Observational Study

Medicine

OPEN

Risk factors for capsular contracture after breast reconstruction with tissue expanders and silicone implants in nonirradiated patients

A retrospective observational cohort study

Yoshiko Iwahira, PhD, MD[a,*], Gojiro Nakagami, PhD, RN[b,c], Hiromi Sanada, PhD, RN, WOCN, FAAN[b,c]

Abstract

Breast reconstruction surgery with tissue expanders and silicone implants is widely performed; however, risk factors for late complications such as capsular contracture have not been fully investigated despite their high prevalence. We investigated the association between expander and implant positions and the development of capsular contracture in patients who underwent breast reconstruction surgery over 10 years previously. In this retrospective observational study, we analyzed 239 patients, among whom 69 (28.9%) had developed capsular contracture of Baker Classification grade II or higher. The position of the expander was classified into six categories based on the inferior margin of the healthy breast. The position of the implant was defined as an upward movement from the position of the expander and was classified into three categories based on the inferior margin of the breast at the time of expander insertion. Using multivariate logistic regression analysis, we assessed whether the misalignment of the expander and silicone implant positions affected capsular contracture development. Both expander and implant positions were significantly different between the groups. The odds ratios, adjusted for confounding variables, were 3.4 and 5.2 for an expander position of 1 and 2 lateral fingers upward, respectively, and 4.8 and 45.4 for a silicone implant position of 2 and 3 lateral fingers upward, respectively. We identified malposition of expanders and silicone implants as risk factors for developing capsular contracture. Correct insertion and adequate dilatation of the expander in the correct position could reduce the risk for capsular contracture.

Keywords: breast neoplasms, contracture, dilatation, mammaplasty, risk factors, tissue expansion devices

1. Introduction

Breast reconstruction surgery with tissue expanders and silicone implants has long been the primary option due to the low level of invasiveness and excellent cosmetic properties.[1] However, early complications of prosthetic breast reconstruction include infection, hematomas, and necrosis due to poor circulation, and late complications such as capsular contracture and rupture have also been reported.[2] In particular, capsular contracture might occur when the skin stretched by the expander shrinks over a long period of time, which not only affects cosmetic properties but also the physical functions of the breast. Baker classification Grade IV would impose a physical burden, such as pain, a twitching sensation, and dyskinesia, which would warrant capsule resection and revision surgery.[3] The prevalence of capsular contracture 10 years after surgery is as high as 23.7%, and measures designed at reducing risk for capsular contracture may be recommended.[4] Therefore, high-risk patient populations that are prone to developing capsular contracture need to be identified in order to initiate preventive measures.

Infection, inflammation, blood species, and irradiation have been reported as risk factors for capsular contracture.[5] However, in the authors' experience, capsular contracture often develops within 10 years of reconstruction for certain conditions, which the risk factors identified in previous studies have not been sufficient to explain. Because capsular contracture, which is stimulated by an immune response to foreign materials in the body, is common in irradiation, infection, and hematoma patients, the enhancement of the foreign body reaction by external stimulation may be a risk.[6] In addition, the authors have experienced an increase in capsular contracture over a long period of time when the expander is improperly positioned. However, the association between expander positional abnormalities and the development of capsular contracture is unclear, as this was not discussed in the paper by Cordeiro et al, which followed patients for a long time after surgery (mean follow-up of 36.7 months).[7]

The authors have no funding and conflicts of interest to disclose.

The datasets generated during and/or analyzed during the current study are not publicly available, but are available from the corresponding author on reasonable request.

[a] Breast Surgery Clinic, Tokyo, Japan, [b] Department of Gerontological Nursing/Wound Care Management, Graduate School of Medicine, The University of Tokyo, Tokyo, Japan, [c] Global Nursing Research Center, Graduate School of Medicine, The University of Tokyo, Tokyo, Japan.

** Correspondence: Yoshiko Iwahira, YCC Takanawa Bldg., 2, 3F, 2-21-43, Takanawa, Minato-ku, Tokyo 108-0074, Japan (e-mail: ganpei@iwahira.net).*

Copyright © 2022 the Author(s). Published by Wolters Kluwer Health, Inc.

This is an open-access article distributed under the terms of the Creative Commons Attribution-Non Commercial License 4.0 (CCBY-NC), where it is permissible to download, share, remix, transform, and buildup the work provided it is properly cited. The work cannot be used commercially without permission from the journal.

How to cite this article: Iwahira Y, Nakagami G, Sanada H. Risk factors for capsular contracture after breast reconstruction with tissue expanders and silicone implants in nonirradiated patients: A retrospective observational cohort study. Medicine 2022;101:48(e31837).

Received: 27 February 2022 / Received in final form: 11 September 2022 / Accepted: 14 September 2022

http://dx.doi.org/10.1097/MD.0000000000031837

Therefore, in this study, we investigated the association between the expander and implant positions and the development of capsular contracture in patients who underwent breast reconstruction surgery over 10 years previously.

2. Patients and Methods

2.1. Research design

This was a retrospective observational study using patient medical records at a clinic for breast reconstruction with implants in Tokyo, Japan. This clinic was selected as one of the facilities in Japan that perform a great number of tissue expander/implant breast reconstructions. Data were collected in March, 2019.

2.2. Participants

We included patients who had undergone breast reconstruction with implants (both the expander and the silicone implant are inserted under the pectoralis major muscle), for whom at least 10 years had passed from silicone implant insertion to the date of investigation, and who visited the clinic once a year. We excluded patients who had been irradiated, and those in whom an expander other than that made by Allergan® had been inserted. A total of 264 patients were assessed for eligibility and 25 patients were excluded according to the criteria (implant year <10 years: eight patients, expander used other than that made by Allergan®: three patients, and irradiated: 14 patients). All eligible 239 patients were included in this study.

2.3. Outcome measure

The degree of capsular contracture was assessed by the plastic surgeon according to the Baker Classification.[3] The severity of capsular contracture was assessed at 10 years after implant placement, and a Baker Classification of grade II or higher was considered to indicate capsular contracture.

2.4. Independent variables

The position of the expander was classified into one of the following six categories based on the inferior margin of the healthy breast: symmetry, 1 lateral finger upward, 2 lateral fingers upward, 1 lateral finger downward, 2 lateral fingers downward, and outside. The position of the implant was defined as an upward movement from the position of the expander and was classified into one of the following three categories based on the inferior margin of the breast at the time of expander insertion: (I) 1 lateral finger upward, (II) 2 lateral fingers upward, and (III) 3 lateral fingers upward.

2.5. Confounding variables

Age, number of years after implant, timing of reconstruction (delayed or immediate), type of papillary surgery, healthy lateral breast surgery, presence of complications during expander insertion, early complications (i.e., reoperation), volume of expander (mL), and volume of implant (mL) were recorded.[8] As all the patients were advised to perform massage by themselves, so this variable was not collected.

2.6. Statistical analysis

Patients were divided into two groups based on the occurrence of capsular contracture and attributes were compared between the groups by a *t* test or a χ-squared test. Whether the misalignment of the expander and silicone implant positions affected the development of capsular contracture was examined by multivariate logistic regression analysis, adjusting for confounding variables. Missing values were ignored in multivariate logistic regression (N = 9). For excluding the potential bias for the interaction in positions between silicone implants and expanders, subgroup analysis of only those with abnormal expander position (category: 1) was conducted. All statistical analyses were conducted using STATA (STATA Corp LP., College Station, TX).

2.7. Ethical considerations

Since this study used reviewed medical chart data as a retrospective observational study, written informed consent from the participants was unnecessary. An announcement regarding the study and the option for participants to opt out was posted on the website of our clinic. The study protocol was approved by the Ethics Committee of the Breast Surgery Clinic, Tokyo, Japan, which included external reviewers.

3. Results

Of the 239 patients, 69 (28.9%) developed capsular contracture. Among 69 cases, there were three grade II capsular contracture cases and 66 grade III cases according to Baker Classification.[3] There were no grade IV cases in the study population. Table 1 reports descriptive statistics for each variable according to the presence or absence of capsular contracture. Mean years after implant insertion was 12.0 years among those without capsular contracture and 12.2 years among those with ($P = .334$). The position of the expander and the position of the implant were significantly different between the groups ($P < .001$, $P < .001$, respectively).

Table 2 shows the results of a logistic regression analysis in which variables that may be risk factors for capsular contracture were included. The odds ratios, adjusted for age, timing of reconstruction, implant volume, and time since implant placement, were 3.4 for an expander position of 1 lateral finger upward, 5.2 for an expander position of 2 lateral fingers upward, 4.8 for a silicone implant position of II, and 45.4 for a silicone implant position of III. Expander positions of 2 lateral fingers downward and outside were omitted in this analysis because of the small number of samples. To exclude the potential bias for the interaction in positions between silicone implants and expanders, subgroup analysis of only those with abnormal expander positions (category: 1) was conducted. Table 3 represents the results of subgroup analysis. The adjusted odds ratios for a silicone implant position were 4.2 for II and 18.6 for III.

Images of typical capsular contracture and a silicone implant within the capsule are shown in Figure 1. Within the capsular contracture (Fig. 1A), the implant was intact but crushed and the shape was unrestored (Fig. 1B). Figures 2 and 3 show the clinical course of, respectively, delayed and immediate cases with capsular contracture. Figure 4 captures the long-term observation of a patient who did not develop capsular contracture and whose expander and implant were properly aligned.

4. Discussion

This study examined risk factors for the development of capsular contracture in patients who could be followed for more than 10 years and for whom the implant replacement was performed by one plastic surgeon, with a focus on the location of the expander and the implant. An abnormal upward position of the expander and an upward misalignment of the implant site were extracted as risk factors. The occurrence of capsular contracture, despite capsular incision or capsular excision at the time of silicone implant insertion in order to achieve symmetry, suggests that even if the position of the silicone implant is temporarily corrected, it moves upward over time and capsular contracture occurs. It is noteworthy that one might argue that it is the contracture which moves the implant up. Further study is

Table 1

Baseline characteristics.

	Without capsular contracture (N = 170)		With capsular contracture (N = 69)		
	N	%	N	%	
	Mean	SD	Mean	SD	*P* value
Age	48.1	0.7	50.7	1.1	.050
Years after implant insertion	12.0	1.6	12.2	1.7	.334
Timing					
Immediate	60	68.2	28	31.8	.453
Delayed	110	72.8	41	27.2	
Expander position					
Symmetry	124	81.0	29	19.0	<.001
1 upward	16	40.0	24	60.0	
2 upward	7	38.9	11	61.1	
1 downward	19	90.5	2	9.5	
2 downward	4	100.0	0	0.0	
Outside	0	0.0	3	100.0	
Nipple plasty (N = 169)					
None	8	66.7	4	33.3	.265
NAG	20	55.6	16	44.4	
NASC flap	0	0.0	1	100.0	
NG	99	75.6	32	24.4	
NSM	21	75.0	7	25.0	
Star flap	17	68.0	8	32.0	
Star flap + NG	1	100.0	0	0.0	
Tattoo	3	75.0	1	25.0	
Implant position (N = 169)					
I	126	88.7	16	11.3	<.001
II	40	55.6	32	44.4	
III	3	12.5	21	87.5	
Complication					
No	162	72.6	61	27.4	.054
Yes	8	50.0	8	50.0	
Reoperation					
No	141	74.2	49	25.8	.038
Yes	29	59.2	20	40.8	

NAG = nipple areola graft, NASC = nipple areola sub-cutaneous flap, NG = nipple graft, NSM = nipple-sparing mastectomy, SD = standard deviation.

Table 2

Related factors for capsular contracture.

Variables	Crude odds ratio	95% CI (Lower)	95% CI (Upper)	*P* value	Adjusted odds ratio	95% CI (Lower)	95% CI (Upper)	*P* value
Expander position (ref: symmetry)								
1 upward	6.4	3.0	13.6	<.001	3.4	1.4	8.5	.008
2 upward	6.7	2.4	18.8	<.001	5.2	1.5	17.4	.008
1 downward	0.5	0.1	2.0	.301	0.9	0.2	4.3	.861
Implant position (ref: I)								
II	6.3	3.1	12.7	<.001	4.8	2.2	10.5	<.001
III	55.1	14.8	205.7	<.001	45.4	10.6	193.7	<.001
Age	1.0	1.0	1.1	.051	1.1	1.0	1.1	.015
Implant volume	1.0	1.0	1.0	.591	1.0	1.0	1.0	.939
Timing (ref: immediate)	0.8	0.4	1.4	.443	1.2	0.5	2.6	.706
Years after implant insertion	1.1	0.9	1.3	.332	0.9	0.8	1.2	.619

needed for concluding the causal relationship between the malposition of implants and occurrence of capsular contracture.

The more the expander was tilted upward, the higher the risk of film contracture. Since the expander is also a foreign body, the first capsule (virgin capsule) is formed for the individual shortly after insertion. The position remains displaced and stretched to form an envelope. The breast shape is most full at the bottom of the breast, otherwise known as the lower pole. The implant itself does not have the ability to stretch the skin. If the skin is inadequately expanded the implant may be displaced upward, even when the capsule is incised and dissected inferiorly. Alternatively, the dissected area where the elastic fibers are stretched but not fully extended may shrink, leading to contraction. Therefore, the risk of capsular contracture is expected to be reduced when the elastic fibers are sufficiently stretched so as to become fully extended.[9]

In the present study, possible risk factors were collected such as implant volume, timing, and years after implant insertion, however they were not considered as risk factors among the study participants.[10,11] This may be due to the difference in the definition of outcome measure. In our study participants, we included minimal to severe capsular contracture as an outcome, and we did not find any cases representing severe contracture: majority of the cases were with moderate capsular contracture.

Table 3

A subgroup analysis among patients with normal expander position.

Variables	Adjusted odds ratio	95% CI (Lower)	95% CI (Upper)	*P* value
Implant position (ref: I)				
II	4.2	1.6	11.0	.004
III	18.6	3.7	93.0	<.001
Age	1.0	1.0	1.1	.160
Implant volume	1.0	1.0	1.0	.621
Timing (ref: immediate)	0.8	0.3	2.3	.724
Years after implant insertion	1.0	0.7	1.3	.995

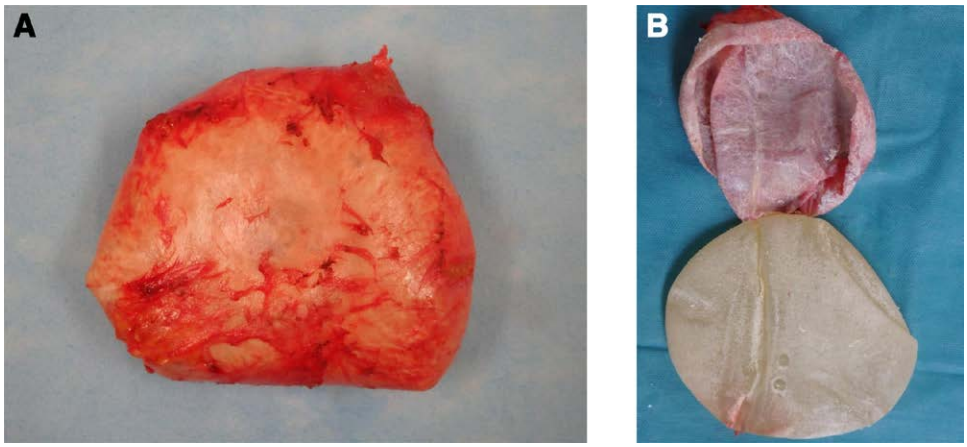

Figure 1. Confirmation of capsular contracture 15 years after implant insertion. (A) Gross appearance of capsule contracture. (B) Silicone implant.

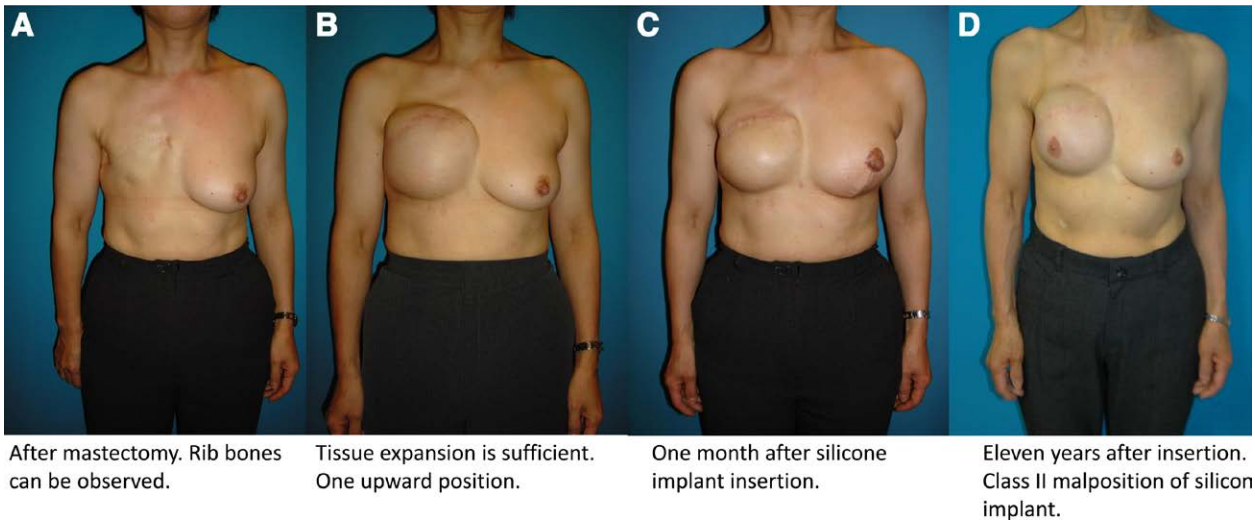

Figure 2. Delayed case with upward displacement of the tissue expander. (A) After mastectomy. Rib bones can be observed. (B) Tissue expansion is sufficient. The expander is in 1 lateral finger upward position. (C) 1 month after silicone implant insertion. (D) 11 years after insertion. Class II malposition of silicone implant.

4.1. Clinical implications

Reconstruction with a tissue expander and implant is especially suitable for Japanese patients, many of whom prefer not to have a new scar elsewhere on the body. When performing breast reconstruction with implants, many plastic surgeons give importance to implant selection, but we show that the most important consideration is that the correct expander is inserted in the correct position. If the expander is inserted in the correct position and sufficient extension of the skin in that area is achieved, a less contractile envelope will be formed and the probability that capsular contracture occurs over time decreases. In other words, forcing the implant into the skin in a location where the skin is not stretched should be avoided. Given the high risk of capsular contracture, even if the position of the implant is later corrected, re-expanding with an expander after resection of capsular contracture is necessary to prevent recurrence of capsular contracture.

Recently, because of breast implant-associated anaplastic large cell lymphoma, textured expanders and implants are no longer used and are being replaced with products with a smooth surface. This makes them prone to positional abnormalities and raises concerns about the possibility of more patients with capsular contracture in the long term. Now more than ever, sufficient skin expansion in the correct position at the time of expander insertion is required.

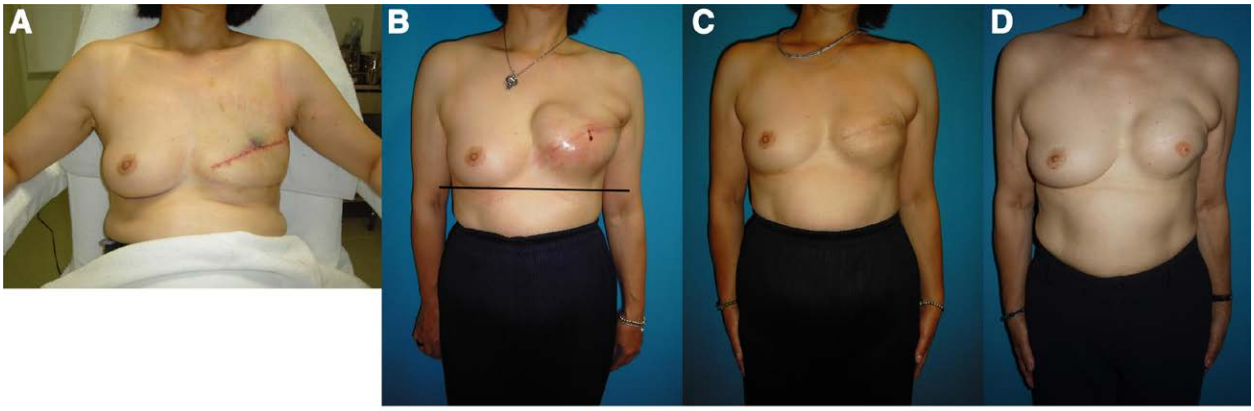

Figure 3. Immediate case with upward displacement of tissue expander. (A) Tissue expander inserted in 2 lateral finger upward position. (B) Full expansion is achieved. (C) 1 month after silicone implant insertion following incision of the capsule. (D) 13 years after insertion. Baker Classification grade III.

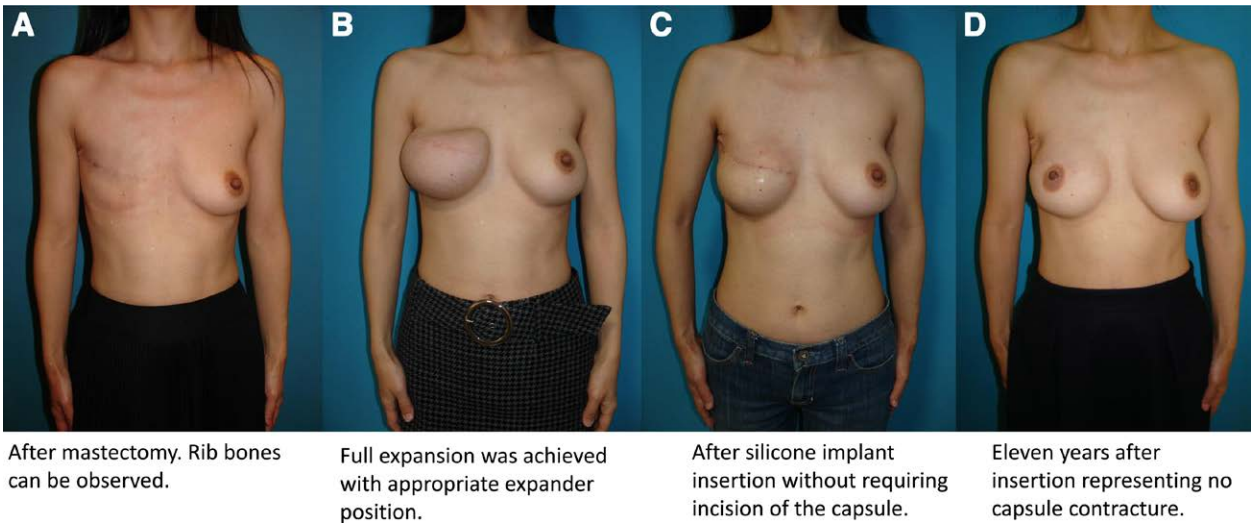

Figure 4. Delayed case without displacement of tissue expander. (A) After mastectomy. Rib bones can be observed. (B) Full expansion is achieved with appropriate expander position. (C) After silicone implant insertion without requiring incision of the capsule. (D) 11 years after insertion demonstrating no capsular contracture.

4.2. Limitations

As a single-center study, caution is advised when generalizing from these results. However, because of the uniformity of the plastic surgeon's procedures, we were able to identify the risk factors for capsular contracture as expander and implant malposition. There may be a sampling bias, as certain categories of patients did not visit the outpatient clinic; for example, those without complications (including capsular contracture) and those who died or were receiving breast cancer treatment. This study did not include pre-pectoral placement, therefore the value would be improved by examining both pre-pectoral and retro-pectoral patients in the future.

5. Conclusion

Malposition of expanders and silicone implants were identified as risk factors for developing capsular contracture, a late complication of breast reconstruction in non-irradiated patients. The odds ratios, adjusted for confounding variables, were 3.4 and 5.2 for an expander position of 1 and 2 lateral fingers upward, respectively, and 4.8 and 45.4 for a silicone implant position of 2 and 3 lateral fingers upward, respectively. Our finding that correct positioning and adequate expansion of the expander might reduce the occurrence of capsular contracture.

Author contributions

Conceptualization: Yoshiko Iwahira, Gojiro Nakagami, Hiromi Sanada.
Data curation: Yoshiko Iwahira.
Formal analysis: Yoshiko Iwahira, Gojiro Nakagami, Hiromi Sanada.
Investigation: Yoshiko Iwahira, Gojiro Nakagami.
Methodology: Yoshiko Iwahira, Gojiro Nakagami, Hiromi Sanada.
Project administration: Yoshiko Iwahira.
Supervision: Hiromi Sanada.
Writing – original draft: Gojiro Nakagami.
Writing – review & editing: Yoshiko Iwahira, Gojiro Nakagami, Hiromi Sanada.

References

[1] Gardani M, Bertozzi N, Grieco MP, et al. Breast reconstruction with anatomical implants: a review of indications and techniques based on current literature. Ann Med Surg (Lond). 2017;21:96–104.

[2] Quinn TT, Miller GS, Rostek M, et al. Prosthetic breast reconstruction: indications and update. Gland Surg. 2016;5:174–86.

[3] Spear SL, Baker JL. Classification of capsular contracture after prosthetic breast reconstruction. Plast Reconstr Surg. 1995;96:1119–23.

[4] Spear SL, Murphy DK; Allergan Silicone Breast Implant U.S. Core Clinical Study Group. Natrelle round silicone breast implants: core study results at 10 years. Plast Reconstr Surg. 2014;133:1354–61.

[5] Headon H, Kasem A, Mokbel K. Capsular contracture after breast augmentation: an update for clinical practice. Arch Plast Surg. 2015;42:532–43.

[6] Benderli Cihan Y, Baykan H, Arslan A. Treatment of capsular contracture after radiotherapy in breast reconstruction. Eur J Breast Heal. 2019;15:203–4.

[7] Cordeiro PG, McCarthy CM. A single surgeon's 12-year experience with tissue expander/implant breast reconstruction: part II. An analysis of long-term complications, aesthetic outcomes, and patient satisfaction. Plast Reconstr Surg. 2006;118:832–9.

[8] Sue GR, Sun BJ, Lee GK. Complications after two-stage expander implant breast reconstruction requiring reoperation: a critical analysis of outcomes. Ann Plast Surg. 2018;80:S292–4.

[9] Kuriyama E, Ochiai H, Inoue Y, et al. Characterization of the capsule surrounding smooth and textured tissue expanders and correlation with contracture. Plast Reconstr Surg Glob Open. 2017;5:1–7.

[10] Maxwell GP, Van Natta BW, Bengtson BP, et al. Ten-year results from the Natrelle 410 anatomical form-stable silicone breast implant core study. Aesthet Surg J. 2015;35:145–55.

[11] McGuire P, Reisman NR, Murphy DK. Risk factor analysis for capsular contracture, malposition, and late seroma in subjects receiving Natrelle 410 form-stable silicone breast implants. Plast Reconstr Surg. 2017;139:1–9.