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Complications Including Capsular Contracture in Direct-to-Implant Breast Reconstruction With Textured Anatomical Versus Smooth Round Implants: A Single Center Retrospective Analysis

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ABSTRACT

Purpose: Implant-based breast reconstruction is the most common reconstruction method used after mastectomy in breast cancer patients. Many studies have compared the smooth round implants and textured anatomical implants. This study aimed to compare the complications, including capsular contracture, between these two implants used in direct-to-implant (DTI) breast reconstruction.

Methods: This retrospective chart review was performed using a prospectively maintained database from a single center. We identified patients who underwent mastectomy with DTI single-stage breast reconstruction at our hospital between August 2011 and June 2021. The overall complications, including capsular contracture, postoperative infection, seroma, hematoma, implant rupture, implant exposure, rippling, implant malposition, and nipple necrosis, were analyzed.

Results: In total, 340 breasts of 323 patients were reconstructed by the DTI approach using either textured anatomical (n = 203) or smooth round (n = 137) implants. The incidence of overall complications and capsular contracture was significantly lower with smooth round implants than with textured anatomical implants. Multivariate analysis showed that smooth round implants were associated with a reduced risk of overall complications (odds ratio [OR], 0.465; 95% confidence interval [CI], 0.265–0.813) and capsular contracture (OR, 0.475; 95% CI, 0.235–0.962). Particularly, smooth round implants were associated with a decreased risk of overall complications in patients not receiving adjuvant chemotherapy and a decreased risk of capsular contracture in patients with body mass index < 25 kg/m² and in those not receiving adjuvant radiotherapy.

Conclusion: Smooth round implants demonstrated a decreased risk of overall complications and capsular contracture when compared with textured anatomical implants. These results may be utilized in counseling patients regarding the advantages and disadvantages of smooth round implants in DTI breast reconstruction.



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Conflict of Interest

The authors declare that they have no competing interests.

Author Contributions

Conceptualization: Kim YS; Data curation: Jeon HB, Lee M, Lee N; Formal analysis: Jeon HB, Kim YS; Investigation: Jeon HB, Lee M, Lee N; Methodology: Jeon HB; Project administration: Roh TS, Kim YS; Resources: Roh TS, Jeong J, Ahn SG, Bae SJ, Kim YS; Supervision: Kim YS; Validation: Roh TS, Jeong J, Ahn SG, Bae SJ, Kim YS; Visualization: Roh TS, Jeong J, Ahn SG, Bae SJ, Kim YS; Writing - original draft: Jeon HB; Writing - review & editing: Kim YS, Lee M. Keywords: Breast Implants; Breast Implantation; Mastectomy

INTRODUCTION

Implant-based breast reconstruction is the most commonly performed breast reconstruction method after mastectomy for breast cancer. It has several advantages, such as a short operative time, lack of donor-site morbidity, and quick return to normal activities [1]. According to the American Society of Plastic Surgeons, two-stage breast reconstruction using a tissue expander accounts for approximately 67% of all reconstructions performed [2]. Nonetheless, direct-toimplant (DTI) breast reconstruction is fascinating for both surgeons and patients. Single-stage DTI breast reconstruction provides complete reconstruction for the patients at the time of mastectomy, resulting in a shorter reconstruction process, elimination of the expansion period, and avoidance of secondary surgery [3]. Previously, a full muscular pocket covering the implant allowed the use of small- to medium-sized implants, while sometimes it did not allow the surgeon to recreate a good lower pole shape and inframammary fold contour [4]. Additionally, several problems, such as pectoralis muscle retraction, implant malposition, and contracture, can occur in DTI breast reconstruction. The acellular dermal matrix (ADM) provides a solution for these problems by holding the released pectoralis muscle stretched and forming a complete pocket around the implant at the desired position [5]. As the frequency of nipple-sparing procedures has increased with the development of ADM, recent trends have demonstrated an increase in the number of patients undergoing DTI breast reconstruction.

Breast implants can be categorized into textured implants and smooth implants based on the surface of their shells. Textured implants were developed to stabilize the implants in the breast pocket and to decrease the rate of capsular contracture [6]. However, many surgeons prefer to use smooth implants, because they find that the contracture rates are comparable between textured and smooth implants [7]. Recently, some studies have reported an increased risk of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) with textured breast implants, which were eventually withdrawn from the market in July 2019 [8]. Hence, many breast reconstruction surgeons prefer to use smooth breast implants. However, studies comparing textured anatomical implants and smooth round implants in patients undergoing DTI breast reconstruction are limited. This study aimed to compare the complications, including capsular contracture, between the two implants used in DTI breast reconstruction.

METHODS

This study involved a retrospective chart review of a prospectively maintained database and was approved by the respective Institutional Review Board (IRB No. 3-2022-0162). We identified patients diagnosed with primary breast cancer, who had undergone mastectomy with DTI breast reconstruction at our hospital between August 2011 and June 2021. The exclusion criteria were previous breast surgery, refusal to sign the consent form, previous radiotherapy, follow-up period < 6 months, and missing data for the pertinent variables.

Each breast was considered individually and categorized according to the type of implant surface as textured anatomical implant or smooth round implant. The implant brands used were Mentor MemoryGel (Mentor Worldwide LLC, Irvine, USA), Allegan (Allergan plc, Dublin, Ireland), and BellaGel (Hans Biomed Corp., Seoul, Korea). Patient demographics, operative characteristics, radiation therapy, medical oncology treatments, and relevant data for the analysis of risk factors were collected by reviewing the medical records. The parameters included age, body mass index (BMI), pathologic tumor stage, mastectomy type (nipple-sparing, skin-sparing, or total mastectomy), axillary surgery (sentinel lymph node biopsy or axillary lymph node dissection), implant size, implant insertion plane, ADM use, laterality, number of dissected lymph nodes or positive lymph nodes, chemotherapy (neoadjuvant or adjuvant), target therapy (trastuzumab), hormone therapy, radiotherapy, comorbidities (diabetes mellitus or hypertension), smoking (non-smoker, ex-smoker, or active smoker), follow-up duration, and drainage duration. Furthermore, complications including capsular contracture, infection, seroma, hematoma, implant rupture, implant exposure, rippling, implant malposition, and nipple-areolar complex (NAC) necrosis were analyzed. Capsular contracture was evaluated by reconstruction surgeons. Any incidence of clinically relevant capsular contracture, defined as Spear–Baker grade III or IV, occurring during the study period was recorded.

Variables were compared between the groups using Pearson χ^2 test or Fisher exact test to examine the associations of the categorical variables. The independent t-test or Mann-Whitney U test was used for continuous variables. Logistic regression models were used to evaluate the risk factors associated with the development of complications and capsular contracture. Multiple logistic regression analyses were performed using a stepwise model selection method to predict the risk factors for overall complications and capsular contracture based on the age, BMI, pathologic tumor stage, mastectomy type, axillary surgery, implant-based breast reconstruction (size, surface, and insertion plane), number of positive lymph nodes, number of dissected lymph nodes, neoadjuvant and adjuvant chemotherapy, target treatment, hormone therapy, radiotherapy, comorbidities of diabetes mellitus or hypertension, smoking, drainage duration, and follow-up duration. Further subgroup analyses were conducted to determine whether the impact of the implant surface on the risk of capsular contracture varies with higher BMI or adjuvant radiotherapy after adjusting for risk factors. We divided the patients into the following two BMI categories according to the World Health Organization classification: $< 25 \text{ kg/m}^2$ and $\ge 25 \text{ kg/m}^2$. Statistical significance was set at *p*-value < 0.05. All statistical analyses were conducted using Statistical Product and Service Solutions (version 24.0; SPSS Inc., Chicago, USA).

RESULTS

In total, 340 DTI reconstructions were performed in 323 patients. There were 203 (59.7%) textured anatomical implants used in 193 patients, of which 183 (94.8%) patients underwent unilateral surgery and 10 (5.2%) underwent bilateral surgery. There were 137 (40.3%) smooth round implants used in 130 patients, of which 123 (94.6%) patients underwent unilateral surgery and 7 (5.4%) underwent bilateral surgery. Differences in laterality, age, BMI, pathologic tumor stage, mastectomy type, axillary surgery, DTI reconstruction, number of dissected lymph nodes or positive lymph nodes, chemotherapy, target therapy, hormone therapy, adjuvant radiotherapy, comorbidities, smoking, and drainage duration between the two groups were not significant. However, significant differences in the implant insertion plane and follow-up duration were observed between the two groups. The pre-pectoral technique was used more frequently in the smooth round implant group than in the textured anatomical implant group (1.0% vs. 13.9%; *p* < 0.001). Furthermore, the mean follow-up period was longer in the textured anatomical implant group than in the smooth round implant group (28.6 ± 19.5 vs. 15.1 ± 8.7; *p* < 0.001) (**Table 1**).

Patient demographics	Textured anatomical implant	Smooth round implant	р
No. of patients	193	130	
No. of breasts	203	137	
Laterality			0.912
Unilateral	183 (90.1)	123 (89.8)	
Bilateral	10 (9.9)	7 (10.2)	
Age at surgery (yr)	47.3 ± 7.8	46.8 ± 7.9	0.527
BMI at surgery (kg/m²)	22.9 ± 3.3	22.3 ± 2.8	0.099
Pathologic tumor stage			0.683
Stage O	62 (30.5)	39 (29.7)	
Stage I	66 (32.5)	53 (35.0)	
Stage II	60 (29.6)	39 (29.1)	
Stage III	14 (6.9)	6 (5.9)	
Stage IV	1 (0.5)	0 (0)	
Surgery			
Mastectomy			0.055
Nipple sparing	172 (84.7)	125 (91.2)	
Skin sparing	20 (9.9)	11 (8.0)	
Total	11 (5.4)	1 (0.7)	
Axillary surgery			0.766
SLNB	171 (84.2)	113 (82.5)	
ALND	32 (15.8)	24 (17.5)	
Direct to implant reconstruction			
Implant size (mL)	240.8 ± 82.0	245.6 ± 89.4	0.607
Insertion plane			< 0.001*
Pre-pectoral	2 (1.0)	19 (13.9)	
Sub-pectoral	201 (99.0)	118 (86.1)	
Use of acellular dermal matrix			-
No	0 (0.0)	0 (0.0)	
Yes	203 (100.0)	137 (100.0)	
No. of dissected lymph nodes	8.2 ± 6.7	9.0 ± 7.2	0.240
No. of positive lymph nodes	0.7 ± 3.1	0.6 ± 1.7	0.662
Chemotherapy			0.152
No	146 (71.9)	88 (64.2)	
Yes	57 (28.1)	49 (35.8)	
Neo-adjuvant chemotherapy	11 (19.3)	34 (69.4)	
Adjuvant chemotherapy	47 (82.5)	19 (38.8)	
Target therapy (trastuzumab)	<i>.</i> .		0.850
No	184 (90.6)	125 (91.2)	
Yes	19 (9.4)	12 (8.8)	
Hormone	<i>.</i> .		0.588
No	120 (59.1)	85 (62.0)	
Yes	83 (40.9)	52 (38.0)	
Adjuvant radiotherapy			0.234
No	169 (83.3)	107 (78.1)	
Yes	34 (16.7)	30 (21.9)	
Diabetes mellitus			0.989
No	200 (98.5)	135 (98.5)	
Yes	3 (1.5)	2 (1.5)	
Hypertension			0.271
No	194 (95.6)	134 (97.8)	
Yes	9 (4.4)	3 (2.2)	0.100
Smoking		107 (100 0)	0.169
Non-smoker	197 (97.0)	137 (100.0)	
Ex-smoker	3 (1.5)	0 (0.0)	
Active smoker	3 (1.5)	0 (0.0)	0.150
Drainage duration (day)	16.4 ± 5.4	15.7 ± 3.6	0.150
Follow-up duration (mo)	28.6 ± 19.5	15.1 ± 8.7	< 0.001*

Table 1. Patient demographics of the patients with textured anatomical versus smooth round implants

Data are presented as mean ± standard deviation or number (%). BMI = body mass index; SLNB = sentinel lymph node biopsy; ALND = axillary lymph node dissection. *The difference is statistically significant.

Among the various complications examined during subsequent follow-ups, the most common postoperative complication was capsular contracture, with a significant difference in its incidence between the smooth round and textured anatomical implant groups (20.7% vs. 10.9%; p = 0.018). However, the differences in infection, seroma, hematoma, implant rupture, implant exposure, rippling, implant displacement, and NAC necrosis were not significant between the two groups. The incidence of overall complications, including capsular contracture, were significantly more in the textured anatomical implant group than in the smooth round implant group (45.8% vs. 23.4%; p < 0.001) (**Table 2**).

In terms of overall complications, only seven of the eight factors selected showed a significant association. These included age (odds ratio [OR], 1.068; 95% confidence interval [CI], 1.033–1.104), implant size (OR, 0.996; 95% CI, 0.993–0.999), implant surface (OR, 0.465; 95% CI, 0.265–0.813), adjuvant chemotherapy (OR, 0.369; 95% CI, 0.183–0.742), adjuvant radiotherapy (OR, 1.906; 95% CI, 1.032–3.521), drainage duration (OR, 1.094; 95% CI, 1.034–1.159), and follow-up duration (OR, 1.025; 95% CI, 1.009–1.041) (**Table 3**).

Subsequent subgroup analysis was conducted to determine whether the impact of the implant surface on the risk of overall complications varies with adjuvant chemotherapy or adjuvant radiotherapy after adjusting for risk factors. Among patients who did not receive adjuvant chemotherapy, the risk of overall complications was approximately 62.6% lower

Table 2.	Complications i	n patients with	n textured	anatomical	versus smoot	h round i	mplants
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complications	implant (n = 203)	implant (n = 137)	ρ
Overall complications			< 0.001*
No	110 (54.2)	105 (76.6)	
Yes	93 (45.8)	32 (23.4)	
Capsular contracture	42 (20.7)	15 (10.9)	0.018*
Infection	8 (3.9)	1(0.7)	0.070
Seroma	8 (3.9)	6 (4.4)	0.842
Hematoma	1 (0.5)	1 (0.7)	0.779
Implant rupture	1 (0.5)	0 (0.0)	0.411
Implant exposure	14 (6.9)	3 (2.2)	0.051
Rippling	10 (4.9)	4 (2.9)	0.361
Implant displacement (malrotation or malposition)	20 (9.9)	7 (5.1)	0.113
NAC necrosis	7 (3.4)	2 (1.5)	0.263

Data are presented as number (%).

NAC, nipple-areolar complex.

Compliantions

*The difference is statistically significant.

Table 3. Factors that	predict the devel	lopment of overal	l complications acc	ording to	logistic reg	gression anal	ysis
							/

Factors	Multivariable analysis*	
	OR (95% CI)	р
Age at surgery (yr)	1.068 (1.033-1.104)	< 0.001 [†]
Implant size (mL)	0.996 (0.993–0.999)	0.019†
Implant surface (textured [ref.] vs. smooth)	0.465 (0.265-0.813)	0.007†
Adjuvant chemotherapy (no vs. yes)	0.369 (0.183-0.742)	0.005†
Adjuvant radiotherapy (no vs. yes)	1.906 (1.032-3.521)	0.039†
Diabetes mellitus (no vs. yes)	9.052 (0.931-87.984)	0.058
Drainage duration (day)	1.094 (1.034-1.159)	0.002 [†]
Follow-up duration (mo)	1.025 (1.009-1.041)	0.002 [†]

CI = confidence interval; OR = odds ratio.

*Adjustment: age, body mass index, pathologic tumor stage, mastectomy, axillary surgery, implant-based breast reconstruction (size, surface, insertion plane), positive lymph nodes, dissected lymph nodes, neo-adjuvant and adjuvant chemotherapy, Herceptin, hormone, radiotherapy, diabetes mellitus, hypertension, smoking, drainage duration, follow-up duration.

[†]The difference is statistically significant.

in the smooth round implant group than in the textured anatomical implant group (OR, 0.374; 95% CI, 0.198–0.707). However, among patients receiving adjuvant chemotherapy, no significant differences in the risk of overall complications were observed between the two groups. In patients who did not receive adjuvant radiotherapy, the risk of overall complications was approximately 54.9% lower in the smooth round implant group than in the textured anatomical implant group (OR, 0.451; 95% CI, 0.235–0.863). However, among patients receiving adjuvant radiotherapy, no significant differences were observed between the two groups (**Table 4**).

In terms of capsular contracture, only seven of the eight factors selected showed a significant association. These included age (OR, 1.078; 95% CI, 1.032–1.126), BMI (OR, 1.275; 95% CI, 1.112–1.461), skin-sparing mastectomy (OR, 0.121; 95% CI, 0.015–0.972), total mastectomy (OR, 4.381; 95% CI, 0.782–24.56), implant size (OR, 0.990; 95% CI, 0.984–0.995), implant surface (OR, 0.475; 95% CI, 0.235–0.962), and adjuvant radiotherapy (OR, 3.261; 95% CI, 1.576–6.746) (**Table 5**).

Subsequent analysis was conducted to determine whether the impact of the implant surface on the risk of capsular contracture varies with BMI. In patients with BMI < 25 kg/m², the risk of capsular contracture was approximately 74.7% lower in the smooth round implant group than in the textured anatomical implant group (OR, 0.253; 95% CI, 0.102–0.624). In contrast, among patients with BMI \ge 25 kg/m², no significant difference in the risk of capsular contracture was observed between the two groups. Furthermore, in patients who did not

Table 4. Subgroup analysis for comparing the developments of overall complications between textured
anatomical and smooth round implants

Subgroup analysis	Confounding-adjusted logistic regression*		
	OR (95% CI)	р	
Adjuvant chemotherapy (textured [ref.] vs. smooth)			
No (n = 274)	0.374 (0.198-0.707)	0.002 [†]	
Yes (n = 66)	1.499 (0.179–12.576)	0.709	
Adjuvant radiotherapy (textured [ref.] vs. smooth)			
No (n = 276)	0.451 (0.235-0.863)	0.016 [†]	
Yes (n = 64)	0.788 (0.103-6.016)	0.818	

CI = confidence interval; OR = odds ratio.

*Adjustment: age, body mass index, pathologic tumor stage, mastectomy, axillary surgery, implant-based breast reconstruction (size, surface, insertion plane), positive lymph nodes, dissected lymph nodes, neo-adjuvant chemotherapy, Herceptin, hormone, radiotherapy, diabetes mellitus, hypertension, smoking, drainage duration, follow up duration.

[†]The difference is statistically significant.

Table 5. Factors that predict the development of capsular contracture according to logistic regression analysis

Factors	Multivariable analysis*	
	OR (95% CI)	р
Age at surgery (yr)	1.078 (1.032-1.126)	0.001 [†]
BMI at surgery (kg/m²)	1.275 (1.112-1.461)	< 0.001 [†]
Skin sparing (vs. nipple sparing [ref.])	0.121 (0.015-0.972)	0.047†
Total (vs. nipple sparing [ref.])	4.381 (0.782-24.56)	0.040 [†]
Implant size (mL)	0.990 (0.984-0.995)	< 0.001 [†]
Implant surface (textured [ref.] vs. smooth)	0.475 (0.235-0.962)	0.039†
Adjuvant radiotherapy (no vs. yes)	3.261 (1.576-6.746)	0.001 [†]
HTN (no vs. yes)	0.118 (0.012-1.155)	0.066

BMI = body mass index; CI = confidence interval; OR = odds ratio; HTN = hypertension.

*Adjustment: age, BMI, pathologic tumor stage, mastectomy, axillary surgery, implant-based breast reconstruction (size, surface, insertion plane), positive lymph nodes, dissected lymph nodes, neo-adjuvant and adjuvant chemotherapy, Herceptin, hormone, radiotherapy, diabetes mellitus, hypertension, smoking, complications (infection, seroma, hematoma, implant exposure, nipple-areolar complex necrosis), drainage duration. [†]The difference is statistically significant.



 Table 6. Subgroup analysis for comparing the developments of capsular contracture between textured anatomical and smooth round implants

Subgroup analysis	Confounding-adjusted logistic regression*		
	OR (95% CI) p		
BMI category at surgery (kg/m²; textured [ref.] vs. smooth)			
< 25.0 (n = 274)	0.253 (0.102-0.624)	0.003 [†]	
≥ 25.0 (n = 66)	0.068 (0.003-1.455)	0.085	
Adjuvant radiotherapy (textured [ref.] vs. smooth)			
No (n = 276)	0.273 (0.104-0.715)	0.008 [†]	
Yes (n = 64)	0.772 (0.066-9.007)	0.836	

BMI = body mass index; CI = confidence interval; OR = odds ratio.

*Adjustment: age, BMI, pathologic tumor stage, mastectomy, axillary surgery, implant-based breast reconstruction (size, surface, insertion plane), positive lymph nodes, dissected lymph nodes, neo-adjuvant and adjuvant chemotherapy, Herceptin, hormone, diabetes mellitus, hypertension, smoking, complications (infection, seroma, hematoma, implant exposure, nipple-areolar complex necrosis), drainage duration. [†]The difference is statistically significant.

receive adjuvant radiotherapy, the risk of capsular contracture was approximately 72.7% lower in the smooth round implant group than in the textured anatomical implant group (OR, 0.273; 95% CI, 0.104–0.715). However, among patients who received adjuvant radiotherapy, no significant difference in the risk of capsular contracture was observed between the two groups (**Table 6**).

DISCUSSION

Breast implants are continuously improving, and fifth-generation implants are currently in use. Based on the shape and surface of their shells, they can be categorized into smooth round implants and textured anatomical implants. Many studies have compared the benefits and risks of breast implants according to their surfaces and shapes [9]. Although when compared with smooth round implants, textured anatomical implants are associated with a lower incidence of capsular contracture, reoperation, implant malposition, and rippling, some controversy does remain. Furthermore, studies comparing textured anatomical implants with smooth round implants in patients undergoing DTI breast reconstruction are limited.

Our results revealed that the smooth round implant group had a significantly lower overall complication rate than the textured anatomical implant group. In the multivariate analysis, older age at surgery, smaller implant size, use of textured anatomical implants, no adjuvant chemotherapy, adjuvant radiotherapy, longer duration of drainage, and longer followup duration were significantly associated with an increased risk of developing overall complications. Subgroup analyses according to patients receiving or not receiving adjuvant chemotherapy and adjuvant radiotherapy were performed for a more specific comparison. Significant differences in the risk of overall complications were noted between the implant groups in patients who did not receive adjuvant chemotherapy and in those who did not receive adjuvant radiotherapy. However, no significant differences between the implant groups were observed in patients who received adjuvant chemotherapy and in those who received adjuvant radiotherapy. Recent studies have shown that adjuvant chemotherapy is not associated with the risk of complications in patients undergoing implant-based reconstruction [10]. The reason for this deviation from our results could be attributed to the small sample size of the patients undergoing adjuvant chemotherapy in this study. Therefore, further studies with larger patient cohorts are warranted.

Furthermore, older age, higher BMI, nipple-sparing mastectomy over skin-sparing mastectomy, total mastectomy over nipple-sparing mastectomy, smaller implant size, use of textured anatomical implants, and adjuvant radiotherapy were significantly associated with an increased risk of developing capsular contracture. The subgroup analysis results indicated that when compared with textured anatomical breast implants, smooth round implants may reduce the rate of capsular contracture in the subgroup of patients with BMI < 25 kg/m² and in those not receiving adjuvant radiotherapy. However, smooth round implants may not reduce the rate of capsular contracture in the subgroup of patients with BMI > 25 kg/m² and in those receiving adjuvant radiotherapy. Thus, high BMI and adjuvant radiotherapy may be stronger risk factors for capsular contracture than the type of breast implant surface.

Capsular contracture is the most common complication requiring reoperation following esthetic and reconstructive breast implant surgery. The potential etiologies of capsular contracture include infection, hypertrophic scarring, silicone gel bleeding, and hematoma [11]. Research on whether the implant's surface texture affects the risk of capsular contracture has yielded mixed results. Many investigators have reported that textured anatomical implants reduce capsular contracture [9]. However, as infection is one of the leading causes of capsular contracture, some prefer smooth round implants over textured anatomical implants because of reduced bacterial adherence to the implant surface [12]. Among the multiple risk factors associated with capsular contracture, our multivariate analysis revealed that smooth round implants tend to prevent capsular contracture.

In our study, the risk of capsular contracture was lower with skin-sparing mastectomy than with nipple-sparing mastectomy. Although nipple-sparing mastectomy is a viable choice with esthetic and psychosocial benefits, it is known to have a higher rate of overall complications, largely due to partial or complete nipple necrosis [13]. In addition to nipple necrosis, bacterial penetration through the weakened dermis may cause subclinical infection, which may increase the risk of capsular contracture in nipple-sparing mastectomy cases [14]. The textured anatomical implant group had a higher rate of implant exposure than the smooth round implant group (6.9% vs. 2.2%) (**Table 2**). The textured anatomical implant group also had a higher NAC necrosis rate than the smooth round implant group (3.4% vs. 1.5%). Although no significant difference was noted, subclinical infection caused by implant exposure, NAC necrosis, or bacterial penetration increased the likelihood of capsular contracture in the textured anatomical implant group. Moreover, capsular contracture was more likely to occur with total mastectomy than with nipple-sparing mastectomy. This could be because when compared with nipple-sparing mastectomy, the amount of skin resection is greater in total mastectomy, and thus the skin tension is greater.

We described capsular contracture as clinically relevant in case of Baker grades III and IV capsular contracture, with or without surgical intervention. Among the 57 capsular contracture events, 38 breasts were salvaged with conservative management, 16 with implant changes, and 3 with implant removal. Textured anatomical implants were used in all capsular contracture cases with surgical intervention. The fact that capsular contracture severe enough for surgical intervention was observed for all textured anatomical implant cases supports our finding that smooth round implants prevent capsular contracture.

Our study has several limitations. First, it followed a retrospective design; therefore, capsular contracture was diagnosed based on the medical charts of the patients, which might have led to underestimation. Second, as the BIA-ALCL issue arose, the trend in implant use shifted

from textured anatomical implants to smooth round implants. Third, despite the 10-year retrospective review, a significant difference in the follow-up duration was observed between the textured anatomical implant and smooth round implant groups. Fourth, this study included only a small sample of patients from a single medical center; hence, we cannot exclude the operator's preference in the selection of implant texture and surgical method over time. Fifth, since smooth round implant cases are more recent surgical cases than the textured anatomical implant cases, the surgeon's surgical technique may have developed over time, and other factors may have affected the results. The development of ADM could have reduced the overall complications and capsular contracture in the recent cases and smooth round implant group in our study. Lastly, because capsular contracture is a complication that occurs after a longer period as compared to the other complications, the results may vary in the long-term assessment.

Nevertheless, smooth round implants decreased the overall complications in patients who did not receive adjuvant chemotherapy or adjuvant radiotherapy. Furthermore, they particularly decreased the capsular contracture risk in patients with BMI < 25 kg/m² and in those who did not receive adjuvant radiotherapy. These results may be utilized in counseling patients regarding the advantages and disadvantages of smooth round implants in DTI breast reconstruction. However, further studies with larger sample sizes and long-term follow-up periods are warranted to confirm the long-term benefits of smooth round implants in DTI breast reconstruction.

REFERENCES

- 1. Colwell AS. Direct-to-implant breast reconstruction. Gland Surg 2012;1:139-41. PUBMED | CROSSREF
- 2. American Society of Plastic Surgeons. 2019. 2019 plastic surgery statistics report. https://www.plasticsurgery.org/documents/News/Statistics/2019/plastic-surgery-statistics-report-2019.pdf. Accessed March 20th, 2022.
- Antony AK, Poirier J, Madrigrano A, Kopkash KA, Robinson EC. Evolution of the surgical technique for "breast in a day" direct-to-implant breast reconstruction: transitioning from dual-plane to prepectoral implant placement. Plast Reconstr Surg 2019;143:1547-56.
 PUBMED | CROSSREF
- Bernini M, Calabrese C, Cecconi L, Santi C, Gjondedaj U, Roselli J, et al. Subcutaneous direct-to-implant breast reconstruction: surgical, functional, and aesthetic results after long-term follow-up. Plast Reconstr Surg Glob Open 2016;3:e574.
 PUBMED | CROSSREF
- Breuing KH, Colwell AS. Inferolateral AlloDerm hammock for implant coverage in breast reconstruction. Ann Plast Surg 2007;59:250-5.
 PUBMED | CROSSREF
- Wang C, Luan J, Panayi AC, Orgill DP, Xin M. Complications in breast augmentation with textured versus smooth breast implants: a systematic review protocol. BMJ Open 2018;8:e020671.
- Fagrell D, Berggren A, Tarpila E. Capsular contracture around saline-filled fine textured and smooth mammary implants: a prospective 7.5-year follow-up. Plast Reconstr Surg 2001;108:2108-12.
 PUBMED | CROSSREF
- de Boer M, van Leeuwen FE, Hauptmann M, Overbeek LI, de Boer JP, Hijmering NJ, et al. Breast implants and the risk of anaplastic large-cell lymphoma in the breast. JAMA Oncol 2018;4:335-41.
 PUBMED | CROSSREF
- Wong CH, Samuel M, Tan BK, Song C. Capsular contracture in subglandular breast augmentation with textured versus smooth breast implants: a systematic review. Plast Reconstr Surg 2006;118:1224-36.
 PUBMED | CROSSREF



- Hart SE, Brown DL, Kim HM, Qi J, Hamill JB, Wilkins EG. Association of clinical complications of chemotherapy and patient-reported outcomes after immediate breast reconstruction. JAMA Surg 2021;156:847-55.
 PUBMED | CROSSREF
- Adams WP Jr. Capsular contracture: What is it? What causes it? How can it be prevented and managed? Clin Plast Surg 2009;36:119-26, vii.
 PUBMED | CROSSREF
- 12. Becker H, Springer R. Prevention of capsular contracture. Plast Reconstr Surg 1999;103:1766-8. PUBMED | CROSSREF
- Agha RA, Al Omran Y, Wellstead G, Sagoo H, Barai I, Rajmohan S, et al. Systematic review of therapeutic nipple-sparing versus skin-sparing mastectomy. BJS Open 2019;3:135-45.
 PUBMED | CROSSREF
- Lee JH, Choi M, Sakong Y. Retrospective analysis between complication and nipple areola complex preservation in direct-to-implant breast reconstruction. Gland Surg 2021;10:290-7.
 PUBMED | CROSSREF