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Breast Surgery

Reoperation Rate After Primary Augmentation With Smooth, Textured, High Fill, Cohesive, Round Breast Implants (RANBI-I Study)

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Abstract

Background: Reoperation after primary breast augmentation remains an important clinical issue.

Objectives: The authors sought to evaluate incidence and causes of reoperation in patients who underwent primary augmentation.

Methods: This retrospective, noninterventional study conducted at 16 Canadian sites reviewed medical records and patient-completed questionnaires of women who underwent primary breast augmentation with smooth or textured Natrelle Inspira implants containing TruForm 1 or TruForm 2 gel. Patients were aged ≥22 years, received implants via inframammary fold incision, and returned for follow-up at 2 to 4 years.

Results: A total of 319 women received Inspira implants (smooth TruForm 2, n = 205; textured TruForm 2, n = 99; smooth or textured TruForm 1, n = 15). At follow-up, 30 women (9.4%) had undergone reoperation, including 19 (9.3%) in the smooth TruForm 2 subgroup and 9 (9.1%) in the textured TruForm 2 subgroup. The mean time to reoperation was 1.2 years; the risk rate for reoperation was 9.9% at 3 years. The most common reasons for reoperation were implant malposition (36.7%), capsular contracture (33.3%), and the patient's request for a change in implant size or style (20.0%). Most women were very or somewhat satisfied with the initial surgery (89.3% overall; 90.7% smooth TruForm 2; 86.9% textured TruForm 2). Thirty-four women (10.7%) reported adverse events, including 20 (9.8%) in the smooth TruForm 2 subgroup and 14 (14.1%) in the textured TruForm 2 subgroup.

Conclusions: This analysis suggests that Natrelle Inspira TruForm 2 implants are safe when used in primary breast augmentation, resulting in low reoperation rates that are consistent with those for other breast implants.

Level of Evidence: 4

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Breast augmentation is one of the most commonly performed aesthetic surgical procedures at an estimated 1.5 million procedures performed worldwide in 2016.[1] In the United States alone, 333,392 breast augmentation procedures were performed in 2017.[2] Reoperation after primary augmentation remains an important clinical

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issue. Reoperation rates increase gradually over time, from 10% by 2 years after implantation and reach approximately 20% by 6 to 10 years after implantation.[3-6] Common reasons for reoperation after primary augmentation include capsular contracture, implant malposition, and the patient's desire for a change in implant size or style.[3,4,6]

Natrelle Inspira breast implants (Allergan plc, Dublin, Ireland) were approved in Canada in September 2011 for use in primary augmentation, revision augmentation, reconstruction, and revision reconstruction procedures; however, these implants were available via Special Access since 2009.[7] Natrelle Inspira implants are available with smooth or Biocell textured surfaces and are filled with either TruForm 1 (formerly known as Cohesive) or TruForm 2 (formerly known as Soft Touch) silicone gel. Herein, we describe the results from the RANBI-I Study, which was a retrospective study conducted in Canada designed to evaluate the incidence and causes of reoperation in patients who underwent primary augmentation with Natrelle Inspira TruForm 1 or TruForm 2 implants. Patient satisfaction and safety outcomes were also captured.

METHODS

Study Design

This retrospective, noninterventional study was conducted at 16 sites in Canada across 4 provinces (Alberta, British Columbia, Ontario, and Quebec) from July 2014 to November 2016. Each site searched their medical records to identify patients satisfying the study inclusion and exclusion criteria and then approached patients consecutively based on the date of primary breast augmentation. Patients expressing an interest in participating were provided with a study information package, which included description of the study and its objectives, a patient consent form, and a patient questionnaire to collect data pertinent to the study. Each study site approached patients until 20 to 30 patients had returned signed consent forms agreeing to participate. The site then collected data anonymously from the patient's medical records and patient questionnaire. The study was conducted in compliance with Good Clinical Practice guidelines and applicable laws and regulations. An institutional review board or independent ethics committee at each site approved the study protocol before any patients were asked to participate. For the British Colombia, Ontario, and Quebec sites, IRB Services (Aurora, Ontario) was utilized; the Health Research Ethics Board of Alberta (Edmonton, Alberta) was utilized for the Alberta sites. This study was registered on ClinicalTrials.gov (identifier number NCT02438332).

Patients

Women aged 22 years and older who had primary breast augmentation (either bilateral or unilateral) 24 to 48 months before data collection were eligible if they had been operated on by the investigating surgeon with an infra-mammary approach with implantation of a smooth or textured Natrelle Inspira TruForm 1 or TruForm 2 device. The implant placement had to be subfascial, submuscular, dual plane, or subglandular. All patients provided written informed consent, and appropriate ethics approval for the study was granted. Patients were excluded if they had breast augmentation for Poland Syndrome or amastia, postmastectomy breast reconstruction, revision or secondary breast reconstruction, augmentation using an axillary or peri-areolar approach, mastopexy augmentation, or had received an implant other than Natrelle Inspira at the initial breast augmentation. Women diagnosed with premalignant or malignant breast disease and those undergoing surgical procedures of the breast unrelated to primary breast augmentation that could adversely affect aesthetic outcome were also excluded.

Data Collection

The patient's medical records were used to collect data on demographics, operative techniques (including implant location, type of anesthesia, pocket irrigation, antibiotic usage, and utilization of sizers, nipple shield, and implant delivery device), and postoperative management (including employment of drains and anti-inflammatory agents and immobilization protocol) as well as information regarding reoperation, time to reoperation, and the reasons for reoperation. The self-administered patient questionnaire also inquired whether reoperation had been performed, and if so, contact information of the reoperating surgical clinic. In addition, the questionnaire asked patients to rate their satisfaction with the initial breast augmentation surgery on a 5-grade scale (very dissatisfied, somewhat dissatisfied, neither dissatisfied nor satisfied, somewhat satisfied, very satisfied). Information on adverse events (AEs), including seriousness, severity, and relationship to study device or procedure, was collected from the medical records. The patient questionnaire also asked for contact information of the clinical site that could provide details about AEs and their treatment. All AEs were coded using the Medical Dictionary for Regulatory Activities. Each participant was allocated a unique identification number and was identified by this number throughout the study.

Statistical Analysis

Patients were stratified into 4 subgroups according to the Natrelle Inspira implant received: smooth TruForm 1, smooth TruForm 2, textured TruForm 1, or textured

Table 1. Preoperative Demographic Data

Characteristic	Overall (n = 319)	Smooth		Textured	
		TruForm 1 (n = 9)	TruForm 2 (n = 205)	TruForm 1 (n = 6)	TruForm 2 (n = 99)
Age, mean (SD), years	34.7 (7.9)	35.6 (10.2)	34.5 (7.5)	32.3 (4.7)	35.0 (8.6)
Race, no. (%)					
Caucasian	296 (92.8)	9 (100)	188 (91.7)	4 (66.7)	95 (96.0)
Asian	15 (4.7)	0 (0)	11 (5.4)	1 (16.7)	3 (3.0)
Black	1 (0.3)	0 (0)	0 (0)	1 (16.7)	0 (0)
Hispanic	1 (0.3)	0 (0)	0 (0)	0 (0)	1 (1.0)
Other	6 (1.9)	0 (0)	6 (2.9)	0 (0)	0 (0)
BMI, median (range), kg/m^2	21.1 (15.0-33.6)	21.7 (18.6-22.8)	21.2 (15.0-33.6)	25.2 (18.8-28.2)	20.8 (16.0-29.2)
Smoker status, no. (%)[a]					
Nonsmoker	199 (62.6)	5 (55.6)	132 (64.7)	3 (50.0)	59 (59.6)
Ex-smoker	72 (22.6)	4 (44.4)	47 (23.0)	0 (0)	21 (21.2)
Current smoker	47 (14.8)	0 (0)	25 (12.3)	3 (50.0)	19 (19.2)
Marital status, no. (%)					
Married	166 (52.0)	5 (55.6)	113 (55.1)	3 (50.0)	45 (45.5)
Single	112 (35.1)	2 (22.2)	68 (33.2)	3 (50.0)	39 (39.4)
Separated	22 (6.9)	1 (11.1)	10 (4.9)	0 (0)	11 (11.1)
Divorced	17 (5.3)	1 (11.1)	12 (5.9)	0 (0)	4 (4.0)
Widowed	2 (0.6)	0 (0)	2 (1.0)	0 (0)	0 (0)
Level of education, no. (%)					
High school	58 (18.2)	0 (0)	34 (16.6)	1 (16.7)	23 (23.2)
College	125 (39.2)	3 (33.3)	77 (37.6)	3 (50.0)	42 (42.4)
University	124 (38.9)	4 (44.4)	86 (42.0)	2 (33.3)	32 (32.3)
Other	12 (3.8)	2 (22.2)	8 (3.9)	0 (0)	2 (2.0)

BMI, body mass index; SD, standard deviation. [a]Smoking status information missing for 1 patient in the smooth TruForm 2 subgroup.

TruForm 2. Demographic, operative, and postoperative data were evaluated within each subgroup using descriptive statistics. Reoperation rates, reasons for reoperation, and the incidence of AEs were also evaluated descriptively. Risk rates for first reoperation were evaluated using Kaplan-Meier methodology with log-log transformation to obtain the 95% pointwise confidence interval (CI).

RESULTS

The study cohort included 319 patients who underwent primary breast augmentation with Natrelle Inspira implants. Of these, 205 patients (64.3%) received smooth TruForm 2 implants and 99 (31.0%) received textured TruForm 2 implants. Only 15 patients (4.7%) received TruForm 1 implants. Overall, the study cohort had a mean (SD) age of 34.7 (7.9) years (range, 20–60 years) and median body mass index of 21.1 kg/m^2 (range, 15.0-33.6 kg/m^2); most patients were Caucasian (92.8%) (Table 1). Demographic characteristics were generally consistent between the subgroups that received smooth or textured TruForm 2 implants. Due to low numbers of patients who received TruForm 1 devices, this article focuses on data from patients who received TruForm 2 devices.

Table 2. Surgical Characteristics of Primary Operations

Parameter, no. (%)	Overall (n = 319)	Smooth TruForm 2 (n = 205)	Textured TruForm 2 (n = 99)
Surgical facility			
Private clinic	297 (93.1)	188 (91.7)	94 (94.9)
Hospital	22 (6.9)	17 (8.3)	5 (5.1)
Implant location[a]			
Dual plane	131 (41.1)	87 (42.4)	39 (39.4)
Submuscular	95 (29.8)	46 (22.4)	45 (45.5)
Subglandular	71 (22.3)	57 (27.8)	8 (8.1)
Subpectoral	18 (5.6)	13 (6.3)	5 (5.1)
Subfascial	4 (1.3)	2 (1.0)	2 (2.0)
Pocket irrigation			
None	63 (19.7)	38 (18.5)	24 (24.2)
Saline only	11 (3.4)	0 (0)	6 (6.1)
Triple antibiotics	150 (47.0)	86 (42.0)	56 (56.6)
Betadine	66 (20.7)	64 (31.2)	1 (1.0)
Bacitracin	29 (9.1)	17 (8.3)	12 (12.1)
Wash of implants			
Saline only	12 (3.8)	6 (2.9)	0 (0)
Triple antibiotics	208 (65.2)	124 (60.5)	75 (75.8)
Betadine	71 (22.3)	58 (28.3)	13 (13.1)
Bacitracin	28 (8.8)	17 (8.3)	11 (11.1)
Sizers used	46 (14.4)	25 (12.2)	12 (12.1)
Nipple shield used	185 (58.0)	111 (54.1)	71 (71.7)
Implant delivery device used	135 (42.3)	99 (48.3)	36 (36.4)

[a]Although the protocol document listed 4 choices for implant locations, some surgeons may have inadvertently interchanged the "dual plane" and "submuscular" terminology.

Operative and Postoperative Characteristics

All patients underwent bilateral primary augmentation, wherin most smooth TruForm 2 devices were implanted in a biplanar or subglandular location and most textured TruForm 2 devices were implanted in a submuscular or biplanar location (Table 2). Most procedures were performed at a private clinic, and all patients received general anesthesia. Most implant pockets were irrigated, generally with antibiotics, although Betadine was often used when implanting smooth TruForm 2 implants. Sizers and implant delivery devices were used in a minority of procedures; drains were not placed in any patients. Postoperatively, support garments were used by 63.9% and 52.5% of patients receiving smooth and textured TruForm 2 implants, respectively, and most utilized the support garments for 2 to 4 weeks (Table 3). Restricted physical activity was recommended for all patients, usually for 4 to 6 weeks. Postoperative anti-inflammatory drugs (usually nonsteroidal anti-inflammatory drugs) were prescribed more frequently in the subgroup receiving textured TruForm 2 implants (49.5%) than in the subgroup receiving smooth implants (25.4%). However, nonsteroidal anti-inflammatory drugs were prescribed in only 4 of the 16 sites included in the study.

Table 3. Postoperative Characteristics

Parameter, no. (%)	Overall (n = 319)	Smooth TruForm 2 (n = 205)	Textured TruForm 2 (n = 99)
Use of drains	0 (0)	0 (0)	0 (0)
Immobilization protocol			
Support garment	197 (61.8)	131 (63.9)	52 (52.5)
Restricted physical activity	319 (100)	205 (100)	99 (100)
Other[a]	38 (11.9)	0 (0)	38 (38.4)
Anti-inflammatory drug use	101 (31.7)	52 (25.4)	49 (49.5)
NSAIDs	100 (31.3)	52 (25.4)	48 (48.5)
Corticosteroids	0 (0)	0 (0)	0 (0)
Other[b]	8 (2.5)	0 (0)	8 (8.1)

NSAIDs, nonsteroidal anti-inflammatory drugs. [a]Included requirement to sleep on back for 1 week postsurgery, prohibition of pure pectoral exercises, and prescription for specific pectoralis major stretching exercise program. [b]Included preoperative or intraoperative corticosteroids and 2 reports of narcotic pain medication (1 oxycodone-acetaminophen, 1 acetaminophen-codeine).

Device Characteristics

Most implanted devices (417/638; 65.4%) featured a full projection, including 296 of 410 smooth TruForm 2 implants (72.2%) and 100 of 198 textured TruForm 2 implants (50.5%). Moderate projection implants accounted for 182 devices overall (28.5%), including 91 smooth TruForm 2 devices (22.2%) and 84 textured TruForm 2 devices (42.4%). Five percent of smooth and textured TruForm 2 devices had an extra full projection. The mean (SD) implant volume was 355.4 (71.8) g for the entire cohort, 351.0 (76.7) g for the smooth TruForm 2 subgroup, and 362.5 (60.1) g for the textured TruForm 2 cohort.

Reoperations

At the time of follow-up (between 2 and 4 years after primary breast augmentation; mean, 2.9 years), 30 women

Table 4. Reoperations and Reasons for Reoperation

Parameter, no. (%)	Overall (n = 319)	Smooth TruForm 2 (n = 205)	Textured TruForm 2 (n = 99)
Reoperation performed[a]	30 (9.4)	19 (9.3)	9 (9.1)
Reoperation without explantation	17 (5.3)	11 (5.4)	4 (4.0)
Implant removal with replacement	12 (3.8)	8 (3.9)	4 (4.0)
Reasons for reoperation, no. (% of reoperations)			
Implant malposition	11 (36.7)	6 (31.6)	4 (44.4)
Capsular contracture	10 (33.3)	5 (26.3)	3 (33.3)
Baker grade II	2	0	0
Baker grade III	7	5	2
Baker grade IV	1	0	1
Patient request for size/style change	6 (20.0)	5 (26.3)	1 (11.1)
Asymmetry	4 (13.3)	3 (15.8)	0 (0)
Suspected rupture	3 (10.0)	1 (5.3)	0 (0)
Hematoma/seroma/fluid	2 (6.7)	1 (5.3)	0 (0)
Scarring	2 (6.7)	2 (10.5)	0 (0)
Ptosis	1 (3.3)	1 (5.3)	0 (0)
Pseudoptosis	1 (3.3)	1 (5.3)	0 (0)
Infection	1 (3.3)	0 (0)	1 (11.1)
Implant palpability	1 (3.3)	1 (5.3)	0 (0)
Nipple complications	1 (3.3)	1 (5.3)	0 (0)
Wrinkling/rippling	1 (3.3)	1 (5.3)	0 (0)

[a]The implant was removed without replacement in 1 patient in the Textured TruForm 2 subgroup.

(9.4%) had undergone reoperation, including 19 women (9.3%) who received a smooth TruForm 2 implant and 9 women (9.1%) who received a textured TruForm 2 implant (Table 4). The other 2 women who underwent reoperation had textured TruForm 1 implants. For 17 women, reoperation was conducted without explantation of the original device. The mean (SD) time to reoperation was 1.2 (0.8) years overall, 1.3 (0.8) years in the smooth TruForm 2 subgroup, and 1.0 (0.6) years in the textured TruForm 2 subgroup. Overall, the risk rate (95% CI) for first reoperation was 5.0% (3.1–8.1) after 1 year, 6.9% (4.6–10.3) after 2 years, and 9.9% (7.0–13.9) after 3 years (Figure 1). No discernable relationship was found between reoperations and demographic, device, or operative characteristics. The most common reasons for reoperation were implant malposition, capsular contracture, and the patient's request for a change in implant size or style (Table 4). Of the 12 reoperations for malposition, 7 implants were displaced caudally, 3 cephalically, and 2 laterally. Of the 10 reoperations for capsular contracture, 7 were Baker grade III and 1 was Baker grade IV. Reoperations based on the patient's request for a change in size/style and for asymmetry were more common with smooth than textured TruForm 2 devices. The mean time for reoperation was 1.2 years for implant malposition, 1.6 years for both suspected rupture and asymmetry, and 1.3 years for capsular contraction.

Patient Satisfaction

Most patients reported being very satisfied (72.2%) or somewhat satisfied (17.7%) with the initial augmentation surgery (Figure 2). High satisfaction rates were reported in both the smooth and textured TruForm 2 subgroups.

Adverse Events

Thirty-four women (10.7%) reported AEs, including 20 (9.8%) in the smooth TruForm 2 subgroup and 14 (14.1%) in the textured TruForm 2 subgroup (Table 5). Overall, the most common AEs were capsular contracture (1.9%), device damage (1.6%), device dislocation (1.6%), and breast pain (1.6%). All other AEs were reported at an incidence $<1\%$. The types and incidence of specific AEs were generally consistent between the smooth and textured TruForm 2 subgroups.

DISCUSSION

This is the first study to our knowledge to describe reoperation data for Natrelle Inspira smooth and textured round implants following primary breast augmentation in Canadian clinical practice settings. Most women received Natrelle Inspira implants containing TruForm 2 gel. Although the rationale for the high preference for TruForm 2 over TruForm 1 was not specified, this preference was likely primarily driven by the surgeons and the patients. Overall, the reoperation rate with the Natrelle Inspira implants was low (9.4%) during 2 to 4 years of follow-up, and the risk rate for a first reoperation was 9.9% at 3 years. The most common reasons for reoperation were implant malposition, capsular contracture, and patient request. Reoperation rates for women receiving smooth or textured implants containing TruForm 2 were comparable (9.3% and 9.1%, respectively). Two of 15 women (13.3%) receiving Natrelle Inspira implants with TruForm 1 gel also underwent reoperation, which is consistent with the reoperation rate for the overall study cohort. However, the

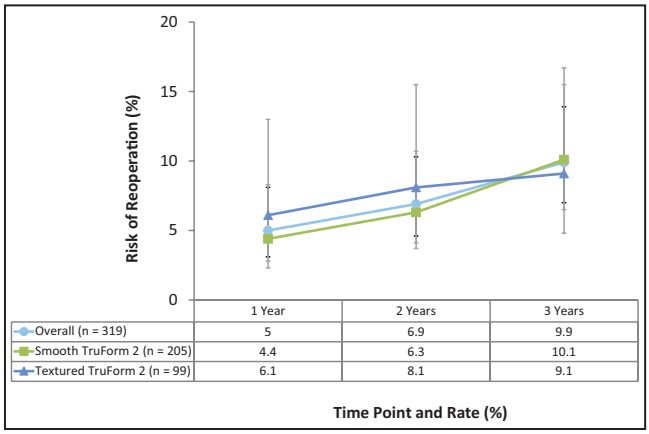

Figure 1. Cumulative incidence of first reoperation.

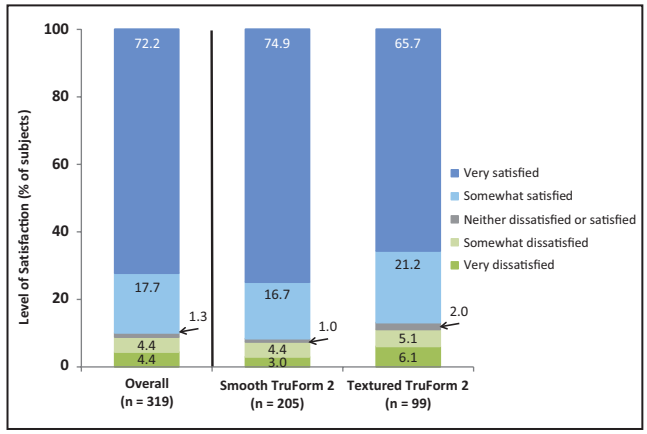

Figure 2. Patient satisfaction with initial surgery.

Table 5. Incidence of AEs After Primary Operations by Patient and by Device

Adverse event, no. (%)	Overall		Smooth TruForm 2		Textured TruForm 2	
	Patients (n = 319)	Devices (n = 638)	Patients (n = 205)	Devices (n = 410)	Patients (n = 99)	Devices (n = 198)
Any adverse event	34 (10.7)	47 (7.4)	20 (9.8)	31 (7.6)	14 (14.1)	16 (8.1)
Capsular contracture	6 (1.9)	9 (1.4)	4 (2.0)	6 (1.5)	2 (2.0)	3 (1.5)
Device damage	5 (1.6)	9 (1.4)	3 (1.5)	6 (1.5)	2 (2.0)	3 (1.5)
Device dislocation	5 (1.6)	6 (0.9)	2 (1.0)	3 (0.7)	3 (3.0)	3 (1.5)
Breast pain	5 (1.6)	5 (0.8)	2 (1.0)	2 (0.5)	3 (3.0)	3 (1.5)
Device optical issue	3 (0.9)	4 (0.6)	3 (1.5)	4 (1.0)	0 (0)	0 (0)
Hypoesthesia	2 (0.6)	4 (0.6)	2 (1.0)	4 (1.0)	0 (0)	0 (0)
Phlebitis superficial	2 (0.6)	3 (0.5)	2 (1.0)	3 (0.7)	0 (0)	0 (0)
Postprocedural hematoma	2 (0.6)	3 (0.5)	2 (1.0)	3 (0.7)	0 (0)	0 (0)
Breast hypoplasia	2 (0.6)	2 (0.3)	0 (0)	0 (0)	2 (2.0)	2 (1.0)
Medical device site scar	1 (0.3)	2 (0.3)	1 (0.5)	2 (0.5)	0 (0)	0 (0)
Postprocedural infection	1 (0.3)	1 (0.2)	0 (0)	0 (0)	1 (1.0)	1 (0.5)
Suture-related complication	1 (0.3)	1 (0.2)	0 (0)	0 (0)	1 (1.0)	1 (0.5)

latter observation should be considered preliminary given the small patient sample.

The main reasons for reoperation observed for the Natrelle Inspira implants are consistent with those for other silicone gel-containing breast implants employed in primary breast augmentation, whereas the reoperation rates for the Inspira implants are lower. The 3-year risk rate for reoperation with smooth or textured round MemoryGel breast implants (Mentor Corp., Santa Barbara, CA) was 15.4% (95% CI: 12.3–18.4), with capsular contracture, patient request, hematoma/seroma, and scarring reported as the most common reasons for reoperation.[8] For smooth round and textured round or shaped Sientra breast implants (Sientra, Inc., Santa Barbara, CA), the 3-year risk rate for reoperation was 12.6% (95% CI: 10.7%–14.8%); capsular contracture, patient request, ptosis, implant malposition, and hematoma/seroma were the main reasons.[9] For smooth and textured round Natrelle Classic breast implants, the 4-year risk rate for reoperation was 23.5% (95% CI: 19.5–27.5), and capsular contracture, implant malposition, and ptosis were the main reasons.[10] Finally, the 3-year risk rate for reoperation with Natrelle Style 410

shaped breast implants was 12.5% (95% CI: 9.5–15.4); implant malposition, patient request, scarring, and hematoma/seroma were the most common reasons.[11]

Reoperation rates following primary breast augmentation are known to increase gradually over time.[3] The primary reasons for reoperation in these longer-term studies were capsular contracture, mastopexy, scarring, and breast mass (the latter generally associated with the need for biopsy to assess potential malignancy).[12,13] In the Core study of Natrelle Classic round smooth and textured breast implants with TruForm 1 silicone gel, the reoperation rate was 28.0% and 36.1% at 6 and 10 years, respectively, and capsular contracture was the leading reason for reoperation.[14,15] In the 10-year data for Natrelle Style 410 shaped breast implants, the reoperation rate was 29.7% (95% CI: 25.6–34.3); patient request and capsular contracture were common reasons.[16]

When queried at the time of enrollment in the present retrospective study, patient satisfaction with the initial augmentation surgery was high, with 89.9% of patients reporting being very satisfied or somewhat satisfied. High satisfaction following primary breast augmentation has similarly been reported in other studies. For example, in the nationwide Breast Implant Follow-Up Study, scores on the 100-point BREAST-Q scale for satisfaction with breasts increased from 31.5 preoperatively to 86.1 at 4 years following primary augmentation with silicone-filled implants.[17] In the Natrelle CORE study, the 6-year satisfaction rate with implants following augmentation was 95%.[14] In the 9-year Mentor core study, global patient satisfaction was assessed by asking patients if they would decide to have breast implant surgery again; 98% responded in the affirmative.[13]

The AE profile was also consistent with those for other breast implants, capsular contracture (1.9%) being the most commonly reported AE. Capsular contracture was also a common complication following primary augmentation surgery with other breast implants. For example, the 3-year rates for Baker grade III/IV capsular contracture were 8.1% with smooth or textured round MemoryGel breast implants[8] and 6.0% with smooth round and textured round or shaped Sientra breast implants.[9] It is possible, however, that collection of AE data retrospectively underestimated the true rate of capsular contracture with the Natrelle Inspira breast implants. In a single surgeon's review of 1,539 consecutive cases of primary breast augmentation, which included 236 round gel implants (15.3% of total), the incidence of Baker grade III capsular contracture was 1.6% during a mean follow-up of 18 months.[18]

In the current study, capsular contracture was reported as a primary reason for reoperation for 10 patients but as an AE in only 6 of these patients. This discrepancy is likely due to the way in which data were handled at the various study sites. Case report forms for reoperation required documentation of the reason for reoperation. However, some sites may not have reported capsular contracture as an AE because a separate case report form was required.

Limitations to this study include the retrospective nature of the data, which may have led to underestimation of reoperation and AE rates. Comparisons across various trials may also be confounded by the retrospective nature of this study such as differences in patient selection, study durations, and the like. In addition, eligible patients had been followed for 2 to 4 years after surgery, which may not be sufficient to draw firm conclusions about certain AEs such as breast implant associated-anaplastic large cell lymphoma (BIA-ALCL) and capsular contracture. BIA-ALCL, for example, occurs predominantly in textured implants at a median of 8 years from implant placement to BIA-ALCL diagnosis.[19] Another limitation of the study was the inclusion of both subpectoral and submuscular as selections for implant location because these terms are largely interchangeable. Finally, as noted above, the study included only a very limited number of patients who received Natrelle Inspira implants with TruForm 1 gel.

CONCLUSIONS

The present results obtained from real-world clinical practice indicate that Natrelle Inspira TruForm 2 gel implants are safe in primary breast augmentation; low reoperation rates are consistent with those for other silicone-gel breast implants.

Disclosures

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