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The Modern Polyurethane-Coated Implant in Breast Augmentation: Long-Term Clinical Experience

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Polyurethane Implants in 2-Stage Breast Reconstruction: 9-Year Clinical Experience

Stefano Pompei, MD; Floriana Arelli, MD; Lara Labardi, MD; Fabio Marcasciano, MD; Dora Evangelidou, MD; and Gianluigi Ferrante, MD, MSc

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The Modern Polyurethane-Coated Implant in Breast Augmentation: Long-Term Clinical Experience

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Abstract

Background: First-generation polyurethane foam-coated breast implants were associated with a low risk of capsular contracture (CC), but the risk of CC with modern polyurethane-coated silicone implants has not been established.

Objectives: The authors sought to determine the long-term rates of CC after primary breast augmentation with Microthane, a polyurethane-coated silicone gel implant.

Methods: A total of 131 patients (255 breasts) were evaluated in a retrospective study. Data were compiled from postoperative follow-up sessions at 2 weeks; 1, 3, 6, and 12 months; and annually thereafter. Rates of various complications, including CC, were determined.

Results: CC developed in 3 of the 255 implanted breasts (1.2%; Baker grade III or IV), and postoperative hematoma occurred in 2 implanted breasts (0.8%). Spontaneous CC that was not associated with other complications was observed in 1 implanted breast (0.4%). All instances of CC occurred before the 31st postoperative month.

Conclusions: For patients who undergo primary breast augmentation with modern polyurethane-coated implants, the long-term risk of CC is low.

Level of Evidence: 3

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Modifications to the shape and composition of breast implants have been made by manufacturers since the introduction of these prostheses in the early 1960s. Today, a patient may choose from a variety of implant shell and content materials. The shell may be textured or smooth and may comprise silicone with or without a coating of polyurethane foam. Implant contents include saline or silicone. High-viscosity, cohesive silicone gel implants have supplanted liquid silicone implants in popularity.

Despite advancements in implant types and an abundance of studies addressing implant selection, capsular contracture (CC) remains a common complication of breast augmentation and is the primary reason for reoperation.[1-3] Plastic surgeons tend to recommend implants that are associated with lower rates of complications (including CC) and decreased likelihood of revisional surgery. In a 25-year study of 1529 patients (3495 implants), first-generation implants covered in polyurethane foam were associated with a relatively low risk of CC.[3] The aim of the present study was to determine the long-term risk of CC with Microthane (Polytech Health & Aesthetics, Dieburg, Germany), a modern polyurethane-coated silicone gel implant.

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METHODS

Patients and Study Design

The anonymized records of 131 consecutive women (255 breasts) who underwent primary breast augmentation or mastopexy-augmentation with Microthane, a polyurethane-coated silicone gel implant, were reviewed retrospectively. Patients underwent surgery from September 2000 to June 2012. Approval for this study was obtained from the ethics review board of Sandro Pertini Hospital (Rome, Italy), and the study was conducted in accordance with guiding principles set forth in the Declaration of Helsinki. Patients were excluded from the study if they underwent breast augmentation with non–polyurethane-coated devices or if they had previously undergone breast surgery.

Surgical Techniques

Breast augmentation and augmentation-mastopexy were performed under general anesthesia by standard techniques. All patients received perioperative care from the senior author (S.P.) and members of his team (A.F.) at Sandro Pertini Hospital. Prophylactic antibiotics were delivered intravenously upon initiation of anesthesia, and patients did not receive adrenaline. The first incision was usually inframammary or periareolar. Dissection of a subglandular or dual-plane pocket was performed with electrocautery, and meticulous hemostasis was achieved with bipolar forceps. Before implant placement, the pocket and Microthane implant were irrigated with cefazolin solution, and the surgical team routinely changed their gloves. Early in this study (2000–2003), most patients received round implants, with anatomic implants predominating thereafter.

Suction drains were placed to remove pocket fluids and maximize the contact surface between the polyurethane foam shell of the implant and the surrounding tissue. This step was necessary to stabilize the implant and prevent displacement.

Postoperative Care and Data Collection

Patients continued to receive intravenous antibiotics for 24 hours postoperatively. Suction drains were removed when there was no indication of hematoma and fluid collection was less than 30 mL/d. Two or more members of the surgical team conducted each postoperative follow-up session at 2 weeks; 1, 3, 6, and 12 months; and annually thereafter. Each patient was encouraged to contact the office for additional consultations if new symptoms arose.

Patient data, including intervention type, implant size and type, surgical approach, date of surgery, complications (including CC), date CC was detected, and duration of follow-up, were compiled in an Excel database prepared by the senior author (S.P.) (Table 1). For this study, only Baker grade III (ie, a firm breast with a noticeable implant) and Baker grade IV (ie, a painful, hard, distorted breast with stretched, tender skin and implant rigidity upon palpation) were considered indicative of CC.

Table 1. Information Collected Retrospectively From Patient Cohort

Patient identification no. and demographic information
Date of surgery
Intervention type (augmentation-mastopexy, augmentation alone)
Surgical approach (subglandular, dual-plane)
Implant type (round polyurethane-coated, anatomic polyurethane-coated)
Implant size
Date and identification of follow-up session
Outcome(s) at follow-up
Diagnosis of capsular contracture (CC; Baker grades III and IV)
Date of onset of CC
Complication(s) other than CC
Date of onset of other (non-CC) complications
Treatment for complication
Date of reoperation
Date of last follow-up
Outcome at last follow-up

CC, capsular contracture.

Statistical Analyses

All analyses were performed with Stata 13 statistical software (StataCorp LP, College Station, TX). Descriptive statistics included implant size, mean and median patient age, and mean and median follow-up time (in months). Complication rates were evaluated overall and by intervention type, implant size, implant type, and pocket position. Poisson regression models were applied to estimate the risk ratios of complications in the subgroups. CC rates were estimated separately for implants and patients by means of the Kaplan-Meier method for cumulative incidence. Time of CC onset was defined as the time from the initial breast surgery to the diagnosis of CC (in months). Patients who did not experience CC were censored after the final follow-up session or at time of reoperation. For all analyses, $P < .05$ was considered statistically significant.

RESULTS

The patients' mean age was 34.7 years (range, 19–56 years), and the median follow-up period was 110 months

(range, 4–175 months) (Table 2). One hundred twenty-four of the 131 patients underwent bilateral breast surgery, and 7 patients underwent unilateral surgery to treat breast asymmetry. Breast augmentation was performed for 140 of the 255 breasts (54.9%), and augmentation-mastopexy was performed for 115 breasts (45.1%). An inframammary incision was made for 73 patients (55.7%), 37 patients received a periareolar with inverted T incision (28.2%), 12 patients received a simple periareolar incision (9.2%), and 9 patients underwent a periareolar with vertical incision (6.9%). A subglandular pocket was created for 175 breasts (68.6%), and a dual-plane pocket was dissected for 80 breasts (31.4%).

Of the 255 implanted breasts, 4 were lost to follow-up, 3 were censored at CC diagnosis, and 9 were censored at reoperation to treat complications other than CC. These 9 patients who underwent reoperation were censored because more than 1 breast surgery was an exclusion criterion for this study. Moreover, it would not have been possible to determine conclusively which operation contributed to the CC if it developed after the secondary breast surgery.

At least 1 complication occurred in 19 implanted breasts (7.4%) (Table 3). Malposition occurred during surgery for 4 breasts (3 patients) implanted in the subglandular plane with anatomic implants. Two patients underwent reoperation to treat this complication; the third patient chose not to undergo treatment. Bilateral rippling was observed in 2 patients (4 implanted breasts). One of these patients underwent 1 session of lipofilling at another office and subsequently was lost to follow-up. The other patient did not undergo treatment for rippling. Two patients experienced unilateral implant rupture 4 years postoperatively; these patients underwent bilateral explantation and implant replacement in a single surgical session.

Cutaneous erythema with spontaneous resolution was observed for 2 patients. Two patients experienced early seroma (at postoperative weeks 8 and 10, respectively) and were treated conservatively. No patient experienced late seroma. Spontaneous inferior dislocation of the implant (ie, displaced lower than the inframammary fold) occurred unilaterally for 1 patient in the fifth postoperative year. This patient did not undergo treatment for inferior implant dislocation. To our knowledge, the mechanism for this complication is unknown.

Baker grade III or IV CC was observed for 3 of the 255 implanted breasts (1.2%; 3 patients); the cumulative incidence of CC during a 14.6-year period is depicted in Figure 1. For 2 of these implanted breasts, CC occurred after hematoma was diagnosed. The other implanted breast developed CC spontaneously despite absence of previous complications. Two of the 3 patients who experienced CC were lost to follow-up

Table 2. Characteristics of Patient Cohort

No. of Patients	131
Age, y	
Mean (SD)	34.7 (8.2)
Range	19-56
No. of implants	255
Follow-up time, mo	
Mean (SD)	107 (41)
Median	110
Range	4-175
No. of implanted breasts (%) by intervention type	
Augmentation-mastopexy	115 (45.1)
Augmentation alone	140 (54.9)
No. of implanted breasts (%) by implant size	
195–255 cc	67 (26.3)
280–390 cc	188 (73.7)
No. of implanted breasts (%) by implant type[a]	
Round	38 (14.9)
Anatomic	217 (85.1)
No. of implanted breasts (%) by pocket position	
Subglandular	175 (68.6)
Dual-plane	80 (31.4)

SD, standard deviation. [a]All patients underwent augmentation with polyurethane-coated silicone gel implants.

Table 3. Complications of Primary Augmentation With Microthane (N = 255 Implanted Breasts)

	No. of Implants	Relative Risk (%)
All complications	19	7.5
Malposition[a]	4	1.6
Rippling	4	1.6
Hematoma followed by CC[b]	2	0.8
Implant rupture	2	0.8
Rash	2	0.8
Seroma	2	0.8
Implant animation with muscle contraction	1	0.4
CC[b]	1	0.4
Spontaneous implant dislocation	1	0.4

CC, capsular contracture. [a]Instances of malposition were the result of poor placement intraoperatively, rather than dislocation over time. [b]CC was defined as Baker grade III or IV.

after the first postoperative year. The remaining patient indicated that she found the aesthetic results acceptable and the CC was not painful (grade III); she did not undergo additional treatment. The Kaplan-Meier estimation of cumulative incidence of CC over 14.6 years was 1.2% for implants (95% confidence interval [CI], 0.39%-3.65%) (Figures 1 and 2) and 2.3% for patients (95% CI, 0.74%-6.93%) (Figure 2). Complication rates by intervention type, implant size, and pocket position are presented in Table 4.

Five patients (7 implanted breasts) with complications of the primary surgery chose to undergo reoperation. Two of these patients, both of whom experienced unilateral rupture after the primary breast surgery, also underwent surgery of the contralateral implanted breast (ie, 9 total reoperated breasts) (Table 5). These patients sought a secondary bilateral procedure to modify the size of both implants. The remaining revisional surgeries corresponded to 3 implanted breasts (2 patients) with malposition and 2 implanted breasts (1 patient) with rippling (Table 5).

No statistically significant differences in the incidence of CC or any other complication were observed with regard to pocket position (ie, subglandular or dual-plane),

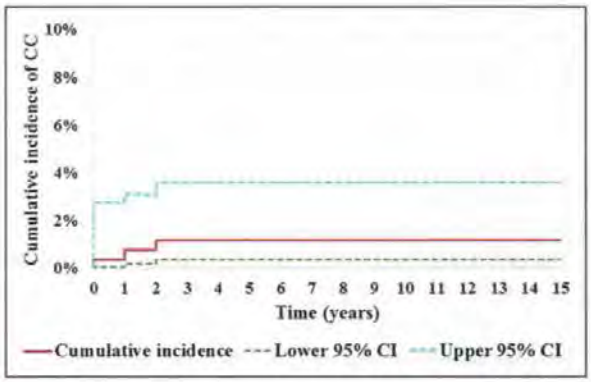

Figure 1. Kaplan-Meier estimation of cumulative incidence (and 95% confidence interval) of capsular contracture (CC) for a series of 255 implanted breasts (131 patients) over 14.5 years. All patients underwent primary breast augmentation with Microthane, a modern polyurethane-coated silicone gel implant.

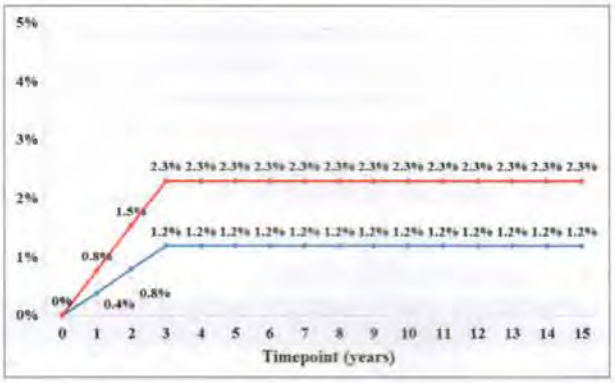

Figure 2. Kaplan-Meier estimation of cumulative incidence of capsular contracture (CC) by implant (blue curve) and by patient (red curve) for a series of 131 patients (255 implanted breasts) over 14.5 years. All patients underwent primary breast augmentation with Microthane, a modern polyurethane-coated silicone gel implant.

Table 4. Overall Complication Rates by Intervention Type, Implant Size, and Implant Pocket

	No. of Implants	No. of Complications (%)	RR	95% CI	*P*
Overall	255	19 (7.5)	NA	NA	NA
Intervention type					
Augmentation-mastopexy	115	11 (9.6)	1		
Augmentation alone	140	8 (5.7)	0.60	0.25-1.44	.25
Implant size					
195–255 cc	67	7 (10.4)	1		
280–390 cc	188	12 (6.4)	0.61	0.25-1.49	.28
Implant type[a]					
Round	38	2 (5.3)	1		
Anatomic	217	17 (7.8)	1.49	0.35-6.20	.59
Pocket position					
Subglandular	175	11 (6.3)	1		
Dual-plane	80	8 (10.0)	1.59	0.66-3.81	.30

CI, confidence interval; NA, not applicable; RR, relative risk. [a]All patients received polyurethane-coated silicone gel implants.

Table 5. Complications, Other Than CC, Treated With Revisional Surgery

Complication	No. of Breasts Reoperated (%)	No. of Patients Reoperated (%)
Implant rupture[a]	4 (1.6)	2 (1.5)
Malposition[b]	3 (1.2)	2 (1.5)
Rippling	2 (0.8)	1 (0.76)
Total	9 (3.5)	5 (3.8)

[a]Patients who underwent surgery for this complication also received replacement of the contralateral, nonruptured implant. [b]Instances of malposition were the result of poor placement intraoperatively, rather than dislocation over time.

intervention type (ie, augmentation alone or augmentation-mastopexy), or incision type (ie, inframammary, simple periareolar, periareolar with inverted T, or periareolar with vertical).

DISCUSSION

We determined the cumulative incidence of CC for 14.6 years and found that CC increased steadily from 0% to 1.2% during the first 2.5 years postoperatively and remained constant for 12 years thereafter (Figure 1). Specifically, the 3 cases of CC diagnosed in this study occurred 8, 12, and 13 months postoperatively (Table 6). Castel et al[1] described a patient who experienced CC 29 years after implantation with first-generation polyurethane-coated devices. Additional studies are needed to establish the long-term incidence of CC with modern implants coated in polyurethane foam.

Since the first descriptions of polyurethane-covered implants by Ashley in 1970[2] and 1972,[3] the number of basic shell layers has increased. In addition, a barrier between the polyurethane coating and silicone contents has been added, and the process of vulcanization during implant manufacture has improved.[4] Early versions of these devices involved stiff, nonelastic polyurethane that was adhered with glue[4] and was not securely attached to the implant core.[5] These implants likely were prone to deterioration and detachment of the polyurethane foam over time, resulting in silicone bleed.

Compared with modern versions, we suggest that early-generation polyurethane implants posed a higher risk of long-term CC. Other authors have hypothesized that complete detachment of the polyurethane foam from the implant shell would result in prosthesis with characteristics of a smooth implant.[1] However, this assertion can only partially explain why CC occurred with these implants after several decades. The increased risk of late silicone bleed and implant rupture could increase the risk of late CC.

It is widely accepted that hematoma increases the risk of CC, especially early-onset CC.[4] Two of the 3 cases of CC in our study occurred in implanted breasts that had developed hematoma in the early postoperative period. CC was diagnosed in these breasts 8 and 12 months postoperatively. Therefore, the results of our study are in accordance with these previous findings.

Table 6. 14.5-Year Kaplan-Meier Estimation of Cumulative Incidence of CC by Implanted Breast and by Patient

Interval, y	Cases of CC	Data by Patient		Data by Implanted Breast	
		RR (%)	95% CI	RR (%)	95% CI
0-1	1	0.76	0.11-5.29	0.40	0.06-2.77
1-2	1	1.53	0.38-5.97	0.79	0.20-3.14
2-3	1	2.29	0.74-6.93	1.19	0.39-3.65
3-4	0	2.29	0.74-6.93	1.19	0.39-3.65
4-5	0	2.29	0.74-6.93	1.19	0.39-3.65
5-6	0	2.29	0.74-6.93	1.19	0.39-3.65
6-7	0	2.29	0.74-6.93	1.19	0.39-3.65
7-8	0	2.29	0.74-6.93	1.19	0.39-3.65
8-9	0	2.29	0.74-6.93	1.19	0.39-3.65
9-10	0	2.29	0.74-6.93	1.19	0.39-3.65
10-11	0	2.29	0.74-6.93	1.19	0.39-3.65
11-12	0	2.29	0.74-6.93	1.19	0.39-3.65
12-13	0	2.29	0.74-6.93	1.19	0.39-3.65
13-14	0	2.29	0.74-6.93	1.19	0.39-3.65
14-15	0	2.29	0.74-6.93	1.19	0.39-3.65

CC, capsular contracture; CI, confidence interval; RR, relative risk.

The rate of CC following primary breast augmentation with Microthane was substantially lower than the rates of CC after primary augmentation with smooth or textured silicone implants. We found that 2.3% of patients experienced CC during 14.6 years of follow-up. In 2014, Spear and Murphy[6] found that CC occurred in 17.2% and 19.9% of patients who underwent implantation with textured or smooth silicone implants, respectively

The lower CC risk associated with implants coated in polyurethane foam, as opposed to smooth or textured implants, is well documented in studies of aesthetic and reconstructive breast surgery.[7-13] The Microthane implant has been given CE marking, indicating that this device conforms to the safety, health, and environmental protection requirements of the European Economic Area.

The most common complication in this study was implant malposition, which was the result of poor placement intraoperatively, rather than implant dislocation over time. If an implant is incorrectly placed during surgery, it can

be difficult to correct its position postoperatively with conservative methods, such as elastic bands or downward-pressure garments. The surface of the Microthane implant is highly adhesive to tissues of the breast pocket, making the implant resistant to rotational or downward forces. Smooth and textured implants lack this feature. Presumably owing to this adhesion, no rotation was observed for breasts augmented with anatomic implants. Moreover, the risk of revisional breast surgery (eg, to treat an oversized pocket or a pocket displaced laterally or medially) likely was reduced. We suggest taking advantage of the unique adhesion of polyurethane-coated implants to achieve favorable results without the need for time-consuming manipulations or expensive materials.

Tissue integration of the polyurethane foam is a dynamic, highly variable process. When we perform explantation soon after primary implantation, the procedure is prolonged because the foam has already adhered tightly to the surrounding tissues. When we carry out explantation several years after implantation, we have observed that some islands of polyurethane foam have integrated into the capsule, and others remain adherent to the textured wall of the implant (data not shown). However, even this partially integrated implant can be removed with scissors or simple manual maneuvers.

Reoperation was performed for 9 of the 255 implanted breasts (3.5%); this reoperation rate is within the range published in the literature (1.2% to 19.9%)[1,7,14] We assume that the 2 patients in our study who experienced CC and were lost to follow-up underwent revisional surgery at another institution. Even with this assumption, malposition, not CC, was the most common complication necessitating reoperation in the current study, a finding that contrasts with that of Handel et al.[7]

The primary limitation of this long-term study was the loss of patients to follow-up (3 patients, 2.3%). These patients experienced complications of the primary surgery (CC for 2 patients, rippling for 1 patient) and sought treatment elsewhere; thus, data for these patients are incomplete. Other authors have advocated polyurethane-coated implants for patients who present for reoperation after experiencing severe or recurring CC with non–polyurethane-coated implants.[15,16] We assert that modern polyurethane-coated implants should be considered for primary augmentation, not just for revisional surgery when CC occurs with smooth or textured implants.

CONCLUSIONS

Primary breast augmentation with Microthane, a modern polyurethane-coated silicone gel implant, results in low long-term risk of CC. The authors advocate utilization of these implants for primary augmentation, rather than only for revisional treatment.

Disclosures

The authors declared no potential conflicts of interest with respect to the research, authorship, and publication of this article.

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Abstract

Background: Capsular contracture (CC) is a major complication of breast surgery with smooth and textured implants. Polyurethane (PU) foam–coated breast implants were developed to decrease the incidence of CC.

Objectives: The authors determined the incidence of CC following 2-stage breast reconstruction using PU foam–covered implants, with and without radiation therapy.

Methods: The records of 92 patients who received 115 PU implants were retrospectively reviewed. The rates of CC over time were compared for irradiated and nonirradiated groups with a Kaplan-Meier analysis and log-rank test. CC rates also were analyzed with respect to age.

Results: The median follow-up time for patients was 103.3 months. Nine patients experienced unilateral Baker grade III or IV fibrous CC, including 6 patients from the irradiated group and 3 patients from the nonirradiated group. The overall cumulative incidence of CC at 9 years was 8.1%. In the irradiated and nonirradiated groups, the 9-year cumulative incidence was 10.7% and 5.5%, respectively. CC occurred within 3 years in the irradiated group and within 7 years in the nonirradiated group. The incidence of CC appeared to be higher among younger patients.

Conclusions: Radiation therapy increases the risk of high-grade CC with textured or smooth implants. PU implants are associated with a much lower cumulative incidence of CC following 2-stage breast reconstruction, even when radiotherapy is performed.

Level of Evidence: 3

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Since the introduction of breast implants in plastic surgery nearly 50 years ago, capsular contracture (CC) has been the leading cause of morbidity and reoperation, with reported incidences as high as 80%.[1-3] Results of many studies have shown that the incidence of CC is higher for breast reconstruction than for primary cosmetic breast augmentation.[4-10] According to the US Food and Drug Administration, women who received reconstruction with silicone gel implants had a nearly 15% risk of CC (Baker grade III or IV), a 25% risk of implant removal or replacement, and an overall reoperation rate of 40% at the end of 4 years.[11]

Radiation therapy (RT) also appears to increase the risk of CC. In several studies of 2-stage breast reconstruction, the incidence of CC was consistently higher for patients who also underwent RT compared with those who did not receive RT.[12-15] Authors of a long-term prospective analysis of a large cohort of women found that CC of grade III or IV

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occurred in 46.6% of irradiated implants but in only 6.4% of nonirradiated implants.[16]

To decrease the high incidence of CC associated with silicone breast implants, polyurethane (PU) foam–coated implants were introduced (by Ashley[17] in 1970). Many investigators have found that the incidence of CC with PU-coated implants is approximately 2%.[3,5,18-25] However, data are scarce regarding the incidence of CC among women who receive PU foam–coated implants during 2-stage breast reconstruction, particularly when the procedure is combined with RT. We sought to determine the long-term incidence of CC following 2-stage breast reconstruction with PU implants in the presence and absence of RT. The secondary outcome was to examine the association between patient age and occurrence of CC.

METHODS

Study Design

For this retrospective cohort study, we reviewed the medical records of patients (all female) who underwent immediate 2-stage breast reconstruction with PU-coated shaped implants with or without RT from June 2002 through February 2015 (12 years, 8 months) at Sandro Pertini Hospital (Rome, Italy). This study was approved by the ethics review board of the hospital. Exclusion criteria were 1-stage breast reconstruction, delayed reconstruction, secondary breast surgery, and any reconstruction involving round implants, smooth or textured implants, saline implants, acellular dermal matrix, or autologous tissue.

An Excel database was prepared with information for 92 patients (115 breast implants). The following variables were included: diagnosis; patient age; date of mastectomy and placement of tissue expander; date of implantation with the PU device; need for RT; implant type, size, and projection; length of follow-up and dates of follow-up visits; and presence and grade of CC. The original patient database, which included all early and late complications, was refined for this study to only indicate CC occurrence during follow-up.

Surgical Techniques

Consultations and surgical procedures were performed by the senior surgeon (S.P.) or members of his team at Sandro Pertini Hospital. All patients underwent mastectomy with immediate 2-stage breast reconstruction. Round or low-height tissue expanders were positioned subpectorally. One or 2 drains were placed, depending on whether the expander was partially or fully covered by the muscle, respectively. Patients who underwent RT received a mean dose of 50 Gy, over the tissue expander only, between 1 and 6 months (mean, 3 months) after the first surgical session and a mean of 3 months prior to placement of the definitive PU-coated implant. Implant choice was based on the surgeon's recommendation. None of the definitive implants was irradiated. All shaped gel implants were covered with MPS, a micro-PU foam (Microthane, Polytech Health & Aesthetics, Dieburg, Germany).

Determination of CC Incidence

Patients were monitored at follow-up visits attended by at least 4 of the 5 senior team members at 1, 3, and 6 months postoperatively. CC was graded by the Baker scale; cases of grades III and IV CC were evaluated further in this study. Grade III CC corresponds to a hard breast and noticeable implant. Grade IV CC denotes a hard and rigid implant with stretched and tender skin, pain, and distortion of the breast. Capsulectomy, excluding the chest wall, was performed when the overlying tissues were sufficiently thick. For patients with inadequate tissue coverage, partial capsulectomy was performed to promote tissue adhesion to the PU surface of the implant and avoid further depletion of the overlying tissues.

Statistical Analysis

An independent epidemiologist (G.F.) performed data analysis. Because the primary objective of this study was to determine the role of micro-PU foam in the prevention of high-grade CC (Baker III or IV) after primary breast reconstruction, we evaluated individual breast implants rather than individual patients. Breast implants were categorized as irradiated or nonirradiated group. "Time to CC" was defined as the time from the first surgical session to the diagnosis of CC. Patients without a diagnosis of CC were censored at last follow-up or death. Rates of CC, determined for 12-month periods, were estimated with the Kaplan-Meier method, with cumulative incidences and 95% confidence intervals (CI). Cumulative incidence curves, stratified by irradiation status and age, were compared with the log-rank test for equality of survivor functions. A multivariate Cox proportional hazards model was applied to study the association between CC and age while controlling for irradiation status. Statistical significance was defined as $P < .05$. All analyses were performed with Stata 13 statistical software (StataCorp LP, College Station, TX).

RESULTS

Sixty-nine of the 92 patients underwent unilateral mastectomy, and 23 underwent bilateral mastectomy. Of the 115 breasts, 64 underwent skin-sparing mastectomy,

26 received nipple-sparing mastectomy, 17 required radical mastectomy, and 8 underwent skin-reducing mastectomy. Fifty-six breasts (49 patients) were irradiated, and 59 breasts (43 patients) were nonirradiated (Tables 1 and 2). The need for RT could not be predicted in any case.

The patients' mean age was 53 years (standard deviation [SD], 10.2 years; range, 27-76 years), and the median follow-up was 103.3 months (range, 6.2-152.4 months) (Table 1). When the study population was analyzed in terms of individual breast implants, the mean age of implants for the nonirradiated group was 54.6 years (SD, 8.6 years; range, 39-75 years), and the mean age for the irradiated group was 50.8 years (SD, 10.5 years; range, 27-76 years) (Table 2). The median follow-up time was 103.9 months (range, 33.8-152.4 months) for the nonirradiated group and 106.6 months (range, 6.2-151.6 months) for the irradiated group (Table 2).

Fibrous CC (Baker grade III or IV) developed in 9 breast implants (9 patients). Each patient who experienced fibrous CC had undergone unilateral mastectomy. Four cases of CC occurred within the first year following implant placement, additional 3 cases occurred within 3 years, and the remaining 2 cases occurred within 7 years. The cumulative incidence of CC at 9 years was 8.1% (95% CI, 4.3-15.0), as shown in Figure 1. Kaplan-Meier survival curves depicted the likelihood of CC over time, with and without RT (Figure 2). Of the 9 breasts that developed CC, 6 had been irradiated. Four of these breasts developed CC within 1 year, and 2 developed CC within 3 years. The cumulative incidence of CC at 9 years in this group was 10.7% (95% CI, 5.0-22.3). For the 3 nonirradiated breasts that developed CC, this complication was diagnosed 3 to 7 years after implantation. The cumulative incidence of CC at 9 years in this group was

Table 1. Data for Patients

	Irradiated Group (N = 49)	Nonirradiated Group (N = 43)	Total (N = 92)
Age, y			
Mean (SD)	51.0 (11.0)	55.2 (9.0)	53.0 (10.2)
Range	27-76	39-75	27-76
Follow-up time, mo			
Mean (SD)	97.1 (39.5)	105.5 (27.4)	101.6 (34.4)
Median	104.0	102.0	103.3
Range	6.0-151.0	33.0-152.0	6.2-152.4

SD, standard deviation.

Table 2. Data for Breast Implants

	Irradiated Group (N = 56)	Nonirradiated Group (N = 59)	Total (N = 115)
Age, y			
Mean (SD)	50.8 (10.5)	54.6 (8.6)	52.8 (9.7)
Range	27-76	39-75	27-76
Follow-up time, mo			
Mean (SD)	99.0 (38.2)	108.7 (27.9)	104.0 (33.5)
Median	106.6	103.9	104.2
Range	6.2-151.6	33.8-152.4	6.2-152.4

SD, standard deviation.

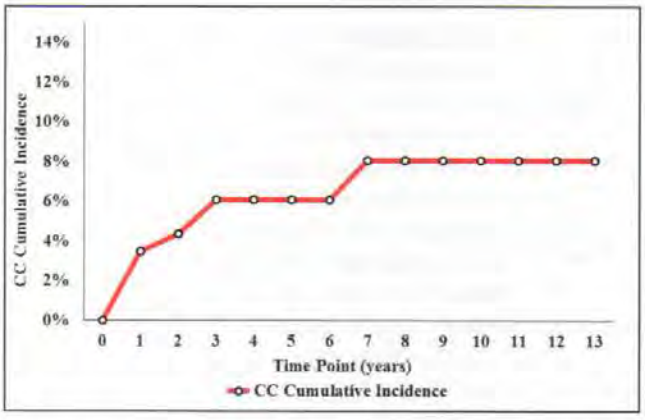

Figure 1. Kaplan-Meier cumulative incidence of capsular contracture (CC) after 2-stage breast reconstruction. The curve depicts the rates of CC over time for the 115 polyurethane (PU) foam–coated breast implants that were analyzed in a retrospective review of hospital records of 92 women. Nine cases of CC (Baker grade III or IV) occurred within 7 years.

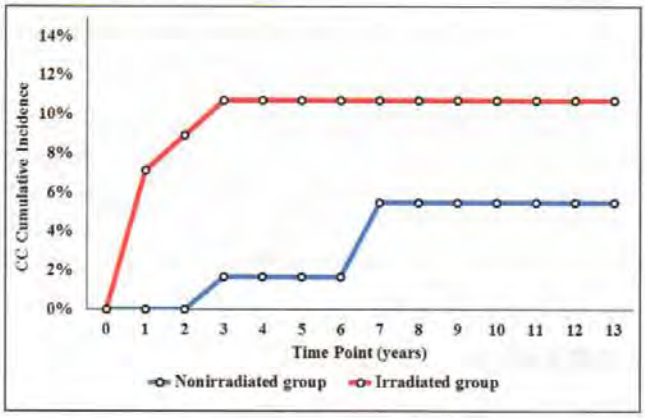

Figure 2. Kaplan-Meier cumulative incidence depicting the rates of capsular contracture (CC) after 2-stage breast reconstruction according to irradiation status. Nonirradiated group, blue curve (n = 59 breast implants). Irradiated group, red curve (n = 56 breast implants). Radiation therapy (RT) was delivered over the tissue expander. Reliable data were available for a median of 9 years of follow-up.

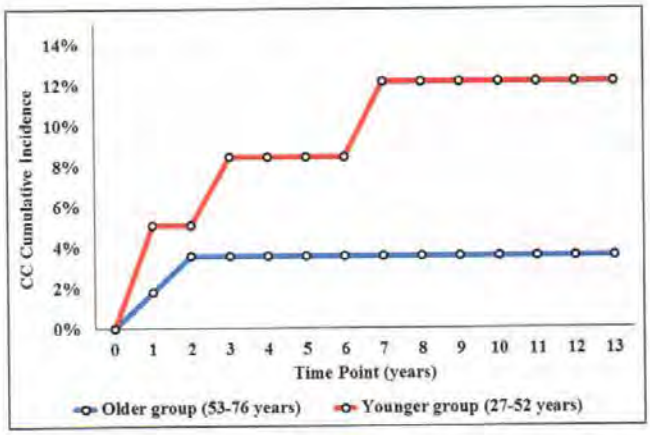

Figure 3. Kaplan-Meier cumulative incidence of capsular contracture (CC) after 2-stage breast reconstruction as a function of age. Older group (27-52 years old), blue curve (n = 56 breast implants). Younger group (53-76 years old), red curve (n = 59 breast implants). The difference between the 2 curves was assessed by the log-rank test (P = .10).

5.5% (95% CI, 1.8-16.1). No statistically significant difference was observed for the cumulative incidence curves for irradiated and nonirradiated groups (log-rank test, P = .23).

To evaluate the role of age in CC occurrence, the PU-coated implants were stratified in two groups using the median age of patients (53 years) as the cut-off value. Fifty-nine breast implants corresponded to patients who were younger (27-52 years old), and 56 breast implants corresponded to patients who were older (53-76 years old). Seven of the 9 breasts with CC, which developed within 7 years, were in the younger group. The remaining 2 breasts with CC, which developed within 2 years, were in the older group (Figure 3). The cumulative incidence of CC at 9 years was 12.2% (95% CI, 6.0-23.9) in the younger group and 3.6% (95% CI, 0.9-13.5) in the older group. The difference between the 2 curves, as determined by the log-rank test, was not statistically significant (P = .10).

Additional epidemiologic analysis was performed to exclude confounding by RT in the association between age and CC. Even after adjustment of the Cox proportional hazards model for RT, the occurrence of CC appeared to be lower among older patients than younger ones (hazard ratio, 0.31; P = .15).

DISCUSSION

Breast augmentation with PU foam–coated implants is associated with a very low risk of CC.[3,5,19,21,22,24-26] In the current study, the 9-year incidence of CC after breast reconstruction with PU implants in nonirradiated breasts was 5.5% (median follow-up, 9 years), which coincides with the results of other investigators.[3,27-29] This rate of CC is among the lowest reported after 2-stage breast reconstruction with textured implants.[16] The results of other studies, in which textured breast implants were monitored for a similar duration, have indicated that a low rate of CC is not guaranteed with these implants. For example, the 10-year incidence of CC associated with Biocell textured implants (Inamed Aesthetics, Santa Barbara, CA) was 14.5% for patients who underwent primary reconstruction, presumably without RT.[30] The CC rate at 9 years for Siltex shaped implants (Mentor, Santa Barbara, CA) was 12.7% for a series of patients who received primary breast reconstruction without specified RT.[31] The CC incidence at 9 years for textured Sientra implants (Sientra, Inc, Santa Barbara, CA) under the same conditions was 14.4%.[32,33]

We found that the incidence of CC following 2-stage breast reconstruction with RT (10.7%; median follow-up, 9 years) reminded the encouraging CC rate for the group that did not receive RT (5.5%; median follow-up, 9 years) (Figure 2). Investigators worldwide have suggested that RT exponentially increases the risk of CC.[14,34-36] Rancati et al[23] recently described a very low incidence of CC after 1-step breast reconstruction with PU-coated implants; however, all 4 cases of Baker grade IV CC observed in that study corresponded to patients who underwent RT. Cordeiro et al[16] examined a large cohort of patients who underwent 2-stage breast reconstruction and found that the most common cause (33%) for implant replacement in the subgroup of patients with RT and textured implants was grade III or IV CC. This complication occurred in 46.6% of irradiated breasts (grade III, 39.7%; grade IV, 6.9%).[16]

In this retrospective analysis, we observed early onset of CC among patients who underwent 2-stage immediate breast reconstruction with adjuvant RT. Specifically, CC occurred within 3 years after breast implantation. In contrast, other investigators have shown that the incidence of CC after breast augmentation or reconstruction with textured or PU-coated implants increases as a function of time for 10 years or more postoperatively.[3,5,24,30,37]

Szycher and Siciliano[38] have noted that the protective effect of PU foam against CC is enduring, and many authors have confirmed the long-term efficacy and safety of PU foam–coated breast implants.[6,22,24,25] PU foam in the capsule degrades very slowly under the influence of inflammatory cell esterases.[39,40] Castel et al[24] noted macroscopic evidence of PU on the surface of implants that were explanted up to 5 years postoperatively. However, these authors performed histologic analyses and found that PU persisted in the capsule for 30 years of monitoring.[24] This observation of persistent microscopic PU and our finding of early onset of CC after 2-stage breast reconstruction with RT strengthen the hypothesis that PU-coated implants are more effective than noncoated implants in decreasing the incidence of CC.

We determined the cumulative incidence of CC in a cohort of women who underwent 2-stage breast reconstruction.

This study may have benefitted from a comparison group of women who received textured implants with or without RT. However, a retrospective comparison of 2 cohorts would have been highly susceptible to bias. We maintain that a descriptive long-term analysis of a cohort and its comparison with similar international cohorts was the optimal design for this study. Moreover, we previously performed a direct comparison between PU implants and textured implants.[20] A randomized controlled trial in which the CC risk associated with PU-coated implants is observed prospectively and compared directly with that of textured implants would provide more definitive results.

Grade II CC was not included in this study design because the international literature generally does not address this grade, even when the rate of CC is the primary objective of the study.[3,5,10,11,16,20,30-33] In addition, grade II CC usually is not painful and does not necessitate intervention. We attempted to account for additional risk factors for CC among patients who underwent 2-stage breast reconstruction (eg, body mass index; age). Patient age tended to influence long-term CC, with the younger group (aged 27-52 years) and the older group (aged 53-76 years) exhibiting 9-year CC incidences of 12.2% and 3.6%, respectively. This difference was not statistically significant, which may be attributed to the small sample size. However, statistical analyses of our data excluded RT as a confounding factor in this potential association. An effect of patient age has been observed in clinical practice for other types of fibrosis. For example, hypertrophic scars generally are more common in younger patients, presumably because younger patients are subject to more physical and hormonal changes.[14,41-43] Further investigation of this finding is warranted.

CONCLUSIONS

The safety of PU foam–coated implants has been demonstrated in clinical practice for more than 4 decades. Compared with textured implants, PU implants are associated with a lower rate of CC, which is the most common complication of breast reconstruction and a frequent reason for reoperation. This attribute of PU implants does not appear to diminish over time and is particularly attractive for patients who undergo RT. The results of this study confirm the low long-term incidence of CC with PU implants and support that these implants are an effective alternative to textured devices, which have failed to attain the benefits of the foam. We advocate recommending PU foam–coated implants as a first choice for patients who undergo 2-stage breast reconstruction with adjuvant RT.

Disclosures

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