

Twelve Years and over 2400 Implants Later: Augmentation Mammoplasty Risk Factors Based on a Single Plastic Surgeon's Experience

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Background: Breast augmentation is one of the most commonly performed aesthetic surgery procedures. Yet, few reports in the literature analyze individual surgeon experiences with a unified surgical method on a large group of patients. This study aimed to analyze a single surgeon's complications rate and experience with the Akademikliniken augmentation mammoplasty method from the beginning of his career.

Methods: A retrospective outcome analysis of all patients (n = 1646) who underwent breast augmentation between 2009 and 2021 performed by a single surgeon was conducted. Complications and reoperation rates were evaluated. In addition, correlations with the patient and implant characteristics and insertion-method-related risk factors were analyzed.

Results: In total, 1212 female patients (mean age, 31.47 years) were analyzed. The minimal follow-up for every patient was 6 months (mean follow-up, 18.35 months). The total complication rate was 7.1%, and the most common complication (2.64%) was capsular contracture (Baker scale III/IV). Implant insertion with a funnel significantly lowered the overall risk of complications ($P = 0.009$). Statistical analysis indicates that the single independent risk factors for primary breast augmentation are patient age younger than 27 years, initial breast size B and C, and tobacco smoking.

Conclusions: This study indicated that capsular contracture and implant rotation are the most common complications of analyzed primary augmentation mammoplasty. It also identifies various risk and protection factors, such as funnel usage, which should be considered by the surgeon when performing this type of procedure. (*Plast Reconstr Surg Glob Open* 2024; 12:e5720; doi: 10.1097/GOX.0000000000005720; Published online 5 April 2024.)

INTRODUCTION

Since their first use in augmentation mammoplasty in the 1960s, implants and surgical techniques have constantly evolved. Despite the increasing recognition of the risk of complications, such as breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) and breast implant illness, the demand for this procedure remains high.¹⁻⁵

Currently, numerous implant types are available on the market, and multiple concepts of implantation methods have been proposed.⁶⁻⁸ Interestingly, the recent report of the American Society of Plastic Surgeons showed that almost half of its members have no experience with anatomically shaped implants.⁹ We believe that surgeons should be able to use alternative implant types and techniques when needed, as obtaining the best result always requires an individual approach in every patient.^{8,10}

In 2001, Hedén presented the Akademikliniken (AK) method, which allows for a straightforward concept of enabling ideal implant placement in relation to nipple position, breast lower pole curvature, and proper soft tissue coverage.^{8,10} By 2022, close to 35,000 implants had been inserted using the AK method at our institution.^{8,10,11}

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Most studies on augmentation mammoplasty present combined results of many surgeons, which may increase the risk of bias due to individual surgical skills. The unique feature of our study stems from the fact that it aimed to present the single surgeon experience of performing operations on over 1600 patients, including the very first patient operated on. For this purpose, a retrospective study was conducted to analyze the safety and general experience with this procedure.

MATERIALS AND METHODS

Study Material

This study followed the Declaration of Helsinki. A retrospective analysis of a clinical database of all consecutive female patients who underwent primary breast augmentation with implants for aesthetic reasons according to the AK method performed by the first author (P.M.) between April 2009 and October 2021 was conducted.^{10,11} Each surgery was planned according to the AK preoperative protocol, which has been described in detail in the previous reports, and a smartphone application entitled “Breast Augmentation Planner” (Per Héden, Stockholm, Sweden). Each patient received only one 300-mg dose of clindamycin intravenously as prophylaxis before the procedure. Every surgery was performed in a highly standardized fashion, through inframammary access and with sharp dissection of the pocket under direct view with meticulous, proactive hemostasis. No drains were ever used. Before the insertion of the implant, a pocket irrigation with clindamycin was conducted.

The same surgeon always assessed all patients at 1 week, 1 month, and 6 months postoperative. A physical breast examination was performed in every case, and diagnosed complications were noted. In case of hematoma or seroma suspicion, an ultrasound or magnetic resonance imaging was ordered. Inclusion criteria for this study were augmentation mammoplasty performed by the senior author according to the AK method and attendance at a follow-up of at least 6 months. Therefore, only patients with a minimum of 6 months postoperative follow-up period were included in the study. Patients who underwent simultaneous breast lipofilling, breast lift, or nipple-areola complex symmetrization were excluded from the study. For each individual, the following data were analyzed: patient age, body mass index (BMI), past pregnancies, tobacco smoking status, preoperative breast size (cup size), implant characteristics, implantation plane, and postoperative course (length of follow-up, and type and time of complication).

Statistical Analysis

The potential influence of specific variables on the occurrence of complications was investigated using the chi-squared test. In the case of statistical significance, an odds ratio (OR) was calculated. Continuous and ordinal variables were converted into dichotomous variables based on the cutoff values determined after the receiver operating characteristic curve analysis.

Takeaways

Question: Analysis of a single surgeon’s experience with augmentation mammoplasty.

Findings: A retrospective analysis of complications and patient and implant characteristics of 1646 patients who underwent breast augmentation performed by a single surgeon was conducted. The total complication rate was 7.1%, and the most common complication (2.64%) was capsular contracture (Baker scale III/IV). Implant insertion with a funnel significantly lowered the overall risk of complications.

Meaning: The capsular contracture and implant rotation are the most common complications of analyzed primary augmentation mammoplasty.

The risk of capsular contraction for every implant type was additionally analyzed with chi-square and Gehan–Wilcoxon tests. Mentor implants were excluded from this analysis due to the lack of any III/IV capsule contraction cases within this group. Multivariate logistic regression analysis was used for the evaluation of independent risk factors for each type of breast augmentation complication.

The statistical significance threshold was set at a *P* value less than or equal to 0.05. All calculations were conducted with IBM SPSS Statistica v.13 (TIBCO Software Inc., Palo Alto, Calif.).

RESULTS

The study enrolled 1212 women (those with a minimum of 6 months follow-up, from a total of 1647 consecutive patients), who were operated on for primary breast augmentation with implants. The patients’ follow-up loss rate was 26.41%. **Table 1** summarizes patient demographics and implant characteristics. The mean age of all patients at the time of surgery was 31.47 years (range, 18–62 years). The average BMI was 20.71 kg per m². In almost 55% of patients, the initial breast size was A cup. The mean follow-up was 18.35 months (range, 6–143 months; median, 8 months). A total of 2424 implants were inserted, with anatomical-shaped implants being the majority (82.01%). All implantations were performed through an inframammary incision. The mean volume of the implants was 316 ± 62.46 mL (**Table 1**).

Complications Summary

Table 2 summarizes the complications reported in the investigated group. With regard to the number of inserted implants, the total complication occurrence was 7.43% (n = 180). There was no report of BIA-ALCL. The most common complication (2.64%) was capsular contracture, defined as grade III and IV contraction according to the Baker scale. Capsular contracture lower than Baker grade III was not considered a complication due to difficulty in its reliable diagnosis and low clinical indications for surgical intervention.^{12,13} A total of 7.34% of all patients required reoperation due to complications. Capsular contracture (2.34%) and implant rotation (2.64%) were the most frequent causes.

Table 1. Patient Demographics and Implant Characteristics

Patient Demographics		Implant Characteristics	
No. patients	1212	No. implants	2424
Age (y)		Placement	
Mean	31.47	Dual-plane	1167 (96.29%)
Range	18–62	Subglandular	45 (3.71%)
18–29	557 (45.96%)	Implant Volume	
30–39	444 (36.63%)	Mean	316.09 mL
40–49	180 (14.85%)	Range	145–615 mL
≥50	31 (2.83%)	Implant Shape	
BMI (kg/m²)		Anatomical	994 (82.01%)
Mean	20.71	Round	218 (17.99%)
Range	15.62–30.8	Implant Type	
Tobacco smokers	119 (9.82%)	Natrelle (Allergan, Dublin, Ireland)	1852 (82.01%)
Past Pregnancy	573 (47.28%)	POLYTECH (POLYTECH Health & Aesthetics GmbH, Dieburg, Germany)	200 (8.24%)
Initial Breast Size		Motiva (Establishment Labs, Costa Rica)	288 (6.28%)
A cup	665 (54.87%)	Mentor (Mentor Worldwide LCC, Irvine, Calif.)	84 (3.47%)
B cup	478 (39.44%)		
C cup	69 (5.69%)		

Table 2. Summary of Complications

Complication	Occurrence Time Mean ± SD (mo)	No. Implants	No. Patients	
			One Breast	Both Breasts
Implant rotation	14 ± 11.39	38 (1.57%)	32	3
Implant rupture	65.75 ± 21.06	5 (0.21%)	3	1
Double-bubble	18.17 ± 14.47	9 (0.37%)	3	3
Bottoming out	12.68 ± 10.89	40 (1.65%)	18	11
Capsular contraction	44 ± 33.2	64 (2.64%)	34	15
Seroma	27.78 ± 27.01	12 (0.50%)	12	0
Hematoma	0.61 ± 1.57	10 (0.41%)	10	0
Infection	0.33 ± 0.04	2 (0.08%)	2	0
No. complicated cases		180 (7.42%)	104*	36*

*Some patients had more than one complication.

Patient-related Risk Factors

Statistical analysis results of complication occurrence and patient-related potential risk factors are presented in Table 3. Women aged younger than 27 years had a significantly higher incidence of complications than older women [$P = 0.013$; OR = 1.48; 95% confidence interval (CI), 1.08–2.02]. No negative influence of previous pregnancy was found on the postoperative course of breast augmentation ($P = 0.914$). Our analysis indicated a BMI of 25 kg per m² and a higher predisposition to an over two times higher complication rate when compared with a lower BMI (13.27% versus 6.84%; $P = 0.016$; OR = 2.08, 95% CI, 1.14–3.82). The OR of women with initial B and C cup sizes to develop postoperative complications was 1.7 times higher than that of women with A cup breast (95% CI, 1.25–2.34). Lastly, the incidence of complications was significantly higher among smokers than in nonsmokers (12.18% versus 6.54%; $P = 0.002$) with an OR of 1.98 (95% CI, 1.30–3.03).

Experience-related Risk Factors

The surgeon's experience in breast augmentation was determined as a total number of consecutively performed

procedures. Thus, the three following levels of expertise were established: low (1–549 cases), moderate (550–1099 cases), and high (1100–1647 cases). In the first 550 patients' group, the complication rate was 7.3% ($n = 65$). In the following two groups, this rate was 7.16% ($n = 59$) and 6.76% ($n = 48$), respectively. No statistically significant difference was found when comparing all three groups' complications incidence ($P = 0.912$).

Implant-related Risk Factors

Some of the implant characteristics seemed to impact the overall risk of complications (Table 4). Round-shaped implants had a higher complication rate than anatomical implants (10.32% versus 6.39%; $P = 0.004$) with an OR of 1.69 (95% CI, 1.18–2.41). As for the shell type, Motiva implants were found to have a significantly higher complication rate (11.11%) than Mentor (2.38%; $P = 0.015$), POLYTECH (4.5%; $P = 0.01$), and Natrelle (7.39%; $P = 0.014$) implants, with an OR of 1.78 (95% CI, 1.19–2.67; Tables 4 and 5).

Kaplan–Meier curve analysis of capsular contraction risk with the chi-square test ($P = 0.049$) and

Table 3. Patient-related Risk Factors

	Complicated Implantations	No. Complications
Age Groups (y)		
<28	8.75% (n = 80)	91.25% (n = 834)
≥28	6.09% (n = 92)	93.91% (n = 1418)
<i>P</i> = 0.013		
BMI Groups (kg/m²)		
<18.5	6.93% (n = 14)	93.07% (n = 188)
18–24.9	6.83% (n = 145)	93.17% (n = 1979)
≥25	13.27% (n = 13)	86.73% (n = 85)
<i>P</i> = 0.016		
Initial Breast Size		
A cup	5.49% (n = 73)	94.51% (n = 1257)
B cup	8.79% (n = 84)	91.21% (n = 872)
C cup	10.87% (n = 15)	89.13% (n = 123)
<i>P</i> = 0.002		
Past Pregnancy		
Yes	7.04% (n = 90)	92.96% (n = 1188)
No	7.16% (n = 82)	92.84% (n = 1064)
<i>P</i> = 0.914		
Tobacco Smoking		
Yes	12.18% (n = 29)	87.82% (n = 209)
No	6.54% (n = 143)	93.46% (n = 2043)
<i>P</i> = 0.002		

Table 4. Learning Curve and Implant-related Risk Factors

	Complicated Implantations	No. Complications
Implantation Plane		
Dual-plane	7.07% (n = 165)	92.93% (n = 2169)
Subglandular	7.78% (n = 7)	92.22% (n = 83)
<i>P</i> = 0.962		
Surgical Experience (No. Patients Operated on): Chi Square		
1–549	7.3% (n = 65)	92.7% (n = 825)
550–1099	7.16% (n = 59)	92.84% (n = 765)
1100–1647	6.76% (n = 48)	93.24% (n = 662)
<i>P</i> = 0.912		
Implant Volume Range		
<370 mL	6.1% (n = 115)	93.9% (n = 1771)
≥370 mL	10.6% (n = 57)	89.4% (n = 481)
<i>P</i> < 0.001		
Implant Shape		
Anatomical	6.79% (n = 135)	93.21% (n = 1853)
Round	10.32% (n = 45)	89.68% (n = 391)
<i>P</i> = 0.004		
Implant Brand		
Allergan	7.39% (n = 137)	92.61% (n = 1715)
Motiva	11.11% (n = 32)	88.89% (n = 256)
Mentor	2.38% (n = 2)	97.62% (n = 82)
POLYTECH	4.5% (n = 9)	95.5% (n = 191)
<i>P</i> = 0.007		
Insertion Sleeve Support		
Yes	4.79% (n = 30)	95.21% (n = 596)
No	7.9% (n = 142)	92.1% (n = 1656)
<i>P</i> = 0.009		

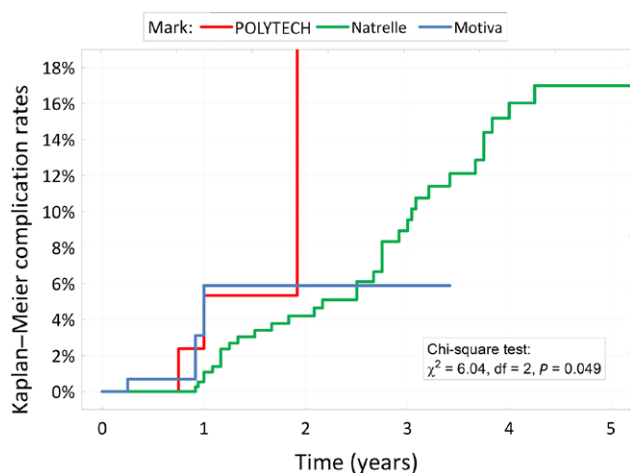
Gehan–Wilcoxon test (*P* = 0.04) detected a statistically significant difference in risk between Natrelle and Motiva implants (Fig. 1).

Data analysis showed that implant volume influences complication risk. With implants larger than 370 mL, a

complication occurred significantly more often than with lower volumes (*P* < 0.004). The receiver operating characteristic curve analysis indicated that the safety threshold equaled 370 mL, above which OR of complication equaled 1.82 (95% CI, 1.31–2.55).

Table 5. A Summary of the Complication Occurrence Rate in Every Implant Type

Complication Type	Implant Type					
	Anatomical			Round		
	Natrelle (n = 1706)	POLYTECH (n = 198)	Mentor (n = 84)	Natrelle (n = 146)	Motiva (n = 288)	POLYTECH (n = 2)
Seroma	9 (0.53%)	0	1 (1.19%)	2 (1.37%)	0	0
Hematoma	6 (0.35%)	1 (0.51%)	1 (1.19%)	0	2 (0.69%)	0
Capsular contracture	55 (3.22%)	4 (2.02%)	0	2 (1.37%)	3 (1.04%)	0
Implant rupture	4 (0.23%)	0	0	1 (0.68%)	0	0
Implant rotation	34 (1.99%)	4 (2.02%)	0	0	0	0
Double-bubble	6 (0.35%)	0	0	2 (1.37%)	1 (0.35%)	0
Infection	0	0	0	0	2 (0.69%)	0
Bottoming out	10 (0.59%)	0	0	6 (4.11%)	24 (8.33%)	0


Fig. 1. Kaplan–Meier curves for grade III/IV capsular contracture risk.

Insertion-method–Related Risk Factors

The implant insertion pocket, subglandular or dual-plane, did not differ in terms of complication risk ($P = 0.962$; Table 4). Breast augmentations in which an insertion sleeve (Keller funnel, Allergan, Ireland) was used had a significantly lower overall complication rate than the procedures performed without it (4.79% versus 7.9%; $P = 0.009$; Table 4). Analysis showed that implant insertions without a sleeve had approximately a 1.7 times higher risk of a total number of complications (95% CI, 1.14–2.55; Table 6).

Independent Risk Factors

The results of a multivariate logistic regression analysis of independent risk factors for each type of breast augmentation complication are presented in Table 7. No statistically significant correlation has been found between any investigated potential risk factor and hematoma, seroma, implant rupture, or double-bubble occurrence ($P > 0.005$).

DISCUSSION

This article summarizes years of experience of a single plastic surgeon with augmentation mammoplasty according to one specific surgical protocol (Figs. 2 and 3).^{10,11}

This allows us to assume that the difference in various factors related to the surgical procedure among different patients was limited to the minimum; thus, one of the most common significant bias factors in this type of study can be excluded. The ability to perform such assessments for the unprecedented number of over 1200 patients, from the very first to the last patient ever operated on by a single surgeon, makes the study unique, as it shows the single surgeon's results and experience gained through his career.

Capsular contracture is considered the most common complication of augmentation mammoplasty.^{7,14} Multiple reports indicate that capsular contracture typically occurs within the first postoperative year.^{7,15,16} The reported rate of capsular contracture is less than 4% in the first 2 years after the surgery.^{11,17,18} In our study group, its occurrence rate was 2.64%, with a mean diagnosis time of 44 ± 33.2 months. Therefore, our findings are consistent with these observations. However, in some studies, the incidence of this complication exceeds 4% within the first 2 years.¹⁹

The etiology of capsular contracture is not well understood. A recent meta-analysis found that the risk is higher for smooth implants and in subglandular pocket implantation.^{15,20} Other possible risk factors may include bacterial contamination, incision type, smoking, and sleeve-supported implantation.¹⁴ Our analysis did not confirm any of these risk factors. However, our observation time was relatively short, which is a considerable limitation, as incidence risk increases over time.⁷ We managed only to observe a significantly higher capsular contracture occurrence rate in women with bigger initial breast sizes, B and C cups ($P = 0.006$; 95% CI, 1.3–4.31; Table 7). To the best of our knowledge, the initial breast size was never considered a potential risk factor for this type of complication.

The initial breast size of B and C cups increased the risk of complications in general compared with patients with smaller breasts ($P = 0.002$; OR = 1.71; 95% CI, 1.25–2.34). Except for the higher risk of capsular contracture, individual risk analysis also found an increased risk for implant rotation ($P = 0.008$; OR = 2.73; 95% CI, 1.32–5.62). Although women with a BMI higher than 25 kg per m² also had a higher general complication rate, the analysis did not indicate it as an independent risk factor for any particular type of complication (Tables 3 and 7).

Table 6. The Influence of Insertion Sleeve on Complication Rate

	Insertion Sleeve	No Insertion Sleeve
Seroma		
Present	0.12 % (n = 3)	0.36 % (n = 9)
Absent	25.7 % (n = 623)	73.8 % (n = 1789)
<i>P</i> = 0.791		
Hematoma		
Present	0.04 % (n = 1)	0.36 % (n = 9)
Absent	25.78 % (n = 625)	73.8 % (n = 1789)
<i>P</i> = 0.433		
Capsular Contracture (Baker grade III/IV)		
Present	0.62 % (n = 15)	2.02 % (n = 49)
Absent	25.21 % (n = 611)	72.15 % (n = 1749)
<i>P</i> = 0.766		
Implant Rupture		
Present	0.04 % (n = 1)	0.16 % (n = 4)
Absent	25.79 % (n = 625)	74.01 % (n = 1794)
<i>P</i> = 0.831		
Implant Rotation		
Present	0.32 % (n = 8)	1.24 % (n = 30)
Absent	25.5 % (n = 618)	72.94 % (n = 1768)
<i>P</i> = 0.624		
Double-bubble		
Present	0 % (n = 0)	0.36 % (n = 9)
Absent	25.83 % (n = 626)	73.8 % (n = 1789)
<i>P</i> = 0.164		
Infection		
Present	0 % (n = 0)	0.08 % (n = 2)
Absent	25.83 % (n = 626)	74.09 % (n = 1796)
<i>P</i> = 0.979		
Bottoming Out		
Present	0.12 % (n = 3)	1.53 % (n = 37)
Absent	25.7 % (n = 623)	72.65 % (n = 1761)
<i>P</i> = 0.013		

Table 7. Separative Analysis of Independent Risk Factors for Each Augmentation Procedure Complication

Complication	Risk Factor	<i>P</i>	OR (95% CI)
Implant rotation	Anatomical implant shape	0.01	14.7 (1.02–21.2)
	Implant volume ≥370 mL	0.022	2.20 (1.10–4.38)
	Age ≥32	0.043	2.17 (1.07–4.4)
	Initial size of B or C cup	0.008	2.73 (1.32–5.62)
	Tobacco smoking	0.048	2.45 (1.01–5.94)
Double-bubble	Round implant shape	<0.001	11.1 (4.96–24.6)
	Age < 32	0.002	4.46 (1.69–11.8)
Capsular contraction	Initial size of B or C cup	0.006	2.37 (1.3–4.31)
Infection	Round implant shape	0.036	23.0 (1.1–48.0)

We believe that crucial prophylactic factors for preventing implant rotation are tight pocket dissection and strict restriction of intense physical activity for 3 months after the operation. Our study shows a rotation incidence of only 1.91% in all inserted anatomical devices. Unsurprisingly, the main risk factors for this complication are large anatomical implant volume (>370 mL) and initial breast size B cup and larger (Table 7). When referring to the previous study published by the first author on this topic, an apparent learning curve can be noticed, as his rotation incidence for the first 531 anatomical implants was 3.58%.²¹ In another recent study, the implant rotation

rate was estimated to be 1.35%–2.6%, similar to our finding.²² Our study shows a rotation incidence of only 1.91% in all anatomical devices, which was detected on average 1 year after the surgery (14 ± 11.39 months). Interestingly, a similar occurrence time was found for the bottoming-out complication (12.68 ± 10.89 months), which also is a form of implant malposition (Table 2). However, as some studies indicate, implant rotation can occur earlier and much more frequently than it seems; however, many cases remain clinically silent with no visible breast deformity.

We found the risk of late seroma to be 0.5%, a significantly lower value than the rates of other studies (1%–2%).^{11,18,23–28}

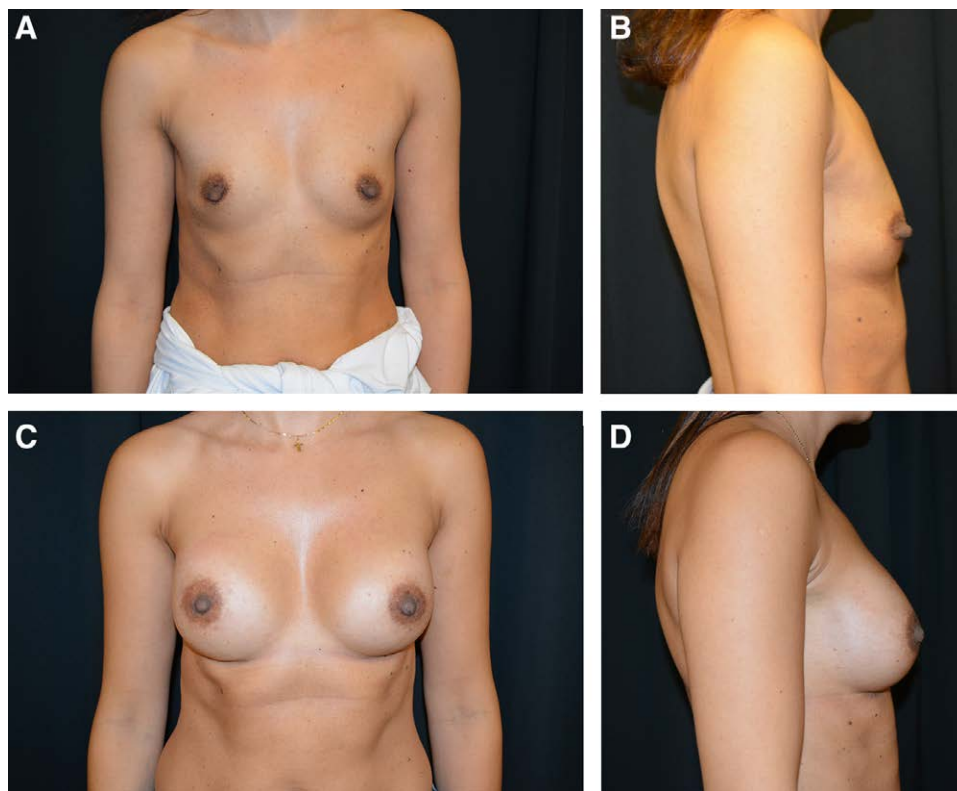


Fig. 2. An exemplary result of breast augmentation. A–B, A 35-year-old woman who underwent breast augmentation with 275-mL POLYTECH anatomical implants. C–D, Appearance at 12 months postoperatively.

Infection and hematoma incidence in primary augmentation is less than 1%.^{28,29} Also, in our study group, hematoma occurrence was very low (0.41%), which resulted from meticulous hemostasis during the surgery, which should be a mandatory step before tension-free wound closure.

We observed five cases (0.21%) of implant ruptures in our patient group, which makes it the second rarest complication we observed. However, this number may be understated, as prosthesis rupture may be symptomless in some patients.³⁰ Our implant rupture detection protocol is mainly based on the positive findings of the imaging tests. After augmentation, patients are advised to conduct periodic breast magnetic resonance imaging or USG imaging according to the Food & Drug Administration recommendations. In addition, they are instructed to report any worrisome breast shape or size change to the clinic.

Our study identified three patient-related independent risk factors that especially novice surgeons should consider. The first significant risk factor is smoking. Smokers tend to have almost a two times higher risk of early complications ($P = 0.017$; OR = 1.10; 95% CI, 1.10–2.62). The second risk factor was the age. Older age (>32 years) seems to predispose to a higher implant rotation rate ($P = 0.021$; OR = 1.45; Table 7). Perhaps more loose breast tissue plays a role in this tendency; however, additional study is needed to investigate this topic. Also, patients younger than 27 years have almost 1.5 times ($P = 0.021$; 95% CI, 1.08–2.02) higher risk of developing early postoperative complications than women older than 27 years.

Also, patients with initial breast size B cup or larger were more predisposed to complication occurrence ($P = 0.001$; OR = 1.78; 95% CI, 1.29–2.44). Similar to another recent study, our results show that parity is not a risk factor for primary breast augmentation ($P = 0.914$), as the complication incidence does not significantly differ from nulliparous patients (Table 3).³¹

According to our statistical analysis, subglandular and dual-plane insertion pockets did not differ in terms of early complications rate ($P = 0.962$), despite the various reports that subglandular placement is burdened with significantly higher capsular contraction.^{7,15} However, we believe that dual-plane should be preferred for thin patients and large volume implants to limit the potentially visible rippling and unnatural transition of the upper breast pole to the chest wall.^{7,11,23}

Our study indicated the importance of implantation supported by an insertion sleeve, which eases the implantation process, especially in large volume implants, while allowing the surgeon to decrease the skin incision length.³² Multiple studies have shown that funnel-assisted augmentations are characterized by lower rates of capsular contracture.^{33–37} Our analysis shows that patients who did not have sleeve-support implantation had a 1.7 times higher risk (95% CI, 1.14–0.55) of developing a complication. However, the analysis did not show a significant influence of sleeve use on any individual type of complication occurrence risk (Table 7). Therefore, the finding that sleeve use lowers the implant bottoming-out risk ($P = 0.013$; OR = 4.36; 95% CI, 1.34–14.2) should be treated as a probable result of bias (Table 5).

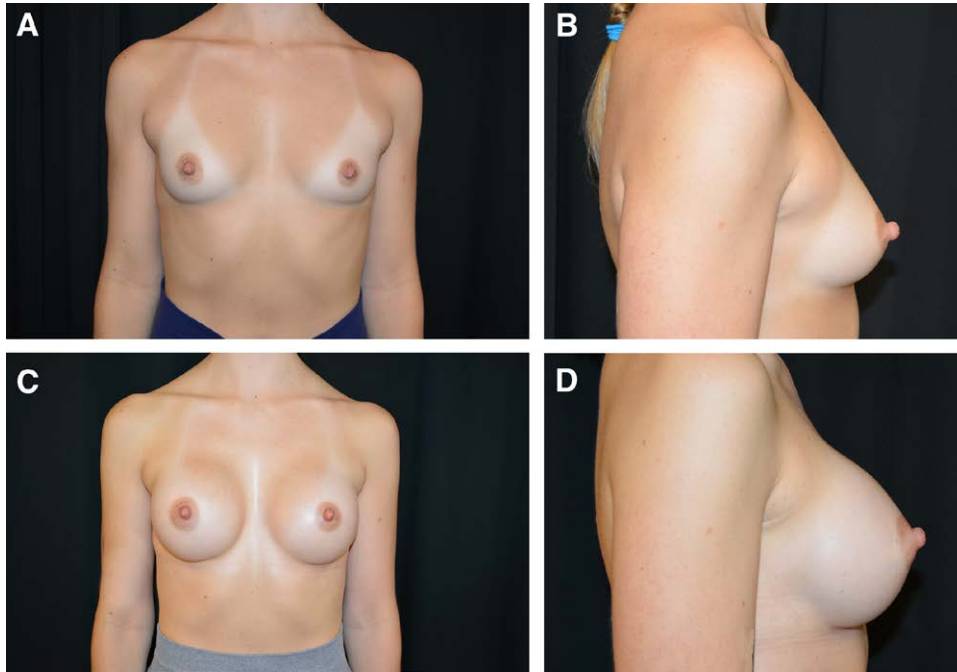


Fig. 3. An exemplary result of breast augmentation. A–B, A 30-year-old woman underwent breast augmentation with 250-mL Mentor round implants. C–D, Appearance at 12 months postoperatively.

One could expect that complication occurrence would decrease as the number of patients operated on increases. However, despite the lower complication rate in every next “experience group” (7.3%, 7.16%, and 6.67%, respectively), the data analysis did not show a statistically significant difference between them (0.912).

Another important finding is a higher risk for postoperative complications in large volume implants. A safety implant volume threshold was determined to be 370 mL, over which there is a 1.82 times higher risk of postoperative complication occurrence (95% CI, 1.31–2.55). Our threshold value matches the one reported by Henriksen et al and Huang et al, both of whom showed that implants larger than 350 cm had increased complication and secondary procedure rates.^{38,39} Implantation of large devices, due to the need for extensive lateral dissection, can cause nipple sensation disturbance.^{7,40} Therefore, inexperienced surgeons should consider performing surgery on patients requesting smaller implants. This agrees with the observed paradigm shift in augmentation mammoplasty in which natural breast shape is preferred over their size.^{10,11,23,41}

In our group, anatomical implants were used in 82% of cases. In contrast, up to 95% of patients in the United States receive round implants.⁷ Our study shows that anatomical implants had an overall lower complication rate than round implants ($P = 0.004$). Round implants had almost a 1.7 times higher risk of developing an early postoperative complication than shaped implants (95% CI, 1.18–2.41). This finding corresponds well with our previous report.²³ However, our study does not conclude that round implants are more prone to complication occurrence. Due to the unequal implant group sizes, a fully reliable comparative analysis cannot be performed. For the

same reason, we did not directly compare complication rates between various implant brands.

Our study has several limitations. First, a selection bias must be acknowledged. The patients’ follow-up loss rate of 26% and relatively short, uneven follow-up time prevent complete insight into postoperative complication occurrence patterns, especially capsular contracture and BIA-ALCL, whose incidence tends to increase with time.^{7,9,12} Also, the present implant rotation incidence can be underestimated, as a recent breast ultrasonography study suggests that the majority of those complication cases are clinically silent, while according to follow-up protocol, a confirmatory imaging study was performed only when obvious symptoms occurred.³⁰ Secondly, due to the patient’s preferences regarding breast aesthetics, our study group had an unequal number of round and anatomical implants, which did not allow for a direct comparison of risk related to both implant types.

Our study also did not include an objective analysis of breast sensation loss after the procedure; as an objective sensation evaluation before the surgery is not a part of our clinical protocol, we cannot present reliable, accurate data on the subject. Another limitation is the lack of aesthetic outcomes evaluation.^{42,43} Nonetheless, we have modified our postoperative follow-up protocol, and in the future, we will be able to show quantitative data on both subjects.

CONCLUSIONS

This study uniquely presents over 10 years of experience of a single plastic surgeon with one specific primary augmentation mammoplasty method. The most common postoperative complications were capsular contracture

and implant rotation. Based on the analysis of the results, a set of risk factors were also identified. These could constitute a guideline, especially for novice plastic surgeons considering performing breast augmentation.

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DISCLOSURES

Dr. Montemurro is a consultant speaker for POLYTECH. Dr. Pietruski has no financial interest to declare in relation to the content of this article.

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