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ORIGINAL ARTICLE BREAST SURGERY

Standardized Practice Reduces Complications in Breast Augmentation: Results with the First 290 Consecutive Cases Versus Non-standardized Comparators

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Abstract

Background Several systematic methods for breast augmentation have been published, providing key principles and technical steps for minimizing complications and optimizing patient satisfaction. The aim of this study was to compare complication rates in patients receiving a breast augmentation performed using a structured, standardized approach versus comparator patients operated on without a standardized approach.

Methods This was a single-center, retrospective review of 290 consecutive breast augmentations performed between October 2016 and September 2017 based on a standardized technique (Randquist's "five P's" combined with Adams' 14-point plan), and 235 comparators who underwent breast augmentations prior to standardization between April 2014 and September 2016. All study subjects were females aged ≥ 18 years, undergoing bilateral breast augmentation, either alone or in the context of augmentation mastopexy or implant replacement. Various implant ranges were used before standardization; most (94.8%) of the standardized procedures used Natrelle® devices. Follow-up lasted for ≥ 12 months.

Results Significantly fewer patients in the standardized surgery group experienced complications (14.5%, $n = 42$) compared with the non-standardized group [29.4%, $n = 69$; Chi square = 6.57; degrees of freedom (df) = 1; $p = 0.01041$]. Complication rates were also significantly lower in the standardized surgery group for each of the three types of breast augmentation surgery assessed separately. Reoperation rates with standardized and non-standardized surgery were 4.1% ($n = 12$) and 11.9% ($n = 28$), respectively (Chi square = 6.4; $df = 1$; $p = 0.01145$). Patient satisfaction was increased post-surgery in both groups.

Conclusions The use of a structured, standardized approach to breast augmentation reduced the risk of postoperative complications.

Level of Evidence IV This journal requires that authors assign a level of evidence to each article. For a full description of these Evidence-Based Medicine ratings, please refer to the Table of Contents or the online Instructions to Authors www.springer.com/00266.

Keywords Breast augmentation · Five P's · 14-Point plan

Introduction

Breast augmentation is one of the most popular aesthetic surgeries worldwide. In the USA, it has been the most commonly performed aesthetic surgery in every year since 2006, and the number of procedures continues to rise by about 4% each year [1].

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Reported complication rates after breast augmentation vary widely, but common adverse events may occur in more than 20% of patients at some point during follow-up [2]. To minimize complications and optimize patient satisfaction, various systematic methods for breast augmentation have been published, elucidating key principles and technical steps to follow throughout pre-, peri- and postoperative processes [3–6].

For example, Randquist and colleagues have developed the principle of the "five P's" (patient selection, proportional thinking, preoperative planning, performance, and postoperative care), which they believe can help to ensure predictable long-term outcomes and reduce complication rates [4]. Meanwhile, Adams and colleagues have developed a 14-point plan for minimizing bacterial load at the time of surgery [5]. This is important because bacteria/biofilm on breast implant surfaces have been implicated as an important cause of complications [7]. Use of the 14-point plan may reduce the development of capsular contracture and other downstream complications, including breast implant-associated anaplastic large-cell lymphoma (BIA-ALCL) [5].

However, while these methods may be associated with low complication rates in the hands of their originators, there is a lack of data to show whether the implementation of these techniques can reduce complications in the hands of surgeons who have previously not followed a structured methodology.

To improve the standardization of our own processes, we have been using Randquist's five 5 P's and the 14-point plan proposed by Adams and colleagues in all breast augmentation cases since October 2016. The aims of the present study were to examine the complication rate among 290 consecutive breast augmentations carried out using the standardized method and to compare it with the complication rate from 235 breast augmentations performed in the period immediately prior to standardization.

Materials and Methods

Study Design

This was a retrospective review of data from 525 patients undergoing breast augmentation at a single center between April 2014 and September 2017. Patients were divided into two groups. The 'standardized surgery' group underwent breast augmentation following a systematic approach, based on the five P's of Randquist [4] and the 14-point plan of Adams and colleagues [5]; these individuals were operated on between October 2016 and September 2017. The 'non-standardized surgery' group underwent breast augmentation at the same center without use of a standardized approach; these patients were operated on between April 2014 and September 2016. The study was approved by the Institutional Review Board and was conducted in accordance with the Declaration of Helsinki.

Patients

All study subjects were females aged $\geq$ 18 years, undergoing bilateral breast augmentation, either alone or in the context of augmentation mastopexy or implant replacement. Implants could be round or anatomical in shape. Written informed consent was obtained preoperatively.

Patients included in both the standardized and non-standardized surgery groups had a minimum of 12 months of follow-up.

Surgical Techniques

In the non-standardized surgery group, preoperative measurements were adapted from Tebbetts [8, 9]. The position of the new inframammary fold (IMF) was used to guide surgery, and the nipple to IMF distance was calculated in relation to the implant weight and not implant width. The surgical incision was made in the areola unless this was too small, in which case the incision was placed in the IMF. Implant pockets were made in the subglandular, submuscular, or dual plane, based on the coverage that could be given to the prosthesis. Blunt dissection was completed with fingers, and residual fibers were then cauterized. Hemostasis was not prospective. Drains were placed, and then the implants were washed with betadine and inserted directly into the pocket. A double subcutaneous-to-cutaneous suture was applied without fixing the fold. Wounds were covered with ultracompressive Tensoplast® bandages (BSN medical, Hamburg, Germany). Drains were removed 24 or 48 h postoperatively. Bandages were taken off after 5 days, and a medical bra applied. Single-antibiotic treatment with cefotaxime 2 g was given to all patients at induction and for 1 week starting on the day after surgery.

In the standardized surgery group, preoperative planning was performed according to the method proposed by Randquist [4]. A number of measurements were taken to inform implant selection and the positioning of the new IMF, including: base width (assessed from the anterior axial line to the lateral part of the 'no touch zone'); nipple-to-IMF distance (measured under maximum stretch from the lower part of the nipple to the existing IMF); intermammary distance (maintained at $\geq$ 3 cm to avoid complications); sternal notch-to-nipple distance; and soft-tissue pinch test (performed in the medial upper pole of the breast, and playing an important role in determining submuscular or subglandular implant placement). The new nipple-to-IMF distance was calculated as implant width

minus 3.5 cm, measured under maximum skin stretch, with a 0.5 cm allowance either way. Surgery was always performed in accordance with the 14-point plan of Adams and colleagues [5]. In particular, an IMF incision was used in all cases, and implants were placed in a dual-plane pocket. Careful prospective hemostasis was employed with every patient. Blunt dissection with fingers was not used. Both the pocket and the implants were washed with antibiotics (cefazolin 1 g and gentamicin 80 mg), in accordance with both Randquist's five P's and Adam's 14-point plan [4, 5]. Antibiotic solution was injected into the box containing the implant to eradicate static electricity. Other steps taken to limit bacterial contamination, in accordance with Adams, included the use of nipple shields, changing of surgical gloves before handling, and avoidance of sizers and drainage tubes [5]. The fold was fixed to the chest wall (rib) or to the fascia. Surgical wounds were closed with three layers of stitching (rib, dermis, epidermis). No compressive patches were used, and a medical bra was applied post-surgery in the operating room. Antibiotics were administered to all patients: cefazolin 2 g given 10 min prior to surgery, gentamicin 80 mg upon awakening from surgery, and cefazolin 2 g for 1 week starting on the day after surgery.

The standardized procedure is shown in detail in the accompanying video.

Assessments

Baseline assessments included age, weight, body mass index (BMI), pregnancy history, smoking status, comorbidities (as per electronic medical records), and concurrent drug therapies received at the time of surgery. Surgical details were also recorded, such as the overall methodology (standardized or not) and the implant volume and manufacturer (Allergan [Dublin, Ireland], BellaGel [Hans Biomed, Daejeon, South Korea], Perthese™ [Mentor, Santa Barbara, CA, USA], Mentor® [Mentor], Sebbin [Boissy-l'Aillerie, France], or Polytech [Dieburg, Germany]).

Table 1 Patient characteristics

	Non-standardized surgery (N = 235)			Standardized surgery (N = 290)		
	Augmentation (N = 138)	Aug. mastopexy (N = 76)	Replacement (N = 21)	Augmentation (N = 193)	Aug. mastopexy (N = 65)	Replacement (N = 32)
Age (years), mean (SD)	30.8 (8.0)	33.7 (8.2)	34.2 (8.3)	30.8 (7.4)	33.5 (9.1)	35.0 (9.0)
Weight (kg), mean (SD)	58.1 (6.6)	61.4 (8.0)	59.7 (7.1)	56.8 (7.4)	61.9 (7.5)	61.0 (7.9)
Height (cm), mean (SD)	164.8 (6.9)	163.5 (6.9)	164.9 (4.5)	163.0 (6.3)	164.0 (5.8)	160.0 (9.5)
BMI (kg/m^2), mean (SD)	21.4 (2.5)	22.7 (2.7)	21.9 (2.1)	21.2 (2.6)	23.1 (2.4)	22.3 (2.4)
Previous pregnancy [n (%)]						
Yes	39 (28.3)	36 (47.4)	11 (52.4)	99 (51.3)	51 (78.5)	20 (62.5)
No	50 (36.2)	13 (17.1)	4 (19.0)	94 (48.7)	14 (21.5)	12 (37.5)
Missing data	49 (35.5)	27 (35.5)	6 (28.6)	0	0	0
Smoker [n (%)]						
Yes	32 (23.2)	30 (39.5)	10 (47.6)	73 (37.8)	24 (36.9)	23 (71.9)
No	62 (44.9)	17 (22.4)	3 (14.3)	120 (62.2)	41 (63.1)	9 (28.1)
Missing data	44 (31.9)	29 (38.2)	8 (38.1)	0	0	0
Comorbidity [n (%)]						
Yes	9 (6.5)	8 (10.5)	2 (9.5)	33 (17.1)	18 (27.7)	8 (25.0)
No	69 (50.0)	34 (44.7)	11 (52.4)	160 (82.9)	47 (72.3)	23 (71.9)
Missing data	60 (43.5)	34 (44.7)	8 (38.1)	0	0	1 (3.1)
Concurrent drug therapy [n (%)]						
Yes	13 (9.4)	6 (7.9)	5 (23.8)	27 (14.0)	7 (10.8)	8 (25.0)
No	72 (52.2)	38 (50.0)	9 (42.9)	164 (85.0)	57 (87.7)	23 (71.9)
Missing data	53 (38.4)	32 (42.1)	7 (33.3)	2 (1.0)	1 (1.5)	1 (3.1)

Aug. augmentation, *BMI* body mass index, *SD* standard deviation

Table 2 Implant specifications

	Non-standardized surgery (N = 235)			Standardized surgery (N = 290)		
	Augmentation (N = 138)	Aug. mastopexy (N = 76)	Replacement (N = 21)	Augmentation (N = 193)	Aug. mastopexy (N = 65)	Replacement (N = 32)
Implant used [n (%)]						
Allergan	45 (32.6)[a]	38 (50.0)[a]	8 (38.1)[a]	179 (92.7)[b]	65 (100)[c]	31 (96.9)[d]
Mentor (round)	6 (4.3)	6 (7.9)	1 (4.8)	0	0	1 (3.1)
Perthese (round)	25 (18.1)	17 (22.4)	8 (38.1)	0	0	0
Polytech (round)	0	0	0	5 (2.6)	0	0
BellaGel (shaped)	53 (38.4)	13 (17.1)	2 (9.5)	4 (2.1)	0	0
Polytech (shaped)	2 (1.4)	0	0	4 (2.1)	0	0
Sebbin (shaped)	7 (5.1)	2 (2.6)	2 (9.5)	1 (0.5)	0	0
Implant volume (cm^3), mean (SD)						
Right	351.9 (46.7)	357.5 (46.5)	414.7 (91.9)	366.0 (41.5)	370.0 (57.4)	426.6 (106.4)
Left	349.3 (38.8)	357.9 (49.1)	413.7 (93.5)	365.2 (43.2)	377.3 (56.5)	429.1 (103.4)

Aug. augmentation, *SD* standard deviation

[a]From the Breast and CUI ranges

[b]Natrelle 410 MX, n = 87; Natrelle 410 MF, n = 31; Natrelle Inspira TSF, n = 57; Natrelle Inspira TSX, n = 4

[c]Natrelle 410 MX, n = 10; Natrelle 410 MF, n = 3; Natrelle Inspira TSF, n = 48; Natrelle Inspira TSX, n = 4

[d]Natrelle 410 MX, n = 6; Natrelle 410 MF, n = 2; Natrelle Inspira TSF, n = 19; Natrelle Inspira TSX, n = 4

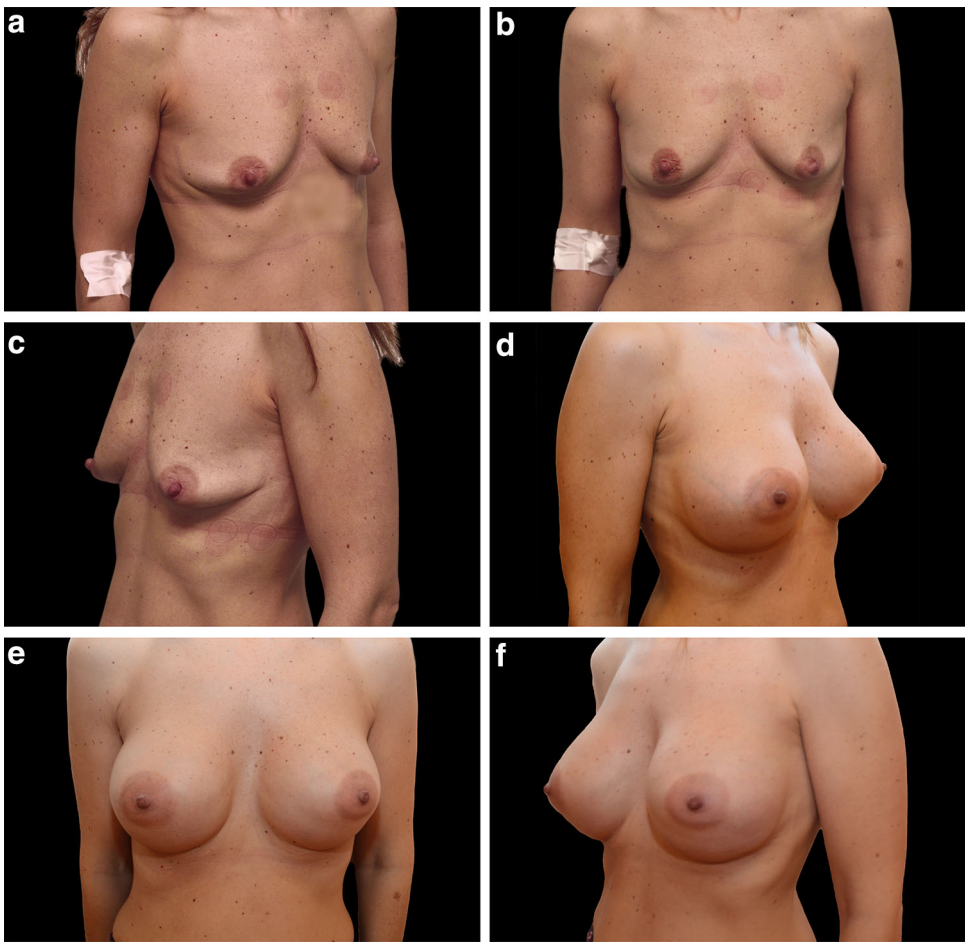

Fig. 1 Breast augmentation: non-standardized. A 34-year-old woman pre-surgery (**a**–**c**) and at 1 year (**d**–**f**) after breast augmentation with round 350-g devices inserted dual plane via an inframammary fold incision. Although the patient was satisfied with the result, the surgeon was not happy with the fold of the left breast. This patient may have benefitted from anatomical implants

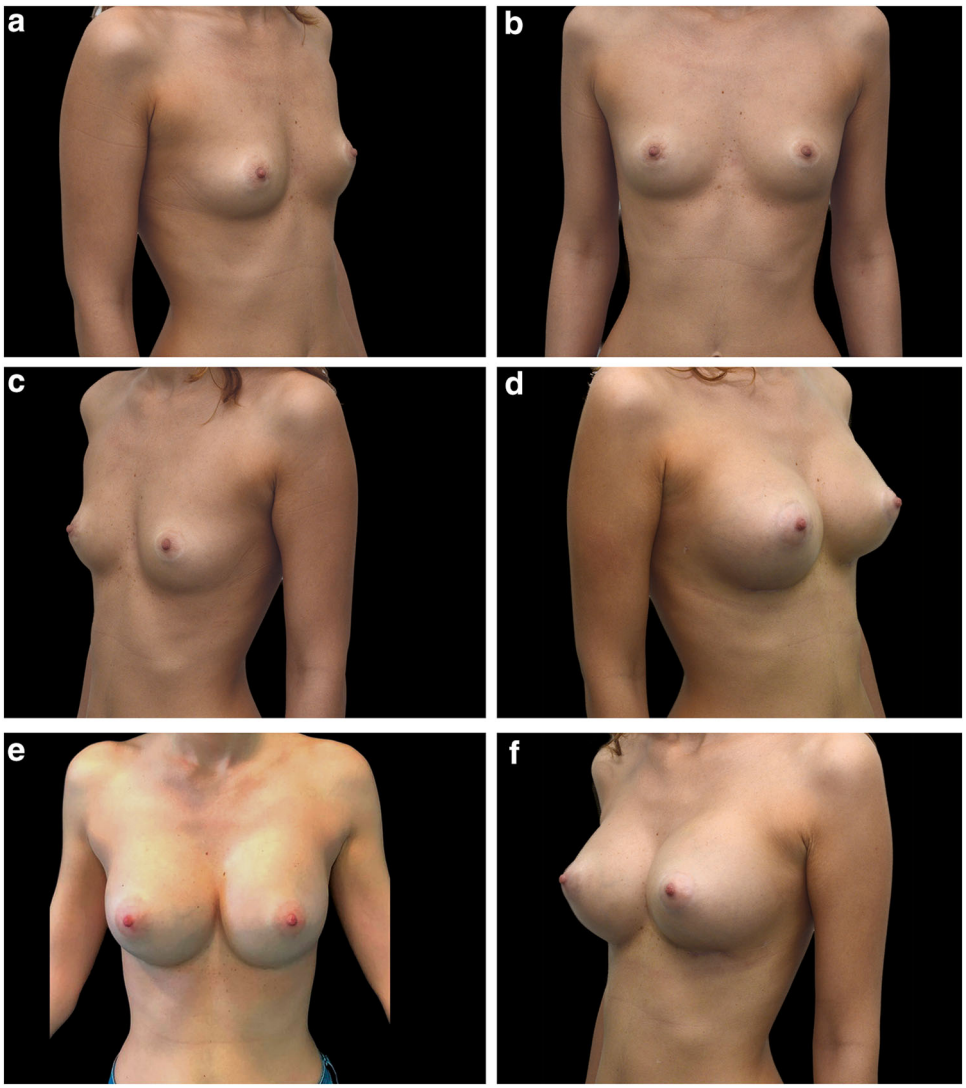

Fig. 2 Breast augmentation: non-standardized. A 25-year-old woman pre-surgery (**a**–**c**) and at 4 years (**d**–**f**) after breast augmentation with anatomical 320-g devices inserted dual plane via an inframammary fold incision. Although the patient was satisfied with the result, the surgeon was not happy with the symmastia

Complications were documented throughout the follow-up period. Rates of reoperation were also recorded. Patient satisfaction with their breasts was assessed preoperatively and at 12 months post-surgery on a scale of 0 (very negative) to 10 (very positive).

Statistical Analysis

Descriptive statistics are provided throughout. For continuous variables, means and standard deviations have been calculated; for categorical variables, absolute frequency and percentage are given.

Statistical analyses were performed using R version 1.0.143 (R Foundation for Statistical Computing, Vienna, Austria). Potential associations between the procedure (standardized or non-standardized surgery) and the development of complications, reoperations, and patient satisfaction were assessed using the Chi-square test or Welch two-sample t test. The differences were considered significant for values of $p < 0.05$.

Results

Baseline Characteristics and Surgical Specifications

A total of 525 patients met the inclusion criteria: 235 in the non-standardized surgery group and 290 in the standardized surgery group. At baseline, the two groups had a comparable mean age (32.0 ± 8.1 vs. 31.9 ± 8.1 years, respectively), weight (59.2 ± 7.2 vs. 58.4 ± 7.8 kg), and BMI (21.8 ± 2.6 vs. 21.7 ± 2.7 kg/m^2).

In the non-standardized surgery group, 138 patients (58.7%) underwent breast augmentation, 76 (32.3%) had an augmentation mastopexy, and 21 (8.9%) received implant replacement. In the standardized surgery group,

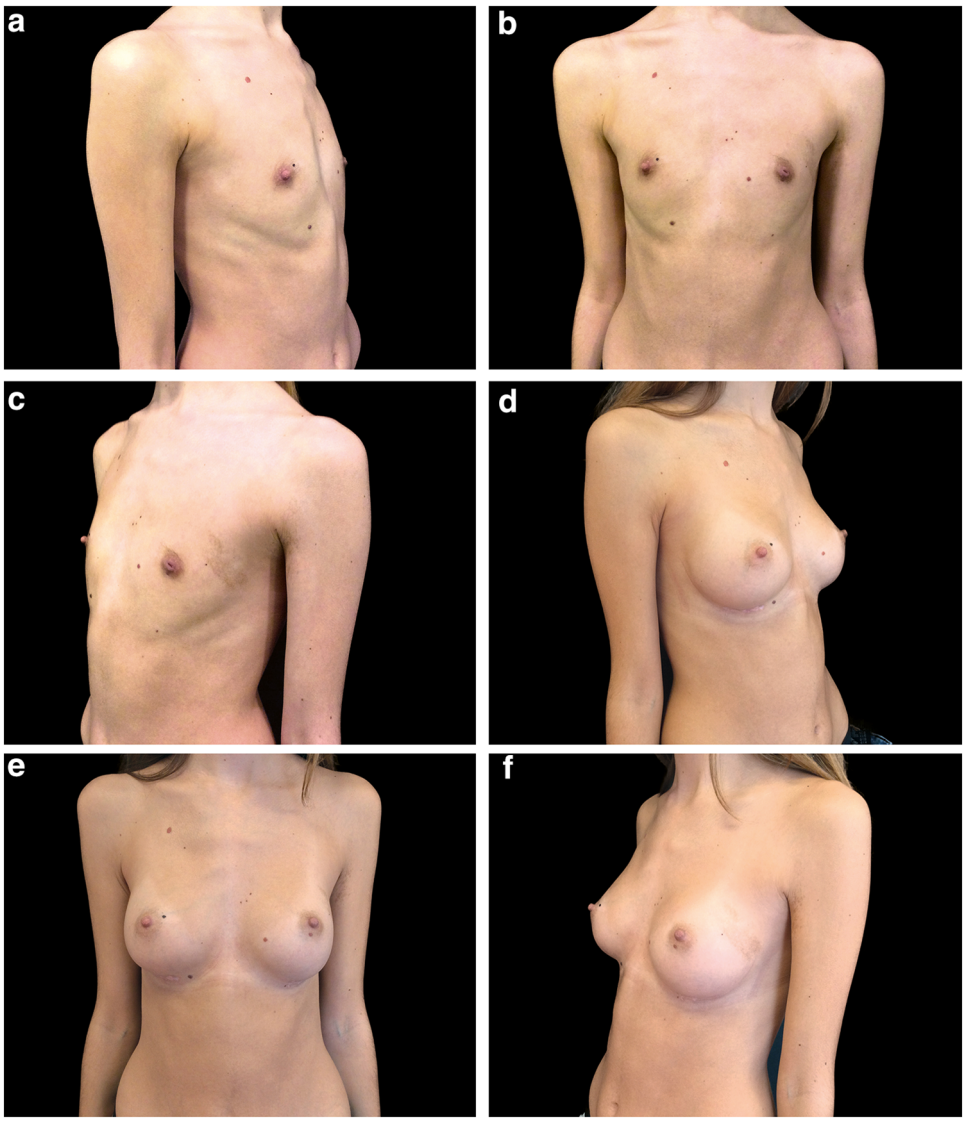

Fig. 3 Breast augmentation: standardized. A 19-year-old woman pre-surgery (**a**–**c**) and at 1 year (**d**–**f**) after breast augmentation with Natrelle 410 MX 225 g devices inserted dual plane via an inframammary fold incision

193 patients (66.6%) underwent breast augmentation, 65 (22.4%) had an augmentation mastopexy, and 32 (11.0%) received implant replacement.

Baseline characteristics in the different patient groups are shown in Table 1. These are broadly comparable between the two groups.

The specifications of the implants used in the non-standardized and standardized surgery groups are summarized in Table 2. The non-standardized surgery group received various types, most commonly from Allergan (n = 91, 38.7%; largely from the Breast and CUI ranges), BellaGel (n = 68, 28.9%; shaped devices), or Perthese (n = 50, 21.3%; round devices). By contrast, the standardized surgery group mostly received Allergan implants from the Natrelle® range of macrotextured devices (n = 275, 94.8%).

Mean follow-up was 15 months (range 12–19 months) in the standardized surgery group, and 32 months (range 12–36 months) in the non-standardized surgery group.

Representative before-and-after photographs from patients in the non-standardized (Figs. 1, 2) and standardized groups (Figs. 3, 4, 5) are provided.

Complications

Complications occurred in 29.4% (n = 69/235) of patients in the non-standardized surgery group. Significantly fewer patients operated on according to the standardized surgical protocol experienced complications [14.5%; n = 42/290; Chi square = 6.57; degrees of freedom (df) = 1; p = 0.0104] (Fig. 6; Table 3).

Complication rates were also significantly lower in the standardized surgery group for each of the three types of

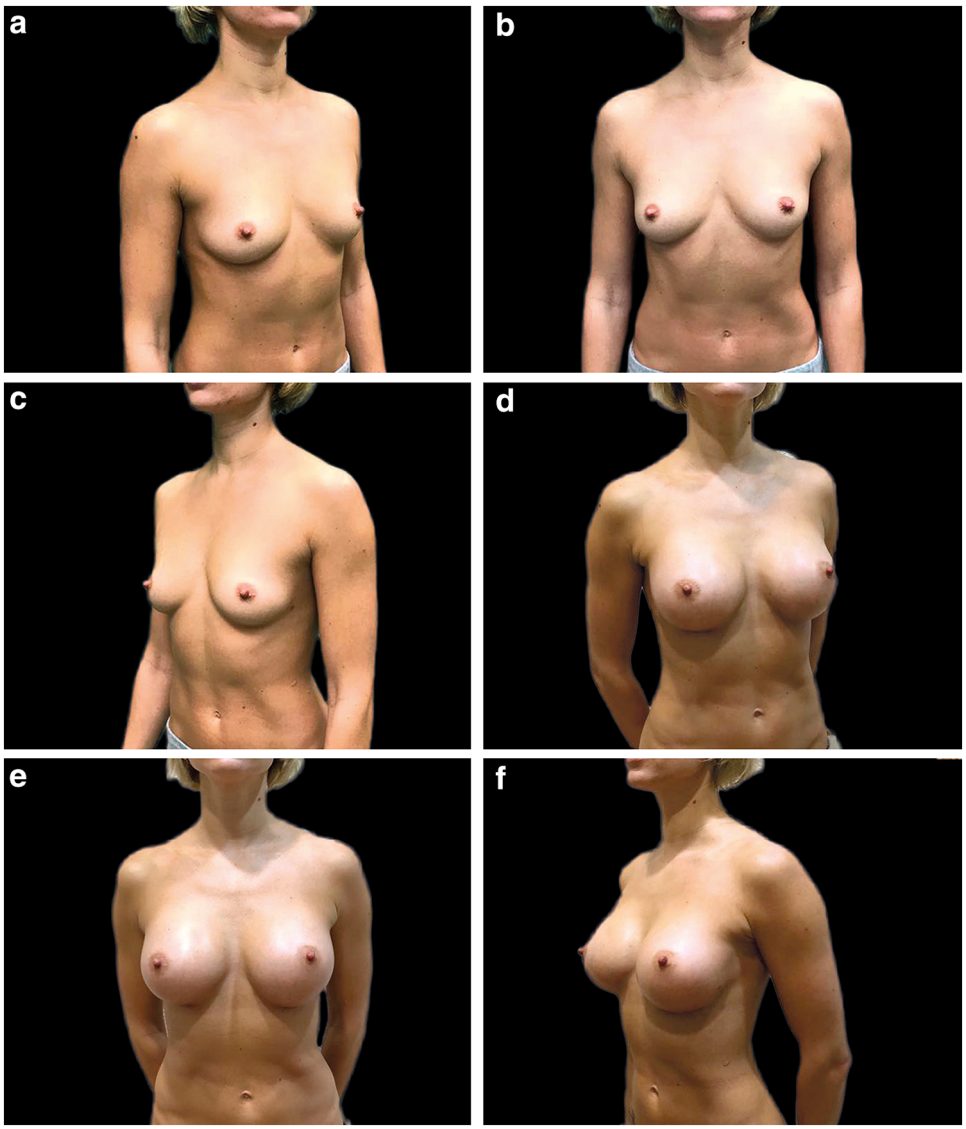

Fig. 4 Breast augmentation: standardized. A 32-year-old woman pre-surgery (**a**–**c**) and at 1 year (**d**–**f**) after breast augmentation with Natrelle 410 MX 370 g devices inserted dual plane via an inframammary fold incision

breast augmentation surgery assessed separately (Fig. 6; Table 3). Among patients receiving augmentation alone, complications occurred in 25.4% (n = 35/138) of those who underwent non-standardized surgery and 15.0% (n = 29/193) of patients in the standardized group (Chi square = 4.87; df = 1; p = 0.0273). In patients receiving augmentation mastopexy, complications occurred in 32.9% (n = 25/76) of the non-standardized group and 16.9% (n = 11/65) of the standardized group (Chi square = 3.90; df = 1; p = 0.0483). Finally, among patients receiving implant replacement, complications occurred in 42.9% (n = 9/21) of the non-standardized group and 6.3% (n = 2/32) of the standardized group (Chi square = 8.23; df = 1; p = 0.0041).

In the non-standardized surgery group, the most common complications were wound dehiscence (n = 25; 10.6%), seroma (n = 10; 4.3%), implant bottoming out (n = 9; 3.8%), implant rotation (n = 6; 2.6%), and implant dislocation (n = 6; 2.6%) (Table 3). In the standardized surgery group, the most common complications were implant bottoming out (n = 7; 2.4%), wound dehiscence (n = 6; 2.1%), seroma (n = 6; 2.1%), high implant (n = 5; 1.7%), and pseudoptosis (n = 5; 1.7%).

The reoperation rate was 11.9% (n = 28/235) in the non-standardized surgery group, compared with 4.1% (n = 12/290) in the standardized surgery group (Chi square = 6.4; df = 1; p = 0.0114).

Patient Satisfaction

In both groups, irrespective of the type of surgery undertaken, patient satisfaction with their breasts was low pre-intervention and was substantially improved at 12 months post-surgery (Table 4). However, these improvements

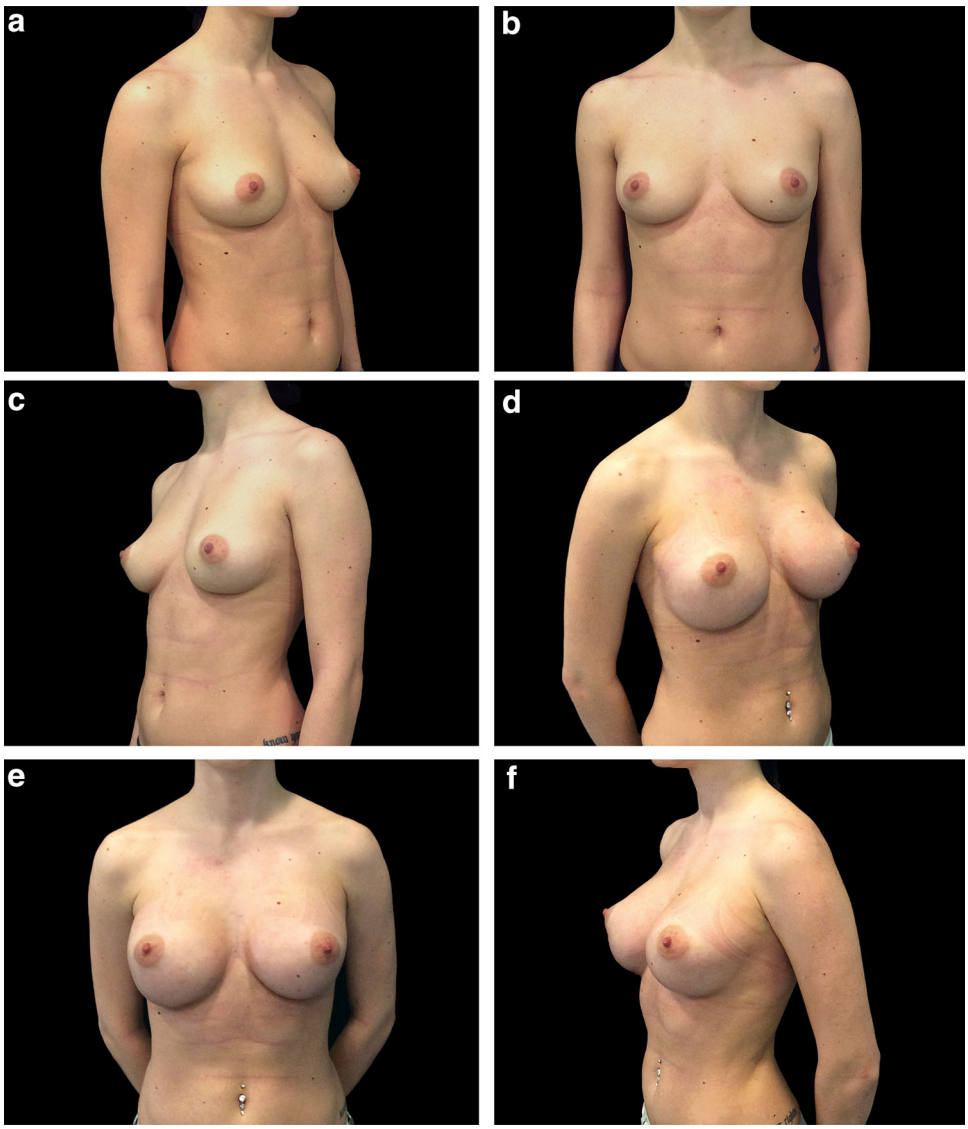

Fig. 5 Breast augmentation: standardized. A 27-year-old woman pre-surgery (**a**–**c**) and at 1 year (**d**–**f**) after breast augmentation with Natrelle 410 MF 375 g devices inserted dual plane via an inframammary fold incision

were greater in the standardized surgery group compared with non-standardized surgery, and this reached statistical significance in patients undergoing breast augmentation alone (mean score improved from 2.60 to 8.30 with non-standardized surgery and from 1.53 to 9.23 in the standardized surgery group; $p < 0.0001$).

Discussion

Breast augmentation is a popular aesthetic surgical intervention, but despite new operative techniques, it is still associated with a high risk of complications [2, 6]. Many factors can increase this risk, including the specific requests of patients, which may incorrectly condition the choice of prosthesis by the surgeon [10]. Other factors, such as smoking or the presence of comorbidities like diabetes, can also increase the risk of complications after breast augmentation [11, 12]. Hence, the expertise of the surgeon in assessing risk, selecting the appropriate implants, and managing the process from beginning to end remains crucial in minimizing complications and maximizing patient satisfaction [2, 3].

In recent years, several methods have been developed to reduce complications [3–6]. We have tested two of these methods in combination—Randquist's five 5 P's and the 14-point plan of Adams et al. [4, 5]. Compared with non-standardized comparators, use of the standardized techniques significantly reduced the complication rate (14.5% vs. 29.4%) and the frequency of reoperation (4.1% vs. 11.9%). Complication rates remained significantly lower with standardized versus non-standardized surgery for each of the three types of surgery considered (augmentation alone, augmentation mastopexy, and implant replacement).

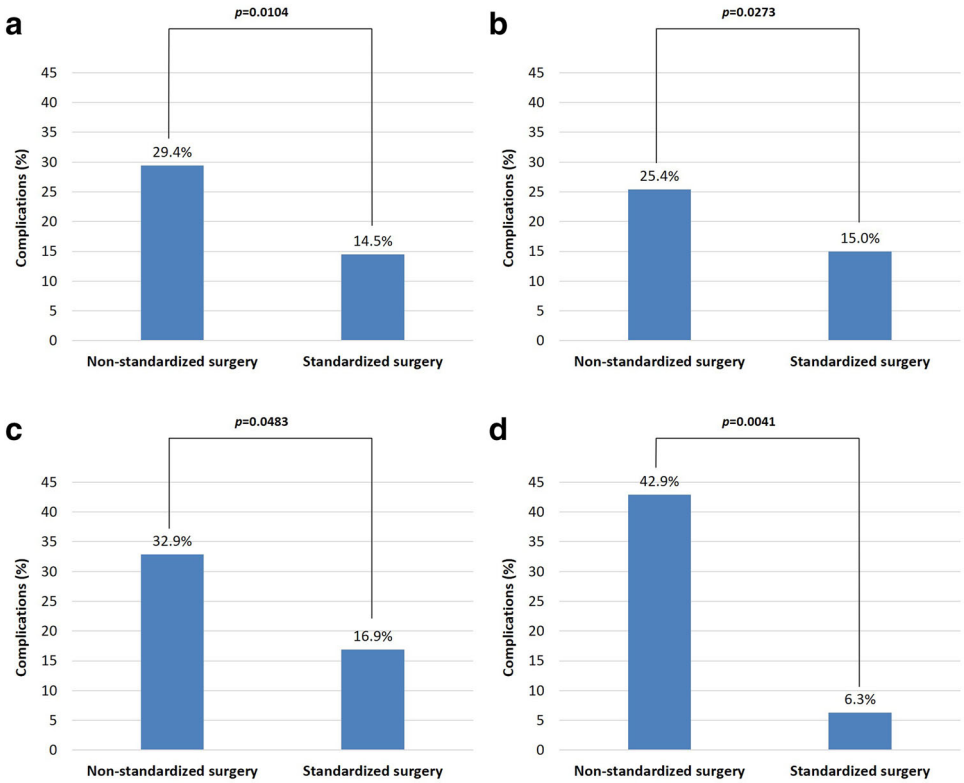

Fig. 6 Complication rates. Rates of complications in the entire study population (**a**), and in the breast augmentation (**b**), augmentation mastopexy (**c**), and implant replacement (**d**) groups considered separately

Although follow-up was longer in the non-standardized group, most complications occurred during the first year, and hence follow-up duration is not a major factor in explaining the lower complication rate in the standardized surgery group.

These results, from an experienced surgeon adopting a standardized methodology, align with recent data from a young surgeon implementing a systematic approach at the start of his career: He had a complication rate of 14.8% and a reoperation rate of 8.7% across 620 breast augmentations [13]; rates did not differ substantially according to implant shape (round vs. anatomical) [14].

There are several aspects of the standardized method that may have contributed to the reduction in complications observed in the present work. With regard to the five P's, key innovations center on the concept of careful patient selection taking into account mental state (first P), and also respect for individual physical proportions (second P), which then relate to the maximum expansion of the implant pocket [4]. Such expansion can be calculated by applying the formulas provided by Randquist. This methodology also provides recommendations on standardizing elements of the surgery (incision, pocket dissection, implants, suturing, etc.) and postoperative care.

With respect to the 14-point plan, these steps define a surgical strategy to reduce bacterial contamination, which has been shown to be associated with development of capsular contracture and BIA-ALCL [5, 15–17]. Key aspects of this plan include the use of multiple antibiotics to wash the implant and pocket, minimization of trauma, and reduced usage of tools that can introduce bacteria (such as sizers and drains) [5]. Use of these techniques in more than 21,000 surgeries, with a mean follow-up of 11.7 years, was associated with a capsular contracture rate of 2.2% and no patients developed BIA-ALCL [5]. Although the use of textured implants has been associated with an increased risk of BIA-ALCL in other studies [18], it remains very rare and the risk is counterbalanced by the advantages of these devices. In the present study, there were only 2 cases of grade III/IV capsular contracture in the 290 patients undergoing standardized surgery (0.7%); however, follow-up was too short to assess BIA-ALCL.

The changes from an areolar incision in most of the non-standardized surgeries to an IMF incision in all of the standardized surgeries could also have played a role in reducing complications. Previous work suggests that the IMF incision may be associated with lower rates of capsular contracture and implant malposition, possibly by allowing a more precise and atraumatic dissection and by limiting exposure to tissue colonized with bacteria [19].

As part of the standardization process, we moved away from using a variety of implant manufacturers toward using a single supplier (Allergan Natrelle). The macrotextured surface of these devices has been designed to maximize

Table 3 Complications

	Non-standardized surgery				Standardized surgery			
	All patients (*N* = 235)	Augmentation (*N* = 138)	Aug. mastopexy (*N* = 76)	Replacement (*N* = 21)	All patients (*N* = 290)	Augmentation (*N* = 193)	Aug. mastopexy (*N* = 65)	Replacement (*N* = 32)
Total	69 (29.4)	35 (25.4)	25 (32.9)	9 (42.9)	42 (14.5)	29 (15.0)	11 (16.9)	2 (6.3)
Wound dehiscence	25 (10.6)	9 (6.5)	11 (14.5)	5 (23.8)	6 (2.1)	2 (1.0)	3 (4.6)	1 (3.1)
Seroma	10 (4.3)	7 (5.1)	3 (3.9)	0	6 (2.1)	6 (3.1)	0	0
Implant bottoming out	9 (3.8)	8 (5.8)	1 (1.3)	0	7 (2.4)	5 (2.6)	2 (3.1)	0
Implant rotation	6 (2.6)	4 (2.9)	1 (1.3)	1 (4.8)	1 (0.3)	1 (0.5)	0	0
Implant dislocation	6 (2.6)	2 (1.5)	1 (1.3)	3 (14.3)	0	0	0	0
Hematoma	4 (1.7)	0	4 (5.3)	0	2 (0.7)	2 (1.0)	0	0
Double-bubble deformity	2 (0.9)	1 (0.7)	1 (1.3)	0	4 (1.4)	2 (1.0)	2 (3.1)	0
Capsular contracture[a]	2 (0.9)	1 (0.7)	1 (1.3)	0	2 (0.7)	1 (0.5)	0	1 (3.1)
High implant	1 (0.4)	1 (0.7)	0	0	5 (1.7)	4 (2.1)	1 (1.5)	0
Implant wrinkling	1 (0.4)	1 (0.7)	0	0	0	0	0	0
Implant extrusion	1 (0.4)	1 (0.7)	0	0	0	0	0	0
Delayed wound healing	1 (0.4)	0	1 (1.3)	0	2 (0.7)	2 (1.0)	0	0
Partial nipple necrosis	1 (0.4)	0	1 (1.3)	0	0	0	0	0
Pseudoptosis	0	0	0	0	5 (1.7)	3 (1.6)	2 (3.1)	0
Implant rupture	0	0	0	0	1 (0.3)	1 (0.5)	0	0
Symmastia	0	0	0	0	1 (0.3)	0	1 (1.5)	0

Data are *n* (%)

[a]Baker grade III/IV

Table 4 Patient satisfaction

	Non-standardized surgery		Standardized surgery		*p* value[a]
	Pre-surgery	12 months post-surgery	Pre-surgery	12 months post-surgery	
Breast augmentation	2.60	8.30	1.53	9.23	< 0.0001
Augmentation mastopexy	2.53	7.25	1.85	8.65	0.0640
Implant replacement	3.47	7.21	3.50	8.36	0.5765

Data are means assessed on a scale of 0 (very negative) to 10 (very positive)

[a]Standardized versus non-standardized at 12 months post-surgery

tissue adhesion and, hence, reduce device mobility [20]. Logically, decreased implant mobility should reduce rates of implant rotation, dislocation and wrinkling [20], and indeed, in the present series, only one such complication was observed with the standardized surgery based on macrotextured implants (a case of implant rotation). By

comparison, 13 such complications occurred in the non-standardized surgery group implanted with a variety of different devices (rotation, $n = 6$; dislocation, $n = 6$; wrinkling, $n = 1$).

Rates of wound dehiscence were also lower in the standardized surgery group compared with the non-standardized group. Several factors could underlie this improvement, including reduced seroma rates, as well as the use of three layers of suturing and greater accuracy in pocket dissection, as recommended in the standardized techniques followed [4, 5].

The key strength of this study was the comparison of methodologies in the hands of the same surgeons. However, we must acknowledge important limitations. First, there was a temporal gap between two groups of patients and therefore the reduced complication rate in the second (standardized surgery) group might simply reflect the 'learning curve' of the surgeons involved. However, the time gap was relatively small (all of the operations took place across < 4 years) and the difference in complication rates is too large for normal evolution of skill to be a satisfactory explanation. Second, the study was retrospective in design; a prospective evaluation of the impact of standardizing surgical methodology would be welcome. Third, mean follow-up in the standardized surgery group was relatively short (15 months), and a greater study duration will be required to assess long-term complications like BIA-ALCL; however, other work has suggested that the use of standardized methods can durably prevent the development of BIA-ALCL with macrotextured implants [5].

Conclusions

Complications associated with breast augmentation can have many different causes. The choice of implants, surgical procedure, and follow-up are key to achieving a good aesthetic result and increased patient satisfaction, while maintaining a low risk of complications. Reproducible surgical methods are also important in preventing serious complications like BIA-ALCL [5]. The present study demonstrates that the use of standardized procedures can significantly reduce overall complication rates, with high levels of patient satisfaction.

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Compliance with Ethical Standards

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

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