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Ideal Implant Structured Breast Implants: Core Study Results through 10 Years

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Background: The Ideal Implant structured breast implant uses different technology than unstructured saline or silicone gel implants, making it a third type of implant. U.S. Food and Drug Administration (FDA) and Health Canada granted approval in November of 2014. This saline-filled implant has an internal structure consisting of a series of nested shells that support the upper pole when upright and control movement of the saline to provide a natural feel. Because women can look in the mirror to know their implants are intact, they have peace of mind. In contrast, most women are concerned about silicone gel implant ruptures, which are silent and require FDA-recommended magnetic resonance imaging or ultrasound scans for detection.

Methods: This U.S. trial enrolled 502 women: 399 for primary and 103 for revision augmentation. Investigators were 45 American Board of Plastic Surgery–certified plastic surgeons at 35 sites. Of the 502 women enrolled, 426 (84.9%) completed 10-year follow-up visits, a higher percentage than all other FDA breast implant trials.

Results: Through 10 years of follow-up, surgeon satisfaction was 94.8% for primary and 87.4% for revision augmentation; and patient satisfaction was 92.7% for primary and 82.3% for revision augmentation. Cumulative Kaplan-Meier risk rates for two major adverse events were lower than in the silicone gel implant trials: Baker class III and IV capsular contracture was 6.6% for primary and 11.5% for revision augmentation; and rupture/deflation was 3.7% for primary and 4.7% for revision augmentation.

Conclusion: Ten-year results from 426 women show the Ideal Implant has high patient and surgeon satisfaction, a low rate of capsular contracture, and a low rate of rupture/deflation. *(Plast. Reconstr. Surg.* 152: 424e, 2023.)

CLINICAL QUESTION/LEVEL OF EVIDENCE: Therapeutic, IV.

The Ideal Implant structured breast implant was designed and developed as a third type of implant to combine the desirable features of the other two types of breast implants, unstructured saline and silicone gel, but without their drawbacks. It was approved by the U.S. Food and Drug Administration (FDA) and Health Canada in 2014, and commercial sales began in 2015.

The unstructured saline-filled implant does not support the shell or control movement of the saline filler, so the upper pole collapses when upright (Fig. 1), and it does not have a natural, tissue-like feel. However, an implant filled with only saline gives women peace of mind because saline is safe and harmlessly absorbed by the body in case of rupture (deflation). In addition, a woman can look at her breasts to know her implants are intact.

The silicone gel-filled implant has a natural, tissue-like feel because of the viscosity of the

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Fig. 1. (*Above*, *left*) Mentor Moderate Plus 325-cc saline implant at minimum fill volume (total implant volume, 325 cc; fill volume + 20 cc empty implant volume, 345 cc). (*Above*, *center*) Allergan Inspira style SRF silicone gel implant (total implant volume, 365 cc). (*Above*, *right*) Allergan Inspira style SSF silicone gel implant (total implant volume, 365 cc). (*Below*, *left*) Allergan Inspira style SCF silicone gel implant (total implant volume, 365 cc). (*Below*, *center*) Ideal Implant 335-cc structured implant at minimum fill volume (total implant volume, 335 cc). (*Below*, *right*) Ideal Implant 335-cc structured implant at maximum fill volume (total implant volume, 375 cc). Standardized oblique photographs were taken perpendicular to the surface of a curved form with a 10-inch diameter that simulates the convexity of the chest wall. The form was tilted 45 degrees up from the horizontal; a 2-cm lip at the bottom of the form kept the implant from sliding off and simulates support from the inferior capsule. (Photographs courtesy of Ideal Implant Incorporated.)

silicone gel, which has been increased by more cross-linking in successive generations of implants over the years and that also makes the silicone gel more cohesive. This cross-linked silicone gel supports the shell to minimize upper pole collapse when upright (Fig. 1). Even with more cohesive silicone gel, a major disadvantage and a concern of women is that ruptures are silent[1] (ie, not clinically detectable) and occur at a relatively high rate (8.7% to 24.2% in 10-year Core studies[2–4]). The FDA's current recommendation is for a magnetic resonance imaging (MRI) or ultrasound scan to detect silent rupture at 5 to 6 years after implantation, then every 2 to 3 years thereafter.[5] Also, the FDA recommends removal of a ruptured implant, which may entail time-consuming procedures such as capsulectomy for complete removal of the silicone gel. In a recent study of 584 women with current versions of silicone gel implants who had high-resolution ultrasound scans, 10.6% had a silent rupture, with ranges of 3.4% to 5.3% if implanted at least 3 but less than 6 years, to 25% to 50% if implanted at least 14 but less than 16 years.[6] Surveys taken before and after the scans revealed women's desire to know whether their implants were ruptured (99.5%) and for removal if found to be ruptured (95.2%). On learning that an implant was ruptured, women reported a variety of concerns about the following: silicone gel in contact with their tissues (76.9%), extent of revision surgery (72.9%), how long the implant had been ruptured (68.8%), and that the rupture was silent (63.4%). Another indication of women's concern about silent rupture is that 95.5% would get ultrasound scans every 3 months to every 2 years, more frequently than the current FDA recommendation of every 2 to 3 years after an initial scan at 5 to 6 years.[7]

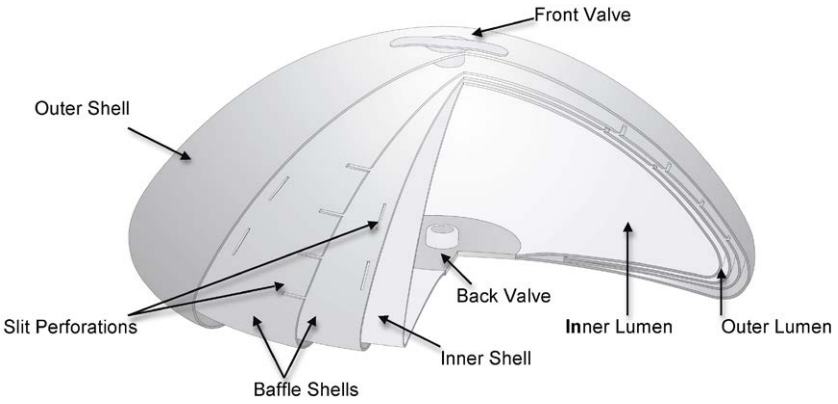

Fig. 2. Cut-away of an Ideal Implant (335 to 555 cc size) showing the inner shell, outer shell, perforated baffle shells floating in the outer lumen, valve in the patch to fill the inner lumen, and valve on the front to fill the outer lumen. (Drawing courtesy of Ideal Implant Incorporated.)

The structured saline-filled implant, the Ideal Implant, is a round, smooth-surface, dual-lumen implant with an internal structure. Approximately two-thirds of the saline is in the inner lumen and one-third is in the outer lumen. Unattached and floating within the outer lumen are one to three baffle shells with slit perforations that control movement of the saline. This internal baffle structure supports the outer shell to prevent upper pole collapse when upright (Fig. 1) and changes the fluid dynamics of the saline filler so that it behaves like viscous silicone gel, giving the implant a natural, tissue-like feel. The structured Ideal Implant has a unique design; it is not just a new generation of the unstructured saline implant, but a completely different type of implant (Figs. 2 and 3).

For all 14 sizes (Table 1), the inner lumen volume is not adjustable, but the outer lumen volume is adjustable within a range proportionate to the size, 25 cc for the smallest implant to 80 cc for the largest implant. This adjustability permits intraoperative correction of asymmetry. Unlike unstructured saline implants, overfilling is not needed to minimize wrinkling. If either lumen deflates, considerable implant volume remains, yet deflation is obvious to a woman by observing a decrease in volume, and replacement can be scheduled electively.

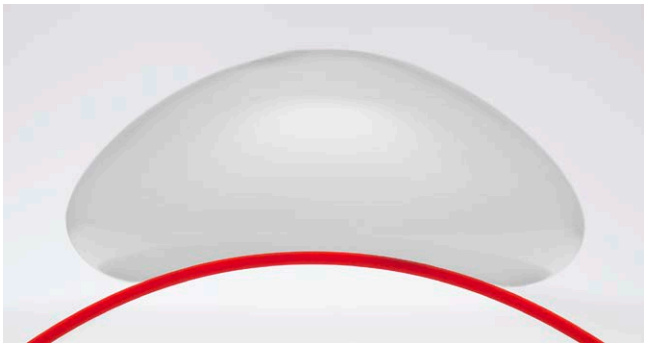

Fig. 3. The edge of the Ideal Implant was designed to be low and contour to the convex surface of the chest wall, so the side of the implant does not bulge outward toward the arm. (Photograph courtesy of Ideal Implant Incorporated.)

The Ideal Implant total volume includes the saline filler plus the empty implant, the same way silicone gel implant total volume includes the shell. Fill volumes were engineered to be percentages of the corresponding mandrel volumes, so when all 14 implant sizes are at the minimum fill volumes, all have the same shape and contour defined as "moderate" profile, and when all 14 implant sizes are at the maximum fill volumes, all have the same shape and contour defined as "full" profile. Adding volume to go from minimum fill to maximum fill increases the projection, but has little effect on the diameter (Table 1).

The 10-year Core clinical study was initiated in 2009 to assess the safety and effectiveness of the Ideal Implant in primary and revision breast augmentation. The 6-year results were published in 2018 in *Plastic and Reconstructive Surgery*.[8] The final Core study data through 10 years of follow-up is presented here. The study was approved by a central investigational review board.

PATIENTS AND METHODS

Study Design

Details of the study design, inclusion/exclusion criteria, and data analysis were presented in

Table 1. Approximate Dimensions and Volumes[a]

Size	Empty (cc)	Inner (cc)	Outer (cc)	Total Volume (cc)	Diameter (cm)	Projection (cm)
210 cc	30	120	60–85	210–235	10.1–10.0	3.5–4.3
240 cc	33	142	65–95	240–270	10.5–10.4	3.6–4.5
270 cc	35	165	70–105	270–305	11.0–10.8	3.8–4.7
300 cc	37	188	75–115	300–340	11.4–11.2	3.9–4.9
335 cc	52	188	95–135	335–375	11.9–11.7	4.0–5.1
370 cc	56	214	100–145	370–415	12.2–12.0	4.1–5.2
405 cc	60	235	110–160	405–455	12.5–12.4	4.2–5.4
440 cc	64	261	115–170	440–495	12.9 -12.8	4.3–5.6
475 cc	68	287	120–180	475–535	13.3–13.1	4.4–5.7
515 cc	72	318	125–190	515–580	13.6–13.4	4.5–5.8
555 cc	76	344	135–205	555–625	13.9–13.8	4.6–6.0
595 cc	94	346	155–230	595–670	14.3–14.2	4.7–6.1
635 cc	102	373	160–235	635–710	14.6–14.5	4.8–6.2
675 cc	110	405	160–240	675–755	14.9–14.8	4.9–6.3

[a]Empty + inner + outer = total volume, measured on a flat surface. Table courtesy of Ideal Implant Incorporated.

the 2018 publication. In summary, this prospective, multicenter, clinical trial had two patient cohorts: primary augmentation and revision augmentation. Follow-up visits were required at 2 months; 6 months; and 1, 2, 3, 4, 5, 6, 7, 8, 9, and 10 years. Safety was assessed by means of the incidence and timing of adverse events and subsequent operations. Effectiveness was determined by patient quality-of-life assessments and patient and surgeon satisfaction-with-outcome assessments.

The study was approved by RCRC IRB (now Salus IRB; Austin, TX). To encourage high rates of patient follow-up, a unique financial incentive plan was used instead of payments for each follow-up visit. Details of this plan have been reported elsewhere.[9]

Subjects

A total of 502 patients were enrolled at 35 investigational sites, 399 in the primary augmentation and 103 in the revision augmentation cohort. The primary augmentation cohort was 82.7% White, with a mean age of 34.5 years, and 92.0% had submuscular implants. The revision augmentation cohort was 83.5% White, mean age was 46.7 years, and 80.6% had submuscular implants. Concurrent breast procedures were performed in 157 of the 798 breasts undergoing primary augmentation (19.7%), of which mastopexy was most common (91.7%), and in 154 of the 206 breasts undergoing revision augmentation (74.8%), of which a capsule procedure was most common (81.2%) (Tables 2 and 3).

In the revision cohort, 24.3% of the implants replaced were silicone gel and 75.7% were saline. The most common primary reason for revision augmentation was capsular contracture, seen in 43.7% of the breasts (Table 4).

Table 2. Demographic Data

Demographic	Primary Augmentation (%)	Revision Augmentation (%)
No.	399	103
Age, yr		
Mean	34.5	46.7
Median	34.0	47.0
Range	18.0–68.0	21.0–67.0
Race		
American Indian Alaska Native	5 (1.3)	0 (0)
Asian	12 (3.0)	2 (1.9)
Black/African American	20 (5.0)	2 (1.9)
Native Hawaiian/Pacific Islander	3 (0.8)	0 (0)
White	330 (82.7)	86 (83.5)
Other	38 (9.5)	15 (14.6)
Ethnicity		
Hispanic or Latino	47 (11.8)	15 (14.6)
Non-Hispanic or Latino	352 (88.2)	88 (85.4)

Through the 10-year follow-up visit, excluding patients who voluntarily withdrew from the trial, had their study implants replaced with other implants, or died, only 27 patients were lost to follow-up in the primary cohort (92.7% follow-up), and only three patients were lost to follow-up in the revision cohort (96.6% follow-up). These follow-up rates are higher than in prior breast implant Core studies.

Statistical Analysis

Data were collected on standardized case report forms, and NAMSA, Inc. (Minneapolis, MN) performed statistical analysis according to

Table 3. Surgical Operative Data, per Implant

Characteristic	Primary Augmentation (%)	Revision Augmentation (%)
No.	798	206
Incision site		
Inframammary[a]	565/798 (70.8)	126/206 (61.2)
Periareolar	177/798 (22.2)	78/206 (37.9)
Axillary	56/798 (7.0)	2/206 (1.0)
Incision length, cm	4.2	4.7
Location		
Submuscular	734/798 (92.0)	166/206 (80.6)
Subglandular	64/798 (8.0)	40/206 (19.4)
Concurrent breast procedure		
Mastopexy	144/157 (91.7)	40/154 (26.0)
Capsule procedure	0/157 (0)	125/154 (81.2)

[a]Two subjects each had two devices implanted by means of abdominoplasty and are reported as inframammary because of the approach used.

Table 4. Initial Breast Implants in the Revision Augmentation Cohort

Measure	Implants (n = 206)
Implant type	
Saline	156/206 (75.7)
Silicone gel	50/206 (24.3)
Location	
Submuscular	138/200 (69.0)
Subglandular	62/200 (31.0)
Reason for replacement	
Capsular contracture	90/206 (43.7)
Dissatisfaction with size	60/206 (29.1)
Wrinkling/scalloping	39/206 (18.9)
Rupture (silicone gel)	13/50 (26.0)
Deflation (saline)	13/156 (8.3)

the protocol using SAS software version 9.4. Data from all sites were pooled, and any two-sided significance testing was at the 0.05 level. All adverse events were included in the analysis except for Baker class II capsular contracture and mild or very mild palpable wrinkling/scalloping, because these were not considered clinically significant problems.

The safety analyses focus on the Kaplan-Meier (KM) risk rates of adverse events because this statistical analysis method takes into account partial follow-up for patients withdrawn over the study. Both time in-study and time to a patient's first occurrence of the event are used in the KM analyses to calculate rate estimates and 95% confidence intervals. For long-term studies, KM analyses are more appropriate than basic proportions at specific time points.

The Breast Evaluation Questionnaire (BEQ)[10] assessed subjects' satisfaction with their breasts before and at 1, 2, 4, 6, 8, and 10 years. The BEQ is a 55-item assessment specifically designed to evaluate breast satisfaction (both self-esteem and body image) among breast surgery patients, including three domains: (1) comfort not fully dressed, (2) comfort fully dressed, and (3) satisfaction with breast attributes.

At follow-up visits, patients and investigators assessed their satisfaction with the outcome in each breast on a five-point scale ranging from definitely satisfied to definitely dissatisfied. To be conservative, a per-subject analysis was performed by taking the worst assessment between the two breasts as the score.

RESULTS

Safety

The key adverse events through 10-years are listed in Table 5. The most common adverse events in both cohorts were subsequent breast operations and implant removals, which accounted for 87.7% of the subsequent breast operations in the primary augmentation cohort and 88.3% of the subsequent breast operations in the revision augmentation cohort. The most common local adverse events included dissatisfaction with implant size, capsular contracture, palpable wrinkling/scalloping, and dissatisfaction with cosmetic result, a broad category that can include already reported adverse events such as capsular contracture.

The KM deflation rate through 10 years is 3.7% for primary augmentation and 4.7% for revision augmentation. These deflation rates include all reported deflations that were attributable to instrument damage, and alleged leaks that could not be reproduced or analyzed because the implant was damaged; and exclude deflations caused by implants with pilot manufacturing-site defects that were addressed before FDA approval with improved manufacturing process controls and inspections[11] at the commercial manufacturing site. Macroscopic and microscopic analyses were performed on all explants. Through 10 years, only four deflations were attributable to a crease-fold of the shell.

The KM capsular contracture rate for Baker grade III and IV capsular contractures through 10 years is 6.6% for primary augmentation and 11.5% for revision augmentation. At each follow-up visit, patients were assessed for palpable wrinkling/scalloping on a five-point grading scale, and for capsular contracture by the Baker classification. Tables 6 and 7 show the

Table 5. Key KM Risk Rates through 10 Years, per Patient

	Primary Augmentation[a]	Revision Augmentation[a]
No.	399	103
Adverse event, %		
Subsequent breast operation[b]	39.4 (34.4–44.9)	50.3 (40.4–61.1)
Implant removal with or without replacement[b]	32.1 (27.4–37.5)	42.6 (33.1–53.6)
Wrinkling/scalloping: moderate or severe	9.0 (6.5–12.4)	21.1 (14.1–30.9)
Dissatisfaction with cosmetic results	11.4 (8.5–15.2)	15.6 (9.7–24.5)
Dissatisfaction with implant size selected	9.3 (6.5–13.1)	13.6 (8.1–22.4)
Baker class III or IV capsular contracture	6.6 (4.5–9.6)	11.5 (6.5–19.7)
Breast lesion: benign	6.6 (4.5–9.7)	7.6 (3.7–15.4)
Breast ptosis: after implant procedure	4.4 (2.7–7.1)	6.2 (2.9–13.4)
Spontaneous deflation[b]	3.7 (2.1–6.4)	4.7 (1.8–12.2)

[a]Values in parentheses are 95% CIs.
[b]The KM rates for these three events are based on patients initially implanted bilaterally with correct size valve attachment component implants: $n = 363$ for primary augmentation and $n = 93$ for revision augmentation. Excluded were the 36 primary augmentation and 10 revision augmentation patients who received an implant with the incorrect size valve attachment component. Also excluded from these three events were spontaneous deflations because of implants with pilot manufacturing site defects.

Table 6. Palpable Wrinkling/Scalloping Assessed at 10-Year Visit, per Implant

	Primary Augmentation (%)	Revision Augmentation (%)
No.	669	161
Severity		
None	557 (83.3)	118 (73.3)
Negligible	22 (3.3)	5 (3.1)
Very mild	36 (5.4)	14 (8.7)
Mild	52 (7.8)	19 (11.8)
Moderate	2 (0.3)	0 (0.0)
Severe	0 (0.0)	5 (3.1)

Table 7. Capsular Contracture Assessed at 10-Year Visit, per Implant

	Primary Augmentation (%)	Revision Augmentation (%)
No.	667	161
Baker class		
I	630 (94.5)	138 (85.7)
II	31 (4.6)	22 (13.7)
III	6 (0.9)	1 (0.6)
IV	0 (0.0)	0 (0.0)

Table 8. Key Reasons for Subsequent Breast Operations through 10 Years

Subsequent Breast Operation	Value (%)
Primary augmentation	
No.	179
Reason	
Dissatisfaction with implant size	24 (13.4)
Inadequate saline volume[a]	11 (6.1)
Baker class III or IV capsular contracture	11 (6.1)
Wrinkling/scalloping: moderate or severe	10 (5.6)
Implant position unsatisfactory	5 (2.8)
Breast lesion: benign or malignant	9 (5.0)
Spontaneous deflation	12 (6.7)
Revision augmentation	
No.	77
Reason	
Implant exposure/extrusion[b]	8 (10.4)
Dissatisfaction with implant size	10 (13.0)
Inadequate saline volume[a]	6 (7.8)
Wrinkling/scalloping	8 (10.4)
Baker class III or IV capsular contracture	6 (7.8)
Dissatisfaction with cosmetic result	4 (5.2)
Spontaneous deflation	1 (1.3)

[a]Inadequate saline volume was observed very early in the course of the trial and addressed by increasing the minimum and maximum fill volumes for the outer lumen to those shown in Table 1.
[b]One patient had implant exposure related to an infection; one patient had three implant exposures associated with multiple operations related to poor wound healing.

prevalence rates at the 10-year follow-up visit, which are less than the KM-estimated adverse event rates presented in Table 2. This is because KM rates incorporate the assessments at all prior follow-up visits, some of which could have been more severe. At the 10-year follow-up visit, only 0.3% of the implants in the primary augmentation cohort had palpable wrinkling/scalloping that was moderate or severe, and only 0.9% of the implants in the primary augmentation cohort had capsular contracture that was Baker grade III or IV. Wrinkling/scalloping may have been overreported in this trial because investigators were required to palpate for wrinkling/scalloping at each follow-up visit and assess the severity. This was not required in other breast implant trials.

The key primary reasons for subsequent breast operations are shown in Table 8. Through 10 years, there were 179 subsequent breast

Table 9. Key Primary Reasons for Implant Removals through 10 Years

Reasons for Implant Removal	Value (%)
Primary augmentation	
No.	157
Reason	
Dissatisfaction with implant size	36 (22.9)
Baker class III or IV capsular contracture	6 (3.8)
Dissatisfaction with cosmetic result	4 (2.5)
Wrinkling/scalloping: moderate or severe	11 (7.0)
Spontaneous deflation	12 (7.6)
Revision augmentation	
No.	68
Reason	
Dissatisfaction with implant size	14 (20.6)
Baker class III or IV capsular contracture	8 (11.8)
Dissatisfaction with cosmetic result	6 (8.8)
Implant exposure/extrusion[a]	4 (5.9)
Wrinkling/scalloping: moderate or severe	8 (11.8)
Spontaneous deflation	1 (1.5)

[a]One patient had implant exposure related to an infection; one patient had three implant exposures associated with multiple operations related to poor wound healing.

operations in 134 patients in the primary augmentation cohort and 77 subsequent breast operations in 45 patients in the revision augmentation cohort. The most common reason for subsequent breast operations was dissatisfaction with implant size, which was the reason in 13.4% of primary augmentation and 13.0% of revision augmentation patients.

The key primary reasons for implant removals are shown in Table 9. There were 157 implants removed in the primary augmentation cohort and 68 implants removed in the revision augmentation cohort. The most common reason was dissatisfaction with implant size.

Effectiveness

Patients in the primary and revision augmentation cohorts experienced statistically significant increases from baseline in each domain of the BEQ at 1, 2, 4, 6, 8, and 10 years, demonstrating patients' continual satisfaction with their breast appearance. Investigators and patients were satisfied with the outcome of the procedure at 10 years. Investigators were definitely or somewhat satisfied with patient outcomes in 313 of 330 in the primary augmentation cohort (94.8%) and 69 of 79 in the revision augmentation cohort (87.4%). Patients were definitely or somewhat satisfied with their outcomes in 306 of 330 in the primary augmentation cohort (92.7%) and 65 of 79 in the revision augmentation cohort (82.3%).

DISCUSSION

The Ideal Implant clinical trial was conducted by plastic surgeons at 35 private practice sites in the United States. Follow-ups through 10 years exceeded all other breast implant Core studies, demonstrating a well-executed clinical trial. The nature, frequency, and severity of the adverse events observed through 10 years are consistent with the 6-year follow-up data reported previously.[8] The most commonly reported adverse event was subsequent breast operation, and the most common reason was dissatisfaction with implant size.

KM rates for subsequent breast operations in the primary and revision cohorts (39.4% and 50.3%) are higher than those reported in Allergan (36.1% and 46.0%),[2] Mentor (25.5% and 43.7%),[3] and Sientra (24.0% and 38.8%)[4] silicone gel Core studies. However, higher rates of subsequent breast operations would likely have been seen in the silicone gel implant studies if ruptures were not silent[5] or if FDA recommendations for MRI screening and explantation of ruptures were followed in the non-MRI cohort.[7]

Although breast implant Core studies follow similar protocols established by the FDA,[12] the patient populations and data collection methods are not identical. Nevertheless, it is useful to compare Core Study data for two key adverse events, capsular contracture and implant failure (deflation/rupture). The Ideal Implant through 10 years had a substantially lower capsular contracture rate and lower failure rate than unstructured saline or silicone gel implants (Tables 10 and 11)[2–4,13–15] for primary and revision augmentation. The explanation for these favorable results is unknown, but may be related to the unique design of the structured implant compared with unstructured saline and silicone gel implants. Several

Table 10. KM Cumulative Risk Rates through 10 Years for Baker Class III or IV Capsular Contracture in Primary Augmentation

Core Study	Primary Augmentation (%)	Revision Augmentation (%)	Combined (%)[a]
Ideal Implant	6.6	11.5	
Allergan Silicone Gel[2]	18.9	28.7	
Mentor Silicone Gel[3]	12.1	24.4	
Sientra Silicone Gel[4]	12.9	13.7	
Allergan Saline[14]			20.8
Mentor Saline[15]			17.5

[a]Primary and revision augmentation not reported separately.

Table 11. KM Cumulative Risk Rates through 10 Years for Implant Deflation or Rupture in Primary Augmentation

Core Study	Primary Augmentation (%)	Revision Augmentation (%)	Combined (%)[a]
Ideal Implant	3.7	4.7	
Allergan Silicone Gel[2b]	9.3	5.4	
Mentor Silicone Gel[3b]	24.2	23.7	
Sientra Silicone Gel[b]	8.7	6.8	
Allergan Saline[14]			13.8
Mentor Saline[15]			24.7

[a]Primary and revision augmentation not reported separately.
[b]MRI cohort.

theories to explain these results are offered here, but further studies are needed to evaluate each possibility.

The low capsular contracture rate may be because the multiple nested shells of the Ideal Implant resist a compressive load more than the single shell of other implants, so there is more resistance to the compressive forces of capsular contracture. Another possible explanation may be that this greater resistance to compression reduces repeated stretching of the outer shell during activities of daily living, thereby reducing repeated microtrauma to the inside surface of the capsule that could stimulate scar contracture. The lower capsular contracture rate may also result from favorable interaction between the scar capsule and the geometry of the Ideal Implant, with the edge low and contoured to the convexity of the chest wall. The implant surface is smooth, so the low capsular contracture rate cannot be attributed to surface texturing.

The low deflation rate may be explained in part by the low incidence of crease folds of the shell. This could be attributable to the underlying baffle shell layers supporting the outer shell, which prevents it from folding upon itself. Also, Ideal Implant shells are fabricated by a computer-controlled robot that dips mandrels while spinning them on their longitudinal axis, which yields shells more uniform in thickness and therefore less likely to crease than shells fabricated by an operator who dips mandrels by hand and cannot spin them. The high technology manufacturing processes demanded by its unique design are why the Ideal Implant cost is similar to that of the silicone gel implant.

Some support for the above theories comes from a report[13] using a new dynamic mechanical test method similar to in vivo conditions to compare Allergan silicone gel implants (SRF and SCF) to the Ideal Implant. When a compressive load was applied, the Ideal Implant was found to change shape less, resulting in lower shell stress and strain, and less implant movement against the capsule (ie, less microtrauma to the capsule). Reduced stress and strain on an implant and its shells caused by the loads of daily activity means the Ideal Implant is more durable and stronger, with longer expected lifetimes compared with silicone gel implants.

The patient's "peace of mind" and her long-term costs of having implants need to be considered and addressed by plastic surgeons when discussing implant choice.[16,17] Many patients are concerned about implant dangers because of recent scientific publications, news stories, and social media posts about breast implant-associated illness, anaplastic large cell lymphoma, and other issues.[18] In a recent study, 62% of women responded that they were at least moderately worried about their implants and were most impacted by the chemical composition of breast implants.[17] Choosing the Ideal Implant addresses some of these concerns (eg, rupture is obvious without a scan, so there is no need for lifelong ultrasound or MRI monitoring for silent rupture, saving patient time and expense). The Ideal Implant's lower capsular contracture and rupture/deflation rates translates into fewer lifetime breast operations and no need for capsulectomy when explanting a ruptured implant, thereby reducing costs and morbidity compared with silicone gel implants.

Although the structured Ideal Implant is saline-filled, it is a distinctly different type of implant than an unstructured saline-filled implant that behaves like a water balloon and gives a less natural result. Therefore, by simply asking patients during the consultation for their choice of filler material with the question, "Do you want saline or silicone gel?" can be misleading, unless they are already familiar with the differences in design and clinical performance of unstructured versus structured saline-filled implants. Based on the unique characteristics of the Ideal Implant, obtaining informed consent as to the choice of implant, not just the filler material, requires explaining and showing patients all three different types of implants: unstructured saline, structured saline, and silicone gel. Although unstructured saline implants may be a choice for those with plenty of breast tissue to camouflage the feel of the implant, for their low cost, or for

the transumbilical approach, based on data from all the 10-year clinical studies, the more appropriate question to ask the vast majority of patients seeking breast augmentation is, "Do you want structured saline or silicone gel implants?"

CONCLUSIONS

The results from this 10-year study show that the Ideal Implant is safe and effective for primary and revision breast augmentation. Similar to how cross-linked silicone gel functions to support the shell, the Ideal Implant's internal structure also supports the shell to minimize wrinkling and upper pole collapse when upright. Comparable to how viscous silicone gel behaves, the Ideal Implant's internal structure controls and governs the movement of the saline filler to give the implant a natural feel. While silent rupture is a concern even with cohesive silicone gel implants,[6] women with the Ideal Implant can simply look in the mirror to instantly confirm their implants are intact, providing the peace of mind they value. In comparison to the 10-year clinical trial performance of silicone gel implants, the Ideal Implant demonstrated a lower risk of deflation/rupture and capsular contracture. Both patients and surgeons reported high satisfaction with the outcome.

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DISCLOSURE

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