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Original article

Immediate Breast Reconstruction after mastectomy with polyurethane implants versus textured implants: A retrospective study with focus on capsular contracture

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ABSTRACT

Background: Capsular contracture (CC) is the most common complication following Immediate Breast Reconstruction (IBR) with breast implants. Different implant surfaces were developed aiming to reduce the incidence of CC. We evaluated the incidence and degree of CC after Direct-to-Implant (DTI) IBR with insertion of textured (TE) or polyurethane (PU) covered implants.
Methods: A retrospective review of consecutive patients treated at our Institution with mastectomy and one-stage IBR and implant reconstruction between 2013 and 2018, with or without post mastectomy radiation therapy (PMRT), was conducted. Immediate breast reconstruction was performed by implanting 186 PU covered implants and 172 TE implants.
Results: Three-hundred-twelve women underwent 358 DTI IBR with PU or TE implants, were analyzed with a median follow-up time of 2.3 years (range 1.0–3.0). The overall rate of CC Baker grade III and IV was 11.8% (95%CI: 8.4–16.3), while, after PU and TE implant placement it was 8.1% (95% CI: 4.1–15.7) and 15.8% (95% CI: 4.1–15.7) [$p = 0.009$]), respectively. Irradiated breasts developed CC more frequently rather than non-irradiated breasts ($HR = 12.5$, $p < 0.001$), and the relative risk was higher in the TE group compared with the PU group ($HR = 0.3$, $p = 0.003$).
Conclusions: After mastectomy and one-stage IBR, the use of PU covered implants is associated with a lower incidence of CC compared to TE implants. This advantage is amplified several folds for patients who necessitate PMRT. Footnote: Capsular contracture (CC); Immediate Breast Reconstruction (IBR); Directto- Implant (DTI); Textured (TE); Polyurethane (PU); Post mastectomy radiation therapy (PMRT); Nipple Sparing mastectomy (NSM).

1. Introduction

Breast implants are employed since 1962, when Cronin and Gerow performed the first breast augmentation [1]. Since then, capsular contracture (CC) has represented the most common complication after breast implants insertion, and the leading cause for re-intervention [2–4]. Capsular contracture represents a normal reaction against the breast implant forming fibrous scar tissue around it, creating a tissue capsule [5]. The capsule is usually thin, soft or slightly firm, but in some cases, it is unusually thick, hard and dense, tightening and squeezing the implant. This condition

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can cause chronic pain and distortion in the shape of the breast, and it can make the breast rise higher on the chest wall [6,7] (Baker grade III and IV) [8]. Several studies have reported an incidence of CC ranging from 0.6 to 19% for breast augmentation to 19–48% for breast reconstruction, therefore identifying this latter group as a high-risk setting [9–17].

Furthermore, it is well known that patients undergoing post mastectomy radiation therapy (PMRT) and Immediate Breast Reconstruction (IBR) are at a higher risk of developing CC [18–23].

Approximately 50 years ago [24], an implant with a polyurethane (PU) foam coating was reported with the aim to prevent the risk of CC associated with silicone breast implants [25]. Thereafter, textured (TE) surfaces have been developed to mimic the shape and the benefits of the PU foam, and several studies have indicated that PU implants have a lower incidence of CC [17,26–36]. Furthermore, two studies have suggested that PU implants are associated with a lower incidence of CC in case PMRT is delivered [32,35].

However, data in the literature is limited by the lack of studies directly comparing the incidence of CC after insertion of PU implants versus TE implants following mastectomy.

The aim of the present study is to analyze the incidence of CC in a consecutive cohort of patients undergoing IBR after mastectomy with DTI, and to retrospectively compare results for PU and TE implants.

2. Methods

2.1. Study design

Consecutive patients undergoing mastectomy and one-stage DTI reconstruction with PU or TE implants at our Institution (Breast Center, San Giovanni-Addolorata Hospital, Rome, Italy) from 2013 to 2018 were retrospective analyzed. Our Breast Center is fully accredited with the Regional Health System, and it has received the European BCCERT Certification in 2017. Approximately 430 women with newly diagnosed breast cancer were surgically treated in 2019. This study was approved by the Institutional review board.

Exclusion criteria for this cohort study were: delayed or two-stage breast reconstruction; autologous tissue reconstruction; the use of round implants; smooth implants; saline implants; synthetic meshes or acellular dermal matrix (ADM), previous radiotherapy; previous surgery.

The following characteristics were included: patient age; patient stage; smoking status; presence of diabetes; bra size; date of surgery; diagnosis; tumor grade; type of surgery; type of implant; implants position; major and minor surgical complications (including all the cases treated with or without re-intervention); neoadjuvant treatments; need for chemotherapy; need for PMRT; aesthetic results; dates of follow-ups; length of follow-up; presence and grade of CC.

Aesthetic results were assessed by two independent, blinded plastic surgeons on a subjective bases.

2.2. Surgical technique

All patients underwent mastectomy with one-stage, DTI IBR inserting the breast implant in a retropectoral or prepectoral pocket. Two closed-suction drains were placed in all the cases. Textured implants used were from Allergan (Natrelle™ 410, Allergan, Inc., Irvine, California) and Silimed (NUANCE 20646, Silimed, Rio de Janeiro, Brazil), and PU covered implants were from Polytech (Microthane®, POLYTECH Health & Aesthetics, Dieburg, Germany). PU implants were more intensively used since 2016, when it was reported an advantage performing breast reconstruction with PU implant [32,35,36].

2.3. Capsular contracture evaluation

Patients were evaluated by at least two plastic surgeons every three months during the first year of follow-up and yearly thereafter. Capsular contracture grade was rated according to the Baker scale, ranging from Baker grade I and II (normal, thin capsule) up to Baker grade III and IV (contracted capsule). Baker grade III represents a moderate contracture with moderate breast firmness, implant easily palpable, and visible breast deformity. Baker grade IV defines a severe contracture with severe breast firmness, pain, and marked distortion. For the purpose of analysis in this study, only CC Baker grade III and IV were considered.

2.4. Statistical analysis

Onset of CC according to implant surfaces and PMRT was explored by using common descriptive statistics such as means and standard deviations for continuous variables or absolute and relative frequencies for categorical variables. Univariate tests were related to these indexes to explore differences in the probability of developing CC Baker grade III-IV, in particular t-tests were used for means and Chi-squared or Fisher's Exact tests for frequencies. Data was then analyzed by using the appropriate technique of the Survival Analysis. Time to event was defined as time between surgical implantation of the implant and the first diagnosis of CC Baker grade III and IV. For patients who did not experience the event, the time was censored to the last contact up to a maximum of 36 months. Rates of CC at the end of follow-up was estimated with the Kaplan-Meier method and expressed in terms of cumulative incidence and 95% confidence intervals (CI). Cumulative incidence curves according to implant surface and presence of PMRT were shown and compared with the Log-rank test for equality of survivor functions. To avoid a possible confounding effect, a multiple Cox model was adopted to estimate the hazard ratio linked to the implant surface and PMRT by adjusting for demographic, tumor and treatment characteristics and possible surgical complications. Threshold of statistical significance was set to 5%. All analyses were performed with Stata 14.2 statistical software (StataCorp LP, College Station, TX).

3. Results

Three hundred and twelve consecutive patients underwent one-stage, DTI, IBR, of whom 266 received unilateral mastectomy and 46 bilateral mastectomies. Thirty-seven IBR (10.3%) were performed after mastectomy for prophylactic reasons, while the others for cancer (Table 1). Other patients' characteristics, oncologic treatments, type of implant inserted, and complications are described in Table 1. Of the 358 breast implants inserted, 320 were placed in retropectoral position, and 38 in prepectoral position (Table 1).

The overall median follow-up was 3.0 years (IQR: 1.9–3.0; min 1.0 - max 3.0). In detail, the median follow-up for PU implants was shorter than TE implant: respectively, 2.3 years (IQR: 1.6–3.0; min 1.0 - max 3.0) and 3.0 years (IQR: 3.0–3.0; min 1.0 - max 3.0) with $p < 0.001$.

Among the 358 procedures, CC Baker grade III and IV was recorded in 32 cases (8.9%) (Table 1). All the patients with a diagnosis of severe CC underwent revisional surgery. The relation between CC and patients' and tumors' characteristics is described in Table 1. Irradiated breasts were higher in patients with CC (25.0% vs 8.0%, $p = 0.006$) (Table 1). A statistically significant difference of CC was found between the use of PU implants and TE implants: TE implants were 75.0% in the group of contracted implants versus

Table 1
Descriptive statistics according to onset of Capsular Contracture Baker grade III-IV at implant level.

Characteristics		CC Baker grade III-IV			p-value
		Overall 358 (100%)	No 326 (91.1%)	Yes 32 (8.9%)	
Demographic characteristics					
Age, mean (SD)		49.3 (8.6)	49.2 (8.5)	50.9 (9.6)	0.270
Bra size, mean (SD)		3.1 (0.9)	3.1 (0.8)	3.0 (0.9)	0.372
Smoke/diabetes, n (%)	No	326 (91.1)	295 (90.5)	31 (96.9)	0.337
	Yes	32 (8.9)	31 (9.5)	1 (3.1)	
Tumor characteristics					
Prophylactic surgery, n (%)	No	321 (89.7)	291 (89.3)	30 (93.8)	0.556
	Yes	37 (10.3)	35 (10.7)	2 (6.3)	
Grade, n (%)	G0	44 (12.3)	42 (12.9)	2 (6.3)	0.352
2 missing -> 0	G1	35 (9.8)	33 (10.1)	2 (6.3)	
	G2	117 (32.7)	102 (31.3)	15 (46.9)	
	G3	162 (45.3)	149 (45.7)	13 (40.6)	
Stage, n (%)	0	65 (20.3)	61 (21.0)	4 (13.3)	0.747
7 missing -> 0	I	130 (40.5)	117 40.2)	13 (43.3)	
No prophylactic surgery	II	84 (26.2)	76 (26.1)	8 (26.7)	
	III	42 (13.1)	37 (12.7)	5 (16.7)	
Oncologic treatments					
Neoadjuvant Chemotherapy (%)	No	233 (65.1)	209 (64.1)	24 (75.0)	0.249
	Yes	125 (34.9)	117 (35.9)	8 (25.0)	
Adjuvant Chemotherapy, n (%)	No	314 (87.7)	287 (88.0)	27 (84.4)	0.571
1 missing - > no	Yes	44 (12.3)	39 (12.0)	5 (15.6)	
Post mastectomy radiation therapy (PMRT) n (%)	No	324 (90.5)	300 (92.0)	24 (75.0)	0.006
1 missing - > no	Yes	34 (9.5)	26 (8.0)	8 (25.0)	
Type of mastectomy					
Year of surgery, n (%)	2013–2014	101 (28.2)	88 (27.0)	13 (40.6)	0.285
	2015–2016	127 (35.5)	118 (36.2)	9 (28.1)	
	2017–2018	130 (36.3)	120 (36.8)	10 (31.3)	
Nipple areola complex necrosis[a], n (%)	No	349 (97.5)	318(97.6)	31 (96.9)	0.574
	Yes	9 (2.5)	8 (2.4)	1 (3.1)	
Skin complications[b], n (%)	No	338 (94.4)	310 (95.1)	28 (87.5)	0.092
	Yes	20 (5.6)	16 (4.9)	4 (12.5)	
Implants characteristics					
Type of implant, n (%)	Polyurethane coated (PU)	186 (52.0)	178 (54.6)	8 (25.0)	<0.001
	Textured (TE)	172 (48.0)	148 (45.4)	24 (75.0)	
Implant position, n (%)	Prepectoral	38 (10.6)	36 (11.0)	2 (6.3)	0.555
	Retropectoral	320 (89.4)	290 (89.0)	30 (93.8)	

SD SD: standard deviation.
P. p-values are referred to a t-Test for means of Fisher's Exact for frequencies.
[a] Nac.
[b] Including all the cases treated with or without re-intervention.

45.4% in healthy implants ($p < 0.001$) (Table 1). Fig. 1 shows the incidence of CC Baker grade III and IV during the 36-month of follow-up.

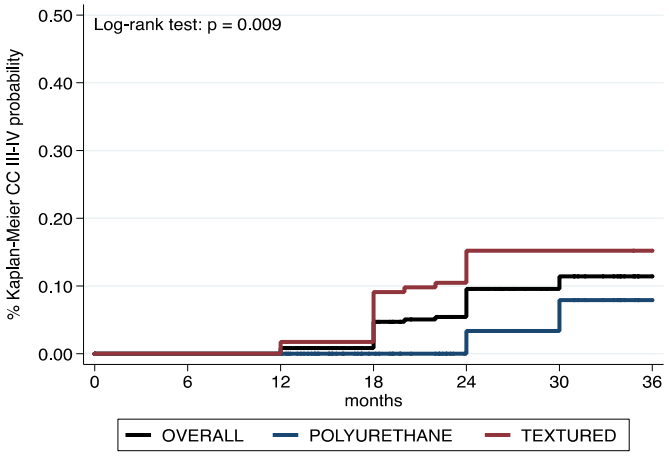

Fig. 1. Kaplan-Meier estimates of incidence of capsular contracture (CC) after one-stage breast reconstruction. Thirty-two cases of CC occurred within a median follow-up of 3 years.

While the incidence of CC for the whole group was 11.8% (95%CI: 8.4–16.3), this was 8.1 (95%CI: 4.1–15.7) and 15.8 (95%CI: 10.9–22.7) for PU and TE breast implants, respectively (Fig. 1). Difference between the two groups was statistically significant (Log-rank test: $p = 0.009$).

The influence of implant type and PMRT on CC incidence was further investigated in order to adjust the model for possible confounders such as implant positioning, patients' age, bra size, tumor grade, tumor stage, post-operative complications, neoadjuvant or adjuvant chemotherapy. This analysis did not show any significant difference between prepectoral and retropectoral positioning ($p = 0.550$). By doing a subgroup analysis, 0/29 cases of CC with PU implants and 2/9 cases of CC with TE implants have been observed in the prepectoral group. The Cox proportional hazards model for CC Baker grade III and IV confirmed a decreased risk of CC of 70% with the use of PUimplants (HR = 0.3, $p = 0.003$), while the delivery of PMRT involved an increase in risk (HR = 12.5, $p < 0.001$) (Table 2). Moreover, this same analysis did not show any significant differences between prepectoral and subpectoral positioning ($p = 0.550$). By doing a subgroup analysis, the difference between PU and TE implants remains significantly in favour of PU implants. In particular, in the prepectoral group there were 0/29 (0.0%) cases of CC with PU implants, and 2/9 (22.2%) cases of CC with TE implants, while in the retropectoral group there were 8/157 (5.1%)

Table 2
Cox-proportional hazards model for Capsular Contracture Baker grade III and IV.

		HR	95%CI	p-value
Type of implant	Textured	*ref.*	–	0.003
	Polyurethane coated	0.3	0.1–0.6	
Radiotherapy	No	*ref.*	–	<0.001
	Yes	12.5	3.9–39.8	

Notes: HR = hazard ratio. Ref = reference level. HRs were adjusted for implant positioning, patients' age, bra size, smoke habitude or diabetes, tumor grade, tumor stage, post-operative complications, neoadjuvant or adjuvant chemotherapy.

cases of CC with PU implants against 22/163 (13.5%) cases of CC with TE implants.

Seventeen breasts reconstructed with TE implants underwent PMRT (9.9%). The incidence of CC Baker grade III-IV over the three-year follow-up was 12.2% (95%CI: 7.7–18.8) in patients not undergoing to PMRT, while it was 62.5% (95%CI: 35.2–89.2) in patients receiving PMRT (Fig. 2). The HR of PMRT adjusted for possible confounders was HR = 13.5 (95%CI: 3.5–52.0, $p < 0.001$). Seventeen breasts reconstructed with PU implants underwent PMRT (9.1%). The incidence of CC Baker grade III and IV in case of PMRT or without PMRT did not differ significantly (Fig. 2) ($p = 0.608$). However, the CC rate at 36 months showed a trend in agreement with the previous results with a three-year incidence rate higher for irradiated breast implants (16.7% vs 7.6%, $p = 0.608$).

No patient experienced infection without an associated skin/NAC (nipple areola complex) necrosis or wound dehiscence.

A good or excellent aesthetic outcome was reported in 298/358 cases (83.2%), while an insufficient result in 12/358 cases (3.4%).

4. Discussion

To the best of our knowledge, this is the first report retrospectively comparing CC after IBR with PU versus TE implants in a consecutive cohort of patients. We found that the incidence of CC following one-stage IBR was 15.8% for TE implants and 8.1% for PU implants, and the difference between the two groups was statistically significant. In addition, although CC rate in case of PMRT following IBR with TE implants was significantly higher compared to that of non-irradiated breasts (62.5% vs 12.2%), no statistical difference was observed between irradiated and non-irradiated cases when PU implants were used (16.7% vs 7.6%).

A systematic review of 18 studies either implant suggested that

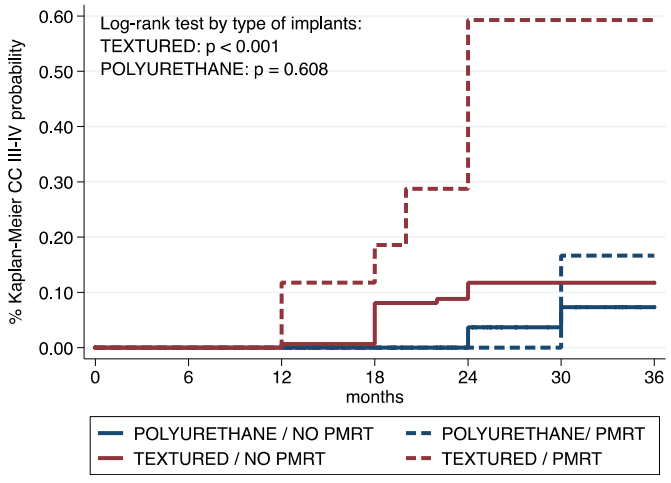

Fig. 2. Kaplan-Meier estimates of incidence of capsular contracture (CC) after one-stage breast reconstruction according to irradiation status and type of breast implants.

PU could be considered as a safe alternative but that the extent of any benefit could not be determined from the available evidence a that additional studies were required to clarify this issue [37].

Capsular contracture is the most frequent complication after breast augmentation and reconstruction with breast implants [3,4,9–11,13–15,17]. Although the etiology of CC is largely unknown [38], many authors have focused the attention on different risk factors such as immunological factors, bacterial contamination, and surgical technique [39–43]. Although none of the proposed theories are definitive, there is a consensus on the fact that breast reconstruction procedure, implants surface, and adjuvant PMRT represent additional causative factors [3,4,9–11,14,15,18–20,22,23,26,28,30,44,45].

We found an overall rate of CC after breast reconstruction of 11.8%, an incidence that is consistent with results of other studies [46–48]. Different implant surfaces may increase or decrease the risk of CC. Several studies described a low incidence of CC with PU implants, a benefit that does not decrease over time [9,31,33,49,50]. After formation of the capsule around the implant, the PU foam breaks down to become an integral part of the capsule, and it is proven that this observed tighten tissue adhesion does not occur with textured silicone implants [17,24,28,35,36]. This is due to the PU coating preventing the organized alignment of myofibroblasts, thereby interrupting the strength required for CC to occur. In fact, it is a very common conceptual mistake, even among the most experienced opinion leaders, to consider PU coated implants as TE implants. The PU foam that covers silicone implants provides a completely different surface, and the mechanisms related to tissue adhesion as well as to fibrous capsule formation differs substantially from those of TE implants. Implant texturing is a created surface irregularity on the silicone shell, whereas PU is a three-dimensional matrix which is incorporated and actually becomes part of the capsule. This has been described multiple times in literature [17,24,28,29,31,33,35].

It is well known that PMRT increases the risk of CC after IBR several fold [20,23,44,45]. However, the use of PMRT is increasingly encouraged and incorporated in national and international guidelines as it decreases the possibility of loco-regional relapse and breast cancer mortality, particularly in case of stage III disease [51]. In general, PMRT is offered to women with large primary tumors (T3), and with multiple nodal positivity (N2). Post mastectomy radiation therapy after IBR with implants has been reported to decrease satisfaction with the breast, along with physical or sexual well-being of patients [52]. For these reasons, patients should be informed, and this multimodality approach planned within a proper timing. In the past, IBR with implants after radiation therapy or in prevision of PMRT was felt to be contraindicated due to the reported high incidence rate of CC, and in general of skin complications [53]. Although outcomes after IBR following mastectomy is considered safe, limited oncologic data is available if PMRT is planned. Recent reports suggest a comparable survival outcome in this setting [54]. Indeed, it has been reported that the frequency of IBR continues to increase along with PMRT, with immediate implant-based reconstruction representing the most commonly utilized method, contrary to traditional recommendations [55]. Furthermore, in the last 15 years an increase in the frequency of mastectomy and bilateral mastectomy for women with breast cancer has been reported, perhaps as a consequence of an improved capability to detect subclinical multicentric disease [56].

An outstanding low CC rate in patients who received PMRT on definitive PU implant or on tissue expander was reported in the last years [32,35]. Our study confirms that the incidence of CC after IBR with PU implants and PMRT is lower compared with the use of TE implants in the same setting, even with a direct comparison with the negative effect of TE implants in combination with PMRT. The

reason for this finding is still unknown. Lo Torto et al. investigated the influence of radiation therapy on the properties of both TE and PU breast implants [57]. Polyurethane implants seem to be more resistant to radiation therapy damage, whereas silicone implants showed more structural, mechanical, and chemical modifications, although additional studies will be needed in order to gather more conclusive evidence.

Nipple Sparing mastectomy (NSM) magnifies the significance of one-stage DTI reconstruction after mastectomy, and our group has fully implemented this approach. Two systemic reviews and metanalysis, incorporating 17 studies, have been recently published and conclude that comparable results may be accomplished with DTI after NSM, although a higher risk of flap necrosis and implant failure may occur [58] [-59].

There are several limitations of our study. First, this is a retrospective, single center experience, and this may have introduced biases in the results. Secondly, the median follow-up is different between the two studied groups, as the vast majority of TE implants were inserted before the year 2016, while most PU breast implants were inserted since that year, and this may have introduced further variables, as our reconstruction technique may have evolved. In fact, it has been reported that the use of prepectoral IBR is associated with a decreased incidence of CC in case of PMRT [60]. However, we believe that our findings suggest a specific benefit, and clinicians should keep this in mind when planning IBR with an implant after mastectomy.

5. Conclusions

The results of this study indicate that IBR after mastectomy with PU implants, when directly compared with TE implants, is associated with a lower incidence of severe CC. The advantage of PU implants is particularly evident if the need of PMRT is anticipated, like for advanced cases or after neoadjuvant chemotherapy. The mechanism of action that allows this protective action of the PU foam is still under investigation. Further studies are needed to confirm these findings.

Note

The authors declare that they have no conflict of interest.

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References

[1] Cronin T, Gerow F. Augmentation mammoplasty: a new natural fell prosthesis. In: Transactions of the third international congress of plastic surgery. Amsterdam: Excerpta Medica Foundation; 1964. p. 41–9.
[2] Szycher M, Lee SJ, Siciliano AA. Breast prostheses: a critical review. J Biomater Appl 1991;5(4):256–81.
[3] Stevens WG, Calobrace MB, Alizadeh K, et al. Ten-year core study data for sientra's food and drug administration-approved round and shaped breast implants with cohesive silicone gel. Plast Reconstr Surg 2018;141:7S–19S.
[4] Pool SMW, Wolthuizen R. Moues-Vink CM Silicone breast prostheses: a cohort study of complaints, complications, and explantations between 2003 and 2015. J Plast Reconstr Aesthetic Surg 2018;71:1563–9.
[5] Prantl L, Schreml S, Fichtner-Feigl S, et al. Clinical and morphological conditions in capsular contracture formed around silicone breast implants. Plast Reconstr Surg 2007;120:275–84.
[6] Gayou RMA. Histological comparison of contracted and non-contracted capsules around silicone breast implants. Plast Reconstr Surg 1979;63:700–7.
[7] Nemecek JA, Young VL. How safe are silicone breast implants? South Med J 1993;86:932–44.
[8] Baker Jr JL, Bartels RJ, Douglas WM. Closed compression technique for rupturing a contracted capsule around a breast implant. Plast Reconstr Surg 1976;58:137–41.
[9] Handel N, Jensen JA, Black Q, et al. The fate of breast implants: a critical analysis of complications and outcomes. Plast Reconstr Surg 1995;96(7):1521–33.
[10] Bengtson BP, Van Natta BW, Murphy DK, et al. Style 410 highly cohesive silicone breast implant core study results at 3 years. Plast Reconstr Surg 2007;120:40S–8S.
[11] Spear SL, Murphy DK, Slicton A, et al. Inamed silicone breast implant core study results at 6 years. Plast Reconstr Surg 2007;120:8S–16S.
[12] Khan UD. The impact of preoperative breast implant size selection on the 3-year reoperation rate. Eur J Plast Surg 2013;36:503–10.
[13] Holmich LR, Breiting VB, Fryzek JP, et al. Long-term cosmetic outcome after breast implantation. Ann Plast Surg 2007;59:597–604.
[14] Marques M, Brown SA, Oliveira I, et al. Long-term follow-up of breast capsule contracture rates in cosmetic and reconstructive cases. Plast Reconstr Surg 2010;126:769–78.
[15] Spear SL, Murphy DK. Natrelle round silicone breast implants: core Study results at 10 years. Plast Reconstr Surg 2014;133:1354–61.
[16] Hipps CJ, Raju R, Straith RE. Influence of some operative and postoperative factors on capsular contracture around breast prostheses. Plast Reconstr Surg 1978;61(3):384–9.
[17] Handel N, Cordray T, Gutierrez J, Jensen JA. A long-term study of outcomes, complications, and patient satisfaction with breast implants. Plast Reconstr Surg 2006;117(3):757–67.
[18] Ascherman JA, Hanasono MM, Newman MI, et al. Implant reconstruction in breast cancer patients treated with radiation therapy. Plast Reconstr Surg 2006;117:359–65.
[19] Jhaveri JD, Rush SC, Kostroff K, et al. Clinical outcomes of postmastectomy radiation therapy after immediate breast reconstruction. Int J Radiat Oncol Biol Phys 2008;72:859–65.
[20] Lam TC, Hsieh F, Boyages J. The effects of postmastectomy adjuvant radiotherapy on immediate two-stage prosthetic breast reconstruction: a systematic review. Plast Reconstr Surg 2013;132:511–8.
[21] Nava MB, Pennati AE, Lozza L, et al. Outcome of different timings of radiotherapy in implant-based breast reconstructions. Plast Reconstr Surg 2011;128:353–9.
[22] Vandeweyer E, Deraemaecker R. Radiation therapy after immediate breast reconstruction with implants. Plast Reconstr Surg 2000;106:56–8.
[23] Cordeiro PG, Albornoz CR, McCormick B, et al. The impact of postmastectomy radiotherapy on two-stage implant breast reconstruction: an analysis of long-term surgical outcomes, aesthetic results, and satisfaction over 13 years. Plast Reconstr Surg 2014;134(4):588–95.
[24] Ashley FL. A new type of breast prosthesis. Preliminary report. Plast Reconstr Surg 1970;45:421–4.
[25] Ashley FL. Further studies on the natural-Y breast prosthesis. Plast Reconstr Surg 1972;49:414–9.
[26] Hester Jr TR, Nahai F, Bostwick J, et al. A 5-year experience with polyurethane-covered mammary prostheses for treatment of capsular contracture, primary augmentation mammoplasty, and breast reconstruction. Clin Plast Surg 1988;15:569–85.
[27] Pennisi VR. Long-term use of polyurethane breast prostheses: a 14-year experience. Plast Reconstr Surg 1990;86:368–71.
[28] Vázquez G. A ten-year experience using polyurethane-covered breast implants. Aesthetic Plast Surg 1999;23:189–96.
[29] Sinclair TM, Kerrigan CL, Buntic R. Biodegradation of the polyurethane foam covering of breast implants. Plast Reconstr Surg 1993;92:1003–13.
[30] Handel N. Long-Term safety and efficacy of polyurethane foam-covered breast implants. Aesthetic Surg J 2006;26:265–74.
[31] Vázquez G, Pellón A. Polyurethane-coated silicone gel breast implants used for 18 years. Aesthetic Plast Surg 2007;31:330–6.
[32] Rancati A, Soderini A, Dorr J, et al. One-step breast reconstruction with polyurethane-covered implants after skin-sparing mastectomy. J Plast Reconstr Aesthetic Surg 2013;66:1671–5.
[33] Castel N, Soon-Sutton T, Deptula P, et al. Polyurethane-coated breast implants revisited: a 30-year follow-up. Arch Plast Surg 2015;42(2):186–93.
[34] Pompei S, Evangelidou D, Arelli F, et al. The modern polyurethane-coated implant in breast augmentation: long-term clinical experience. Aesthetic Surg J 2016;36:1124–9.
[35] Pompei S, Arelli F, Labardi L, et al. Polyurethane implants in 2-stage breast reconstruction: 9-year clinical experience. Aesthetic Surg J 2017;37:171–6.
[36] Vázquez G. Patients' satisfaction with anatomic polyurethane implants. Gland Surg 2017;6(2):185–92.
[37] Duxbury PJ, Harvey JR. Systematic review of the effectiveness of polyurethane-coated compared with textured silicone implants in breast surgery. J Plast Reconstr Aesthetic Surg 2016;69(4):452–60.
[38] Bachour Y, Verweij SP, Gibbs S, et al. The aetiopathogenesis of capsular contracture: a systematic review of the literature. J Plast Reconstr Aesthetic Surg 2018;71:307–17.
[39] Granchi D, Cavedagna D, Ciapetti G, et al. Silicone breast implants: the role of immune system on capsular contracture formation. J Biomed Mater Res 1995;29:197–202.
[40] Bui JM, Perry T, Ren CD, et al. Histological characterization of human breast implant capsules. Aesthetic Plast Surg 2015;39:306–15.
[41] Dobke MK, Svahn JK, Vastine VL, et al. Characterization of microbial presence at the surface of silicone mammary implants. Ann Plast Surg 1995;34:563–9.
[42] Schreml S, Heine N, Eisenmann-Klein M, et al. Bacterial colonization is of major relevance for high-grade capsular contracture after augmentation

mammaplasty. Ann Plast Surg 2007;59:126–30.
[43] Luo S, Chen L, Luo J. Experience in management of capsular contraction through areolar incision after implantation of prosthesis for augmentation mammaplasty. Zhonghua Zheng Xing Shao Shang Wai Ke Za Zhi 1995;11(4):251–2.
[44] Tallet AV, Salem N, Moutardier V, et al. Radiotherapy and immediate two-stage breast reconstruction with a tissue expander and implant: complications and esthetic results. Int J Radiat Oncol Biol Phys 2003;57(1):136–42.
[45] Whitfield GA, Horan G, Irwin MS, et al. Incidence of severe capsular contracture following implant-based immediate breast reconstruction with or without postoperative chest wall radiotherapy using 40 Gray in 15 fractions. Radiother Oncol 2009;90(1):141–7.
[46] FDA summary of safety and effectiveness data. PMA P020056, https://www.accessdata.fda.gov/cdrh_docs/pdf2/P020056b.pdf; 2006. November 17.
47) FDA Summary of Safety and Effectiveness Data. PMA P030053. November 17, https://www.accessdata.fda.gov/cdrh_docs/pdf3/p030053b.pdf; 2006.
[48] FDA summary of safety and effectiveness data. PMA P070004, https://www.accessdata.fda.gov/cdrh_docs/pdf7/p070004b.pdf; 2006. November 17.
[49] Szycher M, Siciliano AA. Polyurethane-covered mammary prosthesis: a nine-year follow-up assessment. J Biomater Appl 1991;5(4):282–322.
[50] Frame J, Kamel D, Olivan M, Cintra H. The in vivo pericapsular tissue response to modern polyurethane breast implants. Aesthetic Plast Surg 2015;39(5):713–23.
[51] Recht A, Comen EA, Fine RE, et al. Postmastectomy radiotherapy: an American society of clinical oncology, American society for radiation oncology, and society of surgical oncology focused guideline update. Ann Surg Oncol 2017;24(1):38–51.
[52] Devulapalli C, Bello RJ, Alsobrooks J, et al. The effect of radiation on quality of life throughout the breast reconstruction process. Plast Recostr Surg 2018;141:579–89.
[53] Bertozzi N, Pesce M, Santi P, Raposio E. One-stage immediate breast reconstruction: a concise review. BioMed Res Int 2017;2017:6486859.
[54] Wu SG, et al. Canc Manag Res 2018;10:1993–2002.
[55] Agarval C, Kidwell M, Farberg A, et al. Immediate reconstruction of the radiated breast: recent trends contrary to traditional standards. Ann Surg Oncol 2015;22(8):2551–9.
[56] Mc Guire KP, Santillan AA, Kaur P, et al. Are mastectomies on the rise? A 13-year trend analysis of the selection of mastectomy versus breast conservation therapy in 5865 patients. Ann Surg Oncol 2009;16:2682–90.
[57] Lo Torto F, Relucenti M, Familiari G, et al. The effect of postmastectomy radiation therapy on breast implants: material analysis on silicone and polyurethane prosthesis. Ann Plast Surg 2018;81:228–34.
[58] Lee KT, et al. Am J Surg 2016;212:336–44.
[59] Basta MN, Gerety PA, Serletti JM, et al. A systematic review and head-to-head meta-analysis of outcomes following direct-to-implant versus conventional two-stage implant. Plast Reconstr Surg 2015;136:1135–44.
[60] Sinnott CJ, Persing SM, Pronovost M, et al. Impact of postmastectomy radiation therapy in prepectoral versus subpectoral implant-based breast reconstruction. Ann Surg Oncol 2018;25(10):2899–908.