BREAST

The Use of Absorbable Mesh in Implant-Based Breast Reconstruction: A 7-Year Review

Heather R. Faulkner, M.D., M.P.H. Lauren Shikowitz-Behr, M.D. Matthew McLeod, M.D. Eric Wright, M.D. John Hulsen, M.D. William G. Austen, Jr., M.D. Boston, Mass.

> 4 THERAPEUTIC

Background: Breast reconstruction is most frequently performed using implants or expanders. Adjunctive materials such as acellular dermal matrix and synthetic meshes are used to support the implant or expander. A paucity of large studies exist on the use of synthetic mesh for breast reconstruction.

Methods: A retrospective chart review of all patients over the past 7 years who had implant reconstruction with synthetic absorbable mesh at the Massachusetts General Hospital was performed. Data were collected on demographic and surgical outcomes. Statistical analysis was performed.

Results: A total of 227 patients (376 mastectomies) were treated with direct-to-implant subpectoral reconstruction with absorbable mesh from 2011 to 2017. The infection rate was 2.1 percent. The rate of capsular contracture was 4.8 percent. Patients who had radiation therapy either preoperatively or postoperatively had a higher rate of complications, including capsular contracture. Cost savings for using mesh instead of acellular dermal matrix surpassed \$1.2 million.

Conclusion: Synthetic absorbable mesh is a safe alternative to acellular dermal matrix in prosthetic breast reconstruction and provides stable results along with significant cost savings. (*Plast. Reconstr. Surg.* 146: 731e, 2020.)

CLINICAL QUESTION/LEVEL OF EVIDENCE: Therapeutic, IV.

mplant-based breast reconstruction is the most common method of breast reconstruction in the United States, with over 80 percent of women choosing this method over autologous tissue reconstruction.¹ Biological (acellular dermal matrix) and synthetic (absorbable and nonabsorbable) meshes are often used in two stage (expander-implant) reconstruction, and are used routinely in most single-stage direct-to-implant reconstructions.

There are many studies detailing the technique, advantages, and pitfalls of using biological meshes (acellular dermal matrices).^{2,3} Studies outlining similar information for synthetic meshes are few, and most are underpowered. Synthetic meshes are a viable, cost-effective alternative to

From the Division of Plastic and Reconstructive Surgery, Massachusetts General Hospital.

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acellular dermal matrices.^{4,5} The first account of synthetic mesh (nonabsorbable) being used for implant-based breast reconstruction was in 1997.⁶ Vicryl (Johnson & Johnson, New Brunswick, N.J.) mesh is completely absorbable: in vivo at 6 weeks, it is relatively intact with minimal change; absorption is completed between 60 and 90 days.⁷

The senior author (W.G.A.) published a review of his first 50 subpectoral direct-to-implant reconstructions using absorbable mesh in 2014.⁸ We now present the largest long-term observational study to date of patients who have undergone single-stage direct-to-implant reconstruction using synthetic absorbable mesh.

PATIENTS AND METHODS

Approval for this retrospective study was obtained from the Massachusetts General Hospital/Partners Healthcare Institutional Review Board. Patient charts were reviewed, and the following information was recorded: demographics, medical and surgical history, details regarding

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mastectomy, reconstruction, and treatment with chemotherapy and/or radiation therapy. Study data were collected and managed using Research Electronic Data Capture (REDCap) electronic data capture tools hosted at Partners Healthcare. Research Electronic Data Capture is a secure, Web-based application designed to support data capture for research studies, providing (1) an intuitive interface for validated data entry; (2) audit trails for tracking data manipulation and export procedures; (3) automated export procedures for seamless data downloads to common statistical packages; and (4) procedures for importing data from external sources.9 Data were analyzed using Stata/IC version 15.1 (College Station, Texas). Two-tailed t tests (and Fisher's exact tests where applicable) were used to compare categorical variables. Linear regression was used to compare continuous variables. Multiple logistic regression was used to identify independent predictors of complications. Alpha was set at the standard of 0.05.

All operations were performed by the senior author (W.G.A.). Patients underwent either nipple-sparing mastectomy through an inferolateral incision or skin-sparing mastectomy through a transverse elliptical incision. Patients received preoperative and intraoperative intravenous antibiotics according to Surgical Care Improvement Project guidelines.¹⁰

All reconstructions were performed subpectorally. The pectoralis major muscle is elevated and released at its inferior border, and a silicone implant is chosen using a sizer. The senior author predominantly uses smooth, round, silicone implants. A piece of knitted polyglactin 910 mesh (Vicryl) (size 30×30 cm) is cut in half (a half piece is used for one breast), and the edges are rounded using curved Mayo scissors. The mesh is sewn in place to the inframammary fold, mastectomy flap, and lateral chest wall using 2-0 Vicryl sutures in interrupted figure-of-eight fashion. The implant is then placed into the pocket that is created, and the superior edge of the mesh is sewn to the released edge of the pectoralis major muscle using 2-0 Vicryl sutures in interrupted horizontal mattress fashion. Excess mesh is either trimmed or tucked under the pectoralis major muscle before the superior edge of the mesh is secured. The mesh is inset without redundancy. Insetting the mesh securely around the implant without redundancy is a critical step. Two no. 15 channel drains are placed, one along the inframammary fold between the mesh and the mastectomy flap, and one along the lateral aspect of the reconstruction. The skin is closed in two layers with absorbable monofilament sutures, and occlusive dressings are placed over the incision and drains. Patients spend one night in the hospital and are discharged on the first postoperative day. Drains are removed when the output is less than 30 ml/day for 2 consecutive days. Patients are maintained on oral antibiotics until the drains are removed.

RESULTS

A total of 227 patients underwent 376 mastectomies with direct-to-implant subpectoral reconstruction, encompassing the years 2011 to 2017. Bilateral cases were performed in 146 patients (65.6 percent). The majority of the mastectomies were performed by a single breast surgeon (88.6 percent), and the majority were nipple-sparing mastectomies (68.9 percent). A test for trend by the year of surgery revealed that a higher proportion of mastectomies performed in recent years were nipple-sparing (p = 0.024) (Table 1).

Mean age at surgery was 51.9 ± 10.3 years (range, 24 to 79.8 years). Mean body mass index was 25.3 ± 4.9 kg/m² (range, 17.8 to 50.6 kg/m²). Most patients were nonsmokers (91.2 percent). A total of 70 patients (30.8 percent) had received either previous breast radiation therapy or postmastectomy radiation therapy. *BRCA1* or *BRCA2* positivity was noted in 14.5 percent of patients. Mean mastectomy specimen weight was 491.2 \pm 289.9 g (range, 73 to 2001.5 g). Mean implant size was 439.3 ml (range, 150 to 800 ml). The ratio of mastectomy specimen weight to implant volume was 1.1 (Table 2).

A total of 83 complications were experienced by 50 patients. The infection rate was 2.1 percent, and the rate of capsular contracture was 4.8 percent (Table 3). The rate of implant loss (removal without replacement) was 4.5 percent, which included five patients who developed implant exposure (one patient with exposure also developed infection). The rate of implant malposition

Table	1.	Surgical	Details
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Variable	No.	Percent per Patient (227)	Percent per Breast (376)
Laterality			n/a
Unilateral	78	34.4	
Bilateral	149	65.6	
Prophylactic Total	128	56.4	34.0
Type of mastectomy			No. of breasts:
Nipple-sparing	154	67.8	259 (68.9%)
Skin-sparing	73	32.2	117 (31.1%)

n/a, not applicable.

Table 2. Demographics

Variable	No. (%)	
Smoking		
Current smoker	9 (4.0)	
Nonsmoker	207 (91.2)	
Missing	11 (4.8)	
Comorbidities (top 4)		
Hypothyroid/hyperthyroid	37 (16.3)	
Hypertension	37 (16.3)	
Obese (BMI $\geq 30 \text{ kg/m}^2$)	39 (17.2)	
GERD/GI diseases	31 (13.7)	
BRCA1 or BRCA2 positive	33 (14.5)	
Previous XRT	24(10.6)	
Postoperative XRT	46 (20.5)	

BMI, body mass index; GERD, gastroesophageal reflux disease; GI, gastrointestinal; XRT, radiation therapy.

Table 3. Complications

Complications	No. (%)
Capsular contracture	18 (4.8)
Implant removal	17 (4.5)
Necrosis requiring excision	13 (3.5)
Implant exposure	11 (2.9)
Infection	8 (2.1)
Implant malposition	7 (1.9)
Hematoma	5 (1.3)
Seroma	4 (1.1)

was 1.9 percent. Patients who had a history of radiation therapy, patients who received postmastectomy radiation therapy, and patients who were current smokers had a significantly higher rate of capsular contracture (Tables 4 and 5). Patients who received radiation therapy (either previously or postmastectomy) were over 2.5 times more likely to experience complications (Table 6). Representative patients are shown in Figures 1 and 2.

Patients who developed Baker grade 3 or grade 4 capsular contractures were offered revision surgery, and seven revision operations were performed in this group (three flaps, four capsulotomies with implant exchange). An additional six patients elected to undergo revision operations for aesthetic reasons such as rippling of the implants.

The current cost of one 8×16 -cm piece of AlloDerm (Allergan, Inc., Dublin, Ireland) is \$3415. The current cost of one 12×12 -inch sheet of knitted Vicryl mesh is \$710. Total cost savings of using Vicryl mesh instead of AlloDerm during the period of this review (2011 to 2017) was \$1,231,610.

DISCUSSION

Absorbable meshes are a viable alternative to acellular dermal matrices in prosthetic breast

Table 4. Univariates for Any Complication

Variable	þ
Age at surgery	0.468
BRCA1 or BRCA2 positive	0.492
XRT	
Previous or after mastectomy	0.001
Previous only	0.139
After mastectomy only	0.006
Axillary LN dissection	0.029
Sentinel LN biopsy	0.674
Overweight or obese (BMI 25.0–29.9 kg/m ²)	0.830
Obesity class 1, 2, 3 (BMI \geq 30 kg/m ²)	0.301
Obesity class 2 and 3 (BMI $\geq 35 \text{ kg/m}^2$)	0.259
Breast surgeon	0.289
On hormone/endocrine therapy	0.260
Implant size	0.314
Specimen weight	0.766
Chemotherapy	
Preoperative or postoperative	0.163
Preoperative only	0.129
Postoperative only	0.327
Mastectomy type (NSM vs. SSM)	0.544
Smoking	0.410

XRT, radiation therapy; LN, lymph node; BMI, body mass index; NSM, nipple-sparing mastectomy; SSM, skin-sparing mastectomy.

Table 5. Capsular Contracture

Variable	þ
XRT	
Previous or postoperative	0.002
Previous	0.999
Postoperative	< 0.001
Axillary LN dissection	0.027
Smoking*	0.087

XRT, radiation therapy; LN, lymph node.

*Test of trend for capsular contracture and smoking: p = 0.056 (smoking ranked as none/former/current).

Table 6. Independent Predictors for Complications

Variable	OR (95% CI)	þ
Radiation therapy (preoperative or postoperative)	2.58 (1.27-5.23)	0.009
Chemotherapy (preoperative or postoperative)	1.07 (0.50-2.28)	0.861
Current smoker	1.74 (0.40-7.57)	0.461
BMI $\geq 30 \text{ kg/m}^2$	0.59(0.23 - 1.52)	0.275

BMI, body mass index.

reconstruction. The U.S. Food and Drug Administration considers the use of any acellular dermal matrix or mesh to be an off-label use, and surgeons should discuss the risks and benefits with their patients. In addition to reliable and safe results, mesh use is associated with a significant cost savings when compared to acellular dermal matrix. Acellular dermal matrices have been used for prosthetic breast reconstruction since 2005 (both single-stage and two-stage).¹¹ Many studies have outlined the advantages and disadvantages



Fig. 1. Bilateral nipple-sparing mastectomies, immediate reconstruction with implants and Vicryl mesh. (*Left*) Preoperative; (*second from left*) 6 weeks postoperatively; (*second from right*) 1 year postoperatively, after left postmastectomy radiation therapy; (*right*) 3.5 years postoperatively, after left postmastectomy radiation therapy.

of using acellular dermal matrices. The disadvantages include increased incidence of seroma; lack of sterility (acellular dermal matrices are aseptic rather than sterile); and exposure to antibiotics within packaging of acellular dermal matrix, which may result in allergic reaction, increased incidence of infection, and high cost.¹²⁻¹⁵

Although meshes have been in existence for a longer period than acellular dermal matrices, use in prosthetic breast reconstruction has not gained popularity until recently. In 2011, the senior author (W.G.A.) started using Vicryl mesh in single-stage direct-to-implant breast reconstruction. In 2014, he published the first study on the use of Vicryl mesh for single-stage breast reconstruction (50 patients/76 reconstructions), demonstrating a low complication rate, excellent cosmetic outcome, and significant cost savings in comparison to the use of acellular dermal matrix.⁸ This current study shows that there is continued safety and reliability of results with the use of Vicryl mesh in single-stage breast reconstruction.

Additional studies have similar findings to ours regarding the use of Vicryl mesh in prosthetic breast reconstruction. In 2014, Haynes and Kreithen published a study on the use of Vicryl mesh in two-stage prosthetic breast reconstruction (46 patients), showing a low complication rate and cost savings relative to the use of acellular dermal matrix.¹⁶ In 2015, Ganz et al. published a study comparing direct-to-implant reconstruction using either a submuscular pocket (46 breasts) or a partial subpectoral pocket with Vicryl mesh extension (115 breasts), and found that use of absorbable mesh was superior to total submuscular coverage, along with a low complication rate and low revision rate.¹⁷ A systematic review in 2015 of the peer-reviewed literature on breast reconstruction with Vicryl mesh showed a low complication rate and significant cost savings.¹⁸ Recently, prepectoral reconstruction has been performed with nonabsorbable mesh, with success (2018).¹⁹

Comparative studies of meshes used for abdominal wall reconstruction have revealed consistently that Vicryl mesh has the lowest risk

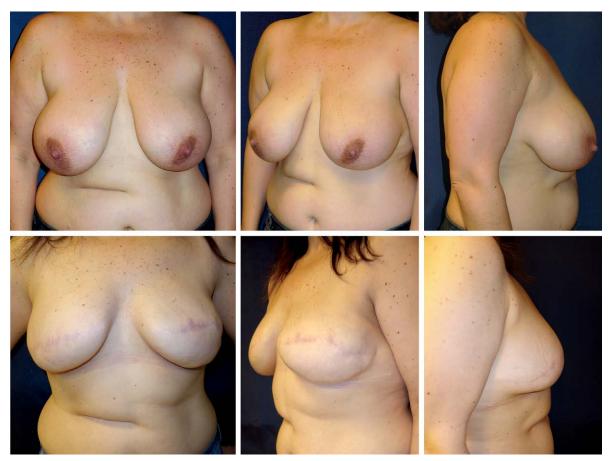


Fig. 2. Bilateral skin-sparing mastectomies; immediate reconstruction with implants and Vicryl mesh. (Above) Preoperatively; (below) 3.5 years postoperatively.

of adhesion formation and foreign body reaction relative to other synthetic meshes such as polypropylene.^{20,21} It may be this property that contributes to the relatively low rate of contracture in prosthetic breast reconstructions with Vicryl mesh.

Complication rate ranges in acellular dermal matrix-assisted breast reconstruction in recent peer-reviewed literature were seroma, 0 to 22 percent; hematoma, 0 to 4.8 percent; infection, 5.3 to 23.8 percent; capsular contracture, 2.7 to 5.2 percent; and implant removal, 1.3 to 18 percent.²²⁻²⁷ The complication rates with the use of Vicryl mesh in prosthetic single-stage breast reconstruction in this study are at the lower end of these ranges. Many studies have shown that radiation therapy either before or after mastectomy is associated with an increased risk of complications, including implant loss and capsular contracture.^{28,29} Our study also found radiation therapy to be an independent predictor of complications. Many patients who have had radiation therapy will go on to have successful implant-based reconstructions, but these results indicate that the risk of complications for this subset of patients is higher, and this increased risk should be communicated to patients preoperatively.

This is the largest long-term study to date on the use of Vicryl mesh in prosthetic breast reconstruction. This study focuses on direct-to-implant subpectoral reconstruction. In 2017, the senior author started using Vicryl mesh for prepectoral reconstruction, and these patients are being followed closely. The use of Vicryl mesh in prepectoral prosthetic breast reconstruction is currently being evaluated in our institution.

> Heather R. Faulkner, M.D., M.P.H. Massachusetts General Hospital 55 Fruit Street WACC 435 Boston, Mass. 02114 Instagram: hrfaulknermd Twitter: BlondeDoc1

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