

One-Stage Immediate Breast Reconstruction With Implants

A New Option for Immediate Reconstruction

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Background: The current standard of care for breast implant reconstruction after mastectomy is 2-stage reconstruction with placement of tissue expanders followed by implants. The immediate use of implants at the time of mastectomy, which eliminates the need for a second operative procedure, has been sparsely reported and is not yet accepted as the standard of care. This study describes a 1-stage immediate implant reconstruction technique and evaluates its risks.

Methods: Between 2005 and 2010, immediate implant reconstruction was performed in 43 sequential patients on a total of 78 breasts. Permanent silicone implants were placed at the time of mastectomy with the assistance of acellular dermal matrix (ADM). Follow-up was for an average of 575 days. Implant sizes varied widely from 175 to 800 mL. In order to create the correct breast shape and implant placement, specific techniques of acellular dermal matrix placement in the reconstruction were critically important. Aesthetic evaluation of the patients was performed, evaluating pre- and postoperative photos by 20 evaluators. Pictures were rated according to a 4-point Harris breast scale. A 2-sided paired *t* test was then used to compare the rating scores.

Results: Complication rates were as follows: seroma occurred in 6.4% of breasts; infection resolving with antibiotics occurred in 2.6%; infection requiring implant removal occurred in 3.8%; and hematoma occurred in 1.3%. Neither preoperative breast size nor implant size correlated to an increased risk of complications ($P > 0.05$). Complication rate increased with age ($P = 0.02$). The average score for the preoperative images was 2.1, whereas the postoperative average was 2.4. This represented a statistically significant improvement above the baseline (preoperative) breasts with a $P < 0.001$, according to a 2-sided paired *t* test.

Conclusions: With complication rates similar to previously reported tissue expander reconstructions, immediate implant reconstruction is a viable alternative to 2-stage expander reconstruction, presenting many advantages over expander reconstruction while offering the same risk profile and eliminating the additional risks, costs, and discomfort of a second procedure. Additionally, aesthetic results were highly satisfactory according to patients themselves and based on evaluation by independent observers.

Key Words: breast, reconstruction, aesthetics, immediate, implant, 1-stage (*Ann Plast Surg* 2011;XX: 000–000)

Mastectomy with implant-based reconstruction is on the rise as women with breast cancer are increasingly choosing mastectomy over breast-conserving surgery and bilateral mastectomy over unilateral, both for prophylaxis and in the course of cancer treat-

ment.¹ Women are also increasingly demanding nipple/areola-sparing (NAS) as well as skin-sparing operations from their surgical oncologists,¹ thus placing increased importance on the plastic surgeon's ability to produce an aesthetic result through small incisions and use as few procedures as possible.

TRADITIONAL "IMMEDIATE BREAST RECONSTRUCTION"

Traditional immediate breast reconstruction with implants requires a 2-stage procedure as follows: subpectoral placement of a tissue expander at the time of mastectomy as the first stage, followed by replacement of the tissue expander with the final breast implant as the second stage after breast expansion has been achieved. Tissue expanders have been an accepted standard for breast reconstruction for over 2 decades. However, the tissue expander technique has disadvantages, most notably the need for 2 stages and the potential for pain with expansion. Also of relevance is the loss of the subcutaneous pocket space of the breast; the breast skin readheres to the underlying pectoralis muscle early during the expansion process, sometimes producing an undesirable final result that is not true to the size or shape of the preoperative breast. This is even more of an issue with NAS procedures, as nipple asymmetry may result from differential adherence of the skin to the underlying pectoral muscle as well as differential expansion.

ACELLULAR DERMAL MATRIX

Expansion times are becoming shorter as utilization of acellular dermal matrix (ADM) is becoming more common. Utilization of ADM allows for increased initial fill volumes, decreased number of postoperative fills,¹ and increased lower pole expansion. There is currently active debate on the effect of the use of ADM on the complication rates as compared with fully submuscular tissue expander placement.²

A NEW WAY

The advent of ADM, which helps to provide complete coverage of a subpectoral implant, allows for immediate implant placement.^{3–5} The purpose of this study is to describe a 1-stage immediate implant reconstruction technique and to evaluate the technique for safety and aesthetic outcome.

PATIENTS AND METHODS

In our study, 43 patients (78 breasts) underwent immediate implant (Allergan, Irvine, CA) placement between 2005 and 2010. Mastectomy was first performed by a surgical oncologist. Patients underwent bilateral or unilateral mastectomies using one of the following 3 incisions: short horizontal, inferior mammary crease, or vertical, as shown in Figure 1. The short, horizontal, skin-sparing F1 scar was preferred with skin-sparing mastectomies in nonptotic breasts. The inframammary crease incision was preferred for the NAS mastectomies (NAS). The vertical incision was preferred in ptotic breasts where excess of skin existed in the lower pole.

Following the mastectomy, ADM was sutured to the pectoralis muscle to create an implant pocket against the chest wall. The

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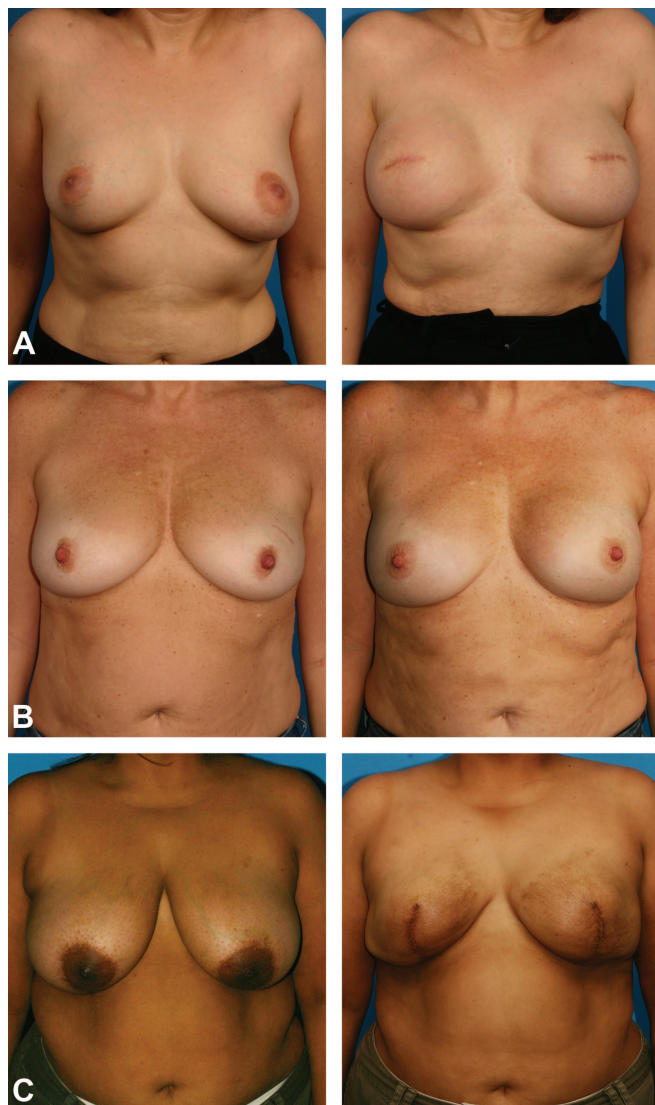


FIGURE 1. Preoperative (left) and postoperative (right) views of the 3 types of incisions used for mastectomy. A, Short horizontal incision. Left breast specimen weighed 350 g. Right breast specimen weighed 300 g. For reconstruction, 421-mL implants were used. B, Inferior mammary crease incision. Left breast specimen weighed 420 g. Right breast specimen weighed 440 g. For reconstruction, 421-mL implants were used. C, Vertical incision. Left breast specimen weighed 910 g. Right breast specimen weighed 1060 g. For reconstruction, 533-mL implants were used.

ADM used in our study was Alloderm (LifeCell, Branchburg, NJ). The pectoralis was raised inferiorly from the chest wall, incising the fascia as low as possible, most often directly at the inframammary crease. The pectoralis muscle incision was lifted from the chest wall medially to the planned final implant position. On the basis of the patient's desired size and ptosis, the size and shape of the ADM were determined. Pieces of ADM were used to form an "internal bra" to support the implant, provide a layer of protection between the skin and the implant, and control the position and ptosis of the resulting new breast mound. The most frequently used ADM shapes are shown in Figure 2, but the described shapes can be adjusted

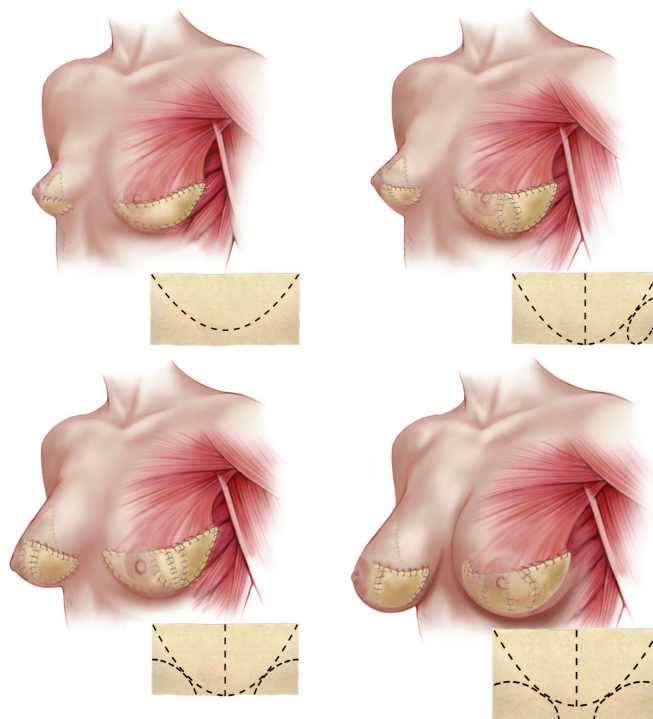


FIGURE 2. Shaping and suturing of acellular dermal matrix to create internal bra.

when necessary to produce the desired level of ptosis. Two sizes of ADM were used: 6 cm by 12 cm (used for A-, B-, and C-sized breasts) and 8 cm by 14 cm (used for size-D and larger breasts). As shown in Figure 2, when reconstructing a size-A or size-B breast, a semi-elliptical 6 cm by 12 cm piece of ADM was used. For a size-B breast, an additional, elliptical piece of ADM ("ADM insert") was used, which was taken from an unused corner of the ADM sheet. For size-C breast, a larger elliptical ADM insert was necessary, created from 2 semi-elliptical pieces, making use of the entire 6 × 12 sheet. For a size-D breast, or for the creation of any size of ptotic breast, the 8 × 14 sheet was used in a manner similar to the size-C breast method, but with the larger size pieces allowing for a larger implant and greater ptosis. After designing the ADM internal bra, the lateral edge of the ADM was sutured to the serratus fascia at the anterior axillary line, but not necessarily to the posterior extent of the mastectomy, which was often too lateral a location to yield a good result. Inferiorly, the ADM was sutured to the chest wall and the inferior mammary crease. Superiorly, it was sutured to the inferior edge of the pectoralis muscle/fascia. Importantly, the ADM internal bra was fully placed and completely sutured prior to the placement of any implant or sizer.

After placement of the ADM, an approximately 3.5-cm incision was made in the ADM to access the subpectoral space for placement of the sizer and implant. The incision must be at least 5 mm from any ADM edge. This allows for silicone implant placement without traumatizing the pectoral muscle, as all retraction stress is taken by the ADM. The sizer was then placed and inflated to the desired size. Size was limited by the skin tightness; it is critical that there be no tension on the final skin closure. Some tension on the ADM and pectoralis muscle is normal and desirable. Best ADM placement was obtained if the excess ADM was positioned centrally, which allowed for more central fullness. Excess lateral or medial ADM would allow an undesirable bulge.

The patient was then seated upright with the sizers in place, not only to check symmetry but to check for easy closure without tension. In cases where the desire was to match the preoperative breast size, an implant was chosen to match as closely as possible the displaced volume of the excised mastectomy (a size different from the preoperative size could be obtained, but, again, an increase in size is limited by the tension on the final skin closure, which must be as minimal as possible). The sizers were then removed, and final implants were placed through the ADM access incisions. Silicone moderate profile implants were used (Allergan). The subcutaneous space was then drained with closed suction, and the skin was sutured closed in standard manner.

The drains were monitored for daily output, and were subsequently removed once the output was less than 30 mL. Intravenous Ancef was continued while in the hospital, and then transitioned to oral Keflex upon discharge home. The antibiotics were continued until drain removal.

Aesthetic evaluation of the patients was performed, evaluating pre- and postoperative photos by 20 evaluators. Pictures were of patient torsos and abdomens, and were rated according to a 4-point Harris breast scale (excellent, good, fair, poor).^{6,7} All identifying marks were removed from pictures. Evaluators consisted of 10 surgical residents and 10 lay people. Preoperative photos were ranked first, followed by postoperative photos according to the Harris scale. The scores were then converted into points (1–4, where 4 represented an excellent score). An average of the scores for all preoperative images was then calculated, and similarly for postoperative images. A 2-sided paired *t* test was then used to compare the averages.

RESULTS

The mean age of the patients was 47 years (range, 26–73 years). Average body mass index of the patients was 24.2 (range, 17–47). The mean mastectomy specimen weight was 407 g (range, 80–1420 g). Implants placed averaged 419 mL (range, 175–800 mL). The mean follow-up was 19 months (range, 6–43 months). Of the breast reconstructions performed, 64.1% (*n* = 50) had skin-sparing mastectomy with a short horizontal scar, 26.9% (*n* = 21) had NAS mastectomy, and 6.4% (*n* = 5) had vertical-incision mastectomy of nipple and areolar complex and excess inferior breast skin. Drains and antibiotics were continued until output was less than 30 mL, ranging from 3 to 14 days.

Outcome data on the rate of hematoma, seroma, infection, capsular contracture, and mastectomy flap necrosis requiring reoperation were collected. The need for secondary revision, chemo/radiotherapy, type of incision, use of methylene blue, and tumor staging were checked for correlation to complication rate. Correla-

tion between all categorical variables was determined with χ^2 test. Correlation between parametric and categorical variables (age vs. complication rate, or breast/implant size vs. complication rate) was determined with unpaired *t* test.

Complications were as follows: hematoma, 1.3%; seroma, 6.4%; infection, 6.4%; capsular contracture, 0%; and mastectomy flap necrosis requiring reoperation, 3.8%. Infection that resolved with IV antibiotics occurred in 2.6% (*n* = 2). Infection requiring implant removal occurred in 3.8% (*n* = 3). The only etiology for implant loss was infection. In the 3 cases of mastectomy flap necrosis, implant loss did not occur. In 1 case, necrotic skin was replaced with a latissimus flap. In the other 2 cases, local skin excision was adequate to remove necrotic portions of the skin flap. Of note, in patients undergoing nipple-sparing mastectomy, there were no cases of full-thickness nipple necrosis (other than 1 of the 3 breasts which had mastectomy flap necrosis). A secondary procedure was performed in 19.2% of breasts (*n* = 15), not including nipple/areola reconstruction only. The most common reason was desire for increased breast size (14.1% of breasts, *n* = 11), which was achieved with increased implant size, fat grafting, or both. Two patients underwent revision for asymmetry (*n* = 4). The occasional need for skin edge revision was not included in secondary revision rates. The health of the skin edge can be improved by conservative trimming of the wound edge before closure. However, because of the proximity of the incision to the ADM in most cases, any areas of poor healing on the superficial skin edge must be aggressively managed and excised between 10 and 14 days postoperatively, compatible with the time to improve circulation with a delayed flap.

The overall risk of a serious complication (hematoma, infection, capsular contracture, and mastectomy flap necrosis requiring reoperation) was 11.5% (*n* = 9). An increased likelihood of complications did not correlate with larger breast size, larger implant size, or higher body mass index. There was an increased risk of complications with increasing age (*P* = 0.02); patients with serious complications were on an average 11 years older (average, 57.2 years) than patients without complications (average, 46.2 years).

Tissue expander reconstruction acts as a benchmark of comparison. In Table 1, our immediate implant reconstruction complication rates are compared with published complication rates of tissue expander reconstruction with and without ADM.^{8–11} The data reveal a similar risk profile for our immediate implant reconstruction when compared with tissue expander reconstruction.

Aesthetic evaluation was performed by 10 lay people and 10 surgical residents. There were 10 females and 10 males. The average score for the preoperative images was 2.1, whereas the postoperative average was 2.4. This represented a statistically significant improve-

TABLE 1. Study Complication Rate vs Published Rates for Tissue Expander

	Studied Patients (<i>n</i> = 78)	McCarthy et al ⁸ No ADM (<i>n</i> = 1170)	Spear et al ⁹ With ADM (<i>n</i> = 58)	Antony et al ¹⁰ With ADM (<i>n</i> = 153)	Chun et al ¹¹ With ADM (<i>n</i> = 415)
Hematoma	1.3% (1)	Included with seroma below	Not cited	2.0%	2.2%
Seroma	6.4% (5)	3.2% (combined with hematoma)	1.7%	7.2%	14.1%
Infection (cellulitis)	2.6% (2)	3.4%	5.2%	3.9%	3.0%
Infection (resulting in loss)	3.8% (3)	1.5%	1.7%	3.3%	5.9%
Infection total	6.4% (5)	4.9%	6.9%	7.2%	8.9%
Mastectomy flap necrosis	3.8% (3)	8.7%	3.4%	4.6%	20.5% ("major" necrosis)
Secondary procedure required/requested	19.2%(15)	100%+	100%+	100%+	Not cited

ment above the baseline (preoperative) breasts with a $P < 0.001$, according to a 2-sided paired t test.

DISCUSSION

There is little doubt that 1-stage reconstruction is superior to 2-stage reconstruction, if other factors—esthetic outcome, complication rate, and relative contraindications—are equal or better. This study therefore sought to answer the following questions: first, how can an esthetic breast be produced in 1 stage? Second, can this procedure be performed without an increase in complications compared with tissue expander reconstruction? Third, what relative contraindications does this procedure have, such as preoperative breast size, patient body habitus, or desired size?

Creating an Aesthetic Breast

Our results show that an esthetic breast can be produced in 1 stage (Fig. 3), no matter what the size of the preoperative breast. The correct utilization of the ADM is critical to produce an esthetic breast. A good outcome requires the surgeon to preoperatively visualize the proper size and shape for the ADM internal bra, create the correct pocket, and provide the appropriate point of maximal projection. The shapes of ADM shown in Figure 2 can be used as a guide to plan for the desired cup size.

Complication Rate

Previous studies discussing 1-stage reconstruction report differing rates of complications. Salzberg published a study of 76 single-stage implant breast reconstructions using ADM and reported no incidence of infection or seroma.¹² Topol et al published a series of 35 reconstructions, some with as little as 1-month follow-up, and reported 4 total complications (11.4%).¹³ Of these complications, 3 (2 infections, 1 dehiscence) resulted in implant loss, for an implant-loss complication rate of 8.6%. The fourth complication was cellulitis successfully managed by washout and implant replacement with intravenous antibiotics. There is no mention of seroma, mastectomy flap necrosis, or hematoma. In our study, aggressive wound management at 2 weeks under no or local anesthesia helped to maintain a relatively low rate of implant loss (3.8%) by preventing exposure of the ADM.

Review of our data suggests that 1-stage immediate implant reconstruction can be performed safely, with a complication rate within the same range as the risks of the first stage of tissue expander reconstruction. As shown in Table 1, reported tissue expander reconstruction complication rates varied widely. Our complication rates fell within the range of published tissue expander reconstruction complication rates, which include studies with reconstructions performed both with and without ADM. Infection rates ranged from 4.9% to 8.9%, compared with our overall infection rate of 6.4%. Implant loss ranged from 1.7% to 7.2%, compared with our rate of 3.8%. Seroma ranged from 1.7% to 14.1%, compared with our rate of 6.4%. Finally, mastectomy flap necrosis ranged from 3.4% to 20.5%, with our mastectomy flap necrosis rate at 3.8%.

The most obvious advantage of this procedure over tissue expander reconstruction is the potential for 1-stage reconstruction. Although 19.2% of breasts in our study had a second procedure, 100% of tissue expander reconstruction patients require a second procedure, and up to 40% of those require a third procedure.⁸ A limitation of this surgery is that during the breast reconstruction, the implant size that can be placed is limited by the tension on the mastectomy flap closure. This may necessitate an initial tissue expander placement instead or a secondary procedure for some patients.

Of particular concern with the immediate placement of a final implant is that mastectomy flap may necrose, leaving the plastic surgeon with few options. However, if the necrosis is minor and near

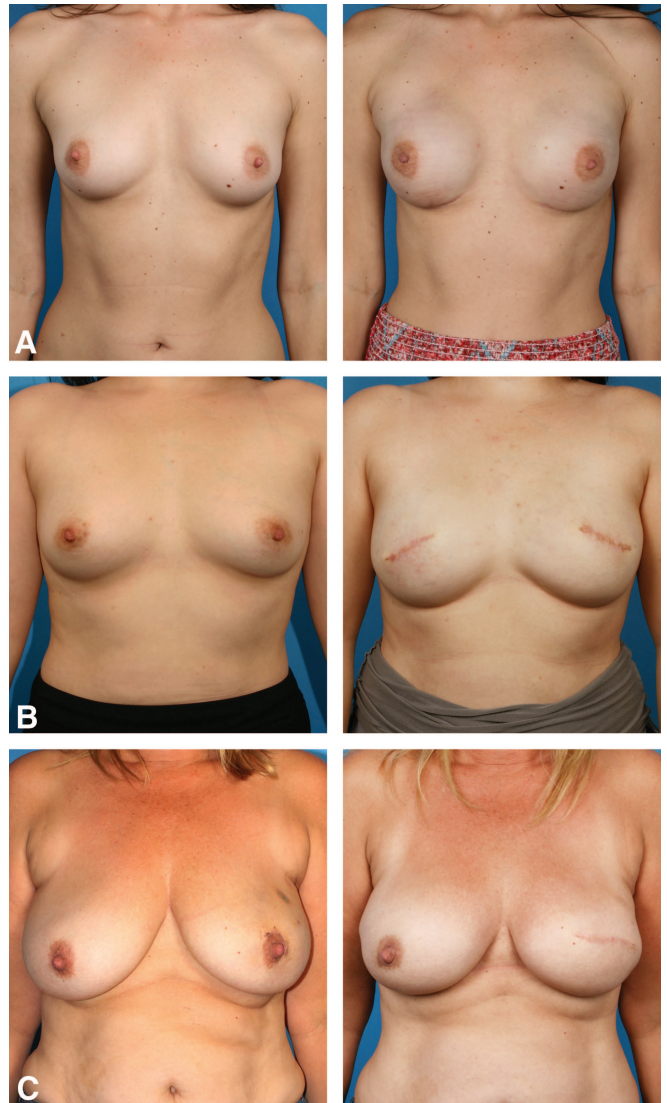


FIGURE 3. Preoperative (left) and postoperative (right) views of 3 different breast sizes. A, Small B-sized breast was increased to a small C-sized one. Left breast specimen weighed 270 g. Right breast specimen weighed 250 g. For reconstruction, 304-mL implants were used. B, Moderate size-C breast was reconstructed to the same size. Left breast specimen weighed 355 g. Right breast specimen weighed 440 g. For reconstruction, 400-mL implants were used. C, Size-D breast was reconstructed to the same size. Left breast specimen weighed 580 g. Right breast specimen weighed 620 g. For reconstruction, 616-mL implants were used.

the edge of the incision, the necrosis is simply resected at 2 weeks and the incision reclosed. Just as with tissue expander reconstruction, if the necrosis involves a critically large area, then an additional operation is required. With an immediate implant, the implant can be swapped for a tissue expander at the second surgery or a salvage latissimus may be used.

Relative Contraindications

If the surgery is esthetic and safe, as well as technically feasible, then who should be chosen to undergo the procedure? Our

data show that younger women have a lower risk of complication from the procedure, as they do with other forms of mastectomy reconstruction.¹⁴ Although our older patients or those with comorbidities had higher complication rates than younger women, a 1-stage reconstruction may be most advantageous to those older or sicker patients who cannot tolerate a secondary surgery, do not desire a multiple-stage surgery, or for whom multiple surgeries would be medically unwise. We have noticed that our older patients often choose 1-stage implant reconstruction because they do not want the bother of the expander, and they “just want something there.” To these patients, it is a choice between the 1-stage implant reconstruction, and no reconstruction at all.

Costs

Another advantage of this procedure is the overall cost savings of averting a second operation, as well as labor costs in the physician office for unpaid tissue expansion visits within the global period. Although ADM represents a high cost (up to \$2500 per sheet), there is also a high cost to the tissue expander (around \$1525). The cost savings of immediate implant reconstruction are fully realized with avoidance of the second surgery with its associated surgeon, hospital, and anesthesia costs. However, this is no financial boon for the plastic surgeon, as the relative value units (RVU) for an immediate implant (CPT 19340, 10.37 RVU) are less than that of a tissue expander (CPT 19357, 39.15 RVU), and there is no billable second surgery of the final exchange to the implant (CPT 11970, 5.6 RVU).

Aesthetics

To evaluate aesthetic outcomes, the Harris breast scale was selected because it is a widely accepted, reproducible, and a reliable scoring system. It allows for a range of scores while not being overly complex.

Our postoperative images were scored higher than the baseline (preoperative) images. This was surprising as we expected a decrease in the scores from baseline to postreconstruction. The higher scores confirmed our and our patients' experience with the highly aesthetic results of the reconstructions.

CONCLUSIONS

Immediate implant reconstruction is a safe, effective, aesthetic, and less-costly alternative to tissue expander reconstruction. The ability to offer a single surgery, the relative simplicity of the procedure, and the elimination of the need for postoperative expander filling makes 1-stage implant reconstruction extremely appealing to both surgeon and patient when compared with 2-stage

reconstruction. As with most breast procedures, the best candidates are those who are younger, with relatively aesthetic preoperative breasts. This procedure should only be used with patients in whom the mastectomy flaps are not involved in disease and can be preserved. When combined with nipple-sparing mastectomy, the result is a 1-stage implant reconstruction at the time of mastectomy without the need for nipple reconstruction.

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