Risk Factor Analysis for Capsular Contracture: A 10-Year Sientra Study Using Round, Smooth, and Textured Implants for Breast Augmentation

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Background: Despite the increased understanding of surgical best practices, capsular contracture remains the most commonly reported complication and reason for reoperation following breast implant surgery. This study provides a long-term update to a previous investigation of potential contributing risk factors for capsular contracture in primary augmentation patients.
Methods: The data used for this analysis include 5,122 implants in 2,565 primary augmentation patients implanted by 34 surgeons based on long-term results from Sientra's clinical study. Potential risk factors, including patient and implant attributes, surgery characteristics, pocket irrigation, and postsurgery characteristics, were analyzed using frequency and multivariate models.
Results: A total of 333 capsular contracture events in 224 patients were reported. The overall Kaplan–Meier rate for capsular contracture was 10.8% by device through 10 years. Results from the multivariate analysis found 8 factors to be independently associated with capsular contracture (implant placement, implant surface, incision site, hematoma or seroma development, device size, surgical bra, steroid, and antibiotic pocket irrigation; all P values < 0.05). Results from correlation analysis found 2 of the 8 factors to be more strongly associated with early onset capsular contracture events, compared with those occurring after 2 and 5 years of implantation (implant surface and steroid pocket irrigation).
Conclusion: The results of this large-scale, multivariate analysis identified several significant risk factors for capsular contracture, including device features (smooth surface, smaller size), surgical factors (periareolar incision, subglandular placement, antibiotic irrigation), the development of hematoma/seroma, and the use of a surgical bra. (*Plast. Reconstr. Surg.* 141: 20S, 2018.)

Despite a reduction in capsular contracture rates resulting from increased adoption of best practices and textured devices,[1–3] capsular contracture remains the most commonly reported complication[4–8] and reason for reoperation following breast implant surgery. Multiple studies have attempted to elucidate the causation and etiology of capsular contracture. Frequently cited causes include infection, radiation, hematoma, and biofilm.[4,9,10] Indeed, an abundance of research suggests that the inadvertent introduction of bacteria at the time of breast implant surgery can over time lead to the occurrence of capsular contracture.[4,11,12] Other factors that

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may affect risk for capsular contracture include implant placement, incision site, and implant surface characteristics.

This report provides a long-term update to the 5-year capsular contracture risk factor analysis performed and published in 2013. The analysis reviews multiple patient and implant characteristics, including surgical techniques and postoperative protocols, to categorize which risk factors, at a later time point, affect the development of capsular contracture after primary breast augmentation.

PATIENTS AND METHODS

Patients

This analysis was based on long-term results from Sientra's Food and Drug Administration–approved, prospective, open-label, U.S.-based clinical study of the safety and effectiveness of silicone breast implants. Subjects were enrolled based on previously described inclusion and exclusion criteria,[10] and informed consent was obtained for all patients by the various surgeons under the institutional review board–approved protocol. The subset of data used for this analysis includes 5,122 implants in 2,565 primary augmentation patients, implanted by 34 plastic surgeons (median, 138.5 implants each). To provide a focused analysis, patients were excluded if they received shaped implants or had transaxillary or mastopexy incisions.

Data Collection

All patients were monitored at 1-year intervals (or more often, as needed) by their study surgeons, and the occurrence of capsular contracture was documented on study case report forms using the Baker Classification Scale. The study protocol included the definitions of the Baker Classification Scale to facilitate consistent data collection across study sites. All patients who developed Baker grade III and IV capsular contractures were included in this analysis. Potential patient- and device-related risk factors were collected on the study case report forms (Table 1).

Statistical Methods

Potential risk factors (Table 1) were analyzed for a possible association with capsular contracture. Continuous factors (ie, device size, patient age, and body mass index) were categorized into 2 groups based on their medians for analysis. Other factors were collected as binomial variables (present/not present), and analyzed as such. All factors (eg, smooth device, surgical bra) were used by at least 5 surgeons. Data were described using frequency and multivariate models. A covariate for implantation time was included, and multivariate generalized estimating equations were employed using the device as the unit of analysis; the potential correlation arising from bilaterally implanted patients was adjusted for in the analysis using PROC GENMOD in SAS (SAS Institute, Inc., Cary, N.C.). First, each factor was modeled individually to evaluate its association to capsular contracture, without adjusting for effects of other variables. Because individual models (exclusion of significant factors) can yield inaccurate estimates, while models with too many factors can yield imprecise estimates and possibly require complex interpretation, final factor identification was done via backward elimination. The initial model included all factors with individual model P values < 0.20, then factors were eliminated 1-by-1 based on their P values. The elimination process continued until only variables with $P < 0.05$ were present in the final multivariate model. Model fit was assessed using Quasi-likelihood under the independence model criterion (QIC),[14] where lower QIC score indicated better model fit.

Kaplan–Meier survival analysis was employed to describe the risk associated with the 2 strongest factors determined from the multivariate analysis through 5 and 10 years. The risk of capsular contracture was calculated within each subgroup of devices and presented with 95% confidence intervals (CIs).

Table 1. Risk Factors Analyzed

Category	Potential Risk Factor
Patient attributes	Age at implantation, body mass index
Device attributes	Surface characteristics (smooth or textured), device size
Surgery characteristics	Anesthesia (general or local), incision site (periareolar or inframammary), device placement (submuscular or subglandular), facility type (office or hospital/surgical center)
Pocket irrigation	Antibiotic, betadine, steroid
Postsurgery characteristics	Hematoma/seroma before capsular contracture, massage recommended, surgical bra used

RESULTS

Patients

Median patient age at the time of enrollment was 36 years (range, 18–66). The majority of patients were Caucasian, married, and had an annual household income > $60,000. The median body mass index was 20.8 kg/m^2 (range, 14.4–40.2). The majority of study patients had completed some college education and about half (48%) held a Bachelor's degree. All implants included in this analysis were round. Additional implant and surgical characteristics are listed in Table 2.

Capsular Contracture

A total of 333 capsular contracture events in 224 patients were reported (109 bilateral, 115 unilateral) through 10 years. Baker grade III capsular contractures were more common than Baker grade IV (85% versus 15%, respectively). Among those with resolution follow-up, 72% were resolved with treatment, 21% resolved without treatment, and 7% refused treatment. Nearly all the events that resolved with treatment (90%) involved a reoperation such as an open capsulotomy, capsulectomy, implant exchange, and/or implant removal without replacement. Other, less commonly employed treatments included closed capsulotomy, massage, and leukotriene modifiers.

Unadjusted Risk Factor Results

Unadjusted risk factor analysis was conducted to identify the individual risk factors for capsular contracture (Table 3). Eight factors were associated with increased odds for capsular contracture development, without adjusting for the effects of the other factors. Variables associated with significantly increased risk for capsular contracture in this unadjusted analysis were similar to those reported in the 5-year analysis and included smooth surface, periareolar incision, subglandular placement, antibiotic irrigation, massage recommended, and surgical bra used. Additional risk factors that attained significance in the current analysis included device size (≤ 355 cc) and hematoma/seroma before capsular contracture. One significant finding from the 5-year analysis, steroid pocket irrigation, was found to be of borderline significance in this analysis ($P = 0.0593$). The remaining factors, including patient age and body mass index, were not significant predictors of capsular contracture ($P = 0.94$ and $P = 0.25$, respectively).

Table 2. Device and Surgical Characteristics

Characteristic	Devices
Device attributes	
Surface characteristics	
Smooth round (%)	62
Textured round (%)	38
Device size	
Median size (cc)	355
Range (cc)	135–700
Surgery characteristics	
Incision site	
Periareolar (%)	29
Inframammary (%)	71
Device placement	
Subglandular (%)	56
Submuscular (%)	44

Multivariate Analysis Results

Of the 9 individual factors that met inclusion criteria for the multivariate model ($P < 0.20$), 8 were found to have sufficient statistical influence ($P < 0.05$) to be included in the final model (Table 4). Assessment of fit showed that QIC decreased, indicating improved model fit from the full model with all factors to the final model. After adjusting for the other variables in the multivariate model, the odds of developing capsular contracture was 4.6 times greater with implants placed in the subglandular position ($P < 0.0001$) and 4.5 greater with smooth implants ($P < 0.0001$). Other statistically significant findings were identified for prior hematoma/seroma development, surgical bra usage, incision site (inframammary/periareolar), antibiotic pocket irrigation, device size, and steroid pocket irrigation (Table 4). All multivariate findings were statistically significant at the alpha = 0.05 level.

Although steroid pocket irrigation was found to have an odds ratio (OR) of 1.5 in the unadjusted analysis (indicating a potential risk factor), it was found to be a significant protective factor (OR, 0.5) after controlling for the other factoring in the multivariate model. By modeling steroid use paired with each of the other 7 significant factors individually, the OR for steroid use ranged from 1.1 to 1.6. Adjusting for antibiotic usage resulted in the largest reduction of significance for steroid use (OR, 1.1; $P = 0.5834$). Table 5 reports the occurrence of capsular contracture by antibiotic and steroid use and shows that the highest percentage of implants with capsular contracture (12.5%) occurs when steroid pocket irrigation was used without antibiotic. However, this combination was rarely used (n = 8). The most common combination (n = 2,598, 50% of devices) was antibiotic pocket irrigation without steroid.

Table 3. Unadjusted Analysis of Potential Risk Factors

Characteristic	No. with Capsular Contracture (%)	Unadjusted OR (95% CI)	*P*
Patient attributes			
Age			
> 36 y	2,493 (6.4)	1.0 (0.74–1.33)	0.9398
≤ 36 y	2,629 (6.6)	1	
BMI			
≤ 21	2,692 (6.9)	1.2 (0.88–1.59)	0.2527
> 21	2,430 (6.1)	1	
Device attributes			
Surface characteristics			
Smooth	3,168 (8.2)	2.2 (1.58–3.08)	< 0.0001*
Textured	1,954 (3.7)	1	
Device size			
≤ 355 cc	2,683 (7.3)	1.3 (1.00–1.79)	0.0472*
> 355 cc	2,439 (5.6)	1	
Surgery characteristics			
Anesthesia			
General	3,831 (6.7)	1.1 (0.76–1.54)	0.6767
Local	1,291 (5.8)	1	
Incision site			
Periareolar	1,475 (8.7)	1.8 (1.31–2.43)	0.0002*
Inframammary	3,647 (5.6)	1	
Device placement			
Subglandular	2,266 (10.2)	2.8 (2.08–3.87)	< 0.0001*
Submuscular	2,856 (3.5)	1	
Facility type			
Physician's office	890 (8.3)	1.2 (0.87–1.74)	0.2455
Hospital/surgical facility	4,232 (6.1)	1	
Pocket irrigation			
Antibiotic			
Yes	3,100 (7.8)	2.2 (1.56–2.99)	< 0.0001*
No	2,022 (4.5)	1	
Betadine			
Yes	537 (4.7)	0.8 (0.45–1.27)	0.2916
No	4,585 (6.7)	1	
Steroid			
Yes	510 (9.4)	1.5 (0.98–2.30)	0.0593
No	4,612 (6.2)	1	
Postsurgery characteristics			
Hematoma/seroma before capsular contracture			
Yes	38 (18.4)	2.9 (1.32–6.45)	0.0083*
No	5,084 (6.4)	1	
Massage recommended			
Yes	2,798 (8.5)	2.0 (1.45–2.71)	< 0.0001*
No	2,324 (4.1)	1	
Surgical bra used			
Yes	3,688 (7.8)	2.7 (1.78–4.11)	< 0.0001*
No	1,434 (3.2)	1	

*Statistically significant at the alpha = 0.05 level.
BMI, body mass index.

Table 4. Multivariate Risk Factor Analysis for Capsular Contracture

Characteristic	Adjusted OR (95% CI)	*P*
Subglandular placement	4.6 (3.22–6.64)	< 0.0001*
Smooth surface	4.5 (3.00–6.71)	< 0.0001*
Hematoma/seroma before capsular contracture	3.7 (1.53–9.11)	0.0039*
Surgical bra used	2.5 (1.59–4.06)	< 0.0001*
Periareolar incision site	2.2 (1.52–3.19)	< 0.0001*
Antibiotic pocket irrigation	1.6 (1.11–2.26)	0.0109*
Device size ≤ 355 cc	1.4 (1.05–1.96)	0.0245*
Steroid pocket irrigation	0.5 (0.29–0.84)	0.0099*

*Statistically significant at the alpha = 0.05 level.

Table 5. Capsular Contracture by Steroid and Antibiotic Pocket Irrigation

Pocket Irrigation	No. Devices	No. with Capsular Contracture (%)
With steroid		
Antibiotic, yes	502	47 (9.4)
Antibiotic, no	8	1 (12.5)
Without steroid		
Antibiotic, yes	2,598	196 (7.5)
Antibiotic, no	2,014	89 (4.4)

Table 6. Five-Year and Ten-Year Kaplan–Meier Rates for Capsular Contracture, by Device Surface and Placement

Characteristic	No. Devices	5 y		10 y	
		No. with Capsular Contracture	KM (95% CI)	No. with Capsular Contracture	KM (95% CI)
Overall	5,122	266	6.8 (6.0–7.6)	333	10.8 (9.6–12.1)
Smooth surface					
Subglandular	972	141	19.3 (16.6–22.4)	172	29.4 (25.2–34.0)
Submuscular	2,194	73	4.3 (3.4–5.4)	89	6.4 (5.1–8.0)
Textured surface					
Subglandular	1,294	44	4.4 (3.3–5.9)	60	8.6 (6.5–11.4)
Submuscular	660	8	1.8 (0.9–3.6)	12	3.6 (1.9–6.7)

KM, Kaplan–Meier.

Kaplan–Meier Analysis

Based on the multivariate analysis, the 2 strongest factors contributing to the development of capsular contracture were subglandular placement and smooth surface. Overall, the Kaplan–Meier rate for capsular contracture was 10.8% (95% CI, 9.6–12.1). Within this overall 10.8%, 4 Kaplan–Meier subset analyses were created. The subset analyses of capsular contracture by device surface and placement are described in Table 6. In these analyses, implants in the submuscular position had the lowest rates of capsular contracture at 10 years, regardless of smooth or textured surface (6.4% and 3.6%, respectively).

Time to Capsular Contracture Occurrence

Almost half of the capsular contractures (41%) occurred within the first 2 years of implantation, and 80% within the first 5 years (Fig. 1). Capsular contracture was assessed by surgical characteristics and onset timing: early (< 2 years) 41%, middle (2–5 years) 38%, and late (> 5 years) 21% percent. Two factors were statistically significantly associated with event timing: smooth surface and steroid pocket irrigation ($P = 0.0069$ and 0.0023, respectively; Table 7).

Surgeon-Focused Analyses

Examination of factors by surgeon showed that many surgeons' implantation technique, device choice, and postoperative care recommendations were the same for almost all their patients. For example, 85% of surgeons predominately used only 1 type of device shell (21 surgeons used smooth implants in over 95% of their implantations, and 8 used textured in over 95% of their implantations). Only 4 surgeons in our analysis employed all 4 combinations of implant surface (smooth/texture) and placement (subglandular/submuscular). Similarly, the use of surgical bra and antibiotic was consistent within each surgeon's data. For example,

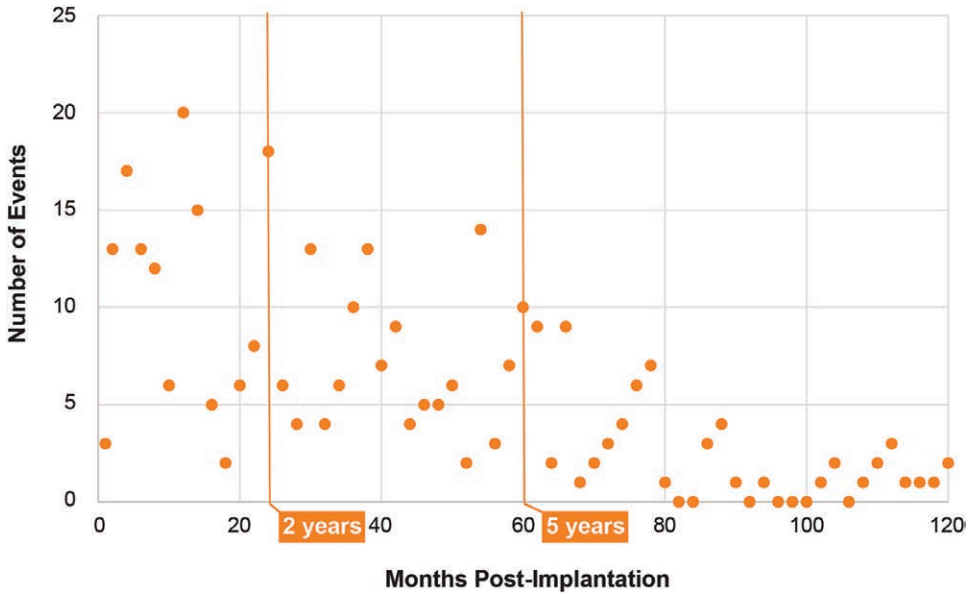


Fig. 1. Frequency/number of capsular contracture event by time postimplantation.

Table 7. Capsular Contracture Occurrence by Surgical Characteristics and Timing

Characteristic	Time of Capsular Contracture Onset*			
	Early (N = 138)	Middle (N = 128)	Late (N = 67)	*P*
Subglandular (%)	72	67	70	0.6895
Smooth (%)	86	75	70	0.0069†
Surgical bra used (%)	81	95	81	0.5026
Hematoma/seroma before capsular contracture (%)	3	1	3	NR
Device size ≤ 355 cc (%)	62	52	66	0.9074
Periareolar incision site (%)	32	46	37	0.2168
Antibiotic pocket irrigation (%)	69	80	69	0.6465
Steroid pocket irrigation (%)	21	12	6	0.0023†

*Early: within the first 2 years of implantation, Middle: between 2 and 5 years of implantation, and Late: after 5 years of implantation.
†$P < 0.05$; Mantel-Hanszel test for association between characteristic and timing of capsular contracture.
NR, not reported due to small sample.

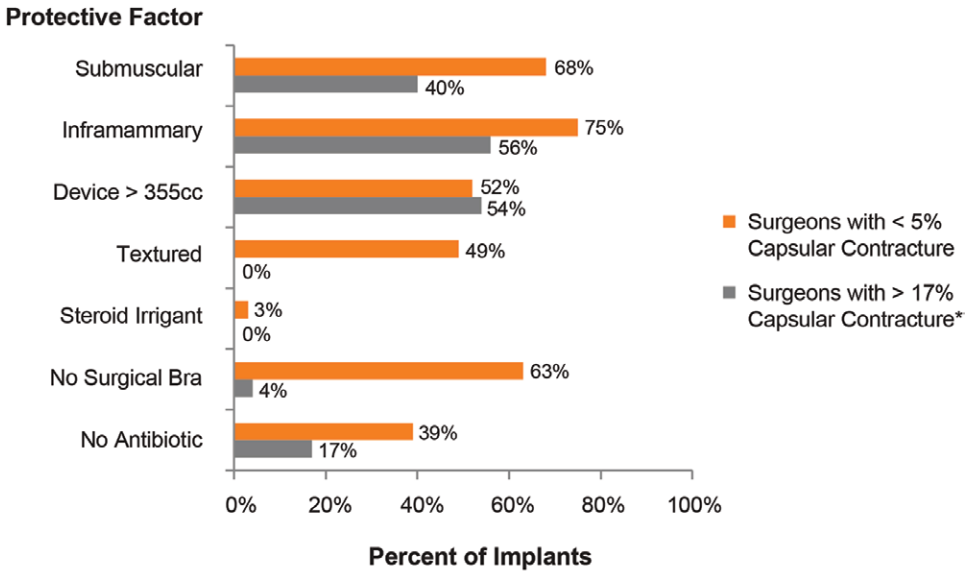
23 surgeons recommended surgical bra in over 95% of their implantations; 17 of those surgeons recommended surgical bra to 100% of their study patients. Seventeen surgeons used antibiotic pocket irrigation in over 90% of their implantations.

Because the previous analysis revealed "common practices" by surgeon, surgeon-specific incidence of capsular contracture as it related to the significant factors (surgical and postoperative practices) was investigated. This analysis was performed using only high volume sites (implanted > 100 devices, 19 sites). Analysis revealed clear differences in device/surgical practices between surgeons with high versus low incidence of capsular contracture. Three surgeons accounted for 54% of the reported capsular contractures within high volume sites, but enrolled only 15% of the devices (Fig. 2). These surgeons used only smooth implants (100%), and more than half of the devices were placed subglandularly (60%).

Conversely, the surgical and postoperative practices of surgeons with low capsular contracture incidence (< 5% each) used smooth implants and the subglandular placement less often. Almost all other protective factors from the multivariate analysis were more common among the surgeons with low capsular contracture rates, except for device size.

DISCUSSION

In this analysis of long-term follow-up data from a large, prospective clinical study, significant risk factors for capsular contracture included



* Three surgeons had >17% capsular contracture; this contributed over 50% of all capsular contractures.

Fig. 2. Distribution of protective factors, by surgeon-specific capsular contracture incidence.

implant placement (submuscular/subglandular), implant surface (smooth/textured), incision site (periareolar/inframammary), device size (≤ 355 cc/> 355 cc), hematoma/seroma before capsular contracture, and use of a surgical bra. These risk factors are consistent with those identified on multivariate analysis of 5-year data from this study population.[10] The diversity of risk factors also highlights the multifactorial nature of risk for capsular contracture, and the influence of any single risk factor must be balanced against risk for other outcomes for individual patients. Indeed, analysis by surgeon practice suggested that the practice patterns of individual surgeons can have a large impact on contracture risk. In the analysis of large-volume sites, a small number of surgeons with certain common practices accounted for a large proportion of cases of capsular contracture. These practices included use of smooth implants and recommendations to use a surgical bra (hypothesized to increase compression for smooth implant cases). Therefore, it may be assumed that surgical bra usage is simply correlated with a strong risk factor (ie, smooth implants), and hence carries no increased risk on its own. However, the overall analysis dataset included more than 1,000 smooth devices without the surgical bra recommendation. This means that the significant finding for surgical bra (from the multivariate model) is a risk factor on its own, and not simply due to a correlation. Because by definition, the multivariate risk analysis has adjusted for the effects of all other variables in the analysis (including smooth).

Other reports have consistently described reduced risk for capsular contracture associated with factors such as textured implants, submuscular implant placement, and inframammary incision sites.[2,3,6,15,16] Very little data exist describing a relationship between implant size and capsular contracture risk. One prospective registry study of 2,277 women undergoing cosmetic breast augmentation found that implant size > 350 cc was associated with increased risk for contracture (relative risk, 2.2; 95% CI, 1.3–4.0).[17] When considering only Baker grade III/IV contracture in this study, however, the relationship was no longer statistically significant. The results of this study found a reduced capsular contracture rate associated with larger implants. In the authors' experience, one proposed mechanism is an observation that very tight skin envelopes can impede implant mobility leading to capsular contractures. The skin envelopes accommodate only smaller sized implants, whereas the looser breast envelopes are more likely to have larger implants placed with increased mobility and lower capsular contracture rates. The larger implants may in fact stretch the pocket more over time due to the implant size, reducing pocket tightness and capsular contracture deformity.

Analysis of the timing of capsular contracture demonstrated that most cases (80%) occurred within 5 years, and nearly half (41%) within 2 years, of the augmentation procedures. This finding suggests that women can be counseled to expect reduced risk for capsular contracture over time. However, it has been previously suggested that the majority of capsular contracture occurred in the first year, and the findings of this study clearly demonstrates the ongoing risk over the first 5 years (80%), with approximately half (41%) in the first 2 years and the other half (39%) occurring over the next 3 years. It also suggests that certain factors may have greater impact on contracture risk, and therefore lead to more events early after surgery. By defining categories of timing of contracture events (< 2 years, 2–5 years, > 5 years), the analysis identified 2 risk factors significantly associated with earlier occurrence: smooth surface and steroid pocket irrigation (Table 7). It may be that these factors have more immediate effects on capsule formation, whereas other risk factors, such as subglandular placement, may exert effects over time.

The potential influence of steroid irrigation of the pocket was an unexpected finding. Steroid use had a protective effect on multivariate analysis (OR, 0.5; $P = 0.0099$; Table 4), but was associated with earlier incidence of contracture events. It must be noted that steroid irrigation was used in < 10% of all implants, and the decision to use steroids is likely influenced by a number of patient or surgical factors that may confound this putative relation. Because of this small sample size and potential confounders, conclusions regarding the influence of steroids on capsular contracture cannot be made based on the current dataset.

One additional potential risk factor identified on multivariate analysis of this long-term dataset was the use of antibiotic irrigation of the implant pocket (OR, 1.6; $P = 0.0109$; Table 4). Examples of the types of antibiotics most commonly reported were cefazolin, bacitracin, gentamicin, and vancomycin. Capsular contracture is commonly believed to involve excessive fibrotic foreign body reaction to the implant, with a central role of the immune system.[4] It has been proposed that the presence of hematoma,

infection, or biofilm may trigger an exaggerated inflammatory response, potentially leading to excessive capsule formation.[18–20] Despite evidence suggesting an association between bacterial colonization or biofilm and capsular contracture, and multiple early published studies demonstrating lower capsular contracture rates leading to the popularization of antibiotic pocket irrigation,[21–23] decreased risk for capsular contracture has not been demonstrated in this study. Consistent with our findings, a recent meta-analysis of 8 studies found significantly increased risk for capsular contracture associated with antimicrobial irrigation (OR, 2.60; 95% CI, 2.3–2.94; $P < 0.00001$).[24] However, there have been recent reports on the relationship between antibiotic pocket irrigation and capsular contracture with inconsistent findings. One study reported reduced risk for capsular contracture with topical antibiotic irrigation.[25] Other cohort studies directly comparing antibiotic irrigation to saline irrigation and controlling for other surgical factors found no difference in capsular contracture rates between groups.[26,27] While our data suggest that antibiotic irrigation may be associated with risk for capsular contracture, it is possible that other correlated surgical or patient factors influence contracture risk. For example, nipple shields, insertion sleeves, and minimal handling may have been more effective in reducing capsular contracture risk than antibiotic pocket irrigation. Therefore, the role of prophylactic antibiotics in capsular contracture remains uncertain. Given this uncertainty, some of the authors continue to employ the 14 Point Plan[11] in their surgical practices; this includes 1 g cefazolin, 50,000 IU bacitracin, and 80 mg gentamicin mixed in 500 cc normal saline for pocket irrigation in most patients.

Limitations

The limitations of this study were described in depth in previous reports.[10] Briefly, these limitations include the nonrandomized design and the exclusion of some potential risk factors (eg, genetic disposition, nipple shields, and blood loss).[28–31] It should be noted that the 2 postoperative recommendation factors (surgical bra and massage) are limited and that avoidance of these measures at this time is premature. These findings were based on surgeon recommendation and not on patient compliance. The utilization of a postsurgical support or massage requires further investigation before any final recommendations can be made.

CONCLUSIONS

The results of this long-term, large-scale, multivariate analysis identified several significant risk factors for capsular contracture following primary breast augmentation. These factors include device features (smooth surface, smaller size), surgical factors (periareolar incision, subglandular placement, antibiotic irrigation), the development of hematoma/seroma, and the use of a surgical bra. Many of these risk factors have been reported by other studies, and the results of this analysis contribute to surgeons' knowledge and ability to individualize preoperative planning for breast augmentation. In particular, this analysis supports the conclusions of previous reports, which provided compelling evidence that textured implants and submuscular placement can significantly reduce the incidence of this important complication. Further research is required to more clearly elucidate the roles of antibiotic and steroid irrigation, device size, and surgical bra use on risk for capsular contracture. A reduction in bioburden has been associated with lower capsular contracture, and it is possible those surgeons forgoing antibiotic irrigation employed other maneuvers to limit bioburden. The 14 Point Plan for reduction in bacteria at the time of implant placement reinforces that this concept includes critical steps to reduce the bacterial load.[11] This study further solidifies the multifactorial nature of capsular contracture and reinforces the importance of sound science into sound surgical technique in all portions of the procedure.

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