

# Immediate Implant-based Breast Reconstruction with Acellular Dermal Matrix Compared with Tissue-expander Breast Reconstruction: Rate of Infection

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**Background:** The risk of infection continues to be a subject of discussion within the field of implant-based breast reconstruction. Studies have shown the feasibility of immediate single-stage procedures with acellular dermal matrix (ADM), yet 2-stage tissue expander techniques continue to be the procedure most often performed. The purpose of this study was to evaluate postoperative infections and to identify associated predictors.

**Methods:** A retrospective study at Papa Giovanni XXIII Hospital was conducted between 2013 and 2017. Patients' demographic data were compared between single-stage and 2-stage procedures. Rate of infection and predictors were examined. Minor infections could be treated by oral antibiotics only, major infections required inpatient treatment. Healing was considered a successful treatment with antibiotics only, whereas any supplementary surgical intervention resulting in the preservation of an implant device was considered salvage. Breast reconstruction was defined a failure in case of implant loss or need for autologous reconstruction.

**Results:** Three hundred ninety-three patients underwent 336 monolateral and 57 bilateral implant-based breast reconstruction. Ninety-two patients had a submuscular direct-to-implant reconstruction with ADM with an infection rate of 11.4% compared with an infection rate of 7.8% among the 268 patients with a 2-stage tissue expander procedure. Beta-binomial regression showed obesity and preoperative radiotherapy as significant predictors for infection (OR, 4.65,  $P = 0.038$ , and OR, 7.13,  $P = 0.015$ , respectively). Average time of onset of infection among the submuscular direct-to-implant with ADM group was 67.1 days compared with 80.1 days among tissue-expander group with postoperative chemotherapy and preoperative radiotherapy having a significant effect on time of infection onset ( $P = 0.014$ ,  $P = 0.034$ , respectively).

**Conclusions:** Direct-to-implant breast reconstruction with ADM is a procedure with acceptable risks of infection in comparison to tissue expander procedures. A profound patient selection pre- and intraoperatively is the basis of successful breast reconstruction. (*Plast Reconstr Surg Glob Open* 2018;6:e1949; doi: 10.1097/GOX.0000000000001949; Published online 14 December 2018.)

## INTRODUCTION

Mastectomy forms part of the oncologic treatment of 36–58% of women affected by breast cancer.<sup>1</sup> The development of mastectomy techniques, mainly nipple-sparing

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mastectomy (NSM), and the evidence of its oncologic safety, made immediate breast reconstruction more prevalent.<sup>2</sup> Implant-based breast reconstructions are the most common method currently used in the field of postmastectomy reconstruction and could conduce to an attractive alternative for many women owing to the great advantages of reducing the amount of surgical procedures and postoperative appointments, and its significant psychosocial benefits for emotional well-being and social functioning for the patient.<sup>3–5</sup> Especially the introduction of acellular dermal matrix (ADM) has significantly added to the feasibility and popularity of direct-to-implant (DTI) reconstruction.<sup>6</sup> The use of ADM could lead to the achievement of better aesthetic results, less capsular contraction, and

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could serve as a possible protection against radiation's side effects.<sup>7-9</sup>

Postoperative infection continues to be one of the most feared complications in reconstructive surgery. In current literature, conflicting data still exist concerning the rate of infections in DTI with ADM reconstruction in comparison with the one in 2-stage expander technique.<sup>6,9,10</sup> The contemporary rise in performed breast reconstructions and above mentioned benefits of DTI procedures emphasize the need for further research in the field.

At the plastic surgery department of Papa Giovanni XXIII Hospital of Bergamo more than 100 different breast reconstructions are performed each year, which offers the opportunity of reviewing a considerable amount of clinical cases. The purpose of the study was to review clinical data, figure out infection rates, and identify the main associated risk factors in single-step and 2-step breast reconstruction and their impact on time of infection onset.

## PATIENTS AND METHODS

A retrospective study was conducted at Papa Giovanni XXIII Hospital, Bergamo, of a total of 472 patients. All patients who underwent therapeutic or prophylactic mastectomy followed by implant-based breast reconstruction between January 2013 and August 2017 were included in the study. Seventy-nine patients were excluded because of any kind of autologous repair (5 patients in total) or due to lack of follow-up (74 patients in total). Patients' demographics were gathered retrospectively from patient medical records and included age at the time of the first procedure, body mass index (BMI), current smoking status, breast size, diabetes, chemotherapy, and radiotherapy (RxT).

Patients were divided into 6 different cohorts of whom 3 underwent single-stage and 3 two-step expander-implant (EI) reconstruction. Cohort 1A included all patients undergoing submuscular DTI with ADM, which were exclusively done in combination with NSM. Cohort 1B comprised all patients who had submuscular DTI with mesh. Cohort 1C described all patients with prepectoral DTI, which were also exclusively done in combination with NSM. Prepectoral implants were covered with ADM pockets. These 3 cohorts were compared with 3 control cohorts: cohort 2A consisting of patients with EI reconstruction and NSM, cohort 2B included EI reconstructions with skin-sparing mastectomy (SSM), cohort 2C had EI reconstructions with mastectomy using the skin-reducing pattern (SRP). No ADM was used among the expander implant reconstruction groups and implants were exclusively inserted submuscular.

Mastectomy was performed by 8 surgical oncologists, breast reconstructions by 10 plastic surgeons. The type of surgical mastectomy incision was deliberated beforehand between surgical oncologist and plastic surgeon. If feasible, lateral inframammary fold incision was preferred while an inverted-T approach was designed for large ptotic breasts.

The possibility of doing an immediate reconstruction was discussed with the patient preoperatively. However,

the final decision was made intraoperatively after the mastectomy by the plastic surgeon based on surgical experience with regard to viability of the flap, its thickness and vascularity. Thick and viable flaps made prepectoral interventions feasible. Whereas, thinner but viable flaps with reliable pectoralis major muscles lead to well executable submuscular DTI options with ADM or meshes. If flaps were not considered reasonably viable, it was decided to switch to a 2-stage procedure. Before the implant placement pockets were irrigated with saline only. ADMs were bovine and fenestrated before use. Intraoperatively, generally 2 drains were placed sub- and prepectoral. Also among prepectoral procedures, 2 drains were placed. For permanent implants, textured silicone filled and mostly anatomy shaped ones were used. Tissue expanders were saline filled only and were merely partially filled during surgery to avoid putting too much tension on the created pocket.

Patients were usually hospitalized for 3 days after the procedure according to a standard protocol of the hospital. Cefazolin was administered [preoperatively 2 g iv, postoperatively 3 daily doses (dd) 1 g iv.]. Antibiotic therapy was continued (3dd 1 g p.o.) until drains were removed; however, not longer than 21 days postoperatively, ordinarily with an output less than 30 cc per 24 hours.

The average follow-up was at least 1 year. In case of tissue-expander procedure, healing was required to be completed before proceeding with the initial inflation of the expander, typically 4-6 weeks after the intervention. Saline expansions were done twice a month until achievement of the desired breast size. In case of postoperative RxT, no further expansion was done until the completion of the RxT.

The primary outcome of interest was a major postoperative infection after the first reconstruction procedure defined as the need for any additional inpatient intervention. With regard to 2-stage reconstructions, cases were included exclusively with postoperative infection after the first step of the procedure, the insertion of the expander, not after the second-stage, the insertion of the final implant.

A minor infection was defined as minor swelling and/or erythema, but no fever or other signs of systemic inflammation, and could be treated with antibiotics p.o. for 2 weeks in an outpatient setting. Major infections were considered conditions with evident swelling, pus, fever, and the need of inpatient treatment. In these cases, a medical salvage protocol set up by the clinic was applied (Table 1). Treatment success based on inpatient antibiotic treatment only was labeled healing. Salvage was defined as any surgical intervention resulting in preservation of a reconstruction device. Breast reconstruction failure was defined as a complete implant removal and/or need for autologous reconstruction. Definitions can be found in Table 1.

For statistical analysis, differences between EI groups and DTI + ADM group in baseline characteristics were assessed by multinomial logistic regression of group assignment on the characteristics with Wald's test on the coefficients. Demographics were summarized at patient level, breast was treated as statistical unit in the analysis

**Table 1. Classification of Infections/Interventions**

Infection/ Intervention	Definition
Minor infection	Minor swelling and erythema, no fever Outpatient treatment with antibiotics p.o. for 2 weeks in total
Major infection	Evident swelling, fever, pus Inpatient treatment Administration of antibiotic salvage protocol (gram positive: Vancomycin iv (1g/250 ml within the first hour, then Vancomycin 1 dd 2g/1,000 ml, 5 days in total); gram negative: Levofloxacin (2 dd 500 mg, 5 days in total))
Healing	Successful inpatient treatment with antibiotic salvage protocol
Salvage intervention	Any surgical intervention resulting in preservation of the implant (curettage, debridement, implant replacement)
Failure	Complete implant removal No further reconstruction/need for autologous reconstruction

iv, intravenously; p.o. oral.

of infection rates. Binary outcomes were analyzed with a beta-binomial regression model accounting for over dispersion due to the clustering structure. Time to onset was analyzed using gamma regression with log-link function of time on potential predictors. All statistical analysis was performed with Stata Version 13.0. A *P* value <0.05 was considered statistical significant.

**RESULTS**

During the 4.7-year period, a total of 393 patients with 336 monolateral and 57 bilateral breast reconstructions with expander/implant were identified. One hundred twenty-five patients had an immediate breast reconstruction: 92 patients underwent 114 submuscular DTI reconstruction with ADM, labeled cohort 1A, 16 patients (17 breasts) had submuscular DTI reconstruction with mesh, categorized cohort 1B, 17 patients (24 breasts) had prepectoral DTI reconstruction, considered cohort 1C. Two hundred sixty-eight patients had EI reconstruction. One hundred fourteen patients (125 breasts) underwent EI reconstruction with NSM, labeled cohort 2A. Eighty-nine patients (96 breasts) had EI reconstruction with SSM, considered cohort 2B. Sixty-five patients (74 breasts) had EI reconstruction with SRP, considered cohort 2C.

During the assessed time period, 39 infections in 37 patients occurred. Among single-stage reconstructions, 13 infections arose in the submuscular DTI + ADM group (11.40%), none infections in the submuscular DTI + mesh group, 3 infections in the prepectoral DTI group (12.50%). Among the 2-step reconstructions, 4 infections occurred in the 2A NSM cohort (3.20%), 8 in the SSM group (8.33%), 11 in the SRP group (14.86%; Table 2). Reconstruction was achieved in 440 cases (97.78% in total, 98.25% in cases with ADM, 97.29% in cases without). The overall rate of failure was 2.22% (1.3% among single-stage, 2.7% among 2-stage reconstruction). Within 74.36% of the infections, a successful reconstruction was achieved.

Of the 13 infections of cohort 1A, 2 were successfully treated with antibiotics, 9 underwent a salvage procedure, 2 had a complete failure of reconstruction (1.8%). Of the 3 infections of cohort 1C, 3 effectively underwent a salvage procedure. Two of the 4 infections within cohort 2A had a salvage procedure, 2 had a failure of reconstruction (1.6%). Cohort 2B had 2 effectively treated with antibiotics, 4 underwent a salvage procedure, 2 were considered failure (2.1%). Within cohort 2C, 2 were successfully remedied with antibiotics, 5 had a salvage procedure, while 4 had a failure of reconstruction (5.4%).

It was decided to consider demographic data exclusively of subsamples of the different cohorts. Clinical characteristics of all patients with infections were gathered and compared with characteristics of control samples of randomly selected patients.

Demographic characteristics were similar between groups. Mean age was 49.3 years (± 8.9). Mean age of the prepectoral DTI group (40.2±14.2) and the submuscular DTI + mesh group (39.8±5.8) was considerably lower. Average BMI in the total DTI group was 22.4 (SD ± 3.4) compared with 24.4 (SD ± 4) in the EI group. Only 14 patients in the DTI group had a BMI >25 compared with 46 patients in the EI group. There were no patients with a BMI >25 in the prepectoral DTI group. Breast size was higher in the EI group than in the DTI group (33.8% breast size ≥4, 7.6% breast size ≥4, respectively). There were few patients with diabetes (3 out of 136). The percentage of irradiation was higher in the DTI group than in the EI group (51.0% versus 26.5%). Multinomial logistic regression showed that patients of the 2A NSM cohort were more likely to undergo neoadjuvant chemotherapy (45.8% versus 11.7%, *P* = 0.016) and smoked more frequently than

**Table 2. Infection Rates and Intervention by Reconstruction Technique**

Group	Breasts	Infections (%)	Intervention		
			Healing	Salvage	Failure (%)
Single-stage reconstruction	155	16	2	12	2 (1.3)
Cohort 1A (Subm. DTI + ADM)	114	13 (11.40)	2	9	2 (1.8)
Cohort 1B (Subm. DTI + mesh)	17	0 (0)	—	—	—
Cohort 1C (prepectoral DTI)	24	3 (12.50)	0	3	0
Two-stage reconstruction	295	23	4	11	8 (2.7)
Cohort 2A (NSM)	125	4 (3.20)	0	2	2 (1.6)
Cohort 2B (SSM)	96	8 (8.33)	2	4	2 (2.1)
Cohort 2C (SRP)	74	11 (14.86)	2	5	4 (5.4)
Total	450	39	6	23	10 (2.2)

Subm., submuscular.

**Table 3. Demographic Characteristics for Patients by Each Group – (%)**

Characteristics	Direct Cohort 1A	To Implant Cohort 1B	(n = 53) Cohort 1C	Expander Cohort 2A	Implant Cohort 2B	(n = 83) Cohort 2C
No.	43	6	4	24	28	31
Mean age ± SD	49.2±8	39.8±5.8	40.2±14.2	50.6±8.4	51.8±9.2	49±8.4
Mean BMI ± SD	22.3±3.6	23.2±3.1	21.6±0.6	23.3±3.5	24.8±4.6	24.9±3.9
Overweight (BMI ≥ 25 kg/m <sup>2</sup> )	8 (18.6)	2 (33.3)	0	7 (29.2)	13 (46.4)	14 (45.2)
Obese (BMI ≥ 30 kg/m <sup>2</sup> )	4 (9.3)	0	0	2 (8.3)	5 (17.9)	5 (16.1)
Smoking						
Nonsmoker	36 (83.7)	6 (100)	2 (50)	14 (58.3)	20 (71.4)	27 (87.1)
Current smoker	4 (9.3)	0	2 (50)	9 (37.5)	7 (25)	2 (6.5)
Breast size						
1	0	1 (2.3)	0	1 (4.2)	0	0
2	11 (25.6)	3 (50)	3 (75)	5 (20.8)	6 (21.4)	1 (3.2)
3	19 (44.2)	3 (50)	1 (25)	11 (45.8)	14 (50)	11 (32.3)
≥ 4	4 (9.3)	0	0	4 (16.7)	7 (25)	17 (54.83)
Chemotherapy						
Preoperative	5 (11.7)	5 (83.3)	2 (50)	11 (45.8)	5 (17.9)	5 (16.1)
Postoperative	11 (25.6)	0	0	3 (12.5)	5 (17.9)	8 (25.8)
Both	1 (2.3)	0	0	0	1 (3.6)	0
RxT						
Preoperative	2 (4.7)	0	1 (25)	1 (4.2)	5 (17.9)	1 (3.2)
Postoperative	21 (48.8)	2 (33.3)	1 (25)	6 (25)	3 (10.7)	6 (19.3)
Both	0	0	0	1 (4.2)	0	0

patients of the submuscular DTI + ADM group (37.5% versus 9.3%;  $P = 0.008$ ). Patients of the SRP group had overall higher breast size compared with the submuscular DTI + ADM ( $P = 0.001$ ) and underwent RxT less often ( $P = 0.016$ ). Patients of the SSM group were less likely to undergo postoperative RxT in comparison to submuscular DTI + ADM ( $P = 0.003$ ; Tables 3, 4).

A beta-binomial regression on predictors of infection was performed comparing the tissue expander group as a

whole with the submuscular DTI + ADM group (Table 5). The analysis showed significant effects of obesity and preoperative RxT on the rate of infection (OR, 4.65,  $P = 0.038$ ; OR, 7.13,  $P = 0.015$ , respectively). Submuscular DTI + ADM procedure on its own was not found to be a statistical significant predictor of infection. When adjusting for groups, the application of preoperative RxT did not raise the risk of infection in the submuscular DTI + ADM group compared with the risk of infection in case of preoperative RxT in EI group. When analyzing the effect of postoperative RxT, there was a trend toward a higher chance of developing a postoperative infection for the DTI + ADM group compared with tissue expander cohort; however, this did not reach statistical significance ( $P = 0.059$ ).

Mean time onset of infection of the submuscular DTI + ADM group was 67.1 days (SD ± 2.4). Average time of infection onset in the tissue expander groups was 80.1 days (SD ± 2.2). Mean time of infection onset within the prepectoral DTI group was remarkably short (25.9 days ± 3), whereas the average time of infection onset within the SSM group was long (115.2 days ± 2.2). A gamma re-

**Table 4. Multinomial Logistic Regression of Demographic Characteristics for Patients by Group (Submuscular DTI + ADM Versus NSM/SRP/SSM)**

Group	Odds Ratio	P	95% CI
<b>NSM</b>			
Age	1.02	0.682	-0.06 to 0.09
BMI	1.08	0.439	-0.12 to 0.27
Breast size	1.36	0.478	-0.55 to 1.18
Chemotherapy preoperative	6.75	0.016*	0.36 to 3.47
Chemotherapy postoperative	0.41	0.358	-2.78 to 1.00
RxT preoperative	0.40	0.443	-3.23 to 1.41
RxT postoperative	0.26	0.065	-2.80 to 0.08
Smoking	9.68	0.008*	0.59 to 3.96
<b>SRP</b>			
Age	0.98	0.588	-0.09 to 0.05
BMI	1.06	0.510	-0.11 to 0.22
Breast size	3.71	0.001*	0.53 to 2.10
Chemotherapy preoperative	1.97	0.418	-0.97 to 2.34
Chemotherapy postoperative	1.04	0.959	-1.38 to 1.46
RxT preoperative	0.32	0.417	-3.88 to 1.61
RxT postoperative	0.19	0.016*	-3.03 to -0.31
Smoking	1.26	0.829	-1.86 to 2.32
<b>SSM</b>			
Age	1.01	0.720	-0.06 to 0.08
BMI	1.14	0.140	-0.04 to 0.30
Breast size	1.67	0.203	-0.28 to 1.31
Chemotherapy preoperative	2.20	0.339	-0.83 to 2.42
Chemotherapy postoperative	1.03	0.967	-1.48 to 1.54
RxT preoperative	1.45	0.716	-1.62 to 2.36
RxT postoperative	0.09	0.003*	-3.98 to -0.80
Smoking	5.31	0.060	-0.07 to 3.40

\*Denotes statistical significance ( $P < 0.05$ ).  
CI, confidence interval.

**Table 5. Beta-binomial Regression Analyses Identifying Variables Associated with Higher Risks of Infection (Tissue Expander Versus Submuscular DTI + ADM)**

Characteristics	Odds Ratio	P	95% CI
Obesity	4.65	0.038*	1.09–19.89
Breast size	1.38	0.248	0.80–2.39
Chemotherapy preoperative	1.36	0.577	0.46–4.03
Chemotherapy postoperative	0.25	0.081	0.05–1.19
RxT preoperative	7.13	0.015*	1.45–34.99
RxT postoperative	0.19	0.143	0.02–1.74
Submuscular DTI + ADM	0.80	0.803	0.14–4.50
RxT preoperative/ submuscular DTI + ADM	1.11	0.955	0.03–39.25
RxT postoperative/ submuscular DTI + ADM	16.16	0.059	0.90–290.16

\*Denotes statistical significance ( $P < 0.05$ ).  
CI, confidence interval.

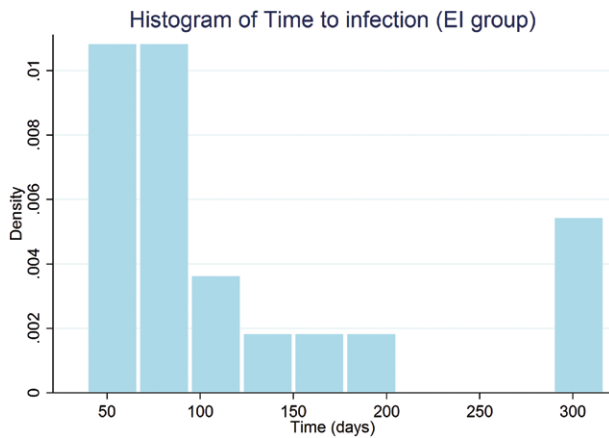


Fig. 1. Time to infection onset (tissue expander).

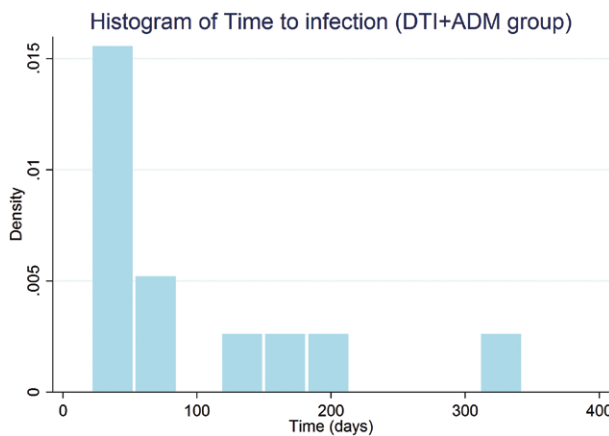


Fig. 2. Time to infection onset (submuscular DTI + ADM).

gression of time to onset of infection on the predictors was performed comparing the submuscular DTI + ADM group to the tissue expander group, which showed an overall significant accelerating effect of postoperative chemotherapy ( $P = 0.014$ ) and a delaying effect of preoperative RxT ( $P = 0.034$ ) on the onset of infection. It also revealed a significant negative effect of the interaction between preoperative RxT and submuscular DTI + ADM group indicating that the onset of infection within the submuscular DTI + ADM group may actually be accelerated with preoperative RxT instead of delayed. Pictures of 4 clinical cases are depicted in Figures 1–6 (Table 6).

### DISCUSSION

DTI breast reconstruction offers a broad range of benefits and is an attractive option for many women today. They not only reduce operating times for patient and surgeons, but also reduce recovery times making it easier for patients to get back to daily routine. Two-stage procedure still remains the most dominant technique as it is considered easier and less risky. Hazard of infection of the procedures vary widely between reported studies.<sup>6,9–11</sup> Surgical-site infections are not only a highly feared complication in reconstructive surgery but are also more commonly seen in reconstruction failures.<sup>12</sup> The aim of this study was to determine apparent differences between single-step and 2-step cohorts concerning age, BMI, breast size, additional therapies, and associated infection rates. It was investigated if there were predictors associated with infection and if so, would these have an impact on time of onset of the latter.

In the present study, infection rates of the different cohorts are similar to ones in currently reported literature. A

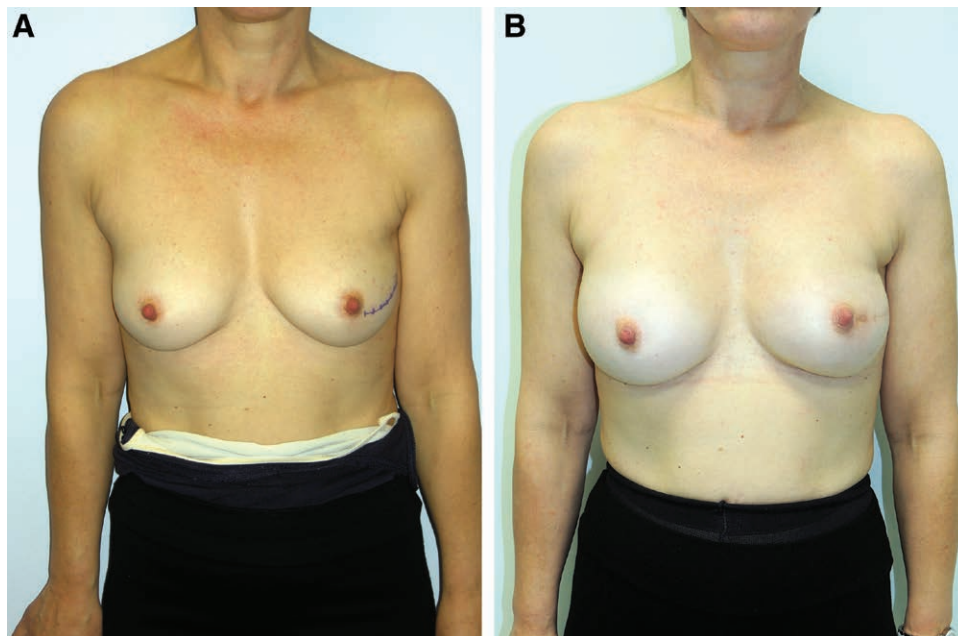
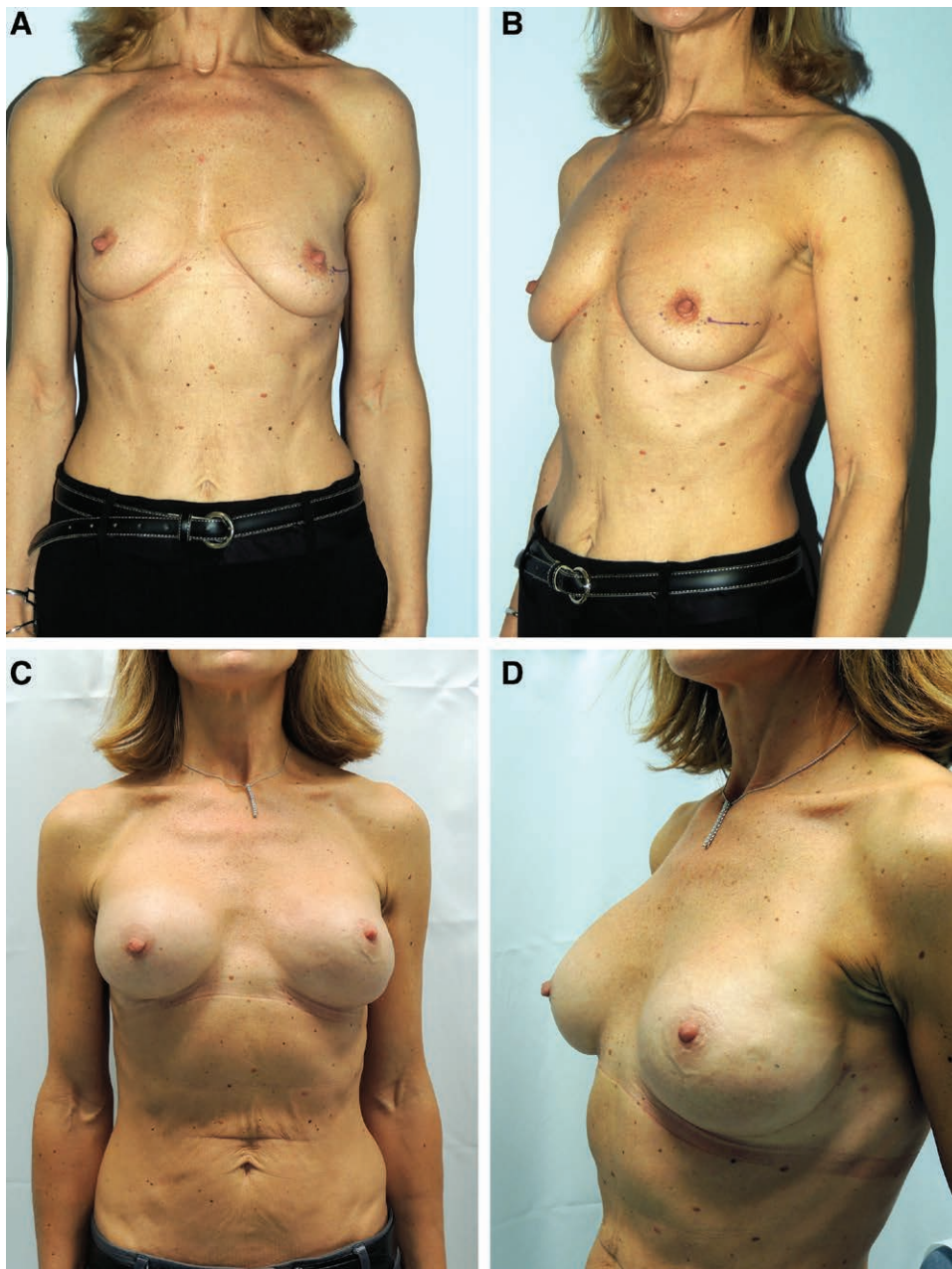


Fig. 3. Immediate single-stage breast reconstruction. A, Preoperative picture of the patient, a line is drawn indicating the intended lateral radial incision. B, Patient is shown 22 months postoperative after bilateral submuscular direct-to-implant with ADM reconstruction.

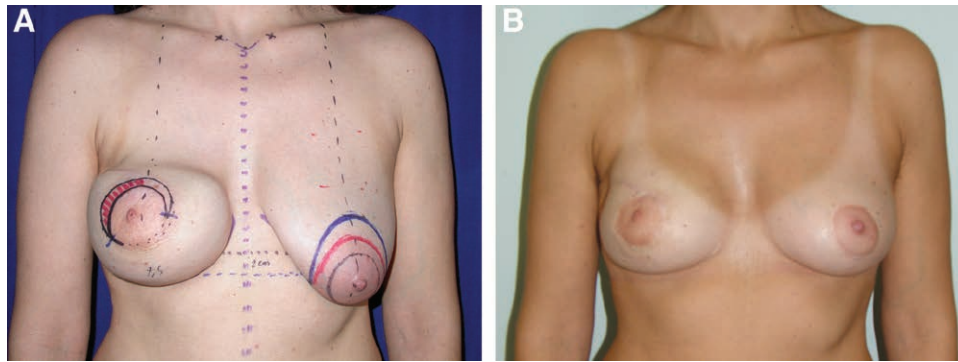


**Fig. 4.** Immediate single-stage breast reconstruction. A and B, Preoperative appearance. C and D, The patient is shown 8 months postoperative after submuscular direct-to-implant breast reconstruction with ADM of the left breast and symmetrization of the right breast.

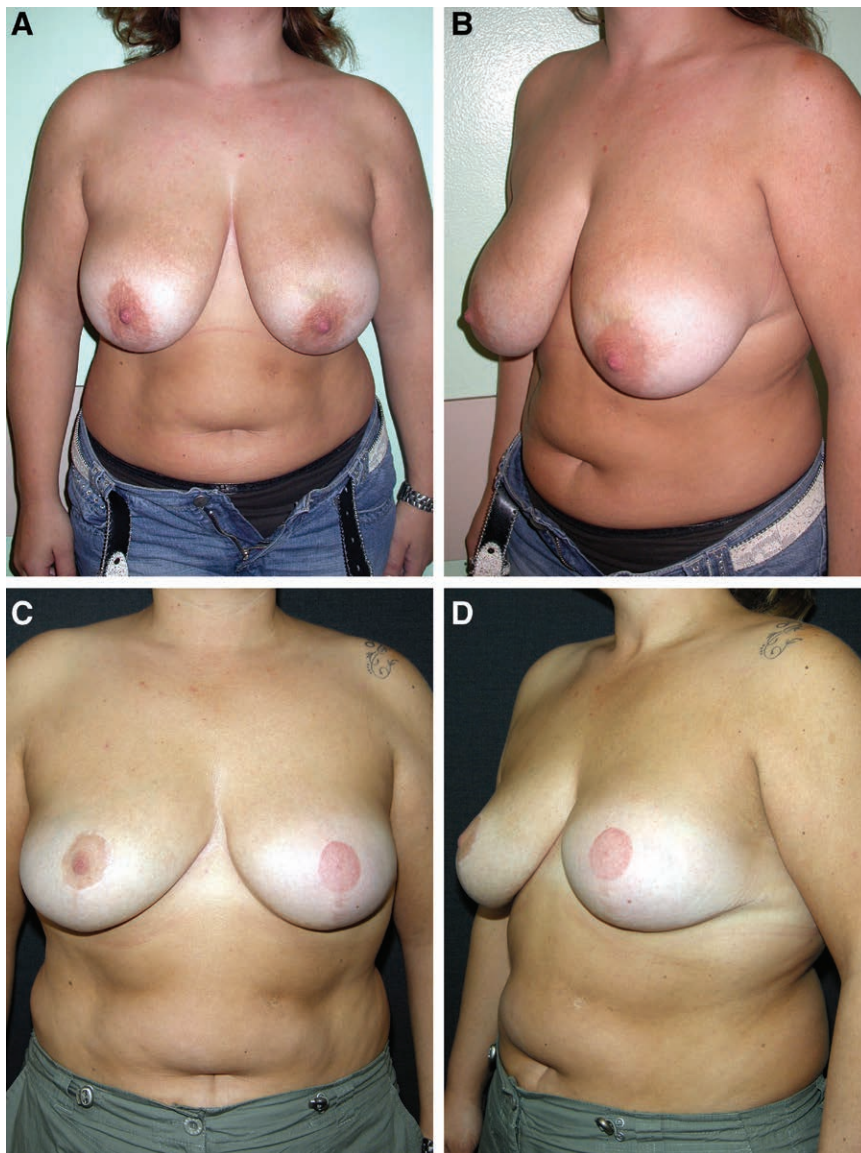
recent study showed the use of ADM alone not being associated with surgical-site infection, which could be supported by results of this study showing no association between a single-stage procedure with ADM and higher risks of infection.<sup>11</sup>

Two significant factors associated with higher risks of infection, obesity, and preoperative RxT were identified. Obesity was determined as significant predictor for postoperative infection, which in the surgical field is a known risk. A recent study stated that the risk for late onset postoperative infection was accelerated by 8% per point rise in BMI.<sup>11</sup> In the present study, it was analyzed that the risk of infection increased 5-fold in obese patients. It was

observed that a great majority of the SRP cohort was overweight (BMI > 25) or obese (BMI > 30). Higher BMI is often associated with macromastia, and the present study perceived significantly higher breast sizes among SRP patients compared with DTI groups. Among the SRP cohort, the highest infection rate was registered (14.86%) in this study, which may be attributed to overall higher BMI and breast size and, thus, associated infection risks. Aforenamed may, therefore, be reasonable to keep in mind when counseling patients about breast reconstruction choices and discuss with them further options like autologous breast reconstruction.



**Fig. 5.** Two-stage breast reconstruction with nipple-sparing-mastectomy. A, Preoperative appearance before the second stage of the procedure, right breast with tissue expander. B, Postoperative appearance, right breast with the final prosthesis, left breast after mastopexy with prosthesis.



**Fig. 6.** Two-stage breast reconstruction with SRP mastectomy. A and B, Preoperative appearance. C and D, Postoperative appearance after skin-reducing mastectomy and nipple-areola-complex reconstruction of the left breast and mastopexy for symmetrization of the right breast.

**Table 6. Gamma Regression of Time to Infection Onset (Tissue Expander Versus Submuscular DTI + ADM)**

Characteristics	Coef.	P	95% CI
Obesity	0.07	0.906	-1.17 to 1.32
Breast size	0.29	0.261	-0.22 to 0.80
Chemotherapy preoperative	-0.03	0.943	-0.94 to 0.87
Chemotherapy postoperative	-1.60	0.014*	-2.86 to -0.33
RxT preoperative	1.03	0.034*	0.08 to 1.99
RxT postoperative	1.11	0.332	-1.13 to 3.34
Submuscular DTI + ADM	0.24	0.707	-1.02 to 1.50
RxT preoperative/submuscular DTI + ADM	-2.24	0.047*	-4.46 to -0.03
RxT postoperative/submuscular DTI + ADM	-0.65	0.554	-2.78 to 1.49

\*Denotes statistical significance ( $P < 0.05$ ).  
Coef., coefficient; CI, confidence interval.

Wang et al.<sup>13</sup> had previously reported the association between RxT and increased risk of infection. This study observed preoperative RxT accelerated the risk of infection by approximately 7-fold. As preoperative RxT may lead to severe tissue damage, it may impede the body's natural protection against infections. Current discussion about ADM's ability to serve as a form of protection against postoperative RxT could not be seen by this study.<sup>8</sup> By contrast, a trend was observed implying postoperative RxT in combination with DTI + ADM as a predictor for infection. Likewise, postoperative RxT results in severe tissue impairment. This may hinder the integration and vascularization of the ADM and may make it more fragile to possible infections.

Sinha et al.<sup>11</sup> distinguished in their recent study between early surgical-site infections (<30 days) and late surgical-site infections (>30 days to 1 year). They reported the majority of infections in tissue expander and direct-to-implant reconstructions being late surgical-site infections, which in return would stress their concerns about current trends of studies with huge patient populations concentrating on the first 30 postoperative days.<sup>11</sup> Results of these studies may give unrealistic impressions on infection rates and may need to be interpreted with caution.<sup>11</sup> This can be supported by findings of the study at hand, which showed the average time to infection was 67 days in the DTI + ADM and 100 days in the tissue expander group. Longer follow-ups seem, thus, crucial. Focusing on the first 30 days may lead to bias, especially when keeping in mind that antibiotic therapy is generally continued about 20 days postoperatively because of intraoperative drain placement. Sinha et al.<sup>11</sup> reported RxT as a significant predictor of late surgical-site infection. The present study did not only observe RxT as a predictor for delayed onset of infection, but found that postoperative chemotherapy may accelerate the onset of infection.

In general, chemotherapy preoperatively or postoperatively was not revealed a predictor associated with higher risk of infection by this study, which is a finding comparable to other trials.<sup>12,14</sup>

In the present study, the rate of failure in the submuscular DTI + ADM group was about 1.8% compared with approximately 2.7% in the tissue expander group. Qureshi et al.<sup>14</sup> found the use of ADM alone was not a predictor of

reconstruction failure, which could be compared with findings of the present study. They reported that even though reconstruction was succeeded in the majority of women, uneventful reconstruction defined as no occurrence of any form of complication till the replacement with a final prosthesis was obtained in less than 50% of the study population.<sup>14</sup> Every supplementary procedure puts further stress on the affected woman. Therefore, it may be reasonable to minimize surgical interventions from the beginning on.

Rodriguez-Feliz and Codner<sup>15</sup> previously stated the safety and feasibility of NSM in single-stage reconstructions with ADM and stressed the importance of patient selection. Daily experience shows that next to a strict patient selection, a tight cooperation between oncologic surgeons and plastic surgeons is crucial. Oncologic surgeons provide the original flap for plastic surgeons, which in turn forms the starting point of intraoperative decision making for the latter.

This study has several limitations. The accuracy of data collection may be limited by its retrospective nature. There may be selection bias due to the final intraoperative decision making of the reconstruction technique. Inter-surgeon variability was not included in the analysis. Due to the small subgroups, study on submuscular DTI with mesh and prepectoral DTI breast reconstruction was limited. This leaves room for further discussion of results within these groups. No data on microbiological results, duration of (neo-)adjuvant therapy, or hormone therapy were included. Further study on the influence of microbiological results could be of interest as studies rarely include the possible effects of the latter.

## CONCLUSIONS

The present study shows the feasibility of direct-to-implant breast reconstruction in daily practice with acceptable infection rates compared with tissue expander procedures. Direct-to-implant breast reconstruction with ADM did not show to affect the risk of infection. Obesity and preoperative RxT were found to be significant predictors of infection risks. A profound patient selection pre- and intraoperatively, therefore, forms a crucial step in the path of successful breast reconstruction. As the average time of onset to surgical-site infection was observed to be more than 30 days postoperative with postoperative chemotherapy and preoperative RxT as significant factors associated with time of onset, this should be taken into account during follow-up times and follow-up counseling concerning risk factors.

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