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Direct-to-Implant versus Two-Stage Tissue Expander/Implant Reconstruction: 2-Year Risks and Patient-Reported Outcomes from a Prospective, Multicenter Study

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Abstract

Background—Direct-to-implant breast reconstruction offers time-saving advantages over two-stage techniques. However, use of direct-to-implant reconstruction remains limited, in part, because of concerns over complication rates.^{1,2} The authors' aim was to compare 2-year complications and patient-reported outcomes for direct-to-implant versus tissue expander/implant reconstruction.

Methods—Patients undergoing immediate direct-to-implant or tissue expander/implant reconstruction were enrolled in the Mastectomy Reconstruction Outcomes Consortium, an 11-center prospective cohort study. Complications and patient-reported outcomes (using the BREAST-Q questionnaire) were evaluated. Outcomes were compared using mixed-effects regression models, adjusting for demographic and clinical characteristics.

Results—Of 1427 patients, 99 underwent direct-to-implant reconstruction and 1328 underwent tissue expander/implant reconstruction. Two years after reconstruction and controlling for covariates, direct-to-implant and tissue expander/implant reconstruction patients did not show statistically significant differences in any complications, including infection. Multivariable analyses found no significant differences between the two groups in patient-reported outcomes, with the exception of sexual well-being, where direct-to-implant patients fared better than the tissue expander/implant cohort ($p = 0.047$).

Conclusions—This prospective, multi-institutional study showed no statistically significant differences between direct-to-implant and tissue expander/implant reconstruction, in either complication rates or most patient-reported outcomes at 2 years postoperatively. Direct-to-implant

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reconstruction appears to be a viable alternative to expander/implant reconstruction. This analysis provides new evidence on which to base reconstructive decisions.

The prevalence of mastectomy (as opposed to breast conservation therapy) is growing, with increasing numbers of patients requesting prophylactic surgery.¹ Implant-based reconstruction is the most common method of postmastectomy breast reconstruction in use today.² Reconstructive surgeons traditionally use tissue expander/implant reconstruction with or without acellular dermal matrix and a second, later operation, for refinement of the breast pocket and implant placement. However, an alternative option is immediate placement of the implant at the time of mastectomy, referred to as direct-to-implant reconstruction. Decades ago, direct-to-implant reconstruction was the original method of breast reconstruction, but it was quickly supplanted by tissue expansion techniques and autologous reconstruction, both of which yielded superior aesthetic results with fewer risks. However, recent innovations, most notably the introduction of acellular dermal matrix for implant-based procedures, have prompted some plastic surgeons to reconsider direct-to-implant reconstruction as a viable alternative to two-stage, tissue expander/implant-based techniques.^{3,4} Particularly in cases of nipple- or skin-sparing mastectomy, direct-to-implant reconstruction techniques have proved useful in producing acceptable outcomes with fewer operations.⁵ Despite its resurgence as a reconstructive option, use of direct-to-implant reconstruction remains limited because of concerns among some surgeons over surgical complications.^{6–10}

The appeal of direct-to-implant reconstruction is clear: a single-stage approach that can be performed immediately after mastectomy, providing well-established psychosocial benefits¹¹ and avoiding further surgery. For these reasons, increasing numbers of surgeons are offering direct-to-implant reconstruction.¹² However, prospective studies evaluating the outcomes of these procedures, compared with two-stage implant procedures, are lacking. Previous research has been largely limited to single-center/single-surgeon and retrospective studies that fail to control for potential confounding variables, including the use of acellular dermal matrix. Furthermore, patient-reported outcome analyses are missing from most reports. Our study's purpose was to compare complications and patient-reported outcomes for direct-to-implant and tissue expander/implant-based reconstructions at 2 years postoperatively.

PATIENTS AND METHODS

Patient Selection and Data Collection

Data for these analyses were gathered as part of the Mastectomy Reconstruction Outcomes Consortium Study. Funded by the National Cancer Institute in 2011, the Mastectomy Reconstruction Outcomes Consortium Study is a prospective cohort study including 57 plastic surgeons in 11 major cancer centers across the United States and Canada. Study sites were chosen to recruit an ethnically, racially, and geographically diverse patient population. With institutional review board approval at all sites, the project enrolled women undergoing first-time breast reconstruction following mastectomy for breast cancer treatment and/or prophylaxis. Patients undergoing immediate implant-based reconstruction with 2-year follow-up from the initiation of reconstruction were included in our study.

Demographic and clinical information was gathered preoperatively and 1 week postoperatively from participants' electronic medical records. The data were uploaded by site coordinators into the Velos eResearch System, a password-secure data collection platform. Demographic variables collected included age, race, ethnicity, education, income, marital status, and employment status. Clinical variables included procedure type, timing (immediate versus delayed reconstruction), laterality (unilateral versus bilateral procedures), body mass index, lymph node management (sentinel lymph node or axillary lymph node dissection), radiation therapy, chemotherapy, diabetes, mastectomy type, and smoking status. Complication data were collected from the electronic medical records at 1 and 2 years postoperatively. For this study, 2-year complications were grouped into the following five categories: any complication, major complication, any wound infection, major infection, and reconstructive failure. A complication was defined as an adverse, postoperative, surgery-related event requiring additional treatment. Major complications were designated as those requiring rehospitalization or reoperation. An infection included documented clinical signs of infection subsequently treated with antibiotics. Major infections required hospitalization for intravenous antibiotics and/or explantation. Reconstructive failures were defined as complications necessitating tissue expander or implant removal. Data from subsequent reconstructive attempts using the same type of reconstruction after initial failure were excluded from our analyses.

Patient-reported outcomes were assessed preoperatively (baseline) and at 2 years after reconstruction. Participants completed a panel of questionnaires, including the BREAST-Q survey, which was analyzed for this study. The BREAST-Q is a validated and condition-specific survey designed for and tested in breast reconstruction patients.^{13,14} Surveys were completed online by means of the password-secure Velos Web site or, for those patients without Internet access, with hardcopy questionnaires. Participants were surveyed before reconstruction, within a 90-day window before surgery. If for any reason surgery was delayed beyond 90 days, the patients were contacted to retake the survey. Those patients who did not complete the survey within 90 days of their initial surgery were removed from our analysis. Surveys were then administered again at 1 week, 3 months, 1 year, and 2 years postoperatively. The 2-year survey results were used for the current analysis. Of note, the assessment times are from the initiation of reconstruction, defined by placement of the tissue expander or the implant. For purposes of this analysis, preoperative and 2-year postoperative survey data were evaluated. Patient-reported outcomes in the current analyses included four domains: satisfaction with breast, psychosocial well-being, physical well-being (chest and upper body), and sexual well-being. According to the Mastectomy Reconstruction Outcomes Consortium Study protocol, BREAST-Q data were not consistently collected for patients whose reconstructions failed. Therefore, only nonfailure patients were included for this part of the analysis.

Statistical Analysis

Initially, patient characteristics and complications were compared between the two procedure types (direct-to-implant reconstruction versus tissue expander/implant) using *t* tests for continuous variables and chi-square tests for categorical variables. For all analyses, patient was the analytic unit. To further explore the effects of procedure type on outcomes,

separate mixed-effects logistic regression models were used for (1) any type of complication, (2) major complications, (3) any type of infection, and (4) major infections. Each model included an indicator for direct-to-implant procedure type as the primary predictor (with tissue expander/implant reconstruction as the reference category). Patient demographic and clinical characteristics were included as covariates, and random intercepts were included for treatment sites (hospitals) to account for between-hospital variability. Adjusted odds ratios with 95 percent confidence intervals were estimated by the model.

For patient-reported outcomes, mean scores preoperatively and 2 years postoperatively were summarized by procedure types. To compare 2-year patient-reported outcomes between the two procedure types, separate mixed-effects regression models were used for each patient-reported outcome measure. Each model was adjusted for the baseline value of the corresponding outcome variable and for clinical and demographic characteristics, and included centers (hospitals) as random intercepts to account for between-center variability. To reduce potential bias from nonresponse or missing patient-reported outcomes at 2 years postoperatively, multiple imputation with chained equations were used to create 10 complete imputed data sets. The regression models specified above were fit for each imputed data set, and the results were then combined using Rubin's rules.¹⁵ All statistical analyses were performed in SAS 9.4 (SAS Institute, Inc., Cary, N.C.).

RESULTS

Of 1427 eligible patients recruited between 2012 and 2014, 99 underwent direct-to-implant reconstruction and 1328 underwent tissue expander/implant reconstruction. Clinical and demographic distributions between the direct-to-implant and tissue expander/implant reconstruction cohorts are described in Table 1. Prophylactic ($p < 0.001$) and nipple-sparing ($p < 0.001$) mastectomies were more commonly performed for direct-to-implant procedures. Expectedly, acellular dermal matrix was used significantly more often in the direct-to-implant reconstruction cohort (92.9 percent versus 51.7 percent; $p < 0.001$). Radiation therapy ($p = 0.04$), adjuvant chemotherapy ($p < 0.001$), and axillary dissection ($p < 0.001$) were more common in the tissue expander/implant reconstruction cohort. The distributions of age, body mass index, and laterality were not significantly different between the two cohorts.

Bivariate analyses on 2-year postoperative complications are summarized in Table 2. Complication rates were generally higher with direct-to-implant reconstruction, compared with tissue expander/implant reconstruction, although these differences were not statistically significant. Overall, 32.3 percent of the direct-to-implant reconstruction cohort and 26.2 percent of the tissue expander/implant cohort experienced a postoperative complication ($p = 0.41$); major complications were observed in 25.3 percent and 19.1 percent of the patients, respectively ($p = 0.37$). Surgical-site infection was found in 16.2 percent of the direct-to-implant reconstruction patients and 10.5 percent of the tissue expander/implant reconstruction patients ($p = 0.19$), with major infections in 10.1 percent and 5.7 percent, respectively ($p = 0.14$). Reconstruction failure rates were 8.1 percent in direct-to-implant procedures versus 7.4 percent in tissue expander/implant reconstruction procedures ($p = 0.88$). Similar results were seen in multivariable analyses (Table 3). After controlling for

baseline patient characteristics, direct-to-implant reconstructions showed higher complication risks compared with tissue expander/implant reconstruction consistently across the various complications, but the differences were not statistically significant. The adjusted odds ratios associated with direct-to-implant reconstruction were 1.34 ($p = 0.26$) for any complication, 1.40 for major complications ($p = 0.23$), 1.65 for any infection ($p = 0.13$), and 1.67 for major infections ($p = 0.20$).

We also evaluated the number of patients who underwent revision surgery in each cohort, and the average number of revisions per patient during 2-year follow-up. Among patients undergoing tissue expander/implant reconstruction, 34.6 percent received additional revisions following the expander-implant exchange. For direct-to-implant reconstruction patients, 28.3 percent underwent revision surgery after original implant placement ($p = 0.20$). There was also no significant difference in the mean number of revisions for the tissue expander/implant cohort (0.8) compared with the direct-to-implant reconstruction cohort (0.9) ($p = 0.49$).

Means for preoperative and 2-year postoperative patient-reported outcome scores from the BREAST-Q are summarized in Table 4. Before reconstruction, patients from both procedure groups reported similar baseline scores in all four domains of the BREAST-Q. Controlling for clinical and demographic characteristics, the mixed-effects regressions showed that sexual well-being was 5 points higher at 2 years for the direct-to-implant reconstruction group ($p = 0.05$). However, the analyses showed no significant procedure type effects on satisfaction with breasts, or on psychosocial, physical, or sexual well-being (Table 5).

DISCUSSION

Although a variety of choices are currently available for postmastectomy reconstruction, implant-based techniques remain the most common.¹⁶ Among these procedures, direct-to-implant reconstruction has become an attractive option for both patients and surgeons because it offers multiple advantages. By opting for a single-stage approach, patients undergoing mastectomy can forego tissue expansion and a second operation. The multiple visits required for expansions and the disability time from a second operation can be avoided. Whether because of surgical complications or because of adjuvant cancer therapies, the time interval between expander placement and exchange may be prolonged for some patients. In our study, approximately 20 percent of women undergoing tissue expander/implant-based reconstruction had still not undergone exchange by 1 year. This subgroup had a higher incidence of expander-related complications, which may explain, in part, the delay in exchange procedures. Predictably, patients who had not undergone exchange by 1 year reported lower patient-reported outcome scores. Thus, as a single-stage approach, direct-to-implant reconstruction eliminates the need for tissue expansion, the inevitability of a second operation, and the possibility of having to tolerate a tissue expander for a prolonged period.

Although patients are requesting single-stage procedures, surgeons may be hesitant to perform direct-to-implant reconstruction because of a perceived higher risk of complications, compared with traditional expander-implant techniques. Previous investigators have analyzed outcomes for direct-to-implant and tissue expander/implant-

based reconstruction, but these studies have been limited by single-center designs or relatively short lengths of follow-up.^{5,17,18} By contrast, the current study is multicenter and prospective in its design, includes 2-year outcomes, and controls for site and multiple demographic and clinical variables. When controlling for these covariates, we found no statistically significant differences between the procedure types for risks of overall complication, major complication, overall infection, or major infection. Although the differences were not statistically significant, the associated odds ratios did range from 1.34 (for any complication) to 1.67 (for major infections), in the direction of greater risks for direct-to-implant reconstruction techniques. It is possible that the lack of statistically significant procedure effects on complications is the result of type II statistical error because of the small number of direct-to-implant reconstruction patients. If indeed 25 percent versus 20 percent is the complication rate associated with direct-to-implant versus tissue expander/implant reconstruction, respectively, the difference would correspond to an odds ratio of 1.33, and the current study would have 20 percent power to detect this difference with a 0.05 level two-sided test. Finally, the regressions did show significant effects on complications by a number of covariates, including age, body mass index, laterality, lymph node management, smoking status, and radiation therapy. The impacts of these variables on complications in breast reconstruction have been or will be further examined in other studies.

Although previous studies have evaluated complication rates for direct-to-implant reconstruction procedures, there is little published research comparing patient-reported outcomes for direct-to-implant versus tissue expander/implant reconstruction. Previous investigators have included complex aesthetic evaluations by plastic surgeons,¹⁹ but patient-reported assessments of satisfaction with reconstruction, body image, and quality of life are largely lacking. The use of patient self-reported measures is consistent with the continued emphasis on assessing patient-centered outcomes in health care^{20,21} and the impact of care on quality of life and general well-being.²² Consumers want to know how these operations will impact their day-to-day lives (i.e., physical functioning, psychosocial well-being, pain, and body image). This knowledge can assist women in making surgical decisions that are compatible with their individual preferences and values.

Unlike two-stage tissue expander/implant reconstruction techniques, direct-to-implant reconstruction is a truly “immediate” reconstruction (i.e., it restores the breast mound in the same operative episode as the mastectomy). As reported recently for autogenous tissue techniques, single-stage, immediate reconstruction conveys measureable benefits, reducing psychosocial distress, body image disruptions, and adverse effects on sexual well-being.²³ Based on our findings, differences in patient-reported outcomes between direct-to-implant and expander-implant reconstructions may be less uniform: in our bivariate and multivariable analyses of patient-reported outcomes comparing 2-year postoperative scores between direct-to-implant and tissue expander/implant reconstruction patients, we observed no significant differences for three of the four BREAST-Q domains. The one exception to these findings was noted for the sexual well-being subscale, in which the direct-to-implant reconstruction cohort was significantly more satisfied than the tissue expander/implant reconstruction cohort in the multivariable analysis (beta = 5.0). Thus, compared with expander-implant techniques, direct-to-implant reconstruction produced comparable or superior (in the case of sexual functioning) patient-reported outcomes.

Despite the strengths of our study, including its multicenter, prospective design, our analyses did have some important limitations. Although we controlled for a wide array of potential demographic and clinical confounding variables, it is conceivable that our results could be attributable to the effects of unknown confounders. Specifically, there is no way to control for surgeon choice of procedure (direct-to-implant versus tissue expander/implant reconstruction). As we know, mastectomy skin flap quality (including thickness, color, and capillary refill) is evaluated intraoperatively, and the decision to pursue direct-to-implant reconstruction is dependent on the surgeon's confirmation that the mastectomy flaps are of adequate quality. Although a randomized, controlled trial design could better adjust for confounding, the prospect of randomizing patients to reconstructive operations presents logistical and (potentially) ethical barriers. As noted earlier, the relatively small size of our direct-to-implant reconstruction cohort may have led to some of our analyses being underpowered to detect statistically significant differences (i.e., statistical type II error). Although not found to be statistically significant in our study, the odds ratios indicated a possible higher risk of complications in the direct-to-implant cohort. With a larger direct-to-implant sample size, these might have been statistically significant. Finally, because 10 of our 11 sites were academic centers, our findings may not be generalizable to patients in all settings, particularly those treated in smaller, nonacademic centers.

Our data do not allow us to identify the "ideal" patient for direct-to-implant reconstruction. However, a better understanding of the relative risks and benefits of direct-to-implant versus expander/implant techniques can allow for more evidence-based decision-making among consumers and their surgeons. Specifically, patients and providers must weigh the potential psychosocial benefits and overall time savings against the potentially greater risks of direct-to-implant reconstruction. Given the logistical advantages of direct-to-implant reconstruction and the tradeoffs between its risks and patient-reported benefits compared with those of traditional expander/implant procedures, direct-to-implant procedures may be worth considering for many patients.

CONCLUSIONS

Trends in breast reconstruction are changing: more patients are opting for mastectomies, prophylactic operations, and single-stage reconstructions. In our prospective, multicenter study, we did not observe significant differences in risks or patient-reported outcomes between direct-to-implant and traditional expander/implant techniques for immediate reconstruction following mastectomy. Although not every patient is a candidate for direct-to-implant reconstruction, the heretofore limited use of this approach because of concerns over significantly higher complication rates may not be warranted. However, the potential time savings and patient-reported outcome benefits of direct-to-implant reconstruction must still be weighed against the associated risks. Our multi-institutional, prospective analyses of complications and patient-reported outcomes provide surgeons and patients with new evidence on which to base reconstruction decision-making.

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Table 1

Clinical and Demographic Characteristics of Patients Overall and by Procedure Type

	Overall (%)	Procedure Type		<i>p</i>
		DTI (%)	TE (%)	
No.	1427	99 (6.9)	1328 (93.1)	
Mean age $\pm$ SD, yr	48.4 $\pm$ 10.5	48.3 $\pm$ 12.1	48.4 $\pm$ 10.4	0.900
Mean BMI $\pm$ SD, kg/m ²	25.6 $\pm$ 5.4	25.2 $\pm$ 6.4	25.7 $\pm$ 5.3	0.429
Laterality				
Unilateral	524 (36.7)	33 (33.3)	491 (37.0)	0.469
Bilateral	903 (63.3)	66 (66.7)	837 (63.0)	
Indication for mastectomy				
Therapeutic	1265 (88.6)	75 (75.8)	1190 (89.6)	<0.001
Prophylactic	162 (11.4)	24 (24.2)	138 (10.4)	
Mastectomy type				
Nipple sparing	253 (17.7)	31 (31.3)	222 (16.7)	<0.001
Simple or modified radical	1174 (82.3)	68 (68.7)	1106 (83.3)	
ADM use				
Used	778 (54.5)	92 (92.9)	686 (51.7)	<0.001
Not used	649 (45.5)	7 (7.1)	642 (48.3)	
Lymph node management				
SLNB	698 (48.9)	51 (51.5)	647 (48.7)	<0.001
ALND	446 (31.3)	12 (12.1)	434 (32.7)	
None	283 (19.8)	36 (36.4)	247 (18.6)	
Diabetes				
Yes	42 (2.9)	3 (3.0)	39 (2.9)	0.958
No	1385 (97.1)	96 (97.0)	1289 (97.1)	
Smoking status				
Nonsmoker	958 (67.8)	74 (76.3)	884 (67.2)	0.094
Previous smoker	423 (30.0)	23 (23.7)	400 (30.4)	
Current smoker	31 (2.2)	0 (0)	31 (2.4)	
Radiation				
Before reconstruction	73 (5.1)	8 (8.1)	65 (4.9)	0.043
During or after reconstruction	282 (19.8)	11 (11.1)	271 (20.4)	
None	1072 (75.1)	80 (80.8)	992 (74.7)	
Chemotherapy				
During or after reconstruction	464 (32.5)	9 (9.1)	455 (34.3)	<0.001
Not during or after reconstruction	963 (67.5)	90 (90.9)	873 (65.7)	

DTI, direct-to-implant; TE, tissue expander/implant; BMI, body mass index; ADM, acellular dermal matrix; SLNB, sentinel lymph node biopsy; ALND, axillary lymph node dissection.

Table 2

Complication Rates Overall and by Procedure Type at 2 Years Postoperatively

	Overall (%)	DTI (%)	TE (%)	<i>p</i>[*]
No.	1427	99	1328	
Complication				
Any complication	380 (26.6)	32 (32.3)	348 (26.2)	0.407
Major complication	279 (19.6)	25 (25.3)	254 (19.1)	0.365
Any infection	155 (10.9)	16 (16.2)	139 (10.5)	0.189
Major infection	85 (6)	10 (10.1)	75 (5.7)	0.138
Reconstructive failure	106 (7.4)	8 (8.1)	98 (7.4)	0.879

DTI, direct-to-implant; TE, tissue expander/implant.

* For the comparison of complication rate between procedure types, adjusting for sites (hospitals).

Table 3
Mixed-Effects Logistic Regression Model on 2-Year Postoperative Complications

	Ally Complication			Major Complication			Any Infection			Major Infection		
	OR	95% CI	p	OR	95% CI	p	OR	95% CI	p	OR	95% CI	p
Age	1.02	1.01–1.04	<0.001	1.03	1.01–1.04	0.001	1.02	1.00–1.04	0.070	1.00	0.98–1.03	0.746
BMI	1.04	1.02–1.07	0.001	1.05	1.02–1.07	0.001	1.06	1.03–1.10	<0.001	1.05	1.01–1.10	0.008
DTI (vs. TE)	1.34	0.81–2.22	0.257	1.40	0.81–2.43	0.227	1.65	0.86–3.18	0.133	1.67	0.77–3.63	0.196
Bilateral reconstruction	1.45	1.10–1.91	0.008	1.52	1.11–2.07	0.009	1.28	0.87–1.89	0.207	1.36	0.82–2.26	0.238
Prophylactic mastectomy	0.72	0.42–1.22	0.219	0.84	0.47–1.53	0.578	0.42	0.18–0.97	0.043	0.54	0.19–1.50	0.236
Mastectomy type												
Nipple sparing		Ref.			Ref.			Ref.			Ref.	
Simple/modified radical	0.73	0.50–1.05	0.093	0.88	0.58–1.36	0.575	0.92	0.53–1.61	0.768	1.04	0.51–2.15	0.911
ADM used	1.04	0.76–1.40	0.823	1.19	0.85–1.67	0.312	1.38	0.89–2.14	0.154	1.64	0.95–2.82	0.076
Lymph node management												
None		Ref.			Ref.			Ref.			Ref.	
SLNB	0.77	0.51–1.18	0.232	0.85	0.53–1.37	0.507	0.68	0.39–1.21	0.192	0.76	0.37–1.57	0.466
ALND	0.58	0.36–0.95	0.030	0.71	0.41–1.22	0.215	0.43	0.22–0.84	0.014	0.54	0.23–1.24	0.144
Diabetes	0.88	0.41–1.88	0.748	0.94	0.41–2.13	0.880	0.76	0.26–2.21	0.613	0.89	0.24–3.29	0.855
Smoking status												
Nonsmoker		Ref.			Ref.			Ref.			Ref.	
Previous smoker	1.06	0.81–1.39	0.677	0.99	0.73–1.35	0.961	1.00	0.68–1.46	0.983	0.82	0.49–1.38	0.454
Current smoker	2.01	0.94–4.29	0.072	3.25	1.50–7.08	0.003	1.44	0.51–4.04	0.488	1.77	0.49–6.33	0.382
Radiation												
None		Ref.			Ref.			Ref.			Ref.	
Before reconstruction	1.73	1.03–2.92	0.039	1.83	1.03–3.26	0.039	2.45	1.28–4.67	0.007	3.56	1.65–7.68	0.001
During/after reconstruction	2.62	1.84–3.73	<0.001	2.86	1.95–4.19	<0.001	2.62	1.62–4.24	<0.001	3.24	1.78–5.90	<0.001
Chemotherapy during/after reconstruction	1.25	0.93–1.68	0.139	1.33	0.95–1.85	0.096	1.42	0.94–2.14	0.100	1.35	0.79–2.32	0.272

Ref., reference; DTI, direct-to-implant; TE, tissue expander/implant; BMI, body mass index; ADM, acellular dermal matrix; SLNB, sentinel lymph node biopsy; ALND, axillary lymph node dissection.

Table 4
Summary of Patient-Reported Outcome (BREAST-Q) by Direct-to-Implant and Tissue Expander/Implant Reconstruction

PRO Measures	Baseline		2 Yr Postoperatively		<i>p</i> [†]
	No. *	Mean ± SD	No. *	Mean ± SD	
Satisfaction with breasts					
DTI	91	66.4 ± 20.3	64	68.3 ± 18.7	
TE	1223	63.7 ± 21.5	720	63.8 ± 17.7	0.239
Psychosocial well-being					
DTI	91	73.4 ± 17.9	64	77.5 ± 18.1	
TE	1220	71.8 ± 17.6	712	74.4 ± 18.9	0.405
Physical well-being (chest and upper body)					
DTI	91	81.9 ± 14.3	64	78.1 ± 15.2	
TE	1223	80.1 ± 14.3	709	77.1 ± 14.1	0.246
Sexual well-being					
DTI	87	59.3 ± 19.9	63	60.2 ± 22.9	0.788
TE	1193	58.7 ± 18.9	687	53.7 ± 20.8	

PRO, patient-reported outcome; DTI, direct-to-implant; TE, tissue expander/implant.

* Denote the number of patients with complete PRO.

[†]For the comparison of baseline PROs between procedure types.

Table 5
Mixed-Effects Regression Model for 2-Year Postoperative Patient-Reported Outcomes (BREAST-Q)

	Satisfaction with Breasts			Psychosocial Well-Being			Physical Well-Being			Sexual Well-Being		
	Beta	95% CI	p	Beta	95% CI	p	Beta	95% CI	p	Beta	95% CI	p
Baseline outcome	0.11	0.04–0.17	0.001	0.43	0.37–0.49	<0.001	0.34	0.26–0.41	<0.001	0.38	0.30–0.45	<0.001
Age	–0.09	–0.22–0.05	0.191	0.12	0.01–0.24	0.028	–0.01	–0.11–0.09	0.914	0.17	–0.03–0.37	0.085
BMI	–0.22	–0.49–0.04	0.097	–0.13	–0.37–0.11	0.294	–0.35	–0.54 to –0.17	<0.001	–0.28	–0.57–0.01	0.059
DTI (vs. TE)	3.46	–1.11–8.04	0.136	0.85	–3.26–4.96	0.684	1.29	–1.68–4.26	0.394	5.00	0.06–9.95	0.047
Bilateral reconstruction	4.28	1.90–6.65	0.001	0.71	–1.85–3.27	0.579	0.55	–1.21–2.32	0.535	1.85	–0.68–4.37	0.151
Prophylactic mastectomy	0.97	–3.15–5.09	0.643	5.83	1.62–10.03	0.007	3.10	–0.06–6.27	0.055	0.98	–4.62–6.58	0.726
Mastectomy type												
Nipple-sparing		Ref.			Ref.			Ref.			Ref.	
Simple/modified radical	0.85	–3.19–4.88	0.671	–0.88	–4.47–2.72	0.624	0.41	–2.17–2.99	0.753	–5.53	–9.44 to –1.63	0.006
ADM used	–0.54	–3.17–2.09	0.683	0.71	–2.25–3.68	0.628	–1.02	–2.87–0.83	0.275	–1.76	–4.44–0.93	0.197
Lymph node management												
None		Ref.			Ref.			Ref.			Ref.	
ALND	–3.01	–7.11–1.09	0.149	0.61	–3.78–4.99	0.783	2.09	–0.98–5.15	0.179	–0.23	–5.28–4.82	0.929
SLNB	–2.42	–5.62–0.78	0.139	1.01	–2.63–4.65	0.582	1.93	–0.66–4.51	0.143	–2.21	–6.32–1.91	0.288
Diabetes	3.52	–3.65–10.69	0.331	7.09	0.23–13.94	0.043	2.32	–3.43–8.06	0.421	5.23	–3.47–13.93	0.232
Smoking status												
Nonsmoker		Ref.			Ref.			Ref.			Ref.	
Previous smoker	–1.81	–4.69–1.07	0.211	–0.65	–3.61–2.32	0.660	–1.51	–3.81–0.79	0.189	–1.30	–4.69–2.09	0.440
Current smoker	–6.41	–15.21–2.40	0.151	–2.39	–11.06–6.28	0.583	0.43	–6.90–7.77	0.905	0.07	–11.75–11.89	0.990
Radiation												
None		Ref.			Ref.			Ref.			Ref.	
Before reconstruction	–2.81	–10.06–4.43	0.431	–2.09	–7.15–2.96	0.413	1.32	–3.06–5.69	0.548	–0.58	–9.09–7.92	0.888
During/after reconstruction	–10.45	–15.13 to –5.77	<0.001	–5.38	–9.18 to –1.59	0.007	–6.60	–9.51 to –3.70	<0.001	–5.31	–8.88 to –1.74	0.004
Chemotherapy during/after reconstruction	–0.72	–3.46–2.02	0.601	–2.21	–4.76–0.33	0.088	0.71	–1.33–2.74	0.492	–4.02	–7.39 to –0.65	0.020

BMI, body mass index; DTI, direct-to-implant; TE, tissue expander/implant; Ref., reference; ADM, acellular dermal matrix; SLNB, sentinel lymph node biopsy; ALND, axillary lymph node dissection.