

Two-Year Outcomes With a Novel, Double-Lumen, Saline-Filled Breast Implant

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Abstract

Background: A double-lumen, saline-filled breast implant with a baffle structure (IDEAL IMPLANT Saline-Filled Breast Implant; Ideal Implant Incorporated, Irving, Texas) was developed to overcome the limitations of single-lumen saline implants by controlling saline movement and providing internal support to the implant edge and upper pole.

Objectives: The authors report 2-year data from a 10-year US clinical trial evaluating the safety and effectiveness of this investigational implant.

Methods: Women seeking primary breast augmentation or replacement of existing augmentation implants were enrolled between February 2009 and February 2010 at 35 private practice sites, where the women underwent surgery to receive the new technology implant. Data collection included incidence and grade of capsular contracture (CC) and wrinkling as well as patient- and surgeon-reported satisfaction measures. All clinical data were reported as Kaplan-Meier risk rates of first occurrence, per patient, in each cohort.

Results: Two-year follow-up visits were completed by 472 of 502 enrolled women (94.0%), 378 of whom had undergone primary breast augmentation and 94 of whom had received replacement augmentation. Patient-reported satisfaction with the outcome was 94.3% for primary augmentations and 92.3% for replacement augmentations; surgeon-reported satisfaction was also high (96.5% and 93.4%, respectively). Baker Grade III and IV CC rates were 3.8% (primary) and 8.2% (replacement), whereas moderate-to-severe wrinkling was 3.8% (primary) and 12.0% (replacement). Deflations occurred in 4.8% of primary augmentations and 3.3% of replacement augmentations. No deflations were caused by a shell fold flaw.

Conclusions: Two-year data from 472 women indicate that this double-lumen saline implant containing a baffle structure has a low rate of wrinkling and a lower rate of CC at 2 years than was reported for current single-lumen saline implants at 1 year.

Level of Evidence: 2

Keywords

breast implant, breast augmentation, breast surgery, saline, baffles, wrinkling, capsular contracture, clinical trial, double-lumen



Although saline-filled implants are a safe, effective alternative to silicone gel-filled implants,¹ the currently available saline-filled implants are essentially balloons filled with freely-moving fluid, which may result in an unnatural feel or suboptimal aesthetic result.²⁻⁵ These implants, which have only a single lumen, tend to be less forgiving than silicone gel implants in terms of palpability, visibility, and rippling.^{5,6} Scalloping or wrinkling, for example, is a well-known problem.⁵⁻⁷ For a more natural result, the only currently available alternative to saline-filled implants are silicone gel-filled implants, which some women will not accept. This may be a significant part of the reason that 31% of women in the United States chose saline-filled implants for breast augmentation in 2011.⁸ This data suggests that many women considering breast augmentation feel more comfortable with implants containing saline instead of silicone gel. Clearly, there is a need for a saline-filled implant that offers a more natural result, without the

wrinkling, bouncing, or globular shape commonly attributed to current saline implants.²⁻⁵

The IDEAL IMPLANT Saline-Filled Breast Implant (Ideal Implant Incorporated, Irving, Texas) is an investigational device with a baffle structure, 2 lumens, and a series of shells of increasing size nested together (Figure 1). It comprises an

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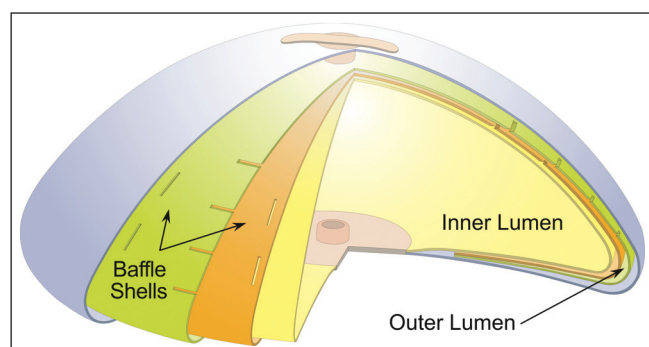


Figure 1. Schematic cut-away view of the IDEAL IMPLANT Saline-Filled Breast Implant (Ideal Implant Incorporated, Irving, Texas). Smaller sizes have 1 baffle shell, medium sizes have 2 baffle shells, and larger sizes have 3 baffle shells. Courtesy of Ideal Implant Incorporated.

inner shell defining the inner lumen, filled through a valve in the posterior patch; an outer shell defining the outer lumen between these 2 shells, filled through a valve in the front; and 1 to 3 additional shells (depending on implant volume) in the outer lumen, perforated and free-floating, to act as a baffle. This baffle structure is designed to control movement of the saline filler so there is no bouncing, to support the upper pole so it does not collapse when the implant is upright, and to support the edges of the implant so scalloping and wrinkling are minimized.

Current saline and silicone gel implants viewed on a convex surface that simulates the typical chest wall convexity behind the breast demonstrate differences in recumbent implant shape, contour to a convex surface, and edge position. When the implant edge is high, they tend to look more globular than when the edge is lower (Figure 2 and Figure 3A). In addition, when the edge is higher, pressure simulating soft tissue can move the edge further toward the underlying convex surface and cause wrinkling. For

these reasons, the investigational double-lumen, saline-filled implant was designed so that the edge lies lower and closer to the chest wall, which potentially provides a better contour compared with current single-lumen saline implants (Figure 3).

For all implant sizes, the inner lumen fill volume in the investigative device is a constant percentage of the inner shell mandrel volume and is not adjustable. The outer lumen is adjustable, and the minimum and maximum fill volumes are each constant percentages of the outer shell mandrel volume. The increment of outer lumen fill volume is a constant percentage of the outer shell mandrel volume, so although the increment of added saline increases with the implant size, all implant sizes look the same when filled to the minimum or to the maximum. This contrasts with some current saline implants that have increments of added saline unrelated to implant size; for example, 30 cc added to a 150-cc implant equals 20%, whereas 30 cc added to a 300-cc implant equals 10%, so these 2 implants look different when filled to the maximum volume. The IDEAL IMPLANT is manufactured in 14 sizes, from 210 cc to 675 cc. The size labels are based on the minimum *total implant* volume, which includes the volume of the empty implant and the minimum volume of the saline inside:

$$\text{Implant Size Label} = \text{Minimum Total Implant Volume} = \text{Empty Implant Volume} + \text{Inner Lumen Fill Volume} + \text{Minimum Outer Lumen Fill Volume}.$$

The size labels of silicone gel implants are also based on the *total implant* volume, which includes the volume of the empty implant and the volume of the silicone gel inside. In contrast, the size labels of current saline implants are based on the recommended minimum *fill* volume; the volume of the empty implant is not included. For example, a current saline implant with a size label of 350 cc actually has a *total implant* volume = 350 cc *fill*

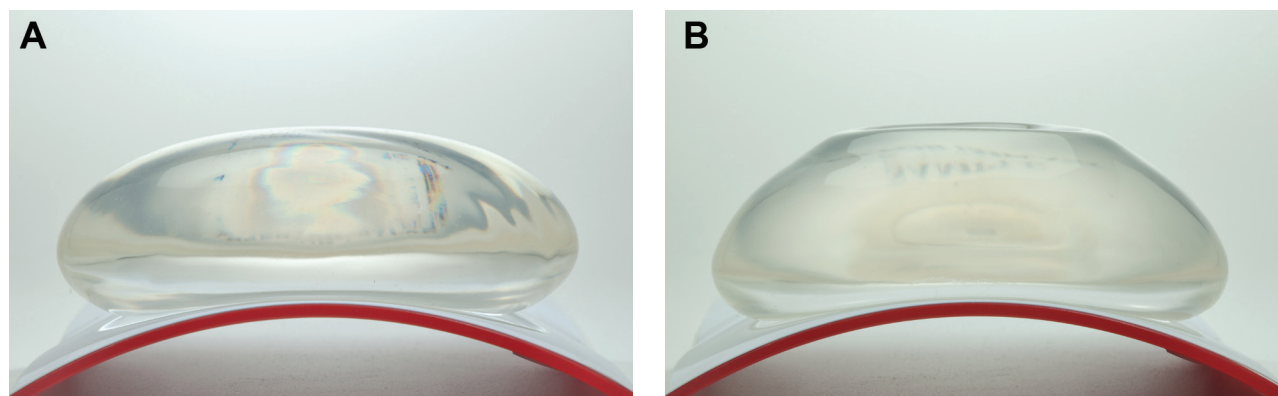


Figure 2. Silicone gel implants on a convex surface simulating the chest wall. (A) Mentor MemoryGel implant, moderate plus profile (Mentor Worldwide LLC, Santa Barbara, California), 350 cc. (B) Allergan Natrelle implant, Style 15, moderate profile (Allergan, Inc, Irvine, California), 371 cc. The edge of Implant B is lower relative to the convex surface, so it contours better to the simulated chest wall and has a more natural, tapered shape than Implant A, which has a more globular shape. Courtesy of Ideal Implant Incorporated (Irving, Texas).

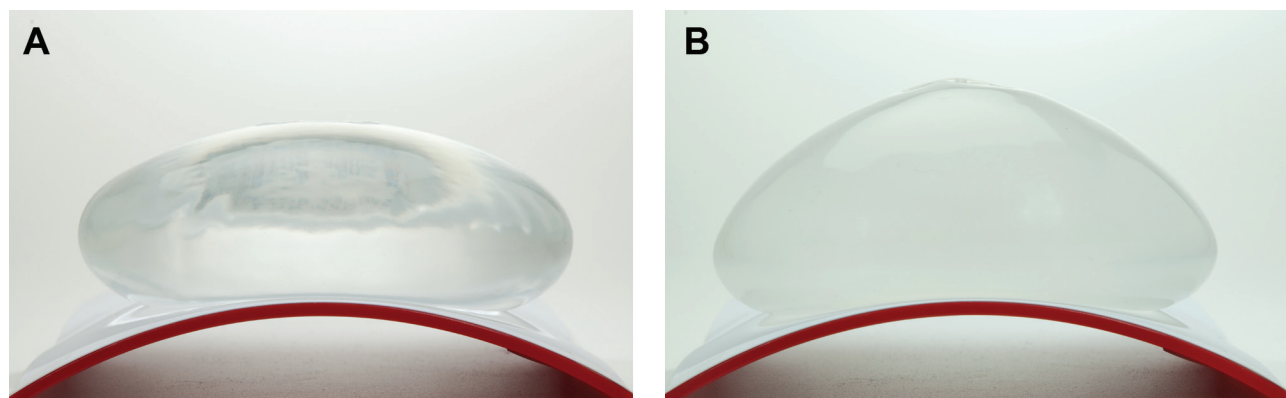


Figure 3. Saline implants on a convex surface simulating the chest wall. (A) Mentor implant, Style 2000, moderate plus profile (Mentor Worldwide LLC, Santa Barbara, California) at minimum fill volume, 350 cc. (B) IDEAL IMPLANT (Ideal Implant Incorporated, Irving, Texas) at minimum fill volume, 405 cc. The edge of Implant B is lower relative to the convex surface, so it contours better to the simulated chest wall and has a more natural, tapered shape than Implant A, which has a more globular shape. Courtesy of Ideal Implant Incorporated.

volume + about 20 cc empty implant volume = 370 cc. In this study, 2-year outcomes are reported from an ongoing clinical trial evaluating the safety and effectiveness of the IDEAL IMPLANT Saline-Filled Breast Implant.

METHODS

Although the IDEAL IMPLANT is made of the same silicone materials as current saline implants, the US Food and Drug Administration (FDA) required complete chemistry, toxicology, and mechanical testing, including cyclic fatigue of the implant, before approving an Investigational Device Exemption (IDE). The trial protocol was approved by an institutional review board (RCRC Independent Review Board, Austin, Texas). The 10-year US clinical trial began in February 2009.

A total of 45 American Board of Plastic Surgery (ABPS)-certified plastic surgeons at 35 private practice sites clustered in 7 metropolitan areas of the United States were the investigators.

Between February 2009 and February 2010, 502 women gave informed consent, were enrolled in the trial, and underwent breast surgery to receive the double-lumen implant: 399 had primary breast augmentation and 103 had existing saline- or silicone gel-filled augmentation implants replaced. A breast reconstruction cohort was not included in this trial.

The implanting surgeons were instructed to use the same preoperative, intraoperative, and postoperative procedures used in their practices for primary breast augmentation or replacement of existing augmentation implants. The study protocol contained no instructions regarding the method of determining implant size, minimum thickness of soft tissue, surgical technique, pocket irrigation, dressings, drains, or postoperative massage.

Each patient was examined at the 2-month, 6-month, 1-year, and 2-year follow-up visits. Capsular contracture

(CC) was graded using the Baker classification system. The absence or presence of palpable wrinkling was determined with the patient standing with arms at her sides. If present, wrinkling was graded on a 5-point scale: negligible, very mild, mild, moderate, and severe. Patient and surgeon satisfaction with the outcome were separately graded at each follow-up visit from “definitely satisfied” to “definitely dissatisfied” on a 5-point scale. Baseline and follow-up clinical data were collected by the investigators on standardized case report forms and tabulated by an independent Clinical Research Organization (CRO) in the format required for submission to the FDA, per patient and per breast. If a score was different for the right and left breasts, the worse score was used for data being reported per patient. All adverse events (AE) were followed until they resolved.

A premarket approval (PMA) application for the double-lumen saline implant was submitted to the FDA after the last patient completed her 2-year follow-up visit, per FDA guidance.⁹

RESULTS

Of the 502 enrolled women, 472 completed all follow-up visits through 2 years, a follow-up rate of 94.0%. Of the 472 women, 378 had primary breast augmentation and 94 had replacement of existing augmentation implants with the investigational implant. Demographic data and surgical information are shown in Table 1. Reasons for replacement of existing implants are shown in Table 2.

At 2 years, patient-reported satisfaction with the outcome was 94.3% for primary augmentations and 92.3% for augmentations that replaced existing implants. Surgeon-reported satisfaction was 96.5% for primary augmentations and 93.4% for replacement augmentations. Examples of outcomes are shown in Figures 4 and 5.

Table 1. Patient Age and Surgical Information, per Breast, by Cohort

	Primary Augmentation (n = 798)	Replacement Augmentation (n = 206)
Patient age, y		
Mean	34.5	46.7
Range	18-68	21-67
Incision, %		
Inframammary	70.3	61.2
Periareolar	22.2	37.9
Axillary	7.0	1.0
Abdominoplasty	0.5	0
Position, %		
Submuscular	92.0	80.6
Subglandular	8.0	19.4
Concomitant procedures, %		
Mastopexy	18.0	19.4
Capsule procedure	NA	60.7
Type of implant replaced, %		
Saline	NA	75.7
Silicone gel	NA	24.3

Abbreviation: NA, not applicable.

Table 3 lists adverse events as Kaplan-Meier risk rates of first occurrence, per patient, for the IDEAL IMPLANT at 1 year compared with the 1-year Large Simple Trial (LST) data used in the PMA applications for the current saline implants manufactured by Allergan, Inc (Irvine, California) and Mentor Worldwide LLC (Santa Barbara, California).^{10,11} In the LST studies, Allergan had a 1-year follow-up rate of 62%, and Mentor had a 1-year follow-up rate of 47%.

Table 4 shows 2-year adverse events for the investigational implants as Kaplan-Meier risk rates of first occurrence, per patient. The 2-year Baker Grade III and IV CC rates for the investigational implants were lower than the rates reported at 1 year for current single-lumen saline implants.^{10,11}

Based on explant analysis of clinical trial implant deflations, none were due to shell failure caused by a shell fold-flaw, the usual cause of shell failure for both single-lumen saline and silicone gel implants. One deflation was due to shell failure from iatrogenic puncture by a surgical needle, confirmed by scanning electron microscopy. One deflation was indeterminate because the implant was inadvertently damaged by the surgeon after explantation. All other deflations (n = 23) were due to early manufacturing defects, including inadequate vulcanization bonds of the posterior valve to the patch, inadequate vulcanization bonds of the

Table 2. Reasons for Replacement of Each Type of Implant^a

	Existing Saline Implant (n = 156), %	Existing Silicone Gel Implant (n = 50), %
Capsule contracture	39.1	58.0
Scalloping/wrinkling	23.7	4.0
Deflation (saline)	8.3	NA
Rupture (silicone gel)	NA	26.0
Dissatisfaction with size	34.6	12.0
Other	26.9	26.0

Abbreviation: NA, not applicable.

^aPatients may have had different reasons for each breast or more than one reason per breast, so they may be counted in more than one category.

patch to the shell, or valve damage during assembly. Changes in manufacturing for the commercial implant have been instituted and validated by the study sponsor to provide adequate vulcanization bonds of the valve-patch and shell-patch joints and to prevent valve damage during assembly.

DISCUSSION

Over the years, many novel designs have been proposed for an improved saline breast implant that would overcome the limitations of current single-lumen saline implants and provide a good alternative to silicone gel implants (Table 5). Adding a baffle to control movement of the saline is not a new concept. However, earlier baffle designs were either complex to manufacture or flawed in that the baffle material could dislocate and concentrate in one area of the implant when the patient changed position. The investigational saline-filled implant discussed in this study was designed to address these earlier design problems: the baffle structure is created by perforating implant shells for ease of manufacturing, and the placement of the baffle structure in the outer lumen, closely fitted between the inner and outer shells, keeps the structure in place when the patient changes position. Although not the subject of the current study, the effect of the baffle structure on saline movement and on upper pole and edge support can also be demonstrated *in vitro*. The investigational implant behaves like it has the viscosity of a silicone gel implant and does not bounce when dropped onto a table, whereas current single-lumen saline implants bounce. Likewise, when held upright on the outstretched hand, the investigational implant maintains upper pole fullness and the edge does not wrinkle, whereas current single-lumen saline implants collapse in the upper pole and wrinkle at the edge.

The clinical trial protocol used in this study closely follows those used for FDA approval of current saline-filled breast implants marketed by Allergan, Inc and Mentor Worldwide LLC. However, in those trials, the investigators reported wrinkling only when they thought it was an AE and completed an AE case report form. Therefore, for

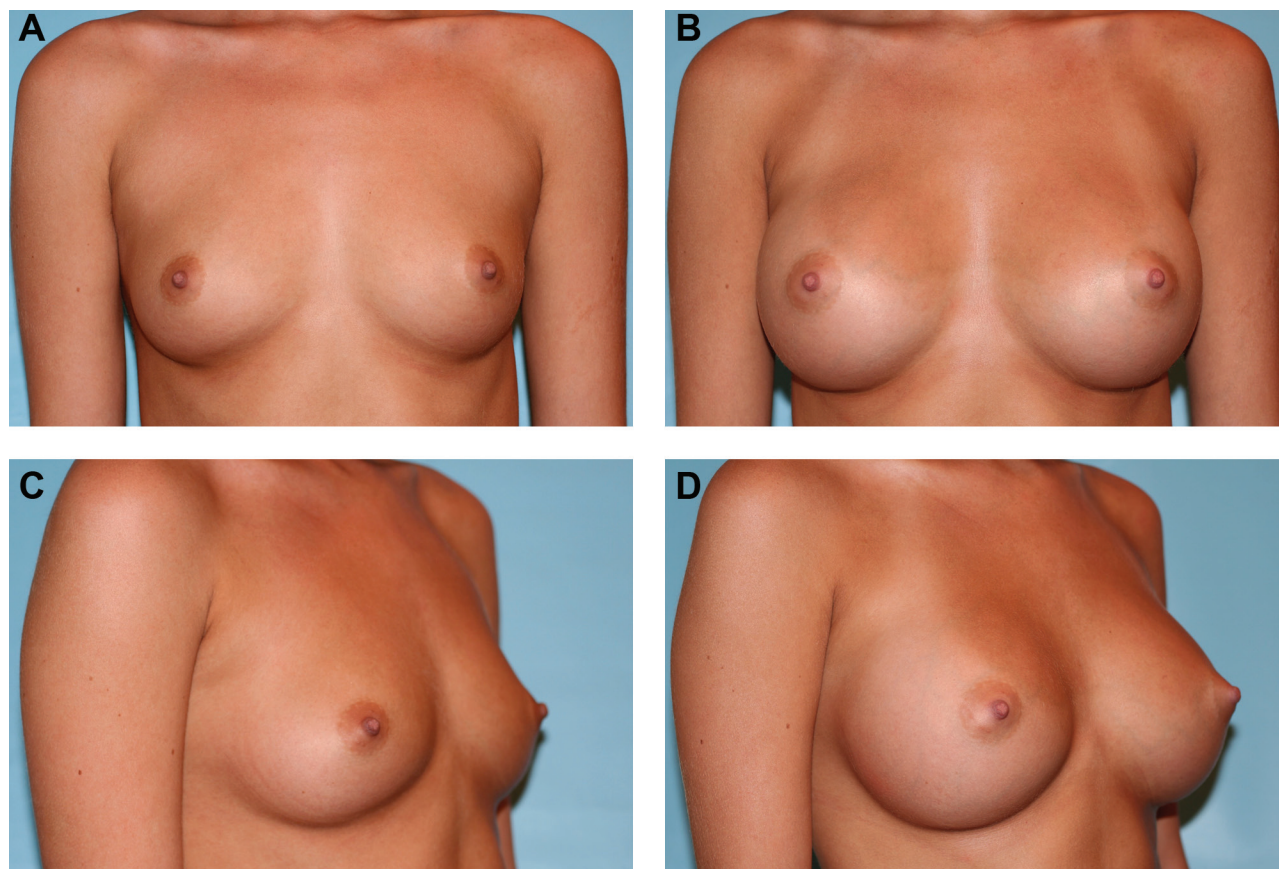


Figure 4. (A, C) This nulliparous 19-year-old woman presented for breast enlargement. (B, D) One year after submuscular breast augmentation with the double-lumen, saline-filled investigational implants (IDEAL IMPLANT; Ideal Implant Incorporated, Irving, Texas), with an implant volume of 305 cc.

example, some investigators in those trials may not have reported wrinkling when it was palpable, only when it was visible. By comparison, wrinkling may have been overreported in this trial because the investigator was required to examine for the absence or presence of palpable wrinkling at every follow-up visit and, if present, to score it from “negligible” to “severe” on a 5-point scale.

Similarly, patient and surgeon satisfaction in this trial may have been underreported because the surgeons and patients were required to assess satisfaction “with the outcome,” which can include such nonimplant items as the quality of the incisional scar, sensory changes, or development of a wound infection. In the Allergan saline implant trial, only patients’ satisfaction “with their breast implants” was assessed,¹⁰ and in the Mentor saline implant trial, only patients’ satisfaction “with the general appearance of their breasts” was assessed as measured by the Breast Evaluation Questionnaire (BEQ).¹¹

One of the most significant and unexpected differences between the investigational implant and current single-lumen saline implants was the low rate of CC. Compared with the published 1-year LST data for primary breast augmentation shown in Table 3, the investigational implant at 1 year had a 1.6 (compared with Mentor data

to 2.6 (compared with Allergan data) times lower rate of Baker III and IV CC. For replacement augmentation, the investigational implant had a 3.0 (Allergan) to 3.6 (Mentor) times lower rate of Baker III and IV CC, even though 39.1% of existing saline implants and 58.0% of existing silicone gel implants in this trial were replaced because of bilateral or unilateral CC. As shown in Table 4, the 2-year CC rates for the investigational implant remain lower than the 1-year rates for current single-lumen saline implants. The reason for this low incidence of CC is unknown.

The 2-year clinical data from this study show that this double-lumen saline breast implant may provide a good alternative for women who do not want a silicone gel implant. In the authors’ opinion, the baffle structure of the double-lumen implant discussed in this study successfully controls movement of the saline, preventing bouncing and providing a more natural result compared with current single-lumen saline implants. In addition, 2-year data from this study show that the incidence of scalloping or wrinkling is lower with the investigational saline-filled implant compared with currently approved single-lumen saline implants. The double-lumen implant is designed with a lower edge to conform better to the chest wall. It is possible that the lower rate of CC reported in this study

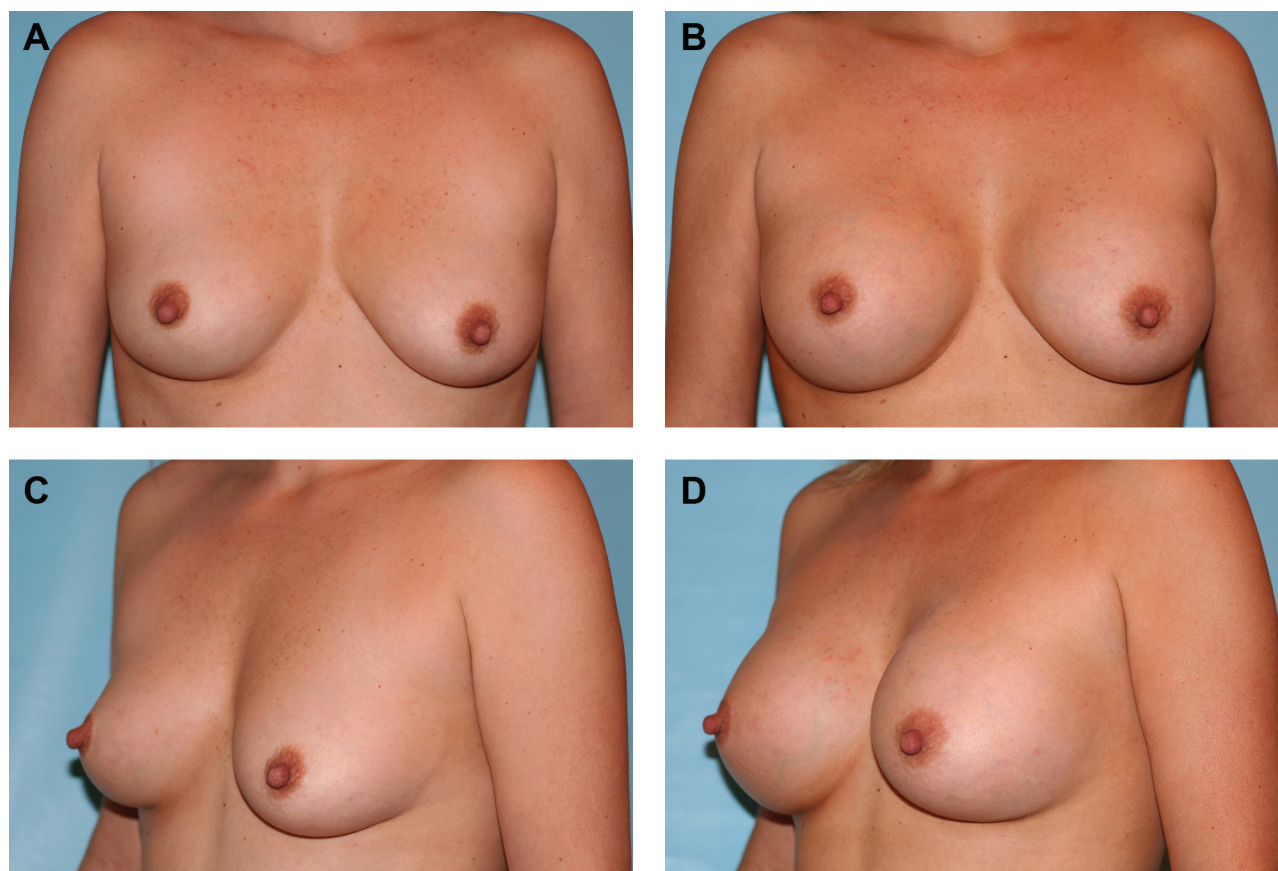


Figure 5. (A, C) This 31-year-old woman presented for restoration of breast volume following delivery and nursing of 2 children. (B, D) One year following submuscular breast augmentation with the double-lumen, saline-filled investigational implants (IDEAL IMPLANT; Ideal Implant Incorporated, Irving, Texas), with an implant volume of 325 cc.

Table 3. One-Year Adverse Events as Kaplan-Meier Risk Rates of First Occurrence, per Patient, for the Double-Lumen IDEAL IMPLANT^a Compared With Allergan and Mentor Saline Implants^b

Adverse Event	Primary Augmentation, %			Replacement Augmentation, %		
	IDEAL	Allergan	Mentor	IDEAL	Allergan	Mentor
Capsular contracture (Baker III and IV)	2.8	7.2	4.6	4.0	11.8	14.5
Infection	0.5	1.5	0.9	1.0	3.3	No data
Removal with or without replacement	6.0	6.1	3.6	10.8	7.8	6.0
Deflation	2.2	3.6	1.4	2.2	5.4	2.3

^aIdeal Implant Incorporated (Irving, Texas).

^bThe Allergan implants are Styles 68, 163, 168, 363, and 468, smooth and textured, round and shaped (Allergan, Inc, Irvine, California, formerly McGhan Medical, Santa Barbara, California), and the Mentor implants are Styles 1600, 2600, 2700, 2900, 5000, 5000PT, 1400, 2400, 2500, 6000, and 6000PT, smooth and textured, round and contoured (Mentor Worldwide LLC, Santa Barbara, California). Data listed for these implants are taken from their respective premarket approval data.^{10,11}

may be related in some way to the lower edge position and better conformity to the chest wall compared with current single-lumen saline implants. Longer follow-up is needed to confirm that these are persistent findings.

Although these 2-year outcomes are favorable, the clinical trial for cosmetic breast augmentation and

replacement of existing augmentation implants is ongoing and will continue to provide data on this new implant for 10 years. However, because the implant is saline-filled, a PMA application was submitted to the FDA after the last patient completed her 2-year follow-up visit.⁹

Table 4. Two-Year Adverse Events as Kaplan-Meier Risk Rates of First Occurrence, per Patient, for the Double-Lumen IDEAL IMPLANT^a

Adverse Event	Primary Augmentation (n = 399), % (95% CI)	Replacement Augmentation (n = 103), % (95% CI)
Capsule contracture (Baker III and IV)	3.8 (2.3, 6.3)	8.2 (4.2, 15.8)
Infection	0.8 (0.2, 2.3)	1.0 (0.1, 7.0)
Wrinkling (moderate to severe)	3.8 (2.3, 6.3)	12.0 (7.0, 20.2)
Deflation (early manufacturing defects)	4.8 (3.0, 7.6)	3.3 (1.1, 10.0)

Abbreviation: CI, confidence interval.

^aIdeal Implant Incorporated (Irving, Texas).**Table 5.** US Patents Related to Improvements in the Design of Saline Implants

Inventor	Patent No.	Date	Description
L. Bartholdson	4,507,810	April 2, 1985	Filled with interconnected cells
J. Bark	5,171,269	December 15, 1992	Filled with fibrous material
R. Peterson	5,246,454	September 21, 1993	Filled with small saline pouches
J. Fisher	5,496,367	May 5, 1996	Internal baffle structures
R. Hamas	5,496,370	May 5, 1996	Double-lumen with baffle material
J. Henley	5,534,023	July 9, 1996	Filled with chain of gas-filled beads
T. Knapp	5,824,081	October 20, 1996	Filled with foam material
D. Carlisle	5,658,330	August 19, 1997	Filled with foam insert
R. Hamas	6,802,861	October 12, 2004	Double-lumen with nested shells
B. Purkait	7,625,405	December 1, 2009	Filled with silicone tubing

CONCLUSIONS

Clinical data at 2 years from 472 women show that this double-lumen, saline-filled implant with a baffle structure has a low rate of wrinkling and a lower rate of CC at 2 years than rates reported in the PMA applications for current single-lumen, saline-filled implants at 1 year. There

were no deflations due to any fold-flaw of the shell, and satisfaction with the outcome was very high for both patients and surgeons. This double-lumen saline implant may provide women with an alternative to current saline or silicone gel implants.

Disclosures

Dr Nichter is a paid clinical trial investigator and Dr Hamas is Founder, President, Medical Director, and stockholder of Ideal Implant Incorporated (Irving, Texas), the manufacturer of the products discussed in this study.

Funding

The clinical trial was entirely funded by the study sponsor (Ideal Implant Incorporated, Irving, Texas).

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