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ORIGINAL PAPER

Prepectoral breast reconstruction using the Braxon® porcine acellular dermal matrix: a retrospective study

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Abstract

Background Breast cancer is the leading cause of death attributable to cancer among women worldwide. Breast reconstruction has become an integrated part of breast cancer treatment due to long-term psychosexual health factors and its importance to breast cancer survivors. Muscle-sparing techniques using an acellular dermal matrix (ADM) (Braxon; DECO med s.r.l., Venice, Italy) can be considered a possible alternative to immediate reconstruction or two-step reconstruction for patients with medium breasts who want to preserve their natural breast shape.

Methods We performed a retrospective analysis of reconstructions using a Braxon porcine-derived ADM at the Breast Unit of the University Hospital of Parma and the Breast Unit of Piacenza Hospital from January 2015 to September 2017. The objective was to evaluate the benefits and complications resulting from this technique.

Results We treated 42 patients and performed a total of 51 muscle-sparing reconstructions using the Braxon porcine-derived ADM. The incidence of cutaneous necrosis was 4% ($n = 2$); the incidence of seroma was 4% ($n = 2$). We had to remove the implants in two cases. Natural and symmetrical breasts with good form, ptosis, and softness were achieved for most patients.

Conclusions Good results were obtained with a high degree of esthetic and functional satisfaction for the majority of patients. A low rate of early complications compared to that reported in the international literature data was observed.

Level of Evidence: Level IV, therapeutic study

Keywords Breast reconstruction · ADM · Muscle-sparing reconstruction · Breast cancer

Introduction

Breast cancer is the most common malignancy in women in the western world and a major cause of premature death [1]. Oncoplastic surgery uses techniques to remove tumors to obtain the best possible esthetic results. These techniques can be conservative or reconstructive. Specifically, with regard to breast cancer surgery, there are two possible approaches: conservative (e.g., quadrantectomy) or demolitive (e.g., simple mastectomy, nipple-sparing mastectomy, and skin-sparing mastectomy). With the second surgical option, we use tissue expanders and implants that are placed below the pectoral muscle that act as security against any infection or trauma of the prosthetic device. In the past 10 years, we have seen an increase in immediate reconstruction using breast implants to decrease the number and duration of surgeries and days of downtime and to increase the quality of life and esthetic results [2–5]. The development of new bio-materials, both synthetic and biological (titanium-coated polypropylene mesh), has allowed the creation of a retromuscular pocket even without the use of skin expanders with the benefit of immediate reconstruction during a single surgery [6–10]. Immediate breast reconstruction ensures excellent esthetic results associated with decreased hospitalization days and surgical costs, especially in comparison with the technique that uses myocutaneous expansion [11–13]. No randomized trials have been performed to compare oncological outcomes in conservative mastectomies with those in nonconservative mastectomies [14]. However, the

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Table 1 Demographics, mastectomy, and implant features (42 patients, 51 breasts)

Age (years)		
Average (range)	53.25 (25 to 75)	
BMI (kg/m^2)		
Average (range)	22.6 (18.3 to 31.6)	
Mastectomy	N. of patients	%
Bilateral	9	21.4%
Unilateral	33	78.57%
Preventive	2	4.76%
Oncologic	40	95.23%
Nipple-sparing	N. of breasts	%
Yes	48	94.11%
No	3	5.88%
Acellular dermal matrix used, Braxon (DECO med s.r.l.)	51	100%
Drainage size (mL)		
Average (range)	75 (25 to 125)	
Prosthesis size (mL)		
Average (range)	418 (180 to 525)	

2016 NCCN guidelines suggest that nipple-sparing mastectomy is oncologically safe provided the following indications are respected: early stage, biologically favorable, invasive breast cancer or DCIS at least 2 cm from the nipple; imaging findings indicating no nipple involvement; nipple margin assessed and found to be clear; no nipple discharge, and no Paget's disease [15]. These recommendations are supported by accumulated experience with conservative mastectomies. A 2015 meta-analysis of 20 studies involving 5594 carefully selected women with early-stage breast cancer investigated overall survival, disease-free survival, and local recurrence in those receiving skin-sparing mastectomy compared to those receiving conventional mastectomy without reconstruction. The study did not detect any differences in oncologic outcomes between the two groups. From these data, we can conclude that, if the indications are respected, nipple skin-sparing mastectomy is oncologically safe [14]. Nevertheless, several complications can arise due to the detachment of the pectoralis major used to host the implant. Furthermore, physiotherapy rehabilitation is frequently required. This procedure may also result in prolonged postoperative pain or even chronic pain [16, 17]. Therefore, we studied the effects and results of a new surgical technique that allows preservation of the pectoralis major. This technique involves the use of a porcine-derived acellular dermal matrix (ADM) that completely wraps the prosthesis and is attached to the pectoralis fascia and subcutaneous tissue by absorbable stitches. This innovative approach can enhance aesthetic results and avoid morbidity through the support provided by the biologic mesh packed

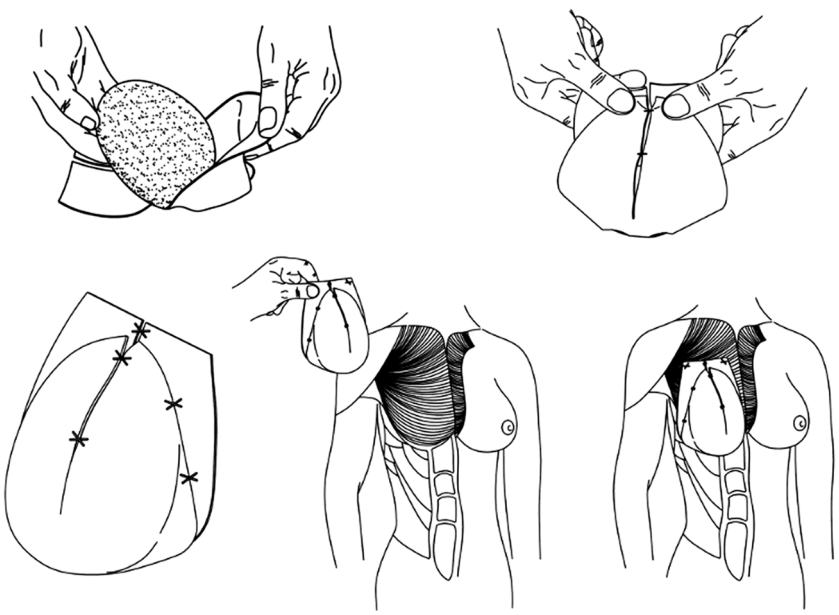
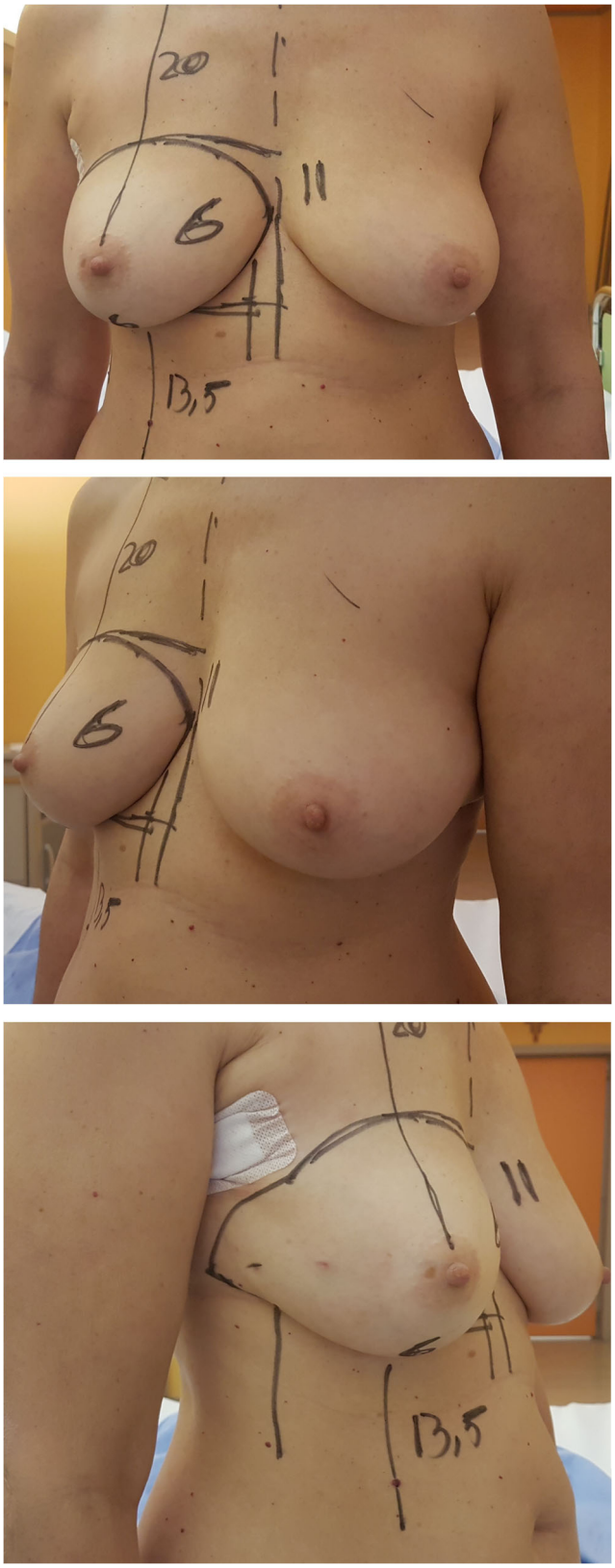
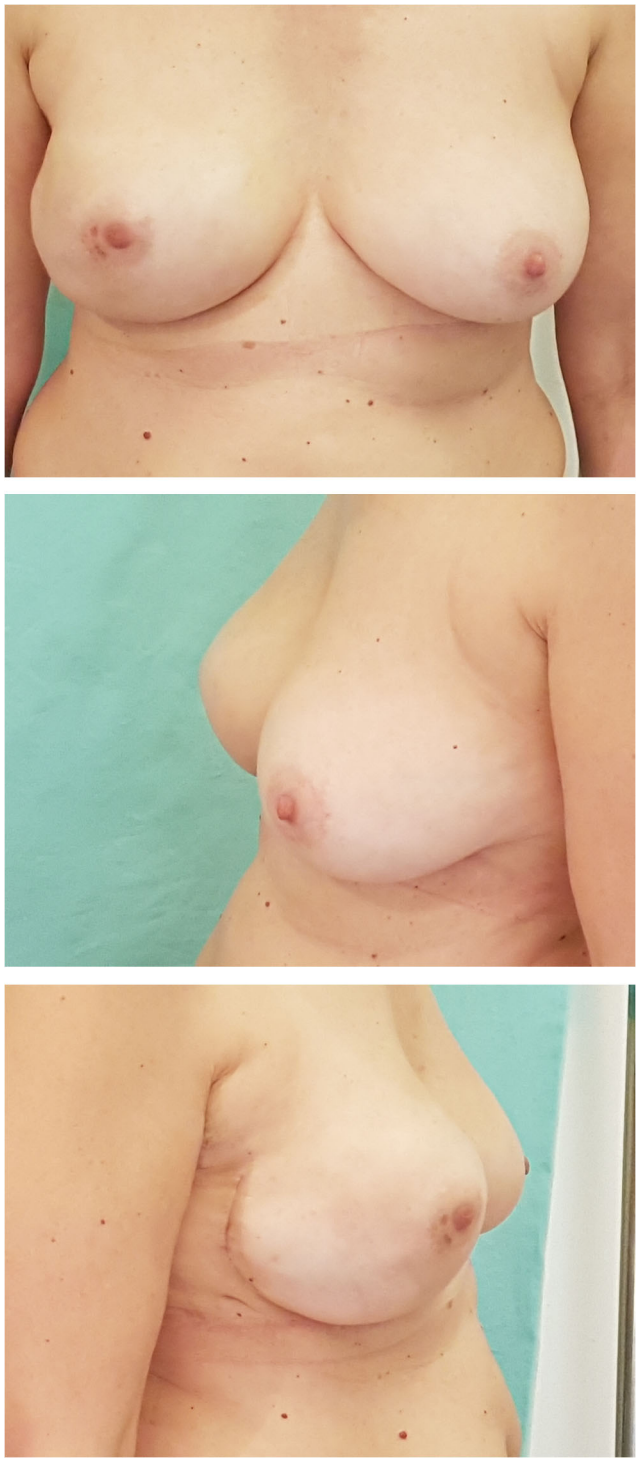


Fig. 1 Braxon® ADM

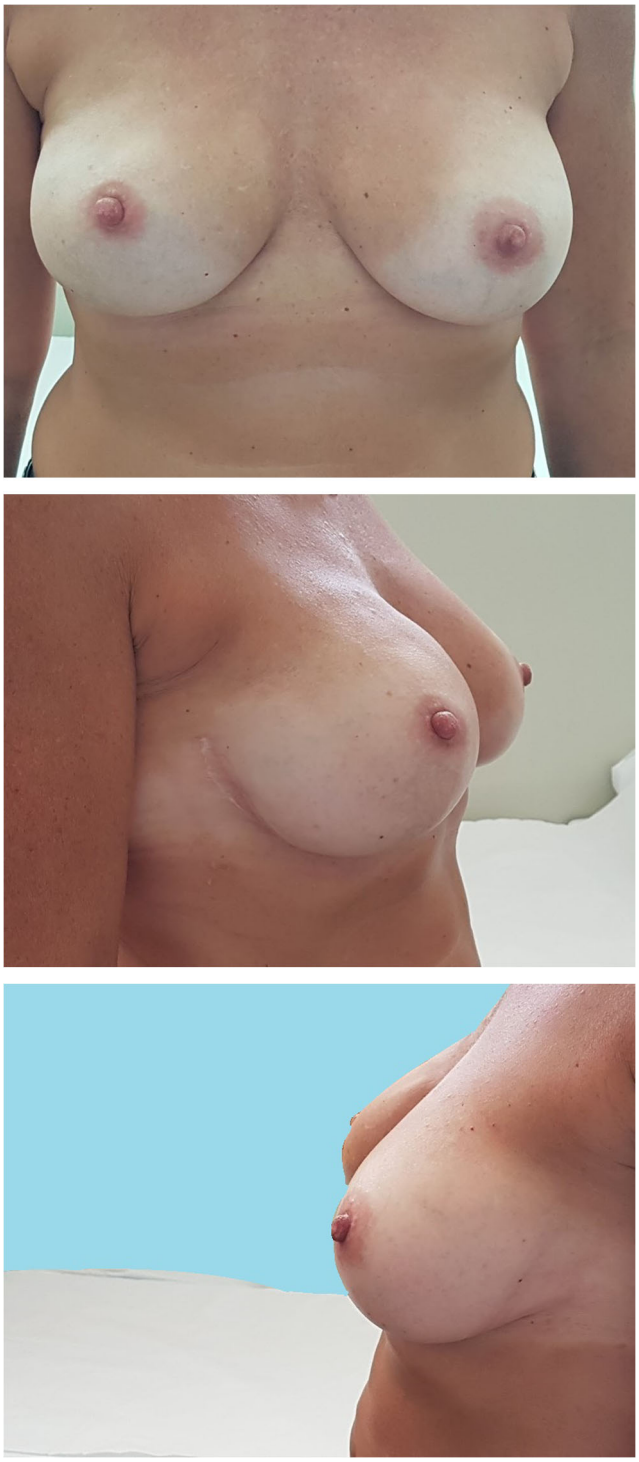


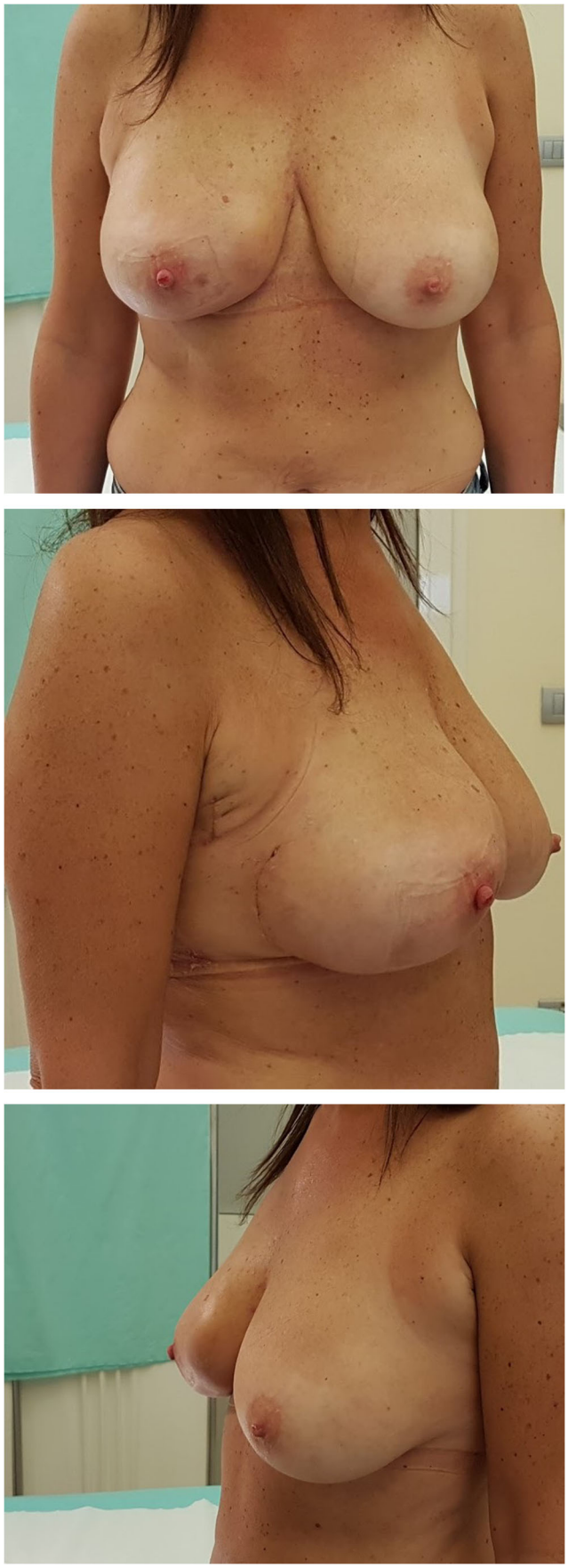
Figs. 2–4 Preoperative drawings—55-year-old woman with a 4-cm ductal carcinoma in situ grading 3, located in the upper-outer quadrant of the right breast. Right skin nipple-sparing mastectomy with muscle-sparing reconstruction and sentinel node biopsy



Figs. 5–7 Results at 1 month—55-year-old woman with a 4-cm ductal carcinoma in situ grading 3, located in the upper-outer quadrant of the right breast. Right skin nipple-sparing mastectomy with muscle-sparing reconstruction and sentinel node biopsy

in the retromuscular pocket. In addition, there are clear economic benefits due to the decreased operating time and hospitalization days. Therefore, we performed a retrospective analysis of reconstruction using the Braxon ADM at the Breast Unit of the





Figs. 8–10 Results at 6 months—43-year-old woman with invasive ductal carcinoma grading 3, hormone receptor positive, of the right breast. Skin nipple-sparing mastectomy with muscle-sparing reconstruction and sentinel node biopsy

University Hospital of Parma and the Breast Unit of Piacenza Hospital from January 2015 to September 2017. The objective was to evaluate the benefits and complications resulting from the use of this technique.

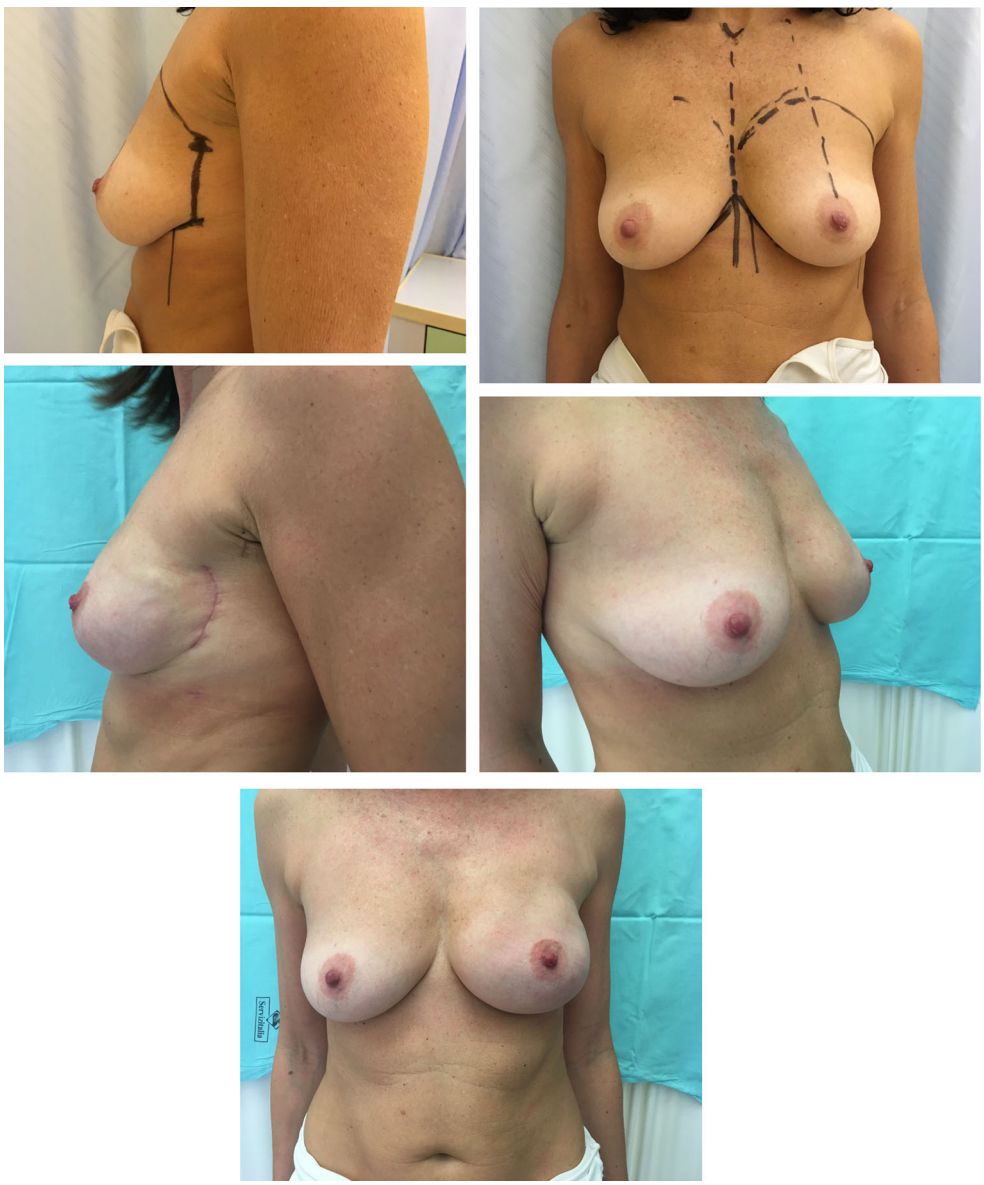
◀ **Figs. 11–13** Results at 14 days—51-years-old woman with invasive ductal carcinoma grading 2, hormone receptor positive, of the right breast. Skin nipple-sparing mastectomy with muscle-sparing reconstruction and sentinel node biopsy

The ADM is a collagen structure with features that allow integration with the receiving tissue. The matrix can be porcine, human, bovine, or synthetic. Its collagen-rich tissues (skin, pericardium, intestinal submucosa) are processed to leave only collagen and elastin. The ADM promotes angiogenesis and fibroblast infiltration. It can be cross-linked or not cross-linked, resulting in major or minor tissue integration and resistance to infection [18–22]. Immediate reconstruction is possible, and there are two possible options:

- Insertion of the retromuscular implant: ADM allows volume expansion of the muscular pocket, thus making a connection between the pectoral muscle and the mammary sulcus.
- Muscle-sparing reconstruction: this involves complete wrapping of the prosthesis. This reconstruction keeps the pectoral muscle intact and allows implant placement in the subcutaneous tissue.

Materials and methods

A retrospective analysis of breast reconstructions using the Braxon porcine-derived ADM was performed between January 2015 and September 2017. Data collection was focused on benefits and postoperative complications (seroma, dehiscence, infection, necrosis, loss of the implant).



Figs. 14–18 Results at 3 months—43-year-old woman with a multifocal, invasive ductal carcinoma of the left breast. Skin nipple-sparing mastectomy with muscle-sparing reconstruction and sentinel node biopsy

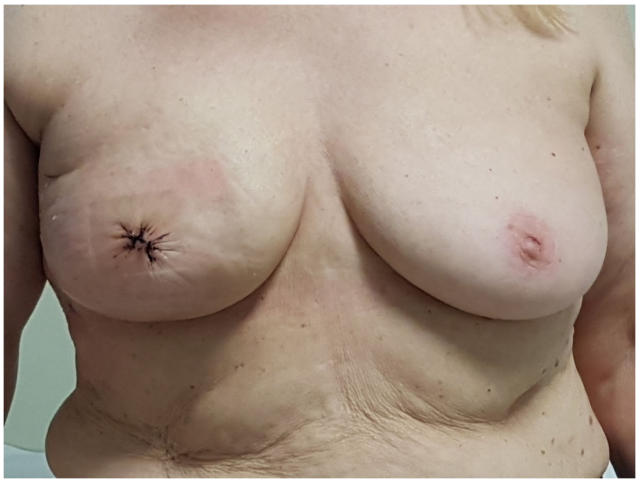


Fig. 19 Results at 21 days—73-year-old woman with a retroareolar invasive lobular carcinoma of the right breast. Skin-sparing mastectomy with muscle-sparing reconstruction and sentinel node biopsy

Furthermore, an accurate comparison with the international medical literature was performed.

The inclusion criteria were patients requiring skin-sparing or nipple-sparing mastectomy, patients with medium breasts, patients with mild to moderate ptosis (< 450 g), patients with a subcutaneous layer that could be evaluated with the pinch test in the upper and medium quadrants (> 1 cm), patients with body mass index < 30, patients not treated with radiotherapy, and nonsmokers (a well-vascularized skin flap is necessary to provide an adequate blood supply to the matrix) (Table 1).

Surgical technique

The standard method of using this device, which includes completely covering the implant, involves a skin-sparing or nipple-sparing mastectomy to ensure adequate skin coverage and a suitable subcutaneous layer that is well-vascularized [23, 24]. As breast unit surgeons, with specific skills in oncoplastic surgery, we performed our own mastectomies

Table 2 Complications (51 breasts)

	N. of patients	%
Complications	7	13.7%
Prosthesis loss/removal	2	3.9%
Infection	0	0.0%
Skin necrosis	2	3.9%
Ischemia (nipple/skin flap)	0	0%
Seroma	2	3.9%
Prosthesis exposure	1	1.9%
Hematoma	0	0%
Acellular dermal matrix exhibition	0	0%
Rippling	1	1.9%

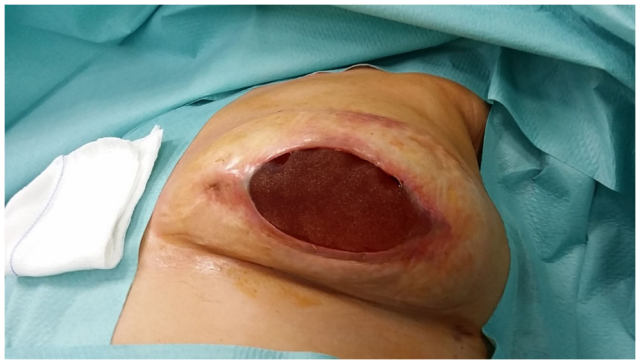


Fig. 20 Skin necrosis with prosthesis exposure

and breast reconstructions. We recommend performing the mastectomy through a lateral vertical incision. We suggest avoiding central incisions (round block or periareolar) to prevent devitalization or weakness of skin areas susceptible to ischemic processes resulting from the pressure of the prosthesis. The advantage of the lateral incision is that the scar appears to be in a hidden area. Moreover, avoiding central or periareolar scars, we minimize the possibility of the appearance of cutaneous ischemia due to the pressure of the prosthesis and avoid skin scars above the mesh used, to favor a complete integration of the ADM. When skin reducing is mandatory, we perform the inverted-T incision. A 0.6-mm-thick Braxon ADM was wrapped around the anatomical prosthesis, which had a volume between 150 and 550 mL. In this study, we used only anatomical Allergan (Dublin, Ireland) implants. Before using the implant, the ADM requires approximately 5 min of rehydration in sterile saline, as described on the prosthesis leaflet. As a second step, the edge of the mesh is sutured (Fig. 1). Once packed, everything is placed in the pocket over the previously muscular area, and the symmetry and proper positioning of the patient are verified. The implant is placed in the subcutaneous tissue using monofilament absorbable stitches Monosyn 2.0–3.0 (B Braun Melsungen AG, Germany). We do not recommend iodine antiseptics to wash the pocket before insertion of the device because they are

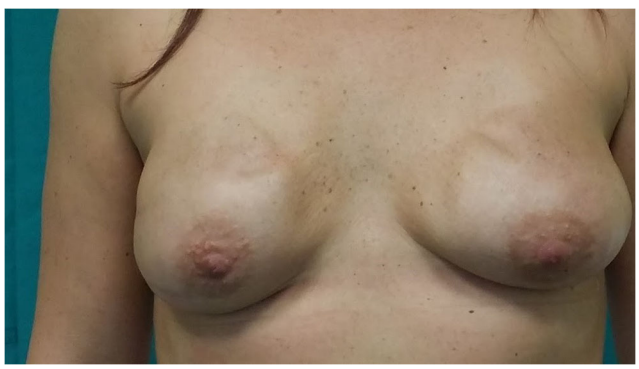


Fig. 21 Bilateral upper cutaneous rippling in a 45-year-old woman with BRCA 1 mutation treated with bilateral skin nipple mastectomy

cytotoxic to fibroblasts and immune system cells involved in the reshaping and integration of the array [25–27]. We used an antibiotic solution containing cefazoline 1 g plus gentamycin 80 mg and saline. Finally, a drainage tube was placed at the inframammary fold (for patients undergoing axillary dissection, we also place a drain in the axilla). Depending on the experience, drainage was maintained for approximately 7 to 10 days and then stopped when the amount of serum reached 45 to 50 mL for at least two consecutive days. We noticed in the immediate postoperative period the appearance of cutaneous erythema on the operated breast. The routine use of compresses with boric acid at 3%, at least two to three times a day, seems to significantly reduce the erythema from the second postoperative day. The skin was sutured in two layers with resorbable monofilament. All patients were subjected to antibiotic prophylaxis with cefazoline 2 g endovenous or ciprofloxacin 400 mg endovenous (if allergies to penicillin were reported). Patients were discharged from the hospital approximately after 1 day with their drains still in situ to reduce their hospital stays.

Results

We treated 42 patients with muscle-sparing reconstruction (a total of 51 surgeries and 9 bilateral implants) with a mean follow-up of 15.36 months (Figs. 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, and 18). We performed sentinel node biopsy at the same intraoperative session. Intraoperatively, we always performed a retroareolar tissue histological examination. If the cancer infiltrated it, we removed the nipple–areola complex and we sutured the central defect by a purse string suture. Only one patient underwent axillary lymph node dissection due to a positive sentinel node. In one case, we had to remove the nipple–areola complex due to cancer infiltration: in this case, we used an anatomical Allergan (Dublin, Ireland) LF 350-g implant. The outcome was good (Fig. 19). None of the patients underwent neoadjuvant nor adjuvant radiotherapy. Postoperative complications were recorded (Table 2).

The average patient age was 54 years and the average body mass index was 25.5 kg/m^2. The surgical drains were removed after an average of 7 to 10 days. We applied a boric acid 3% cutaneous solution (boric water) compress three times per day for 7 days and Ozonia 10% cream twice per day on the operated breasts. One preshaped 0.6-mm-thick mesh was used for all implants. The incidence of cutaneous necrosis was 4% (n = 2); the incidence of seroma was 4% (n = 2). The implants had to be removed in two cases (Fig. 20). None of the patients experienced postoperative pain, even after 1 month or more, due to preservation of the pectoral muscle. None of the patients reported functional limitations. Natural and symmetrical breasts with good form, ptosis, and softness were achieved. A well-defined inframammary fold was created and the nipple–areola complex was located in the correct position. The breasts had natural movement when the women raised their arms. We did not encounter capsular contracture or migration of the implant in patients who underwent surgery in the past year. However, we reported a case of persistent bilateral skin rippling that was treated using autologous fat grafting. (Fig. 21).

Discussion

The complication rates that occurred for our patients reflect those reported in the literature. The use of the ADM for implant-based breast reconstruction is a technique that is gaining increased acceptance among reconstructive breast surgeons. There are multiple clinical benefits of this technique, such as an increased ability of the surgeon to define the placement of both the inframammary fold and the expander/implant position, an increased layer of protection between the prosthetic implant and potentially devascularized mastectomy skin, a larger initial submuscular pocket leading to the improved use of native mastectomy flaps, more rapid expansion, and less time until complete reconstruction [28–31]. In addition, the ADM may have the ability to help reduce the formation of breast capsules [32]. Despite the many potential benefits, widespread acceptance of techniques using the ADM in breast reconstruction has been tempered. This is mainly attributable to concerns regarding the increased potential for complications such as seroma and infection [28]. Sbitany et al. [28] showed that the efficacy and safety of procedures using the ADM are largely equivalent to those using full submuscular coverage. Of all the complications analyzed in this study, only the differing incidence of seroma between the two cohorts was found to be statistically significant (4.3% for the submuscular cohort and 8.4% for the ADM cohort). This finding was not surprising given the nature of the material. Although it is clearly not possible to eliminate the incidence of all seromas, many of these are likely attributable to the learning curve that accompanies the use of a new product such as the ADM. Seroma rates decrease as surgeons learn that proper intraoperative fill reduces the dead space above the matrix, thus leading to improved vascularization, and as they gain more experience in general [33]. Despite the higher incidence of seroma in the ADM cohort, the rate of infection requiring explantation was found to be comparable between the two groups (3.2 versus 3.4%). The rate of partial mastectomy flap necrosis was found to be higher in the ADM group (9.3%) relative to the submuscular group (7.2%), although this difference was not found to be statistically significant. Despite this higher rate of skin flap compromise overlying the ADM, the fact that the two cohorts maintained similar explantation rates is supportive of the ability of ADM to provide a full layer of protection overlying the prosthetic. In cases of skin flap or incisional breakdown, the incorporated ADM has the

ability to protect implants and reduce the need for implant removal. In many of these cases, without the ADM covering, explantation would almost certainly be required. In general, patients with poorly perfused mastectomy flaps are at increased risk for complications with the use of ADM-assisted reconstruction and will likely not tolerate the excessive filling of the implant allowed by the ADM [28].

The operating time has an adverse influence on wound complication and implant loss [34]. With the prepectoral technique, the operating time is reduced because it is a less complicated technique and the surgeon can begin to perform the ex vivo procedure of suturing the Braxon ADM around the implant after the mastectomy while hemostasis and irrigation of the prepectoral space are being performed. Berna et al. did not report any implant loss in their small series of 15 implant-based immediate breast reconstruction using the Braxon ADM [35]. Vidya et al. demonstrated a very low implant loss rate of 2% in a series of 100 cases [36]. We have had experience with 51 implants using the Braxon ADM, and only two cases involved implant loss. Studies have shown that the use of the ADM reduces capsular contracture [37]. Total wrapping of the ADM has been proven to reduce capsular contracture in animal studies and in a small series of subpectoral implant-based reconstructions by Cheng et al [38, 39].. Downs et al [34] showed promising results in their 2-year follow-up study of prepectoral implants and ADM, with a capsular contracture rate of 10%. A recent publication of 4-year follow-up for a small series of Braxon ADM reconstructions showed no evidence of capsular contracture [40].

We have not encountered any capsular contracture since the reconstructions were performed during January 2015 to September 2017. The prepectoral ADM also possibly prevents malposition and rotation of the implant, and none of our patients had this complication during short-term follow-up [41]. Another advantage is the potential cost-effectiveness of the treatment. Although this technique requires more ADM per implant than standard approaches, it is probably still cost-effective because it is a single-step reconstruction, thereby avoiding the need for additional procedures and reducing the hospital stay [41].

Skin rippling is one of the possible short-term complications of prepectoral reconstruction with the Braxon ADM. However, at 1 month after surgery, the progressive integration of the dermal matrix tends to restore the correct breast profile. Skin rippling persisted at 6 months after surgery for only one case; it was treated by autologous fat grafting. The use of lipofilling allows patients with adipose tissue availability to undergo corrections of irregularities after breast reconstruction, such as skin rippling or postsurgical scars [42–50].

Conclusions

Good results were obtained with a high degree of esthetic and functional satisfaction for the majority of our patients. We found a low rate of early complications compared to those reported by the international literature data [30, 31]. A muscle-sparing technique using the Braxon ADM can be considered a possible alternative to immediate reconstruction or two-step reconstruction in patients with medium breasts who want to preserve their natural breast shape. We used Braxon® because it was the first ADM placed on the market and gave us excellent results so we continued to use it. Other colleagues use the TiLOOP® Bra Pocket, but we have no experience with it. The complication rates of the muscle-sparing technique are acceptable if performed by experienced surgeons with specific skills in oncoplastic breast surgery. Athletic young women are attracted to this technique because it preserves the integrity of the pectoral muscle, thereby ensuring quick resumption of physical activity without requiring physiotherapeutic rehabilitation. Another possible application of this technique involves correcting capsular contracture or malposition of a prosthesis. An additional benefit is the possibility to implant a retromuscular prosthesis in the case of failure of the first intervention. No patient developed chronic pain or functional limitations. The cost of the biological membranes was offset by the reduction in hospitalization days and the reduction in the number of surgeries and rehabilitation sessions performed. At present, the results of our work are encouraging. Limitations of the study were the small number of cases and the retrospective nature of the study. Although we have used a special type of ADM, many products are available; they are not all identical and may differ in outcome and complication rates. Further studies are needed to address this point. New prospective observational studies would be desirable to minimize biases inherent in the retrospective nature and provide an opportunity to evaluate the long-term capabilities and complications of this technique.

Compliance with ethical standards

Conflict of interest Marco Gardani, Francesco Simonacci, Giuseppina De Sario, Francesca Cattadori, Edoardo Raposio, and Dante Palli declare that they have no conflict of interest.

Ethical approval For this kind of retrospective study formal consent from a local ethics committee is not required.

Informed consent Informed consent was obtained from all individual participants included in the study.

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