

Prepectoral Breast Reconstruction with Prosthesis and Acellular Dermal Matrix: A New Technique of ADM Implantation and Fixation

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Background: Direct-to-implant (DTI) immediate breast reconstruction has proven to be an oncologically safe technique and linked to better overall results. The introduction of new surgical techniques has prompted us to develop an acellular dermal matrix fixation technique that reduces the rate of complications and implant loss.

Methods: We retrospectively analyzed data from patients who underwent DTI prepectoral breast reconstruction with two different techniques of acellular dermal matrix fixation to the chest wall. Descriptive statistics were reported using frequencies and percentages for categorical variables, and means and SDs for continuous variables. Pearson chi-square test was used to compare differences in categorical variables. Univariable and multivariable logistic regression models were fitted to investigate the predictors of complications.

Results: From October 2019 to March 2023, 90 DTI breast reconstructions were performed, 43 using the standard technique and 47 using the new technique. The new technique demonstrated a significant reduction of major complications ($P = 0.010$), namely seroma (13.9% versus 2.3%), skin necrosis (9.3% versus 2.3%), implant loss (7% versus 0%), wound dehiscence (9.3% versus 0%), and infection (4.7% versus 0%). Compared with the standard technique, the new one reduced the risk of complications by 76% (OR 0.24; 95% confidence interval 0.09–0.68; $P = 0.007$) and 73% (aOR 0.27; 95% confidence interval 0.08–0.92; $P = 0.037$), at univariable and multivariable regression models. No other significant predictor of complications was identified.

Conclusions: The procedure performed with the proposed modality proved to be advantageous. Careful fixation of the prosthetic implant and the placement of two drains, were the keys to a drastic reduction in complications. (*Plast Reconstr Surg Glob Open* 2024; 12:e5895; doi: [10.1097/GOX.0000000000005895](https://doi.org/10.1097/GOX.0000000000005895); Published online 14 June 2024.)

INTRODUCTION

Since the 1960s, various methods of heterologous breast reconstruction have evolved, achieving commendable results in both aesthetics and safety.^{1,2} In 1971,

Snyderman and Guthrie³ introduced a subcutaneous placement of silicone breast implants, deviating from the traditional subpectoral position.^{4,5} This approach preserved the anatomical integrity of the pectoralis major muscle, resulting in a natural-looking breast profile. Despite its early adoption, the technique was abandoned due to issues like capsular contracture, implant exposure, and prosthesis malposition.⁶

Renewed interest in the prepectoral approach emerged with advancements in surgical techniques and prosthetic devices. Modern mastectomies, ranging from radical to skin-sparing, have become less aggressive, emphasizing perfusion and viability assessment. The use of acellular dermal matrices (ADMs) in the two-plane approach suggested the potential for total implant coverage without elevating the pectoralis major muscle. Prepectoral breast

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reconstruction and ADM use have evolved into a safe and effective method, associated with minimal morbidity and satisfactory cosmesis.⁷ The ADM Braxon, a collagen membrane developed for breast reconstruction,⁸ exhibits tissue-specific properties, preventing rejection, reducing dead space, managing weight distribution, and preventing skin necrosis.⁹ Fixation of the ADM is crucial for stability and adequate contact between the matrix, and the skin graft is vital for revascularization, recellularization, and matrix incorporation into the host tissue. Our study explores two techniques for ADM fixation and positioning, comparing complication rates and outcomes to provide valuable insights into the effectiveness and safety of these procedures.

METHODS

This study encompasses all patients undergoing immediate prepectoral reconstruction with ADM Braxon at the University Hospital Trust of Sassari, Italy, spanning from October 2019 to March 2023. The cohort is categorized as follows: two implants in 2019, eight implants in 2020, 31 implants in 2021, 21 implants in 2022, and 28 implants in 2023. Breast surgeons performed all mastectomies, whereas plastic surgeons conducted immediate reconstructions. Patients were thoroughly informed about prosthesis use, indications, and potential complications, with written informed consent obtained. Preoperative assessments included routine blood tests and cardiac examinations. Inclusion criteria comprised neoplasia less than 5 cm, a neoplastic mass distance more than 0.5 cm from the pectoral muscle, no skin or chest wall invasion, no history of previous breast radiotherapy, body mass index (BMI) less than 35, controlled diabetes, well-preserved subcutaneous layer, and a well-perfused mastectomy skin flap. Beyond reconstructive considerations, oncological factors played a pivotal role. Patients with large tumors (>5 cm), tumors close to the pectoralis major muscle (<0.5 cm), chest wall involvement, axillary involvement, advanced breast cancer, and a high risk of recurrence were not suitable for prepectoral positioning. The oncological safety of this approach in such cases remains unknown, with aggressive adjuvant therapies in advanced cases potentially precluding immediate reconstruction. In the absence of contraindications, a preliminary assessment of patient suitability was conducted in all cases. Measurements were taken on the day before surgery to guide the reconstruction process.^{10,11} After mastectomy, intraoperative assessment of flap viability was crucial, requiring close collaboration with the breast surgeon. Only well-perfused skin flaps allowed for immediate prepectoral reconstruction. Flap viability assessment involved clinical and instrumental methods.¹² Clinically, a well-perfused flap exhibited bleeding incision margins and approximately 0.6-cm thickness of subcutaneous tissue. The “pinch test” and instrumental assessments,¹³ including angiography, were also used to evaluate skin thickness and vascularization in real time.^{14,15} Mastectomy flap thickness and vascularization were fundamental criteria for prepectoral reconstruction, and after confirmation of good perfusion and flap viability,

Takeaways

Question: What complications does the new ADM fixation technique prevent in prepectoral breast reconstruction?

Findings: This retrospective study analyzed 90 cases of direct-to-implant prepectoral breast reconstruction, comparing standard and novel acellular dermal matrix fixation techniques. The new technique demonstrated a significant reduction in major complications, including seroma, skin necrosis, implant loss, wound dehiscence, and infection, when compared with the standard method. Logistic regression models revealed a 76% overall risk reduction in complications with the novel ADM fixation technique, emphasizing its substantial benefits in enhancing patient outcomes and minimizing postoperative challenges.

Meaning: The study highlights a superior acellular dermal matrix fixation technique in prepectoral breast reconstruction, significantly reducing complications and improving patient outcomes.

assessment of internal dimensions determined the final implant size.^{16–21} Achieving a complete fit between the implant and the periprosthetic space was crucial.²² Implant size considerations aimed to prevent dead space, seroma formation, and complications like rippling, wrinkling, and skin necrosis.

PREPECTORAL RECONSTRUCTION PROCEDURE AND DIFFERENCES FROM PREVIOUS TECHNIQUE

Following mastectomy and a thorough assessment of flap thickness and viability through visual examination, pinch test, and indocyanine green angiography (Fig. 1), the prosthetic implant preparation process was initiated. The mastectomy gland's weight served as a crucial parameter in implant size determination. Implants exceeding 500–550 g were associated with increased complications and suboptimal aesthetics. Patients with breasts exceeding 500 g were advised to consider contralateral breast reduction to avoid implants surpassing the aforementioned weight limit. Selection of the implant type and size involved consideration of patient preferences, breast and chest wall measurements, as well as gland width, height, and projection. Several sizers were considered, and the chosen prosthesis was inserted into the pocket with the patient in a semiseated position, to achieve the goal of symmetry with the contralateral breast. After selecting the final implant, complete sterility was maintained during the membrane handling to prevent infection risks. A suction drain was placed, and the pocket was irrigated with saline solution and H₂O₂. The Braxon membrane was designed to cover the anterior projection of the implant. Before implantation, the porcine collagen matrix was rehydrated with sterile saline solution for approximately 5 minutes, enhancing its adaptability and minimizing the formation of pinches and empty spaces. Antibiotic solutions can be used for ADM soaking, serving as an adjunct to systemic

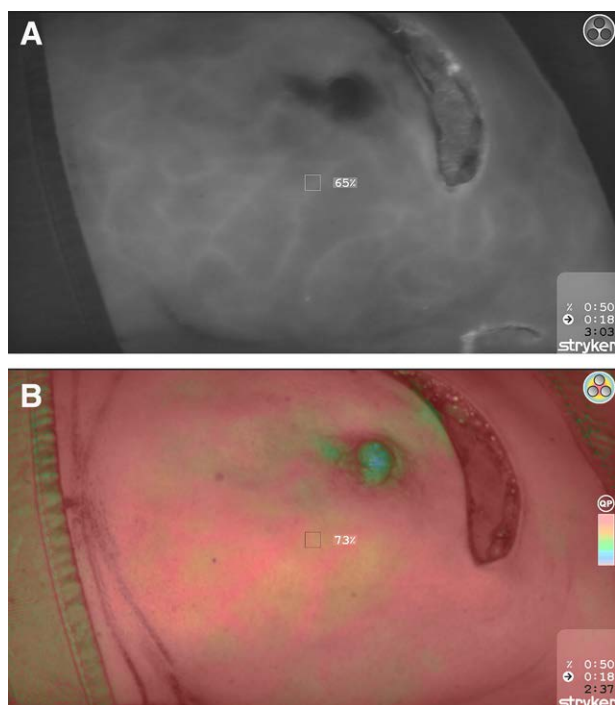


Fig. 1. Preoperative assessment of the viability of the mastectomy flaps with the indocyanine green angiography. A, Black-and-white view. B, Color view.

antibiotic prophylaxis. The standard technique entailed the placement of the ADM within the prepectoral pocket, followed by the subsequent insertion of the prosthesis into the ADM, which was secured with sutures. However, this method led to inadequate adherence between the prosthesis and the ADM. A novel approach has been implemented, concealing the prosthetic implant within the dermal matrix and securely attaching it to the prepectoral pocket. The matrix was stitched with interrupted absorbable sutures (Vicryl 2/0) where overlapping flaps matched, minimizing dead space between the ADM and the prosthesis, and reducing the risk of complications. [See Video (online), which displays how the matrix was stitched with interrupted absorbable sutures (Vicryl 2/0) with matching overlapping flaps, minimizing dead space between the ADM and the prosthesis.] Excess matrix was trimmed after suture completion.⁵ The implant and overlying matrix were then ready for insertion into the pocket, emphasizing extensive and stable contact between the matrix and healthy vascularized tissue. The membrane was secured to the pectoral and serratus muscle and fascia with numerous stitches (usually 12–15 Vicryl 2/0 stitches), leaving at least 1 cm between stitches (Figs. 2 and 3). Before skin closure, subcutaneous tissue and matrix were sutured together to ensure proximity and stability. The anterior face of the membrane was secured to the subcutaneous tissue of the mastectomy flap with two or three stitches (Fig. 4). This method is not reliant on the Braxos ADM and can be applied to other ADMs or mesh constructs that are shell-shaped with anterior-posterior coverage. Postoperatively, patients were advised to wear a surgical supportive bra

for at least 30 days to maintain breast stability and promote continuous contact between the matrix and tissues for optimal implant integration. Arm movements on the operated side were restricted for 7–15 days to minimize postoperative serum production and facilitate a smoother recovery. Differences in postoperative care were notable compared with previous techniques. Continuous monitoring of serum production was crucial, with drains removed when the collection was consistently less than 30 mL for 2 consecutive days. Patients were typically discharged with drains in place for 3–5 days after surgery. Follow-up appointments occurred at 1, 3, and 6 months postoperative, with adjustments made based on individual recovery progress and intervening complications (Fig. 5).

STATISTICAL ANALYSIS

A statistical analysis was conducted to assess the relationship between surgical techniques and the occurrence of complications. The contingency table (Table 1) illustrates the distribution of cases based on whether complications occurred or not for each surgical technique. For the standard technique, out of 35 cases, 17 had no complications, and 18 had complications. For the new technique, out of 39 cases, 31 had no complications, and eight had complications. The overall total of patients was 74, with 48 having no complications and 26 experiencing complications. A Pearson chi-squared test was performed, yielding a chi-squared statistic of 7.7359 with a corresponding *P* value of 0.005, indicating a statistically significant relationship between the surgical technique choice and complications. A second statistical analysis examined the relationship between the two techniques and the occurrence of complications categorized into minor and major complications according to the Clavien-Dindo classification.²³ The contingency table (Table 2) demonstrates the distribution of cases for each combination of technique and complication type. A Pearson chi-squared test yielded a statistic of 9.2831, with a corresponding *P* value of 0.010, suggesting a statistically significant association between surgical technique and complication type. Comparing the standard technique with the new technique, the latter reduced the risk of complications by 76% [OR 0.24; 95% confidence interval (CI) 0.09–0.68; *P* = 0.007] and 73% (aOR 0.27; 95% CI 0.08–0.92; *P* = 0.037) in univariable and multivariable regression models, respectively. No other significant predictors of complications were identified (all *P* > 0.05). A univariable logistic regression analysis investigated the relationship between ADM fixation technique and complications (Table 3), revealing a statistically significant association (LR χ^2 = 7.87, *P* = 0.005). The odds ratio for the standard technique was 0.2437 (*P* = 0.007), indicating its significant association with complications. A multivariable logistic regression analysis (Table 4), considering factors like the operator's technique, number of implants, age, and BMI, produced a nonstatistically significant model (LR χ^2 = 5.70, *P* = 0.2227). The operator's technique had a statistically significant odds ratio of 0.2664 (*P* = 0.037), and other variables did not significantly predict complications. In summary, the operator's choice of technique emerged as a significant predictor of complications,

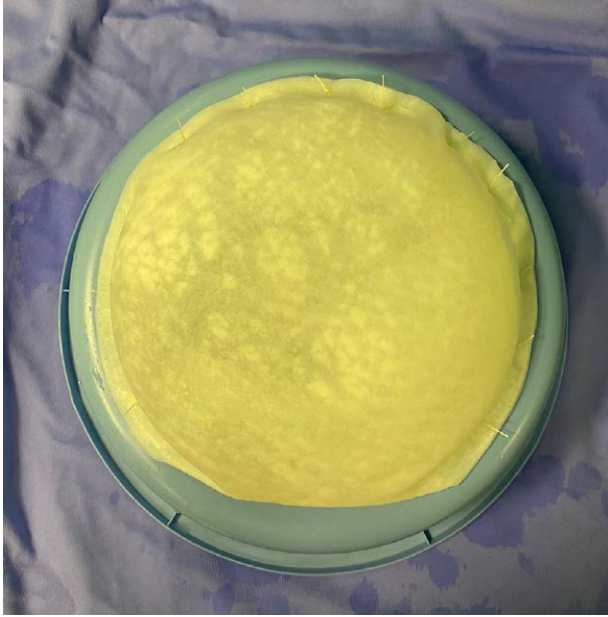


Fig. 2. The membrane was secured to the pectoral muscle in the superior pole with numerous stitches (usually 12–15 Vicryl 2/0 stitches).

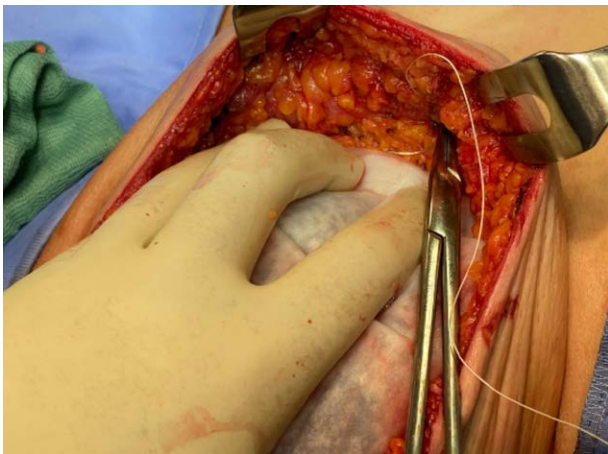


Fig. 3. The membrane was secured to the pectoral muscle and the fascia with numerous stitches (usually 12–15 Vicryl 2/0 stitches) leaving at least 1 cm between stitches.

and other variables such as the number of implants, age, and BMI did not significantly contribute to complication prediction in this analysis.

RESULTS

From October 2019 to March 2023, our plastic surgery unit conducted a total of 90 immediate reconstructions utilizing the prepectoral technique along with ADM. Of these, 43 implants were placed following the conventional method, whereas the remaining 47 implants were placed using the recently introduced fixation technique. The mean patient age was 55.44 years (SD 11.93), and the mean BMI was 24.02 (SD 3.81). The mean prosthesis

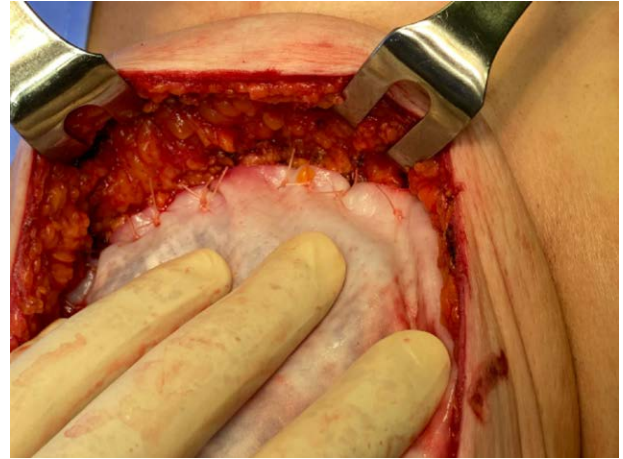


Fig. 4. The anterior face of the membrane was secured to the subcutaneous tissue of the mastectomy flap with two or three stitches.

size was 345 mL, with implants ranging from 150 mL to 560 mL. The most common complications before the use of the new fixation technique were seroma (13.9%), skin necrosis (9.3%), implant loss (7%), wound dehiscence (9.3%), and infection (4.7%). Since the introduction of the new technique, complications have decreased dramatically. No implants were removed following the introduction of the new fixation technique. Complications encountered after introducing the new technique were one case of seroma and one case of nipple necrosis, which resolved after 40 days, three cases of rippling and two cases of wrinkling with contralateral breast asymmetry. In comparison with the standard surgical technique, the new surgical approach demonstrated a significant reduction in the likelihood of complications, with a risk decrease of 76% as indicated by the odds ratio (OR 0.24; 95% CI 0.09–0.68; $P = 0.007$) in the univariable regression model. This relationship persisted in the multivariable regression model, with a 73% reduction in risk (aOR 0.27; 95% CI 0.08–0.92; $P = 0.037$). Additionally, in the analysis, no other factors were found to be statistically significant predictors of complications (all P values > 0.05). This suggests that the choice of surgical technique remains the primary and most influential determinant of complications, whereas other variables under consideration did not exhibit a significant impact on the likelihood of experiencing postoperative complications.

DISCUSSION

Immediate breast reconstruction following mastectomy is a widely accepted and beneficial treatment for women requiring mastectomy, offering improved quality of life, low morbidity, and oncological safety.²⁴ Patients undergoing immediate reconstruction experience enhanced health-related quality of life, comparable clinical outcomes, and similar patient-reported outcomes when compared with two-stage expander/implant reconstructions.^{25,26} This method is associated with a higher satisfaction rate and better aesthetic results, making it preferable for

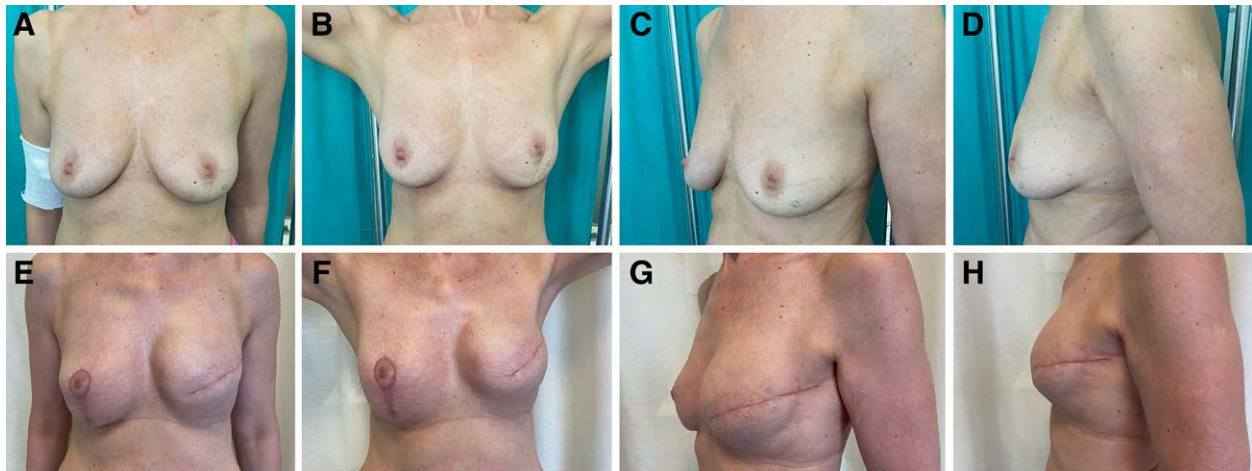


Fig. 5. A 62-year-old patient who underwent left skin-reducing mastectomy and direct-to-implant reconstruction with ADM and prepectoral positioning of the implant, and contralateral breast reduction. A–D, Preoperative images. E–H, Postoperative photographs.

Table 1. Statistical Analysis to Assess the Relationship between the Surgical Techniques and the Occurrence of Complications

Technique	No. Patients	Complications		
		No	Yes	Total
Standard	43	17 35.42%	18 69.23%	35 47.30%
New	47	31 64.58%	8 30.77%	39 52.70%
Total	90	48 100.00%	26 100.00%	74 100.00%

Pearson $\chi^2(1) = 7.7359$ Pr = 0.005

The contingency table illustrates the distribution of cases based on whether complications occurred or not for each surgical technique.

Table 2. Statistical Analysis to Examine the Relationship between the Two Techniques and the Occurrence of Complications According to the Clavien-Dindo Classification

Clavien-Dindo	Technique		
	Standard	New	Total
No complications	17 48.57%	31 79.49%	48 64.86%
Minor complications	11 31.43%	7 17.95%	18 24.32%
Major complications	7 20.00%	1 2.56%	8 10.81%
Total	35 100.00%	39 100.00%	74 100.00%

Pearson $\chi^2(2) = 9.2831$ Pr = 0.010

The contingency table demonstrates the distribution of cases for each combination of technique and complication type.

eligible patients.²⁷ Ideal candidates for immediate reconstruction using the prepectoral technique are those with a normal BMI, small or medium-sized breasts, few comorbidities, and well-perfused mastectomy flaps. Although slight deviations in BMI or breast hypertrophy are not absolute contraindications, they can increase surgery difficulty and postoperative complications.²² Our study focuses on demonstrating the reduced rate of postoperative

complications with our new technique of implant and membrane positioning. The results show a significant reduction in complications; however, it is crucial to acknowledge potential drawbacks and address complications effectively for optimal outcomes. Seroma was significantly improved (2.3% incidence with our new technique) by anchoring the dermal matrix securely to avoid dead spaces, maintaining sterility, performing antibiotic irrigation, placing drains intraoperatively and leaving one drain for at least 14 days, applying compression bandages, and limiting postoperative arm movement. Caputo et al.²⁸ used the Braxton standardized wrapping technique to conduct a comprehensive study on the occurrence of seroma in ADM-assisted prepectoral breast reconstruction. Based on their analysis of scientific evidence up to 2021, they found that prepectoral breast reconstruction with complete ADM-implant coverage had an overall seroma incidence of 4.9%, which falls within the acceptable 5% complication threshold in clinical practice. Hematoma occurrence was minimal with the standard technique (23%) and absent with our new ADM fixation technique, aligning with low rates reported in other direct-to-implant procedures.²⁹ Infection rates were 4.7% with the standard method, but no cases occurred with our new technique, a notable difference with the experience of Urquia et al, in which infection was the most common reason for reoperation,

Table 3. Univariable Logistic Regression Analysis Investigating the Relationship between the ADM Fixation Technique and the Occurrence of Complications

Variable	No. Patients	Odds Ratio	P	95% Confidence Interval
New surgical technique	47	0.24	0.007	[0.09, 0.68]

Table 4. Multivariable Logistic Regression Analysis Examining the Relationship between Several Factors, Including the Operator's Choice of Technique, the Number of Implants, Age and BMI, and the Occurrence of Complications

Variable	Odds Ratio	P	95% Confidence Interval
Surgical technique			
Old (43 patients)	1.00	(base)	(base)
New (47 patients)	0.27	0.037	[0.08–0.92]
No. implants (monolateral-bilateral)			
Monolateral (64 patients)	1.00	(base)	(base)
Bilateral (13 patients)	0.63	0.543	[0.14–2.79]
Age	1.00	0.878	[0.95–1.05]
Body mass index	1.12	0.176	[0.95–1.32]

occurring in 7.65% of all breasts.³⁰ While the new technique demonstrated overall improvement, matrices have been associated with a higher rate of rippling and wrinkling, observed as a late complication. Patients experiencing grade 2 and 3 rippling were successfully treated with lipofilling, using harvested fat from different body areas.³¹ Follow-up and lipomodelling procedures are essential for managing cosmetic expectations.³² Understanding and optimizing the integration process of breast matrices is crucial for reducing complications. In our unit, we use Braxon ADM, a dermal matrix that mimics the structure and composition of breast subcutaneous tissues, inducing remodeling processes, promoting cellular infiltration, physiological degradation, inflammation modulation, deposition of a new extracellular matrix, and neovascularization.³³ The difference between the technique proposed in this article and others, including those previously used in our unit and those described in the literature, is the standardization of certain cornerstones, including the maintenance of drainage in situ for 14 days, and the maximum number of stitches, both at the stage of packing the prosthetic implant and at the stage of fixation. The standard approach for Braxon prepectoral breast reconstruction was first described by Berna et al³⁴ using implants ranging from 150 to 450 mL and comparing a rectangular piece of 0.9 mm-thick porcine ADM with a 0.6 mm-thick Braxon ADM. Their technique involved suturing the edges of the ADM and tightly wrapping the breast implant. The prosthesis was placed in the breast pocket and secured with absorbable sutures above the pectoralis major muscle, with drains in place for 7–15 days. In comparison with the Berna et al technique, our novel approach significantly reduces complications ($P = 0.010$), including seroma (13.9% to 2.3%), skin necrosis (9.3%–2.3%), implant loss (7%–0%), wound dehiscence (9.3%–0%), and infection (4.7%–0%). Braxon-assisted prepectoral breast reconstruction is mainly indicated for skin- and nipple-sparing mastectomy, but evidence supports its use in skin-reducing mastectomy with modified surgical techniques. Our approach involves anchoring the matrix to surrounding tissues and a dermal flap, minimizing the risk of seroma and dead spaces. In

2019, Onesti et al³⁵ introduced a technique involving Braxon-covered implants positioned above the pectoralis muscle, covered by a dermal flap. The anterior fascia of the pectoralis major was sutured to the ADM using resorbable sutures, defining the inframammary fold. Closure of the pocket attached the dermal flap to the muscle and serratus anterior fascia, creating a simulated natural bra. An inverted-T incision closed the skin after drain insertion. For enhanced stability, the matrix was anchored with one to two stitches to the dermal flap, reducing the risk of seroma and dead spaces. Moreover, Onesti et al³⁵ placed one vacuum drain in the inframammary fold and removed it when the fluid collected was below 30 mL in 24 hours. Other surgeons, including Maruccia et al,³⁶ have applied similar methods, using quilting sutures between the ADM and dermal flap. They used absorbable sutures superiorly and a dermal sling inferiorly, unlike our approach, where the inferior pole is not sheltered by a dermal sling. Instead, we directly suture the inferior portion of the ADM to the anterior dermal flap. Additionally, they inserted two suction drains in subcutaneous and axillary pockets for lymph node dissection, removing them when drainage is below 20–25 mL per day for 2 days. In 2020, Cuomo et al³⁷ introduced a novel intraoperative approach to enhance aesthetic outcomes in prepectoral reconstructions. For patients undergoing nipple- or skin-sparing mastectomy, they created a concave croissant-shaped marking in the upper breast pole. The gland was detached, preserving about 1 cm of tissue and 2 cm of subcutaneous fat in the marked area to enhance upper pole fullness. Using a Braxon-wrapped prosthesis, the procedure achieved superior breast contour and definition compared with traditional methods. The technique by Cuomo et al is applicable with specific criteria, such as cancer localization in the lower pole and adequate fat in the upper pole, though our center typically opts for mastectomy for oncological safety, leaving a thin anterior dermal sling (<2 cm). Vidya et al³⁸ used a distinctive approach, incorporating two windows in the posterior side of the ADM to facilitate seroma drainage and prevent pocket accumulation. In contrast, we focus on minimizing seroma complications by maximizing contact

between the matrix graft and host tissue, reducing sliding movements. Furthermore, only one drain was applied, and discontinued if the daily output remained below 20 mL for a consecutive 48-hour period, deviating from our originally suggested 14-day timeframe with the new technique. Compared with submuscular plane implant positioning and microsurgical options, prepectoral breast reconstruction seems to be faster, easier, and equally safe, and recovery seems to be less painful for our patients. Cattelani et al³⁹ compared prepectoral ADM-wrapped implant reconstruction to subpectoral or tissue expander reconstruction. Immediate breast reconstruction by using prepectoral muscle-sparing ADM resulted in lower pain intensity and significant upper limb functional advantages compared with submuscular placement. Over recent years, prepectoral reconstruction regained a new life, and it represents the first option in many breast units for selected patients.^{40–42} The main limitation is the cost of ADMs, but the advantages are clear, and the results obtained using our new standardized technique provide excellent evidence to consider.

CONCLUSIONS

Immediate prepectoral reconstruction utilizing our novel ADM fixation technique exhibited a notable decrease in the incidence of complications when compared with our conventional surgical method. Our findings strongly support the efficacy of the proposed approach and the importance of precise ADM fixation, prolonged drain management, and a postoperative resting period of 30 days. This underscores the importance of surgical innovation aimed at mitigating complications and optimizing patient outcomes.

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DISCLOSURE

The authors have no financial interest to declare in relation to the content of this article.

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