Five-Year Safety and Satisfaction With the Lightweight Breast Implant

Govrin-Yehudain Orel, MD; Calderon Noam, MD; and Govrin-Yehudain Jacky, MD

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Abstract

Background: The B-Lite lightweight breast implant (LWBI) weighs approximately 30% less than traditional silicone implants while maintaining an equivalent size, form, and function. The LWBI thus places less stress on breast tissues and preserves tissue stability and integrity over time, reducing weight-related complications and reoperation rates.

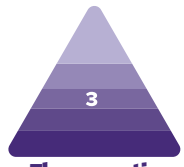
Objectives: The authors sought to assess the long-term (>5 years) safety and performance of the LWBI in primary and revision augmentation procedures.

Methods: A retrospective, single-center, single surgeon analysis of prospectively collected data was performed on 827 consecutive primary and revision augmentation patients operated between December 2013 and January 2019. A total 1653 implants (250-835 cc, mostly round, textured, extra high-profile) were implanted employing standard surgical techniques. Direct physician-to-patient follow-up ranged from 6 to 67 months. Chart data on reoperations and overall complications as well as patient and surgeon satisfaction were analyzed.

Results: The 5-year per patient Kaplan–Meier reoperation free rate was very high (97.1%). Only 2 of 5 total cases of capsular contracture (CC) grade III required reoperation (Kaplan–Meier rate = 0.2%, CI = 0.1–1.0). No cases of rupture or breast implant-associated anaplastic large cell lymphoma were recorded. A total 94.9% of patients rated the aesthetic outcome, and 95.5% of patients rated the natural look and feel of their breasts at 4 to 5 (satisfied-very satisfied). Similarly, the surgeon rated 4 to 5 on 95.4% of the patients' aesthetic outcomes.

Conclusions: The favorable safety profile, high patient and surgeon satisfaction, and inherent benefits of reduced weight should make the LWBI a strongly considered strategic alternative to traditional implants.

Level of Evidence: 3



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Since the introduction of silicone gel-filled breast implants by Thomas Cronin and Frank Gerow into the United States in 1962,[1] breast augmentation has gained increasing popularity.[2] Statistics compiled by the American Society for Aesthetic Plastic Surgery have shown that the number of breast augmentations, at 329,914 in 2018, has been increasing each year in the last decade, with a 15.2%

Dr Orel is a plastic surgery resident, Tel Aviv Sourasky Medical Center, Tel Aviv, Israel. Dr Noam is head of the Plastic Surgery Department, Bnai-Zion Medical Center, Haifa, Israel. Dr Jacky is a founding plastic surgeon, Beit Harofim Medical Center, Haifa, Israel.

Corresponding Author:
Dr Orel Govrin, Tel Aviv Sourasky Medical Center, 6 Weizmann Street, Tel Aviv 6423906, Israel.
E-mail: orel.govrin@gmail.com; Instagram: @orelgovrin

increase between 2014 and 2018,[3] and is now ranked as the most common surgical aesthetic procedure for women in the United States.[2] However, despite the widespread popularity and well-established safety profile of procedures involving breast implants,[4,5] they may be associated with a variety of postoperative complications and carry a high incidence of revisionary surgeries. Although there have been improvements in surgical techniques, shells and surfaces, and some properties of the fillers, all implants available since the introduction of the first silicone-filled breast implant have been of roughly the same density: 1 mL of volume equates to 1 g of weight.[6-9]

The breast is an unstable and dynamic organ composed of skin, fat, and glandular tissues, influenced by endogenous and exogenous factors such as gravity, age, hormonal status, and body mass index. Over the course of a woman's lifetime, through the different stages of puberty, pregnancy, lactation, and menopause, the breasts change in size and shape. Over time, the breast tissue becomes atrophic and the skin becomes thinner and its elasticity reduced.

Maxwell et al have reported long-term and often permanent tissue deformities resulting from breast augmentation, with adverse events including tissue atrophy, accelerated ptosis, sensory loss, and inframammary fold migration.[10] Vegas and Martin del Yerro postulate that all these effects are directly related to the biomechanical (viscoelastic) properties of soft tissues and their response to loading and compressive forces. Moreover, secondary mastopexy and related complications of revisional surgery chiefly stem from the augmentation-induced modifications of the breast tissue.[6] When there are natural breast asymmetries, the larger breast always sags more. Intuitively, we attribute the sagging to the breast's size, whereas in reality the underlying reason is the breast's weight. This holds true both for breasts with and without implants. In his second law of mechanics, Sir Isaac Newton described one of the most fundamental laws of physics: $F = ma$ (where F is the force, m is the mass, and a is the acceleration). When the constant acceleration force is due to gravity, Newton's second law becomes $F = mg$ (where g is gravitational acceleration). Consistent with the above equation, the formula expresses quite simply that the force (weight) acting downwards on an object is only dependent on the mass of the object and the effect of gravity. Volume therefore is not a factor in this formula.[8] Rather, we should remember that weight is the force by which a body is pulled downwards by gravity. In fact, a large portion of our work as plastic surgeons is to repair the undesirable effects of gravity that worsen over time.

A spring-mass model provides a simple but effective approximation of elastic systems, such as breast tissue. According to Hooke's Law, we can see that the degree of tissue stretching will be proportional to breast + implant mass and inversely proportional to its stiffness (inelasticity).

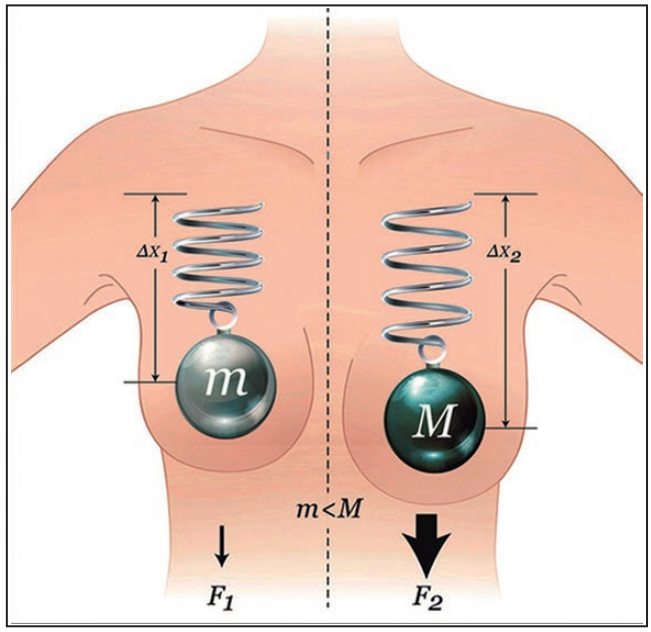

Figure 1. Hooke's law and breast tissue responses. The elastic tissue of the breast is symbolized by a spring with constant K. The displacement is described as ΔX = F/K, where ΔX is the displacement, F is the force applied (weight, or m*g), and K is the spring constant (tissue stiffness). A heavier implant will result in increased forces and consequential stretch of the breast compared with a lighter implant. Therefore, when m < M, this results in F1 < F2 and ΔX1 <ΔX2. Reprinted with permission from G&G Biotechnology Ltd., Haifa, Israel.

In a static, upright posture, the weight of an implant will displace the breast downwards with a force proportional to the weight of the implant. The tissue's stretch is linear (within the elasticity limits of the tissue), and therefore, tissue displacement will increase in direct correlation to the implant weight. The greater the weight, the greater the displacement. A heavier implant will therefore result in increased forces and consequential stretch of the breast compared with a lighter implant (Figure 1).[8]

Furthermore, when maintaining an upright, static posture, the pull of gravity on the breast is constant and unidirectional. In dynamic states such as walking, descending stairs, dancing, or running, accelerative forces result in significant breast movement and tissue impact. According to Scurr et al, in breast kinematic measurements made on a treadmill, the amplitude of breast movement is multidirectional and in direct proportion to weight and not related to volume.[11]

An additional study by Norris et al demonstrated that a combination of implant location (subglandular) and reduced mass (utilizing a LWBI) minimized nipple kinematics dynamic activity. This reduced loading on breast structures may help to decrease ptosis and increase the longevity of procedure outcomes.[12]

Following breast augmentation, both volume and weight are intertwined to act on the soft tissues and create strain. This sudden increase in strain initially triggers a stress-relaxation response where the breast tissues gradually undergo relaxation and expand. As a result, as long as the implant's volume does not violate the viscoelastic capabilities of the breast tissue, the effect of the volume of the implant gradually diminishes over time. In contrast, the effect of weight of the implant results in a permanent and longstanding stress; it does not diminish over time but rather persists throughout a woman's lifetime, causing a continuous creep deformation.[6] Recognizing that clinical presentations can vary widely and the breast tissues and implants do not always act as a single unit, comprehensive modeling of the complex interaction between implants and tissues under accelerative forces is beyond the scope of this article. However, for a specific patient, given all other factors are equal, implant weight is the single-most dominant variable affecting long-term outcomes. In fact, from now on, the weight of the implant should be considered the dominant exogenous mechanical factor affecting the breast tissue.

Therefore, the authors' extensive clinical experience, together with consideration of the weight-dependent adverse effects, fundamental laws of physics, and viscoelastic properties of soft tissues, led them to formulate the scientific precept that it was the implant weight, rather than its volume, that stood at the basis of breast tissue compromise and deformation.[8]

The recognition that a lighter-weight breast implant would be advantageous for improved long-term outcomes for breast augmentation and breast reconstruction patients fueled the re-evaluation of current thinking—namely, to uncouple weight from volume to overcome the weight-dependent impact of mechanical forces on breast tissues. The recognition of breast implant weight as a critical determinant of long-term clinical outcomes prompted the development of the first light-weight breast implant, B-Lite (G&G Biotechnology Ltd., Haifa, Israel & Polytech Health & Aesthetics GmbH, Dieburg, Germany), which was able to uncouple weight and volume for the first time.[9] This sixth-generation, form-stable, silicone gel lightweight breast implant (LWBI) was designed to be a lightweight alternative to traditional silicone breast implants. The LWBI allows a reduction in implant weight of up to 30% while maintaining the equivalent size, form, and function of traditional breast implants. The addition of this lightweight implant to available implant choices is expected to enable the surgeon to achieve the patient's desired breast size and shape while reducing the impact on long-term tissue stability or integrity induced by additional weight.[8]

The aim of the present study was to carry out a large case series with follow-up of over 5 years to assess the long-term safety of the B-Lite LWBI. A second aim was to measure both patient and surgeon satisfaction with the results of primary and revision augmentation procedures employing this LWBI.

METHODS

A single-surgeon, single-center retrospective analysis of prospectively collected data included all consecutive cases of primary and revision breast augmentations utilizing the B-Lite LWBI. All surgeries were performed by the author (J.G.) at the Italian Hospital, Haifa, Israel. A standard surgical procedure was employed. Prior to the incision, intravenous prophylactic antibiotics are administered, topical iodine scrub is applied, and nipple shields are attached. A dry pocket is created, hemostasis is performed, and rinses with cefazolin and gentamicin are applied to the pocket. The implant is also soaked in the same solution. Prior to implant insertion, iodine solution is reapplied to the skin around the incision, a new set of gloves is worn, and new draping is added. The implant is inserted manually avoiding focused digital pressure. Fixation is conducted employing absorbable sutures to the submammary fold and finally, closure in layers. In some challenging cases, the author utilizes internal incisions to redrape the tissues and achieve the desired aesthetic results. All follow-up visits took place at the Beit Harofim Medical Center, also in Haifa. Chart data were extracted on variables and complications, including reoperations and adverse events, and were analyzed.

Patients

Adult women who underwent surgeries between December 2013 and January 2019 were consecutively included in the analysis. The study was approved by the local ethic committee of Bnai Zion Medical Center, Haifa, Israel.

Patient status was monitored throughout the follow-up period according to the appropriate standards of care. At the data cutoff point, this analysis included all patients with at least 6 months of follow-up. Patients were followed-up telephonically immediately following the surgical procedure and then in person (see Appendix). Demographic and baseline characteristics of the study participants, the detailed parameters of their surgeries, any complications following surgery, and patient and physician satisfaction measurements were recorded.

Demographic and baseline characteristics included the study participants' age at the time of surgery, the number of births, lactation history, and smoking status.

Surgical Procedure

Most of the study participants underwent standard surgical procedures with inframammary incisions. Implantation placement was either subglandular or subpectoral. B-Lite implants encompassed implants within the size range of 250 to 835 cc, round or anatomical shaped with a smooth or textured surface. The reasons that the study participants underwent a primary or revision implantation procedure in addition to all other surgical parameters were recorded.

Safety Outcomes

Primary safety outcomes included assessment of the risk for reoperation, CC (grade III-IV), and rupture.

Secondary safety outcomes included overall analysis of complications (eg, seroma, hematoma, and breast implant-associated anaplastic large cell lymphoma [BIA-ALCL]).

Efficacy Outcomes

Efficacy outcomes included subjective ratings from both patients and the surgeon following the implantation procedures. Ratings collected during the last follow-up visit were included in the analysis. Patients rated their satisfaction with the surgical procedure on a scale of 1 to 5, where 1 = "most dissatisfied" and 5 = "most satisfied." Similarly, they rated their breast appearance and naturalness/softness of how their breasts felt following surgery on a scale of 1 to 5, where 1 = "not at all" and 5 = "natural and soft." Finally, the surgeon rated his satisfaction with the operative results on a scale of 1 to 5, where: 1 = "poor" and 5 = "excellent."

Statistical Analysis

The database was constructed with Excel (Microsoft Corporation, Redmond, WA). The descriptive statistics employed for quantitative variables were mean and SD (missing values were excluded from the analysis). Some variables were measured by percentage and frequency in general study population or in subgroups (primary augmentation and revision augmentation). A small number of patients (5.2%) underwent mastopexy as part of their procedure (4.3% and 8.7% in the primary and revision augmentation groups, respectively). Given the relatively small number of patients in the mastopexy group, we included these patients as part of the overall primary and revision augmentation groups for the purpose of the analysis.

Table 1.

Age (y)	
Primary augmentation (mean ± SD)	32.25 ± 8.9
Revision augmentation (mean ± SD)	40.32 ± 9.3
Births	
Births (yes/no), %	No (34.5%), yes (65.5%)
Number of births	
Primary augmentation (mean ± SD)	1.5 ± 1.5
Revision augmentation (mean ± SD)	2.2 ± 1.2
Min, max	0,11
Breastfeeding history (yes/no), %	No (34.6%), yes (65.4%)
Smoking (yes/no), %	No (60%), yes (40%)

Additionally, reoperations due to size change requests were not included in the current analysis. The overall complication rate was calculated and presented only for primary complications (complications rate per implant >0.5%).

Survival analysis curves generated employing the Kaplan–Meier methodology depicted the likelihood of a patient remaining free of postoperative complication resulting in reoperations over time. These calculations included all first occurrences of a complication. The risk rates (1 − the complication-free survival rate) and 95% CI are represented as well. Statistical significance was defined as $P < 0.05$.

RESULTS

Over 1000 female patients underwent augmentations with the B-Lite LWBI of whom 827 were followed-up for at least 6 months and were included in the analysis. Table 1 summarizes the demographic and baseline characteristics of the study participants.

The average follow-up was 2.2 ± 1.2 years (0.5-5.6). The maximum follow-up duration during the study period was 5.6 years. Figure 2 shows the distribution of follow-up time periods of the study participants.

Primary augmentations were carried out on 655 (79%) women aged a mean of 32.2 ± 8.9 (17.0-67.1) years, and 172 (21%) women aged 40.3 ± 9.6 (22.1-66.2) years underwent revision augmentations. The majority (65.5%) of study participants had previously given birth, of whom most had had 1 to 3 births (86.6%).

A total of 1653 B-Lite implants were implanted; 1310 in primary augmentations and 343 in revision augmentations. The B-Lite implants utilized were nearly all (99.85%) of the round and textured type

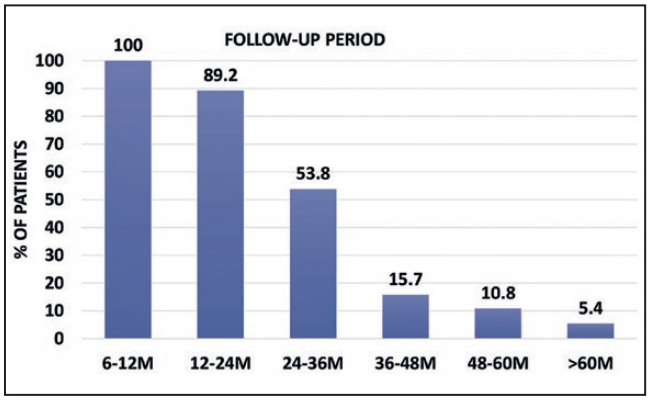

Figure 2. Follow-up periods of the patient cohort.

Table 2.

Procedure	
Primary augmentation	n = 655, 79.3%
Revision augmentation	n = 172, 20.7%
Breast implant volume range	250-835 cc
Breast implant shape	Round (99.85%), anatomical (0.15%)
Breast implant profile	Extra-high (95%), high (2.6%), moderate (2.4%), low (0)
Implant position	
Primary augmentation	Subglandular (88.5%) subpectoral (11.5%)
Revision augmentation	Subglandular (80.4%) subpectoral (19.6%)
Surgical approach	
Primary augmentation	IMF (95.7%) Lejour circumvertical (4.3%)
Revision augmentation	IMF (91.3%) Lejour circumvertical (8.7%)

(B-Lite-POLYtxt), with the majority of implant volumes in the 300-cc to 500-cc range. Implant placement was mostly subglandular (88.5% in primary cases and 80.4% for revision cases) vs only 11.5% of primary cases and 19.6% of revision cases placed subpectoral. Most surgical procedures were carried out via the inframammary approach (94.8%). Table 2 summarizes the surgery and implant-related data.

The top 3 indications for undergoing primary augmentations were small breasts (94.2%), ptotic breasts (71.5%), and asymmetry (43.8%). The top 3 indications for revision augmentation were patient concern/request (55.2%), breasts sagged with their current implant (39.5%), and patient wanted a size change (11.0%). Implant-related complications, CC, and rupture accounted for an additional 5.8% each.

Table 3. Overall Complications[a] in Primary Augmentation Patients

Complications	Primary augmentation		
	No. of patients (n = 655)	No. of implants (n = 1310)	Rate (%)
Capsular contracture Baker II	14	17	1.3
Implant palpability	12	12	0.9
Transient swelling	14	14	1.1
Inversion (back-to-front flipping)	11	11	0.8

[a]Complications rate per implant >0.5%.

Table 4. Overall Complications[a] in Revision Augmentation Patients

Complications	Revision augmentation		
	No. of patients (n = 172)	No. of implants (n = 343)	Rate (%)
Capsular contracture Baker II	2	2	0.6
Implant palpability	5	6	1.7
Transient swelling	3	3	0.9
Inversion (back-to-front flipping)	2	2	0.6
Hematoma	2	3	0.9
Wound dehiscence	3	3	0.9
Infection	1	2	0.6

[a]Complications rate per implant >0.5%.

Safety Outcomes

The overall rate for any complication per implant was 6.3% (105 complications), with a 5.9% (77) complication rate in patients who underwent primary augmentation and 8.2% (28) for revision augmentation. Overall complication rates per implant are detailed in Tables 3 and 4 for the primary and revision augmentation groups, respectively).

There were no recorded cases of rupture or BIA-ALCL.

Reoperation

In total, there were 26 reoperations in 22 women. A Kaplan–Meier analysis showed that at 5 years, 97.1% of the participants were reoperation free (Figure 3).

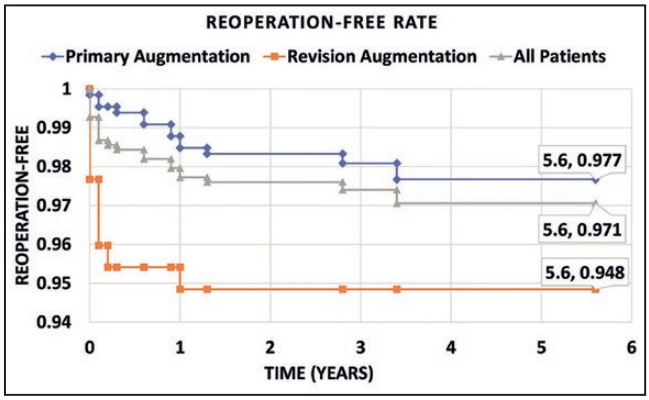

Figure 3. Kaplan-Meier estimator of reoperation-free rate.

Furthermore, 97.7% of all primary augmentation participants and 94.8% of all revision augmentation participants were reoperation free at 5 years. The reoperation-free rate in the primary augmentation group at 5 years was significantly higher than in the revision augmentation group (97.7% vs 94.8%; $P < 0.01$).

The most significant reasons for reoperation are detailed in Tables 5 and 6. The majority of adverse events leading to reoperation occurred within the first year of follow-up (69.2%). The most common adverse events resulting in reoperation in all patients (per implant) were hematoma (0.3%), infection (0.3%), and wound dehiscence (0.2%).

Five participants (5 breasts) suffered a grade III CC during the follow-up period. There were no participants with a grade IV CC. The overall (primary and revision augmentation groups) 5-year risk of grade III CC was 0.6% (95% CI = 0.3-1.5) per patient. The overall risk of grade III CC resulting in reoperation was 0.2% (95% CI = 0.1-1.0) with only 2 patients requiring reoperation. All (n = 2) CCs leading to reoperation occurred in the first year of follow-up, at 7 months and 11 months postoperatively, both in the primary augmentation group.

In all patients, other less common adverse events that required surgical intervention included grade III CC, inversion (back-to-front flipping), seroma, malposition and NAC revision.

Efficacy Outcomes

Satisfaction rates following breast augmentations with the B-Lite LWBI were overwhelmingly excellent: 94.9% of patients rated their satisfaction with the aesthetic outcome at the highest ratings of 4 and 5 (Figure 4A). Even more (95.5%) rated a 4 or 5 on the naturalness of the look and feel of their breasts (Figure 4B). Similarly, the surgeon rated 4 or 5 on 95.4% of the patients in the aesthetic outcome (Figure 4C).

Before and after photographs of clinical outcomes are shown in Figures 5–7.

DISCUSSION

This study represents the largest single-surgeon experience with the B Lite LWBI worldwide to date to our knowledge. Overall, the findings are favorable, with the LWBI being successfully implanted in all patients employing surgical techniques and implantation sites standard to breast augmentation procedures. There were no cases of rupture and a very low rate of reoperations and CCs with high subjective patient and surgeon satisfaction with the aesthetic and tactile result. There were no reports of folds and 1 report of wrinkles, no recurrent ptosis and consistent subjective reports of postoperative reduced pain, and faster recovery, in line with our previous publication.[13] Patients further reported significant comfort with their breasts during daily activities. These reports, although supporting the hypothetical benefits of lighter weight, were not collected systematically, and further research is needed to validate the anecdotal data.

In the present report, out of 655 primary augmentation and 172 revision augmentation procedures involving the LWBI, the risk for reoperation at 5 years remained consistently low for both primary augmentation and revision groups (2.3%, 1.3-4.2; and 5.2%, 3.0-8.8, respectively).

The significantly higher percentage of revision augmentation patients requiring reoperation is supported by the literature where numerous studies show that breast implant revision augmentation surgery may be associated with more reoperations and adverse events.[10,14,15] Although no direct head-to-head comparison is available for breast implants at similar time periods, the results of the 2 largest manufacturers in their FDA studies show that of 455 primary augmentation procedures involving traditional silicone-filled breast implants, the reoperation risk rate was 23.5% (19.5-27.5) in the first 48 months (4 years), and in another study involving 551 primary augmentation procedures, the reoperation risk rate was 15.4% (12.3-18.4) in the first 36 months (3 years).[14,15]

There were no cases of rupture in our study, a finding that compares more favorably than reported incidences at similar time frames with traditional silicone implants. KM risk rates for ruptures recorded with traditional implants at similar timeframes for the MRI cohort were 2.7% for primary augmentation patients (n = 455) and 4.0% for revision augmentation (n = 147) and lower for the non-MRI cohort (0.4 % and 1.2%, respectively).[14] Similarly reported silicone-filled breast implant rupture rates for an MRI cohort at 3 years were 0.5% for primary augmentation and 7.7% for revision augmentation, and there were no reports of rupture in the non-MRI cohorts for either augmentation group.[15]

Table 5. Primary Augmentation, 5 Years, KM (95% CI) Risk Rate of Reoperation Per Complication[a]

	No. of patients (n = 655)	Patients %	KM (CI) per patient	No. of implants (n = 1310)	Implants %	KM (CI) per implant
Overall reoperation	13	2	2.3 (1.3-4.2)	14	1.1	1.2 (0.7-2.2)
Hematoma	3	0.5	0.8% (0.2-2.8)	3	0.3	0.4 (0.1-1.4)

[a]Calculated for complications with per patient rate >0.5%. KM, Kaplan-Meier.

Table 6. Revision Augmentation, 5 Years, KM (95% CI) Risk Rate of Reoperation Per Complication[a]

	No. of patients (n = 172)	Patients %	KM (CI) per patient	No. of implants (n = 343)	Implants %	KM (CI) per implant
Overall reoperation	9	5.2	5.2 (3.0-8.8)	10	2.9	2.9 (1.8-4.8)
Hematoma	2	1.2	1.2% (0.3-4.6)	2	0.6	0.6 (0.1-2.3)
Wound dehiscence	3	1.7	1.8% (0.6-5.3)	3	0.9	0.9 (0.3-2.7)
Infection	1	0.6	0.6% (0.1-4.1)	2	0.6	0.6 (0.1-2.3)
Dog ear IMF	1	0.6	0.6% (0.1-4.1)	1	0.3	0.3 (0-2.1)
Delayed wound healing	1	0.6	0.6% (0.1-4.1)	1	0.3	0.3 (0-2.1)
Dimple	1	0.6	0.6% (0.1-4.1)	1	0.3	0.3 (0-2.1)
Scar revision	1	0.6	0.6% (0.1-4.1)	1	0.3	0.3 (0-2.1)

[a]Calculated for complications with per patient rate >0.5%. IMF, inframammary fold; KM, Kaplan-Meier.

The low risk of grade III CC in the primary augmentation and the revision augmentation group (KM% = 0.6, 95% CI [0.2-1.6] and 0.6% [0.1-4.3], respectively) and the low risk of reoperation at 5 years due to grade III CC (KM = 0.3%, 95% CI [0.1-1.2] and 0%) in primary and revision augmentation, respectively, indicates a favorable safety profile for the LWBI. In our study, we had a total of 5 grade III CCs, 2 of which occurred after a year but less than 2 years postoperatively. While the causes for CC are not clearly known and may be multifactorial,[16] we postulate that the low incidence with the LWBI could be related to the effect of less weight causing less mechanical irritation over time, and therefore we see a decreasing trend for CC in the long term as opposed to the steady growth in CC that we see in other studies with traditional implants within similar time frames. CC rates with widely employed traditional implants at 6 years of 4.6% (3.0-7.1) in the primary augmentation cohort of 492 patients and 6.9 % (3.8-12.5) in 156 revision augmentation patients were reported with reoperation due to grade III/IV CC of 6.4 % and 13.6% in primary and revision augmentation, respectively.[10] A further study reported a 5.6% incidence of grade III CC at 5 to 9 years of follow-up.[17] In another study, the 5-year risk of reoperation due to CC in patients implanted with textured cohesive breast implant was 1.9% (0-3.5) in the primary augmentation group and 15.8% (0-38.3) in the revision augmentation group.[18] Ongoing studies of other round (smooth and textured) silicone implants in 1007 women found that the risk of Baker grade III/IV at 3 years was 8.1% in primary augmentation patients and 18.1% in revision augmentation patients.[19] A similar study looking at shaped (anatomical) implants reported a 2.4% and 9.7% risk of Baker grade III/IV CC in primary and revision augmentation patients, respectively, at 6 years follow-up.[20]

We found that while being consistently low, the leading causes of reoperation were hematoma, infection, and wound dehiscence, It is worthwhile noting that the surgeon's technique involves a fair amount of tissue manipulation aimed to improve aesthetics results, which may in part explain the incidence of hematoma in both primary and revision augmentation patients. Although there were no reported cases of BIA-ALCL, which is a promising finding, we acknowledge that this finding is limited by the relatively short follow-up period of 5 years for this particular complication. The surface in 99.85% of these implants employed was a textured surface (identical to POLYtxt by Polytech Health and Aesthetics GmbH, Dieburg, Germany) classified as micro-textured (average roughness 10-50 microns) according to ISO 14607:2018.[21] Ongoing follow-up will determine whether this positive finding is supported over time.

Implant inversion was reported in 0.8% of the cases. A possible explanation is that, due to near circle geometry of the extra-high profile, the susceptibility to inversion is expected to be higher than in lower projecting implants. Given the fact that majority of the patients were implanted

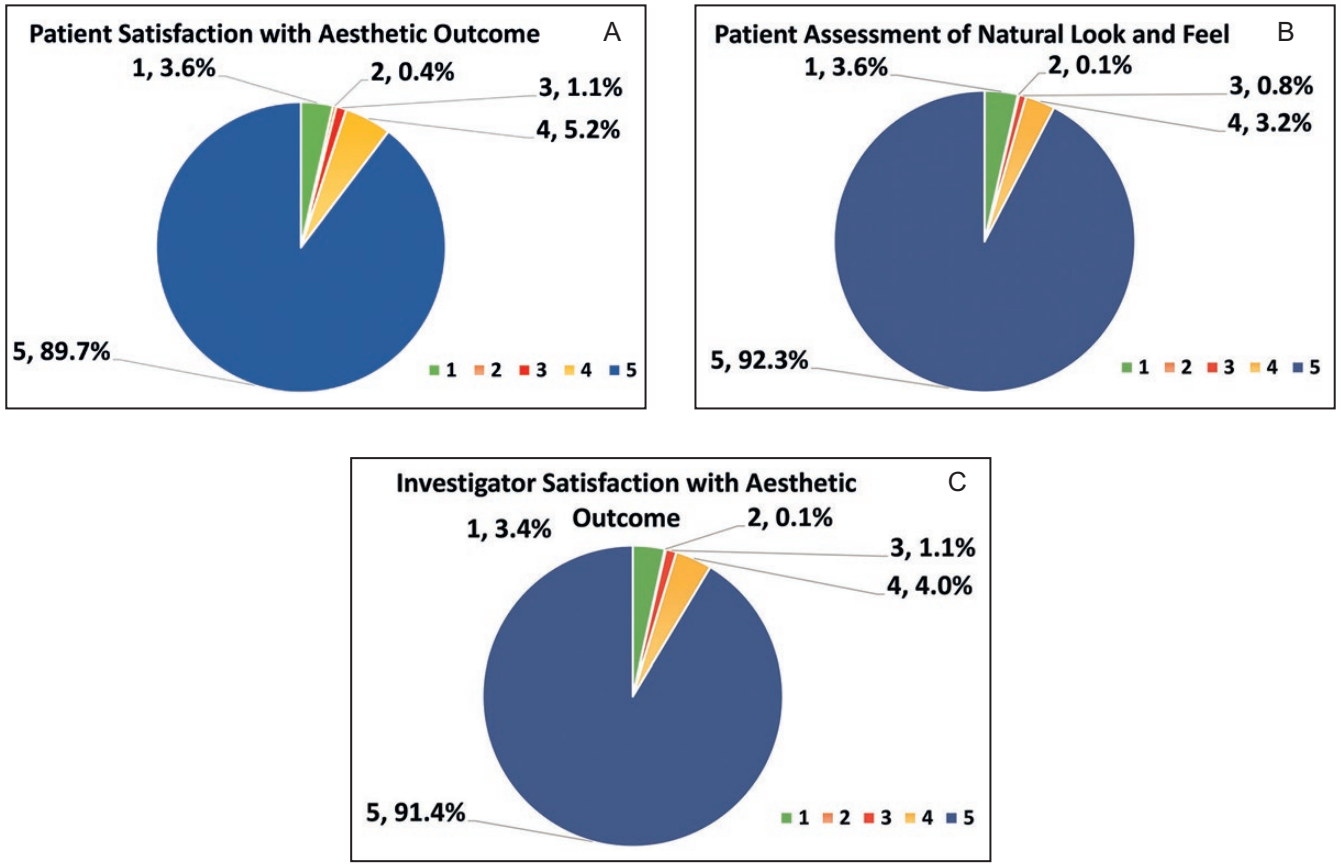

Figure 4. (A) Patient satisfaction with aesthetic outcome. (B) Patient assessment of natural look and feel. (C) Investigator satisfaction with aesthetic outcome. (A) Patients rated their satisfaction with the surgical procedure on a scale of 1 to 5, where 1 = "most dissatisfied" and 5 = "most satisfied." (B) Patients rated their breast appearance and naturalness/softness of how their breasts felt following surgery on a scale of 1 to 5, where 1 = "not at all" and 5 = "natural and soft." (C) The surgeon rated his satisfaction with the operative results on a scale of 1 to 5, where 1 = "poor" and 5 = "excellent."

with extra-high profile (95%) and based on our experience with traditional extra high-profile implants, these numbers are not unusual.

Of particular note, no reports of folds and 1 report of wrinkling were reported compared with rates of 0.7% to 2.7% seen with primary and revision augmentation traditional silicone implants at 6 years in 1 study and corresponding rates of 1.8% and 1.7% of other traditional implants with primary and revision augmentation patients, respectively, at 3 years in another study.[14,15]

There were also no reports of recurrent ptosis in our study, comparing favorably with that of traditional implants at similar timeframes, where recurrent ptosis rates of 1.4% to 1.5% and 2.3% to 3.1% for primary and revision augmentation procedures, respectively, are reported.[14,15] Within the limitation of the present study, LWBI have a favorable safety profile compared with traditional silicone implants.

The high satisfaction rates of both patients and surgeon on the aesthetic look and natural feel of the LWBI augmented breasts is very promising. Furthermore, our subjective anecdotal experience is that patients are reporting daily comfort, with less pain, more relief, and a faster recovery with the LWBI after surgery. Indeed, this supports our previous study where we found reduced pain and accelerated recovery following primary breast augmentation with the LWBI compared with traditional silicone filled full-mass implants.[13]

There are various limitations to the study that may bias the findings. For example, a single surgeon carried out all the surgical procedures. Given that the author (J.G.) carried out all the breast augmentations and is highly experienced in his field, having performed over 15,000 breast implantations, the single-surgeon experience limits the comparison with multicenter studies where different surgeons' skills may have an effect on the outcomes. Because the sample size was substantial, the study's findings may be considered reliable. We also cannot exclude the bias of patient satisfaction with the aesthetic outcome in patients who were willing to pay more for the perceived value of the LWBI as well as patients who had significant complications from previous implants and therefore chose the LWBI as an alternative.

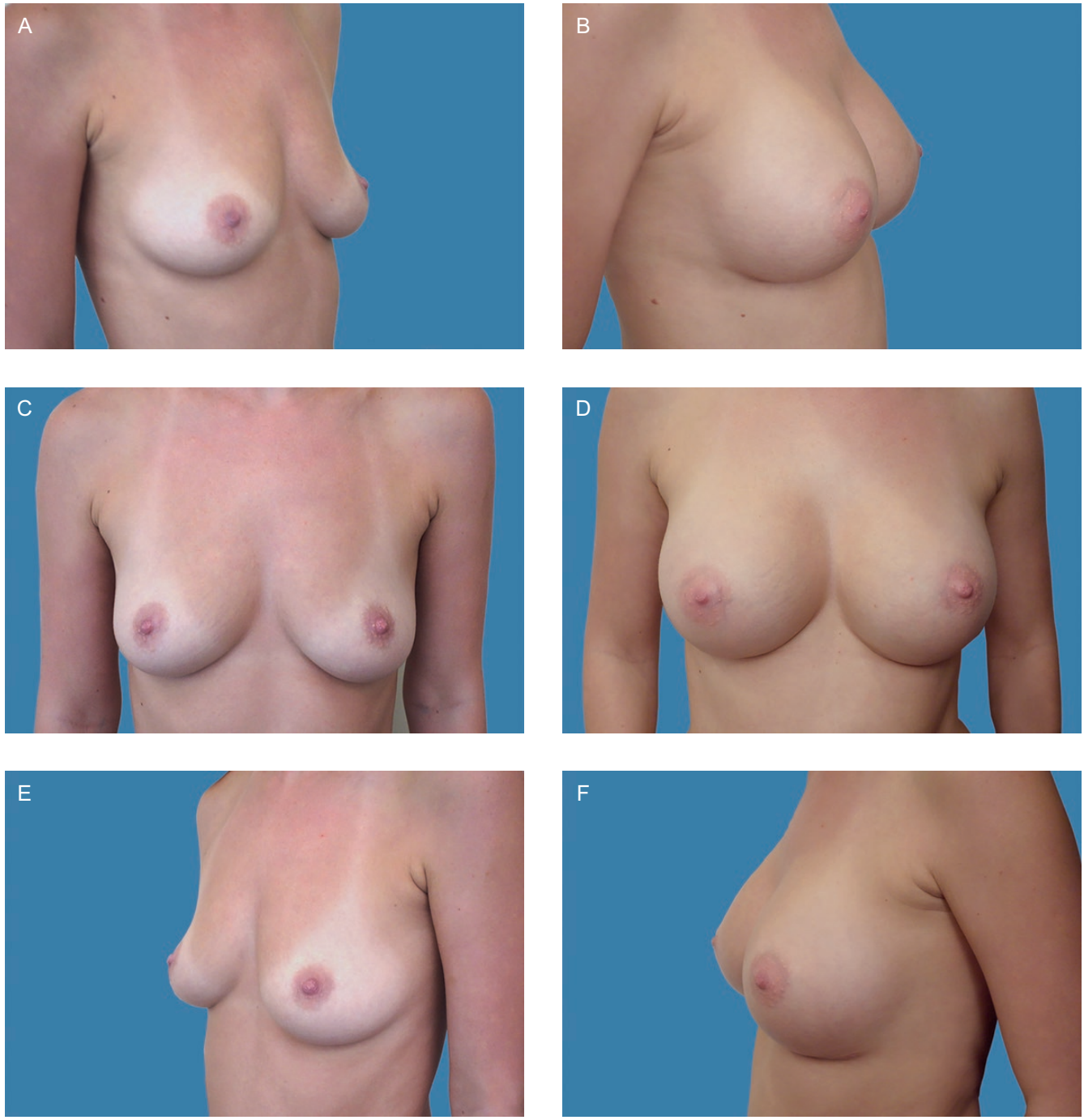

Figure 5. (A, C, E) This 33-year-old woman presented for breast augmentation. (B, D, F) The same woman 5 years following augmentation with B-Lite, Round 325cc, HP, bilateral, subglandular placement.

Another limitation is that although the well-established KM estimate was utilized to extrapolate complications data up to 5.6 years, only 53.8% of the patients reached their third year follow-up; therefore, the data should be interpreted with some care and publication of longer-term data should follow. The vast majority of the implants utilized in this study were micro-textured, and further studying the effects of different implant's surfaces combined with reduced weight is expected to provide valuable insights.

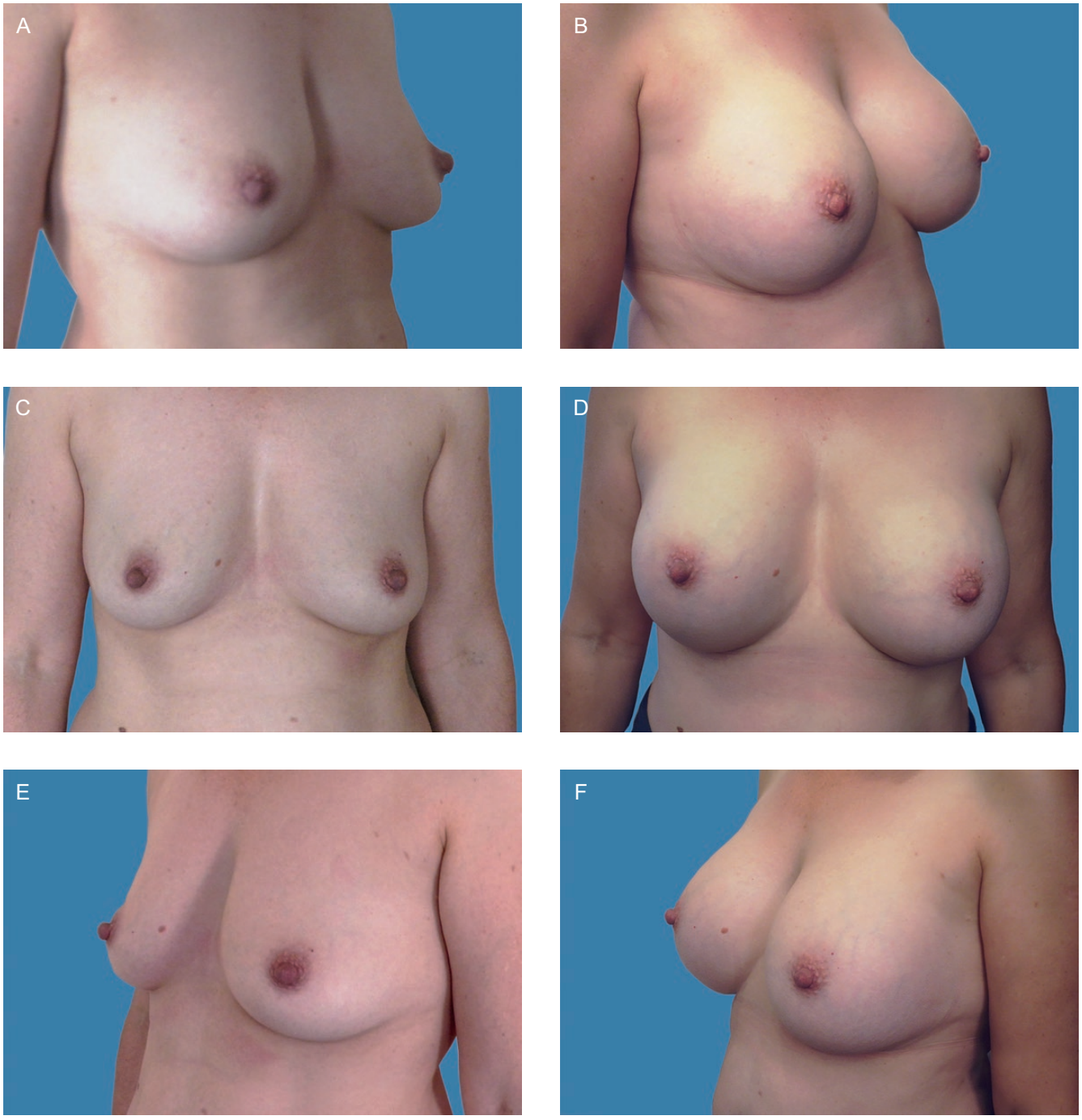

Figure 6. (A, C, E) This 51-year-old woman presented for breast augmentation. (B, D, F) The same woman 5.5 years following augmentation with B-Lite, Round, 440cc, XHP, bilateral, subglandular placement.

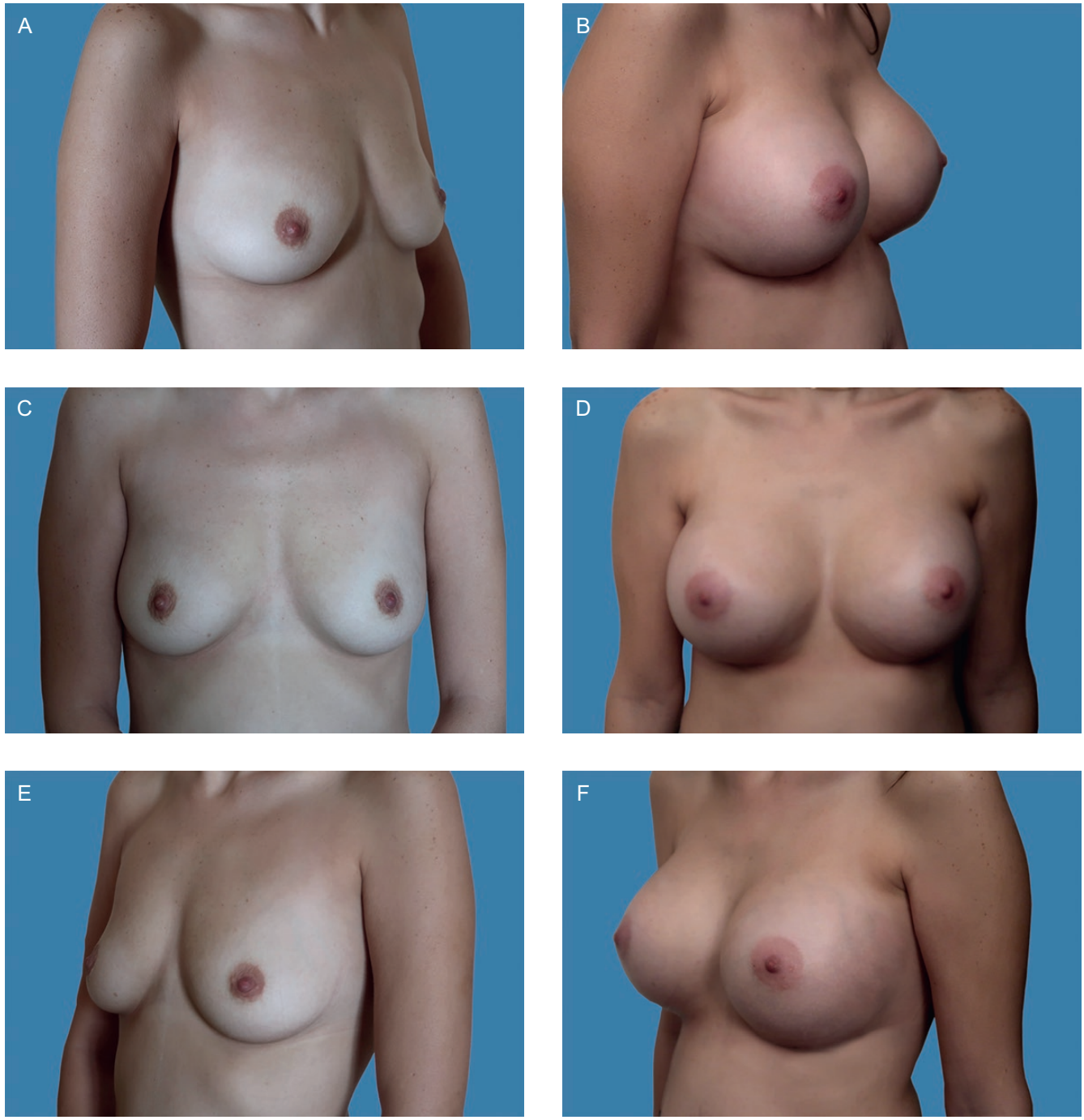

Figure 7. (A, C, E) This 27-year-old woman presented for breast augmentation. (B,D,F) 4.5 years following augmentation with B-Lite, Round 345cc, XHP, bilateral, subglandular placement.

CONCLUSIONS

In this largest cohort study that has been carried out on the B-Lite LWBI worldwide, the results are overwhelmingly positive in terms of both safety and subjective satisfaction. CC and reoperation rates were very low and favorable compared with other popular traditional silicone implants. These findings support the science behind the LWBI's design where a lower weight is a major component in preventing breast tissue complications in the long term. Future studies will expand on the low rate of CC, which was not an immediate expectation and warrants further investigation and focus on parameters sensitive to implant

weight. In addition, ongoing safety and performance monitoring, given the reassuring current profile of the LWBI, will be evaluated in future publications.

Supplemental Material

This article contains supplemental material located online at www.aestheticsurgeryjournal.com.

Disclosures

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