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Outcomes, indications and predictive factors for complications in postmastectomy prepectoral reconstructions with polyurethane foam-coated implants

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A B S T R A C T

Background: Implant-based reconstruction (IBR) is the most common reconstructive strategy following mastectomy. Advancements in surgical techniques and materials have led to improvement in perfusion and thickness of mastectomy skin flaps and they have renewed interest in prepectoral breast reconstruction (PBR). The aim of this study was to analyze the surgical outcomes of skin or nipple-sparing mastectomies with direct-to-implant (DTI) reconstructions with prepectoral polyurethane foam–coated implants.

Methods: A retrospective study was conducted on consecutive patients undergoing postmastectomy IBR-DTI with prepectoral polyurethane foam-coated implants between 2020 and 2022. Inclusion criteria were a preoperative pinch test >0.8 cm and well-perfused mastectomy flaps. Preoperative radiation therapy was not an exclusion criterium. Complications were classified as "major" if they required urgent re-intervention, and as "minor" if they required only outpatient management.

Results: A total of 250 patients and 317 breast reconstructions were included. The mean (±SD) age was 50.5 ± 10.9 years with a mean BMI of 23.8 ± 4.0. The mean follow-up was 12.2 ± 1.2 months. The overall rate of major complications was 6.3 %, being infection the most common major complication (2.5 %), followed by mastectomy flap necrosis (1.6 %), bleeding (1.6 %), and wound dehiscence (0.6 %). The overall minor complications rate was 27.8 %. Across minor complications, rippling was recorded as the most common (14.5 %), followed by capsular contracture (7.6 %), seroma formation (2.5 %), skin necrosis (2.2 %), hematoma (0.6 %) and wound dehiscence (0.3 %).

Conclusion: In our cohort, DTI-PBR with PU implants had a 6.3 % risk of major complications requiring urgent re-intervention. Hypothyroidism, diabetes, and overweight have been identified as risk factors associated with higher risk of complications.

1. Introduction

Implant-based reconstruction (IBR) is the most common reconstructive strategy following mastectomy [1,2]. According to the last American Society of Plastic Surgery (ASPS) report (2022), 77.8 % of breast reconstructions were implant-based [3].

Breast implants were first introduced in the 1960s, and they were originally placed subcutaneously, beneath the mastectomy flaps and above the pectoralis muscle [4,5]. While this approach preserved muscular integrity, the lack of adequate tissue support led to a high rate of complications such as flap necrosis and implant exposure and, more frequently, capsular contracture [4]. Therefore, the sub-pectoral approach, where the implant is positioned underneath the pectoralis major muscle, replaced subcutaneous reconstruction and it became the primary approach in breast reconstruction. Nevertheless, the sub-muscular placement can result in significant morbidity due to muscular fibers disruption and leading to post-operative pain and animation deformity [6,7]. Additionally, this approach has been associated with

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loss of muscle strength, and inadequate lower pole fullness at the reconstructed breast [8]. More recently, the advancements in surgical techniques, materials and perfusion imaging technology have led to improvement in perfusion and thickness of mastectomy skin flaps and they have renewed interest in prepectoral breast reconstruction (PBR) [9]. In PBR, the implant is placed between the skin envelope and the pectoralis major muscle fascia, preserving anatomical and functional muscular integrity. This technique offers satisfying aesthetic outcomes with minimal functional impairment [10].

In addition, to minimize the risks associated with PBR, the use of acellular dermal matrices (ADMs) or polyurethane (PU) foam-coated implants are preferred to modulate the foreign body reaction at the interface between the implant and the mastectomy flap and their use has been associated with a reduction of the risk of capsular contracture [11, 12].

Most of the available literature about PBR focused on the use of ADMs as adjunctive materials able to help support, protect, control implant position, and camouflage the implant itself, while a paucity of literature exists on PBR using PU foam–coated implants [4,13,14]. Moreover, regarding ADM, the current literature has shown a higher risk of morbidity without a corresponding improvement in patient-reported quality of life when immediate breast reconstruction with ADM was compared to two-stage reconstruction [15,16]. Furthermore, early studies have reported a higher incidence of seroma and infection when ADM is used in PBR compared to PU-coated implants [11,17].

PU-coated breast implants are characterized by a unique surface that differentiate them from traditional silicone or saline implants and the low rate of capsular contracture associated with PU-coated implants is linked to their distinct degradation process of PU particles on the implant outer shell. This process activates and mobilizes giant cells and macrophages, which phagocytize PU fragments, leading to a granulomatous reaction similar to a foreign body response. As a result, numerous non-coalescing "microcapsules" form around the implant during the inflammatory response. These capsules remain distinct and do not merge together and decrease the rate of capsular contracture [18, 19]. These particular characteristics have contributed to the growing popularity of PU implants. However, the largest studies evaluating PU implants in prepectoral breast reconstruction have employed strict exclusion criteria [20–23]. The aim of this study was to analyze the outcomes of skin (SSMs) or nipple-sparing mastectomies (NSMs) with direct-to-implant (DTI) reconstructions with prepectoral PU foam–-coated implants in a large population, in order to identify predictive factors of complications.

2. Methods

We retrospectively collected data from our prospectively maintained institutional database, including all consecutive patients undergoing postmastectomy IBR-DTI with prepectoral polyurethane foam-coated implants between March 1st, 2020 and December 31st, 2022. All implants were PU foam–coated implant by Polytech Microthane Sublime Line, Dieburg, Germany.

Institutional review board approval was obtained (UID4260). Patient informed consent form was obtained before surgery. The study was registered on www.clinicaltrials.gov (NCT06216106). Charts and operative reports were collected. Data extracted included patient demographics (age, BMI), smoking status, comorbidities (hypothyroidism, hypertension, diabetes), indication for surgery (therapeutic or risk reducing mastectomy), cancer histology, breast cancer TNM and staging, oncological therapies (neoadjuvant and adjuvant chemotherapy, hormonotherapy, HER2-target therapy) and radiation therapy, sentinel lymph node biopsy or lymph nodes dissection, mastectomy type, volume, and type of breast implant. All patients were initially evaluated by both the breast and plastic surgeons.

Inclusion criteria for prepectoral reconstruction were patient age >18 years, a preoperative pinch test at the upper breast quadrants >0.8 cm and well perfused mastectomy flaps. On the contrary, exclusion criteria were preoperative clinical signs of radiation-induced skin dystrophy in patients who previously have undergone radiation therapy and intraoperative signs of ischemia or congestion of the mastectomy flaps. Preoperative radiation therapy was not an absolute contraindication for DTI-PBR with PU.

Two types of Polytech PU implants were utilized: Replicon (anatomical shape with a round base) and Opticon (anatomical shape with an oval base). All SSM and NSM were performed through a traditional lateral oblique incision. Neither mesh nor ADM was used. A Blake-type suction drain was placed in each operated breast. After surgery, drains were removed when the output was serous and less than 50 cc daily.

Patients were evaluated in person at 1, 3, 6, and 12-month follow up by breast surgeons and plastic surgeons.

Patients with a follow-up shorter than 12 months were excluded from this case series.

Complications were classified as “major” if they required urgent re-intervention, and they include bleeding, infection, full-thickness mastectomy flap necrosis, and wound dehiscence. While they were classified as “minor” if they required only outpatient management, and they include seroma, rippling, partial-thickness mastectomy flap necrosis, hematoma, dehiscence, and capsular contracture Baker III or IV. All complications were assessed after complete physical examination. Reconstructive failure refers to the complete loss of the reconstructed breast, requiring removal of the implant without immediate replacement. This results in the patient not having a reconstructed breast, either temporarily or permanently, or having an autologous breast reconstruction.

2.1. Statistical analysis

Socio-demographic and clinical characteristics were analyzed using descriptive statistics. Categorical variables were reported with absolute frequencies and percentages, continuous variables with mean and standard deviation (SD). The Chi-square test was used to compare the frequency of complications, reconstructive failure and capsular contracture among irradiated and not irradiated patients. Univariable Cox proportional hazard regression models were fitted to assess the association of socio-demographic and clinical characteristics on the occurrence of minor or major complications and capsular contracture during follow-up. Hazard ratio (HR) and 95 % confidence intervals (CI) were reported.

All analyses were performed with SAS software v. 9.4 (SAS Institute, Cary, NC).

3. Results

A total of 250 patients, including 317 breast reconstructions, underwent DTI-PBR with PU following skin or nipple-sparing mastectomy and were included in the analysis. Patients’ demographic and clinical characteristics are summarized in Table 1. The mean (±SD) age was 50.5 ± 10.9 years with a mean BMI of 23.8 ± 4. Only 8.4 % of patients were obese. Active smokers were 10.8 %. The most common comorbidity was autoimmune hypothyroidism. Genetic mutations predisposing to breast cancer were identified in 15.6 % of patients, while 18.3 % of patients had a history of a prior breast surgery.

Breast’ clinical and pathological characteristics are shown in Table 2. In 66.6 % of the cases breast cancer presented at stage 1 or 0 in case of risk reducing mastectomies, and in 71.3 % no lymph node involvement (Nx/0) was observed. Axillary dissection was necessary in 10.1 % of cases. In most of the cases (92.7 %) a NSM was performed. The mean breast implant volume was 429 ± 114 cc with the majority of implants (33.8 %) included within the range of 400–499 cc, while implants larger than 500 cc were used in 25.2 % of cases. Interestingly, surgery on the contralateral healthy breast was performed in only 14.2 % of cases to

Table 1
Patients' demographic and clinical characteristics (n = 250 patients).

	Overall (N = 250)	
	N	%
Year of surgery		
2020	44	17.6
2021	95	38.0
2022	111	44.4
Age (years)		
<40	35	14.0
40-49	92	36.8
50-59	69	27.6
60+	54	21.6
Mean ± SD	50.5 ± 10.9	
BMI		
Normal weight (<25)	161	64.4
Overweight (25–30)	64	25.6
Obese (≥30)	21	8.4
Missing	4	1.6
Mean ± SD	23.8 ± 4.0	
Smoking status		
Non-smoker	181	72.4
Ex-smoker	42	16.8
Current smoker	27	10.8
Comorbidities		
No	204	81.6
Yes	46	18.4
Autoimmune hypothyroidism	*26*	*56.5*
Hypertension	*17*	*37.0*
Diabetes	*3*	*6.5*
Mutation		
No	211	84.4
Yes	39	15.6
BRCA1	*24*	*61.5*
BRCA2	*9*	*23.1*
CHEK2	*2*	*5.1*
Not specified	*4*	*10.3*
Number of days of hospitalization, mean ± SD	3.7 ± 1	
Number of days of drainage, mean ± SD	10.7 ± 4.2	
Chemotherapy		
No	153	61.2
Yes, neoadjuvant only	40	16.0
Yes, adjuvant only	48	19.2
Yes, neoadjuvant + adjuvant	9	3.6
Endocrine therapy		
No	122	48.8
Yes	128	51.2
Monoclonal antibodies		
No	223	89.2
Yes	27	10.8

achieve symmetry. The mean duration of hospitalization was 3.7 ± 1 days, while drains remained in place for a mean of 10.7 ± 4.2 days (Table 1).

3.1. Major and minor complications

After a mean follow-up of 12.2 ± 1.2 months, the overall rate of major complications was 6.3 %, being infection the most common major complication (2.5 %), followed by mastectomy flap necrosis (1.6 %), bleeding (1.6 %), and wound dehiscence (0.6 %; Table 3). Among breasts who did not undergo radiotherapy (RT) neither before nor after surgery (N = 247), major complications occurred in 7.3 % of cases; while among irradiated breasts, the major complications rate was 2.9 % (p-value = 0.18). In the subgroup of breasts who received RT before surgery (N = 20) there was only one bleeding with no cases of full-thickness skin necrosis. In the subgroup of breasts receiving post-operative irradiation (N = 50), one infection was reported.

The overall minor complications rate was 27.8 %. Across minor complications, rippling was recorded as the most common (14.5 %), followed by capsular contracture (7.6 %), seroma formation (2.5 %), skin necrosis (2.2 %), hematoma (0.6 %) and wound dehiscence (0.3 %). Among breasts who did not undergo RT neither before nor after surgery (N = 247), minor complications occurred in 25.9 % of cases, while among irradiated breasts it was 34.3 % (p-value = 0.17). Among those who received RT before surgery (N = 20) the rate of minor complications was 40.0 %. Capsular contracture was the most common minor complication (20 %), followed by rippling (15 %) and partial-thickness skin necrosis (5 %). In the subgroup of reconstructions receiving RT after surgery (N = 50), minor complications occurred in 32.0 % of cases with rippling being the most common (16 %), followed by capsular contracture (10 %), necrosis (4 %), and seroma (2 %).

Only 11 reconstructive failures (3.5 %) were reported out of 317 reconstructions. Considering the entire cohort, capsular contracture (Baker III-IV) rate was recorded to be 7.6 %. However, the rate of contracture varied across groups, with a prevalence of 6.1 % in patients not requiring RT and 12.9 % in those irradiated (specifically, 20.0 % in those who received RT before surgery and 10.0 % in those receiving RT after surgery; Table 3).

A total of 43 (13.6 %) fat grafting procedures were performed to correct for rippling and camouflage of implant edges. Fat grafting was also performed to improve soft tissue quality in patients receiving or having received RT.

3.2. Risk factors

The results of the univariable analysis for major complications, minor complications, and capsular contracture are presented in Table 4. Age and smoking status did not show a significant association with complications, while being overweight was significantly associated with major complications (HR 2.99, 95 % CI: 1.24–7.19, p = 0.01). Among comorbidities, diabetes significantly increased the risk of minor complications (HR 5.08, 95 % CI: 1.59–16.2, p = 0.006). Autoimmune hypothyroidism was associated with a higher risk of minor complications (HR 2.46, 95 % CI: 1.40–4.33, p = 0.002). Chemotherapy did not show to have a clear impact on complications; however adjuvant chemotherapy alone showed a trend towards a higher risk of minor complications (HR 1.59, 95 % CI: 0.98–2.59, p = 0.06). The breast implant volume was not associated with a significantly higher risk of complications. RT was not associated with higher risk of major (HR 0.38, 95 % CI: 0.09–1.62, p = 0.19) or minor complications (HR 1.36, 95 % CI: 0.85–2.17, p = 0.20), while it showed a higher risk of capsular contracture (HR 2.42, 95 % CI: 1.04–5.59, p = 0.04). Similar trends were observed in the subgroups of pre-irradiated breasts for major complications (HR 0.65, 95 % CI: 0.09–4.89, p = 0.68), minor complications (HR 1.63, 95 % CI: 0.78–3.39, p = 0.20) and capsular contracture (HR 4.03, 95 % CI: 1.32–12.3, p = 0.01), as reported in Table 5. RT performed after surgery did not significantly influence the risk of major or minor complication and capsular contracture.

4. Discussion

PBR is experiencing a remarkable surge in popularity in recent years [24]. However, although there is extensive literature on PBR using microtextured or smooth implants, there is still limited information on the use of PU-foam coated implants in PBR, as this technique is relatively new [9,25].

When compared to the standard submuscular implant placement, patients undergoing prepectoral reconstruction report less discomfort postoperatively, no animation deformity and more natural-looking results [13]. To reduce the risk of capsular contracture associated with the prepectoral placement of the implant both ADM and PU implants can be used [11,17,26]. However, ADM are associated with higher costs and higher rates of complications [11,17].

De Vita et al. [27] first described the prepectoral use of PU implants in 21 patients reporting excellent outcomes. They have recently published their updated experience, including 784 mastectomies in 453 patients and representing the largest cohort in literature [21]. Our case

Table 2
Breasts' clinical and pathological characteristics (n = 317 breasts).

	Radiotherapy								Overall (N = 317)	
	Not performed (N = 247)		Performed (N = 70)		Performed before surgery (N = 20)		Performed after surgery (N = 50)			
	N	%	N	%	N	%	N	%	N	%
Histotype										
Lobular	39	15.8	3	4.3	2	10.0	1	2.0	42	13.2
Ductal	160	64.8	50	71.4	12	60.0	38	76.0	210	66.2
Other	26	10.5	15	21.4	5	25.0	10	20.0	41	12.9
Missing	22	8.9	2	2.9	1	5.0	1	2.0	24	7.6
TNM - T status										
Tis/Tx	57	23.1	7	10.0	4	20.0	3	6.0	64	20.2
T0	18	7.3	6	8.6	2	10.0	4	8.0	24	7.6
T1	93	37.7	25	35.7	8	40.0	17	34.0	118	37.2
T2	43	17.4	23	32.9	2	10.0	21	42.0	66	20.8
T3	2	0.8	4	5.7	0	–	4	8.0	6	1.9
Missing	34	13.8	5	7.1	4	20.0	1	2.0	39	12.3
TNM - N status										
Nx	10	4.0	3	4.3	3	15.0	0	–	13	4.1
N0	178	72.1	35	50.0	12	60.0	23	46.0	213	67.2
N1	22	8.9	18	25.7	0	–	18	36.0	40	12.6
N2	0	–	7	10.0	1	5.0	6	12.0	7	2.2
N3	2	0.8	2	2.9	0	–	2	4.0	4	1.3
Missing	35	14.2	5	7.1	4	20.0	1	2.0	40	12.6
Stage										
0	83	33.6	12	17.1	8	40.0	4	8.0	95	30.0
I	98	39.7	18	25.7	7	35.0	11	22.0	116	36.6
II	52	21.1	25	35.7	2	10.0	23	46.0	77	24.3
III	4	1.6	11	15.7	1	5.0	10	20.0	15	4.7
IV	0	–	1	1.4	0	–	1	2.0	1	0.3
Missing	10	4.0	3	4.3	2	10.0	1	2.0	13	4.1
Previous surgery										
No	215	87.0	44	62.9	0	–	44	88.0	259	81.7
Yes	32	13.0	26	37.1	20	100.0	6	12.0	58	18.3
Mastectomy										
Nipple-sparing	232	93.9	62	88.6	19	95.0	43	86.0	294	92.7
Total	15	6.1	8	11.4	1	5.0	7	14.0	23	7.3
Sentinel lymph node biopsy										
No	14	5.7	18	25.7	1	5.0	17	34.0	32	10.1
Yes	175	70.9	39	55.7	12	60.0	27	54.0	214	67.5
Missing	58	23.5	13	18.6	7	35.0	6	12.0	71	22.4
Axillary dissection										
No	175	70.9	39	55.7	12	60.0	27	54.0	214	67.5
Yes	14	5.7	18	25.7	1	5.0	17	34.0	32	10.1
Missing	58	23.5	13	18.6	7	35.0	6	12.0	71	22.4
Prosthesis type										
Opticon 745	105	42.5	38	54.3	20	100.0	18	36.0	143	45.1
Opticon 746	75	30.4	13	18.6	0	–	13	26.0	88	27.8
Replicon 735	25	10.1	8	11.4	0	–	8	16.0	33	10.4
Replicon 736	42	17.0	11	15.7	0	–	11	22.0	53	16.7
Prosthesis volume (cc)										
<300	37	15.0	6	8.6	0	–	6	12.0	43	13.6
300-399	74	30.0	13	18.6	1	5.0	12	24.0	87	27.4
400-499	75	30.4	32	45.7	19	95.0	13	26.0	107	33.8
≥500	61	24.7	19	27.1	0	0	19	38.0	80	25.2
Mean ± SD	424 ± 116		448 ± 105		441 ± 18		451 ± 124		429 ± 114	
Symmetrization										
No	209	84.6	63	90.0	19	95.0	44	88.0	272	85.8
Yes	38	15.4	7	10.0	1	5.0	6	12.0	45	14.2

series is different from the one by De Vita et al. [21] since they used more restrictive criteria for patient selection. Indeed, they excluded obese patients (BMI >30), smokers, diabetic, women with active connective tissue disorders, and women who have received previous chest wall irradiation. Moreover, all patients underwent NSM for clinical T1 staged cancers with peripheral localization, and clinically negative axilla, therefore not candidate to post-operative RT. Additionally, they excluded patients with large and ptotic breasts from their analyses. De Vita et al. [21] reported 0 % rate of major complications and only 11.2 % rate of minor complications managed conservatively. Their encouraging results stimulated us to expand indications for DTI-PBR with PU implants to a larger population and to identify risk factors associated with unfavorable outcomes. Therefore, we offered prepectoral reconstruction with PU implants to all patients with preoperative pinch test >0.8 cm and intraoperative viable mastectomy flaps, although previously irradiated and without clinical signs of severe radiation-induced skin dystrophy. We also included patients affected by significant comorbidities, large and ptotic breasts as well as patients who had previously received chest wall RT, without clinical signs of skin dystrophy. Even if prior RT might compromise the blood supply of mastectomy skin flaps, Sinnott et al. [28] observed that patients undergoing subpectoral reconstruction and post-mastectomy RT had a capsular contracture rate three times greater and more severe contractures (Baker grade III or IV) than the patients receiving PBR and post-mastectomy RT. Indeed, in case of pre-irradiated pectoralis major muscle, it does not effectively protect the implant from capsular contracture due the fibrotic involution following RT. Hence, in case of an adequate preoperative pinch test at the upper pole and a viable mastectomy flap intraoperatively, we did not consider

Table 3
Complications (N = 317 breasts).

	Radiotherapy								Overall (N = 317)	
	Not performed (N = 247)		Performed (N = 70)		P-value	Performed before surgery (N = 20)		Performed after surgery (N = 50)		
	N	%	N	%		N	%	N	%	N	%
Major complications					0.18						
No	229	92.7	68	97.1		19	95.0	49	98.0	297	93.7
Yes	18	7.3	2	2.9		1	5.0	1	2.0	20	6.3
Dehiscence	2	0.8	0	–		0	–	0	–	2	0.6
Infection	7	2.8	1	1.4		0	–	1	2.0	8	2.5
Mastectomy flap necrosis	5	2.0	0	–		0	–	0	–	5	1.6
Bleeding	4	1.6	1	1.4		1	5.0	0	–	5	1.6
Minor complications					0.17						
No	183	74.1	46	65.7		12	60.0	34	68.0	229	72.2
Yes	64	25.9	24	34.3		8	40.0	16	32.0	88	27.8
Capsular contracture	15	6.1	9	12.9		4	20.0	5	10.0	24	7.6
Dehiscence	1	0.4	0	–		0	–	0	–	1	0.3
Hematoma	2	0.8	0	–		0	–	0	–	2	0.6
Necrosis	4	1.6	3	4.3		1	5.0	2	4.0	7	2.2
Rippling	35	14.2	11	15.7		3	15.0	8	16.0	46	14.5
Seroma	7	2.8	1	1.4		0	–	1	2.0	8	2.5
Reconstructive failure					0.75						
No	237	96.0	68	97.1		20	100.0	48	96.0	305	96.2
Yes	9	3.6	2	2.9		0	–	2	4.0	11	3.5
Missing	1	0.4	0	–		0	–	0	–	1	0.3
Capsular contracture					0.06						
No (Baker I, II)	232	93.9	61	87.1		16	80.0	45	90.0	293	92.4
Yes (Baker III, IV)	15	6.1	9	12.9		4	20.0	5	10.0	24	7.6

Table 4
Risk factors for major and minor complications and capsular contracture (N = 317 breasts).

	Major complications			Minor complications			Capsular contracture		
	HR	95 % CI	P-value	HR	95 % CI	P-value	HR	95 % CI	P-value
Age (years)									
<40	n.e.	–	–	Ref.			Ref.		
40-49	Ref.			0.86	0.47–1.58	0.63	0.72	0.26–2.04	0.54
50-59	1.30	0.49–3.47	0.60	1.09	0.59–2.00	0.79	0.70	0.24–2.08	0.52
60+	0.97	0.29–3.24	0.97	0.70	0.33–1.44	0.33	0.30	0.06–1.51	0.14
Smoking status									
Non-smoker	Ref.			Ref.			Ref.		
Ex-smoker	1.45	0.47–4.44	0.52	1.19	0.70–2.03	0.52	1.06	0.36–3.12	0.92
Current smoker	1.69	0.48–5.92	0.41	0.51	0.21–1.27	0.15	0.85	0.20–3.67	0.83
BMI									
Normal weight (<25)	Ref.			Ref.			Ref.		
Overweight (25–30)	2.99	1.24–7.19	0.01	1.12	0.68–1.83	0.65	1.25	0.52–3.03	0.62
Obese (≥30)	n.e.	–	–	1.41	0.70–2.85	0.34	n.e.	–	–
Comorbidities									
No	Ref.			Ref.			Ref.		
Autoimmune hypothyroidism	1.03	0.24–4.44	0.97	2.46	1.40–4.33	0.002	2.05	0.69–6.10	0.20
Hypertension	n.e.	–	–	1.46	0.67–3.18	0.34	1.55	0.36–6.73	0.56
Diabetes	4.39	0.58–33.0	0.15	5.08	1.59–16.2	0.006	4.95	0.66–37.3	0.12
Previous surgery									
No	Ref.			Ref.			Ref.		
Yes	0.49	0.11–2.11	0.34	1.45	0.89–2.37	0.13	2.33	1.00–5.44	0.051
Prosthesis volume (cc)									
<300	Ref.			Ref.			Ref.		
300-399	0.49	0.10–2.43	0.38	0.79	0.41–1.53	0.48	0.51	0.16–1.57	0.24
400-499	0.94	0.24–3.64	0.93	0.86	0.46–1.61	0.63	0.68	0.25–1.87	0.46
≥500	1.28	0.33–4.94	0.72	0.77	0.39–1.52	0.45	0.19	0.04–0.93	0.04
Chemotherapy									
No	Ref.			Ref.			Ref.		
Yes, only neoadjuvant	0.53	0.12–2.33	0.40	0.97	0.53–1.79	0.92	1.03	0.34–3.14	0.96
Yes, adjuvant only	0.41	0.09–1.81	0.24	1.59	0.98–2.59	0.06	1.23	0.47–3.21	0.67
Yes, neoadjuvant + adjuvant	1.73	0.39–7.60	0.47	0.46	0.11–1.87	0.28	n.e.	–	–
Radiotherapy									
Not performed	Ref.			Ref.			Ref.		
Performed	0.38	0.09–1.62	0.19	1.36	0.85–2.17	0.20	2.42	1.04–5.59	0.04
Performed before surgery	0.65	0.09–4.89	0.68	1.63	0.78–3.39	0.20	4.03	1.32–12.3	0.01
Performed after surgery	0.26	0.04–1.97	0.19	1.25	0.72–2.17	0.42	1.84	0.66–5.10	0.24

Abbreviation: n.e., not estimable.

Table 5
Patients characteristics (N = 19 patients) with at least 1 breast irradiated before surgery

	Overall (N = 19)	
	N	%
Year of surgery		
2020	4	21.1
2021	6	31.6
2022	9	47.4
Age (years)		
<40	1	5.3
40-49	5	26.3
50-59	7	36.8
60+	6	31.6
Mean ± SD	54.1 ± 8.5	
BMI		
Normal weight (<25)	14	73.7
Overweight (25–30)	3	15.8
Obese (≥30)	1	5.3
Missing	1	5.3
Mean ± SD	23.2 ± 2.8	
Smoking status		
Non-smoker	13	68.4
Ex-smoker	4	21.1
Current smoker	2	10.5
Comorbidities		
No	16	84.2
Yes	3	15.8
Autoimmune hypothyroidism	*3*	*100.0*
Mutation		
No	15	78.9
Yes	4	21.1
BRCA1	*3*	*75.0*
BRCA2	*1*	*25.0*
Number of days of hospitalization, Mean ± SD	3.6 ± 0.8	
Number of days of drainage, Mean ± SD	9.6 ± 3.1	
Chemotherapy		
No	13	68.4
Yes, neoadjuvant only	2	10.5
Yes, adjuvant only	3	15.8
Yes, neoadjuvant + adjuvant	1	5.3
Endocrine therapy		
No	14	73.7
Yes	5	26.3
Monoclonal antibodies		
No	17	89.5
Yes	2	10.5

pre-irradiation as a contraindication to DTI-PBR. In our analysis, previous RT did not demonstrate a significant impact on the risk of major (p = 0.68) and minor complications (p = 0.20) in DTI-PBR with PU implants. However, there was a higher risk of capsular contracture in preirradiated patients compared to those who did not undergo any RT (p = 0.01). Additionally, we not only achieved safe and satisfactory outcomes in cases of large and ptotic breasts, but we have also anecdotally observed a reduced need for symmetrization procedures on the contralateral healthy breast compared to submuscular breast reconstruction due to the possibility to re-create the pre-existing ptosis.

As previously described by Salgarello et al. [23], we agree that the most important factors for a successful prepectoral approach include an adequate flap perfusion and a sufficient flap thickness. Differently from Salgarello et al. [23] who used fluorescent images with indocyanine green angiography to evaluate the mastectomy flaps perfusion, we relied only on clinical evaluation.

Notably, Salgarello et al. [23] demonstrated that in PU prepectoral reconstruction, greater flap thickness correlates with reduced risk of rippling and increased patient satisfaction. In our cohort, 13.6 % of patients received secondary lipofilling to improve the upper pole appearance and conceal the implant edges and rippling.

Catanuto et al. [29] have recently published their series of 63 patients and 74 NSM reconstructed with DTI-PBR using PU implants. They included patients with comorbidities and previously irradiated breasts and they reported a 6.7 % rate of unplanned re-admissions and implant loss [29]. Due to the small number of patients included in the series, risk factors for complications could not be calculated.

Coyette et al. [22] included in their retrospective analysis of 50 consecutive patients (64 mastectomies approached with DTI-PBR using PU implants) also patients with significant comorbidities, pre-irradiated breasts and active smokers. They reported a 9.4 % rate of major complications requiring re-intervention, compared to 6.3 % risk of major complications observed in our study. However, according to their analysis, Coyette et al. [22] identified hypothyroidism as the only factor associated with a higher risk of complications. Despite our results confirm that hypothyroidism predisposes to complications as well as the negligible impact of prior radiation therapy, we also identified diabetes and overweight as additional factors associated with a higher risk of minor and major complications, respectively.

Moreover, whereas Coyette et al. [22] had a single surgeon performing all reconstructive procedures, in our series several breast and plastic surgeons performed surgical procedures, enhancing the reliability and adaptability to real life situations of our results. We believe that these findings enhance the credibility of our conclusions and should encourage plastic surgeons to confidently engage with this type of reconstruction.

Concerning capsular contracture, we observed a rate of 7.6 % with a mean follow-up of 12.2 ± 1.2 months, that increases to 10 % in case of postoperative irradiation and 20 % in preirradiated breasts.

The safety of polyurethane-coated implants has been debated, particularly after their 1991 withdrawal from the U.S. market due to concerns about cancer risk from degrading materials (2,4 Toluene Diamine) [30,31]. However, further analysis showed that the lifetime risk was extremely low (1 in 1.1 million), and the FDA did not recommend explantation [18]. Polyurethane has a long history of safe use in various medical devices, with no documented toxic or carcinogenic effects. These implants remain widely used and considered safe in Europe [18,32,33].

Our study has some limitations. First, the retrospective nature and the lack of a control group and long-term follow-up are significant weaknesses. Second, we did not report patient reported outcomes such as BREAST-Q which are paramount when assessing the efficacy of a novel approach to breast reconstruction. Indeed, we focused primarily on surgical outcomes and the safety of the procedure in a heterogenous and large population. Third, definitive conclusions on the impact of previous and post-operative RT cannot be drawn due to the small number of patients included in the series. Additionally, the available sample size and the limited number of events restricted the feasibility of constructing robust multivariate models, which could have allowed the identification of potential confounders. Lastly, despite we did not observe any case of breast implant associated anaplastic large cell lymphoma (BIA-ALCL) [34], the overall short follow-up in this study did not allow us to draw any conclusion about the potential risk of developing BIA-ALCL in DTI-PBR using PU implants.

We believe that the main strengths of our study are the enrollment of consecutive patients and the large sample size, patient selection and several surgeons involved in surgery. These factors make our findings more reflective of real-life scenarios compared to previous literature on the topic. Nevertheless, future well-designed prospective studies are needed to confirm our findings and improve the understanding of the impact of pre-operative and post-operative RT on surgical outcomes and complications. Additionally, future research should focus on patient satisfaction and quality of life following DTI-PBR using PU implants. For preirradiated breasts, future studies should focus on the comparison between patient quality of life after DTI-PBR with PU and autologous reconstructions in the short- and long-term. This comparative analysis would offer valuable insights into the optimal approach in this challenging patient population.

5. Conclusions

DTI-PBR with PU implants has a low risk of major complications requiring urgent re-intervention. Hypothyroidism, diabetes, and overweight have been identified as risk factors associated with higher risk of complications in DTI-PBR using PU implants. Preoperative irradiation should not rule out the possibility of DTI-PBR with PU, if an accurate clinical evaluation of the mastectomy flap demonstrates appropriate viability, robustness, and thickness, without clinical signs of radiation-induced skin dystrophy. While additional evidence is required to validate our findings, when adhering to appropriate indications, DTI-PBR with PU implants could be suitable for a larger population than initially presumed.

CRediT authorship contribution statement

Andrea Lisa: Conceptualization, Writing – original draft. **Francesca Riccardi:** Data curation, Conceptualization, Writing – original draft. **Mario Alessandri-Bonetti:** Data curation, Conceptualization, Writing – original draft. **Luca Mazzocconi:** Data curation, Investigation. **Manuela Bottoni:** Methodology, Investigation. **Benedetta Barbieri:** Writing – review & editing, Investigation. **Alessandra Gottardi:** Methodology, Investigation. **Marco Palmesano:** Writing – review & editing, Methodology. **Valerio Cervelli:** Writing – review & editing, Methodology. **Vincenzo Bagnardi:** Data curation, Formal analysis. **Eleonora Pagan:** Data curation, Formal analysis. **Paolo Veronesi:** Validation, Visualization, Supervision. **Francesca De Lorenzi:** Validation, Visualization, Supervision. **Mario Rietjens:** Supervision, Validation.

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Declaration of competing interest

The authors declare no conflict of interest.

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