

Smooth versus Textured Implants and Their Association with the Frequency of Capsular Contracture in Primary Breast Augmentation

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Background: Capsular contracture is the most frequent complication of breast implant augmentation. Although studies indicate that textured implants have a low incidence of contracture, they have been associated with anaplastic cell lymphoma, which influences the choice of surface. This study estimated and compared the annual capsular contracture rate of both smooth and textured implants in primary breast implants.

Methods: Two hundred fifty-three patients (506 implants) were evaluated from January of 2017 to July of 2019; 42.2 percent of the implants were smooth and 57.8 percent were textured. The inframammary approach was used in the subfascial (55.3 percent) and submuscular (44.7 percent) pockets. The primary outcome was the appearance of capsular contracture (Baker grade II, III, and IV) within the first postoperative year.

Results: Smooth implants had a higher capsular contracture rate at 1 year postoperatively compared with textured implants, although with borderline statistical significance ($p = 0.06$). Smooth surface breast implants in the subfascial plane had a 4-fold higher risk of contracture than those with a textured surface in the same plane (OR, 4.4; 95 percent confidence interval, 1.6 to 12.4). However, when placed in the submuscular plane, both textures had a similar contracture risk. The rate of contracture was similar after 2 years postoperatively ($p = 0.21$).

Conclusions: Using the inframammary approach and a standardized technique, there were no significant differences in the incidence of capsular contracture between the smooth and textured implants. In the subfascial plane, the contracture rate with smooth implants was higher than with textured implants. However, in the submuscular plane, there was no difference between the surfaces. (*Plast. Reconstr. Surg.* 149: 373, 2022.)

CLINICAL QUESTION/LEVEL OF EVIDENCE: Therapeutic, III.

According to the latest report from the International Society of Aesthetic Plastic Surgery, breast implant augmentation was the most common plastic surgery operation worldwide in 2018, with almost 2 million procedures performed.¹ Among these, capsular contracture is the most commonly reported complication, with the highest morbidity and reintervention rate.²⁻⁴

The prevalence of capsular contractures varies from 0.5 to 30 percent and depends on multiple

factors, such as the type of implant; the type of surgery; preoperative, intraoperative, and postoperative surgical procedures; and other unidentified factors.^{3,5-11}

Most breast implant studies have been oriented to determine and reduce the incidence of complications, specifically, capsular contracture.¹²⁻¹⁷ Current research on textured implants suggested an association with the development of anaplastic large cell lymphoma.¹⁸⁻²⁰ As of September 22, 2020, the American Society of Plastic Surgeons confirmed 964 cases of breast implant-associated anaplastic large-cell lymphoma (BIA-ALCL)

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worldwide.²¹ Consequently, surgeons reconsidered the use of implants with this type of surface and increased the medical recommendation for smooth implants.^{22–24} The objective of this study was to compare the capsular contracture rate in patients with primary breast smooth and textured implants, placed in subfascial or submuscular pockets, at 12- and 24-month follow-up using an inframammary approach.

PATIENTS AND METHODS

A nonrandomized analytical retrospective study was conducted with women who underwent primary cosmetic surgery for bilateral augmentation mammoplasty between January of 2017 and July of 2019. Of 458 women registered during the period, 253 met the inclusion criteria.

All patients were operated on by two of the authors of this article (G.F.S. and S.F.) using the same surgical technique. The operations were performed at the Centro Quirúrgico Rosario and the Sanatorio de la Mujer, both in Rosario, Argentina, after patients signed the corresponding written informed consent form. The study was performed in accordance with the Declaration of Helsinki and guidelines for Good Clinical Practice.

Inclusion criteria consisted of women older than 18 years who underwent inframammary primary cosmetic surgery with implants containing cohesive silicone gel, with a smooth or textured surface, placed in the subfascial or retropectoral plane (total or dual-plane). Exclusion criteria consisted of patients with prior breast augmentation, history of surgery or previous breast abnormalities, tuberos breasts, breast ptosis, combined operations, or patients in whom the areolar approach was used.

To calculate the sample size, it was considered that the capsular contracture rate of smooth and textured implants within 1 year was approximately 19 percent, with no significant differences between the two types of surface.²⁵ Considering a margin of error (5 percent) and minimal rate variation ($d = \pm 0.2$ percent), it should be necessary to include approximately 250 implants.

Two hundred fifty-three patients (506 implants) were included in the study; 107 patients received implants with a smooth surface and 146 received implants with a textured surface. The brands used were Mentor (Irvine, Calif.), Nagor (GC Aesthetics, Glasgow, United Kingdom), Allergan (Dublin, Ireland), Polytech (Dieburg, Germany), and Eurosilicon (GC Aesthetic; Apt, France). The shape of the implants was round or anatomical and they had textured or smooth surfaces. The choice of the implant was a shared

decision between the patient and surgeon after evaluating the advantages and disadvantages on a case-by-case basis.²⁶ The choice of implant placement plane was made through an ultrasound study of the thickness of the tissues that remained above the implant, known as an upper pole Ecotest, described by the authors, in addition to the classic “pinch test.”²⁷

Surgical Technique

All patients took a shower with chlorhexidine gluconate at the night and morning before surgery. Intravenous cephalothin (2 g) was administered 1 hour before surgery and nipple shields (Tegaderm; 3M, St. Paul, Minn.) were used. Infiltration was performed with local anesthesia (40 ml of lidocaine with 2% epinephrine, 400 ml of physiologic solution, and 1 mg/liter of epinephrine) plus intravenous sedation and laryngeal mask.

A 4.5-cm incision was made in the inframammary fold using a no. 11 scalpel. Gentle atraumatic pocket dissection was performed using an electrosurgical unit with a cutting function. Rigorous hemostasis while avoiding the dissection of the mammary parenchyma was maintained. The pocket was packed with a wet gauze with saline solution and the contralateral procedure was performed in the same manner. Blood pressure was increased by 10 mmHg above that at admission to the operating room to maintain hemostasis. Pocket irrigation was performed using 150 ml of physiologic saline solution. Sizers were not used. Disinfection of the inframammary region was performed using an antiseptic (Pervinox; Laboratorio Elea Phoenix S.A., Buenos Aires, Argentina), and contamination was prevented by changing and washing gloves. The implant was irrigated with a saline solution before opening, and the implant packaging was opened immediately before placement. Drainage was not performed routinely. In patients in whom the submuscular pocket and smooth implants were used, the inframammary fold was fixed with 3-0 mononylon nonabsorbable sutures to avoid descent because of the force of the muscle. In a dual-plane, a technique described by Tebbetts²⁸ and modified by Ventura et al. was used, where the implant is covered by the pectoralis major on its upper pole and by the fascia on the lower pole.²⁹ The inframammary fold incision was closed in a multilayer fashion.

Indications

Twice-daily cefadroxil (500 mg) and diclofenac (50 mg) combined with acetaminophen (400 mg) for 5 days were prescribed. In addition,

the patients were required to wear a compressive bandage for 48 hours and a sports bra for 30 days after surgery. Physical exercise was prohibited for 1 month.

Sixty patients (23.7 percent) received preventive treatment with montelukast (Montrate, Casasco, Argentina), a selective leukotriene receptor antagonist, 10 mg once per day for 1 month and underwent 10 ultrasound sessions after 1 month. Complications related to capsular contracture (e.g., seroma, hematoma, infection, and rupture) were quantified. Controls were performed and recorded at 2-, 7-, 14-, 30-, and 60-day follow-up, and then again at 3, 6, and 12 months, with a follow-up ultrasound. Of 164 patients operated on before August 1, 2018, 162 underwent a clinical ultrasound control at 24 months.

The primary outcome was the appearance of capsular contracture within the first year, staged as grade II, III, or IV according to the Baker classification (Table 1).³⁰ We included Baker grade II because we believe that including specially in the submuscular space could lead to diagnostic errors because of increased muscle thickness and subjectivity of the classification method. Despite the authors' experience of more than 20 years (G.F.S. and S.F.), diagnosis continues to be a problem specifically at Baker grade II. Ultrasound elastography could have been useful for more objective classification of capsular contracture after breast augmentation, but in our institution, this diagnostic method is not currently available.³¹

Statistical Analysis

For data collection, an Excel (Microsoft Corp., Redmond, Wash.) spreadsheet was prepared, in which the following variables were recorded: identification data, age, anatomical placement plane (subfascial, submuscular, dual-plane), placement of drainage tubes, and implant

characteristics (brand, size, shape, volume, and surface). Likewise, major complications (hematoma, seroma, infection, implant rupture, and capsular contracture), preventive treatments, history of smoking, diabetes, and postoperative controls were also recorded.

The statistical analysis was performed using IBM SPSS Version 21.0 (IBM Corp., Armonk, N.Y.). All the patient data were anonymized to perform data analysis.

Every variable was tested with the Shapiro-Wilk test. Then, a univariate descriptive study of patients was carried out. Furthermore, a bivariate study comparing the two surfaces was performed, estimating the chi-square test or Fisher's test when corresponding. A comparison of capsular contracture rate during follow-up was evaluated estimating the odds ratios and their 95 percent confidence intervals. Considering the univariate variables associated with implant surface, we also performed an adjusted comparative analysis of contracture rate at 1-year and 2-year follow-up. In all cases, the level of statistical significance was 5 percent ($p < 0.05$).

RESULTS

Univariate Analysis

Five hundred six implants placed in 253 women were included in the study. The mean age of the patients was 33.5 ± 0.5 years (range, 18 to 58 years). The mean implant size was 350 cc (range, 240 to 520 cc); 42.2 percent of the implants had a smooth surface ($n = 214$) and 57.8 percent were textured ($n = 292$). In addition, 93 percent (470) were round and 7 percent ($n = 36$) were anatomical. The implants were placed in the subfascial plane in 140 procedures (55.3 percent), 102 (40.3 percent) were placed in a dual-plane, and 11 (4.4 percent) were placed in the total subpectoral plane. None of them were placed in the subglandular plane. The immediate postoperative complication rate was 9.5 percent (48 of 506). Six breasts (three patients had bilateral) had seroma and wound dehiscence (1.1 percent); 16 breasts had hematomas (3.1 percent) (13 were surgically drained, two spontaneously drained, and one was reabsorbed); and five patients (1 percent) had unilateral infection and were treated with broad-spectrum antibiotics and underwent implant preservation. There were no implant ruptures or BIA-ALCL in the period evaluated. Of the 21 breasts (4.1 percent) that developed capsular contracture during the postsurgical year of follow-up, nine (42.9 percent) breasts had experienced

Table 1. Baker Classification Scale

Grade	Degree of Contracture	Description
I	Absolutely normal breast	Tender to palpation; implant not palpable or visible
II	Minimal	Greater breast firmness than desired; implant palpable but not visible. The patient may notice a slight increase in tenderness but no symptoms.
III	Moderate	Moderate breast firmness; implant easily palpable. Visible breast deformity is perceived by the patient.
IV	Severe	Severe breast firmness; breast pain, distortion, and marked deformity perceived by the patient.

previous complications typical of the surgery (i.e., hematoma, seroma, and infection) (Table 2).

When the nine breasts with capsular contracture (caused by apparent complications such as hematoma, seroma, or infection) were excluded, the percentage of capsular contractures per se was 2.3 percent instead of 4.1 percent. At 1-year follow-up, nine patients showed unilateral and six showed bilateral capsular contracture, with a total of 21 breasts (4.1 percent) (Baker grade II, $n = 15$; Baker grade III, $n = 3$; and Baker grade IV, $n = 3$). Seven patients were smokers and none had diabetes.

The three breasts with Baker grade IV capsular contracture had hematoma as a postoperative complication. Total capsulectomies were performed and smooth devices replaced; one of them was changed to subpectoral pocket and two implants remained in the same subpectoral plane. Two of the three breasts with Baker grade III capsular contracture underwent complete capsulectomy, replaced with new implants with the same surface (textured and smooth, respectively), one remained the same (dual-plane), and the other was changed to the subpectoral plane. The last case was not operated on.

Ten sessions of ultrasound and montelukast for 2 to 4 months were indicated for the patients with Baker grade II and grade III capsular contracture. The same preventive treatment was carried out in the reoperations. Mesh was not used in any patient. After 2 years of follow-up, of 162 patients (324 breasts), nine had unilateral capsular contracture and two had bilateral contracture, with a total of 13 breasts (4 percent) (Baker grade II, $n = 8$; Baker grade III, $n = 2$; and Baker grade IV, $n = 3$).

Two breasts reversed to Baker grade II at 2 years in response to ultrasound and montelukast treatment. Five Baker grade III and IV breasts underwent reoperation. Total capsulectomy was performed, and the capsules were sent to the pathology and bacteriology departments. All cultures were negative for germs and fungi, and the biopsy specimens did not show neoplastic cells. Three breasts maintained their capsular contracture because the patients did not consider the replacement aesthetically necessary. Eleven breasts that developed capsular contracture at 1-year follow-up could not be evaluated because they had not completed the 2 years postoperatively yet. No patient developed a recurrent contracture until 2-year evaluation.

Bivariate Analysis: Smooth versus Textured Implants

We compared the clinical and perioperative characteristics of patients who received breast implants with a smooth or textured surface

(Table 3). Our findings showed that textured implants were mostly placed in the subfascial plane, and that patients with smooth implants underwent preventive postoperative treatment with a significantly higher frequency.

The general postoperative complication rate (i.e., hematoma, seroma, and infection) was similar with both types of breast implant surfaces. At 1-year follow-up, smooth implants had a higher capsular contracture rate than textured implants, but with borderline statistical significance ($p = 0.06$). At 2-year follow-up, the rate was similar ($p = 0.12$) (Table 4). Annual capsular contracture risk was quantified considering some important characteristics of breast implants and surgery (Table 5). The results of the analysis showed the following:

1. Smooth and textured implants had a similar annual capsular contracture risk in round profile, without statistical significance ($p = 0.12$). Anatomical profile could not be evaluated.
2. When a smooth implant was placed in the subfascial plane, it had a risk of capsular contracture four times higher than the textured implant in the same plane (OR, 4.4; 95 percent CI, 1.6 to 12.4). However, when the implants were placed in the subpectoral plane, both textures had a similar capsular contracture risk ($p = 0.84$).
3. When implants had a postoperative complication, those with a smooth surface had a risk of capsular contracture eight times higher than textured implants (OR, 8.4; 95 percent CI, 1.3 to 56.1). When implants had no postoperative complications, the capsular contracture rate was independent of the implant surface ($p = 0.39$).

Of 60 patients who received preventive treatment with montelukast and ultrasound, the capsular contracture ratio was similar between the smooth and textured implants (13 of 88 and four or 32 at 1-year follow-up, respectively; $p = 0.75$ using the chi-square test).

The biannual risk of capsular contracture considering several characteristics of the breast implant and surgery was quantified (Table 6). The results of the analysis showed the following:

1. Smooth and textured implants had a similar capsular contracture risk in round profile, without statistical significance ($p = 0.21$). Anatomical profile could not be evaluated.

Table 2. Clinical and Surgical Characteristics of Cases with Capsular Contracture

Patient	CC	Age (yr)	Smoking	DM	Side	Implant Shape	Implant Volume (cm ³)	Implant Surface	Pocket Location	Surgical Complications	POP Prevention Treatment	3-Mo Control	6-Mo Control	12-Mo Control	24-Mo Control
1	1	32	No	No	Right	Round	350	Texture	Subfascial	No	US + montelukast	Baker II	Baker II	Soft	Soft
2	2	29	No	No	Left	Round	350	Texture	Subfascial	No	US + montelukast	Baker II	Baker II	Soft	Soft
3	3	25	No	No	Left	Round	310	Texture	Dual plane	No	No	Soft	Soft	Baker II	Baker II
4	4	35	No	No	Right	Round	330	Texture	Subfascial	Infection	No	Soft	Soft	Baker II	Baker II
5	5	35	No	No	Right	Round	340	Texture	Subfascial	No	US + montelukast	Baker II	Baker II	Baker II	Soft
6	6	43	No	No	Left	Round	375	Texture	Subfascial	Infection	US + montelukast	Baker II	Baker II	Soft	Baker IV
7	7	38	No	No	Right	Round	420	Texture	Subfascial	No	US + montelukast	Soft	Soft	Soft	Baker III
8	8	33	No	No	Right	Round	390	Texture	Subfascial	Hematoma	No	Soft	Soft	Soft	Baker III
9	9	37	Yes	No	Right	Round	350	Texture	Subfascial	Seroma	US + montelukast	Baker II	Baker II	Baker II	Baker II
10	10	33	No	No	Right	Round	390	Texture	Subfascial	Hematoma	No	Soft	Soft	Baker III	Baker III
11	11	40	No	No	Left	Round	420	Texture	Subfascial	No	US + montelukast	Soft	Soft	Baker II	Cx <24 mo
12	12	54	Yes	No	Right	Round	330	Texture	Subfascial	No	No	Soft	Baker II	Baker II	Cx <24 mo
13	13	20	No	No	Right	Round	300	Smooth	Subfascial	No	US + montelukast	Soft	Baker III	Baker III	Baker III
14	14	25	No	No	Left	Round	330	Smooth	Subfascial	No	US + montelukast	Soft	Soft	Baker II	Baker II
15	15	30	Yes	No	Right	Round	420	Smooth	Subfascial	No	US + montelukast	Soft	Soft	Soft	Baker II
16	16	30	Yes	No	Left	Round	390	Smooth	Submuscular	No	US + montelukast	Soft	Baker II	Soft	Soft
17	17	37	Yes	No	Right	Round	375	Smooth	Subfascial	Hematoma	US + montelukast	Soft	Baker II	Baker IV	Baker IV
18	18	20	Yes	No	Left	Round	375	Smooth	Subfascial	Hematoma	US + montelukast	Soft	Baker II	Baker III	Baker IV
19	19	27	Yes	No	Left	Round	330	Smooth	Subfascial	No	US + montelukast	Baker II	Baker II	Baker II	Cx <24 mo
20	20	27	Yes	No	Right	Round	425	Smooth	Subfascial	No	US + montelukast	Soft	Baker II	Baker II	Cx <24 mo
21	21	46	No	No	Left	Round	425	Smooth	Subfascial	No	US + montelukast	Soft	Baker II	Baker II	Cx <24 mo
22	22	46	No	No	Right	Round	300	Smooth	Subfascial	Hematoma	US + montelukast	Baker IV	Baker IV	Baker IV	Cx <24 mo
23	23	58	No	No	Left	Round	300	Smooth	Dual plane	Hematoma	US + montelukast	Baker IV	Baker IV	Baker IV	Cx <24 mo
24	24	42	No	No	Right	Round	400	Smooth	Dual plane	No	US + montelukast	Baker III	Baker III	Baker II	Cx <24 mo
25	25	42	No	No	Left	Round	300	Smooth	Subfascial	No	US + montelukast	Soft	Baker II	Baker II	Cx <24 mo
26	26	42	No	No	Right	Round	300	Smooth	Subfascial	Hematoma	US + montelukast	Soft	Baker II	Baker II	Cx <24 mo
27	27	42	No	No	Left	Round	300	Smooth	Subfascial	Hematoma	US + montelukast	Soft	Baker II	Baker II	Cx <24 mo
28	28	42	No	No	Right	Round	300	Smooth	Subfascial	Hematoma	US + montelukast	Soft	Baker II	Baker II	Cx <24 mo
29	29	42	No	No	Left	Round	300	Smooth	Subfascial	Hematoma	US + montelukast	Soft	Baker II	Baker II	Cx <24 mo

CC, capsular contracture; DM, diabetes mellitus; POP, postoperative; US, ultrasound; Cx, surgery.

Table 3. Comparison of the Clinical and Surgical Characteristics of Patients Who Received Smooth or Textured Surface Breast Implants

	Smooth Implants (%)	Textured Implants (%)	<i>p</i> *
No.	107	146	
Patient age, yr			0.87 (NS)
Mean $\pm$ SEM	33.5 $\pm$ 0.8	33.4 $\pm$ 0.7	
Median	34	33	
Range	19–58	18–56	
Pocket plane			0.000004
Subfascial	44 (41.2)	96 (65.8)	
Total subpectoral	11 (10.3)	—	
Dual plane	52 (48.6)	50 (34.2)	
Implant shape			0.0002
Round	107 (100)	128 (87.7)	
Anatomical	—	18 (12.3)	
Implant volume, cc			0.88 (NS)
200–300	25 (23.3)	27 (18.5)	
301–400	74 (69.2)	103 (70.5)	
401–500	7 (6.5)	6 (4.0)	
>500	1 (1.0)	—	
Preventive POP treatment			0.0000003
Yes	44 (41.1)	16 (11)	
No	63 (58.9)	130 (89)	

NS, not significant; POP, postoperative.

* χ^2 test, except for age, where the Z-normal test was used.

- When the implants were placed in the subfascial plane, the risk of capsular contracture of the smooth implants was four times higher than textured implants in the same plane (OR, 4.1; 95 percent CI, 1.2 to 13.2). However, when the implants were placed in the subpectoral plane, both surfaces had a similar capsular contracture risk ($p = 0.68$).
- Both surfaces showed a similar risk of postoperative complications (i.e., hematoma, seroma, and infection) ($p = 0.63$). In addition, patients with smooth implants without postoperative complications had a seven times higher risk of capsular contracture

Table 4. Comparison of Complications between Smooth and Textured Implants

	Smooth Surface (%)	Textured Surface (%)	<i>p</i> *
No. of breasts	214	292	
No complications	203	276	
Common complications	11	16	0.87 (NS)
Seroma	—	6	
Hematoma	11	5	
Infection	—	5	
Rupture	—	—	
BIA-ALCL	—	—	
Capsular contracture			
12 POP mo	13/214 (6.1)	8/292 (2.7)	0.06 (NS)
24 POP mo†	6/80 (7.5)	7/244 (2.9)	0.12 (NS)

NS, not significant; POP, postoperative.

*From χ^2 or Fisher's test, when appropriate.

†Evaluated in 40 patients with smooth implants and 122 patients with textured implants.

than those with textured implants (OR, 7.2; CI 95, 1.3 to 40.4).

The evidence suggested that postoperative complication increased the probability of developing contractures seven times during the first year of follow-up (OR, 7.0; 95 percent CI, 2.8 to 18.0) ($p = 0.00002$) from Fisher's test. Comparing by implant surface, it was noteworthy that the interaction of smooth implants (OR, 33.6; 95 percent CI, 8.2 to 137.1) ($p \approx 0$) with respect to textured implants showed a similar risk of crude calculation (OR, 6.4; 95 percent CI, 1.2 to 34.8) ($p = 0.01$) (Table 7).

DISCUSSION

Since 2011, textured implants have concerned plastic surgeons because of their association with BIA-ALCL.^{24,32} Consequently, we reconsidered their use and evaluated their associated complications. To this end, we placed a similar number of implants with both surfaces and evaluated the types of complications in the first year. Multiple factors can affect capsular contracture, such as patient characteristics (altered immune response, smoking, or diabetes), type of surgery, surgical approach, implant pocket placement, drainage tubes, preventive treatment with montelukast and ultrasound, contamination, and biofilm formation, including implant material and coverage.¹⁷

In this study, we observed capsular contracture in 21 breasts; nine breasts had obvious postoperative complications such as hematoma, seroma, or infection. Although we cannot be sure that the 12 patients regardless of the complications mentioned could have had some nonapparent complications (e.g., contamination, subclinical infection, undiagnosed seroma), it could be stated that the contractures are attributable to apparent or nonapparent postoperative complications. This lack of accuracy in determining the complications raises the need for new studies about the relationship between any postoperative complication and capsular contracture development during the follow-up period. The evidence suggested that the postoperative complication increased the probability of developing contractures seven times during the first year of follow-up.

Many publications refer to the positive effect in the treatment and prevention of capsular contracture with selective leukotriene receptor antagonists. Nevertheless, our limited number of patients who accepted and completed preventive

Table 5. Quantification of the Risk of Capsular Contracture 1 Year after Surgery and Potential Associated Factors

	Smooth Surface (%)	Textured Surface (%)	OR (95% CI)	<i>p</i> *
No.	13/214	8/292		
Implant shape				
Round	13/214 (6.0)	8/258 (3.1)	2.0 (0.8–4.9)	0.12 (NS)
Anatomical	—	0/36 (0)	†	†
Pocket				
Subfascial	11/88 (12.5)	6/192 (3.1)	4.4 (1.6–12.4)‡	0.002‡
Subpectoral plus dual plane	2/126 (1.6)	2/100 (2.0)	0.8 (0.1–5.9)	0.84 (NS)
POP complications				
Yes	6/11 (54.5)	2/16 (12.5)	8.4 (1.3–56.1)	0.05
No	7/203 (3.4)	6/276 (2.1)	1.6 (0.5–4.9)	0.39 (NS)

POP, postoperative; NS, not significant.

*From χ^2 or Fisher's test, when appropriate.

†The odds ratio could not be calculated.

‡Statistically significant.

Table 6. Quantification of the Risk of Capsular Contracture 2 Years after Surgery and Potential Associated Factors

	Smooth Surface (%)	Textured Surface (%)	OR (95% CI)	<i>p</i> *
No.	6/80	7/244		
Implant shape				
Round	6/80 (7.5)	7/214 (3.3)	2.4 (0.8–7.8)	0.21 (NS)
Anatomical	—	0/34 (0)	†	†
Pocket				
Subfascial	6/46 (13)	6/168 (3.6)	4.1 (1.2–13.2)‡	0.03‡
Subpectoral plus dual plane	0/34 (0)	1/76 (1.3)	†	0.60 (NS)
POP complications				
Yes	2/14 (14.3)	5/18 (27.8)	0.4 (0.1–2.7)	0.63 (NS)
No	4/66 (6.1)	2/226 (0.9)	7.2 (1.3–40.4)‡	0.03‡

NS, not significant; POP, postoperative.

*From χ^2 or Fisher's test, when appropriate.

†The odds ratio could not be calculated.

‡Statistically significant.

treatment with montelukast and ultrasound were not enough to be able to define the influence on capsular contracture.^{8,33–37} This treatment may have biased the results of our study. To date, the mechanism of capsular contracture, risk factors, and true prevalence is unclear.^{9–11}

Many authors demonstrated that the incidence of capsular contracture is higher within the first year of primary breast augmentation.^{6,25,38,39} Another study, with 23.3 years of follow-up (mean, 37.4 months), showed a contracture (Baker grade

III or IV) rate of 1.9.⁴ The contracture is a progressive phenomenon, and the longer any group of patients is followed, the greater the cumulative risk of developing contracture.

In our study, we included Baker grade II capsular contractures, which are generally not included by other authors. If we had considered only Baker grade III and IV capsular contractures, the annual capsular contracture rate would be 1.2 percent (six breasts) and 1.5 percent (five breasts) at 2 years.

Table 7. Relationship between Postoperative Complications* and Capsular Contractures

Surface	Breast with Capsular Contracture	Breast without Capsular Contracture	<i>p</i> †	OR (95% CI)
Total	21	485		
With POP complications	8	39	0.00002	
Without POP complications	13	446		7.0 (2.8–18.0)
Smooth	13	201		
With POP complications	6	5	≈0	
Without POP complications	7	196		33.6 (8.2–137.1)
Textured	8	284		
With POP complications	2	14	0.01	
Without POP complications	6	270		6.4 (1.2–34.8)

POP, postoperative.

*Complications: hematoma, seroma, and infection.

†From χ^2 or Fisher's test, when appropriate.

Implant Surface and Filling

Various publications have reported that textured implants have a lower risk rate of capsular contracture than those with a smooth surface, whereas others reported similar rates.^{9,40} The high rate of capsular contracture in older smooth implants could be attributed to low gel cohesiveness, elastomer degradation, and gel bleeding.⁴¹ New-generation breast implants with higher gel cohesiveness have a low incidence of bleeding and capsular contractures.⁴²

Textured implants may be associated with a lower incidence of capsular contractures because of the way they interact with the surrounding tissue, by disrupting the contractile force around it.⁴³ Recent publications focus on the cost-to-benefit equation for the use of smooth implants, which could increase the rate of complications and reoperations.⁴⁴ From our experience, the evidence suggests that the implant coverage was independent of the capsular contracture. However, it is necessary to consider that many factors could affect the contracture risk, and these factors deserve further evaluation. In this study, five different implant companies were used; the relationship with the complications was not statistically evaluated because the main surgeons did not intend to generate conflicts with manufacturers.

Incision Type

Different approaches have advantages and disadvantages.⁴⁵ Wiener relates the incision approach with capsular contracture because of the potential for implant contamination by bacteria colonizing the breast ducts. The periareolar incision had a 9.5 percent incidence of contracture versus 0.59 percent when using the inframammary fold.⁴⁶ We use only the inframammary approach.

Biofilm

Manav et al. studied the contracture around smooth, textured, and polyurethane miniature implants in rats. They showed that, in the case of bacterial contamination, the possibility of capsular contracture in implants with a textured surface was much higher than that in the smooth or polyurethane implants. Because biofilm formation is also associated with BIA-ALCL, the use of textured implants carries an additional risk.⁴⁷ Lista et al. compared smooth and textured implants in the subglandular plane, with a similar rate of capsular contracture. They suggest that a technique that maintains minimal bacterial contamination is more important than the implant surface.⁴⁸ In

2017, Adams et al. established a 14-step plan with the aim of reducing the bacterial load and biofilm formation in breast augmentation.⁴⁹ Our group routinely performs the steps mentioned by Adams et al.

Pocket

We used the subfascial pocket in patients with adequate soft-tissue coverage in the upper pole of the breast. The subfascial pocket is a well-defined anatomical space that does not dissect the mammary parenchyma and allows good implant coverage while avoiding the dynamic breast.^{50–52} In very thin patients, we used the subpectoral plane or the dual-plane modified by Ventura et al.^{29,51}

A randomized controlled trial found a reduction in capsular contracture symptoms with the use of textured implants in the submuscular plane.⁵³ In our study, smooth and textured implants placed there had similar capsular contracture rates at the 1-year follow-up. However, when smooth implants were placed in the subfascial plane, their capsular contracture rate was significantly higher than textured implants.

Limitations

Our study was limited by the relatively short follow-up. Furthermore, we were only able to evaluate 64 percent of the patients at 2 years, where we found a similar contracture rate between smooth and textured implants. We will follow the study patients for a longer term. Given the significant differences of some covariates and large sample sizes, we could have conducted the propensity score matching before using the comparison tests.

We were unable to apply a multivariate analysis (e.g., logistic regression, model-based analysis) because there were no cases in strategic explanatory variables. There were no cases of textured implants in the total subpectoral pocket (there were no available anatomical implants with a smooth surface; likewise, postoperative preventive treatment did not have a uniform indication criterion among surgeons). If we apply the results of such analysis, they could lead to incorrect inferences. That is why we decided to show the magnitudes with an analysis adjusted to 1- and 2-year follow-up. As a strength, we have included Baker grade II contracture in the general rate because it is a clinical manifestation that could evolve to a greater degree.

CONCLUSIONS

In our experience, by using the inframammary approach and a standardized technique that

minimizes bacterial contamination, there is no significant difference in the crude incidence of capsular contracture between smooth and textured implants. The evidence suggested that a complication immediately postoperatively increased 8.4 times the probability of developing contractures during the first year of follow-up. In the subfascial plane, until 2-year follow-up, the contracture rate with smooth implants was higher than with textured implants. However, when they were placed in the submuscular plane, there was no difference between the two surfaces. The implant surface does not affect the risk of capsular contracture at 1 or 2 years following primary breast augmentation. The most critical factor seems to be the plane in which the implants are placed, where subpectoral or dual-plane placement decreases the risks of capsular contracture.

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REFERENCES

1. International Society of Aesthetic Plastic Surgery. ISAPS global survey 2018 press release. Available at: <https://www.isaps.org/wp-content/uploads/2019/12/ISAPS-Global-Survey-2018-Press-Release-Spanish.pdf>. Accessed May 6, 2020.
2. Coroneos CJ, Selber JC, Offodile AC II, Butler CE, Clemens MW. US FDA breast implant postapproval studies: Long-term outcomes in 99,993 patients. *Ann Surg*. 2019; 269:30–36.
3. Bachour Y, Bargon CA, de Blok CJM, Ket JCF, Ritt MJPF, Niessen FB. Risk factors for developing capsular contracture in women after breast implant surgery: A systematic review of the literature. *J Plast Reconstr Aesthet Surg*. 2018;71:e29–e48.
4. 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;117:757–767.
5. Siggelkow W, Faridi A, Spiritus K, Klinge U, Rath W, Klosterhalfen B. Histological analysis of silicone breast implant capsules and correlation with capsular contracture. *Biomaterials* 2003;24:1101–1109.
6. Araco A, Caruso R, Araco F, Overton J, Gravante G. Capsular contractures: A systematic review. *Plast Reconstr Surg*. 2009;124:1808–1819.
7. Malahias M, Jordan DJ, Hughes LC, Hindocha S, Juma A. A literature review and summary of capsular contracture: An ongoing challenge to breast surgeons and their patients. *Int J Surg Open* 2016;3:1–7.
8. Scuderi N, Mazzocchi M, Fioramonti P, Bistoni G. The effects of zafirlukast on capsular contracture: Preliminary report. *Aesthetic Plast Surg*. 2006;30:513–520.
9. Headon H, Kasem A, Mokbel K. Capsular contracture after breast augmentation: An update for clinical practice. *Arch Plast Surg*. 2015;42:532–543.
10. Bui JM, Perry T, Ren CD, Nofrey B, Teitelbaum S, Van Epps DE. Histological characterization of human breast implant capsules. *Aesthetic Plast Surg*. 2015;39:306–315.
11. Calobrace MB, Stevens WG, Capizzi PJ, Cohen R, Godinez T, Beckstrand M. Risk factor analysis for capsular contracture: A 10-year Sientra study using round, smooth, and textured implants for breast augmentation. *Plast Reconstr Surg*. 2018;141(Sientra Shaped and Round Cohesive Gel Implants):20S–28S.
12. Tandon VJ, DeLong MR, Ballard TN, et al. Evolving trends in textured implant use for cosmetic augmentation in the United States. *Plast Reconstr Surg*. 2018;142:1456–1461.
13. Chang EI, Hammond DC. Clinical results on innovation in breast implant design. *Plast Reconstr Surg*. 2018;142(The Science of Breast Implants):31S–38S.
14. Wan D, Rohrich RJ. Modern primary breast augmentation: Best recommendations for best results. *Plast Reconstr Surg*. 2018;142:933e–946e.
15. Maxwell GP, Gabriel A. The evolution of breast implants. *Plast Reconstr Surg*. 2014;134:12S–17S.
16. Wong CH, Samuel M, Tan BK, Song C. Capsular contracture in subglandular breast augmentation with textured versus smooth breast implants: A systematic review. *Plast Reconstr Surg*. 2006;118:1224–1236.
17. Barnsley GP, Sigurdson LJ, Barnsley SE. Textured surface breast implants in the prevention of capsular contracture among breast augmentation patients: A meta-analysis of randomized controlled trials. *Plast Reconstr Surg*. 2006;117:2182–2190.
18. Nava MB, Adams WP Jr, Botti G, et al. MBN 2016 aesthetic breast meeting BIA-ALCL consensus conference report. *Plast Reconstr Surg*. 2018;141:40–48.
19. Groth AK, Graf R. Breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) and the textured breast implant crisis. *Aesthetic Plast Surg*. 2020;44:1–12.
20. Swerdlow SH, Campo E, Pileri SA, et al. The 2016 revision of the World Health Organization classification of lymphoid neoplasms. *Blood* 2016;127:2375–2390.
21. American Society of Plastic Surgeons. BIA-ALCL physician resources. Available at: <https://www.plasticsurgery.org/for-medical-professionals/health-policy/bia-alcl-physician-resources>. Accessed September 29, 2020.
22. Swanson E. The textured breast implant crisis: A call for action. *Ann Plast Surg*. 2019;82:593–594.
23. Zingaretti N, Galvano F, Vittorini P, et al. Smooth prosthesis: Our experience and current state of art in the use of smooth sub-muscular silicone gel breast implants. *Aesthetic Plast Surg*. 2019;43:1454–1466.
24. U.S. Food and Drug Administration. Medical device reports of breast implant-associated anaplastic large cell lymphoma. Available at: <https://www.fda.gov/medical-devices/breast-implants/medical-device-reports-breast-implant-associated-anaplastic-large-cell-lymphoma>. Accessed September 29, 2020.
25. Baker J. Augmentation mammoplasty. In: *Symposium on Breast Surgery of the Breast*. St. Louis, Mo: Mosby; 1978:256–263.
26. Swanson E. Plastic surgeons defend textured breast implants at 2019 U.S. Food and Drug Administration hearing: Why it is time to reconsider. *Plast Reconstr Surg Glob Open* 2019;7:e2410.
27. Siemieniuc G, Filiciani S, Cappio B, Albertengo A, Nozzi G, Caggioli M. Breast Ecotest: A new tool for choosing the pocket location of the implants. *Cir Plast Iberolatinoam* 2016;42:5–11.
28. Tebbetts JB. Dual plane breast augmentation: Optimizing implant-soft-tissue relationships in a wide range of breast types. *Plast Reconstr Surg*. 2001;107:1255–1272.
29. Ventura OD, Rosati RE, Marino H, Marcello G. Breast augmentation in dual plane: A subfascial alternative

- towards optimizing indications. *Cir Plast Iberolatinoam*. 2008;34:249–258.
30. Spear SL, Baker JL Jr. Classification of capsular contracture after prosthetic breast reconstruction. *Plast Reconstr Surg*. 1995;96:1119–1123.
 31. Prandl L, Englbrecht MA, Schoeneich M, Kuehlmann B, Jung EM, Kubale R. Semiquantitative measurements of capsular contracture with elastography: First results in correlation to Baker score. *Clin Hemorheol Microcirc*. 2014;58:521–528.
 32. Heidekrueger PI, Sinno S, Hidalgo DA, Colombo M, Broer PN. Current trends in breast augmentation: An international analysis. *Aesthet Surg J*. 2018;38:133–148.
 33. Reid RR, Greve SD, Casas LA. The effect of zafirlukast (Accolate) on early capsular contracture in the primary augmentation patient: A pilot study. *Aesthet Surg J*. 2005;25:26–30.
 34. Bastos EM, Neto MS, Garcia EM, et al. Effect of zafirlukast on capsular contracture around silicone implants in rats. *Acta Cir Bras*. 2012;27:1–6.
 35. Schlesinger SL, Ellenbogen R, Desvigne MN, Svehlak S, Heck R. Zafirlukast (Accolate): A new treatment for capsular contracture. *Aesthet Surg J*. 2002;22:329–336.
 36. Scuderi N, Mazzocchi M, Rubino C. Effects of zafirlukast on capsular contracture: Controlled study measuring the mammary compliance. *Int J Immunopathol Pharmacol*. 2007;20:577–584.
 37. Mazzocchi M, Dessy LA, Alfano C, Scuderi N. Effects of zafirlukast on capsular contracture: Long-term results. *Int J Immunopathol Pharmacol*. 2012;25:935–944.
 38. Adams WP Jr, Rios JL, Smith SJ. Enhancing patient outcomes in aesthetic and reconstructive breast surgery using triple antibiotic breast irrigation: Six-year prospective clinical study. *Plast Reconstr Surg*. 2006;118:46s–52s.
 39. Stutman RL, Codner M, Mahoney A, Amei A. Comparison of breast augmentation incisions and common complications. *Aesthetic Plast Surg*. 2012;36:1096–1104.
 40. Hall-Findlay EJ. Breast implant complication review: Double capsules and late seromas. *Plast Reconstr Surg*. 2011;127:56–66.
 41. Jacombs A, Tahir S, Hu H, et al. In vitro and in vivo investigation of the influence of implant surface on the formation of bacterial biofilm in mammary implants. *Plast Reconstr Surg*. 2014;133:471e–480e.
 42. Moyer HR, Ghazi BH, Losken A. The effect of silicone gel bleed on capsular contracture: A generational study. *Plast Reconstr Surg*. 2012;130:793–800.
 43. Steiert AE, Boyce M, Sorg H. Capsular contracture by silicone breast implants: Possible causes, biocompatibility, and prophylactic strategies. *Med Devices (Auckl)*. 2013;6:211–218.
 44. Danilla SV, Jara RP, Miranda F, et al. Is banning texturized implants to prevent breast implant-associated anaplastic large cell lymphoma a rational decision? A meta-analysis and cost-effectiveness study. *Aesthet Surg J*. 2020;40:721–731.
 45. Hidalgo DA. Breast augmentation: Choosing the optimal incision, implant, and pocket plane. *Plast Reconstr Surg*. 2000;105:2202–2216.
 46. Wiener TC. Relationship of incision choice to capsular contracture. *Aesthetic Plast Surg*. 2008;32:303–306.
 47. Manav S, Ayhan MS, Deniz E, et al. Capsular contracture around silicone mini-implants following bacterial contamination: An in-vivo comparative experimental study between smooth, textured and polyurethane implants. *J Plast Reconstr Aesthet*. 2020;73:1747–1757.
 48. Lista F, Austin RE, Saheb-Al-Zamani M, Ahmad J. Does implant surface texture affect the risk of capsular contracture in subglandular breast augmentation and breast augmentation-mastopexy? *Aesthet Surg J*. 2020;40:499–512.
 49. Adams WP Jr, Culbertson EJ, Deva AK, et al. Macrot textured breast implants with defined steps to minimize bacterial contamination around the device: Experience in 42,000 implants. *Plast Reconstr Surg*. 2017;140:427–431.
 50. Graf RM, Bernardes A, Rippel R, Araujo LR, Damasio RC, Auersvald A. Subfascial breast implant: A new procedure. *Plast Reconstr Surg*. 2003;111:904–908.
 51. Ventura OD, Marcello G, Gamboa C, Miro A. Breast implants in the subfascial plane in replacement of the subglandular pocket: A logical change. *Cir Plast Iberolatinoam*. 2006;32:11–16.
 52. Adams WP Jr. Capsular contracture: What is it? What causes it? How can it be prevented and managed? *Clin Plast Surg*. 2009;36:119–126, vii.
 53. Poepl N, Schreml S, Lichtenegger F, Lenich A, Eisenmann-Klein M, Prantl L. Does the surface structure of implants have an impact on the formation of a capsular contracture? *Aesthetic Plast Surg*. 2007;31:133–139.