-four patients underwent 60 breast reconstructions with the use of templates.

The most common complication was delayed healing at the mastectomy incision site and/or nipple/areola epidermolysis in 38 reconstructions (28.4%) in 28 patients (Table 3). About 33.3% of the complications required early reoperation for delayed wound healing or mastectomy skin flap necrosis. Of the patients with delayed healing who required surgical debridement and/or revision, 31.5% were managed in the office setting. Seroma after drain removal was seen in 24 reconstructions (25.9%) in 20 patients, but we regard this more as a sequela rather than a true complication. All of the patients with recurrent seroma were managed conservatively with aspiration in the office, or occasionally by the radiologist with ultrasound guidance. About 43.6% of the reconstructions had late revisions for aesthetic refinement, either with a change in size, a minor pocket adjustment, or an implant conversion from round to anatomic, or vice versa.

There were no deaths, and 2 rehospitalizations, one of which was in a healthy 36-year-old woman who underwent prophylactic mastectomies for a positive BRCA2 gene mutation who developed a pulmonary embolus on postoperative day 13, but was successfully treated with anticoagulation therapy without sequelae. Interestingly, she was one of the patients who had 1 operation only. The other early rehospitalization was in a patient who underwent bilateral mastectomies and reconstructions for a unilateral cancer, but had significant skin flap necrosis requiring an early conversion to an autologous reconstruction.

The overall failure rate in this series, defined by explantation, was 16 implants of 134 reconstructions (11.9%), but when divided into those who underwent surgery before the introduction of templates versus those in whom templates were used, the explantation rate was 14.9% in the pretemplate group versus 8.3% in the template group, an overall reduction of 44%.

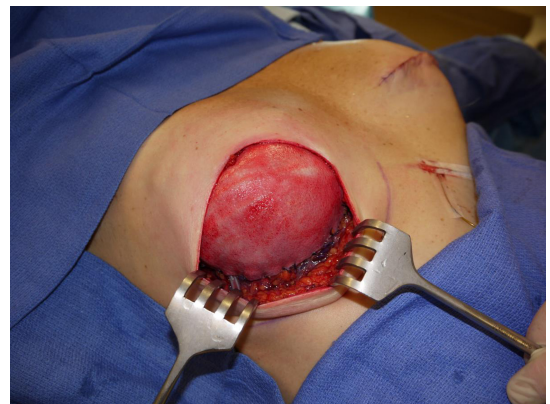


FIGURE 5. IMF and LMF suture line for ADM inset completed along markings predetermined by the 2-D template before final closure.

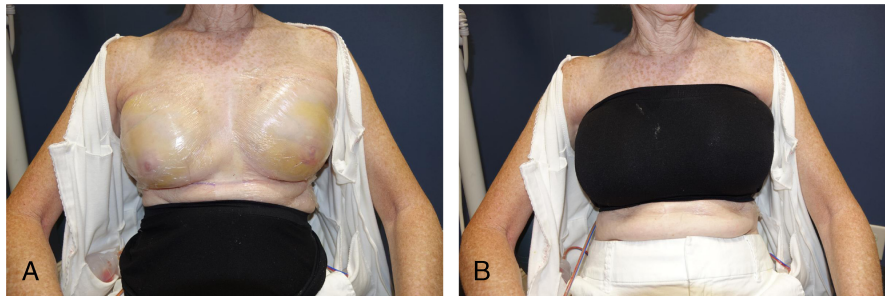


FIGURE 6. A, B, Postoperative occlusive dressing and noncompressive garment.

The overall incidence of reoperation in this series for any reason was 60%. The converse of this is that 53 reconstructions (40%) in 33 patients (27%) had no complications and no reoperations (Figs. 7–9). Of this number, 18 of 43 (41.9%) were in the pretemplate group, and 15 of 34 (44.1%) in the template group.

About 25.4% of reconstructions required reoperation in the operating room setting for delayed healing, but when subdivided into the pretemplate and template group, 73% were in the pretemplate group. Of the 38 patients in the overall series who demonstrated delayed healing, 68% were managed in the operating room. In the patients in whom templates were used, only 7 of 60 (11.6%) required early operative revision for delayed healing versus 19 of 74 in the pretemplate group (25.6%).

DISCUSSION

The overall incidence of reoperation for any reason in this series was 60%. The converse of this is that 53 reconstructions in 33 patients (40%) had no complications and no reoperations, all of whom would have required a de facto second operation wherein they would have been reconstructed in 2 stages with an expander and implant.

Although there was no clear correlation found between the incidence of complications or reconstruction failures with the oncologic breast surgeon performing the mastectomy, it is clear that the quality of the skin flaps and the experience of the breast surgeon with skin- and nipple-sparing mastectomies is a critical determinant of a successful outcome. For example, in the 1 patient in whom a bilateral DTI required early explantation due to skin flap necrosis with conversion to an autologous reconstruction, the oncologic breast surgeon was both senior and experienced, yet it was the first time he had performed a nipple-sparing mastectomy via an inframammary incision. In this case, it was also admittedly the error in judgment of the senior author not to use intraoperative laser angiography to assess the skin

flaps, which would have almost certainly led to a decision to insert an expander rather than a permanent prosthesis.

One recent adjustment we have made in our coordinated surgical protocol with our oncologic surgeons is to rely solely on radionuclide and discourage the use of methylene blue in the identification of sentinel nodes, because the use of methylene blue has been associated with a higher risk of wound skin edge necrosis,^{31–34} and this indeed played a role in our series.

Several factors might explain the disparity in complications reported in the literature (Table 1). These might include differences in surgical technique, type of ADM selected, differences in protocols with regard to the use of drains, and perhaps most importantly, differences in clinical experience; specifically, variability in the experience of the oncologic breast surgeons and the reconstructive plastic surgeons, both individually and as a surgical team. With regard to properly interpreting the literature, the data can be arguably disputed as equally valid if a reported series includes multiple oncologic surgeons and multiple plastic surgeons, all from 1 institution wherein the “institutional experience” is being reported^{5,6,10,17} versus a report by a single team following strict standardized protocols.^{1,8}

Because of the acknowledged probability that revision surgery would be required at some future date, it is important to portray DTI reconstruction to our patients as a technique that bypasses the need for the insertion of a tissue expander, rather than a de facto “single stage” breast reconstruction. It is not, in our view, a merely semantic point to regard revision surgery as another “stage,” and therefore, in the interest of full disclosure, we inform our patients that their DTI reconstruction may or may not be the only operation they require to achieve the final desired outcome.

In our practice, patients tend to be preselected for implant-based reconstructions, as articulated by the patient to their oncologic breast surgeon as their preferred method of reconstruction. Because DTI reconstruction is our preferred method, we find that our patients

TABLE 3. Complications

	Overall	Without Template	With Template	P
Hematoma	0	0	0	—
Seroma	24/134 (17.9%)	10/74 (13.5%)	14/60 (23.3%)	0.14
Infection	3/134 (2.2%)	2/74 (2.7%)	1/60 (1.7%)	0.000002*
DVT/PE	1/77 (1.3%)	0	1/34 (2.9%)	—
Explantation (per breast)	16/134 (11.9%)	11/74 (14.9%)	5/60 (8.3%)	0.25
Malposition (per patient)	9/77 (11.7%)	8/43 (18.6%)	1/34 (2.9%)	0.03*
Delayed healing (per breast)	38/134 (28.4%)	26/74 (35.1%)	12/60 (20%)	0.05*
Return to OR for delayed healing	26/134 (19.4%)	19/74 (25.7%)	7/60 (11.7%)	0.04*
Deaths	0	0	0	—

*Statistically significant by *P* value ≤ 0.05 .

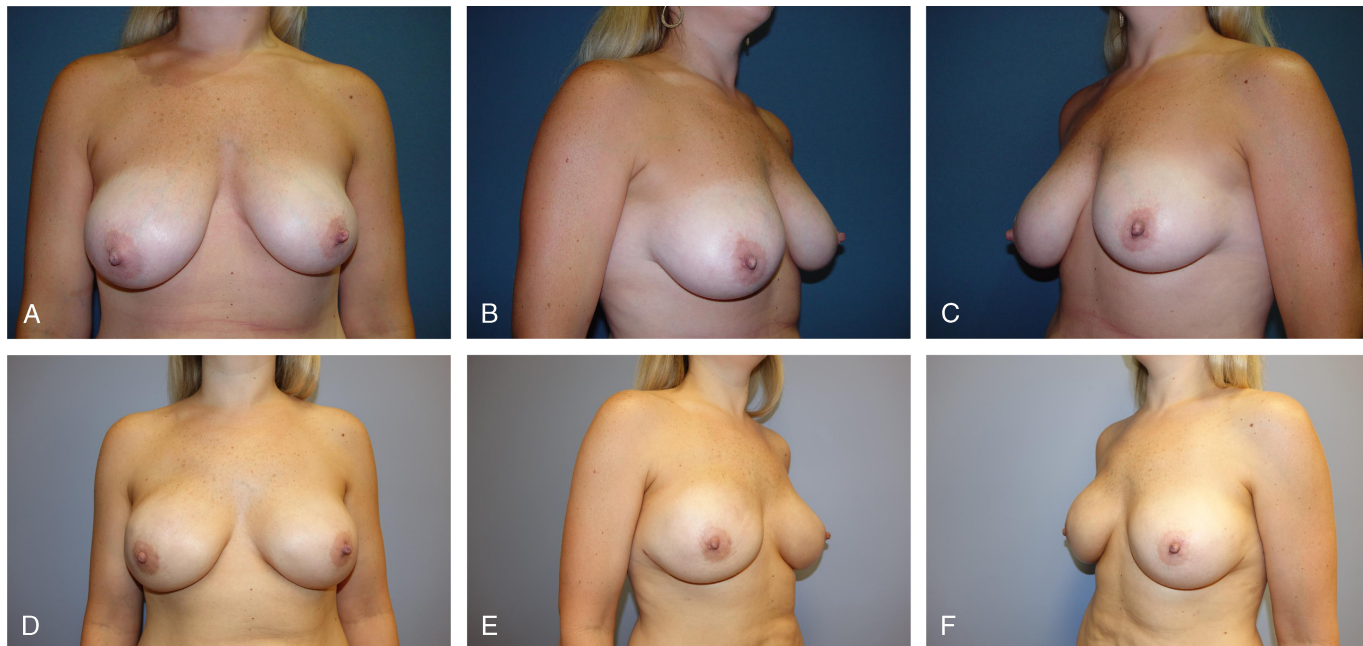


FIGURE 7. This 35 year old mother of two with the BRCA1 gene mutation lost her mother and older sister to breast cancer. She underwent elective bilateral nipple sparing mastectomies and bilateral salpingo-oophorectomies with immediate DTI reconstructions. Two dimensional templates were used in her reconstructions. No revision surgery was performed after her initial surgery. She is seen before, and nine months after her surgery.

are often arriving at their consultation reasonably well informed and hopeful that they are indeed good candidates for DTI reconstruction. Nevertheless, all options are reviewed with the patient, including autologous and implant/expander-based techniques. The patients most suitable for DTI reconstruction can range from A cup to D cup, with up to grade III ptosis, and those who wish to remain about the same

breast size postoperatively, slightly smaller, or slightly larger. Those with grade IV ptosis or breast hypertrophy with or without a diagnosis of invasive cancer can be more challenging for DTI reconstruction and might be better served with a first stage mastopexy or reduction mammoplasty, followed no sooner than 6 weeks later with a skin- and nipple-sparing mastectomy. Those who want to be significantly larger

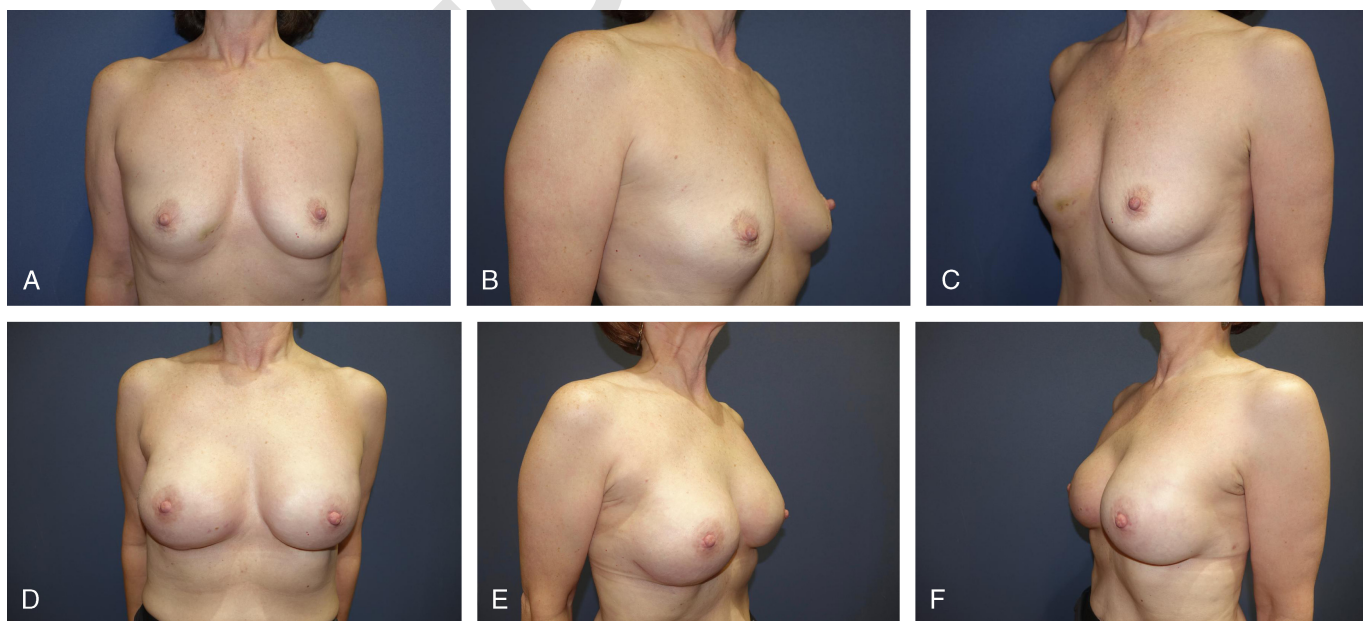


FIGURE 8. This 59 year old woman with invasive intraductal carcinoma in the right breast and DCIS in the left breast underwent bilateral nipple sparing mastectomies and immediate DTI reconstructions. Two dimensional templates were used in her reconstructions. No revision surgery was performed after her original mastectomies and reconstruction. She is seen before, and six months after her surgery.

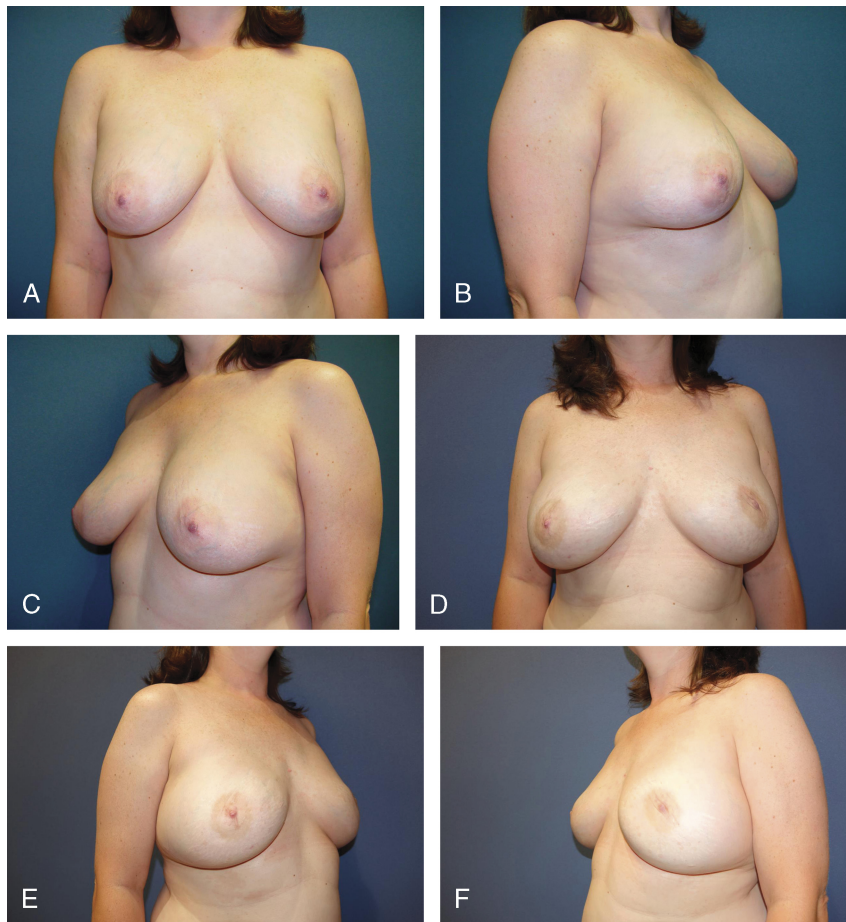


FIGURE 9. This 36 year old mother of two with the BRCA 2 gene mutation elected to proceed with bilateral nipple sparing mastectomies and immediate DTI breast reconstructions. Two dimensional templates were used in her reconstructions. She is seen before, and one year after her surgery. She had no revision surgery after her initial mastectomies and reconstruction. Unfortunately her post-operative course was complicated by a significant unilateral pulmonary embolus 12 days post-operatively, which was successfully treated with anticoagulation therapy without sequelae. [A, B, C: Pre-op D, E, F: Post-op]

are better served with a staged expander reconstruction, and this should always remain a back up option even for the plastic surgeon experienced with DTI reconstruction.

CONCLUSIONS

Traditional 2-stage expander/implant reconstructions by definition require at least 2 operations. Forty percent of the patients in this 1-surgeon series had 1 operation only without complications or revisions. Despite a learning curve, DTI immediate breast reconstruction has proven to be safe and effective, and often preferable to traditional 2-stage expander/implant reconstructions with comparable or better complication and revision rates. A simple 2-D template has been shown to be useful in reducing both complications and the rate of reoperation. Plastic surgeons should challenge themselves to become comfortable with the technique of DTI reconstruction and add this to the list of reconstruction options they can offer to their patients.

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