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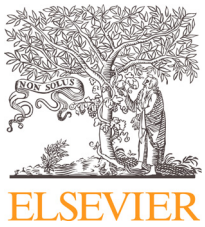

Prepectoral immediate breast reconstruction with polyurethane foam-coated implants: Feasibility and early results in risk-reducing and therapeutic mastectomies

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Summary *Background:* There is a renewed interest for prepectoral reconstruction. We aimed to describe the feasibility and the early complications associated with immediate one-stage direct-to-implant (DTI) reconstruction using prepectoral anatomical polyurethane (PU) foam-coated implants alone, for women with breast cancer or mutation carriers undergoing risk-reducing surgery.
Methods: We performed a single-center, retrospective review of 50 patients (mean age of 49 years), who underwent skin-sparing mastectomy (SSM) or nipple-sparing mastectomy (NSM) and immediate prepectoral PU implant-based reconstruction. All procedures were performed by the same senior operator, from July 2018 to March 2020.
Results: A total of 64 mastectomies (25 SSMs and 39 NSMs) with one-stage prepectoral PU foam-coated implant reconstruction were performed. Out of 50 patients, 6 required surgical revision within 30 days, because of hematoma (2), wound dehiscence (2) infection (1), and full thickness nipple-areolar complex (NAC) necrosis (1). Four patients developed a cutaneous rash with spontaneous resolution. Statistical analysis showed a significant influence of hypothyroidism and previous radiotherapy on the risk of complications. The association with prior radiotherapy (pRT) was not significant using binary logistic regression. When excluding oncological reasons

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and patient's wish for NAC excision, our decision to perform an NSM was influenced by breast cup size, preoperative measurements, and breast weight.
Conclusions: Early experience with immediate prepectoral DTI reconstruction with PU-covered implants alone suggests that it is a reliable procedure. Prior breast irradiation does not increase postoperative complication rates in our series. NAC preservation was decided according to preoperative lower breast measurements.

1. Introduction

Implant-based reconstruction remains the most common approach to restore the breast volume and mound after mastectomy [1,2]. For decades, subpectoral implant placement has been the recommended practice to overcome the high complication rates related to the subcutaneous location. Because the muscle interface underneath the skin is well vascularized, it was thought to offer better device protection in case of wound breakdown and to decrease the risk of capsular contracture (CC) [3,4]. Despite these advantages, pectoralis elevation has drawbacks which include breast animation deformity (BAD), pain associated with muscle spasm, and potential impairment to shoulder motion [5,6].

Over the past few years, the evolution of mastectomy and reconstructive procedures combined with the emergence of new tools and materials, has allowed prepectoral prosthetic-based breast reconstruction to regain popularity [7–11].

In our department, we shifted from submuscular toward subcutaneous device placement for all implant-based breast reconstructions. Single-stage prepectoral reconstruction is performed with polyurethane (PU) foam-coated implants, with no further coverage in both risk-reducing and therapeutic cases. In addition to the benefits of the prepectoral plane, we believe that this approach offers a reliable and cost-effective alternative, compared with total implant coverage with acellular dermal matrix (ADM). In this study, we sought to evaluate our early outcomes with this technique. We also investigated the potential risk factors for postoperative complications and how the preoperative breast measurements influenced our decision-making for the nipple-areolar complex (NAC) preservation. No esthetic evaluation of the results was carried out for this study.

2. Patients and methods

2.1. Patient selection

A retrospective review was performed to identify all consecutive patients who underwent an immediate direct-to-implant (DTI) breast reconstruction with prepectoral PU foam-coated implants, from July 2018 to March 2020. Criteria for NAC resection were clinical or radiological nipple involvement, tumor-to-nipple distance (TND) < 2 cm and significant breast ptosis evaluated by the nipple to inframammary fold (N-IMF) distance and the inframammary fold to lower pole of the breast (IMF-BLP) distance (Fig. 1). Patient's choice for NAC removal was considered in risk-reducing surgery. One-stage prepectoral DTI reconstruction was systematically offered during the preoperative consultation either to the patients who were not eligible for autologous reconstruction or according to the patient's preference. Prior radiotherapy (pRT) and the need for post-mastectomy radiotherapy (PMRT) were not considered as a contraindication. Active smokers were not excluded, but were asked to stop for at least 4 weeks before the scheduled surgery. Patients with small breasts requiring NAC or skin excision in order to obtain safe oncological margins were not included, as they were offered a two-stage procedure with immediate prepectoral expander placement. All patients were informed that the decision to perform a single-stage DTI reconstruction would depend on preoperative mastectomy flap perfusion. The probability of additional revision surgeries with lipofilling was made clear.

2.2. Surgical technique

Both the mastectomy and the reconstructive procedures were performed under general anesthesia by the senior author (M.C.). The axillary procedures, sentinel lymph node dissection (SLND) or axillary lymph node dissection (ALND), were performed by a breast surgeon, either through a separate axillary incision or through the mastectomy incision. Nipple-sparing mastectomy (NSM) was usually performed using a 6–7 cm lateral IMF incision except for patients with pre-existing hemiareolar scars. Skin-sparing mastectomy (SSM) was performed through a circular incision surrounding the NAC. If required, a skin reduction was achieved using a trans-vertical incision. For all mastectomies, we proceeded first with an infiltration of a saline epinephrine-containing solution (1 mg/mL epinephrine/1 L NaCl) followed by anterior blunt and sharp scissor dissection. Electrocautery was used only to detach the breast tissue from the pectoral muscle fascia. The pocket was systematically inspected to ensure that there was no residual breast tissue. For NSM, the tissue underneath the nipple was excised to be pathologically evaluated. No frozen sections were sent. NAC and/or mastectomy flap perfusion were clinically evaluated based on coloration, capillary refill, and dermal bleeding from surgical wound edges after minimal skin excision. Pectoralis nerves and serratus plane (Pecs) blocks were performed by injection under direct vision control, of local anesthetic (ropivacaine 0.5%). Implant selection was based on preoperative measurements, breast footprint and skin quality. Accordingly, a sizer implant was placed in the mastectomy pocket to confirm the chosen volume and shape. Two 10

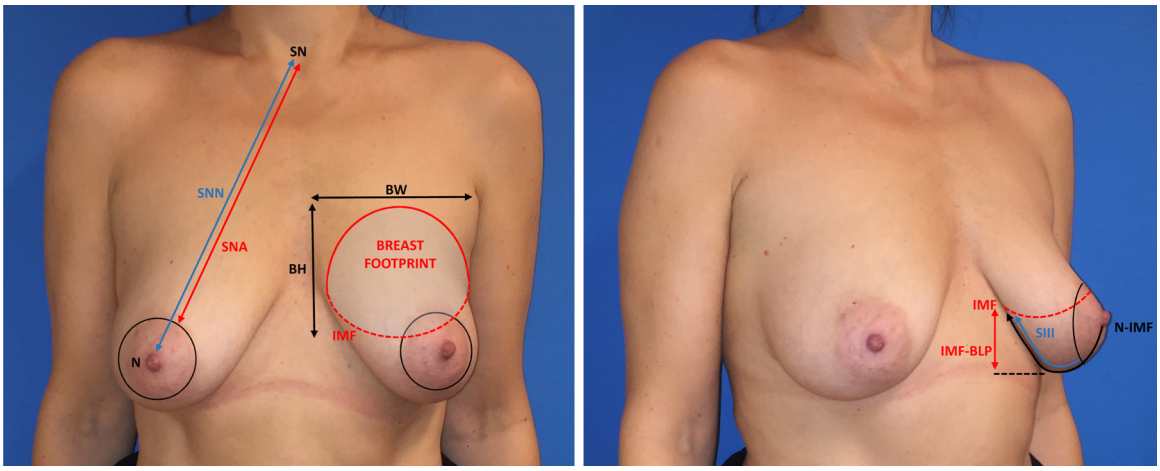

Fig. 1 Clinical breast measurements: The following anthropomorphic parameters were collected for each breast: sternal notch to nipple distance (SNN), sternal notch to areola distance (SNA) breast width (BW), breast height (BH), N-IMF, areola to inframammary fold distance (SIII), IMF-BLP.

French Blake® (Ethicon, Johnson-Johnson, Somerville, New Jersey, USA) drains were placed prior to implant insertion. The definitive prosthesis soaked in povidone-iodine was inserted thereafter in the prepectoral pocket. The correct positioning was carefully controlled with the patient in upright sitting position. Drains were removed when their daily output was less than 30 mL and patients remained on oral antibiotics until then. After discharge, follow-up was planned every 2 weeks for 1 month, every 3 months for 6 months, and then yearly.

2.3. Data collection and analysis

Patient demographics and clinical characteristics were recorded including age, body mass index (BMI), smoking history, comorbidities, prior breast surgery and irradiation or neoadjuvant treatment, breast morphological measurements, pre-existing scar location, indication of surgery (therapeutic or prophylactic), mastectomy type (NSM versus SSM), axillary management (SLND and ALND), specimen weight, implant characteristics, and adjuvant treatments. All the implants used in this study were micro PU foam-coated anatomical breast implants (Microthane® POLYTECH, Health & Aesthetics, Dieburg, Germany). Early postoperative complications, up to 30 days, were collected.

Statistical analyses were conducted considering each patient or each breast independently, using IBM SPSS Statistics for MAC version 26 (IBM Corp., Armonk, NY, USA). Independent Student's t-tests were used to compare means of continuous variables. We used the chi-square method to analyze the influence of ordinal variables. All results were confirmed with uni- and multivariate binary logistic regressions.

3. Results

Fifty patients were included with a mean age of 49 years (MIN 30 - MAX 75; STD DEV 11.483) and a mean BMI of 22.94 kg/m^2 (MIN 17.40 - MAX 38.20; STD DEV 3.98). Fourteen patients ($n=14/50$; 28.0%) underwent bilateral reconstruction. Five patients suffered from arterial hypertension ($n=5/50$; 10.0%) and five from hypothyroidism ($n=5/50$; 10.0%), Five patients were previous smokers (smoking stopped more than 6 months before surgery; $n=5/50$; 10.0%), while six were active smokers ($n=6/50$; 12.0%). Seven patients presented other comorbidities: terminal renal failure, factor V of Leiden mutation, anemia, dyslipidemia, and HIV positive. Ten patients ($n=10/50$; 20.0%) presented a BRCA-1 gene mutation, five a BRCA-2 gene mutation ($n=5/50$; 10.0%), 3 a PALB2 gene mutation ($n=3/50$; 6.0%), and four presented a significant familial breast cancer history, with no identified breast-related genetic mutation. Considering risk-reducing mastectomy, seven patients ($n=7/50$; 14.0%) had no personal history of breast cancer. Seventeen patients benefited from neoadjuvant treatment ($n=17/50$; 34.0%) with chemotherapy and/or immunotherapy. On average, surgery was performed 4.79 weeks after the end of the neoadjuvant treatment.

In total, 64 mastectomies were performed with a mean specimen weight of 367.57 g (MIN 101.0 - MAX 889.0; STD DEV 188.22). Twenty-seven SLND ($n=27/64$; 42.2%) and eight ALND ($n=8/64$; 12.5%) were performed. In 16% of the cases ($n=8/50$), a concomitant procedure was performed: 3 bilateral adnexectomies, 2 contralateral secondary breast reconstructions with expanders, 1 contralateral lumpectomy, 1 contralateral immediate breast reconstruction with expander and 1 port-a-cath removal.

The preoperative breast measurements are shown in Fig. 1. Measured cup sizes were distributed as follows: 8 A-cup ($n=8/64$, 12.5%), 19 B-cup ($n=19/64$, 29.7%), 17 C-cup ($n=17/64$, 26.6%), 15 D-cup ($n=15/64$, 23.4%), and 5 E-cup ($n=5/64$, 7.8%). Three breasts were previously irradiated ($n=3/64$; 4.7%). Fifteen breasts presented scars due to previous surgeries ($n=15/64$; 23.4%), of which 8 presented skin retractions ($n=8/15$; 53.3%). Twenty-five patients ($n=25/50$; 50.0%) received adjuvant treatment. A total of 9 breasts were irradiated ($n=9/64$; 14.1%).

Thirty-nine NSM ($n=39/64$; 60.9%) were performed of which, 33 through an IMF incision ($n=33/39$; 84.6%) and 6 through an existing periareolar scar ($n=6/39$; 15.4%). Out

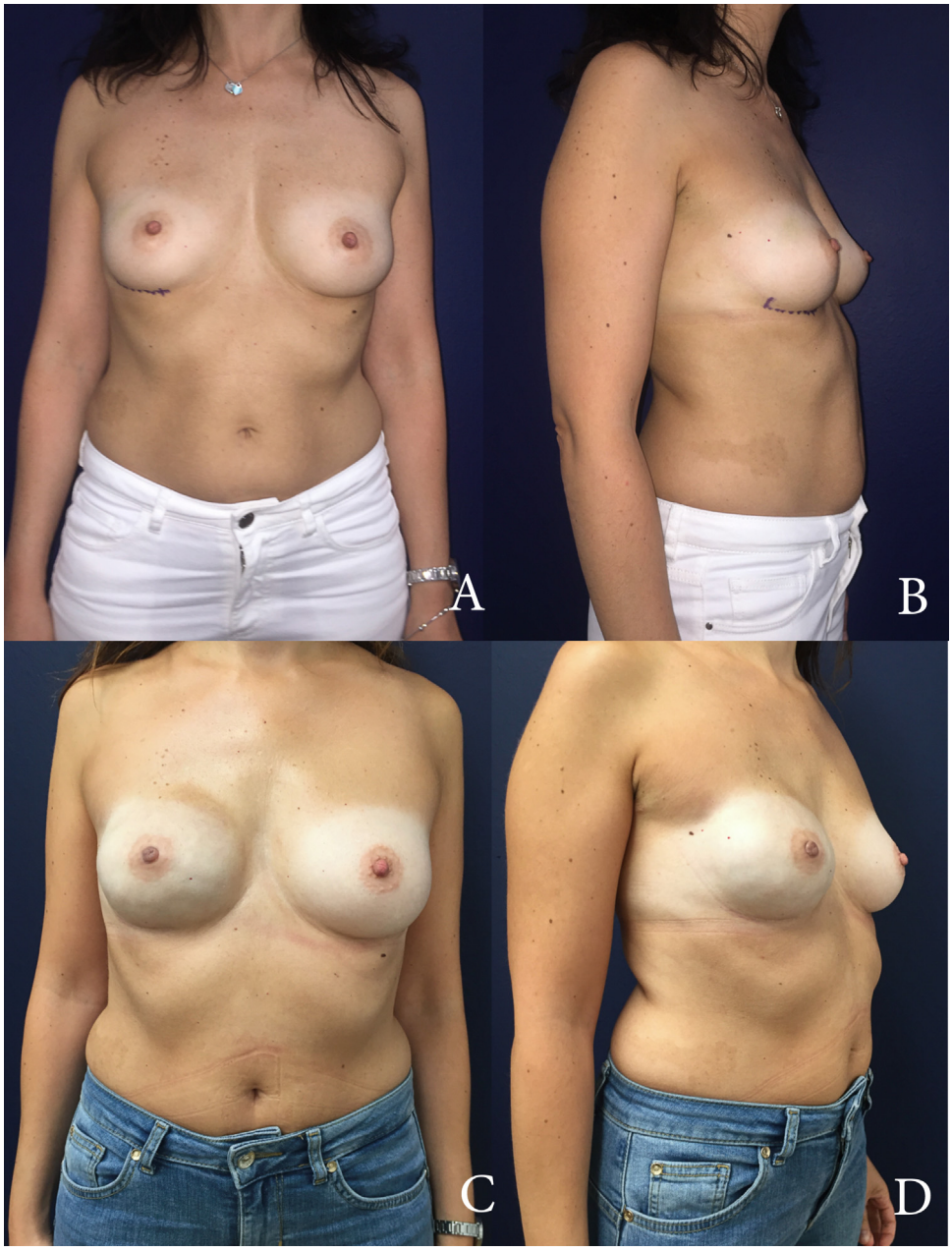

Fig. 2 A 42-year-old patient with multifocal ductal carcinoma in situ component (DCIS) and Invasive ductal carcinoma (IDC) grade 1 of the right breast preoperatively (A-B) and 1 year postoperatively (C–D) after right NSM with immediate prepectoral PU foam-coated implant reconstruction.

of the 25 SSM ($n = 25/64$; 39.1), 21 were performed through a circular incision surrounding the NAC ($n = 21/25$; 84.0%), 3 with a transvertical incision ($n = 3/25$; 12.0%) and 1 with a vertical incision ($n = 1/25$; 4.0%), due to local skin involvement. Pre- and postoperative photographs are shown in Figs. 2-4. Out of the 20 women ($n = 20/50$; 40.0%) who underwent an SSM, 9 did not have an oncological indication for NAC excision ($n = 9/20$; 45.0%). For 8 patients ($N = 8/9$; 88.8%), the decision to perform an SSM was made in order to minimize the risk of skin necrosis, while 1 patient ($n = 1/9$; 11.1%) asked for bilateral NAC removal.

We observed 10 complications ($n = 10/64$; 15.6%), 6 of which required surgical revision ($n = 6/10$; 60.0%). We had 2 hematoma drainages ($n = 2/10$; 20.0%) and 2 mastectomy scar dehiscences ($n = 2/10$; 20.0%) resulting in delay of adjuvant radiotherapy treatment in one patient. The 4 implants were abundantly washed and put back in place. One patient ($n = 1/10$; 10.0%) presented seroma with clinical signs of infection. The prosthesis was removed and replaced by a prepectoral expander after a thorough pocket washing. The last patient ($n = 1/10$; 10.0%) presented full-thickness NAC necrosis requiring secondary excision and implant replacement by an expander. A transient cutaneous rash on the reconstructed breast was seen in 4 patients ($n = 4/10$; 40.0%).

Statistical analysis showed a significant influence of hypothyroidism and previous radiotherapy on the risk of complications, as shown in Table 1. The influence of hy-

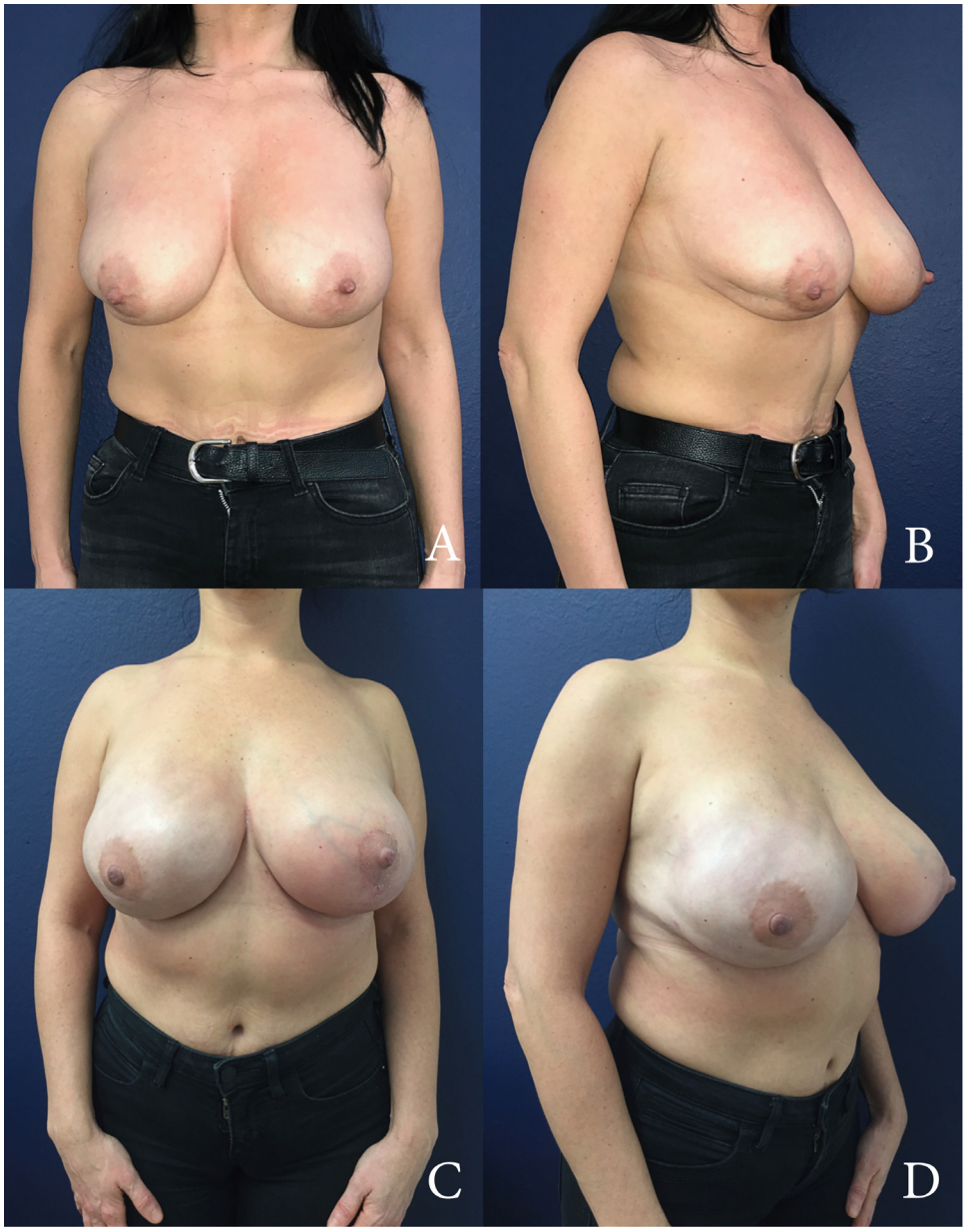

Fig. 3 A 43-year-old patient with positive margins for DCIS grade III of the right breast after lumpectomy showing skin retraction (A-B). Photographs (C–D): 6 months postoperatively after right NSM by hemiareolar approach with immediate prepectoral PU foam-coated implant reconstruction and 3 months after right breast lipofilling and contralateral mastopexy.

pothyroidism was confirmed with univariate binary logistic regression and was associated with an increased risk of complication (P-value = 0.036; odds ratio = 8.143). The association with previous radiotherapy was not significant using binary logistic regression.

Excluding oncological indication or patient's choice, our decision to excise the NAC ($n = 8/50$ patients; $n = 12/64$ breasts), was influenced by breast cup size, preoperative measurements and mastectomy specimen weight. Using univariate binary logistic regression, only the preoperative breast measurements and specimen weight stayed significant. Multivariate analysis did not highlight the superiority of one measurement over the others as they are all very highly correlated. Receiver operating characteristic curve (ROC) analysis indicated a slight superiority of the N-IMF and IMF-BLP measurements, as shown in Fig. 5.

4. Discussion

4.1. Evolution of our surgical practice

Our surgical approach has shifted from sub- to prepectoral breast reconstruction due to complaints about animation deformity, regardless of good esthetic results among younger patients undergoing risk-reducing surgeries. Beyond postoperative pain, the main downside of subpectoral implant-based reconstruction is the visible deformity of the

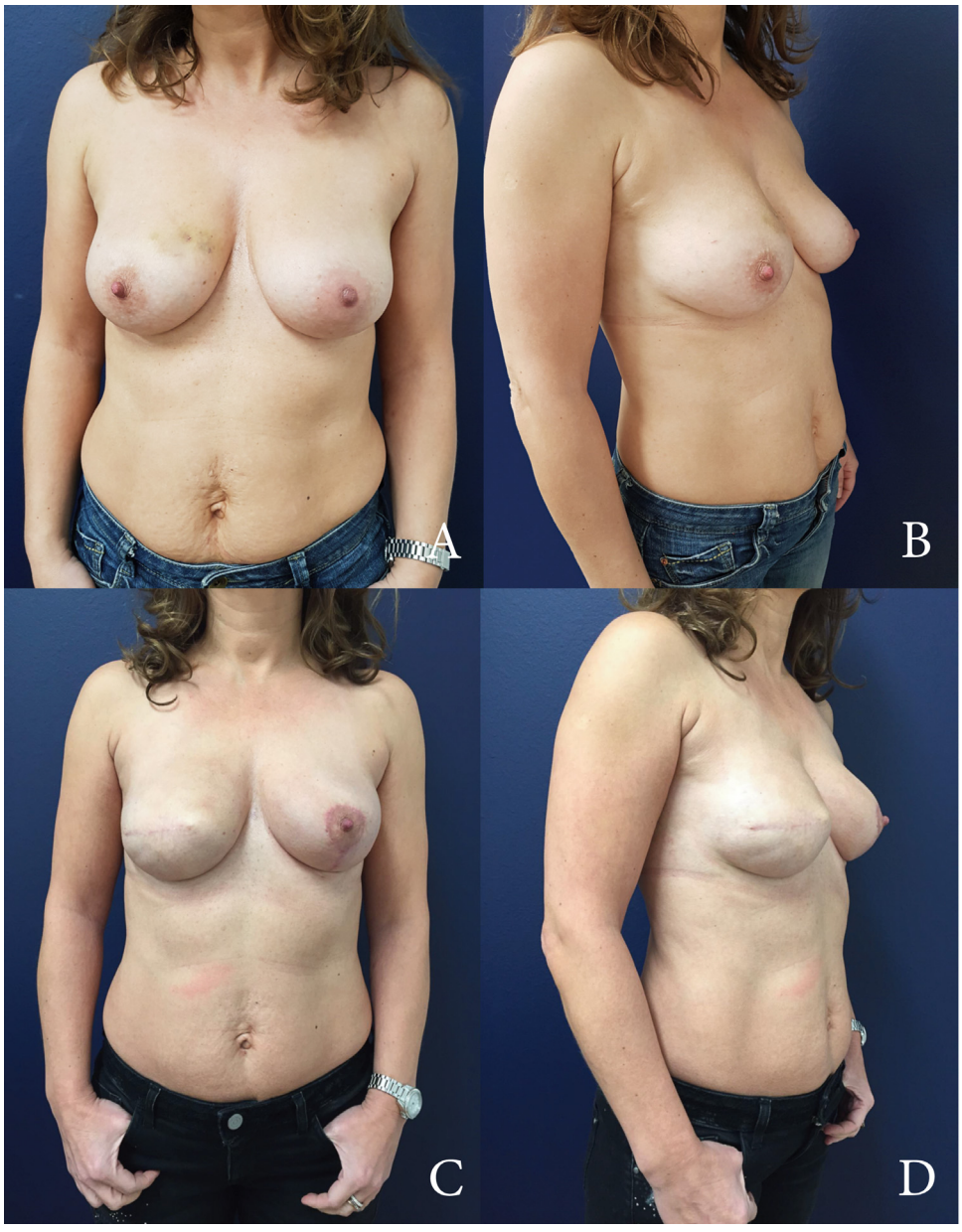

Fig. 4 A 46-year-old patient with multifocal DCIS grade III of the right breast preoperatively (A–B) and 6 months (C–D) after SSM with immediate prepectoral PU foam-coated implant reconstruction and 3 months after right breast lipofilling and contralateral mastopexy.

breast during pectoralis major contraction. BAD can affect patient's quality of life and may represent a major concern for women [5,6]. Prepectoral reconstruction preserves muscle function and anatomy, thus solving this problem [12]. This evolution of our practice was facilitated by two major factors: better mastectomy flap control and the use of last generation PU foam-coated implants.

4.2. Mastectomy flap control

Adequate mastectomy flap perfusion is the *sine qua non* condition for successful breast reconstruction [13]. In our department, a tumescent mastectomy technique is performed by the plastic surgeon if an immediate reconstruction is planned. We find it helps to create a relatively bloodless dissection plane and minimizes thermal damage to the skin flaps. In case of NSM, the inframammary approach is our first choice. Nevertheless, we performed mastectomies through pre-existing periareolar scars without a significant increase in complication rates. We assumed that the previous scar allows a delay phenomenon on the NAC blood supply and that no further incision should be made in order to preserve its remaining perfusion. We did not set a minimal thickness cut-off to perform prepectoral reconstruction and tissue perfusion was only clinically assessed. When in doubt, we prefer to delay the reconstruction rather than place an expander.

Table 1 Influence of variables on the risk of complications showing that only hypothyroidism is statistically significant with univariate binary logistic regression (P-value < 0.05). The influence of previous radiotherapy was not confirmed to be significant using binary logistic regression.

Variable	Type of variable	Test used	CHI-SQUARE / T-TEST P-VALUE	Regression P-value
ASA status	Ordinal	Chi Square	0.562	0,97
Diabetes	Dichotomous	Chi Square	0.470	0,999
HTA	Dichotomous	Chi Square	0.239	0,999
Hypothyroidism	Dichotomous	Chi Square	0.018	0,036
Previous smoker	Dichotomous	Chi Square	1	1
Active smoker	Dichotomous	Chi Square	0.828	0,828
Age	Continuous	Independent T-Test	0.552	0,544
BMI	Continuous	Independent T-Test	0.159	0,173
Neoadjuvant treatment	Dichotomous	Chi Square	0.256	0,356
Concomitant procedure	Dichotomous	Chi Square	0.958	0,451
Previous radiotherapy	*Dichotomous*	*Chi* Square	*<0.001*	*0,999*
Adjuvant treatment	Dichotomous	Chi Square	0.840	0,947
ALND	Dichotomous	Chi Square	0.531	0,442
SLND	Dichotomous	Chi Square	0.809	0,879
NSM	Dichotomous	Chi Square	0.633	0,947
SSM	Dichotomous	Chi Square	0.633	0,947
Scars	Dichotomous	Chi Square	0.741	0,596
NAC involvment	Dichotomous	Chi Square	0.242	0,442
Cup Size	Ordinal	Chi Square	0.427	0,986
Therapeutic vs prophylactic	Dichotomous	Chi Square	0.879	0,684
Breast weight	Continuous	Independent T-Test	0.500	0,356
SNA	Continuous	Independent T-Test	0.222	0,505
SNN	Continuous	Independent T-Test	0.334	0,608
NIMF	Continuous	Independent T-Test	0.413	0,981
SIII	Continuous	Independent T-Test	0.446	0,906
NIMF-BLP	Continuous	Independent T-Test	0.689	0,925
Base	Continuous	Independent T-Test	0.127	0,316
Height	Continuous	Independent T-Test	0.210	0,409

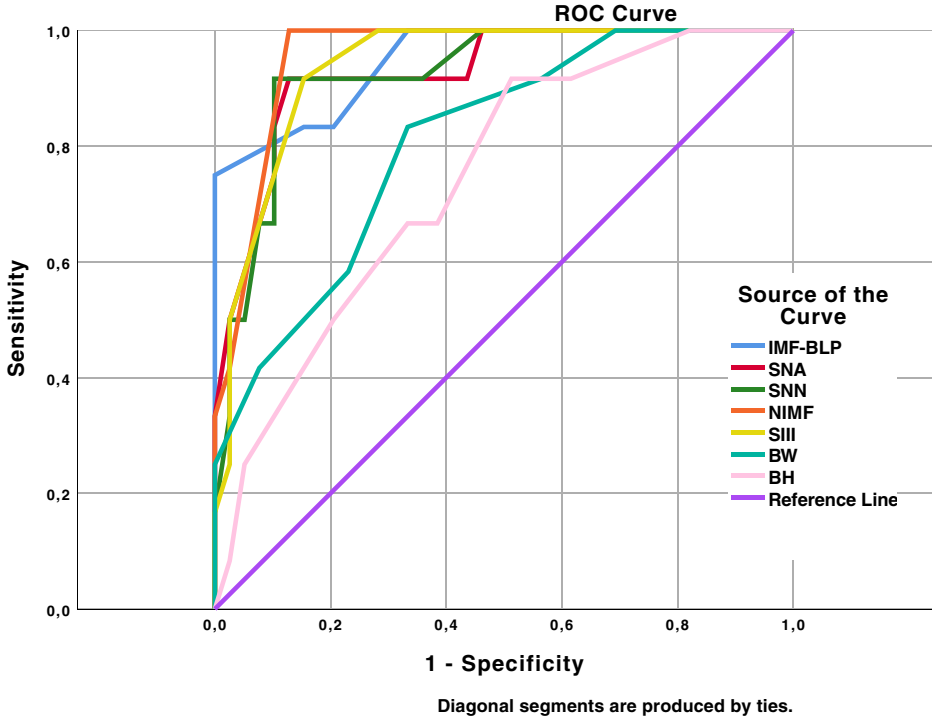

Fig. 5 ROC analysis illustrating the influence of variables on the propensity to propose an SSM and showing an important correlation between breast measurements with a slightly higher area under the curve for the IMF-BLP and N-IMF distances.

4.3. Polyurethane-coated implant use

One of the difficulties of prepectoral reconstruction is to reduce the mastectomy cavity, preventing lateral or inferior implant displacement. This can be achieved either by creating a tight pocket or by fixing the implant. In order to do so, the use of biological and synthetic meshes has been widely adopted [14]. Implementation of ADM has been a decisive factor for many surgeons to reconsider prepectoral reconstruction [15,16]. However, higher complication rates [17], combined with expensive prices could hinder their use [18]. High additional costs are not automatically covered by insurances through all countries. With the PU foam, the implant stays fixed to the chest wall, without the need for extra mechanical support. However, it has to be immediately properly positioned. Surgeons unfamiliar with this type of prosthesis should expect a learning curve. Early results of de Vita et al. confirmed the feasibility and cost-effectiveness of this technique in NSM [19].

Implants with a PU foam cover have been used by plastic surgeons since 1970 [20-24]. Concerns about a potential carcinogenic risk related to PU degradation products led to the device withdrawal from the American market in the early 90 s [25]. Modern versions of this device remained available throughout Europe and other parts of the world and have been part of the current practice of numerous surgeons [26,27]. Several reports attest their safety and their advantages with an extremely low incidence of CC [28-30].

Out of 64 breasts, we recorded 4 cutaneous erythema, 2 of which had been previously irradiated. Red breast syndrome (RBS) was diagnosed after an infectious cause was ruled out. Resolution was observed in all patients. Associated symptomatic itching was treated with non-steroidal anti-inflammatory and anti-histaminic drugs during 3–5 days. Cutaneous rashes have been previously described by several authors with a favorable evolution [21,23,28,31]. This hypersensitivity-like reaction is not exclusively associated with PU devices and has been associated with the use of ADM and with textured implants as well [32]. Gradual release of antiseptic solution due to the retaining capacity of the foam, transient lymphatic obstruction related to the biointegration process and pRT could have favored the occurrence of RBS in our series. But this needs further investigations.

Breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) is a rising concern in prosthetic breast surgery. As other authors previously advocated [33], PU foam-coated implants cannot be classified as high-textured implants and therefore linked to a higher risk of BIA-ALCL. Genetic predisposition, immune system response, friction between the device and surrounding tissues, infection, biofilm formation, as well as the implant surface, are under research to explain the pathogenesis of this rare disease [34]. Not only are our patients thoroughly informed of the risk of BIA-ALCL, but all women who have undergone a mastectomy reconstruction procedure are subject to close clinical and radiological follow-up.

4.4. Careful patient selection

Careful patient selection is essential when proposing prepectoral DTI reconstruction [16]. Obesity [35], large and ptotic breasts [36] along with increasing mastectomy weight [37] are some of the commonly described risk factors for complications in implant-based reconstruction. However, recent studies have pointed out that prepectoral implant placement could be a better reconstructive option compared with the subpectoral plane in a high BMI population [38]. In the present series, cup size, breast weight, and BMI were not associated with increased complication rates. This might be explained by our choice to renounce on NAC preservation in large and ptotic breasts. Our preoperative measurements of the lower breast (N-IMF and IMF-BLP distances) seem to be the most significant factors in our decision making and should be further investigated.

Identification of hypothyroidism as a significant risk factor of complications among our population may be attributed to our small sample size. Previous irradiation had no significant influence using binary logistic regression in our studies, but this needs to be confirmed on a larger population. Some authors showed that prior breast irradiation should not be a contraindication to NAC sparing surgery when immediate DTI reconstruction is performed [39]. Nevertheless, patients with irradiated breasts are not commonly offered prepectoral definitive implant placement [40]. In our institution, an autologous option is always preferred in the setting of pRT. However, immediate prepectoral PU implant-based reconstruction can be safely offered to patients for whom this option is not available or to those who are seeking a less invasive procedure.

5. Conclusion

This study shows that prepectoral one-stage DTI reconstruction with PU foam-covered implants alone is a reliable procedure. Cautious management of the breast envelope ensures adequate mastectomy flap perfusion, while the characteristics of the PU foam allow correct implant position without the need for extra mechanical support. Careful patient selection is mandatory, but prior breast irradiation should not be considered as a contraindication to prepectoral PU device placement. BMI, cup size, and mastectomy specimen weight were not associated with increased complication rates. The influence of the lower breast measurements on decision-making for NAC preservation should be explored. esthetic evaluation and outcomes of PMRT need to be evaluated in a longer term.

Declaration of Competing Interest

None declared

Funding

None.

Ethical approval

Not required.

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