

Breast Reconstruction Actualized in Nipple-sparing Mastectomy and Direct-to-implant, Prepectoral Polyurethane Positioning: Early Experience and Preliminary Results

Roy de Vita,¹ Ernesto Maria Buccheri,¹ Amedeo Villanucci,^{1,2} Marcello Pozzi¹

Abstract

We report on our early experience with nipple-sparing mastectomy and direct to polyurethane implant breast reconstruction using a prepectoral approach.

Background: Implant-based breast reconstruction after nipple-sparing mastectomy has been the most common breast reconstruction procedure performed, for both breast cancer treatment and prophylactically. Subpectoral implant placement with partial detachment of the pectoralis major muscle has been the procedure of choice for staged reconstruction and direct-to-implantation. Prepectoral implant placement has recently increased in popularity among plastic surgeons owing to the high rates of animation deformity, loss of muscle function, and chronic pain observed with submuscular implant placement. Acellular dermal matrices or synthetic meshes have been used for implant coverage and support to avoid capsular contracture and implant visibility. In the present study, we have introduced breast reconstruction actualized in nipple-sparing mastectomy and direct-to-implant with prepectoral polyurethane positioning (BRAND4P). **Patients and Methods:** A total of 34 nipple-sparing mastectomies and immediate direct-to-implant breast reconstructions with prepectoral polyurethane-coated implant placement were performed in 21 patients (13 bilateral and 8 unilateral). The implant was placed subcutaneously in the exact place of the excised breast parenchyma with no further coverage. **Results:** After a mean follow-up of 4 months, no major complications had been observed. No patient presented with animation deformity or grade III-IV capsular contracture. Patient satisfaction, assessed using the BREAST-Q, was excellent. **Conclusions:** The BRAND4P method represents a novel prepectoral approach and a feasible alternative to subpectoral implant placement among the available implant-based breast reconstruction techniques.

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Introduction

At present, breast reconstruction is considered an essential step in the therapeutic *iter* of breast cancer. Moreover, the knowledge of genetic and hereditary factors and additional scientific evidence of

the benefit of the prophylactic procedure has consequently increased reconstruction requests for prophylactic purposes. In accordance with this trend, the necessity for reconstructive procedures that can provide a natural breast appearance regarding the contour, volume, and position (and no longer a simple mound on the chest) should be the standard of care.¹

When correctly indicated, nipple-sparing mastectomy (NSM) and implant-based breast reconstruction (IBR) is an oncologically safe procedure with satisfying aesthetic outcomes. For decades, NSM plus IBR, also called “2-stage” reconstruction has dominated in the plastic surgery field because of the advantages related to an improved breast shape, better implant positioning, implant protection, and the reduced rate of capsular contracture.² Two-stage reconstruction consists first in the placement of a tissue expander

¹Department of Plastic and Reconstructive Surgery, Istituti Fisioterapici Ospitalieri, Regina Elena National Cancer Institute, Rome, Italy

²Department of Biotechnological and Applied Clinical Sciences, General Surgery Section, L'Aquila University, L'Aquila, Italy

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Address for correspondence: Amedeo Villanucci, MD, Department of Plastic and Reconstructive Surgery, Istituti Fisioterapici Ospitalieri, Regina Elena National Cancer Institute, Via Elio Chianesi 53, Rome 00144, Italy
E-mail contact: amedeo.villanucci@gmail.com

in the submuscular space and the subsequent replacement with a definitive implant. The coverage and support provided by the pectoralis muscle not only minimize implant-related complications but also mitigate the risk of capsular contracture and produce a more natural-looking breast.³

The introduction of acellular dermal matrices (ADMs) and synthetic meshes for lower pole coverage led surgeons to perform reconstructive procedures with definitive implantation without the need for expansion, so-called direct-to-implant (DTI) reconstruction.^{4,5} Single-stage procedures reduce to a minimum the psychological effect of mastectomy, psychosocial distress, body image disruptions, and adverse effects on sexual well-being, because they restore the breast mound during the same operative session, with preservation of good aesthetic outcomes and complete implant coverage.⁶

Nevertheless, animation deformity has remained the main outcome reported by the patients who have received this type of breast reconstruction. A recent study found a 100% prevalence rate of animation deformity in a 25-patient cohort who had undergone previous submuscular prosthetic breast reconstruction. Of these 25 patients, 80% were bothered by their deformity and 28% sought revision surgery.⁷ In attempt to reduce the number of revision surgeries and avoid breast animation, the use of a muscle-sparing prepectoral approach has been reported. Investigators have advocated ADM or synthetic mesh use for total or subtotal anterior/inferior coverage of the implant.⁸⁻¹⁰

The aim of the present study was to report our early experience with 34 NSMs and DTI breast reconstructions (21 patients) using a prepectoral approach and micropolyurethane sponge-coated implants from December 2017 to April 2018. This type of implant can offer prepectoral DTI breast reconstruction with the advantages of an integrated ready-to-use device without further coverage. Our encouraging early results have convinced us to present this new IBR technique as a valid and feasible alternative in the field of breast reconstruction surgery. We have termed it breast reconstruction actualized in NSM and DTI with prepectoral polyurethane positioning (BRAND4P).

Patients and Methods

Patients and Study Design

We conducted a retrospective study of 21 patients selected from our department. The first patient had undergone surgery in December 2017 and the last in April 2018. This provided a minimum of 2 months to a maximum of 6 months of follow-up. All the patients had provided written informed consent. The present study was conducted in accordance with guiding principles set forth in the Declaration of Helsinki. The exclusion criteria were a body mass index $> 30 \text{ kg/m}^2$, age > 65 years, active smoking, comorbid conditions such as uncontrolled diabetes and immunogenic disorders, and previous radiotherapy to the chest wall. We identified 13 patients who had undergone bilateral prophylactic NSM and 8 patients with cancer who had undergone unilateral therapeutic NSM. Data were collected from the patients' clinical records, operative registers, and surgeon logs. Photographs had been taken before surgery and at the follow-up visits at 1, 2, and 6 months postoperatively to evaluate the cosmetic results and assess the outcomes. Patient satisfaction was

assessed using the BREAST-Q preoperatively and at the follow-up visits at 1, 2, and 6 months postoperatively.

Surgical Technique

All the BRAND4P procedures were performed with the patient under general anesthesia by the senior author at both the oncologic and the reconstructive stages. The preoperative markings were performed on the day of the scheduled surgery with the patient in an upright position and including the middle and parasternal lines, inframammary folds, and the incision site. Mastectomy was performed with scissors to achieve the best control of skin flap thickness and reduce tissue trauma to a minimum. In all cases, the site of incision was placed at the inframammary fold. At the end of the oncological procedure, the skin flap thickness was measured using a caliber, and the state of vasculature was assessed by checking the bleeding from the wound edges. The breast implant was placed directly into the subcutaneous pocket using a sterile bag to prevent contamination during passage through the incision edges. We have always used the micropolyurethane foam-coated anatomic implant from the Microthane Sublime Line (Polytech, Dieburg, Germany). Particular care was taken in the correct positioning of the implant. A suction drainage was routinely placed into the pocket, and the dressing was performed with impregnated gauze on the skin and nipple and gentle compression with cotton and an elastic bandage.

Postoperative Care

All patients were discharged on second postoperative day after dressing removal and restraining sport-bra placement, with the drainage tube in place. The drainage tube was removed when the amount of fluid collected was $< 50 \text{ mL}$ within 24 hours. The patients received levofloxacin, at a dosage of 500 mg, every 24 hours until drain removal and were advised to continue wearing a sports bra for 1 month.

Results

From December 2017 to April 2018, 21 patients had been selected for BRAND4P. Overall, 34 NSMs had been performed, including bilateral procedures in 13 patients who carried the *BRCA* gene mutation for cancer risk reduction and 8 unilateral therapeutic procedures for cancer. The patients with cancer had satisfied the oncologic criteria for NSM.¹¹ All 8 patients had a tumor size staged as T1, a tumor-to-nipple distance $> 2 \text{ cm}$, a peripheral tumor location, and clinically negative axilla. These 8 patients, therefore, underwent sentinel lymph node dissection with negative extemporaneous histologic examination findings. Because of the cancerous involvement of the subnipple tissue, found by intraoperative frozen section examination, 1 patient had undergone areola-sparing mastectomy with nipple resection,¹² followed by the same reconstructive procedure, and was also enrolled in the present study.

The mean age of the 21 patients was 42 years (range, 31-48 years). The mean body mass index was 26 kg/m^2 (range, $19\text{-}30 \text{ kg/m}^2$). The mean operative time was 60 minutes (range, 50-90 minutes) per breast. The mean skin flap thickness was 0.8 cm (range, 0.7-0.9 cm). We always used round-base, high-projection, anatomic profile

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Table 1 Summary of Results of 34 BRAND4P Procedures

Characteristic	Mean (Range)
Age, y	42 (31-48)
Body mass index, kg/m ²	26 (19-30)
Operation time (per breast), min	60 (50-90)
Skin flap thickness, cm	0.8 (0.7-0.9)
Volume implanted, cm ³	395 (350-495)
Duration of drainage, d	8 (6-10)
Follow-up time, mo	4 (2-6)

Abbreviation: BRAND4P = breast reconstruction actualized in nipple-sparing mastectomy and direct-to-implant with prepectoral polyurethane positioning.

implants (Replicon MHS; Polytech Microthane Sublime Line). The mean volume implanted was 395 cm³ (range, 350-495 cm³). The mean duration of drainage was 8 days (range, 6-10 days; Table 1).

No minor complications, such as sterile seroma, nipple-areola complex (NAC) or skin flap necrosis, or late wound healing, were observed. Only 1 patient presented with an itching rash of the breast skin flaps, which had completely healed with topical steroid cream. No major complications, such as implant displacement, hematoma, NAC or skin flap necrosis, implant infection, or wound dehiscence, were observed. At the follow-up visits, no patient had presented with Baker grade III-IV capsular contracture, wrinkling/rippling, or implant edge visibility or palpability. None of the patients had reported breast pain, and no pain-control drugs were required after

surgery. The patients' arm and shoulder mobility showed no restrictions, and no motion-associated pain was reported. The patients' satisfaction, assessed using the BREAST-Q concerning the cosmetic outcomes, was excellent after a mean follow-up of 4 months (range, 2-6 months). No breast animation was observed when the patients contracted their pectoralis muscle. Representative patient photographs are shown in Figures 1 and 2 and Supplemental Video 1 (available in the online version).

Discussion

IBR with a prepectoral silicone implant was first described in the early 1970s by Snyderman and Guthrie.¹³ This subcutaneous approach was simple and quick and preserved the integrity of the pectoralis muscle. However, the approach was associated with a number of complications, including a high rate of reconstruction failure due to skin flap necrosis and poor long-term aesthetic outcomes caused, essentially, by capsular contracture, upper implant edge visibility, especially among thin patients, and wrinkling/rippling. Schlenker et al¹⁴ reported a skin necrosis rate of 13.5%, device extrusion rate of 6.7%, capsular contracture rate of 56%, and explantation rate of 28% within the first year.¹⁴ Because of the high complication rate, prepectoral techniques have been abandoned for decades. Thus, IBR evolved into a submuscular 2-stage (tissue expander followed by definitive implant) approach, which provided the best implant coverage and reduced the complication rates. In 1998, Spear and Majidian¹⁵ reported their experience with textured expanders and integrated valves. They reported a capsular

Figure 1 Photographs of a 36-year-old Woman Who Had Presented With a *BRCA-2* Gene Mutation and Had Undergone Bilateral Breast Reconstruction Actualized in Nipple-sparing Mastectomy and Direct-to-implant With Prepectoral Polyurethane Positioning (BRAND4P) for Cancer Risk Reduction. (A) Preoperative Frontal Photograph. (B) Frontal Photograph 4 Months After Bilateral BRAND4P, With the Polytech Microthane Replicon MHS, 445-cm³ Volume Implant Positioning. (C) Preoperative Three-quarter Left Side View. (D) Postoperative Three-quarter Left Side View. (E) Preoperative Three-quarter Right Side View. (F) Postoperative Three-quarter Right Side View

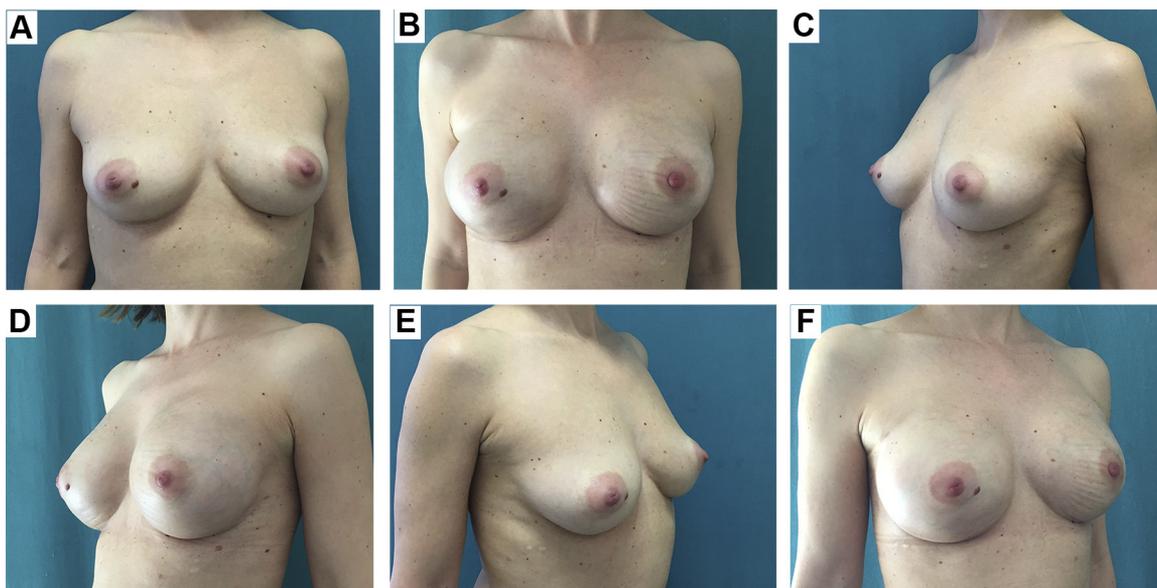
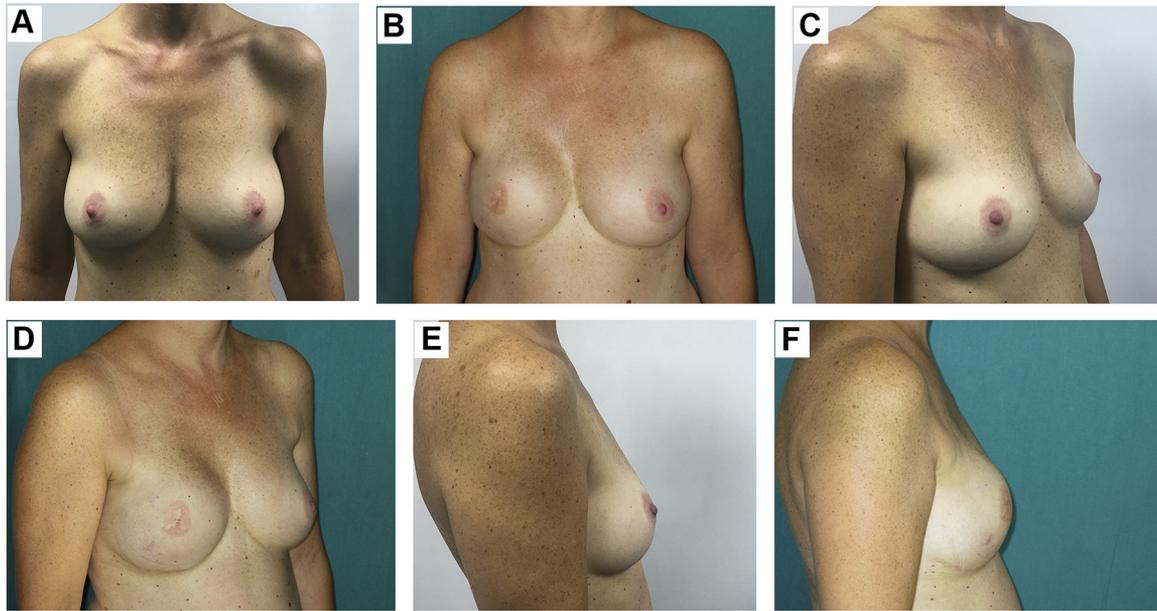


Figure 2 Photographs of a 41-year-old Woman Who Had Presented With Right Breast Stage T1 Ductal Carcinoma and Had Undergone Right Bilateral Breast Reconstruction Actualized in Nipple-sparing Mastectomy and Direct-to-implant With Prepectoral Polyurethane Positioning (BRAND4P) With a Polytech Microthane Replikon MHS 350-cm³ Volume Implant. (A) Preoperative Frontal Photograph. (B) Frontal Photograph 6 Months After Right Therapeutic BRAND4P and Nipple Resection Because of Positive Intraoperative Subareolar Tissue Frozen Section Findings. (C) Preoperative Three-quarter Right Side View. (D) Postoperative Three-quarter Right Side View. (E) Preoperative Lateral Right Side View. (F) Postoperative Lateral Right Side View



contraction rate of 3%, infection rate of 1.2%, and an overall deflation rate of 1.8%.¹⁵ More importantly, 98% of their patients reported satisfaction with their prosthetic reconstruction.¹⁵ The efficacy of the aesthetic results, combined with the development of less-aggressive and more conservative techniques regarding skin flaps and the NAC, led to the staged IBR procedure to become the most common breast reconstruction procedure performed.¹⁶

The introduction of skin-sparing mastectomy and the availability of ADMs and synthetic meshes radically changed this trend, allowing surgeons to perform, in most cases, immediate DTI breast reconstruction, simulating total muscle coverage of the implant without the need for expansion.^{4,5} This approach includes division of the pectoralis major muscle, which is then incorporated with the mesh to form a pocket for the implant. The mesh and muscle form an internal bra to hold the definitive implant, providing the additional support needed at the inferior and lateral pole. The advantages include single-stage reconstruction, improved lower pole projection, and better psychological outcomes. A multicenter study reported no significant differences in the complication rates between the DTI and the traditional expander/implant techniques for immediate reconstruction after mastectomy.¹⁷

Moreover, it has been well demonstrated that DTI prosthetic breast reconstruction is cost effective relative to staged, expander-implant reconstruction. This cost reduction has mainly resulted from the great cost differences between the 2 procedures and the similar complication rates.¹⁸ However, some complications

resulting from pectoralis elevation, including animation deformity, function impairment, and chronic pain, have remained unsolved. All patients with subpectoral implants will experience some degree of animation deformity, and this has been considered to be an expected occurrence.⁷ The deformity occurs during normal activities and exercise that involves flexion, adduction, and medial rotation of the arm. The deformity occurs because as the pectoralis muscle contracts, the subpectoral implant is forced to move from its normal position as a single unit. Furthermore, the adhesion of the mastectomy flap and the degree of retraction of the pectoralis muscle can affect the degree of animation.¹⁹ Functional impairment, in particular, impaired adduction, anteversion, and inward rotation of the upper limb during pectoralis contraction, and severe pain requiring analgesics, have been frequently reported postoperatively after subpectoral implant placement.^{20,21} Animation deformity often contributes in time to breast asymmetry resulting from prolonged implant displacement.¹⁸ One study assessing the effects of breast symmetry on patients' quality of life found that women with pronounced breast asymmetry were more likely to experience poor psychosocial functioning and have a greater risk of developing depression.²² The animation deformity phenomenon causes considerable impairment of breast reconstructions and is 1 of the most frequent indications for revision interventions. The currently available treatments for patients after submuscular reconstruction have included botulinum toxin injections, selective neurectomy, fat grafting, pectoralis muscle release or division,

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capsulotomy, capsulectomy, and an implant size change. However, these treatments have usually only offered a temporary or incomplete solution.²³⁻²⁵

Recently, the interest in DTI breast reconstruction with the prepectoral implant has been reawakened by the need to resolve the complications and impairment of the outcomes resulting from the submuscular placement of the implant. The muscle-sparing approach preserves the integrity and functionality of the chest wall musculature and completely bypasses the problem of animation deformity. The implant is placed in the subcutaneous layer, exactly in the place of the excised breast parenchyma. Prepectoral breast reconstruction using a silicone gel-filled implant totally wrapped with porcine ADM was first described in 2015.⁷ Becker and Fregosi⁷ reported good cosmetic outcomes, no breast animation, and no capsular contracture with a mean follow-up of 6 months. Vidya et al²⁶ reported the results from a multicenter study of 100 cases using the preshaped ADM Braxon implant (DECOMed, Marcon, Italy), with a follow-up period of 17.9 months. The complications included a 2% rate of implant loss, 1% rate of wound breakdown, 5% rate of seroma, and 2% rate of hematoma.²⁶ Casella et al^{9,27} reported similarly good outcomes using the TiLOOP bra mesh (pfm medical titanium GmbH, Nürnberg, Germany).

With concerns regarding the high healthcare costs, objections have been raised regarding the cost-effectiveness of these techniques. Thus, we sought to perform the best and most cost-effective procedure, maintaining the advantages of DTI and prepectoral reconstruction without increasing the complication rate, by introducing our BRAND4P method. The polyurethane foam-coated breast implant is a well-known device in the breast prosthetic panorama, both for augmentation and for reconstruction.²⁸ Since their introduction, investigators have reported a very low capsular contracture rate (<1%).^{29,30} Polytech Microthane implants are provided with a 1.4-mm micropolyurethane sponge layer that covers the whole implant, forming an integrated ready-to-use device. Thus, the breast implant does not require further coverage with an ADM or a synthetic mesh and can be safely placed in the prepectoral space, resulting in a more cost-effective procedure. Because the implant does not require implant preparation or manipulation, its use also reduces the operating time. We have reported encouraging results from our early experience, with no major complications, satisfactory cosmetic outcomes, and excellent patient satisfaction. We believe our outcomes resulted mainly from accurate patient selection, a proper operative technique, and the implant features. Because the implant is placed close to the breast skin flaps, with coverage by less vascularized soft tissue, the surgeon must use specific patient selection criteria and careful intraoperative assessment of the breast skin flap quality.^{31,32} Uncontrolled diabetes mellitus, active smoking, obesity, a history of radiotherapy to the chest wall, and similar conditions in which patients have compromised microvascular circulation and poor soft tissue quality are absolute criteria of exclusion owing to the highly increased risk of skin breakdown and consequent extrusion and/or infection of the implant. Recently, intraoperative laser-assisted indocyanine green fluorescent angiography has been used to demonstrate the safety and reliability of the immediate reconstruction after NSM.³³ In the same report, the investigators advocated the central role of the oncoplastic surgeon as a "one man band" to manage

breast cancer from the oncologic procedure to the breast reconstruction. Accurate oncoplastic techniques represent a key point to avoid major complications such as skin and NAC necrosis. We have assumed that the use of scissors for subcutaneous mastectomy results in a safe oncologic procedure with an adequate skin flap thickness and vascularization.³⁴ In addition, prepectoral positioning completely avoided all the complications usually reported by the patients who have undergone submuscular breast reconstruction, including animation deformity, chronic pain, and the loss of muscular function. The polyurethane coating is reabsorbed by the body and contributes to form an ideal capsule that hides the implant and reduces upper pole visibility and palpability, the rippling phenomenon, and, most importantly, capsular contracture, resulting in soft and natural-appearing breasts. The extremely adherent texture prevents implant rotation and displacement and, consequently, the need for revision surgery. Seroma is the most common complication reported after breast reconstruction using ADMs and can lead to implant explantation.³⁵ Surgeons have advocated a longer duration of drainage to reduce seroma formation; however, this can contribute to an increased risk of infection.³⁶ We have reported a short duration of drainage and during our follow-up period, we do not find any types of early or late seroma formation. We did have 1 patient who had developed a cutaneous hypersensitivity-like reaction associated with the breast implant. This occurrence has been reported in previous studies using both textured or polyurethane-coated implants. The attempted treatments have included topical and oral corticosteroids, montelukast, and antibiotics.³⁷ Most patients have required implant removal for symptom resolution. At our 6-month follow-up examination, implant explantation has not been required. Also, our patients did not require revision surgery.

Conclusions

As reported, NSM and DTI reconstruction is a safe oncologic procedure with satisfactory aesthetic outcomes.¹¹ The use of muscle-sparing prepectoral implant positioning avoids the occurrence of animation deformity and other complications that result from submuscular placement. In our experience, NSM and prepectoral polyurethane-coated implant positioning represent a quick and simple procedure with excellent outcomes and high patient satisfaction without increasing the complication rate. One limitation of our study was that it was retrospective. Our experience was also affected by other limitations, including the short follow-up duration and the limited number of patients treated. We expect to have a greater number of patients and longer follow-up time and to evaluate the effect of radiotherapy on breasts reconstructed with this technique to standardize our new BRAND4P procedure.

Clinical Practice Points

- We have introduced breast reconstruction after nipple-sparing mastectomy and direct-to-implant with prepectoral polyurethane positioning.
- The BRAND4P method represents a novel prepectoral approach and a feasible alternative to subpectoral implant placement among the available implant-based breast reconstruction techniques.

Disclosure

The authors declare that they have no competing interests.

Supplemental Data

The supplemental video accompanying this article can be found in the online version at <https://doi.org/10.1016/j.clbc.2018.12.015>.

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