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CAPSULAR CONTRACTURE AND INCISION: CORRELATION AND INFLUENCE IN SUBMUSCULAR BREAST AUGMENTATION WITH POLYTECH® MICROTEXTURED IMPLANTS

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Summary

Capsular contracture (CC) remains the most common complication and the primary cause of reoperation following breast augmentation surgery. It is a complication associated with the use of implants, although surgical technique and the use of prophylactic strategies are significantly related with its onset. This article thoroughly examines the influence of different incision placements on the development of CC, based on our three-year experience with 127 dual-plane breast augmentations using Polytech® microtextured implants. Our study protocol divided patients into two groups based on the type of incision: inframammary and periareolar. We assessed the incidence rate of CC in both groups: the overall incidence of CC in the 127 patients who underwent dual-plane breast augmentation was 8.66%, with 11 unilateral cases. Our retrospective study then revealed that the periareolar incision is associated with a higher risk of CC: the rate of contracture was significantly at 22% (8 patients out of 34 ≈ 23%), compared to the inframammary incision group, where the rate of capsular contracture was 3.32% (3 patients affected out of 93, p value: 0.00117). Therefore, the incidence rate in the periareolar incision group was 567% higher compared to the inframammary incision group, representing a five-fold increase. These results have been discussed relating them to the current literature.

Key words: incision, capsular contracture, complication, submuscular, implants

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INTRODUCTION

Capsular contracture remains the most common complication and the primary cause of reoperation following breast augmentation surgery [1]. Reported incidence rates range from 0.60 to 19% [2].

It occurs when scar tissue that forms around the breast implant contracts abnormally, leading to hardening and, in some cases, breast pain. This phenomenon can alter the shape and position of the implant, making additional surgery necessary to resolve the complication. Although capsular contracture has become increasingly rare due to advanced surgical

techniques and improvements in implant materials, it remains one of the major complications. Proper surgical techniques and careful postoperative management are essential for its prevention [1,2].

The risk factors for capsular contracture act synergistically. Each surgery and each patient present a unique combination of risks, and it is challenging to definitively determine the influence of a single variable on such a complex process. Capsular contracture is a risk associated with implants, influenced by various factors. Textured implants tend to reduce the risk compared to smooth implants, but they do not eliminate it entirely [6]. The implant position is critical: submuscular implants have a lower likelihood of contracture than subglandular implants, due to the protection provided by the muscle [3]. Postoperative infections and inflammation significantly increase the risk by stimulating an immune response that leads to excess scar tissue formation [2]. Implant duration also plays a role: the longer the implant remains in the body, the greater the likelihood of developing CC, particularly in the first 2-3 years [19]. Genetic predisposition and smoking can further increase the risk [23,24].

Surgical techniques and access routes are crucial: a poorly executed procedure can predispose to complications. Ultimately, the choice of access route has a significant impact on the likelihood of developing this complication [5,6].

Proper pre- and postoperative management, along with the selection of appropriate techniques and thorough pre- and postoperative patient assessment, can substantially reduce the risk of capsular contracture. This study aims to investigate the impact of different incision types in breast augmentation on CC rates, in order to provide stronger evidence and more definitive clinical recommendations.

MATERIALS AND METHODS

We conducted a retrospective study based on our surgical practice, focusing on breast augmentation procedures performed between January 2019 and January 2022 at IRRCS-CROB Institute, Rionero in Vulture, Italy. The potential correlation and influence between incision placement and the incidence of capsular contracture were assessed.

This study was conducted in accordance with the principles of the Declaration of Helsinki. The research protocol was reviewed and approved by the Institutional Review Board (IRB) of IRCCS-CROB, with approval number 28503. Informed consent for surgery and preoperative photographs were obtained for all patients prior to the procedure. All participants provided written informed consent prior to inclusion in the study. The patients included in the study underwent a meticulous selection process based on risk factors that could confound our results. Patients with a BMI greater than 25 or less than 20 were excluded, thus selecting only patients with normal weight.

Microtexturization was preferred in accordance with the literature, which suggests that the textured surfaces of implants can reduce the formation of contracture, as fibroblasts anchor to the deep, random pattern, and consequently may not be able to align in a planar fashion [22]. This pathogenic mechanism is widely recognized and studied for all types of implants, including the latest generation polyurethane coated implants [31].

All breast augmentations were performed using dual-plane implant placement. Patients who received subglandular implants were excluded from the sample. Our institution has a moderate number of cases involving subglandular implants, but we chose to exclude them from the statistical analysis, as the literature consistently shows that the submuscular plane, by providing greater protection to the implant, significantly reduces (RR, 0.3; 95% CI, 0.2-0.8) the risk of capsular contracture [22]. This decision helped minimize the influence of a second variable, thus making our sample more uniform for analysis.

Volume of breast implants ranged from a minimum of 200 cc to a maximum of 550 cc, with an average of 375 cc. The implant volume was evenly distributed between the two groups with different incision: neither group had a significantly different pool of implants from the other, as the average volume was the same in both groups.

In breast augmentations with inframammary access, an incision of at least 4 cm and no more than 6 cm was made for the insertion of the implant. For the periareolar breast augmentation, an incision was made around the areola-nipple complex, creating an access route in the lower region until the pectoral muscle was visible.

The pocket dissection was performed under direct visualization using an electrosurgical scalpel. All procedures were conducted under local anesthesia with sedation. To reduce contamination, the surgical team wore powder-free gloves, and the breast pocket was irrigated with a 50:50 solution of Betadine and saline. The gloves were changed by the entire surgical team before opening the implant, and manipulation of the implant was minimized to the necessary extent. Patients received standard preoperative antibiotic prophylaxis, consisting of 2 g of Cefazolin IV immediately before entering the operating room and 1 g the morning and 1g the evening of the day following the surgery. No different antibiotic therapies were applied between the two incision types.

All patients received drains, which were placed after the pocket dissection, at the intersection of the inframammary fold and the anterior axillary line, before inserting

the implants. Drains were kept for a mean of 48 h (minimum 24 hours – maximum 96 hours) and they were removed when their content was under 20 cc of fluid in 24 hours.

Capsular contracture most commonly develops within the first year after surgery [19], so patients were followed up at 90, 120 days, 1 year, and 3 years. This study included all degrees of Baker contracture, with the severity of the contracture assigned to symptomatic cases based on breast deformity [25].

We evaluated patients' satisfaction for their surgical outcome with patient-reported outcome measures (PROMs) surveys, which were submitted at 1 year post-op.

Patient-reported outcomes (PROs) are a type of Clinical Outcome Assessment (COA) that allows to describe, monitor, and reflect, in a standardized way, how a patient feels, functions, or generally lives. The FDA defined a PRO as "a measure of a patient's health status as reported directly from the patient without added interpretation by a healthcare worker or anyone else" [33].

RESULTS AND STATISTICAL ANALYSIS

A total of 127 procedures were performed using breast implants, with only periareolar and inframammary incisions utilized, while axillary approaches were not considered. Of the 127 patients who underwent breast augmentation, 93 received implants through an inframammary incision and 34 through a periareolar incision.

In accordance with the recommendations in the literature, which considers MRI as the gold standard for diagnosing pathologies associated with breast implants [26,27], all patients underwent MRI evaluation 1 year and 3 years post-surgery to assess capsular contracture. Therefore, patients with a clinical diagnosis were confirmed by imaging findings from radiology [28].

The overall incidence of capsular contracture in the 127 patients who underwent dual-plane breast augmentation was 8.66%, affecting 11 patients. All cases involved unilateral capsular contracture. Specifically, 8 patients had contracture in the right breast, while 3 patients had it in the left breast. All the patients were undergoing their first breast augmentation surgery.

The average BMI was 22. By doing so, we excluded the potential influence of body weight on the outcomes. 11% of the patients were smokers, totaling 14 patients. Among the 11 affected patients, 3 were smokers, representing 27.27% of the total.

The average age of the patients was 42 years, with the youngest being 18 and the oldest 67 years.

In GROUP 1, with the inframammary incision, the rate of capsular contracture was 3%, with 3 patients affected out of 93. In GROUP 2, with the periareolar incision, the rate of contracture was significantly higher at 23%, as 8 out of 34 patients were affected. Therefore, the incidence rate in the periareolar incision group was 567% higher compared to the inframammary incision group, representing a five-fold increase with a p-value of 0.00117, thus statistically relevant.

In our experience, 63.63% of the contractures were predominantly of Baker Grade I (7 patients in total, including 5 with Baker Grade I and 2 with Baker Grade II) at 1 year (Figs. 1,2), while 36.36% of the contractures were predominantly of Baker Grade II at 3 years (4

Figure 1. Patient 1, preoperative.

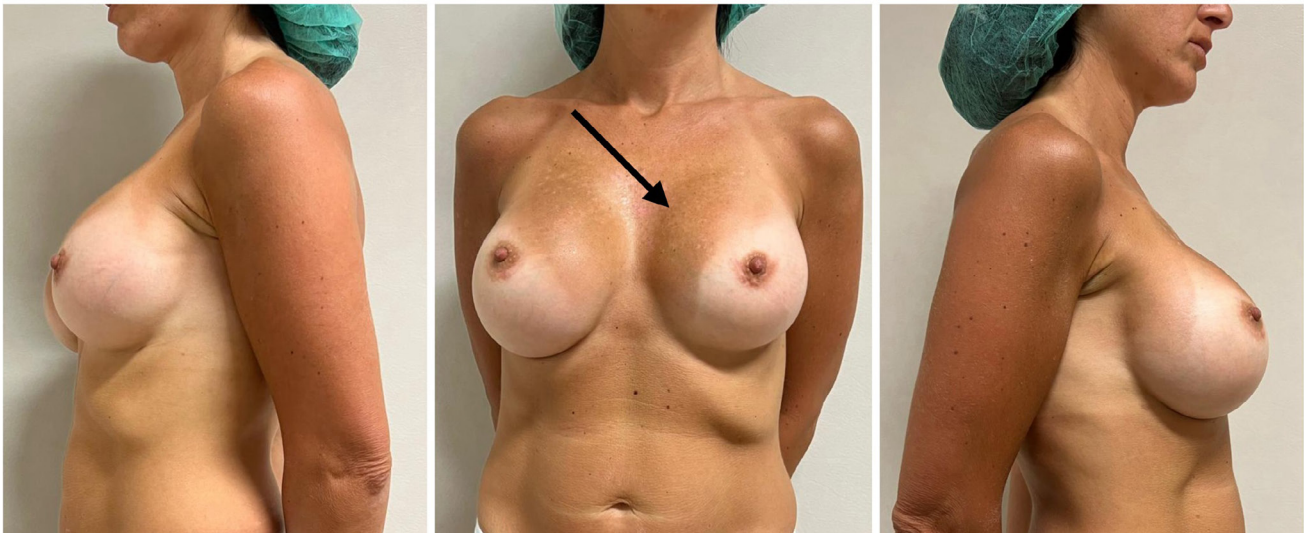

Figure 2. Patient 1, 1 year after periareolar breast augmentation: left breast shows a mild capsular contracture, which was radiologically evaluated as Baker Grade II. The upper pole looks tighter and more defined (arrow).

patients in total, including 3 with Baker Grade II and 1 with Baker Grade III [Figs. 3,4]).

An analysis of sample homogeneity between the two groups (inframammary *vs* periareolar) was performed (Fig. 5A-C). For age, the Mann-Whitney test yielded a p-value of 0.0055, indicating a statistically significant difference; thus, as already determined during patients selection, the groups are not homogeneous in terms of age. In contrast, the p-values for BMI (0.775) and smoking habits (0.797, Chi-square test) were not significant. Therefore, the groups are considered homogeneous in both BMI and smoking status.

Capsular contracture occurrence in relation to the incision was subjected to statistical analysis and their statistical significance was assessed. A chi-square test was performed (Tab. I) to evaluate the association between type of incision and capsular contracture: the p-value was 0.00117, well below 0.05, therefore the association between incision type and capsular contracture is statistically significant.

Capsular contracture is therefore more frequent in patients with a periareolar incision (8 out of 34 ≈ 23%) compared to those with an inframammary fold incision (3 out of 93 ≈ 3%).

The influence of other variables on capsular contracture was evaluated through statistical analysis. The chi-square test was used to assess the role of smoking, age, and BMI. Smoking (Tab. III) was found to be not statistically significant, with a p-value of 0.195.

Age (Tab. IV) and BMI (Tabl. V) were likewise not relevant variables in the development of capsular contracture, with p-values of 0.614 and 1.000 (BMI was constantly normal) respectively, and therefore not statistically significant.

In conclusion, only the type of incision (inframammary fold vs. periareolar) shows a statistically significant association with capsular contracture (p = 0.00117).

No statistically significant associations were found with:

- Smoking
- Age
- BMI

We also assessed the potential influence of implant volume on the development of capsular contracture. The average volume of implants used was 375 cc. Among patients who developed capsular contracture, we observed a significantly higher average volume: all 11 cases had implants larger than 300 cc, with a mean of 450 cc. We compared the average implant volume between patients with and without CC using an independent samples t-test. The capsular contracture group (n = 11) had a mean volume of 450 cc (SD = 32.1), while the non-CC group (n = 116) had a mean of 375 cc (SD = 76.2). The difference between the two groups was statistically significant (t = 6.64, p value < 0.001). This suggests that higher implant volumes may be associated with an increased risk of capsular contracture.

Patients' satisfaction with their surgical outcome was evaluated using patient-reported outcome measures (PROMs) surveys. The results of the questionnaires (Tab. VI) were predominantly positive: 70% reported being "very satisfied," "quite satisfied," or "satisfied" with the outcome of their breast surgery.

- 60% reported feeling very confident, quite confident, or confident in their body after breast augmentation;
- 65% stated that the postoperative pain was manageable;
- 80% said they would undergo the surgery again;

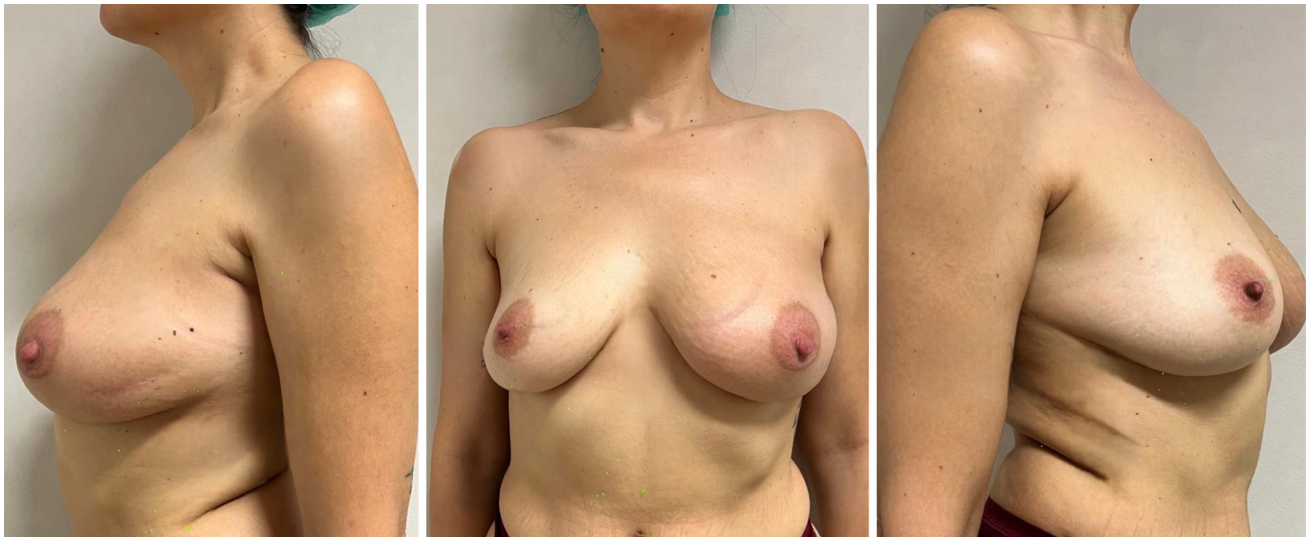

Figure 3. Patient 2, preoperative.

Figure 4. Patient 2, 3 years after periareolar breast augmentation: left breast shows a severe capsular contracture, which was radiologically evaluated as Baker Grade III. The whole breast looks higher and deformed, especially the nipple-areola-complex, which is visibly retracted.

- 70% reported they would recommend the same procedure to a friend who meets the conditions for undergoing it.

Even patients who experienced a complication tended to give an average rating (from “a little” to “quite”) in the questionnaires.

Overall, patients are satisfied with the outcome of the surgery despite the relatively modest occurrence of complications.

DISCUSSION

Our goal is to guide the choice of incision to be performed based on scientific evidence, particularly for patients with a history of capsular contracture and those who do not have a clear preference for the incision type but rather seek precise guidance on the advantages and disadvantages of each approach. This polarized

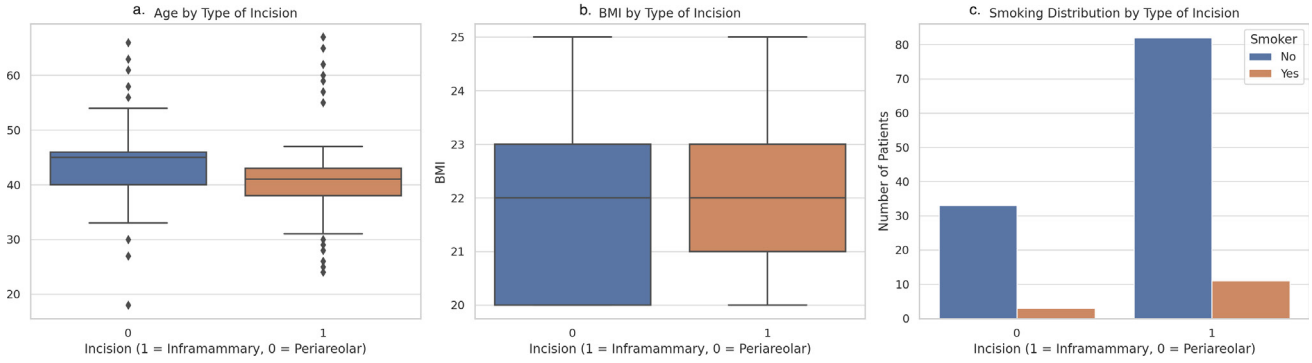

Figure 5. **A**) age by type of incision: shows a significant difference in age between the groups; **B**) BMI by type of incision: similar distribution across groups; **C**) smoking distribution by type of incision: nearly identical proportions.

Table I. Shapes and profiles of implants used.

	Round implants	Anatomical implants
Moderate profile	77	17
High profile	21	12
Total	98	29

Table II. Statistical correlation between incision and CC.

Incision	Contracture = 0	Contracture = 1	Total
0 = periareolar	26	8	34
1 = inframammary	90	3	93
Total	118	11	127

p value (Chi-squared test): 0.00117 → Statistically significant.

Table III. Statistical correlation between smoking and CC.

Smoking status	No contracture	Contracture	Total
No	105	8	113
Yes	11	3	14
Total	118	11	127

p-value (Chi-squared test): 0.195 → Not statistically significant.

Table IV. Statistical correlation between Age and CC.

Age group	No contracture	Contracture	Total
< 30	7	0	7
30-40	41	5	46
> 40	68	6	74
Total	117	11	127

p-value (Chi-squared test): 0.614 → Not statistically significant.

Table V. Statistical correlation between BMI and CC.

BMI category	No contracture	Contracture	Total
Normal	116	11	127

BMI is constantly normal → Not statistically significant.

result can be better understood by delving into some fundamental anatomical principles and reviewing the existing literature on the subject.

The commonly used incisions for implant placement are three: inframammary, periareolar, and transaxillary. Each type of incision has its own advantages and disadvantages. The periareolar incision is suitable for patients with larger areolas or those who prefer a less visible scar in social context. On the other hand, the inframammary incision is commonly preferred in Western countries, especially for patients with a well-defined inframammary fold located optimally [10]. The transaxillary incision was not considered in our study, as it is an outdated technique that is rarely performed in our facilities. There is a strong correlation between the access route used during breast augmentation surgery and the risk of developing capsular contracture. Numerous studies have linked periareolar access to an increased risk of capsular contracture [6,8]. The periareolar incision, by cutting through the edge of the areola and its ducts, may increase the risk of infections and inflammation – factors that promote excessive scar tissue formation and, consequently, capsular contracture [3].

Conversely, studies have shown that the inframammary route, which involves an incision under the breast, carries a lower risk of capsular contracture compared to other techniques. This is because the inframammary incision is less exposed to contamination and provides greater precision in implant placement. Therefore, the choice of access route significantly influences the risk of developing this complication, and a well-executed surgical technique can substantially reduce the incidence

Table VI. Patients' satisfaction evaluation through PROMs surveys.

	Not at all	A little	Quite	Very	Completely
Do you feel satisfied with your results?	10	28	28	29	32
Do you feel more confident in your body after your results?	15	36	24	25	27
Did you feel like post-op pain was manageable?	20	25	26	27	29
Would you do it again?	10	15	32	35	35
Would you recommend the same procedure to a friend who needs it?	12	26	25	32	32

of contracture, improving aesthetic results and patient well-being [14]. The inframammary fold is also a crucial anatomical landmark in breast surgery, whether reconstructive or aesthetic, so its restoration after using it for implant insertion can be extremely challenging [32].

One hypothesis suggests that the sectioning of the ductal system, which is certainly not sterile, could lead to subclinical infections, triggering capsular contracture [2,3]. On the other hand, other studies have reported lower rates of contracture after breast augmentation with a periareolar approach [5,9], and there is no definitive evidence supporting the hypothesis of subclinical infection.

As stated by Steiert et al. The development of a septic biofilm at the time of implant placement or within the first minutes or hours, along with subclinical infection of the foreign material, particularly by *Staphylococcus epidermidis* and *Propionibacterium acnes*, is described by many authors as having a strong effect on the formation of capsular contracture [2]. The primary microorganism implicated in capsular contracture is *Staphylococcus epidermidis* [18]. In the literature, microbiological research on removed capsules frequently identifies *S. epidermidis* as a colonizing bacterium, suggesting it may play a crucial role in the formation of contracture. Virden et al. [20], for example, confirmed that bacteria were detected in 56% (15 out of 27) of implants surrounded by contracted capsules and in 18% (5 out of 28) of those without capsular contracture ($p < 0.05$).

Consistent with these results, Tamboto et al. developed an in vivo model in pigs, where female animals underwent breast augmentation using mini-implants filled with gel, followed by inoculation of the pocket with *S. epidermidis*. The main parameters were the clinical Baker grade and additional laboratory tests on capsules removed 13 weeks after implantation. This group demonstrated that the presence of a septic biofilm leads to subclinical infection and was associated with a four-fold increase in subsequent contracture formation [19,21].

Several studies on capsular contracture and the use of Betadine (7.5% iodine-povidone) have shown a significant reduction in contracture rates with the correct use of Betadine [15,16].

Moreover, the pathogenesis of inflammation in capsular contracture has been extensively demonstrated in the literature. Medical treatments that reduce specific inflammatory pathways have been shown to be effective in treating capsular contracture, especially in mild cases [29].

For example, as highlighted by D'Andrea F. et al., Capsulase® (Boswellia serrata phospholipid INDENA®, palmitoylethanolamide (PEA), quercetin phytosome INDENA®, bromelain 2500 GDU/g, and vitamin E acetate, by Biosphaera Pharma srl) was proven effective. In fact, a positive response (complete or partial) was obtained in 71% of treated breasts ($p < 0.05$). None of the patients experienced a worsening of the condition. Improvement was maintained up to the 6th month in 77.7% of those who had responded positively. Subjectively, firmness improved by 50% and pain by 91.1% at 6 months [30].

As hypothesized by Wiener et al. [3], the periareolar incision directly cuts through larger terminal ducts near the areola-nipple complex, which contain the greatest amount of intraductal material. Being closer to the nipple openings, these ducts harbor the highest number of bacteria and present a greater risk of bacterial colonization. Even with meticulous surgical technique, these ducts may continue to release bacterial-laden secretions until complete healing occurs [3,11,12].

As Henriksen et al. [14] state, therefore, surgical approaches other than the inframammary route and drainage of the implant pocket have been associated with an increased risk of capsular contracture. Their prospective study indicates that surgical procedures are the most important predictive factors for local complications (short-term) compared to implant characteristics or patient heterogeneity [24].

However, as Calobrace et al. highlighted, and according to our evidence, capsular contracture seems to develop more frequently in implants of bigger volumes: implant size > 350 cc was associated with increased

risk for contracture [34]. This evidence is consistent with the literature and with the pathogenesis of CC: higher volume means larger surface, therefore bigger implants are more susceptible of bacterial contamination and, eventually, chronic inflammation [2,4,34].

Our experience is unique in that, to the best of our knowledge, there are no studies in the literature where all patients were selected so homogenously and underwent homogeneous breast augmentation with a submuscular plane and Polytech® microtextured implants. For this reason, our results cannot be compared or contrasted with similar experiences reported by other authors.

However, our study has some limitations. Since capsular contracture is influenced by multiple factors, our patients exhibited some residual heterogeneity, despite meticulous selection based on risk factors and characteristics. This heterogeneity stemmed from variations in areolar size, different ages, and variations in implant shape/projection characteristics.

CONCLUSIONS

In our experience, the periareolar access incision demonstrated higher rates of capsular contracture: the incidence rate in the periareolar incision group was 567% higher compared to the inframammary incision group, representing a five-fold increase with a p-value of 0.00117, thus statistically relevant.

Other risk factors have been proven not to be relevant in the development of CC: age, BMI and smoking were not statistically correlated to higher rates of CC. Only higher implant volumes (more than 300 cc) have shown to be correlated to higher risk of CC. Our findings are consistent with the current literature which proves a strong correlation between bacterial contamination and capsular contracture, as well as implant size and surface.

To strengthen our findings, high-quality randomized controlled clinical trials (RCTs) should be conducted in the future.

Lastly, given the progressive nature of capsular contracture over time, it is necessary to study patients with follow-up periods longer than 3 year to determine if our results may change over time.

Conflict of interest statement

The authors declare no conflict of interest.

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Author contributions

MPG: A, D, DT
FA: W
SL: DT, S
PI: A, D, DT, S, W

Abbreviations

A: conceived and designed the analysis
D: collected the data
DT: contributed data or analysis tool
S: performed the analysis
W: wrote the paper

Ethical consideration

This study was conducted in accordance with the principles of the Declaration of Helsinki. The research protocol was reviewed and approved by the Institutional Review Board (IRB) of IRCCS-CROB, with approval number 28503.

All participants provided written informed consent prior to inclusion in the study.

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