Beyond Biologics: Absorbable Mesh as a Low-Cost, Low-Complication Sling for Implant-Based Breast Reconstruction

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Background: There is an intense push to decrease overall healthcare costs in the United States. Although the use of acellular dermal matrix in implant-based reconstruction has grown significantly over the past decade, potential drawbacks remain a source of debate. Matrices are costly and not universally available across institutions, whereas Vicryl mesh is widely available, relatively inexpensive, and resistant to bacteria biofilm formation. With the intent of maximizing the reconstructive and economic advantages of direct-to-implant breast reconstruction, the authors report the first experience in the literature using an absorbable mesh as an inferolateral sling.

Methods: A retrospective review was performed of the first 50 consecutive patients (76 reconstructions) who underwent implant-based breast reconstruction with Vicryl mesh from August of 2011 until June of 2012.

Results: Fifty patients underwent 76 direct-to-implant reconstructions with Vicryl mesh between August of 2011 and June of 2012 (mean follow-up, 1.2 years). Five breasts (6.6 percent) had complications, with only one complication resulting in implant loss (1.3 percent). Implant positioning and contour were excellent, with only two patients [three breasts (3.9 percent)] undergoing revision procedures, for size enlargement. Using costs available at the authors' institution, use of Vicryl mesh instead of acellular dermal matrix resulted in a direct material cost savings of $172,112 in 10 months.

Conclusions: Results to date have been encouraging, with a low complication rate (6.6 percent) and excellent aesthetic results. The technique has resulted in $172,112 in direct material cost savings over 10 months. Continued follow-up is planned to evaluate long-term results. (*Plast. Reconstr. Surg.* 133: 90e, 2014.)

CLINICAL QUESTION/LEVEL OF EVIDENCE: Therapeutic, IV.

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THERAPEUTIC

Prosthesis-based breast reconstruction accounts for over 70 percent of all breast reconstructions in the United States. Immediate single-stage, direct-to-implant reconstruction has been gaining popularity as a surgical option for breast reconstruction after therapeutic and prophylactic mastectomy.[1–8] Use of acellular dermal matrices has served as a workhorse for direct-to-implant reconstruction for the past decade, allowing greater pocket control[9–12] and improved cosmesis.[11,13] There are several reported advantages to using acellular dermal matrices in immediate breast reconstruction, including reducing the need for musculofascial dissection for inferior pole coverage,[11] improving lower pole expansion, allowing for a more natural appearing breast,[9,14] providing better control of inframammary and lateral mammary folds,[11,14] reducing expander or implant migration,[13,14] and maximizing use of mastectomy skin flaps,[9,14,15] facilitating greater intraoperative implant volume.[11,16,17]

As has been demonstrated in both the media and the literature, there is an intense push to decrease overall health care costs in the United States, and the scrutiny of health care spending has influenced all aspects of surgery, including breast reconstruction. Although the use of acellular

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dermal matrix in implant-based reconstruction has grown significantly over the past decade, there are potential drawbacks that remain a source of debate. Acellular dermal matrices are costly and not universally available across institutions. The expense for use of acellular dermal matrices offsets much of the potential economic advantage gained through direct-to-implant reconstruction. Furthermore, there have been many published reports of increased complications with the use of acellular dermal matrices in immediate breast reconstruction,[17–27] including higher rates of infection,[19,24–26] seroma,[23–27] mastectomy flap necrosis,[18,24] and explantation.[21,22,26]

With the intent of maximizing the reconstructive and economic advantages of direct-to-implant reconstruction and mitigating the potential drawback of implanting biologic materials in prosthetic reconstruction, the senior author (W.G.A.) began using polyglactin 910 (Vicryl; Ethicon, Inc., Somerville, N.J.) mesh for an inferolateral sling in direct-to-implant reconstruction in 2011. Vicryl knitted mesh is widely available, relatively inexpensive, resistant to bacteria biofilm formation,[28] and easy to use; demonstrates little inflammatory response; and is nonallergenic. This absorbable synthetic has been widely used in many surgical specialties, with a low complication profile. The present study reports the early outcomes for the first 50 consecutive patients (76 reconstructions) at our institution that underwent skin-preserving mastectomies with immediate direct-to-implant reconstruction using knitted Vicryl. This is the first significant case series reported in the literature for the use of resorbable synthetic material for direct-to-implant reconstruction.

PATIENTS AND METHODS

After obtaining approval from the Institutional Review Board of the Massachusetts General Hospital, we conducted a retrospective review of the first 50 consecutive patients (76 reconstructions) who underwent skin-preserving mastectomy and immediate direct-to-implant reconstruction with Vicryl mesh from August of 2011 until June of 2012 performed by the senior author (W.G.A.). Patient selection, indications for mastectomy technique, and the ability to perform direct-to-implant as opposed to staged expander reconstruction remained unchanged. Only those patients that underwent direct-to-implant reconstruction were included in the study.

Outcome measures examined included complications, need for revision surgery, and institution-based costs. Complications were defined as infection requiring intravenous antibiotics, mastectomy flap and/or nipple-areola complex necrosis requiring surgical intervention, seroma or hematoma, and implant loss. Costs were based on internal institutional data at the Massachusetts General Hospital and based on material costs for acellular dermal matrix and synthetic mesh materials. Patient demographics and operative details were recorded from detailed examination of patient charts. A smoker was defined as someone who had smoked in the 6 months leading up to surgery or in the 3-month period after surgery.

Surgical Technique

After completion of skin-preserving mastectomy by the breast surgery team, the senior surgeon (W.G.A.) made the final determination for direct-to-implant versus staged reconstruction with observation of skin flap viability. This determination was based on surgeon experience and included parameters of skin color, capillary refill, flap thickness, and change in flap viability, with inflation of a saline sizer to the appropriate desired volume.

The reconstructive technique began with elevation of a subpectoral pocket. Release of the pectoralis major muscle on the sternum proceeded to the 4- and 8- o'clock levels, with adjustment as necessary to accommodate the desired implant. A saline sizer was then chosen based on mastectomy weight and measurements of the patient's breast base diameter. The sizer was then placed in the partial subpectoral pocket and inflated with normal saline to the desired volume. A marking pen was then used to trace the projected outline of the implant to assist tacking of the Vicryl knitted mesh in proper position. The knitted Vicryl mesh was then sutured in place using 2-0 Vicryl sutures, ensuring proper lateral and inferior fold placement (Fig. 1). After securing the inferior and lateral mammary folds, the sizers were placed into the created pocket; the skin flaps were stapled closed; and the patient was placed in a seated position to observe symmetry, contour, and proper fold placement. The patient was then returned to the supine position, the final implant was chosen and placed in the pocket using a minimal touch technique, and the Vicryl was secured to the pectoralis with Vicryl 2-0 sutures in horizontal mattress fashion. Two 19-French Bard drains were placed through a tunnel of subcutaneous tissue and placed in the subpectoral and subcutaneous space. Final

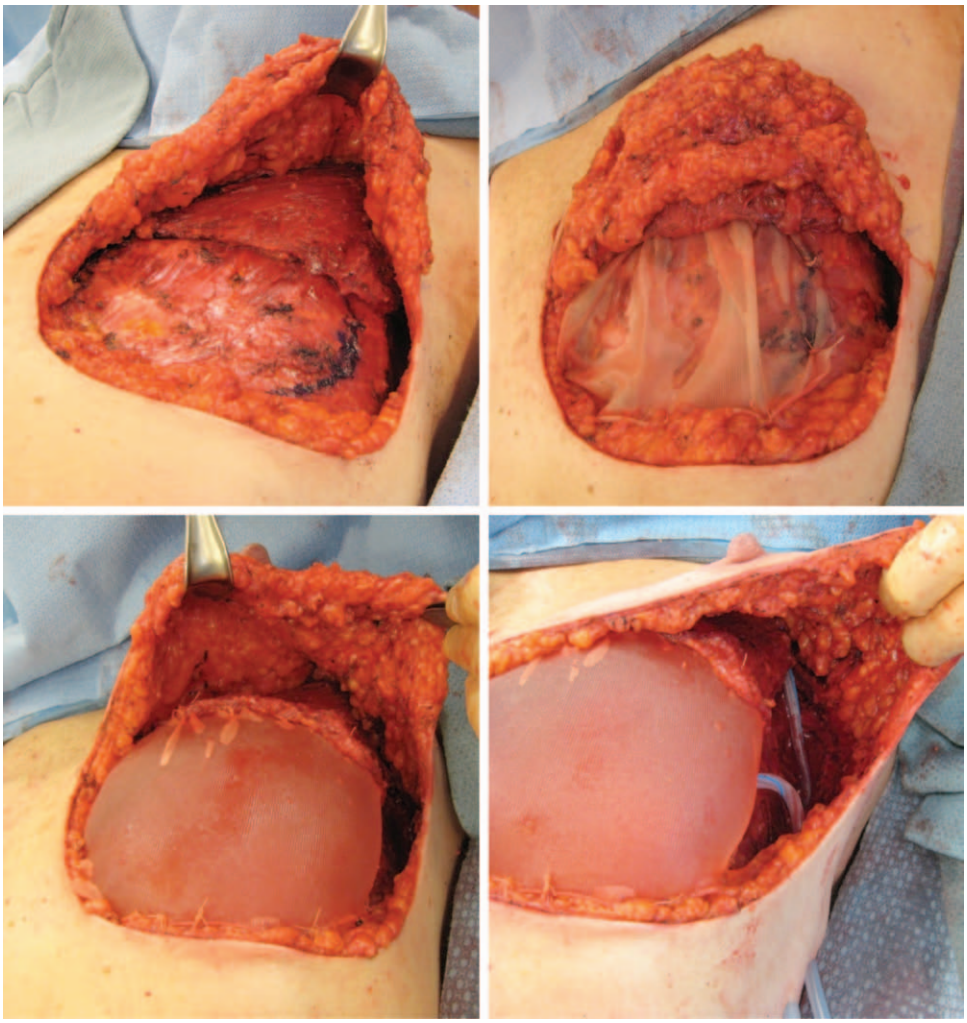

Fig. 1. Immediate direct-to-implant breast reconstruction. (*Above*) The inferior border of the pectoralis muscle is released, and (*below*) the Vicryl mesh is sutured into place as an inferolateral sling.

adjustments were made as necessary, hemostasis was ensured, and the wound was then closed and dressed with Dermabond (Ethicon) glue. A surgical bra was placed and the patient was admitted to the hospital for 24 to 48 hours postoperatively (Figs. 2 through 4).

RESULTS

Fifty patients underwent 76 direct-to-implant reconstructions with Vicryl knitted mesh between August of 2011 and June of 2012. The average age of the patients was 50.6 years (range, 31 to 70 years) and the average body mass index was 25.9 (range, 18.3 to 50.6). The most common medical conditions were obesity [nine patients (11.8 percent)], hypertension [seven patients (9.2 percent)], and hypothyroidism [six patients (7.9 percent)]. There were no active smokers in this series (Table 1). Over half of the patients received therapeutic (61.8 percent) as opposed to prophylactic (38.2 percent) mastectomy. Nipple-sparing mastectomy was performed in 45 reconstructions (59.2 percent), and bilateral reconstruction was performed in over two-thirds of cases (68.4 percent). In this series, 14 breasts (18.4 percent) received either preoperative (5.3 percent) or postoperative (13.2 percent) radiotherapy (Table 2). Reconstruction time was 90.8 minutes (range, 64 to 115 minutes) for unilateral cases and 122.3 minutes (range, 74 to 188 minutes) for bilateral reconstruction. A mean implant volume (in cubic centimeters) to specimen weight (in grams) ratio of 1.0 was achieved over the course of the series (Table 3 and Fig. 5). The average length of hospital stay was 1.6 days. The average duration of drains staying in place was 10.2 days. No drains were left longer than 14 days for any patient in this study.

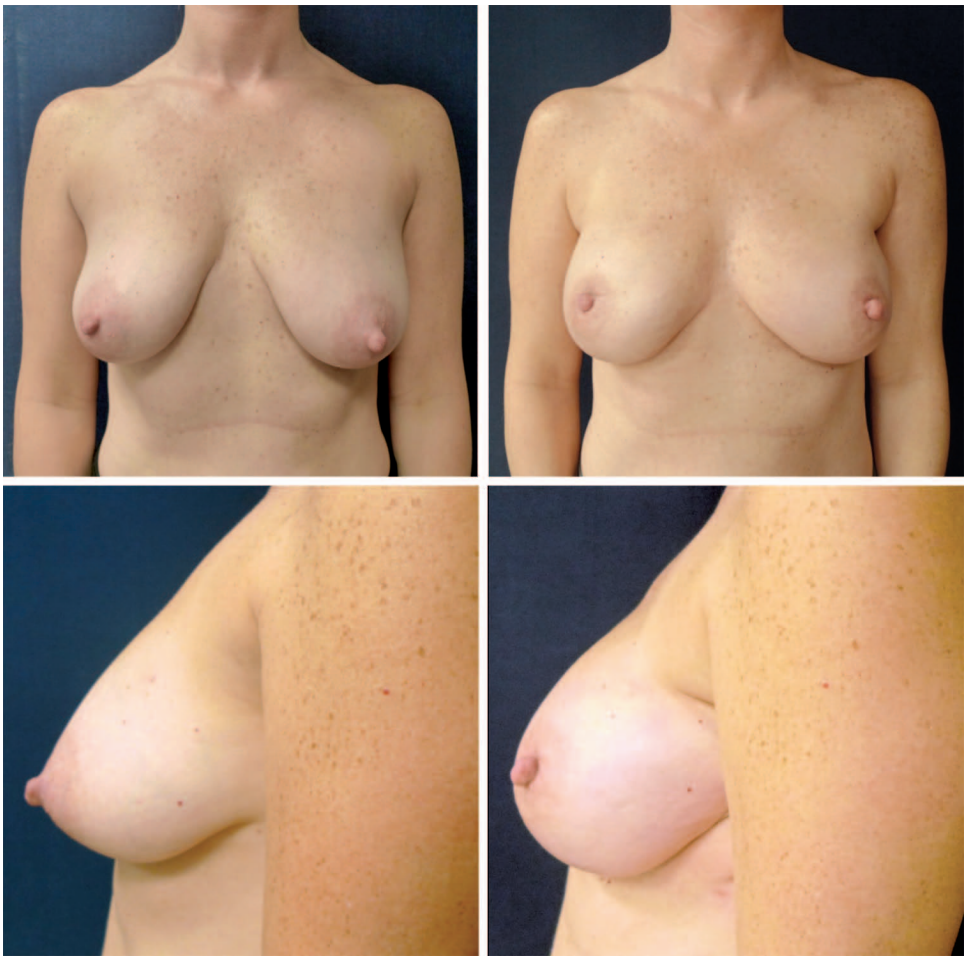

Fig. 2. A 40-year-old woman with left breast ductal carcinoma in situ who underwent bilateral nipple-sparing mastectomy through inferolateral incisions (*left*). She underwent reconstruction with 400-cc silicone implants and Vicryl mesh. Postoperative results are shown at 6 months after reconstruction (*right*).

Complication outcomes are listed in Table 4. Five breasts (6.6 percent) suffered from complications, with only one complication resulting in implant loss (1.3 percent); this was caused by an infection from *Serratia* species. Two complications of mastectomy skin necrosis were treated with sharp débridement in the office. One patient received postoperative radiotherapy, resulting in capsular contracture that was later revised 14 months postoperatively with autologous reconstruction (ipsilateral transverse rectus abdominis musculocutaneous flap). The final complication was a type IV hypersensitivity reaction to bacitracin (diagnosed by the allergy service). Of the 45 nipple-sparing mastectomies, there were no nipple-areola complex ischemia–related complications requiring intervention. Furthermore, no patients presented with detectable seroma or hematoma throughout the study period. Two patients [three breasts (3.9 percent)] underwent revision procedures for size enlargement. One patient was pleased with her results but desired larger bilateral implants, and the second patient decided to attempt to increase implant volume rather than undergo a contralateral reduction symmetrizing procedure.

Using costs available at our institution, use of Vicryl mesh instead of acellular dermal matrices resulted in a direct material cost savings of $172,112 in 10 months. From these data, direct-to-implant reconstruction with Vicryl absorbable mesh costs less than two-thirds in total expenditures of the previous most cost-efficient technique.

DISCUSSION

Results of this study indicate that the use of absorbable mesh in the setting of direct-to-implant reconstruction is a time- and cost-efficient

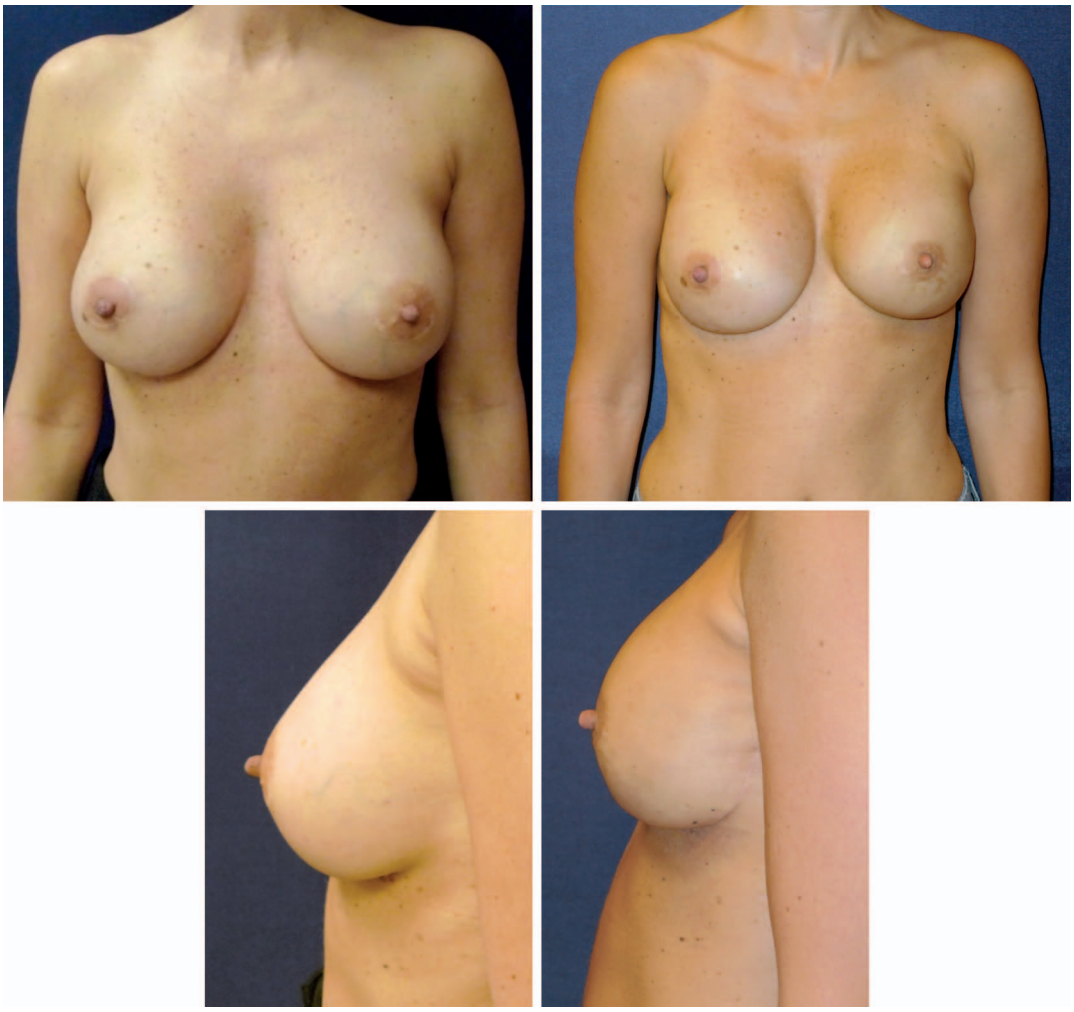

Fig. 3. Reconstruction of the irradiated breast of a 42-year-old woman with a history of previous bilateral breast augmentation who was later diagnosed with left breast invasive cancer and underwent bilateral nipple-sparing mastectomies (*left*). She underwent reconstruction with 450-cc silicone implants and Vicryl mesh. She underwent postoperative radiation therapy of the left breast. Postoperative results are shown at 12 months after reconstruction (*right*).

procedure that produces excellent aesthetic results with a low complication profile with a relatively short average follow-up of 1.2 years. The combined complication (6.6 percent) and surgical revision rate (3.9 percent) was 10.5 percent, which compares favorably with reported complication profiles of up to 44 percent for direct-to-implant reconstruction with biologics[29–31] and over 40 percent rates of combined complication and revision in the Mentor and Allergan core studies.[32–36] Although the follow-up period for this study is considerably shorter than for these comparison studies, our results to date are encouraging.

As experience has been gained with acellular dermal matrix products in the past 10 years, there have been conflicting data on whether acellular dermal matrix is an independent risk factor for complications, including infection and seroma. The literature on prosthetic breast reconstruction using acellular dermal matrices is difficult to interpret because of wide variation in operational definitions of complications, techniques used, and discrepant institutional experience with the materials, and remains a topic of debate.[29,37,38]

Vicryl mesh has been demonstrated to be a safe product that has been widely used in numerous surgical specialties with a low complication profile for many years. Vicryl knitted mesh is widely available and relatively inexpensive, demonstrates little inflammatory response, and is nonallergenic. Nyame et al.[28] used bacterial adhesion assays to demonstrate that synthetic materials such as Vicryl mesh produce decreased rates of bacteria-mediated biofilm formation. It is possible

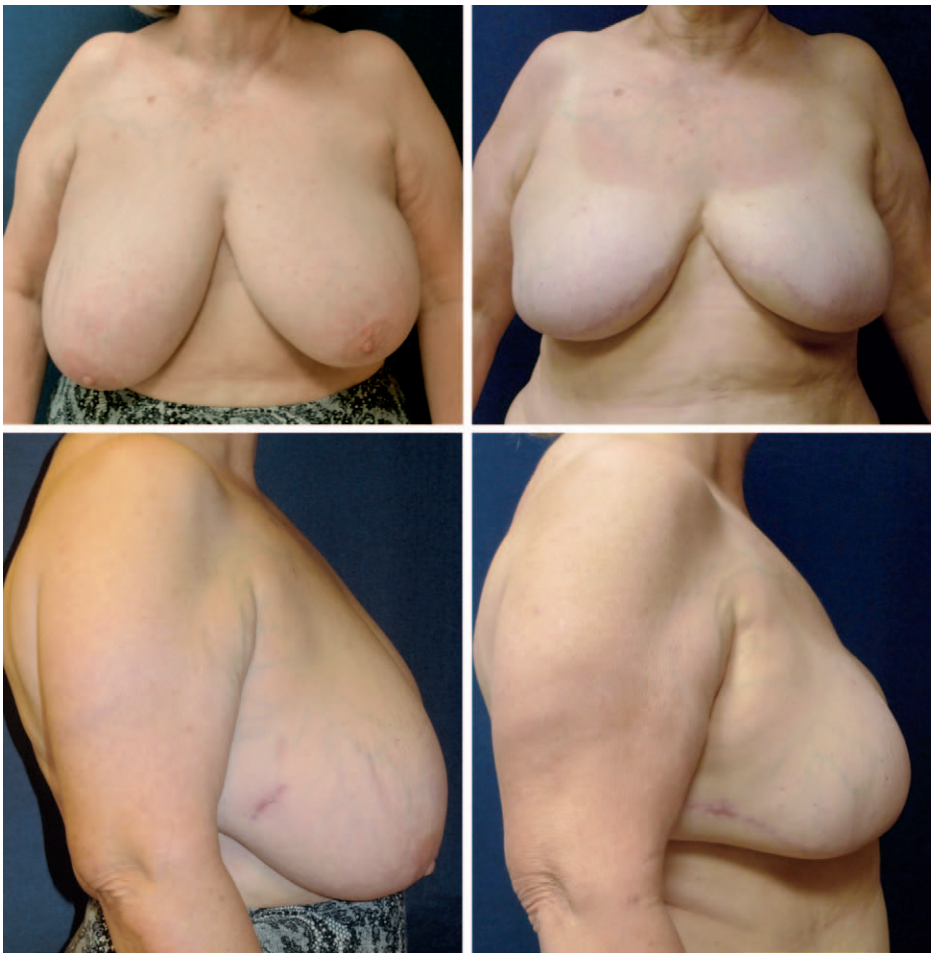

Fig. 4. Reconstruction of the large ptotic breast of a 63-year-old woman with right breast ductal carcinoma in situ who underwent bilateral mastectomies (*left*). She underwent reconstruction with 800-cc silicone implants and Vicryl mesh. Postoperative results are shown at 11 months after reconstruction (*right*).

that this resistance to biofilm in the setting of a foreign body implant could have a protective effect on inflammation, infection, seroma, and capsular contracture.

One of the hypothesized advantages of using biologics is the belief that it may attenuate capsular contracture and improve long-term aesthetic outcomes, such as bottoming-out, rippling, and mechanical shift.[13,31,39,40] Several retrospective series with up to 2.5 years of follow-up show decreased rates of capsular contracture.[18,30,31,40] This is supported by experimental rabbit,[41] monkey,[42] and human histologic[43] models. The major criticism of these reviews is the short-term follow-up when compared with the 6-year Mentor and Allergan core study results showing contracture rates of 10 to 17 percent.[32–36] In the present study, with a mean follow-up of 1.2 years, implant positioning and contour have been excellent, with only two patients [three breasts (3.9 percent)] undergoing revision procedures, both of which were for size enlargement. For studies of prosthesis-based breast reconstruction, extended follow-up is critical, as many complications develop long after the initial operation. Long-term follow-up is necessary, particularly in the evaluation of capsular contracture. The patients in this study will continue to be followed to better ascertain the full effects of substituting synthetic mesh for biologics; however, trends continue to be encouraging.

One of the major concerns with using an absorbable mesh as a sling is the risk of bottoming-out of the implant. With an average of 1.2 years of follow-up, we have not seen bottoming-out as a problem in these patients. Vicryl mesh typically is resorbed at 3 to 4 weeks. At the time of revision surgery, we find that the capsule formation in these patients is similar to that of a breast augmentation capsule. We used smooth implants for the first 50 cases; however, after completing the first 50 cases, we

Table 1. Patient Demographics

Characteristic	Value
Age, yr	
Mean	50.6
Range	31–70
Body mass index, kg/m^2	
Mean	25.9
Range	18.3–50.6
Follow-up, yr	
Mean	1.2
Range	0.8–1.6
Significant medical history, no. of patients (%)	
Obesity	9 (11.8)
Hypertension	7 (9.2)
Hypothyroidism	6 (7.9)
Hematologic condition	5 (6.6)
Diabetes mellitus	2 (2.6)
Collagen-vascular disease	1 (1.3)
Active smoker	0 (0)
Former smoker	13 (17.1)

Table 2. Surgical Demographics

	No. of Reconstructions (%)
Mastectomy type	
Therapeutic	47 (61.8)
Prophylactic	29 (38.2)
Mastectomy technique	
Nipple sparing	45 (59.2)
Skin sparing	31 (40.8)
Laterality	
Bilateral	52 (68.4)
Unilateral	24 (31.6)
Radiotherapy	14 (18.4)
Preoperative	4 (5.3)
Postoperative	10 (13.2)

Table 3. Operative Details

	Value
Specimen weight, g	
Average	471.8
Range	73–1400
Implant volume, cc	
Average	471.6
Range	150–800
Reconstruction time, min	
Unilateral	
Average	90.8
Range	64–115
Bilateral	
Average	122.3
Range	74–188

have used Vicryl mesh for textured tissue expanders, and this appears to work well in early results (data not included in this study). At an average follow-up of 1.2 years, we have not seen any cases of skin erythema thought to be associated with the Vicryl mesh, as one may see with acellular dermal matrix.

Of the 14 patients who received radiation therapy in our series, two (14.3 percent) suffered a complication. One patient with neoadjuvant radiation therapy presented with impending skin flap failure that was treated with simple excision and closure under local anesthesia without further complication. The other underwent postoperative radiotherapy that resulted in postreconstruction asymmetry and painless contracture. Irradiation is a well-documented independent risk factor for complications with prosthetic reconstruction, and reports of using biologics in the setting of radiation therapy are mixed.[11,23] Long-term follow-up results of prosthetic reconstruction using synthetic materials other than acellular dermal matrix in the setting of irradiation are required and are eagerly anticipated in future studies of this patient population.

There were no active smokers in this study. We defined an active smoker as someone who had smoked in the 6 months leading up to surgery or in the 3-month period after surgery. The incidence of active smokers in our breast reconstruction patient population was extremely low. In the first 50 patients, we did not have any active smokers. Active smoking was not an exclusion criterion in our patient selection. After performing the first 50 cases, we have successfully performed direct-to-implant reconstruction with Vicryl mesh in active smokers (data not included in this study).

As mentioned previously, there is an intense push to decrease overall health care costs in the United States, and the scrutiny of health care spending has influenced all aspects of surgery, including breast reconstruction. There are several cost and internal institution analyses demonstrating a cost benefit of direct-to-implant and biologic-assisted reconstruction.[18,29,44,45] Although it is hard to dispute the evidence put forth in these publications, it is readily apparent that a significant percentage of the cost savings accrued from direct-to-implant reconstruction is lost on material costs of acellular dermal matrix. Macadam and Lennox[18] performed a well-designed cost-minimization analysis comparing traditional staged and direct-to-implant reconstruction. Sensitivity analysis revealed that direct-to-implant was cost efficient if the biologic cost was less than $4168 and reconstructive time was under 2.25 hours, and that expected cost savings for direct-to-implant reconstruction with acellular dermal matrix was 26.2 percent compared with expander/implant reconstruction. Absorbable Vicryl mesh in the setting of direct-to-implant reconstruction recaptures the lost efficiency from high-cost biologics. Our average operative time was 90.8 minutes for unilateral reconstruction and just over 2 hours

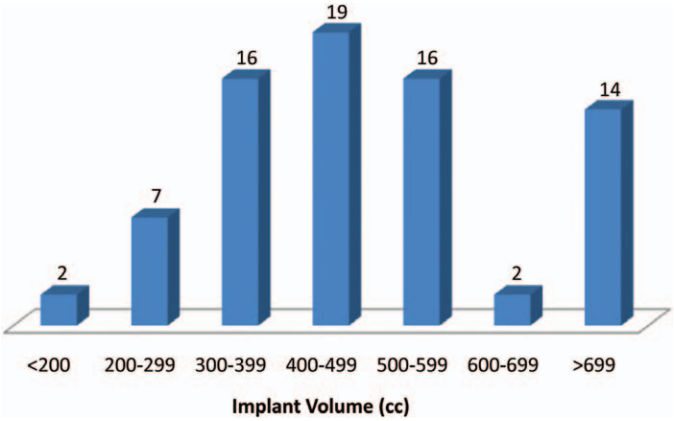

Fig. 5. Implant size distribution. The average mastectomy weight was 471.8 g (range, 73 to 1400 g). The average implant size was 471.6 g (range, 150 to 800 g). A mean implant volume (in cubic centimeters) to specimen weight (in grams) ratio of 1.0 was achieved over the course of the series.

Table 4. Complications

	No. of Breasts (%)
Mastectomy skin flap necrosis	2 (2.6)
Infection (*Serratia* sp.)	1 (1.3)
Contracture requiring operative revision (postirradiation)	1 (1.3)
Type IV delayed hypersensitivity*	1 (1.3)
Implant failure†	1 (1.3)
Seroma	0 (0)
Hematoma	0 (0)
NAC necrosis	0 (0)
Total	5 (6.6)

NAC, nipple-areola complex.
*Allergy to bacitracin diagnosed by the allergy service.
†Explantation because of infection in the same patient (same breast reconstruction) who suffered *Serratia* infection.

(122.3 minutes) for bilateral reconstruction. The cost of Vicryl mesh is under $200 per breast. Placing these numbers into this detailed model would result in an additional 46 percent cost reduction per breast.

As with other comparative studies investigating prosthesis-based breast reconstruction, our study is limited by its retrospective nature and sample size. As with all such studies, the conclusions could be stronger with additional patients and longer follow-up. This is the first significant case series reported in the literature for the use of resorbable synthetic material for direct-to-implant reconstruction, and we therefore limited the report to the first 50 patients (76 reconstructions). An additional limitation of this study is the lack of information regarding patient satisfaction with the outcome of breast reconstruction. Many breast reconstruction patient satisfaction surveys, such as the BREAST-Q, are intended for prospective studies.[46] Patient satisfaction surveys were not performed at the time of this study but will be of interest in future studies of this patient population.

CONCLUSIONS

Beginning in August of 2011, the senior author (W.G.A.) began using absorbable mesh (Vicryl) in the setting of direct-to-implant reconstruction. As of the date of this submission, 93 patients and 145 reconstructions had been performed, and we are reporting on the first 50 consecutive patients (76 reconstructions) for whom this technique was used. Results to date have been encouraging, with a low complication rate (6.6 percent) and excellent subjective patient satisfaction and aesthetic results. The technique is time-efficient and has resulted in $172,112 in direct material costs over 10 months. Continued follow-up is planned to evaluate long-term results.

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