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# Evaluation of the effectiveness of the prepectoral breast reconstruction with Braxon dermal matrix: First multicenter European report on 100 cases

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## Abstract

We report the outcomes of the European prospective study on prepectoral breast reconstruction using preshaped acellular dermal matrix for complete breast implant coverage. Seventy-nine patients were enrolled between April 2014 and August 2015 all over Europe using a single protocol for patient selection and surgical procedure, according to the Association of Breast Surgery and British Association of Plastic Reconstructive and Aesthetic Surgeons joint guidelines for the use of acellular dermal matrix in breast surgery. The preshaped matrix completely wraps the breast implant, which is placed above the pectoralis major, without detaching the muscle. A total of 100 prepectoral breast reconstructions with complete implant coverage were performed. This series, with mean follow-up of 17.9 months, had two cases of implant loss (2.0%) including one necrosis of the nipple and one wound breakdown (1.0% respectively). No implant rotations were observed. Good cosmetic outcomes were obtained with natural movement of the breasts and softness to the touch; none of the patients reported experiencing pain or reduction in the movements of the pectoralis major muscle postoperatively. The use of preshaped acellular dermal matrix for a complete breast implant coverage in selected patients is safe and gives satisfactory results, both from the aesthetic view point and the low postoperative complication rates. Further studies reporting long-term outcomes are planned.

KEYWORDS

acellular dermal matrix, breast reconstruction, muscle-sparing, pectoralis muscle, prepectoral

## 1 | INTRODUCTION

The history of implant-based breast reconstruction started in 1962, when the first silicone breast implant became available.[1] The immediate implantation of such prosthesis after subcutaneous mastectomy improved the aesthetic outcomes offering the possibility to reconstruct the breast in a one-stage surgery without the need to expand or add skin.[2] On the other hand, the major problems relating to the subcutaneous breast implant positioning were the high rates of capsular contracture, implant malposition, and exposure.[2,3]

Since Radovan introduced tissue expander,[4] the immediate subcutaneous breast reconstruction technique lost its popularity, giving way to the submuscular breast implant placement after the expansion of the pectoralis major. Nevertheless, such submuscular implantation, in addition to extend the time of reconstruction in two surgeries, limits the proper positioning and projection of the prosthesis resulting in a contrived breast.[5] With the aim of improving the result of the reconstruction, the use of acellular dermal matrix (ADM) to complete the subpectoral pocket was proposed.[6] A sling of ADM, sutured between the lower pole of the released muscle and the submammary fold, allows the submuscular placement of a definitive breast implant in a single surgical procedure, achieving a more natural breast contouring.[7] Despite the healthy mammary gland naturally overlies pectoralis major muscle,[8] the submuscular placement of the breast implant reduces the visibility of a stiff fibrosis around it by providing a better coverage to the implant.[4,5] Nevertheless, considering the latest findings about the use of ADM to reduce capsular fibrosis in human and primate models[9-12] and observing the corroborated use of these matrices in breast surgery, a new method for breast reconstruction preserving the pectoralis major has been described in 2014 by Berna et al. The breast implant is placed in a subcutaneous plane, totally wrapped with a preshaped ADM, avoiding any postoperative complication related to the detachment of the pectoralis such as muscular pain and shoulder or arm weakness and improving the esthetic outcomes with a more physiological positioning of the breast implant.[13]

As the small number of patients and the short follow-up are a significant limitation for the paper, other studies try to confirm the outcomes by Berna et al., but they used only a frontal coverage for the implant.[14,15] We therefore report the outcomes of a prospective multicenter European study about the prepectoral breast reconstruction technique with complete ADM implant coverage on a larger series with longer follow-up.

## 2 | PATIENTS AND METHODS

A prospective data collection of the prepectoral breast reconstructions with Braxon ADM performed in a 16-month period was carried out by the authors. A common protocol following the indications of the preliminary study by Berna et al. as regards the selection of the patient and the surgical technique was instituted and approved by the coordinating center review board.

All patients that fit selection criteria from British Association of Plastic Reconstructive and Aesthetic Surgeons and Association of Breast Surgery associations[16] had the possibility to have the prepectoral reconstruction with ADM for the complete breast implant coverage; a written informed consent with detailed information concerning its advantages, disadvantages and complication rates were given, supported by scientific data present in medical literature, according to the declaration of Helsinki. Patients that declined to have the prepectoral procedure had traditional breast reconstruction techniques.

Authors noted demographic data in a common form, including only patients fitting inclusion criteria as a body mass index (BMI) less than 30 kg/m$^2$, no previous or planned radiotherapy, an estimated mastectomy weight of <600 g and a good subcutaneous layer (pinch test >1 cm, measured pre- and intra-operatively on the upper and medial quadrants). The hallmarks were proposed to ensure the integration of the matrix and to reduce the complications related to the failure of the remodeling process.

Peri-operative and postoperative data were collected using a common password-protected access data base. Details regarding postoperative complications were examined during the periodic checks at 7, 15, 30, and 90 days and at 6, 12, and 24 months.

Early complications rates as visible rippling, red-breast syndrome, hematoma, dehiscence, necrosis, seroma collection, infection, and implant loss rates were the outcome of primary interest, in order to evaluate the effectiveness of the prepectoral procedure with ADM.

STATA software (StataCorp, College Station, TX) was used for simple descriptive statistics.

### 2.1 | Surgical technique

The hospital centers involved in the study used the preshaped 0.6-mm-thick Braxon porcine ADM (Decomed S.r.l., Venezia, Italy). The matrix has a patented shape designed to totally wrap both round and anatomical breast implants ranging from 150 to 500 cc. As the device is sterile and dry, without preservatives; it requires only 5 minutes of rehydration in sterile saline solution.

The protocol standardizes the surgical approach for the prepectoral breast reconstruction, involving only skin or nipple-sparing mastectomy. The use of mono-polar electrocautery was reduced for the dissection of the mammary gland from the subcutaneous tissue, in order to maintain a well perfused skin envelope and reduce the risks of thermal trauma. In order to avoid dehiscences and necrosis of the skin flap, an adequately sized incision was required to prevent excessive traction and to reduce the postoperative acute inflammatory response.

After skin or nipple-sparing mastectomy, the patient was placed in a sitting position, an implant sizer was inserted into the breast pocket to determine adequacy of the position and shape of the breast mound. The definitive implant selection had no restrictions by type and brand of the implant used; the size was limited to a maximum of 500 g. The selected prosthesis was then placed on a sterile desk and the matrix wrapped over it to form a tight pocket, which envelops the implant intimately.

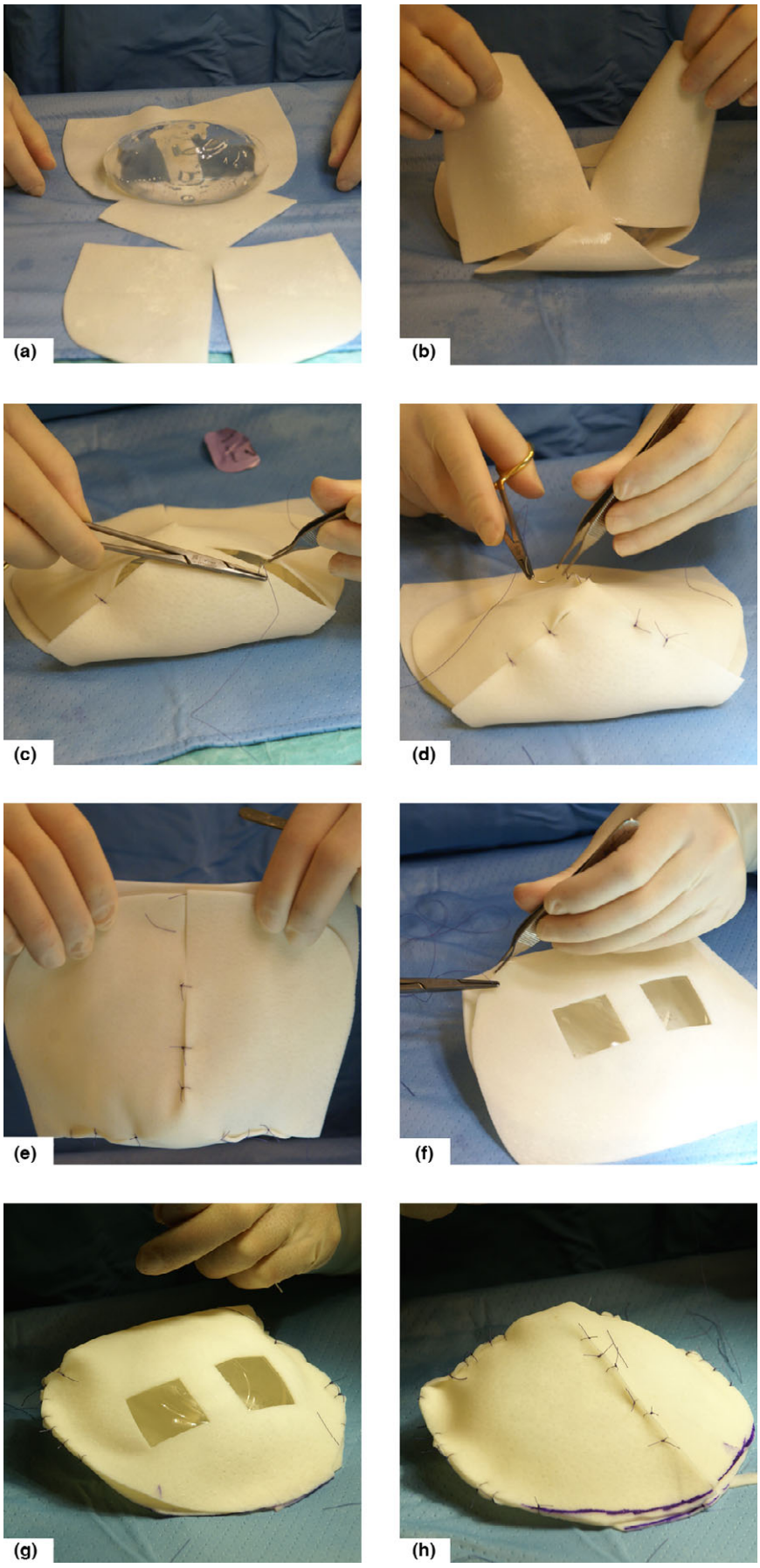


**FIGURE 1** Dressing phases of the implant with Braxon. A, Sizer positioning on the preshaped hydrated Braxon membrane; B, Sizer covering with the membrane; C, Edges of the lateral slits of Braxon are sutured with few loose absorbable stitches; D, Edges of the central opening are sutured, completing an intuitive frontal shell; E, Matching carefully frontal and posterior parts of Braxon membrane in the upper pole of the implant; F, Suturing the membrane along the breast implant contour in order to obtain a close-fitting wrapping; G, Trimming the lateral excess of Braxon leaving about 1 cm of margin to secure the device to the pectoralis muscle; H, The sizer is replaced with the permanent breast implant

The use of povidone-iodine solution was precluded for breast pocket and implant irrigation as well as for matrix rinse, since it was reported to be cytotoxic for fibroblasts and cells of the immune system involved in the remodeling of the ADM.[17]

The edges of Braxon were sutured together with a 3-0 absorbable suture avoiding any bulky seams, as in Figure 1, and the excess matrix was trimmed. The Braxon ADM containing implant was placed into the breast pocket over the pectoralis major muscle to verify the symmetry. The device allows to fix the implant in the most appropriate position, with cranio-caudal and medio-lateral adjustments on the frontal plane, with two or three single stitches in the cardinal points to the pectoralis major using absorbable sutures (2-0 or 3-0). Two vacuum drains (12 F) were inserted superiorly and inferiorly, and a quilting absorbable suture was performed between the frontal part of the ADM and the subcutaneous layer, in order to locate the matrix in close contact with the vascularized tissue. Finally, the skin was closed in layers.

Prophylactic antibiotics were administered for 5 days after surgery. Women were routinely discharged from the hospital with their drains still in situ; their removal took place when the daily serum amount was less than 30 cc, for 2 days consecutively.

## 3 | RESULTS

Between April 2014 and August 2015, seventy-nine patients underwent skin- or nipple-sparing mastectomy for a total of 100 prepectoral breast reconstructions with the Braxon ADM, 58 unilateral (73.4%) and 21 bilateral procedures (26.6%). Patient characteristics are shown in Table 1; the average age was 55.8±13.6 years (range, 28-74), the average BMI was 24.4±4.0 Kg/m$^2$ (range, 20.3-27.6) and the median volume of the implant was 336.6±78.5 g (range, 205-525 g). There were no intra-operative complications, neither red-breast syndrome nor other cutaneous inflammatory reaction to the implanted material in the immediate postoperative period.

**TABLE 1** Demographic data

| Characteristics | Data (%) |
|---|---|
| No. of patients | 79 |
| Age, years | |
| Mean±SD | 55.8±13.6 |
| Range | 28-74 |
| BMI, Kg/m$^2$ | |
| Mean±SD | 24.4±4.0 |
| Range | 20.3-27.6 |
| Radiotherapy | |
| Preoperative | 0 (0.0) |
| Postoperative | 3 (3.8) |
| Breast reconstructions | 100 |
| Unilateral | 58 (73.4) |
| Bilateral | 21 (26.6) |
| Size of the implant, g | |
| Mean±SD | 336.6±78.5 |
| Range | 205-525 |
| Follow-up time, months | |
| Mean±SD | 17.9±3.6 |
| Range | 9.5-25.7 |

At the time of this report, patients have been followed for up to 25.7 months (average 17.9±3.6 months). No tumor recurrence or cases of cancer mortality were recorded in our series. Implant loss occurred in two cases (2.0%) due to one wound breakdown and one necrosis of the NAC (1.0% respectively), in correspondence with an high-stressed part of the skin during the mastectomy procedure. Hematoma was experienced in two breasts (2.0%) and dehiscence resulted in three (3.0%). Five implants had seroma (5.0%) aspirated under ultrasound guidance. Dehiscence, hematoma, and seroma cases were resolved as outpatients, without the need of a second surgery. There was no need to remove the ADM in any case. We did not have any case of infection or visible rippling, nor cases of implant rotation in our series as reported in Table 2.

The esthetic results in terms of symmetry, shape, and ptosis was highly satisfactory. The reconstructed breasts had natural movement and softness to touch. Figure 2 reports frontal and lateral pictures of unilateral and bilateral prepectoral breast reconstruction.

## 4 | DISCUSSION

After the first use of ADMs in breast surgery,[6] the idea of implant-based breast reconstruction radically changed. During the last years, several authors confirmed the advantages related to the immediate *one-stage* breast reconstruction technique using biologic meshes.[18] ADM acts as a support and coverage in the lower pole of the implant, allowing an easier submuscular implant positioning in a single operation with improved esthetics.[19] Nevertheless, the better cosmetic is associated with the same loss of muscle function present with the use of expander and physiotherapy sessions are often required after both procedures.[20] About 16% of reconstructed patients experience decreased pectoralis strength during postoperative isometric muscle tests.[21,22]

With the aim of avoiding the pectoralis major impairment, a *muscle-sparing* breast reconstruction technique has been proposed by Berna et al. using a complete ADM implant coverage[13] that totally

**TABLE 2** Postoperative complications on 100 cases

| Complications | N (%) |
|---|---|
| Rippling | 0 (0.0) |
| Red-breast syndrome | 0 (0.0) |
| Hematoma | 2 (2.0) |
| Dehiscence | 3 (3.0) |
| Necrosis | 1 (1.0) |
| Seroma | 5 (5.0) |
| Infection | 0 (0.0) |
| Implant rotation | 0 (0.0) |
| Implant loss | 2 (2.0) |

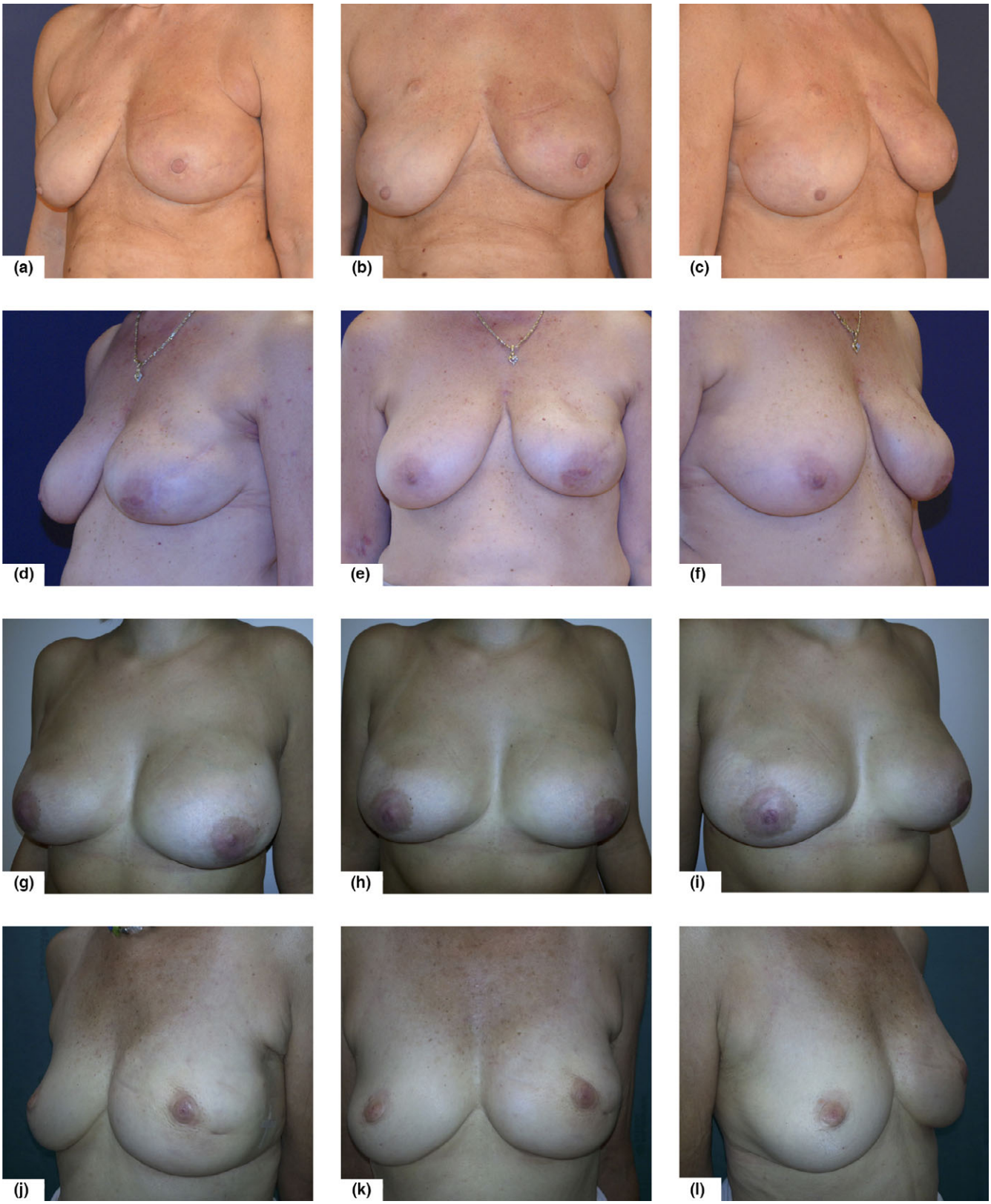


**FIGURE 2** Esthetic outcomes. A-C) Patient 5 months after left prepectoral breast reconstruction; slight asymmetry, in agreement with the patient choice to not operate the contralateral breast. D-F) Left reconstruction at 12 postoperative months. G-I) Bilateral prepectoral reconstruction after 7 months. J-L) Left implant, 4 months postoperative

envelopes the definitive breast implant avoiding complications related to muscle detachment and to the direct contact of the silicon with the subcutaneous tissue.[11,12]

Despite the prepectoral reconstructive technique was reported by some authors also with other materials,[14,15,23] we performed the study with the Braxon ADM because it is the only matrix approved for this specific indication and its preshaped feature has several advantages. Indeed, from a surgeons perspective, the use of the preshaped Braxon ADM has a short learning curve, is simple, fast and reduces operating times and thus the risk of postoperative infections. The complete absence of chemicals inside the matrix does not amplify postoperative inflammatory reaction, commonly triggered by preservative agents, as we appreciated by the absence of red-breast syndrome (Table 2). Moreover, the patented shape allows a complete breast implant envelope, which gives greater guarantees to reduce capsule formation than a sole frontal breast implant coverage made of ADM, as reported by other authors with a less intuitive and partial ADM breast implant covering technique.[14,15]

The short follow-up of our experience limits the considerations on capsule contracture issue, but scientific literature has effectively shown lower incidence of capsular contracture in breast reconstruction with the use of ADM.[18,19] Several histologic findings support that acellular dermal matrices prevent from capsular contracture showing decreased capsular fibrosis and fibroblast cellularity.[9-12] Fahad et al.[24] as well observed the integration of Braxon matrix in the breast pocket, confirming the effectiveness of the device.

Although our experience with the prepectoral implant-based breast reconstruction does not have a sufficient follow-up to confirm the outcomes in a long period, the results after approximately 1 year and half of medium follow-up appear highly satisfactory. The implant loss rate of our cohort (2.0%) is considerably lower than similar published data about the use of ADMs in subpectoral breast reconstruction (implant loss was reported between 5.0% and 19.2%).[25-27]

The preservation of the pectoralis conserves the functionality of shoulder movements such as adduction, anteversion, inward rotation of the upper limb, limiting postoperative pain and eliminating the development of breast animation during pectoralis major contraction that frequently need an analgesic therapy.[28]

Notwithstanding our experience appears highly satisfactory and confirm the outcomes of the preliminary study on a larger series, the limited data on capsule contracture require us to verify our hypothesis with longer follow-up and a randomized trial comparing prepectoral breast reconstruction with the traditional sub-muscular ADM-assisted technique. The preservation of the pectoralis major turns out to be a great advantage for selected patients, especially athletes and women with a job that requires a frequent use of the pectoralis major muscle, as the saving of an anatomical part is always preferable to its loss.

## 5 | CONCLUSIONS

The use of a preshaped acellular dermal matrix to completely cover the breast implant represents a new option among all breast reconstruction techniques. The prepectoral procedure offers highly satisfactory results on a large series of patients, both from the esthetic viewpoint and the low postoperative complication rates.

## CONFLICT OF INTEREST

None.

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