

A Pericardium Bovine Matrix Pocket in DTI Prepectoral Breast Reconstruction

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Abstract

One of the recent advancements in breast reconstruction is the use of prepectoral implants in combination with synthetic and biological material as a natural and effective coverage. To date, there is little published data on breast reconstruction using acellular bovine pericardium matrix and most concern submuscular breast reconstruction. This study aimed to describe the multicentric-multisurgeon experience in performing direct to implant (DTI) prepectoral breast reconstructions using acellular bovine pericardium matrix (ABPM) pocket. A total of 65 breast reconstruction were included in the study. A total of 65 breast reconstruction were included in the study.

Breast reconstructive surgery has evolved significantly over the years. One of the recent advancements is the use of prepectoral implants in combination with synthetic and biological material as a natural and effective coverage. To date, there is little published data on breast reconstruction using acellular bovine pericardium matrix and most concern submuscular breast reconstruction. This study aimed to describe the multicentric-multisurgeon experience in performing direct to implant (DTI) prepectoral breast reconstructions using acellular bovine pericardium matrix (ABPM) pocket. A retrospective multicentric data collection of the all the immediate prepectoral breast reconstructions using acellular bovine pericardium was carried out by the authors. Surgical data including type of mastectomy, axillary surgery, type and size of implant, size of ABPM, duration of surgery were collected for each patient. Postoperative data including adjuvant treatments, complications, necessity to perform other interventions, patient's satisfaction were collected. Cosmetic results were also evaluated by 7 different observers at minimum 1 year follow-up. A total of 65 breast reconstruction were included in the study. Mean follow up was 21.3 months. Average surgical time was 1,42 hours. Minor complications occurred in 4 breasts; major complications occurred in 2 breasts. After 6 months follow-up, 7 patients underwent fat grafting to correct any rippling and /or wrinkling. Breast aesthetic and patients reported outcomes were satisfactory. Not significant capsular contracture was noted at the follow up control. To date, this is the largest study about prepectoral breast reconstruction with ABPM. On the basis of our results, prepectoral breast reconstruction ABPM assisted is a reliable, safe and suitable option providing good patient satisfaction outcomes.

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Introduction

Breast reconstructive surgery has evolved significantly over the years, offering more options and improved outcomes for women

who have undergone mastectomies or who require postreconstruction revision surgery.^{1–3} One of the recent advancements in breast reconstruction is the use of prepectoral implants in combination with synthetic and biological material (acellular dermal Matrix [ADM] and bovine pericardial membranes) as a natural and effective coverage.^{4–6} This innovative approach, not only enhances the aesthetic results, but also provides a safe and biocompatible solution for women seeking breast reconstruction.⁵

Traditionally, breast implants for reconstruction were placed in a submuscular position, beneath the chest muscles. However, this approach often led to discomfort, pain, and animation deformities when the muscles contract.⁷ Prepectoral breast reconstruction, on the other hand, involves placing the implants above the chest

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muscles, directly under the skin and subcutaneous tissue. This technique has gained popularity because it offers several advantages: leading to reduced postoperative pain and a quicker recovery, offers a more natural-looking breasts with improved contour and projection and avoid the risk of animation deformities.⁸

Bovine pericardial membranes, sourced from cattle, have become a valuable tool in this new breast reconstructive setting, proving to be highly biocompatible.⁹ They integrate with the patient's own tissues, providing an additional layer of protection for the implants, reducing the risk of implant visibility and palpability.^{6,9} Moreover, some studies suggest that using bovine pericardial membranes may help reduce the risk of capsular contracture and discomfort.⁶

To date, there is little published data on breast reconstruction using acellular bovine pericardium matrix and most are monocentric studies. Moreover, the studies almost entirely concern submuscular breast reconstruction. We recently published a large case series of prepectoral breast reconstruction using polyurethane foam-covered implant reporting good aesthetic outcomes, elevated self-reported patients' satisfaction and low complications rate.¹⁰ This study aimed to describe the multicentric-multisurgeon experience in performing prepectoral breast reconstructions using acellular bovine pericardium matrix (ABPM). In detail, we analyze the outcomes in terms of complications, aesthetic results and patient reported outcomes.

Material and Methods

A retrospective multicentric data collection of the all the nipple sparing, skin sparing and wise pattern (WP) mastectomies combined with prepectoral breast reconstructions using ABPM performed between July 2019 and January 2023 was carried out by the authors.

This study followed the Declaration of Helsinki on medical protocols and ethics, and the ethical review board of all the institutions involved in the study had already approved the use of acellular bovine pericardium matrix for breast reconstruction. A written informed consent with information concerning its complication rates, advantages and disadvantages was given to all patients. The study has been reported in line with STROBE guidelines.¹¹

Patients' Selection

Inclusion criteria include:

- (1) immediate prepectoral breast reconstruction after nipple sparing, skin sparing or WP mastectomies.
- (2) cancer or risk-reducing surgery.

Exclusion criteria include:

- (1) radical mastectomies.

History of preoperative radiation or previous breast surgery were not considered as exclusion criteria.

Patients expected to receive postoperative radiation therapy were not excluded from the study.

Collected Data

Preoperative. Demographic data (eg, age, body mass index), medical history (eg, smoking, diabetes, hypertension, preoperative chemotherapy, radiation therapy or breast surgery).

Intraoperative. Surgical data including type of mastectomy, axillary surgery, type and size of implant, size of ABPM, duration of surgery were collected for each patient.

Postoperative. Postoperative data including adjuvant treatments, complications, necessity to perform other interventions, patient's satisfaction were collected.

Complications were listed as minor or major, early and late. Minor complications were defined as those events that could be treated conservatively; major complications were defined as those events that required additional surgical intervention. Early complications were defined as those events that developed < 3 months after surgery, late complications were defined as those events that developed > 3 months after surgery.

Cosmetic results were evaluated by 7 different observers (5 plastic surgeons, 2 nurses blinded with surgical details) with frontal, lateral, 3/4 left and 3/4 right views of photographs at minimum 1 year follow-up. Breast shape and breast symmetry were considered.

The observers reviewed the photographs and scored the results on a 5-point Likert scale¹² that ranged from "poor result" (1) to "excellent result" (5). A mean score greater than 4 was considered as a satisfactory result.

Patient's satisfaction was measured using BreastQ¹³ ("satisfaction with breast"-"satisfaction with outcome" domains). Patients were invited to complete a postoperative BREAST-Q questionnaire at 1 year follow-up. BREAST-Q outcome (satisfaction with breasts, satisfaction with outcome, psychosocial well-being, sexual well-being, physical well-being) were analyzed using the Q-Score Scoring Software package. Analysis of variance and Chi-square was used to analyze differences in patients' characteristics and postoperative outcomes between the different surgical groups.

Surgical Technique

We used an ABPM extracted from solvent preserved bovine pericardium (Exashape, Bioshield Pocket®). It is a thin (0.5 mm) fenestrated product composed of bi-layer noncrosslinked acellular collagen matrix of bovine pericardium.

Intravenous perioperative antibiotics were used for all patients according to guidelines.¹⁴ Before insertion, ABPM was hydrated in 0.9% normal saline.

We utilized 1 single thread (Vicryl 0/0) crossing sides behind the implant in order to secure the wrapping. Care must be taken in order to choose a long thread. Our favorite choice is Vicryl 0/0 70 cm. The implant wrapping was performed on a back table simultaneously with hemostasis, drain positioning and disinfection of the surgical site in order to minimize operative time.

The ABPM-implant is then inserted in the prepectoral pocket making sure the point of maximal projection is in proper position (nipple areola complex). A trick to aim the perfect positioning of the ABPM-implant is to mark the midline of the prosthesis directly on the ABPM with the marking pen allowing the proper orientation.

Position of the drains at inframammary fold were verified.

In case of WP mastectomy a dermic flap is always harvested to improve the inferior coverage of the ABPM-implant.

The drains were removed when output was less than 50 mL in 24 hours.

Table 1 Demographic Features of Patients

Variable	Value (n°)	Value (%)
Age		
0-49	20	43.4
50-69	24	52.1
> 70	2	4.3
BMI		
< 18	1	2.1
18 - < 25	39	84.7
25 - < 30	5	10.8
≥ 30	1	2.1
Comorbidity		
Ischemic heart disease	-	
Diabetes	1	2.1
Arterial hypertension	3	6.5
Dyslipidemia	5	10.8
Active smoker	11	23.9
Previous RT	6	13.04
Previous breast surgery	9	19.5
Previous axillary surgery	9	19.5

Results

Between January 2019 and January 2023, a total of 65 breast reconstruction using APBM (46 patients) were included in the study. Mean follow up was 21.3 months (12-53)

Preoperative (Demographics)

Mean age at the time of surgery was 50.5 years (26-73 years) and mean BMI was 23.5 kg/m² (17.8-32.5 kg/m²). Table 1 reports demographic characteristics of patients and data about medical history.

The 86.9 % of patients (40) underwent nipple-sparing mastectomy (NSM) and 10.8% of patients (5) received skin sparing or skin-reducing mastectomy (SSM/SRM). One patient was included in the series at the time of the prepectoral transposition, after previously submuscular reconstruction with tissue expander.

Intraoperative

The 69.6 % of patients (32) underwent therapeutic mastectomy, 84.3 % of these (27) for primary breast cancer, 15.6% of these (5) for post quadrantectomy recurrence. Axillary surgery was combined in 30.4 % cases (14), 92.5% of these (13) in the form of sentinel lymph node biopsy and 7.5% of these (1) as axillary dissection. In 30.4% of cases (14) a prophylactic mastectomy was performed for BRCA 1 to 2 mutation carriers, 2 of whom underwent simultaneous risk-reducing salpingo-oophorectomy. Contralateral breast simmetrization was performed in 2 cases.

Average surgical time was 1.42 hours. Once prepectoral pocket was prepared, mean surgical time of implant-ABPM positioning was 3 minutes. A meshed bilayer bovine pericardium membrane in the medium sized (20 cm x 16 cm x 0.5 mm) Exashape™ Bioshield Pocket configuration (Advanced Biomedical Concept Srl) was used in all cases, as a covering for anatomical microtextured implants (Mentor MemoryShape Johnson & Johnson Medical S.P.A

and POLYTECH Health & Aesthetics, Dieburg, Germany) of low (24.4 %), moderate (52.3 %) and high (19.7 %) projection. The average volume of the definitive implant was 311 cc (215-605 cc).

When SRM is indicated and the implant volume adopted is larger than 450 cc. In order assure a complete anterior implant's coverage, an useful trick is to split the pocket along the inferior midline and inset the inferior dermal flap in the space created by the division (Figure 1). In this way the inferior part of the pocket opens up, thus enabling the projection of the implant to fully recreate the lower pole.

Postoperative

The mean hospital stay was 3.3 days (2-5 days). Drains from the reconstructed breast area were removed after 11.6 days on average (7-22 days).

Minor complications occurred in 4 breasts (listed in Table 2), all presented as early complications. Major complications occurred in 2 breasts (listed in Table 2). Two patients showing wound dehiscence were smokers. One patient underwent implant removal and autologous tissue reconstruction with transverse upper gracilis due to full thickness necrosis, wound dehiscence and implant exposure. This patient underwent previous breast conserving surgery and radiotherapy. One patient underwent implant removal due to infection. Table 3 shows the association between complications and risk factors.

After 6 months follow-up, 7 patients underwent fat grafting to correct any rippling and/or wrinkling.

With respect to breast aesthetic results evaluated by 7 observers using the 5-point Likert scale, mean score for score for breast shape was 4.18 (3.14-4.72), and mean score for breast symmetry was 4.15 (3.14-4.62). Figure 2, 3 and 4 show postoperative results at > 1 year follow-up.

Not significant capsular contracture (Backer III-IV) was noted at the follow up control.

Patients showed high satisfaction as expressed by BREAST-Q scores (details in Table 4). After > 1 year follow up, the scores demonstrate good results, all well above the average of 50 (scores 0-100), except for the "Sexual well-being" domain, which is just below.

Discussion

The use of ABPM in breast reconstruction is a relatively recent option and it represents an effective alternative to the use of ADM. However, there is still little data in literature and the number of studies published on ADM outpace that on ABPM.

Moreover, to date, the majority of the studies about ABPM describes cohort of patients undergoing retromuscular breast reconstruction. Modif et al.,¹⁵ published in 2012 a retrospective study analyzing data about 54 subjects undergone 2 stage or 1 stage breast retromuscular reconstruction using Veritas bovine. Gubitosi et al.,¹⁶ in 2014 reported complications about immediate submuscular breast reconstruction (ISBR) using Tutomesh bovine pericardium in 24 patients. Eichler et al.,¹⁷ performed a retrospective study in 2017 comparing Tutomesh bovine pericardium (27 cases) and Surgimend (18 cases) in ISBR. This study assessed that complication rate between the 2 methods are not statistically different and

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Figure 1 Intraoperative image. Splitting of the pocket along the inferior midline and inset of the inferior dermal flap in the space created by the division in order to assure a complete lower pole coverage.

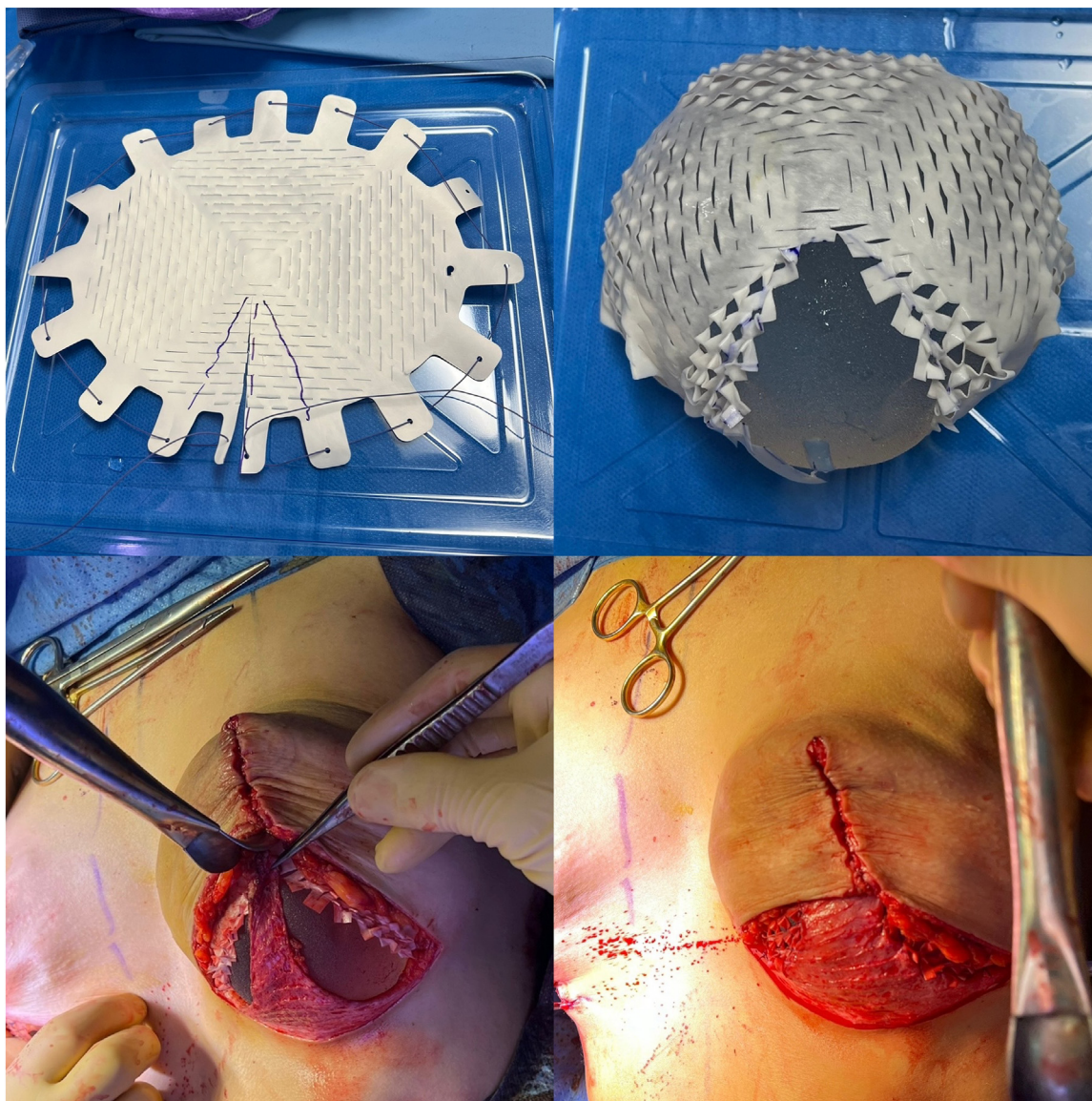


Table 2 Incidence of Complications

Complications	N	%	Treatment
Minor			
Seroma	-	-	-
Wound dehiscence	4	8.6	dressings
Epidermolysis	-		
Major			
Skin necrosis (full thickness)	1	2.1	implant loss
Infection	1	2.1	implant loss
Capsular contracture	0	-	

Table 3 Association Between Risk Factors and Complications

Complications	n	%	Risk Factor
Minor			
Wound dehiscence	4	8.6	2 smokers
Major			
Skin necrosis (full thickness)	1	2.1	RT
Infection	1	2.1	No

Figure 2 Patient with previous QUART of the right breast, submitted to prophylactic bilateral NSM for BRCA2 mutation + prepectoral implant ABPM assisted immediate reconstruction (anatomical microtextured implants, moderate projection; 415 cc). Preoperative (first row) and 1 year postoperative (second row).**Table 4** BREAST-Q

Domain	Postoperative Mean (\pm SD)
Satisfaction with breast	71.1 (\pm 13.02)
Psychosocial well-being	67.7 (\pm 19.07)
Sexual well-being	45.5 (\pm 13.5)
Physical well-being (chest)	61.5 (\pm 17.9)
Overall satisfaction with outcome	61.5 (\pm 11.3)

BREAST-Q scores recorded 1 year postoperatively, expressed as mean \pm standard deviation.

that it is possible to opt for the cheaper alternative (ABPM). Castagnetti et al.,¹⁸ published a retrospective series of 123 patients with a significant follow up period (24-91 months) supporting safety of

ABPM (Veritas) in immediate retromuscular breast reconstruction. Another comparative study was published in 2021 by Wang.¹⁹ This article portrays a series of 100 patients divided in 3 groups: ABPM submuscular reconstruction (44 cases), latissimus dorsi flap assisted reconstruction (45 cases) and 2 stages reconstruction (11 cases). Wang concluded that ABPM is a safe and convenient option for ISBR, producing overall patient satisfaction when compared with latissimus dorsi assisted and 2 stage ISBR procedures. In this study the use of ABPM reduced the duration of surgery maintaining a low rate of complications and did not increase the costs compared to 2-stage ISBR.

However, all the aforementioned studies analyze the use of ABPM in retromuscular breast reconstruction. To our knowledge there has been only 1 publication about prepectoral breast reconstruction.

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Figure 3 Patient submitted to prophylactic bilateral NSM for BRCA2 mutation + prepectoral implant ABPM assisted immediate reconstruction (anatomical microtextured implants, moderate projection; 420 cc). Preoperative (first row) and 1 year postoperative (second row).



tion ABPM assisted after nipple sparing or skin reducing mastectomy.²⁰ This study included 21 patients (37 breasts) who undergone breast reconstruction using Exashape Bioshield Pocket. The exclusions criteria of the study consisted in previous radiation therapy or previous breast surgery, BMI index > 30 Kg/m, high degree of breast ptosis and prosthesis volume > 550 cc. Moreover, the study excluded patients candidate to postradiation therapy and patients presenting risk factor affecting skin microcirculation (smoke > 20 cigarettes, connective inflammatory disease, diabetes). The overall complication rate was 13.5% (4 cases of wound dehiscence resolved with surgical revision and 1 case of infection leading to implant loss). No cases of capsular contracture were reported. Health related quality of life results using Breast Q (overall satisfaction with breasts, psychosocial and sexual well-being domains) were satisfactory. Table 4 summarizes all the publications currently present in the literature on the use of bovine pericardium in breast reconstruction.

To date, our study represents the largest one about the use of ABPM in prepectoral breast reconstruction (46 patients and 65 breasts). Furthermore, our inclusion criteria were more tolerant towards risk factors such as radiotherapy, smoking, comorbidities and previous breast surgery. This allowed us to push the indications and have a more complete analysis of complications. Our overall complication rate was similar to the one of the over mentioned study

(12.8%). In detail, minor complications, defined as the 1 treated conservatively, represented the 8.6 % while the major complication, defined as the 1 treated surgically, represents only the 4.3%. Although 4 patients had previously undergone breast conserving surgery followed by radiotherapy, in only in 1 cases, did a major complication occur (Table 3).

The ideal wrap material for use in breast reconstruction includes all of the advantages that have been previously noticed with ADM but reduces complications rates and has an advantageous relative cost of the products. The lower risk of complications contributes to an overall positive experience during the recovery process, improving self-confidence and quality of life of women facing the challenging journey of breast reconstruction. The number of studies published on ADM outpace that on bovine pericardial membrane.²¹⁻²⁴ It is therefore difficult to make a statistically significant comparison regarding complications between the 2 techniques. Costs also change based on the type of ADM and country so it is difficult to accurately compare the various option.

With respect to complications, the studies published to date seem to suggest that the overall complication rate is not greater than those observed using ADM. It will be necessary to conduct prospective randomized studies to better analyze the complication rate of the 2 different techniques.

Figure 4 Patient submitted to bilateral NSM for right breast cancer, ipsilateral sentinel lymph node biopsy + prepectoral implant ABPM assisted immediate reconstruction (anatomical microtextured implants, high projection; 345 cc). Preoperative (first row) and 1 year postoperative (second row).



Regarding minor complications, 4 postoperative wound dehiscence were noted. Two of them were active smokers. Smoking is known to be a risk factor for surgical wounds healing affecting mastectomy flap vascularization. Notwithstanding this, only 2 out of 9 active smokers patients present in our sample reported a minor complication, managed with dressings. We therefore do not believe that smoking represents an exclusion criteria for this type of reconstruction. Concerning major complication, 1 of the 2 patients with implant loss underwent preoperative radiation therapy and breast conservative surgery. As with smoking, it is known that radiotherapy represents a risk factor for prosthetic reconstruction. However, only 1 out of the 6 patients with history of previous radiation therapy showed a major complication and underwent autologous breast reconstruction. In our opinion, radiation therapy doesn't represent an exclusion criteria itself.

Table 5 shows current available data on complication rate linked to the use of ABPM in both retropectoral and prepectoral breast reconstruction.

Our study included 1 case of delayed reconstruction placing the implant from retropectoral to prepectoral pocket. To our knowledge this is the only case of prepectoral conversion using ABPM in literature. Mazzocchi et al.,²⁰ not reported the eventual necessity to perform fat graft session. In our cohort of patients, we decided to

refine the results performing 1 or 2 session of lipofilling in 7 cases. This allowed to solve any postoperative rippling.

With respect to cosmetic results the evaluation of breast shape and symmetry was satisfactory reporting a mean score up to 4. Patients self-evaluation demonstrated satisfactory results as well.

In our opinion, the main limit of this study is the absence of a prospective comparison to a cohort of patients undergoing ADM prepectoral reconstruction. Another interesting point to analyze in the future will be the comparison between the use of ABPM and the use of PU in prepectoral breast reconstruction.

Although this study does not present a control group, we compared our results with the results recently published by Khan et al.,²⁸ concerning prepectoral implant based breast reconstruction using an anterior implant coverage by bovine ADM. This retrospective cohort study described a sample of 65 patients who underwent nipple or skin reduction mastectomy who exhibited similar demographic characteristics as our patient sample. In details the 6.2% of patients were smokers, the 4.6% of patients had previously received radiotherapy, the mean BMI was 22 (20.4-24.4). The median volume of implant was 445 cc (400-475 cc). Mean follow up was 18 months. With respect to complications, 7 cases developed skin mastectomy flap necrosis leading to implant loss in 3 cases and conversion to a tissue expander in 1 case. A

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Table 5 Current Available Data on Complications Rate Related to the Use of ABPM in Breast Reconstruction

Study	n°pts (breasts)	Implant Positioning	Seroma	Wound Dehiscence	Infection	Skin Necrosis	Implant Loss	Capsular Contracture
Borgognone ²⁵ 2011	1 (2)	RP	-	-	-	-	-	-
Semprini ²⁶ 2012	1 (2)	RP	-	-	-	-	-	-
Modif ¹⁴ 2012	54 (93)	RP	7	-	6	5	2	-
Dawson ²⁷ 2013	7 (12)	RP	-	-	-	-	-	-
Gubitos ¹⁵ 2014	24 (28)	RP	5	-	2	-	1	-
Eichler ¹⁶ 2017	45 (27) Comparative with 18 cases ADM	RP	-	-	5	0	1	6
Castagnetti ¹⁷ 2020	123 (141)	RP	4	5	2	5	3	1
Wang ¹⁸ 2021	100 (44) Comparative with 45 cases LD assisted; 11, 2 stages	RP	-	-	1	3	2	1
Mazzocchi ¹⁹ 2022	21 (37)	PP	1	4	0	0	1	0

Legend: "RP": retropectoral implant-ABPM assisted breast reconstruction reconstruction; "PP": retropectoral implant-ABPM assisted breast reconstruction reconstruction.

higher risk of postoperative complications was noted to be link to high BMI and larger implant volume. On the other hand, our cohort of patients presented a greater number of preoperative risk factors such as smoking (28.9% vs. 6.2%), previous radiotherapy (13.04% vs. 4.6%) and BMI (12.9% BMI > 25 vs. 0 BMI > 25). Furthermore, even if the mean implant volume was lower (311 vs. 445 cc), the implant volume range (215-605 cc vs. 400-475 cc) was significantly larger including implant volumes > 600 cc. Despite this, the rate of major complications was similar between the 2 groups (4.2% vs. 4.5%) suggesting that the use of bovine pericardium in immediate prepectoral reconstruction can be safely adopted in a large percentage of patients.

Conclusion

The authors present a multicenter retrospective studies of ABPM use in immediate prepectoral breast reconstruction describing the surgical technique and analyzing surgical data, complications and patient reported outcomes. To date, this is the largest study about prepectoral breast reconstruction with ABPM. On the basis of our results, prepectoral breast reconstruction ABPM assisted is a reliable, safe and suitable option providing good patient satisfaction outcomes. Prospective randomized control studies are necessary to better assess the advantages of ABPM over ADM in prepectoral breast reconstruction in terms of complications.

Clinical Practice Points

Authors should complete a short summary (250 words or less) detailing the clinical importance of the study. The summary should address the following questions:

- What is already known about this subject?

- What are the new findings?
- How might it impact on clinical practice in the foreseeable future?

One of the recent advancements in breast reconstruction is the use of prepectoral implants in combination with synthetic and biological material as a natural and effective coverage. To date, there is little published data on breast reconstruction using acellular bovine pericardium matrix and most concern submuscular breast reconstruction. This study aimed to describe the multicentric-multisurgeon experience in performing direct to implant prepectoral breast reconstructions using acellular bovine pericardium matrix pocket. On the basis of our results, prepectoral breast reconstruction ABPM assisted is a reliable, safe and suitable option providing good patient satisfaction outcomes.

Disclosure

Prof. De Vita is a temporary consultant for Exashape.

The other authors have no conflict of interest to declare.

CRedit authorship contribution statement

Roy De Vita: Validation. **Maria Lucia Mangialardi:** Writing – original draft. **Marcello Pozzi:** Methodology. **Veronica Vietti Michelina:** Data curation. **Jacopo Nanni:** Data curation. **Nicola Zingaretti:** Investigation. **Pier Camillo Parodi:** Supervision. **Giovanni Zoccali:** Supervision.

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Ethical Approval

All participants provided written informed consent prior to enrolment in the study. This study was approved by the I.R.C.C.S. "Regina Elena" National Cancer Institute of Rome Ethics Committee.

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