AICPE
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Breast Surgery

Transitioning From Conventional Textured to Nanotextured Breast Implants: Our Early Experience and Modifications for Optimal Breast Augmentation Outcomes

Aesthetic Surgery Journal
2020, 1–7

DOI: 10.1093/asj/sjaa169
www.aestheticsurgeryjournal.com
OXFORD
UNIVERSITY PRESS

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Abstract

Background: Nanotextured breast implants were hailed as an innovation that may address capsular contracture and breast implant-associated anaplastic large cell lymphoma and may provide the sweet spot between smooth and conventional textured implants.

Objectives: This study aimed to evaluate the introduction of nanotextured implants alongside conventional textured implants and to compare early complications.

Methods: Patients who underwent breast augmentation from the introduction of nanotextured implants in the author's practice with at least 1 year of follow-up were included. They were divided into nanotextured and conventional textured implant groups and then into 3 chronological subgroups. Patient characteristics, implant specifications, operative factors, and complication rates were compared.

Results: A total 415 cases with a mean follow-up of 26.9 months were identified, of which 38.8% utilized nanotextured implants and 61.2% conventional textured implants. Utilization of nanotextured implants increased from 26.9% in period 1 to 54.5% in period 3. Complication rates for the conventional textured group were 0.8% at 1 year and 3.5% on overall follow-up, with mostly capsular contractures; for the nanotextured group, complication rates were 6.8% and 8.7%, respectively, and "bottoming out" was most common. When analyzed across chronological subgroups, complication rates decreased for nanotextured implants by period 3.

Conclusions: A learning curve and associated complications are expected for early adopters of new implants. In our series, nanotextured implants were associated with higher complication rates at 1 year and on overall follow-up. Modifications in patient selection, intraoperative techniques, and postoperative care reduced complications in the later period.

Level of Evidence: 4

Editorial Decision date: June 11, 2020; online publish-ahead-of-print June 24, 2020.

Since the first-generation devices of the 1960s, breast implants and implantation techniques have evolved substantially over the past 6 decades. Implant-based breast augmentation has weathered through different seasons of gloom and concern. These include the historical ban of silicone gel implants by the US Food and Drug Administration in 1992,[1] the emerging risk of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL),[2,3] and most

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recently the evolving recognition of breast implant illness.[4-6] Despite these challenges, advances in implant technology and understanding of tissue-implant interactions have contributed to the state of the art today. Nonetheless, the risk of capsular contracture, implant rupture, malposition, and BIA-ALCL has not been completely eliminated.

The advent of "nanotextured" implant shell surface has been hailed as an innovation that may address both the risks of capsular contracture and BIA-ALCL. Surface texturization was previously purported to reduce the risk of capsular contracture by avoiding the parallel alignment of collagen fibers.[7,8] However, more recent studies have challenged the notion, and "macrotextured" shell surfaces are now being implicated for late seroma, double capsule formation, increased risk of biofilm formation, and subsequent development of BIA-ALCL.[8] The new generation of Motiva breast implants with "nanotextured" shell surface (Establishment Labs, Alajuela, Costa Rica) was marketed as a sweet spot between smooth and conventional textured implants. Plastic surgeons previously utilizing smooth or conventional textured implants were therefore intrigued by these new devices. Of note, the latest ISO 14607:2018 definition classifies the SilkSurface shell surface as "smooth." Early adopters might be thwarted by the initial learning curve and be frustrated by a global lack of experience with its peculiarities and long-term outcomes. Importantly, the limited literature reports the outcome of these "nanotextured" implants without direct comparison with other surface types and the prevailing complication rate at the surgeons' practice.[9-11] In this study, we aimed to evaluate our early experience when introducing the utilization of "nanotextured" implants alongside conventional textured implants. Through the review of our experience, we sought to discern the complication rate and potential pitfalls with "nanotextured" implants compared with conventional textured implants. In addition, we discussed the modifications in patient selection, surgical techniques, and postoperative care that we have adopted with this new generation of implants.

METHODS

Patients and Database Management

A clinical database of primary breast augmentations performed by the first author (P.M.) between July 2016 and March 2019 was utilized for retrospective chart review. Patient characteristics, implant specifications, operative factors, and complications were routinely recorded for the purpose of clinical audit. Patients from the date on which nanotextured implants were introduced into our practice were included. Patients with less than 1 year of follow-up were excluded. The dataset was rendered anonymous by an institutional trusted third party and organized into 2 main implant groups (ie, conventional textured and nanotextured). The groups were further organized chronologically into 3 period subgroups for analysis of period effect. Patient characteristics included age, body mass index, smoking status, parity, and preoperative cup size. Implant specifications such as height, projection, and volume, and operative factors such as incision, plane of implant placement, and date of surgery were recorded. Presence of complication was recorded as binary endpoints at 1 year and at start of analysis, which is employed to derive the complication rate at 1-year follow-up and overall complication rate, respectively. The type of complication (ie, rotation, Baker grade III/IV capsular contracture, malposition, infection, double-bubble deformity, double capsule formation, seroma, implant rupture) and time to complication were recorded. Statistical analysis and modeling were performed utilizing STATA/IC 15.1 (StataCorp LLC, College Station, TX). Informed consent was waived because the study is non-interventional and an anonymous database without identifiers was analyzed by the authors. All aspects of this study were conducted in accordance with the Declaration of Helsinki and the subsequent revisions.

Preoperative Consultation and Planning

All patients underwent a standardized preoperative assessment and counseling by the first author (P.M.) and trained nurse clinicians before surgery. Preoperative planning and marking were performed utilizing the AK method,[12] and the exact implants were decided based on patient's desires and tissue characteristics. Conventional textured implants included both round and anatomic implants from Mentor (CPG Gel with SILTEX surface; Mentor Worldwide LLC, Irvine, CA), Polytech (Replicon with MESMO sensitive surface; Polytech Health & Aesthetics GmbH, Dieburg, Germany), and Allergan (Natrelle 410 or INSPIRA with Biocell surface, Allergan, Dublin, Ireland). Nanotextured implants utilized were Motiva Round or Ergonomix silicone gel implants with SilkSurface (Establishment Labs, Alajuela, Costa Rica).

Surgical Technique

The inframammary fold incision was utilized in all cases. A no-touch technique utilizing electrostatic mitigation, antibiotic wash, nipple shields, pre-insertion glove change, and insertion sleeve (Keller funnel, Allergan) were routine in all cases. No drain or postoperative antibiotics were utilized. The inframammary fold was fixed and the incision was closed utilizing barbed sutures as previously described in the "4-layered closure technique."[13]

Table 1. Patient Demographics, Breast Characteristics, Implant Volume, and Plane of Implantation

	Conventional textured group	Nanotextured group
No. of patients	254 (61.2%)	161 (38.8%)
Mean follow-up, mo (SD)	28.6 (9.26)	24.3 (8.17)
Mean age, y (range)	33.5 (18-60)	30.8 (18-62)
Mean BMI, kg/m^2 (SD)	20.92 (1.912)	20.36 (1.691)
Mean parity (SD)	1.35 (1.179)	0.93 (1.189)
Number of tobacco users (%)	18 (7.1%)	15 (9.3%)
Preoperative cup size, count (%)		
A	165 (65.0%)	118 (73.3%)
B	81 (31.9%)	35 (21.7%)
C	8 (3.1%)	8 (5.0%)
Mean volume of implant, mL (SD)	322.0 (59.56)	341.82 (69.32)
Dual plane type, count (%)		
1	0 (0%)	0 (0%)
2	128 (50.4%)	120 (74.5%)
3	107 (42.1%)	28 (17.4%)
Subglandular	19 (7.5%)	13 (8.1%)

BMI, body mass index; SD, standard deviation.

Postoperative Care and Follow-up

Postoperatively, the patients were started on a specialized support brasserie immediately after surgery and continued to wear it day and night for up to 3 months. They are discharged on the same day and allowed to resume light exercises after 3 weeks (ie, no chest exercise and running). They were reviewed at 1 week, 6 months, and 1 year by the operating surgeon. Follow-up review at the end of the first year was encouraged by the waiver of fees for any related revisional surgery within the first year. Any patient noted to have a complication was additionally evaluated by the operating surgeon when needed.

RESULTS

A total 415 cases of primary breast augmentation with a mean follow-up of 26.9 months (range, 12.2-45.3 months) were identified based on the inclusion and exclusion criteria. Of these, 254 cases (61.2%) aged a mean of 33.5 years (range, 18-60 years) utilized conventional textured implants, and 161 cases (38.8%) aged a mean of 30.8 years (range, 18-62 years) utilized nanotextured implants. All patients were female. The patient characteristics of the conventional textured and nanotextured groups were largely comparable (Table 1). When divided into 3 chronological subgroups, the utilization of nanotextured implants demonstrated a steady increase from 26.9% of implants in period 1 to 54.5% of implants employed in period 3 (Table 2). In period 3, the number of patients receiving either implant type was comparable.

Table 2. Subgroups by Chronological Periods

	Conventional textured group	Nanotextured group
No. of patients	254	161
Period 1	136 (73.1%)	50 (26.9%)
Period 2	67 (57.3%)	50 (42.7%)
Period 3	51 (45.5%)	61 (54.5%)

The complication rate at the 1-year follow-up was 0.8% (2 cases) for the conventional textured group with 1 case of rotation and 1 case of seroma. For the nanotextured group at 1-year follow-up, 6.8% (11 cases) of patients experienced complications with all recorded as "bottoming out." Of these, most occurred in period 1 (7 cases). The higher complication rate with nanotextured implants at 1-year follow-up is statistically significant ($P < 0.01$). The overall complication rate for the conventional textured group was 3.5% (n = 9) with 4 cases of Baker III/IV capsular contracture, 3 cases of rotation, and 2 cases of seroma at a mean follow-up of 28.6 months (range, 12.2-45.3 months). The overall complication rate was 8.7% (n = 14) for the nanotextured group, with 12 cases of bottoming out and 2 cases of Baker III/IV capsular contracture at a mean follow-up of 24.3 months (range, 12.3-45.3 months). The higher complication rate with nanotextured implants in overall follow-up was also statistically significant ($P < 0.05$).

When the period subgroups were compared, a statistically significant decline in complication rate at 1-year follow-up was seen in the nanotextured group over time (ie, from 14.0% to 1.6%, $P < 0.05$; Table 3). No significant difference in complication rates was noted for the conventional textured group over time ($P > 0.05$; Table 3). Logistic regression demonstrated the utilization of conventional textured implants was associated with lower risk of complications at 1-year follow-up (odds ratio: 0.108; 95% confidence interval [CI]: 0.024-0.495) and at overall follow-up (odds ratio: 0.386; 95% CI: 0.163-0.913) when compared to nanotextured implants (Table 4). When age, chronological subgroup, body mass index, parity, and volume of implants were considered, conventional textured implants were significantly associated with lower risk of early complication

Table 3. Complication Rates at 1-Year and Overall Follow-up

	Conventional textured group	Nanotextured group	*P* value
Complications at 1-year follow-up			
Period 1	1 (0.7%)	7 (14.0%)	<0.01
Period 2	0 (0%)	3 (6.0%)	NS
Period 3	1 (2.0%)	1 (1.6%)	NS
Total	2 (0.8%)	11 (6.8%)	<0.01
Overall complications			
Period 1	5 (3.7%)	8 (16.0%)	<0.01
Period 2	1 (1.5%)	3 (6.0%)	NS
Period 3	3 (5.9%)	3 (4.9%)	NS
Total	9 (3.5%)	14 (8.7%)	<0.05

NS, not significant.

(adjusted odds ratio: 0.140; 95% CI: 0.028-0.710) when compared to nanotextured implants. Utilizing stepwise logistic regression modeling, implants ≥400 cc (adjusted odds ratio: 5.15; 95% CI: 1.32-20.2) were also identified as a predictor of complication at 1-year follow-up.

Representative results of breasts augmented with nanotextured implants and with conventional textured implants are shown in Figures 1 and 2, respectively.

DISCUSSION

Early Complication Rates With Nanotextured and Conventional Textured Implants

Interestingly, with the new generation of nanotextured implants, the type of complication and time of presentation differed from our experience with the conventional textured implants. We observed a high occurrence of bottoming out (n = 11) as the prime complication as early as in the first year of follow-up. This was not seen in the conventional textured group, which presented mainly with complications after the first year including seroma, capsular contracture, and implant rotation. The higher rate of bottoming out in the nanotextured group may be explained by the thinner capsules that we have observed during the explant or exchange of these implants and its performance being similar to smooth implants. Further studies may be needed to confirm the causality and examine the quality of the capsule formed with nanotextured shell surface. Capsular contractures were noted in both conventional textured and nanotextured implants. The overall complication rates are ostensibly higher in the nanotextured group, but higher rates in the earlier period of introduction likely skewed this. The short duration of follow-up precludes any conclusion on the occurrence rate of capsular contracture over a longer time period. No BIA-ALCLs were noted in the overall follow-up period of our study.

Learning Curve When Transitioning to Nanotextured Implants

As with any transition to a new surgical technique or medical device, a learning curve was observed in our study. The utilization of preoperative planning methods, surgical techniques, and postoperative care employed with conventional textured implants resulted in a higher complication rate with nanotextured implants (ie, 14.0%) in period 1. The complication rate decreased over the study period to match the conventional textured implant group by period 3. We noted that this coincided with the restriction in patient selection and modifications in surgical techniques devised by the authors to address the early occurrence of bottoming out. However, for surgeons from a predominantly smooth implant practice, the learning curve may be different or less steep. This is because the required approach in patient selection and surgical technique may be similar with that taken in the utilization of smooth implants. Nonetheless, whether the behavior of nanotextured implants is identical to that of smooth implants is still undetermined. Future basic and clinical studies that compare the capsule characteristics and long-term outcomes may provide answers.

Modifications in Planning, Surgical Technique, and Postoperative Care for Nanotextured Implants

The observation of a higher rate of bottoming out on early follow-up prompted the authors to modify planning, surgical technique, and postoperative care that may prevent its occurrence. By period 3, the authors began to use the nanotextured implants only in patients with good soft tissue elasticity (small and firm breasts) and lower intended implant volume (<350 cc) due to the observation of higher complications among patients not satisfying these criteria. The main modification in surgical technique is the dissection of a very tight pocket to minimize inferior and lateral migration. In patient postoperative care, the authors reinforced the advice to utilize a support brasserie for up to 3 months by period 2. Patients were also strongly advised to resume strenuous activities only after 3 months with the strict utilization of a sport brassiere. The authors opined

Table 4. Odds Ratios for Complication Demonstrated Lower Risk With Utilization of Conventional Textured Implants

	Odds ratio for complication (95% CI)		Adjusted odds ratio[a] for complication (95% CI)	
	1-year follow-up	Overall	1-year follow-up	Overall
Use of conventional textured implants[b]	0.108 (0.0237-0.495)	0.386 (0.163-0.913)	0.110 (0.0226-0.539)	0.393 (0.154-1.01)

BMI, body mass index; CI, confidence interval. [a]When adjusted for age, chronological subgroup, BMI, parity, implant >400 cc. [b]When compared to nanotextured implant as the reference category for logistic regression computation.

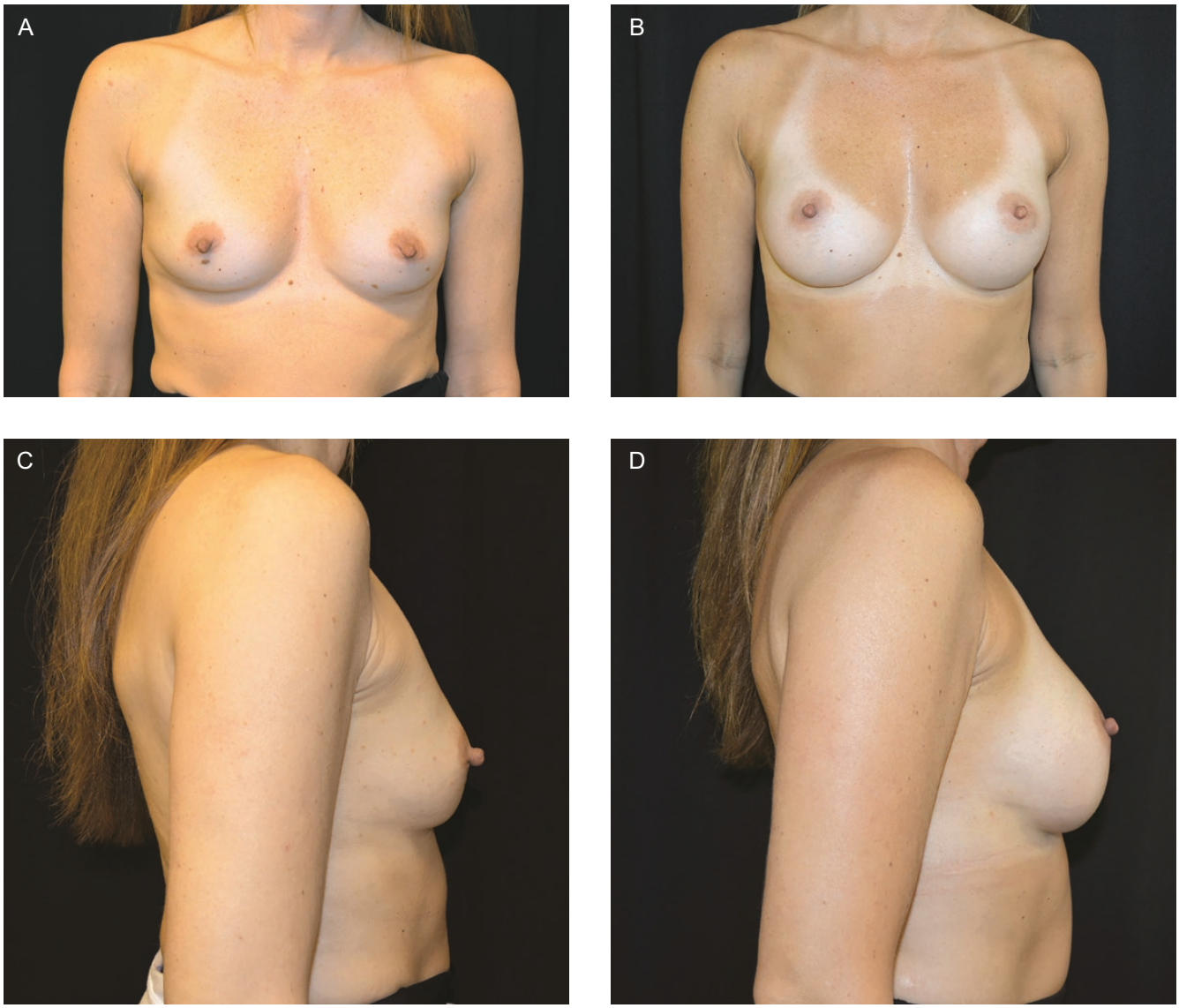

Figure 1. (A, C) Preoperative photos of this 38-year-old woman who underwent primary breast augmentation with 230-cc nanotextured implants. (B, D) Appearance at 13 months postoperatively.

that nanotextured implants should be treated similarly as smooth surface implants in decision-making and choice of surgical technique. As a result, a steady decrease in usage of nanotextured implants was seen (19% of all implants; unpublished data) beyond period 3 of this study (from April 2019 to February 2020) in our practice due to the stricter patient selection criteria and concern for the higher early complications observed in this review.

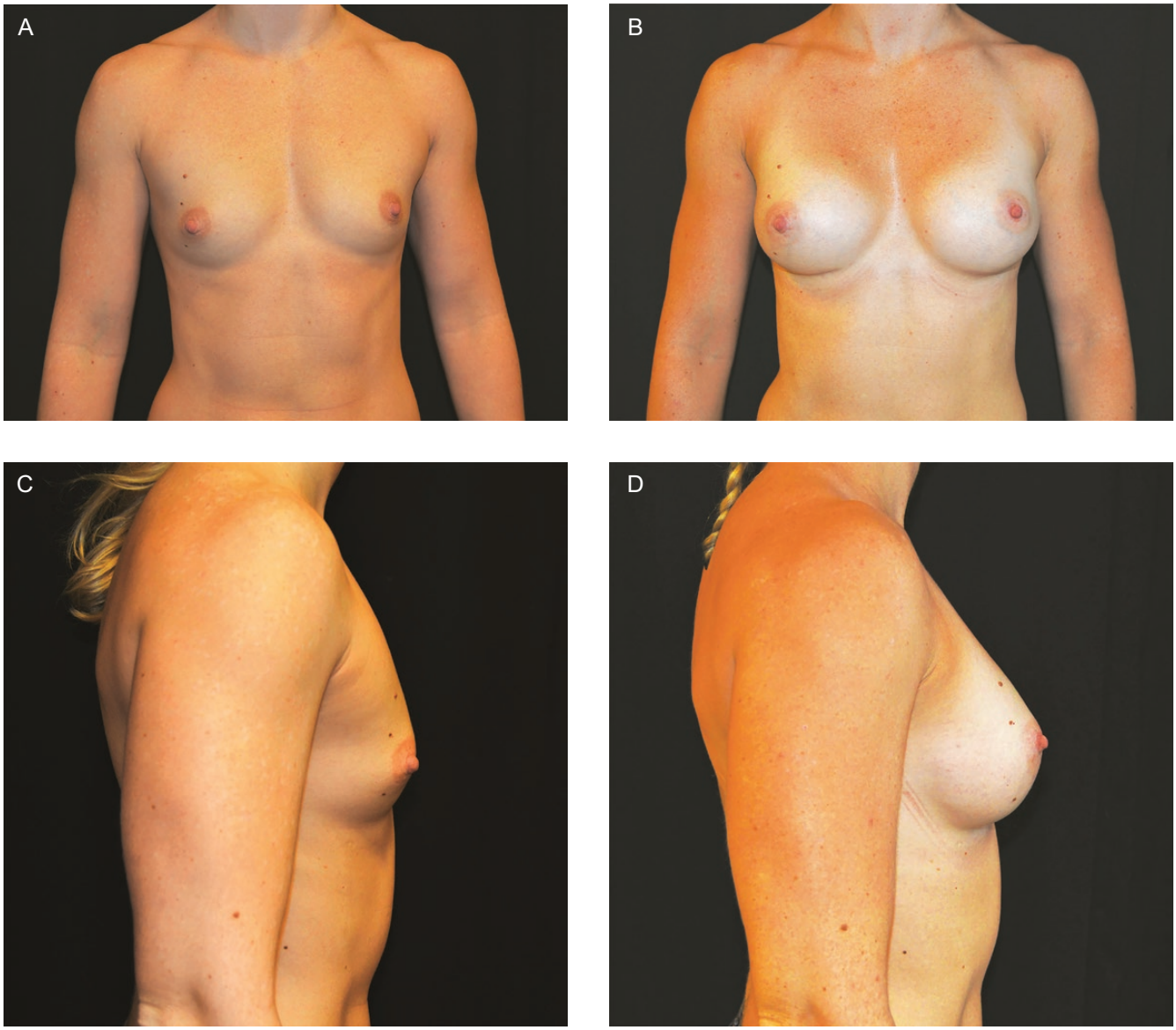

Figure 2. (A, C) Preoperative photos of this 30-year-old woman who underwent primary breast augmentation with 240 cc conventional textured implants. (B, D) Appearance at 14 months postoperatively.

Limitations

One of the limitations of this study is the retrospective approach without randomization and blinding. The possibility of observer bias or under-detection of complications should be acknowledged. However, as an unsponsored study it provides early data that compares the utilization of nanotextured implants with the ongoing employment of conventional textured implants. Importantly, a considerable sample size is utilized with good follow-up for early complications at 1 year. Despite the absence of blinding, Baker grade III/IV capsular contractures were detected in both groups through routine clinical care. This provides a missing perspective not previously reported in literature, to our knowledge. This study is informative to readers amid the paucity of clinical literature on outcomes with this new generation of implants.

We acknowledge that the gradual change in patient selection, surgical technique, postoperative care, and increase in experience with the nanotextured implants may have confounded the comparison over the study period. Therefore, in addition to the broad comparison of the 2 implant types, we have attempted to analyze the data in chronological subgroups. The period subgroups comparison detected the period effect and illuminated the learning curve.

Another limitation is the comparison of nanotextured implants against all other textured implants with no

breakdown according to manufacturer or subtype. However, it was not statistically sound to further reduce the group size. Therefore, we could only draw conclusions of nanotextured implants against a backdrop of existing practice with various textured implants.

The single-center and single-surgeon nature of the study may limit generalizability of our results to other centers. However, it also provides consistency in surgical techniques and experience to illuminate the effect of learning curve and implant type on complication rate.

Lastly, the short follow-up period may only describe the early complications observed with these implants. It may not capture incidence of late complications like capsular contracture, implant rupture, late seroma, and BIA-ALCL. However, the 1-year timepoint was reliable in our setting with the notably good follow-up that was attributed to the 1-year revision fee waiver at our clinic. Further randomized controlled trials and longer term studies may be useful in confirming our conclusion and elucidating late complication rates.

CONCLUSIONS

The perfect breast implant does not exist. However, with each new and innovative generation of implant, the armamentarium of the plastic surgeon is enriched to address the varying needs of the patients. In our series, compared with conventional textured implants, nanotextured breast implants were associated with a higher number of complications, especially on initial introduction. Nonetheless, restriction in patient selection, modifications of surgical technique, and reinforcement of aftercare were effective in reducing the incidence of these complications, as shown in the later period. The aesthetic plastic surgeon needs to remain impartial and choose the appropriate implant and surgical technique for the patient.

Disclosure

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

Funding

The authors received no financial support for the research, authorship, and publication of this article.

REFERENCES

1. Cole NM. Consequences of the U.S. food and drug administration-directed moratorium on silicone gel breast implants: 1992 to 2006. *Plast Reconstr Surg*. 2018;141(5):1137-1141.
2. Leberfinger AN, Behar BJ, Williams NC, et al. Breast implant-associated anaplastic large cell lymphoma: a systematic review. *JAMA Surg*. 2017;152(12):1161-1168.
3. Ghosh T, Duncavage E, Mehta-Shah N, McGuire PA, Tenenbaum M, Myckatyn TM. A cautionary tale and update on breast implant-associated anaplastic large cell lymphoma (BIA-ALCL). *Aesthet Surg J*. 2020;sjz377. doi: 10.1093/asj/sjz377.
4. Magnusson MR, Cooter RD, Rakhorst H, McGuire PA, Adams WP Jr, Deva AK. Breast implant illness: a way forward. *Plast Reconstr Surg*. 2019;143(3S A review of breast implant-associated anaplastic large cell lymphoma):74S-81S.
5. Rohrich RJ, Kaplan J, Dayan E. Silicone implant illness: science versus myth? *Plast Reconstr Surg*. 2019;144(1):98-109.
6. Mcguire PA, Haws MJ, Nahai F. Breast implant illness: how can we help? *Aesthet Surg J*. 2019;39(11):1260-1263.
7. Adams WP Jr. Capsular contracture: what is it? What causes it? How can it be prevented and managed? *Clin Plast Surg*. 2009;36(1):119-126, vii.
8. Munhoz AM, Clemens MW, Nahabedian MY. Breast implant surfaces and their impact on current practices: where we are now and where are we going? *Plast Reconstr Surg Glob Open*. 2019;7(10):e2466.
9. Huemer GM, Wenny R, Aitzetmuller MM, Duscher D. Motiva Ergonomix Round SilkSurface silicone breast implants: outcome analysis of 100 primary breast augmentations over 3 years and technical considerations. *Plast Reconstr Surg*. 2018;141(6):831e-842e.
10. Quirós MC, Bolaños MC, Fassero JJ. Six-year prospective outcomes of primary breast augmentation with nano surface implants. *Aesthet Surg J*. 2019;39(5):495-508.
11. Sforza M, Zaccheddu R, Alleruzzo A, et al. Preliminary 3-year evaluation of experience with Silksurface and Velvetsurface Motiva silicone breast implants: a single-center experience with 5813 consecutive breast augmentation cases. *Aesthet Surg J*. 2018;38(suppl_2):S62-S73.
12. Montemurro P, Agko M, Quattrini Li A, Avvedimento S, Hedén P. Implementation of an integrated biodimensional method of breast augmentation with anatomic, highly cohesive silicone gel implants: short-term results with the first 620 consecutive cases. *Aesthet Surg J*. 2017;37(7):782-792.
13. Montemurro P, Avvedimento S, Hedén P, Quattrini Li A. A four-layer wound closure technique with barbed sutures for stable reset of the inframammary fold in breast augmentation. *Aesthet Surg J*. 2016;36(8):966-971.