Sientra Portfolio of Silimed Brand Shaped Implants with High-Strength Silicone Gel: A 5-Year Primary Augmentation Clinical Study Experience and a Postapproval Experience—Results from a Single-Surgeon 108-Patient Series

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Background: The Sientra portfolio of silicone gel breast implants was approved by the Food and Drug Administration on March 9, 2012, and included the first approved shaped implants in the United States. The 5-year results from Sientra's Core Gel and Continued Access Study and the results of a single surgeon are presented.
Methods: This analysis used the data of 640 shaped implants in 321 primary augmentation patients implanted by 16 study surgeons through 5 years. The Kaplan-Meier method was used to analyze safety endpoints. In addition, analysis is presented for a single surgeon's results of 213 shaped implants in 108 postapproval patients through up to 16 months of follow-up (9-month mean) using a separate frequency analysis.
Results: The overall risk of rupture for primary augmentation patients through 5 years was 0.4%, the risk of infection was 1.4%, and the risk of capsular contracture (Baker grade III/IV) was 3.9%. Reported surgeon satisfaction was 100%, and patient satisfaction remained high. In the separate single-surgeon analysis, after 16 months, 4 of the 108 patients experienced a complication (3.7%) and 3 underwent a reoperation (2.8%). Complications included infection, ptosis (0.9%, each), and capsular contracture (1.9%).
Conclusions: The results of Sientra's large clinical study and the postapproval data from a single surgeon demonstrate the safety and effectiveness of Sientra's shaped implants. The review of the data and author's experience illustrate the ease of incorporating shaped implants into any surgical practice. (*Plast. Reconstr. Surg.* 134: 38S, 2014.)

Since the first breast implants were introduced in the early 1960s,[1] there have been various design improvements to the round implant, which had been the only shape commercially available for over 50 years. As breast implant surgery became more popular across a larger demographic and patients requested a more "natural" shape, the need for an anatomically shaped silicone implant became apparent. Although widely available and popular in Europe,[1] anatomically shaped implants were only available in the United States through clinical studies until Sientra's recent approval.

On March 9, 2012, the Food and Drug Administration approved Sientra's portfolio of its Silimed brand silicone gel breast implants based on the clinical study data from its large pivotal study. This approval also marked the introduction of the first shaped silicone gel implant in the United States. The following data present a summary of the results from Sientra's Core Gel and Continued Access Study of its shaped implants through

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Received for publication November 8, 2013; accepted January 16, 2014.

DOI: 10.1097/PRS.0000000000000346

Disclosure: *Drs. Haws, Schwartz, and Berger are clinical study investigators for Sientra and received standard research support for conducting their studies. Ms. Daulton is an employee of Sientra.*

5 years. Additionally, the data from a single surgeon's postapproval experience with Sientra's shaped implants through up to 16 months of follow-up (9-month mean) are summarized. These collective results provide evidence of the strong safety profile of these implants and the ability to provide additional viable surgical options for surgeons and patients.

PATIENTS AND METHODS

Patients

The analysis in this article was based on 5-year results from Sientra's Food and Drug Administration–approved large, prospective, open-label, United States–based clinical study. Patients were enrolled following defined inclusion and exclusion criteria.[2] The subset of data used for this analysis includes 640 shaped implants in 321 primary augmentation patients implanted by 16 study surgeons.

Device Description

Sientra's anatomically shaped implants are available in 3 base footprints: classic (taller than wide), oval (wider than tall), and round base (equal height and width) (Fig. 1). These "footprints" encompass 3 projections: low, moderate, and high. The gel fill is composed of High-Strength Cohesive silicone (HSC+) specifically formulated for these shaped implants. The plus (+) indicates a slight increase in cross-linking compared with the round Sientra devices (HSC). All HSC+ implants have a distinct white orientation mark intended to provide a clear visual guide for final implant placement. Sientra's shaped implants feature Silimed's TRUE Texture, a proprietary texturing method designed to promote tissue ingrowth that does not use sodium chloride, sugar, soak/scrub, or pressure-stamping methods.[3]

Data Collection

Study patients were seen by their surgeon for a physical examination annually, or more often, as needed. Study endpoints, including the occurrence of complications, were collected on case report forms and were double data entry validated in the clinical database. Adverse events were assessed on a severity scale of 1 to 5. Consent to participate in this institutional review board–approved study was obtained from all patients. These data were used to conduct safety and effectiveness analyses of Sientra's shaped silicone gel breast implant in primary augmentation patients.

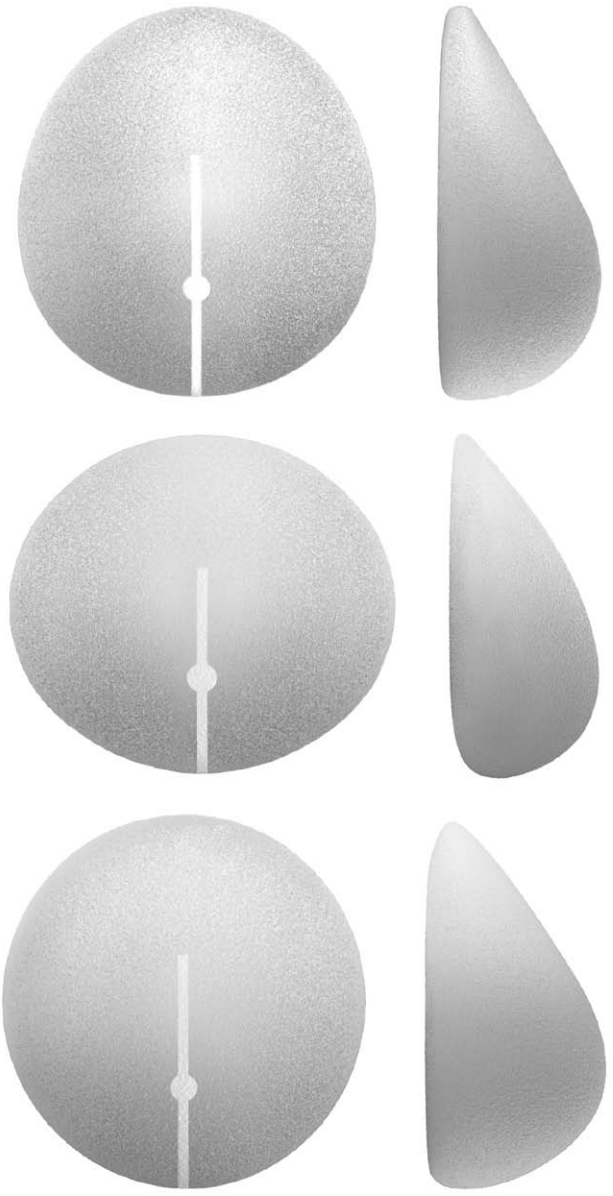

Fig. 1. The footprint and profile views of the classic (*above*), oval (*center*) and round (*below*) bases.

Statistical Methods

Safety assessment was analyzed using the incidence of reported complications. The cumulative incidence of first events was estimated based on Kaplan-Meier risk rates (one minus the complication-free survival rate) along with 95% confidence intervals calculated using Proc LifeTest in SAS (SAS Institute, Cary, N.C.). Effectiveness assessments include a comparison of preimplantation to postimplantation bra cup sizes and patient-reported satisfaction.

Rupture analysis used data from the magnetic resonance imaging cohort that received regular magnetic resonance imaging scans at approximately

every 2 years. Patients' scans were read by a local radiologist and a blinded central radiologist. A suspected, indeterminate, or determinate rupture reading from either the local or central radiologist was counted as a rupture and used in the analysis. This article presents the safety and effectiveness results through 5 years of follow-up.

RESULTS

Patients

Analysis was performed on 321 primary augmentation patients. The reported median patient age at the time of enrollment was 36 years. The majority of patients (60%) reported having an annual household income of over $60,000, and 85% had at least some college education. The median height and weight at enrollment were 5′5″ (SD, 2.7) and 128 lbs (SD, 21.0), respectively, and median body mass index was 21 (SD, 3.1).

All implants included in this analysis (Table 1) were Sientra HSC+ implants. An inframammary incision site was most commonly used (67%), and the majority of implants were placed in the subglandular position (63%), with an incision size ranging from 3 to 6 cm (91%).

Safety Experience

Table 2 summarizes the complication rates for all reported complications through 5 years postsurgery. Within the key complications, the overall risk of rupture for primary augmentation patients implanted with Sientra shaped implants was 0.4%, the risk of capsular contracture was 3.9%, and the risk of infection was 1.4% (Table 2). Other complications occurring with a risk over 2.0% were breast mass/lump/cyst, implant malposition, and wrinkling/rippling.

Table 3 reports the rates of reoperation and removal. Forty-four patients underwent reoperation after implantation, with two thirds (68%) of reoperations occurring before 2 years in vivo (30 of 44 patients). The risk of reoperation was 16.0% by patient and consistent with or lower than that with the other approved shaped implants.[4,5] Of the 44 patients who underwent a reoperation, 21 patients were explanted with replacement and 8 patients were explanted without having implants replaced. The risk of explantation (with or without replacement) was reported to be 10.3%. The 2 most common reasons for explantation were style/size change (46%) and capsular contracture (12%); all other reasons occurred at less than 10%.

Table 1. Device and Surgical Characteristics (by Implant)

Characteristic	Primary Augmentation
No. of implants	640
Device placement	
Submuscular	36.9%
Subglandular	63.1%
Incision type	
Inframammary	66.9%
Mastopexy	1.3%
Periareolar	31.9%
Incision size	
0–3 cm	3.4%
3–6 cm	90.9%
6–9 cm	5.6%

Table 2. Risk of Key Complications (by Patient)

Local Complication	KM Rate (%)	95% CI
Rupture		
Rupture (overall)	0.4	0.1, 2.5
Rupture (MRI cohort)	0.0	—
Asymmetry	1.8	0.7, 4.2
Breast mass/cyst/lump	2.7	1.2, 6.0
Breast pain	0.4	0.1, 2.7
Capsular contracture (Baker III/IV)	3.9	2.0, 7.5
Double capsule	0.0	—
Gel fracture	0.0	—
Hematoma	0.6	0.2, 2.5
Hypertrophic/abnormal scarring	0.7	0.2, 2.7
Implant extrusion	0.7	0.2, 2.9
Implant malposition	2.3	1.1, 4.9
Implant palpability	0.7	0.1, 4.6
Infection	1.4	0.5, 3.7
Lymphedema	0.4	0.1, 2.5
Necrosis	0.3	0.0, 2.2
Ptosis	1.4	0.4, 4.4
Redness	0.0	—
Rotation	0.0	—
Seroma/fluid accumulation	1.7	0.7, 4.1
Skin rash	0.3	0.1, 2.3
Skin sensation changes	1.1	0.4, 3.4
Swelling	2.0	0.8, 4.9
Upper pole fullness	0.0	—
Wrinkling/rippling	2.8	1.3, 5.9

CI, confidence interval; KM, Kaplan Meier; MRI, magnetic resonance imaging.

Effectiveness

At the completion of the implant surgery, 100% of surgeons reported satisfaction with the surgical results for all procedures. Over 87% of patients increased their bra cup size by at least one size. Additionally, the majority of patients felt that

Table 3. Reoperations and Implant Removals (by Patient)

	KM Rate (%)	95% CI
Reoperation	16.0	12.0, 21.0
Implant removal	10.3	7.3, 14.6
With replacement	7.6	5.0, 11.5
Without replacement	2.9	1.5, 5.8

CI, confidence interval; KM, Kaplan Meier.

their implants made them feel more feminine, look natural and soft, and made their clothes fit better (Fig. 2).

Single-Surgeon Methods

To explore a single surgeon's experience, a separate frequency analysis was performed on surgical characteristics (incision site and implant placement) and incidence of complications for a series of 108 primary and revision augmentation cases by one of the authors (M.R.S.). This author did not participate in any of the shaped core studies; therefore, he had no prior experience using shaped implants. Patients implanted with Sientra's shaped implants between June 2012 and October 2013 were included in this analysis. The data reported are through up to 16 months of follow-up time, with a mean follow-up of 9 months.

Single-Surgeon Results

A single surgeon's experience with 108 patients and 213 shaped implants was analyzed. For this population, 95% of the implants were submuscularly placed and the remaining 5% were placed in the subglandular position (Table 4). The majority of the implants (82%) were placed via an inframammary incision (Table 4). Photographic results are shown in Figure 3.

Of the 108 patients implanted, 4 experienced a complication (3.7%) (Table 5) and 3 underwent a reoperation (2.8%) for ptosis, infection, and capsular contracture through 16 months. The single-surgeon complications presented in Table 5 were capsular contracture (1.9%), implant malposition, infection, and ptosis (0.9% each).

Table 4. Single-Surgeon Surgical Characteristics

Characteristic	*n*	% (*N* = 213)
Placement		
Subglandular	10	4.7
Submuscular	203	95.3
Incision site		
Periareolar	31	14.6
Inframammary	174	81.7
Mastopexy	8	3.7

Data provided/collected by Dr. Michael R. Schwartz.

Clinical Experience

There are 3 styles of shaped implants, each with a unique base: oval, round, and classic. Each base fulfills an individualized need to address the wide variety of body and breast sizes and shapes and allows the surgeon the ability to provide a shape to women who were not previously able to achieve an acceptable outcome with round implants.

The oval base is appropriate for women who want more volume without compromising a softer, more natural upper pole. A patient population that can benefit from an oval-base implant is women with a wide chest wall and wide breast base (Fig. 4).The oval base is also helpful in patients with axillary fullness to prevent pushing more tissue into this area.

The round-base shaped implant is appropriate for most women desiring a softer upper-pole transition while heightening the position of the nipple-areola complex and expanding the lower pole (Fig. 5). This shape is helpful in women with a tight lower pole or constricted breast base and women with an average breast width and shape who want a natural augmentation.

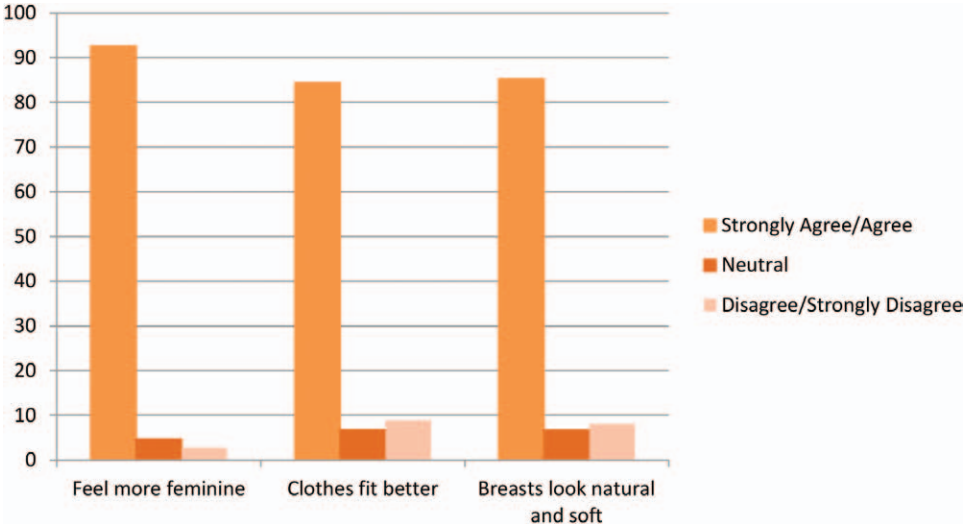

Fig. 2. Patient satisfaction shown in percentage.

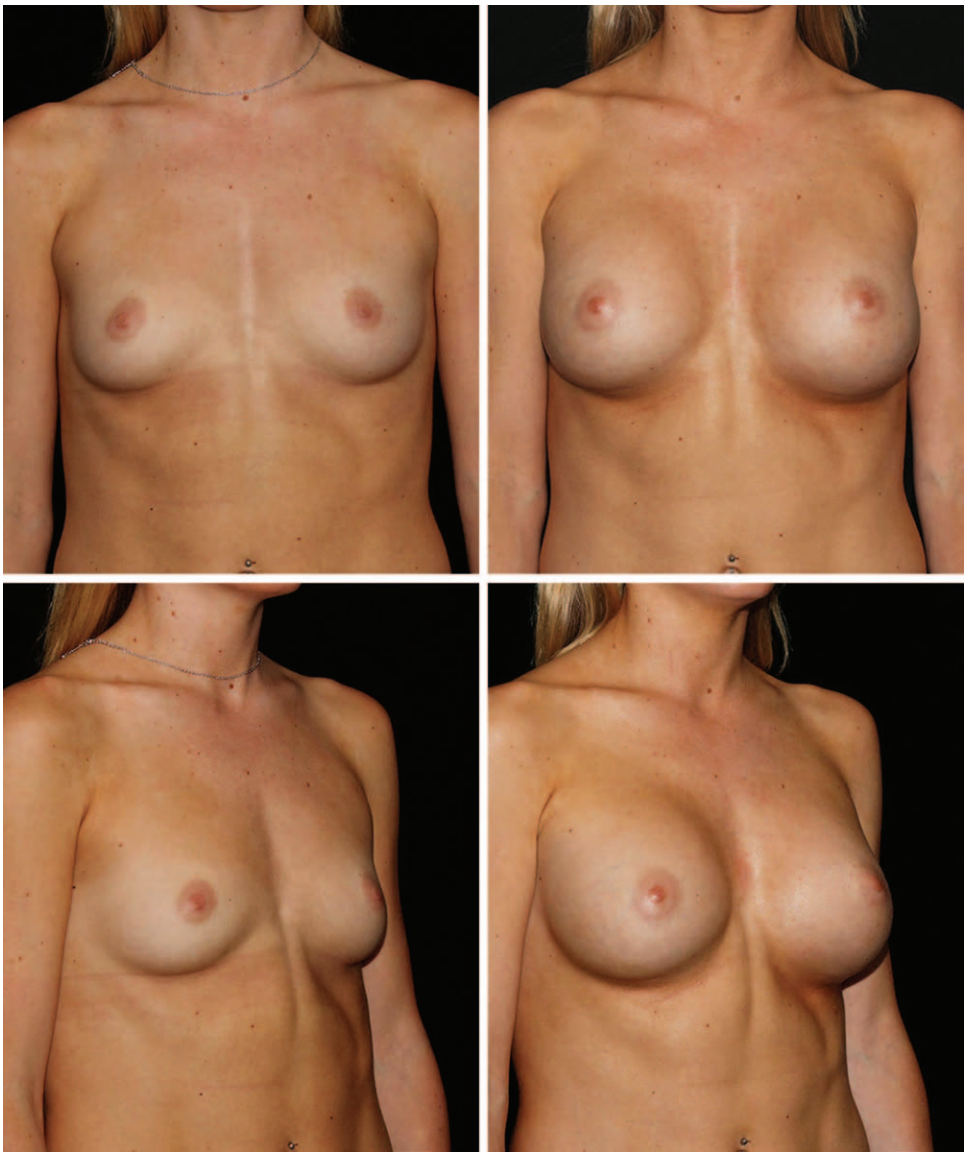

Fig. 3. Preoperative (*left*) and 6-month postoperative (*right*) views of a bilateral primary augmentation patient with Sientra classic base, 350-cc shaped implants. Used with permission from Michael R. Schwartz. Copyright 2014, Michael R. Schwartz, MD, all rights reserved.

The classic-base shaped implant, slightly taller than it is wide, is appropriate for women who have a long chest or low inframammary folds. This classic-base shaped implant prevents the emptiness just above the breast that can be observed in these "long-chested" patients.

Table 5. Single-Surgeon Complications

Characteristic	*N*	% (*N* = 108)
Capsular contracture	2	1.9
Ptosis	1	0.9
Implant malposition	1	0.9
Infection	1	0.9
Reoperation	3	2.8

Data provided/collected by Dr. Michael R. Schwartz.

Although both round implants and the shaped implants provide aesthetically pleasing and safe surgical outcomes, they provide 2 distinct outcomes in shaping the breast. The difference can be noted in the more natural, upper-pole slope with the shaped implant compared with the more rounded upper pole of the round implant (Fig. 6). This figure depicts a primary augmentation patient with no complications but dissatisfaction with the roundness in the upper pole and the desire for a more natural shape to her breasts. The patient previously had 600-cc high-profile, smooth, round implants that were replaced with Sientra's classic-base shaped 450-cc, moderate-profile, textured implants to provide the preferred natural

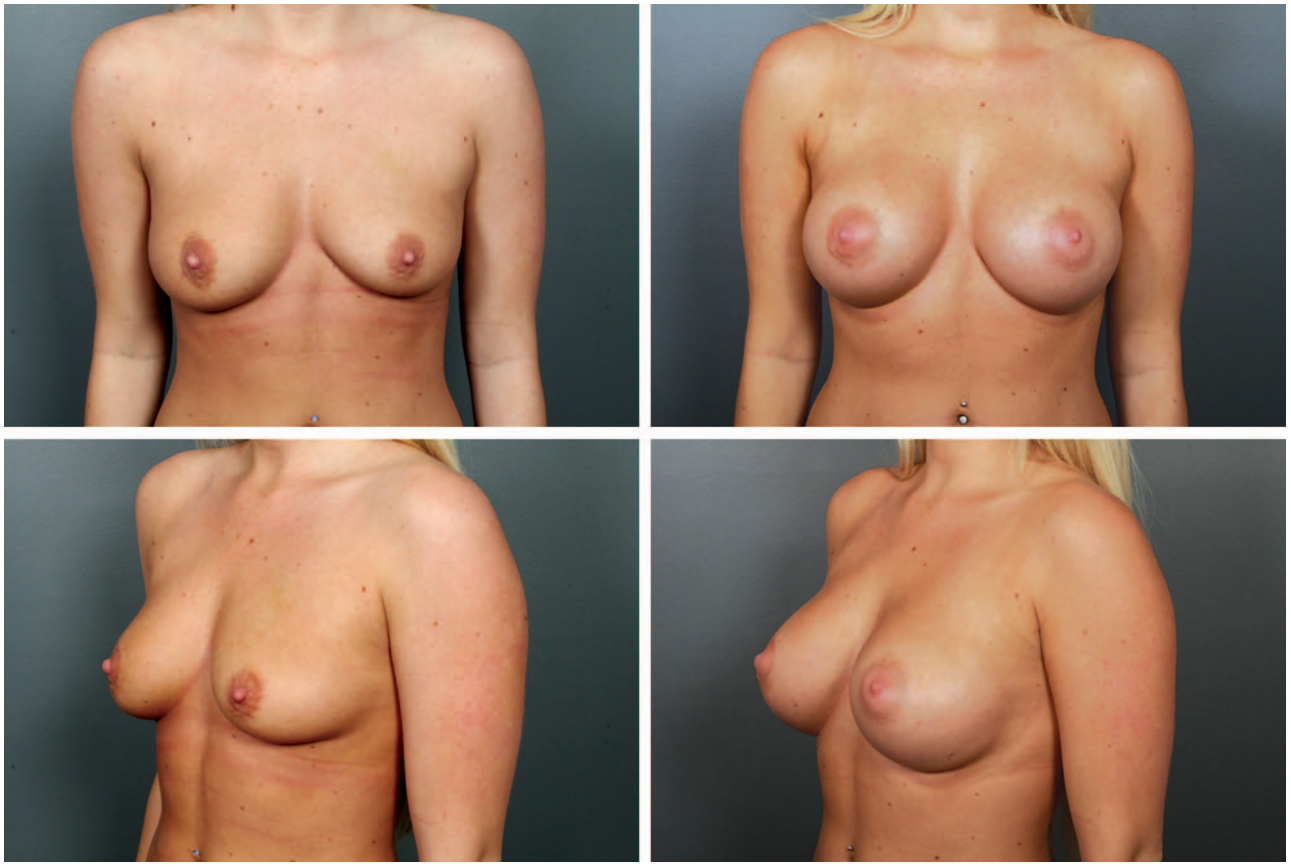

Fig. 4. Preoperative (*left*) and 4-month postoperative (*right*) views of a bilateral primary augmentation patient with asymmetry who was implanted with Sientra's oval-base, 400-cc/330-cc moderate-profile shaped implants. Photographs courtesy of Melinda J. Haws, MD.

look. Integrating shaped implants into a surgeon's implant selection provides a wider range of surgical options to individually match patients' desires.

In addition to the desire for a more natural upper-pole slope, patients also present requesting a firm, youthful breast and can benefit from the HSC+ implant's slightly firmer gel that provides shape and structure, thereby returning the breast to a more youthful appearance. In the case where a patient seeks a very soft outcome, a round gel may better provide that result.

DISCUSSION

The Food and Drug Administration's approval of Sientra's Silimed brand portfolio of silicone gel breast implants in March 2012 marked the first approval of shaped breast implants in the United States.

Consistent with Sientra's overall 5-year results, the shaped implant 5-year results continue to support the safety and effectiveness of the HSC+ implants and provide evidence of high satisfaction rates when used in women for breast augmentation. There were no reports of rotation in Sientra's study population, which may be attributed to precise pocket creation by the operating surgeons. Tight, precise pockets allow better control of breast shape and implant position.

A reported advantage to Sientra's shaped implants is the white orientation line at the 6-o'clock position of the implant. This line is easily visualized through an inframammary fold incision and allows the surgeon to be certain of the positioning of the implant before closure (Fig. 7). Some of the rotation reported (1.1%[4] and 2.9%[5]) with the 2 shaped implants of other manufacturers may be attributed to the initial malposition from surgery as those implants have different mechanisms for placement guiding. One employs palpable dots for the operative surgeon to rely on tactile perception to confirm positioning.[4] The second has a short raised mark at the 6-o'clock position on the implant[5]; however, the mark is transparent, devoid of any color to help distinguish it from the surrounding implant surface. In the authors' experience, the transparent mark is also more difficult to use to confirm correct implant positioning. The visible orientation line in HSC+ implants not only

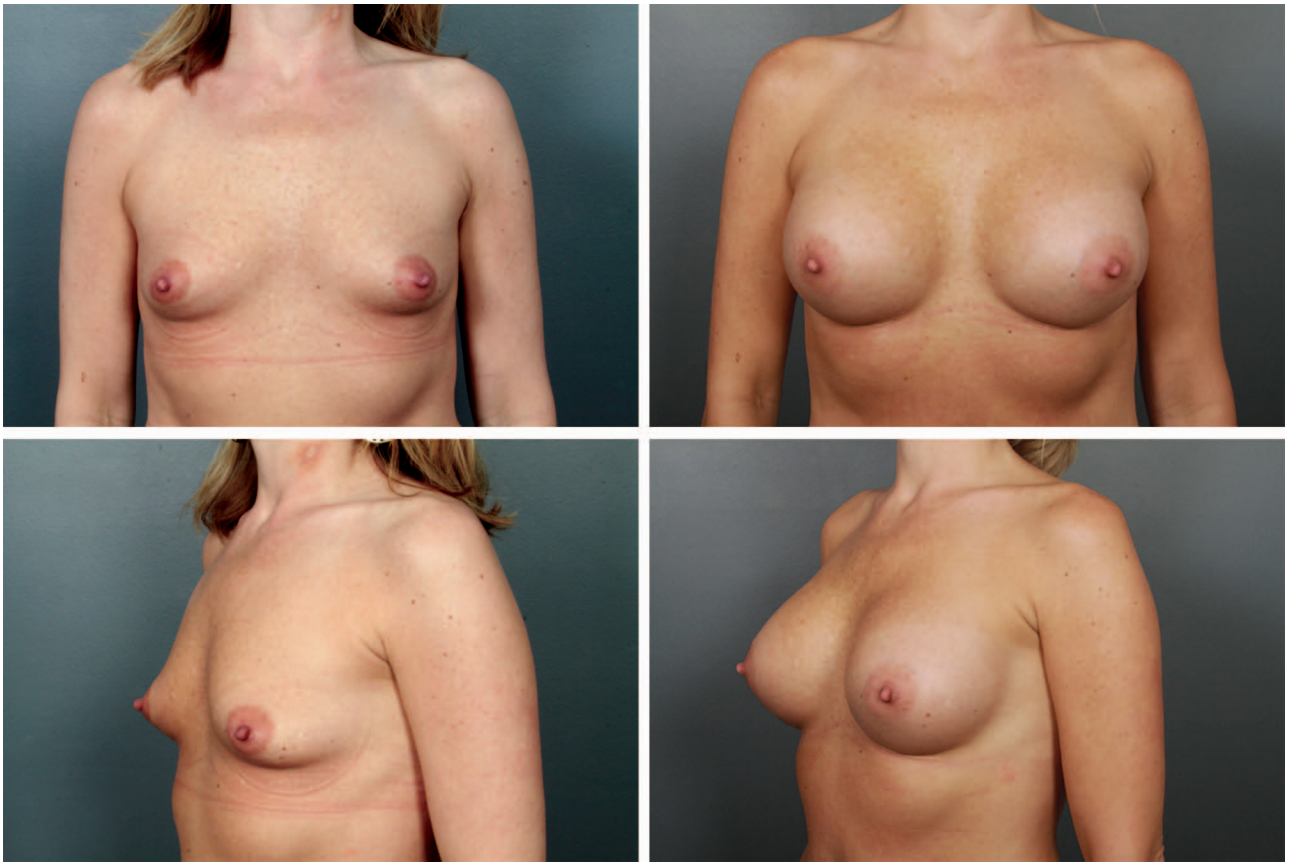

Fig. 5. Preoperative (*left*) and 4-month postoperative (*right*) views of a bilateral primary augmentation patient with a constricted breast base who was implanted with Sientra's round-base, 370-cc shaped implants. Photographs courtesy of Melinda J. Haws, MD.

reduces operative time but also provides reassurance on positioning, which is critical to placement of shaped implants.

Reoperations due to capsular contracture continue to be a chief cause of reoperations and primary concern for surgeons and patients.[6,7] The reported rate of capsular contracture within this population was 3.9%. This is significantly lower than the capsular contracture rate reported in the source population that included smooth and textured shelled implants (8.8%).[2] The lower rate may indicate that either the shape or the texturing or both had an effect on reducing capsular contracture. The hypothesis that texturing is associated with lower rates of capsular contracture has historically been investigated,[8] and more recently, it has been supported in literature.[9,10] Although further research is needed with respect to all variables involved in the causation of capsular contracture, the results presented in this article support the hypothesis of capsular contracture protection with the use of textured implants.

Other complications that have been associated as a potential limitation to shaped implants are double capsule and gel fracture. Double capsule consists of the formation of both internal and external capsules around the breast implant and observed in other studies of shaped implants.[11] The authors postulate that trauma or extreme activity produces some degree of hematoma or delayed seroma that causes the original capsule to separate and a second pseudocapsule to form. Gel fracture refers to fissures or cracks in the gel of the implant.[12] Neither event has been reported in Sientra's clinical study through 5 years. Similarly, in the authors' experience using these implants postapproval, there have been no observations of gel fracture or double capsule.

In addition to the results from the Food and Drug Administration clinical study, the results of a single-surgeon 108-patient analysis with recent postapproval access of the surgeon to these Sientra shaped implants were additionally reviewed, as presented in Tables 4 and 5. The results demonstrate that the low complication and reoperation rates as reported in the multicenter study are translatable to a surgeon's practice, one with no prior shaped device experience. The access to these implants

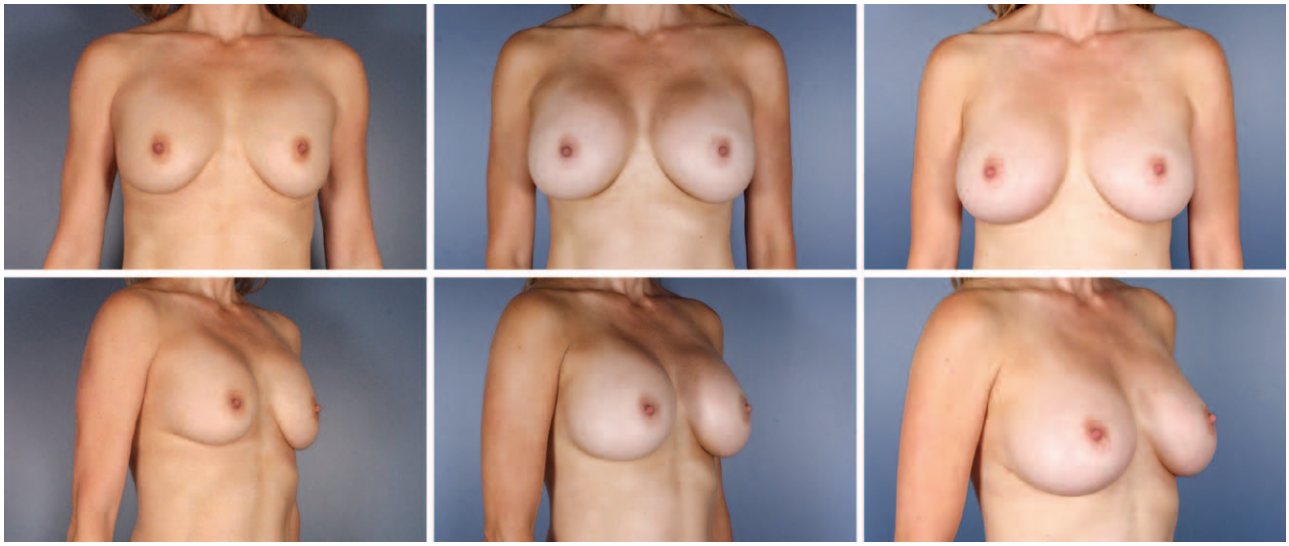

Fig. 6. Preoperative (*left*), postoperative round (*center*), and postoperative shaped (*right*) views of a bilateral revision augmentation patient. Postoperative patient had round, 600-cc high-profile gel implants and was revised with Sientra's classic-base, 450-cc moderate-projection shaped implants. Photographs demonstrate upper-pole shape change between round and shaped implants in the same patient. Used with permission from David L. Kaufman. Copyright 2014, David L. Kaufman, MD, all rights reserved.

provides new options to surgeons in the United States and can contribute to improved individualized results and outcomes for patients.

It is interesting to note that the majority of implants in the multisurgeon study were subglandular augmentations, whereas in the single-surgeon experience, 95% of the implants were placed submuscularly. This seems to be due to surgeon preference and may be based on experience and patient population. Some surgeons may select submuscular or dual-plane placement when there is a paucity of soft tissue in the upper pole to avoid visibility and palpability and to decrease capsular contracture. Other surgeons may choose subglandular placement when there is enough soft tissue to avoid animation deformity that can be seen in some patients with submuscularly placed implants.

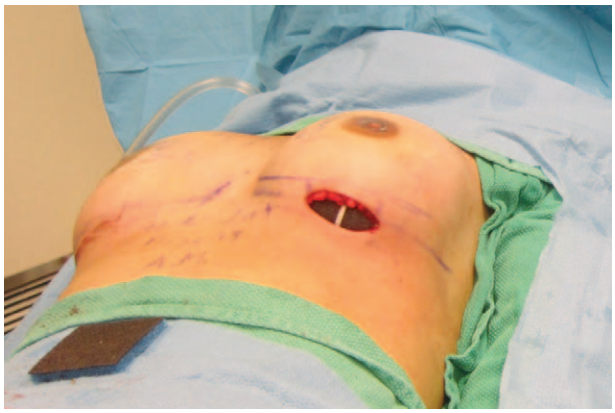

Fig. 7. Sientra's shaped-implant orientation line is shown intraoperatively. The line is easily visible through the incision, allowing the surgeon to confirm placement.

With the incorporation of the shaped implants into new practices, there may be an initial uncertainty as surgeons navigate selecting the best candidates for shaped implants. However, many surgeons with experience with the use of shaped implants assert that almost any patient is a good candidate for shaped implants. Through experience with these implants, authors have compiled lessons learned when placing a shaped implant.[13,14] In addition, Sientra provides training on shaped implants to board-certified and board-eligible plastic surgeons through educational forums and surgical preceptorships.

The introduction of shaped breast implants into the commercial market allows surgeons to have more control over breast shape and to better match the implant results to the patient's desires. The safety and effectiveness results of Sientra's large clinical study, in addition to the data presented from a single surgeon, demonstrate the continued safety and consistent clinical outcomes of HSC+ shaped implants. The review of the experience of a single surgeon with no previous access to shaped implants illustrates the ease of incorporating shaped implants into any surgical practice. Sientra's anatomically shaped implant is a valuable option to add to the surgeon's toolbox, giving surgeons the ability to

customize breast shape and provide the desired youthful outcome with the confidence of a demonstrated safety profile.

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ACKNOWLEDGMENTS

The authors thank Rosalyn d'Incelli for clinical and review input and Maggi Beckstrand, MPH, for biostatistical assistance and editing. R. d'Incelli is an employee of Sientra. M. Beckstrand is a Sientra consultant.

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