Sientra® High-Strength Cohesive Gel Implants

Guest Editors: Felmont Eaves III, MD, FACS
Renato Saltz, MD, FACS

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Welcome to the Aesthetic Surgery Journal supplement devoted to Sientra (Santa Barbara, CA) fifth-generation cohesive round and shaped silicone gel implants. Implant technology has most certainly advanced over the past 2 decades, and with recent United States (US) Food and Drug Administration (FDA) approval, plastic surgeons in the US now have the opportunity to offer their patients new technologies that have been available in much of the world for some time. As such, the articles in this supplement will be of particular interest to surgeons within the US who are just beginning to gain experience with these new devices. The 4 articles in this supplement address 2 key foci related to these devices: the first is to communicate long-term data related safety and efficacy, and the second is to share clinical experience.

From a standpoint of evidence-based medicine, these 4 articles provide a ready example of how different levels of evidence can communicate different types of valuable information. The articles by Stevens et al\(^1\) (LOE = 3) and Haws et al\(^2\) (LOE = 2) respectively, assess the 8-year follow-up data and the magnetic resonance imaging (MRI) and rupture data from the US clinical trials for FDA approval of both round and shaped high-strength cohesive silicone gel implants. Both are large, prospective studies that provide important information concerning the long-term incidence of key clinical endpoints, including implant rupture, capsular contracture, and reoperation. Large, long-term studies such as these reassure both surgeons and patients alike to the safety and efficacy of silicone breast implants. Furthermore, by quantifying risk levels in large, prospective studies with mandatory reporting, these data allow surgeons to more accurately communicate the risks and benefits of surgery to patients considering placement of these devices. Because the levels of complications were low, many of the potentially clinically-relevant factors related to outcomes did not rise to clinical significance; none-the-less, these studies address important questions about the role of surgeon-specific factors in gaining long-term success in both aesthetic and reconstructive breast surgery.

The 2 included panel discussions (LOE 5)\(^,3,4\) on the other hand, provide valuable information concerning strategies, patient selection, surgical technique, and other considerations that will help surgeons incorporate these devices into their clinical practice and take full advantage of their unique characteristics. This type of information—the “pearls” of judgment and experience—is not readily assessed by large prospective cohort studies or randomized, controlled trials, yet it is key to clinical success. US readers will find this information particularly valuable as an entire generation of US surgeons has grown up with smooth, round saline and fourth-generation silicone gel implants. Textured round and shaped highly cohesive silicone gel implants require different approaches and techniques that are most readily learned through the sharing of information among surgeons, such as the experiences shared by the panelists after implantation of more than 2000 round and 700 shaped devices.

As Guest Editors of this supplement, we are very familiar with the developments and FDA approval of Sientra’s round and shaped breast implants containing high-strength cohesive silicone gel. We welcome the addition of this line of implants for aesthetic and reconstructive breast surgery. For a very long time, the devices of only 2 manufacturers (INAMED/Allergan, Irvine, CA and Mentor/Johnson & Johnson, Santa Barbara, CA) were available in the US. Silimed, the third largest global manufacturer of silicone implantable devices is well established in the international community, where for more than 30 years surgeons have had access to their silicone breast implants.

We thank the authors for bringing this information to the readers of Aesthetic Surgery Journal.

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REFERENCES
Original Article

Eight-Year Follow-Up Data from the U.S. Clinical Trial for Sientra’s FDA-Approved Round and Shaped Implants with High-Strength Cohesive Silicone Gel

W. Grant Stevens, MD; Jennifer Harrington, MD; Kaveh Alizadeh, MD; David Broadway, MD; Kamakshi Zeidler, MD; and Tess B. Godinez, BS

Abstract

Background: On March 9, 2012, the Food and Drug Administration (FDA) approved Sientra’s premarket approval application for its portfolio of silicone gel breast implants based on their review of Sientra’s 3-year study data from the largest pivotal silicone gel breast implant study to date. This included the first approval of shaped breast implants in the United States.

Objectives: The authors provide an update to the 8-year safety and effectiveness of the Sientra High-Strength silicone gel breast implants.

Methods: The Sientra Core study is an ongoing 10 year open-label, prospective, multi-center clinical study, which includes 1788 patients implanted with 3506 Sientra implants across four indications (Primary Augmentation, Revision Augmentation, Primary Reconstruction, and Revision Reconstruction). For the safety analysis, the incidence of post-operative complications, including all breast implant–related adverse effects (eg, infection, asymmetry), was estimated based on Kaplan-Meier risk rates. The effectiveness analyses include surgeon and patient satisfaction and changes in bra/cup size.

Results: Through 8 years, the overall risk of rupture was 4.6%, the risk of capsular contracture was 11.8% (rates were lower when using True Texture™), and the risk of reoperation was 28.3%. Out of the 580 reoperations in 456 patients, over half of all reoperations were due to cosmetic reasons (n = 299). The most common reasons for reoperation were capsular contracture (19.0%), style and/or size change (18.4%), and asymmetry (8.8%). Patient satisfaction remains high through 8 years, with 87% indicating that their breast implants make them feel more feminine than prior to enrollment.

Conclusions: Safety data from the FDA Core study continues to support a comprehensive safety and effectiveness profile of Sientra’s portfolio of round and shaped implants through 8 years.

Level of Evidence: 3

Accepted for publication January 22, 2015.

On March 9, 2012, the Food and Drug Administration (FDA) approved Sientra’s premarket approval application for its portfolio of High-Strength Cohesive silicone gel breast implants based on their review of Sientra’s 3-year study data from the largest pivotal silicone gel breast implant study to date. This included the first approval of shaped breast implants in the United States.

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implants in the United States. Shortly following approval, several clinical study results and analyses were published: the 5-year follow-up results of the Sientra Core study and the “Risk Factor Analysis for Capsular Contracture” were published in 2013. Additionally, the 5-year shaped results were included in the Sientra supplement published in 2014. The 8-year follow-up data presented here are an update to the previously-published 5-year results, and are based on Sientra’s pivotal study data in order to update the plastic surgeon community with the most current safety data and evidence-based outcomes.

METHODS

Patients

The Sientra Core implant study is an ongoing 10-year open-label, prospective, multi-center clinical study and is the largest pivotal breast implant study to date designed to assess the safety and effectiveness of Silicone Gel Implants. The study includes 1788 patients implanted with 3506 Sientra implants across four indications: 1116 primary augmentation, 363 revision augmentation, 225 primary reconstruction, and 84 revision reconstruction patients. Patients were enrolled into the reconstruction cohorts for a variety of reasons, including post-mastectomy/lumpectomy, trauma, congenital deformities, and contralateral augmentation for symmetry. From the 1788 enrolled patients, 571 patients were dually enrolled into an MRI cohort, and underwent MRIs to identify potential ruptures biennially.

Device Description

The Sientra gel implant portfolio includes fifth generation round and shaped silicone gel implants (Figure 1). Applied Silicone (Santa Paula, CA) formulates the high-strength silicone gel exclusive to the Sientra breast implants in the United States. The round implant line includes both textured and smooth round High-Strength Cohesive (HSC) implants with projections that include Low, Moderate, Moderate Plus, Moderate High, and High Profiles. The shaped implant line encompasses the High-Strength Cohesive Plus (HSC+) textured implants with a round, classic, or oval implant base in varying projections. All HSC+ implants have distinct white orientation marks to assist with implant placement.

Figure 1. Sientra’s portfolio of silicone gel implants include (A) High-Strength Cohesive (HSC) textured round, (B) HSC smooth round, (C) High-Strength Cohesive Plus (HSC+) textured shaped round, (D) classic, (E) oval base. Reprinted with permission from Sientra, Inc. (Santa Barbara, CA).
Both the textured round and shaped implants feature the Silimed True Texture™ technology (Rio de Janeiro, Brazil). True Texture is a proprietary method of texturing designed to promote tissue in-growth, and it does not utilize sodium chloride, sugar, soak/scrub, or pressure-stamping methods.\textsuperscript{3,6}

**Data Collection**

All study patients are followed through 10 years with postoperative follow-up examinations at 6-10 weeks and annually, starting at 1 year. Adverse events and complications are assessed at each examination and reported on a severity scale of 1 (very mild) to 5 (severe).\textsuperscript{2} Complications that are reported as very mild (1) or mild (2) are not included in the analysis.

A subgroup of patients participating in the MRI cohort receive non-contrast MRI screenings for silent rupture (to assess shell integrity) beginning at year 3 and continuing every other year through 10 years. The MRI cohort consists of 571 patients encompassing all four indications. Each scan was reviewed by both a local radiologist and an expert central radiologist. If either radiologist, local or central, read a scan as an indeterminate or definitive rupture, the

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Primary Augmentation</th>
<th>Revision Augmentation</th>
<th>Primary Reconstruction</th>
<th>Revision Reconstruction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of implants (%)</td>
<td>2230 (63.6%)</td>
<td>725 (20.7%)</td>
<td>412 (11.8%)</td>
<td>139 (4.0%)</td>
</tr>
<tr>
<td>Device distribution</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smooth round</td>
<td>57.8%</td>
<td>46.9%</td>
<td>45.9%</td>
<td>40.3%</td>
</tr>
<tr>
<td>Textured round</td>
<td>30.8%</td>
<td>39.2%</td>
<td>41.7%</td>
<td>47.5%</td>
</tr>
<tr>
<td>Textured shaped</td>
<td>11.5%</td>
<td>13.9%</td>
<td>12.4%</td>
<td>12.2%</td>
</tr>
<tr>
<td>Device placement</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Subglandular</td>
<td>42.9%</td>
<td>39.3%</td>
<td>27.2%</td>
<td>8.6%</td>
</tr>
<tr>
<td>Submuscular</td>
<td>57.1%</td>
<td>60.7%</td>
<td>72.8%</td>
<td>89.9%</td>
</tr>
<tr>
<td>Other</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1.4%\textsuperscript{a}</td>
</tr>
<tr>
<td>Incision site</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Periareolar</td>
<td>33.5%</td>
<td>33.4%</td>
<td>17.0%</td>
<td>6.5%</td>
</tr>
<tr>
<td>Intramammary</td>
<td>61.6%</td>
<td>60.6%</td>
<td>28.4%</td>
<td>33.8%</td>
</tr>
<tr>
<td>Mastectomy or other scar</td>
<td>0.0%</td>
<td>0.3%</td>
<td>45.1%</td>
<td>55.4%</td>
</tr>
<tr>
<td>Other (eg, transaxillary)</td>
<td>4.8%</td>
<td>5.8%</td>
<td>9.5%</td>
<td>4.3%</td>
</tr>
<tr>
<td>Incision size</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0–3 cm</td>
<td>22.0%</td>
<td>19.3%</td>
<td>15.8%</td>
<td>10.1%</td>
</tr>
<tr>
<td>3–6 cm</td>
<td>67.5%</td>
<td>68.1%</td>
<td>36.9%</td>
<td>29.5%</td>
</tr>
<tr>
<td>6–9 cm</td>
<td>10.4%</td>
<td>12.6%</td>
<td>47.3%</td>
<td>60.4%</td>
</tr>
<tr>
<td>Not provided</td>
<td>0.1%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Pocket irrigation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No pocket irrigation</td>
<td>7.3%</td>
<td>8.7%</td>
<td>3.9%</td>
<td>8.6%</td>
</tr>
<tr>
<td>Yes pocket irrigation</td>
<td>92.7%</td>
<td>91.3%</td>
<td>96.1%</td>
<td>91.4%</td>
</tr>
<tr>
<td>Antibiotics only</td>
<td>41.2%</td>
<td>37.0%</td>
<td>61.1%</td>
<td>63.0%</td>
</tr>
<tr>
<td>Anesthetic only</td>
<td>6.2%</td>
<td>4.8%</td>
<td>2.5%</td>
<td>1.6%</td>
</tr>
<tr>
<td>Other solutions/ combinations (eg, antibiotic, betadine, steroid solutions)</td>
<td>52.6%</td>
<td>58.2%</td>
<td>36.4%</td>
<td>35.4%</td>
</tr>
</tbody>
</table>

From Stevens et al.\textsuperscript{2} Reprinted with permission from Wolters Kluwer Health.\textsuperscript{a}One revision reconstruction patient had bilateral implants placed during a subcutaneous mastectomy.
device was reported as ruptured. As a condition of approval, the remaining study patients were eligible to receive MRI screenings every other year and are included in the overall rupture rate. Estimates of rupture risk were assessed overall (ie, using the full cohorts) and within the MRI cohort. All study patients consented and were followed per study protocol.²

**Statistical Analysis**

The Sientra Core clinical study will run through a 10-year follow-up period post-implantation. The safety and effectiveness results presented in this article represent data through 8 years. Both pre- and post-enrollment data were collected and had double data entry from standardized case report forms. For the effectiveness analyses, pre-implantation bra/cup sizes were compared to post-implantation sizes to assess anatomical changes (ie, bra/cup size change). Changes in patient satisfaction scores were assessed through a de-identified patient-completed paper questionnaire and completed at biennial study visits. Satisfaction questions covered topics such as whether the implants make the patient feel more feminine, feel more sensual, look healthier, or improve their social life. The answers were collected via a 5-point scale with responses of “Strongly Agree,” “Agree,” “Neutral,” “Disagree,” and “Strongly Disagree.”

For the safety analysis, the incidence of post-operative complications, including all breast implant-related adverse effects (eg, infection, asymmetry), was estimated based on Kaplan-Meier risk rates. This method includes all first occurrences of a complication anytime between implantation and 8 years post-implantation; all complications with severity ranging from moderate to very severe were included. These rates (one minus the complication-free survival rate) were calculated using PROC LifeTest in SAS (SAS Institution, Inc., Cary, NC); 95% confidence intervals for these rates were also estimated and reported. In addition to estimating the overall incidence via Kaplan-Meier, the incidence was also evaluated for each individual implanting surgeon, with frequency analyses, using PROC FREQ in SAS.

Analysis of reoperations and ruptures was similar to the analysis of complications described above, although some elements varied. Regarding reoperations, not only was the rate of reoperation calculated using Kaplan-Meier, but also the primary reasons for reoperation were analyzed. Regarding rupture, this analysis was limited to the MRI cohort, a subset of the population that underwent regular MRI screenings in addition to their per-protocol office visits. This study enrolled

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### Table 2. Risk of Complications by Patient Kaplan-Meier Risk Estimates and 95% Confidence Intervals

<table>
<thead>
<tr>
<th>Local Complication</th>
<th>Primary Augmentation N = 1116</th>
<th>Revision Augmentation N = 363</th>
<th>Primary Reconstruction N = 225</th>
<th>Revision Reconstruction N = 84</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asymmetry</td>
<td>1.7% (1.0%, 2.7%)</td>
<td>3.1% (1.7%, 5.8%)</td>
<td>11.5% (7.7%, 17.1%)</td>
<td>17.2% (8.8%, 29.3%)</td>
</tr>
<tr>
<td>Breast Mass/Cyst/Lump</td>
<td>3.0% (2.1%, 4.4%)</td>
<td>2.8% (1.4%, 5.9%)</td>
<td>2.9% (1.2%, 6.9%)</td>
<td>4.7% (1.5%, 13.9%)</td>
</tr>
<tr>
<td>Breast pain</td>
<td>1.1% (0.6%, 2.0%)</td>
<td>2.1% (0.9%, 4.7%)</td>
<td>4.7% (2.3%, 9.3%)</td>
<td>3.1% (0.8%, 12.1%)</td>
</tr>
<tr>
<td>Capsular contracture</td>
<td>11.2% (9.3%, 13.4%)</td>
<td>12.6% (9.2%, 17.2%)</td>
<td>12.8% (8.6%, 18.8%)</td>
<td>14.6% (7.6%, 26.8%)</td>
</tr>
<tr>
<td>Hypertrophic/Abnormal scarring</td>
<td>1.0% (0.6%, 1.9%)</td>
<td>1.6% (0.7%, 3.8%)</td>
<td>4.1% (2.0%, 8.5%)</td>
<td>2.9% (0.7%, 11.1%)</td>
</tr>
<tr>
<td>Implant extrusion</td>
<td>0.1% (0.0%, 0.7%)</td>
<td>0.9% (0.3%, 2.8%)</td>
<td>2.1% (0.8%, 5.6%)</td>
<td>–</td>
</tr>
<tr>
<td>Implant malposition</td>
<td>2.6% (1.8%, 3.9%)</td>
<td>4.8% (2.9%, 7.9%)</td>
<td>5.2% (2.7%, 9.6%)</td>
<td>8.6% (3.9%, 18.4%)</td>
</tr>
<tr>
<td>Infection</td>
<td>0.9% (0.5%, 1.7%)</td>
<td>1.5% (0.6%, 3.6%)</td>
<td>5.1% (2.9%, 9.1%)</td>
<td>1.2% (0.2%, 8.3%)</td>
</tr>
<tr>
<td>Nipple sensation changes</td>
<td>5.8% (4.4%, 7.5%)</td>
<td>4.4% (2.5%, 7.7%)</td>
<td>2.6% (1.0%, 6.7%)</td>
<td>2.4% (0.3%, 15.7%)</td>
</tr>
<tr>
<td>Rupture, Overall</td>
<td>4.9% (3.3%, 7.2%)</td>
<td>3.7% (1.7%, 8.1%)</td>
<td>1.4% (0.2%, 9.3%)</td>
<td>16.6% (5.6%, 43.2%)</td>
</tr>
<tr>
<td>Rupture, MRI cohort only</td>
<td>7.2% (4.8%, 10.8%)</td>
<td>5.5% (2.3%, 12.8%)</td>
<td>3.0% (0.4%, 19.6%)</td>
<td>–</td>
</tr>
<tr>
<td>Ptosis</td>
<td>3.9% (2.9%, 5.5%)</td>
<td>3.4% (1.8%, 6.2%)</td>
<td>2.7% (1.1%, 6.4%)</td>
<td>–</td>
</tr>
<tr>
<td>Redness</td>
<td>0.6% (0.3%, 1.4%)</td>
<td>0.6% (0.2%, 2.5%)</td>
<td>2.6% (1.1%, 6.1%)</td>
<td>–</td>
</tr>
<tr>
<td>Seroma/Fluid accumulation</td>
<td>1.2% (0.7%, 2.2%)</td>
<td>1.6% (0.7%, 3.8%)</td>
<td>2.4% (1.0%, 5.8%)</td>
<td>1.2% (0.2%, 8.4%)</td>
</tr>
<tr>
<td>Swelling</td>
<td>0.9% (0.5%, 1.7%)</td>
<td>0.3% (0.1%, 2.3%)</td>
<td>1.5% (0.5%, 4.7%)</td>
<td>–</td>
</tr>
<tr>
<td>Upper pole fullness</td>
<td>0.1% (0.0%, 0.7%)</td>
<td>0.4% (0.1%, 3.0%)</td>
<td>1.2% (0.3%, 4.9%)</td>
<td>–</td>
</tr>
<tr>
<td>Wrinkling/Rippling</td>
<td>1.9% (1.2%, 3.6%)</td>
<td>4.9% (3.0%, 8.1%)</td>
<td>2.4% (0.9%, 6.2%)</td>
<td>3.0% (0.7%, 11.3%)</td>
</tr>
</tbody>
</table>

Other local complications not listed in Table 2 occurred at a risk rate of <2% in all cohorts.
571 patients into this subset and, to date, remains the largest MRI cohort in breast implant pivotal trials. The analysis of this subset was performed via Kaplan-Meier and the results from the MRI scans were able to inform the rupture status of the devices. Because each MRI scan was read by two radiologists (ie, a local radiologist and a blinded central expert radiologist), only the worst-case rupture read from either radiologist was used to inform the analysis (eg, if either radiologist indicated a possible or definitive rupture, that patient was considered ruptured in the analysis).

RESULTS

Patient and Surgical Characteristics

The majority of study patients were Caucasian, married, with a median household income exceeding $60,000. The average age at implantation was 38 years old (ranging from 18 to 72), while the average height and weight was 5 feet 5 inches and 128 pounds, respectively. Complete study demographic information has been previously reported and can be referenced in the 5-year study update.2

The device distribution for this study is reported in Table 1. The submuscular placement was used in the majority of cases across all cohorts, and the inframammary incision was favored for primary and revision augmentation cases (62% and 61%, respectively), while the mastectomy scar was most often used for primary and revision reconstruction cases (45% and 55%, respectively).

Safety Experience

Table 2 summarizes the complication rates for various complications across each of the four study cohorts. Overall, the risk of rupture was 4.6%, the risk of capsular contracture was 11.8%, and the risk of reoperation was 28.3%. An additional risk factor analysis performed showed reduced risk of capsular contracture with textured \((p < 0.0001)\) and submuscular placement \((p = 0.0007)\).

There were 580 reoperations in 456 patients through 8 years (Table 3 and Figure 2). Over half (51.4%) of all reoperations were due to cosmetic reasons \((n = 299; \text{Figure 3})\). Cosmetic reasons include reoperations for aesthetic indications, such as style/size change, asymmetry, and scarring. Additionally, the primary reasons for reoperation results were individually assessed for the primary and revision augmentation and reconstruction groups. Within the combined augmentation group, the most common reasons for reoperation were capsular contracture (22.1%) and style/size change (17.8%). Within the combined reconstruction group, the most common reasons for reoperation were style/size change (20.1%) and asymmetry (18.3%).

Regarding post-operative reports of cancer and connective tissue disease, the overall rate of breast cancer through 8 years was 1.0%. Other reports of cancer include: lung cancer (0.2%), skin cancer (0.7%), and metastatic cancer (0.7%). The highest reported connective tissue disease was rheumatoid arthritis (0.4%); all others were reported \(\leq 0.2\%\).

Additional Safety Analysis

As detailed in the 5-year follow-up, a comparable number of patients were implanted with smooth (53%) and textured (47%) implants. An updated 8-year analysis demonstrates that textured implants continue to provide a reduction in the risk of capsular contracture. At 8 years, the overall risk
of capsular contracture for the Sientra study was 11.8%. When the analysis is performed based on implant surface, the reduction in the risk of capsular contracture was statistically significant in textured devices (7.3%, 95% confidence interval 5.6–9.6) as compared to smooth devices (15.8%, 95% confidence interval 13.4–18.6).

Additionally, an investigator-specific updated analysis was performed for two key complications: capsular contracture and rupture. The three sites with the highest capsular contracture rates enrolled only 18% of the total study patients but accounted for almost half (44%) of the reported capsular contractures. Similarly, the three sites with the highest reported rupture rates enrolled 12% of the total study patients with 54% of the reported ruptures.

Effectiveness

At the completion of the implant surgery across all cohort indications, 99.5% of surgeons reported their satisfaction with the results. Analysis of preoperative and postoperative bra cup size analysis performed within the primary augmentation cohort found that 60% of the patients increased their bra cup size by at least 1.5 cup sizes. Figure 4 illustrates patient-reported postoperative satisfaction through 8 years. Primary augmentation patients reported the highest satisfaction with the natural and soft feel of their breasts, while revision augmentation patients reported the highest satisfaction with their increased feeling of femininity. Both primary reconstruction patients and revision reconstruction patients reported high satisfaction with the way the breast implants made them look “normal,” while revision reconstruction patients were also highly satisfied with the way the breast implants made their clothes fit better.

DISCUSSION

The 8-year results of the ongoing Core study support the safety and effectiveness of Sientra’s High-Strength Cohesive...
Silicone Gel Breast Implants, as well as continuing high satisfaction results across all cohorts, consistent with the published 3- and 5-year study results.2,4,7,8

Through 8 years, capsular contracture continues to be the most common complication for the primary augmentation (11.2%) and revision augmentation (12.6%) groups. For the primary reconstruction cohort, capsular contracture was the most common complication, followed by asymmetry (12.8 and 11.5%, respectively). Asymmetry (17.2%) remains the most common complication in the revision reconstruction cohort. Cosmetic reasons, including style/size change, asymmetry, and ptosis, continue to account for over half of the reoperations. As expected, the percentages for reoperation due to asymmetry, style/size change, and “other” were far greater in the breast reconstruction cohorts than with the augmentation cohorts. This would be expected, as matching an existing breast in reconstruction or matching in a bilateral reconstruction can be a challenge. Differences in scarring, radiation, and specimen size are all obstacles that are considered when reconstructing the breast mound. Although it is outside of the scope of this 8-year update, the authors would be interested in assessing what role the different generations (ie, fourth and fifth) may play in subsequent reasons for reoperation.

The by-investigator analysis of capsular contracture and rupture continues to show evidence of a correlation between surgical technique and complication occurrence. This indicates that both the surgeon and surgical technique clearly play a role in the overall success and decreased key complication rates. Both patient selection and operative planning are key elements in reducing complication rates at large. Intra-operative attention to detail with respect to hemostasis, tissue and implant handling, precise pocket dissection, and appropriate incision size play a role in overall patient satisfaction and success. A more comprehensive multivariate regression analysis is warranted to identify specific risk factors.

Consistent with the 5-year analysis, the overall cancer and connective tissue disease remains low. This finding continues to support the body of research indicating that there is no correlation between Sientra silicone gel breast implants and these disease outcomes. The authors have found that the True Texture specific to Sientra’s implants has provided an additional advantage in maintaining placement even through 10 years (Figure 5). The authors have also observed a reduction in capsular contracture, an increase in implant pocket stability, and an overall improved aesthetic outcome with respect to patient satisfaction.

There has also been an observed advantage to the high-strength cohesive gel contained in the smooth and textured devices as it relates to a better look, softer feel, and increased stability.9 The authors have found that the Sientra smooth round implants made with HSC fifth generation silicone provide more upper pole fullness than similar counterparts, likely due to slightly more cohesive gel, a higher fill ratio, and gel shell integration.9 Textured round implants have resulted in less traction rippling, even in reconstruction patient, and provide a predictable and long-lasting result without being too firm.

CONCLUSION

Consistent with previously published results, the 8-year Core study results for the Sientra portfolio of HSC and HSC+ implants show that complication rates remain low, while patient satisfaction remains high. The data presented in this article further demonstrate the continued safety and effectiveness of the Sientra implant.

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Disclosures

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Figure 5. (A, D, G) This 41-year-old woman presented for revision-augmentation. (B, E, H) Five years after implantation of Sientra True Texture High Profile 525 cc implants. (C, F, I) Ten years following implantation. Printed with permission from W. Grant Stevens, MD.
**Special Topic**

**Sientra High-Strength Cohesive Textured Round Implant Technique: Roundtable Discussion**

W. Grant Stevens, MD; M. Bradley Calobrace, MD; Robert Cohen, MD; Michael A. Fiorillo, MD; and Bill G. Kortesis, MD

**Abstract**

A panel of board-certified plastic surgeons chaired by Dr Grant Stevens convened to discuss their respective experiences with the Sientra High-Strength Cohesive (HSC) Textured Round silicone gel breast implants. The authors have implanted a combined total of approximately 2100 patients. Surgical pearls, complication avoidance, and practice integration tips are among the topics reviewed. The surgeons also present challenging cases and describe how the HSC textured implants helped them achieve a successful outcome.

**Level of Evidence: 5**

Accepted for publication February 2, 2015.

A panel of plastic surgeons convened via electronic and telephone communication in November and December 2014 to discuss their experience with Sientra textured round High-Strength Cohesive (HSC) Silicone Gel breast implants (Sientra Inc., Santa Barbara, CA). The moderator of the panel is one of the most experienced Sientra implant users in the United States, with extensive pre- and post-approval experience spanning the past 12 years. The panel consists of surgeons who have gained substantial experience with the Sientra textured round implants, with a combined total of approximately 2100 patients. The surgeons share their expertise with the Sientra textured round implant and share their most challenging cases.

**PANEL**

*M. Bradley Calobrace, MD:* Dr Calobrace is located in Louisville, Kentucky and has been in practice for 18 years. Dr Calobrace uses the Sientra textured round implant in approximately 90% of his primary and revision augmentation cases, totaling over 400 cases in the last 2 years.

*Robert Cohen, MD:* Dr Cohen has been in practice for 10 years in Paradise Valley, Arizona. Dr Cohen has used the

**MODERATOR**

*W. Grant Stevens, MD:* Dr Stevens has experience with Sientra implants for over 12 years and is participating as an Investigator in the Sientra Core as well as Post Approval Study. Dr Stevens has been in practice in Marina del Rey, California for 28 years and selects Sientra textured round implants for the majority of his augmentation and revision cases, totaling over 900 cases to date.

Dr Stevens is Clinical Professor of Surgery, Division of Plastic Surgery, University of Southern California School of Medicine, and Director of the University of Southern California–Marina del Rey Aesthetic Surgery Fellowship Program, Los Angeles, California. Dr Calobrace is a plastic surgeon in private practice in Louisville, Kentucky. Dr Cohen is a plastic surgeon in private practice in Paradise Valley, Arizona. Dr Fiorillo is a plastic surgeon in private practice in Pearl River, New York. Dr Kortesis is a plastic surgeon in private practice in Charlotte, North Carolina.

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Sientra textured implants in the majority of his primary and revision breast augmentation cases totaling approximately 400 cases in the last 3 years.

Michael Fiorillo, MD: Dr Fiorillo is located in Pearl River, New York and has been in practice for 17 years. Dr Fiorillo’s cases are mostly primary and revision augmentation and he uses the Sientra textured round implant in 75% of his surgeries totaling over 300 cases in the past 3 years.

Bill Kortesis, MD: Dr Kortesis has been in practice in Charlotte, North Carolina for the past 5 years. Dr Kortesis uses the Sientra textured round implant in 90% of his primary and secondary surgeries totaling over 200 cases in past 2 years.

BACKGROUND

In contrast to our European colleagues, the US market was a late adopter of textured silicone gel devices. Dissatisfaction with textured saline devices, particularly deflation and wrinkling, led surgeons to use the smooth saline implant. Already familiar and comfortable with the smooth surface of the saline implant, the transition to smooth gel implants was natural.

The European markets were accustomed to the benefits attributed to textured implants, including the protective effect against capsular contracture, the predictability of placement, and the increased pocket control. In the past two years there has been rapid advancement in available options in the United States led by Sientra’s approval in 2012. With more options available, it is important that surgeons increase their experiential knowledge of these new products.

The Sientra implants are the only round implants filled with fifth generation gel with a textured line that features Silimed’s TRUE Texture technology and has the proprietary texturing method designed to promote tissue ingrowth that does not use sodium chloride, sugar, soap, or pressure-stamping methods. This panel of board certified plastic surgeons was selected to discuss their experiences and techniques, benefits and challenges, and surgical pearls for integrating the Sientra True Texture HSC Round implants in their practices.

What prompted you to start using the Sientra True Texture round implant? Also, considering other textured products now available in the US, what are the benefits of Sientra’s implant?

GRANT STEVENS: I started using the Sientra implant in 2002 and was attracted to the textured round because I had been using textured devices in 1991. In 1991 I was using another manufacturer’s textured device because I had lower capsular contracture occurrence with these implants and polyurethane had been taken off the market. I considered the smooth round implant to be under-filled. I had good experience with texturing, and it was a natural transition. My impression of the three types of texturing:

1. Mentor Worldwide LLC (Santa Barbara, CA): Siltex™ has the least integrated texturing. While capsular contracture is lower with Siltex than smooth, there is no integration and is the least effective in limiting mobility and providing pocket control.

2. Allergan (Irvine, CA): Biocell® (similar to a “velcro”-like effect) has more integration, which limits implant mobility, which is sometimes good, sometimes bad. This results in pseudo-capsule formation, which can progress to hardening, seroma formation, hematoma (if it tears), and increased revision rate.

3. Sientra: Utilizes True Texture technology and has the lowest capsular contracture rate, even lower than Siltex. There is no pseudo-capsule formation.

BRAD CALOBRACE: My dissatisfaction with the available textured implants in the US led me to use mostly smooth silicone implants since 2006. Based on my knowledge of the rest of the world, I became increasingly interested in incorporating textured implants. When I first incorporated Sientra implants in my practice two years ago, I was immediately impressed with the uniqueness of the texturing as compared to the others available in the US. The texturing grips the tissue to create adherence without incorporation of the implant to the capsule. This limits but does not eliminate implant movement, giving a more natural, softer, mobile feel. Additionally, the increased fifth generation cohesive gel with a unique gel-to-shell interface provides an implant that holds its projection and maintains its upper pole volume, even under the pressure of the overlying pectoralis muscle, to provide a rounded, youthful look. They now have become my implant of choice for primary and secondary breast augmentation as well as with augmentation mastopexies.

ROB COHEN: I was fortunate to be a fellow with Dr Grant Stevens in 2004-2005, when he was one of the investigators in the Sientra Core study. During that time, I had the chance to be involved with hundreds of breast augmentations using these implants, and I really appreciated the softness of the implant combined with a supple textured shell that had a nice degree of friction with the tissues. When Sientra entered the marketplace in 2012, I was very eager to use this implant based on the very positive experience during my fellowship. In my opinion, the feature that most distinguishes these implants is the textured shell which has the feel of a thinner, smooth implant combined with the stability and lower capsular contracture rate associated with textured implants. The aggressiveness of the texture is halfway between Siltex and Biocell and the shell-to-gel
adherence is strong so I have never seen a delamination. I continue to use all three brands of breast implants, but because of the positive features of Sientra’s True Texture, their implants represent the majority of the devices I use.

MIKE FIORILLO: From the first time I felt the Sientra implants years ago, I was intrigued especially since my international colleagues raved about them. These fifth generation devices were long overdue in the US and the texturing in my opinion is the best on the market. I didn’t like how the smooth implants would drop or lateralize. The Sientra HSC textured implant provides the best tissue adherence and leads to better predictability while is not too aggressive that it creates too much incorporation (Figure 1). The increased fill ratio also leads to minimal rippling. I have only had one patient complain of rippling out of 300 cases.

BILL KORTESIS: The data surrounding the Sientra HSC textured fifth generation implants is notable, specifically the lower capsular contracture rates, higher fill volume, and potential longevity of the implants. This data impressed me as it appears that the long-term complication rates with this newer generation of implant are superior to previous generations. I have found a lower incidence of capsular contracture, and have not detected any seromas with the Sientra textured round implants. When analyzing my photographs at follow-up, it appears that upper pole fullness is maintained better than with other round devices I have used (Figure 2).

PATIENT SELECTION

Describe your preferred or target patient for the textured round implant. What is your consultation process?

BRAD CALOBRAICE: I counsel all my patients on the differences between smooth and textured breast implants. I believe textured implants are most beneficial in patients with any chest wall abnormality or asymmetry since the texturing provides long-term stability of the implant with a lower incidence of malposition or lateral drift. Textured implants are very helpful in secondary cases, especially when treating capsular contracture to lower the risk of recurrence, and implant malposition to stabilize implant in the repaired pocket.

ROB COHEN: When using a Sientra textured round implant, it is important to remember that these implants will have a higher fill ratio and more relative projection than a smooth round gel implant. As a result, the Sientra textured round MP implants will fall between a moderate plus and high profile Mentor MemoryGel® (Santa Barbara, CA) and between an Allergan Natrelle® Style 15 and Style 20 implant (Irvine, CA). I use the round textured Sientra implants on patients who prefer a fuller, more augmented look with a fair amount of upper pole volume.

BILL KORTESIS: The patient consultation process involves a full discussion of all the implant types available including demonstration of stability and feel. I provide my patients data on manufacturer complication rates and warranties. Sizing is accomplished through discussion of the desired result (many times patients will bring in photos of their ideal result), trying on tester implants, and reviewing 3D imaging.

MIKE FIORILLO: My preferred patient is anyone who desires the full round look, for example, a post-partum patient or a weight-loss patient who wants to regain superior pole fullness. I use a combination of 3D imaging and have the patient try the implants on in the office and review before and after photos for available options.

When would you not use a textured round implant?

GRANT STEVENS: Consensus by the authors is that most patients would benefit from a textured round implant with the following exceptions:

1. Thin, tight-chested patients who may present with wrinkling postoperatively.
2. Implant exchange cases with a pre-existing smooth implant as long as there is no capsular contracture and the replacement implant is the same size or smaller, so as not to impact the capsule.
3. Patients that prefer a softer transition in the upper pole of the breast and a natural appearance in which case a shaped implant would provide better result.
4. Patients with a long thoracic chest to avoid the convexity that can sometimes be present with round implants.

CONSIDERATIONS

Have you seen a reduction in any postoperative complications using this implant?

GRANT STEVENS: The general consensus of the panel is that in using these implants we have observed a decrease in the complication rates of:

1. capsular contracture
2. bottoming out
3. malposition and lateral migration
4. less asymmetry in cases of chest wall abnormalities

Over the years, the panel has found capsular contrac-
tures to be the most challenging and disheartening post-
operative complication to manage. The low incidence observed with the Sientra textured round implants is a welcome improvement in outcomes.
What types of postoperative complications and initial challenges have you encountered using this implant? How have you mitigated them?

BRAD CALOBRACE: At first I experienced a few implants that sat too high or dropped less than smooth devices as the texture and increased gel cohesivity tend to hold the implants in position and create less stretch of the lower pole over time. The correction was simple: create a pocket that is perfectly situated for the implant in all dimensions, position the implant at the base of the pocket, and close the incision without displacing the implant upward into the pocket. Inframammary fold lowering may be required in some patients to position the implant correctly as opposed to leaving the distance short and relying on the implant to stretch the lower pole over time, as is seen with smooth implants (Figure 3).

The most significant challenge was to make sure my clinical staff understood the unique differences with the textured implants and changes in our postoperative protocols with our textured implant patients. The staff needed to become accustomed to confirming which implant was used [smooth or textured] when providing instructions to patients. We currently have a “pop-up” that is activated when opening the patient’s chart in EMR to notify the provider of what type of implant was used in the patient.

GRANT STEVENS: There is some suggestion that textured implants may be more prone to develop seromas. I have had very minimal occurrence of this complication and my guidance on avoidance is: use electro-cautery for a bloodless dissection, maintain precise hemostasis, and control pocket size (less friction). I never use drains on primaries since I do not close the patient until complete hemostasis is achieved.

Figure 1. Dr Fiorillo’s challenging case. (A, C) This 25-year-old woman with a constricted pole and minimal breast tissue underwent bilateral dual plane augmentation with Sientra textured round high profile 440 cc implants. The inframammary fold was lowered and suturing was performed on the superior and inferior fascia down to the chest wall. (B, D) Photographs obtained 12 months postoperatively show an improved pole with controlled tissue expansion.
There is a small learning curve when switching from smooth to textured implants. Initially I had patients with implants that were higher than preferred, despite patients being satisfied. The recognition that the textured implants do not settle like smooth implants changed my placement to a lower position and set the fold by suturing the pocket down to the chest fascia or periosteum with fantastic results.

**Figure 2.** Dr Kortesis' challenging case. (A, C, E) This 37-year-old woman with previous submuscular saline augmentation 2 years prior presented with bottoming out in the right breast and capsular contracture in the left breast. The patient desired larger, symmetric, soft breasts. She underwent bilateral submuscular revision with Sientra textured round moderate profile implants (485 cc implant in the right breast, 525 cc implant in the left breast). Inferior capsulorrhaphy and superior capsulotomy was performed on the right breast and a complete capsulectomy was performed on the left breast. (B, D, F) Photographs obtained 6 months postoperatively demonstrate that the textured implants prevented repeat capsular contracture and maintained implant position. A large, soft, symmetric result was achieved.
ROB COHEN: I have had very few complications with Sientra implants. During a simple implant exchange my first year, I placed textured implants in a smooth pocket. The implants did not settle properly and I eventually performed a complete capsulectomy and repositioned the original implants. Having more knowledge now, I believe that placing textured implants in a smooth pocket requires more pocket adjustment.

Figure 3. Dr Calobrace’s challenging case. (A, C, E) This 27-year-old woman presented with tuberous breast deformity and narrow breasts on a wide chest with associated ptosis. She underwent bilateral submuscular dual plane 3 augmentation with Sientra textured round moderate profile implants (525 cc implant in the right breast, 485 cc implant in the left breast). (B, D, F) Photographs obtained 8 months postoperatively. The dual plane 3 procedure, textured surface, and stability and cohesiveness of the gel provided resistance to the constricted tissues in the lower pole. The inframammary fold was lowered and radial scoring performed to expand the lower pole for the implant.
The biggest challenge is to simply understand how the shapes and profiles will affect the breast over time compared to a softer, less form stable smooth implant. I think once a surgeon has a solid understanding of how these implants interact with tissues, the relatively minor technique adjustments are fairly straightforward.

Figure 4. Dr Cohen’s challenging case. (A, C, E). This 37-year-old woman presented with 15-year-old 600 cc submuscular saline implants with superior malposition, ptosis, and an unnatural appearance. She underwent an implant exchange with Sientra textured round moderate profile 435 cc implants. An anterior/medial capsulectomy was performed as well as placement of ADM and an inverted T-scar mastopexy. (B, D, F) Photographs obtained 6 months postoperatively. Down-sizing and release of the pectoralis muscle allowed for proper positioning of the implant. Lower pole tissue removal was performed for re-draping of tissue over the implant. The textured implant stabilized the position and a “popcorn technique” reduced the size of the pocket perimeter. The ADM stabilized the muscle and limited lower pole stretch and animation deformity. The mastopexy reduced the skin envelope.
MIKE FIORILLO: The implant will tend to stay where it is placed. So you have to make sure that it is precisely placed in the right size pocket. They don’t drop months later like a smooth implant does.

GRANT STEVENS: The textured round implants are particularly effective in revision cases for implant malposition and capsular contracture. The round textured implant is the solution to the problem of capsular contracture, and malposition cases especially benefit from texture as the new pocket location is preserved.

What is your experience and impression of the textured round implant in revision cases?

BILL KORTESIS: Revision surgery comprises over a third of my breast practice. I prefer using textured round implants in revision cases because I can control the pocket and feel comfortable this implant will stay where I place it. I have also noted a significant decrease in capsular contracture rates when a smooth implant is removed along with a capsulectomy and replaced with a Sientra HSC textured round implant.

MIKE FIORILLO: These implants are great in revision cases. They provide better control of placement and better cleavage. I also feel more confident using them in capsular contracture cases.

ROB COHEN: Revision is often about regaining control of a situation where some degree of control has been lost due to poor elasticity, tissue changes, prior over-dissection, implant migration, etc. (Figure 4). To gain more control over the pocket, I will often use a neosubpectoral pocket in conjunction with textured implants to increase my confidence that the device will stay where I place it. If keeping the original smooth implant pocket mostly intact, I will generally replace the implant with a new smooth silicone implant. However, when the pocket has fresh tissue that will be in contact with the implant, having a textured device adds an important layer of predictability.

BRAD CALOBRACE: I use these implants almost exclusively in revision cases due to the implant’s textured surface providing control in secondary cases. The more stable implant places less tension and pressure against the repair and holds its position better when pockets are less controlled. The textured device is mandatory when switching the implant to the subglandular position or when treating a capsular contracture due to the protective effect on future capsular contractures.
Figure 6. Dr Stevens’ challenging case. (A, C, E) This 32-year-old woman presented with small breasts, and asymmetry and contour deformity of the lower pole in the right breast. She underwent bilateral submuscular augmentation with Sientra textured round high profile implants (300 cc implant in the right breast, 255 cc implant in the left breast). Fat grafting was also performed in the right breast to address contour deformity. An electro-cautery bloodless dissection was performed to create a controlled pocket. Sizers were utilized to determine optimal implant size. (B, D, F) Photographs obtained 6 months postoperatively. The new infra-mammary fold allowed for controlled tissue expansion of the lower pockets.
SURGICAL TECHNIQUE

What is your operative technique with this implant? Have you modified any of your operative techniques with this implant (Figure 5)?

ROB COHEN: Overall, my pocket dissection is more precise with textured implants. I generally use an inframammary incision but could also use a periareolar incision in most. I like to check patients in the supine and seated position prior to closure to ensure the best symmetry as the implants will hold their position much more than smooth implants. I am also more inclined to use dual plane 2 and 3 techniques to expand a constricted lower pole or fill mild glandular ptosis as the implants will settle less than smooth implants.

MIKE FIORILLO: I only place them through the inframammary fold so I have better control. I lower the inframammary fold in almost every case for inframammary positioning.13 Once I have them in the proper position, I secure the inframammary fold with 2-0 vicryl sutures from fascia to fascia of chest wall.

BILL KORTESIS: With an inframammary approach, pockets are either subfascial or dual-plane depending on the amount of overlying breast parenchyma. I use monopolopolar electrocautery for a bloodless field. To minimize bacterial colonization, a touchless technique with the assistance of a funnel is used. I set the inframammary fold with sutures placed to the chest wall fascia or rib periosteum to maintain the position of the incision at the level of the fold and to control the final position of the implant.

What are your top tips for new Sientra textured round users?

GRANT STEVENS: The panel recommends:

(1) Do not be afraid to try these implants. They will improve your precision and allow for more long-term predictability. Technique is not significantly different between smooth and textured implants.

(2) Observe a few cases with a surgeon that has experience with these implants.

(3) Start with cases that are more straightforward. This will allow you to become comfortable with the handling the nuances of pocket dissection and placement before moving to complex revisions.

• Try these implants on primary augmentation cases where you would normally consider a higher profile type implant and you will be pleasantly surprised by the shape and relative ease of the transition to texture (Figure 6).

(4) Select patients that will not need inframammary fold lowering as this may complicate one’s ability to fairly evaluate the results.

(5) These implants will take longer to reach their final result, inform your patients of this ahead of time.

CLOSING THOUGHTS

GRANT STEVENS: I would like to thank the panelists for sharing their experience and knowledge. As discussed and demonstrated by this group of surgeons with experience in approximately 2100 patients, the Sientra True Texture HSC silicone gel implant has great utility in almost all cases. The presentation of challenging primary and revision cases provides evidence of the versatile application and enhanced aesthetic outcomes with these implants. This panel has found that the Sientra HSC round fifth generation gel fill and True Texture surface provides an evolved implant with better pocket and surgical control, predictability of outcomes and an increased safety profile. Transitioning to this implant has been relatively straight forward and widely beneficial for the surgeons on this panel.

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Special Topic
Sientra High-Strength Cohesive Shaped Technique: Roundtable Discussion

Michael R. Schwartz, MD; Peter J. Capizzi, MD; Kiya Movassaghi, MD, DMD; and Mia Talmor, MD

Abstract
A panel of board-certified plastic surgeons chaired by Dr Michael Schwartz convened to discuss their respective experiences with the Sientra High-Strength Cohesive (HSC+) shaped silicone gel breast implants (Sientra, Inc., Santa Barbara, CA). The authors have implanted a combined total of over 700 patients. Preoperative planning, surgical techniques, and practice integration tips are among the topics reviewed. The surgeons also present breakthrough cases and describe how the HSC+ textured implants helped them achieve a successful outcome.

Level of Evidence: 5

Accepted for publication February 2, 2015.

An expert panel of plastic surgeons convened via electronic and telephone communication in November and December 2014 to discuss their experience with Sientra’s textured shaped High-Strength Cohesive Silicone Gel breast implants (HSC+). This panel was chaired by Dr Michael Schwartz, one of the earliest adopters of Sientra shaped implants, who trains surgeons through his surgical preceptorships for Sientra. The panel consists of surgeons who have substantial knowledge and familiarity with the Sientra shaped implant with a combined total of over 700 patients within the three years that Sientra received its Food and Drug Administration (FDA) approval. The surgeons share their expertise with the Sientra HSC+ implant and review their breakthrough cases.

MODERATOR
Michael Schwartz, MD: Dr Schwartz has extensive experience with Sientra implants and trained in Sweden under Dr Charles Randquist in a surgical preceptorship. Dr Schwartz has been in practice in Westlake Village, CA for 16 years and selects Sientra shaped implants for the majority of his augmentation and revision cases, totaling over 200 patients.

PANEL
Peter Capizzi, MD: Dr Capizzi focuses his practice on cosmetic implant and reconstructive breast surgery. Dr Capizzi has been in practice for 17 years and has offices in Charlotte and Huntersville, NC. Dr Capizzi uses the Sientra shaped implant in approximately 90% of his augmentation and reconstruction cases, totaling over 175 patients since approval.

Kiya Movassaghi, MD, DMD: Dr Movassaghi is a Clinical Assistant Professor of Plastic and Reconstructive Surgery at Oregon Health and Science University, and has been

Dr Schwartz is a plastic surgeon in private practice in Westlake Village, CA. Dr Capizzi is a plastic surgeon in private practice in Charlotte, NC. Dr Movassaghi is a Clinical Assistant Professor of Plastic and Reconstructive Surgery at Oregon Health and Science University, Eugene. Dr Talmor is an Associate Professor of Plastic and Reconstructive Surgery at Weill Cornell Medical Center, New York City, and an Attending Surgeon at New York Presbyterian Hospital, New York City.

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in practice 13 years in Eugene, Oregon. Dr Movassaghi trained in Sweden under Dr Charles Randquist in a surgical preceptorship and has used Sientra shaped implants in the majority of his augmentation, revision, and reconstructive cases, totaling over 170 patients in the past three years.

Mia Talmor, MD: Dr Talmor is an Associate Professor of Plastic and Reconstructive Surgery at Weill Cornell Medical Center and has been an Attending Surgeon at New York Presbyterian Hospital for 14 years. Her practice focuses on reconstructive breast surgery and she performs over 200 device-based reconstructions per year. She uses Sientra shaped and textured round implants in the majority of her surgeries.

BACKGROUND

Breast augmentation is one of the most common cosmetic procedures in the United States,1 and a demand by patients and surgeons to have more choices available to them has increased. Although other countries have had access to shaped cohesive implants for the last 20 years, the United States had been limited to round implants until recently.2-4

In 2012, the Food and Drug Administration approved the Sientra portfolio of High-Strength Cohesive silicone gel implants including HSC+ shaped implants5, and ushered in a new and exciting time of breast implant options for patients and surgeons in the United States.

The panelists were selected given their extensive knowledge and experience of Sientra textured shaped implants. These HSC+ implants are filled with fifth generation gel and feature Silimed’s True Texture™ (Rio de Janeiro, Brazil) technology, a proprietary texturing method designed to promote tissue ingrowth that does not use sodium chloride, sugar, soak, scrub, or pressure-stamping methods.6 This panel was convened to discuss their experience and the techniques, benefits, challenges, and surgical pearls for integrating the Sientra HSC+ implants in their practices.

What Prompted You to Start Using the Sientra Shaped Implant?

MIKE SCHWARTZ: I had the opportunity to travel to Sweden over five years ago and learn about the versatility, beauty, and safety of shaped implants. I had helped with the educational material for another device, but never got to use a shaped implant for elective cosmetic patients until the approval of the Sientra HSC+ devices in 2012. I wanted to get better results than I had obtained with round devices. Besides being the first shaped device to be FDA approved in the US market, I found the Sientra shaped implant to be soft and breast-like, unlike the firmer implants I had felt in Sweden. Finally, I am able to use a device that can help with both capsular contracture and implant malposition, and provide a better aesthetic outcome in the correctly selected patient.

PETER CAPIZZI: The HSC+ implant has many great attributes, but it was the softness in a naturally shaped implant that first attracted my attention. I was a co-investigator for the Allergan (Irvine, CA) Natrelle® Style 410 devices and had become accustomed to the firmness of the implant, which is noticeably firmer than native breast tissue. I have kept an eye on advances in gel implant technology and given their natural feel, shape, and performance, the Sientra devices intrigued me from the very beginning.

KIYA MOVASSAGHI: I am continually in search of the best device for my implant-based breast surgeries. Unfortunately, in the US market, due to lack of availability of shaped implants, we have become habitual users of smooth round implants. These smooth devices, however, are prone to bothersome complications such as capsular contracture and pocket instability and result in higher reoperation rates. When the Sientra textured devices (both round and anatomic) became available, I began introducing them to all my breast implant cases. My outcomes mirror or surpass the data published by Sientra. The improvement in the predictability and stability of my results has been very refreshing.

MIA TALMOR: While I was previously satisfied with the results I achieved with smooth round implants after skin-sparing mastectomy, as we started doing more nipple-sparing mastectomies, the aesthetic bar rose, and the problems of bottoming out, rippling, and lateral implant malposition became increasingly troublesome, prompting high revision rates. I was initially hesitant to switch from a device which I felt comfortable had a very well-established safety record, but then had an opportunity to review the published data for the Sientra devices. I began using the implants in May of 2012, and they have since become the device I use most frequently. Approximately 90% of my patients undergo nipple-sparing mastectomies, and approximately 80% have Sientra devices placed. I reviewed the outcomes of 100 patients entered prospectively into my nipple-sparing mastectomy database prior to March of 2012 to determine the effect that a change from smooth round to textured shape has had. I found a significantly lower revision rate after I switched.7

PATIENT SELECTION

Describe Your Preferred or Target Patient for the Shaped Implant. What Are Your Considerations?

PETER CAPIZZI: Broadly speaking, women who are healthy, active, professional, and desire a natural appearance are...
ideal candidates for shaped implants. The shaped implant is also a very good choice for challenging cases. Specifically, reconstruction patients with minimal to no breast tissue or shape, as well as cosmetic breast revision patients seeking an exchange to correct an unnatural appearance. In my practice for both cosmetic and reconstructive breast patients, there is little to no role for a round implant. Reconstruction patients with previous mastectomies frequently have upper pole hollowing which becomes more pronounced and evident with a round device. The shaped device can naturally fill part of this space and provide a discernable improvement. In fact, because of advances in shaped implants, my reconstruction results now rival cosmetic results in many cases.

KIYA MOVASSAGHI: In my practice I spend a great deal of time educating my patients that with all the different devices available today, we no longer “volumize” but instead “shape” the breasts. Any patient who wishes to have a full, natural result with excellent upper-pole but without the “fullness” seen with round implants is a candidate for an anatomic implant. Obviously, the patient’s anatomy and needs will dictate which implant shape to use. The anatomic implants are especially helpful in patients with inadequate soft tissue coverage or after a mastectomy. In the past three years, I have done many revisions for this group of patients, replacing round implants with the anatomic ones, and have achieved a more natural outcome with improved satisfaction.

MIA TALMOR: The ideal patient is a primary reconstruction in either one or two stages. The Sientra shaped device is my default implant for all patients undergoing nipple-sparing mastectomies. Augmentation patients with tight, thin, soft-tissue envelopes benefit from a shaped device. While I had been hesitant to use subglandular planes in the past, the textured shaped implant has a lower rate of implant visibility and rippling, with a natural shape which lends itself to subglandular placement in some cases. Patients will have a more natural and durable result, but must be counseled with respect to the firmer nature of the implant as opposed to a smooth round.

MIKE SCHWARTZ: I agree with the panelists that the Sientra shaped implants are best for the patient who wants a natural result. With over 200 of these cases under my belt, I have become somewhat more selective, both based on patient characteristics and patient desires. A patient with good upper-pole soft-tissue coverage may not have much benefit from a shaped device as long as their size request is not too large. A round device will suffice in this situation. The shaped implants excel in the patient with limited upper-pole soft-tissue coverage, constricted breasts, or short nipple to IMF distance, and in the patient demanding a large implant with a natural result (Figure 1). In addition, the patient who requires a subglandular augmentation for anatomy or lifestyle can have a soft natural augmentation with this device.

When Would You Not Use A Shaped Implant?

MIKE SCHWARTZ: The panel agrees that in the following situations, a shaped implant would not be a primary consideration:

1. A woman who desires a round, obvious, and unnatural “augmented” shape.
2. The patient undergoing augmentation mastopexy with adequate soft tissue. In this case the lift shapes the breast, and a round implant is all that is needed to provide adequate volume.
3. In the case of some revision patients who desire a smaller size, the surgeon must consider that the large pocket may be difficult to control. Shaped implants can still be used in this situation, but will require either a well-executed mastopexy with parenchymal reconstruction, or internal pocket control using either acellular dermal matrix (ADM), newer synthetic mesh, or capsulorrhaphy.
4. Patients who require extensive capsulorrhaphy at the time of the exchange due to risk of implant rotation.
5. Patients who have had or will have radiation may benefit from a less cohesive implant, although recently it has been postulated that a firmer implant might fight the capsule formation from radiation.

Do You Use 3D Imaging or Another Sizing System?

KIYA MOVASSAGHI: I use the ABC algorithm (base diameter, height, projection) for implant selection. Based on the desired volume and the patient’s anatomy, I choose the shape and volume of the implant. My patients use sizers to determine the desired volume. I have had great success with this system of measurements, as I never use intraoperative sizers nor do I bring more than one size to the operating room (except for cases of significant asymmetry). Although the 3D imaging technology has improved significantly, the accuracy is still not to my satisfaction.

MIA TALMOR: I size the patients based on: (1) base width; (2) height; (3) projection; and (4) volume. Of these, volume is the least important estimate. I have never used a 3D system. Intra-operatively, I use a combination of shaped saline sizers or round silicone sizers to evaluate the horizontal fill of the pocket. I use the latter in every
direct-to-implant reconstruction (Figure 2), and use ADM to precisely delineate the pocket around the chosen sizer.

**PETER CAPIZZI:** I use a combination of traditional sizing methods and 3D innovation. The patient’s individual breast measurements are taken (nipple to sternal notch, width of each breast, nipple to crease, and nipple to nipple). The patient will wear implant sizers to obtain the desired look and appearance as well as review before-and-after pictures. 3D imaging is also important in my practice. I have tried three

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**Figure 1.** Dr Schwartz’s breakthrough case. (A, C, E) This 48-year-old woman with a severely tight inframammary fold desired a larger, natural augmentation. She underwent bilateral subglandular breast augmentation with Sientra Classic Base 450 cc implants. (B, D, F) Photographs obtained 24 months postoperatively show a new inframammary fold and a stable, soft, and natural result.
available systems: Vectra (Fairfield, NJ); Axis (Miami, FL); and Crisalix (Lausanne, Switzerland). The concept of 3D is becoming ubiquitous in our culture and patients ask about imaging. The promise of seeing your result before surgery is obviously attractive; however, the expectation may exceed the deliverable, and 3D imaging is a tool, not a guarantee.

MIKE SCHWARTZ: I know elective breast patients are going to demand a certain volume, and my sizing system combines the use of all of the information above to match each patient’s goals and anatomy as closely as possible. I use the Vectra 3D image system (Vectra, Fairfield, NJ) to measure the patient’s base diameter, and then allow them to use volumetric sizers in a sports bra to show me the size they would like. I next select the implant height I feel is best based on their frame and body characteristics. With these three variables, I am forced into a given projection that solves any patient’s size request. If that projection or size is not available, I revert to a round textured implant. I do not use sizers unless there is breast or chest wall asymmetry.

Figure 2. Dr Talmor’s breakthrough case. (A, C) This 47-year-old-woman underwent bilateral nipple-sparing mastectomy and direct-to-implant reconstruction with Sientra Round Base 320 cc implants. (B, D) Photographs obtained eight months postoperatively show correction of ptosis with improved skin draping over the lower pole. The direct-to-implant procedure provided the desired result.
CONSIDERATIONS

Considering the Shaped Products Available through Other US Manufacturers, What Are Some of the Benefits when Using the Sientra Shaped Implant?

MIA TALMOR: The shape and projection are superior in the Sientra device, while the other shaped devices give a more “matronly” shape to the breast. The Sientra devices are less firm than the other available devices. The pocket and skin drape well over this implant, leading to less implant visibility, particularly in the superior pole.

PETER CAPIZZI: The Sientra shaped devices are softer than the Allergan Natrelle Style 410 and have the right amount of texturing. Until recently, the Mentor MemoryShape® device has had limited use in my practice due to limited projection and size, so I cannot comment on it. Sientra has a stronger warranty than either the Allergan (Irvine, CA) or Mentor Worldwide LLC (Santa Barbara, CA) products, extensively covering both rupture and capsular contracture.

KIYA MOVASSAGHI: As a plastic surgeon, I like to use the safest and most effective device for my patients, and published long-term data from each manufacturer is critical. The data provided by all three manufacturers demonstrate safety and efficacy of these medical devices. We are, however, still in the infancy period in regards to the use of these devices and should strive to provide ongoing data and sound science. I also appreciate Sientra’s pledge to exclusively sell these devices to board-certified plastic surgeons, especially as we see a growing number of non-plastic surgeons encroaching upon our specialty.

MIKE SCHWARTZ: I agree with the panelists that we US surgeons are still learning about these shaped devices. I find that the Sientra shaped implant has the ideal balance of shape, softness, and control with the True Texture surface to give me results I could not achieve with round implants in the past. It sounds corny, but I explain to my patients that this implant is like Goldilocks and the three bears: it’s “just right.”

What Type of Results Have You Observed That Are Unique to the Sientra Textured Implant?

MIKE SCHWARTZ: The panel has observed the following:

1. Decreases in postoperative complications, including pain, malrotations, capsular contractures, erosions, fractures, double-capsules, unnatural ridging in the upper pole, nipple malpositioning, and postoperative rippling.

2. Stable results with no significant settling. Shaped implants give an immediately beautiful breast with a stable shape and position.

3. No lateralization, as previously observed with the smooth round implants.


5. For reconstruction cases, shaped devices have led to an increase in direct-to-implant reconstructions and no longer depend on the tissue expander to shape the pocket.

6. Patient compliance is better and does not require painful postoperative massage.

Do You Have a Preferred Projection, Profile, or Base Within the Sientra Implant Matrix? If so, Why?

PETER CAPIZZI: My preferred implant for cosmetic procedures is the Round Base because it offers the most youthful shape and size, which suits my active, healthy, athletic patient population well (Figure 3). With reconstruction, I most commonly use the Oval and Round Base shaped implants.

KIYA MOVASSAGHI: My preferred implant is the Classic Base. This implant provides the most natural look for the majority of my patients. If the desired implant dimension is not available, I will switch to an alternate base shape with the appropriate dimensions or an equivalent round textured implant.

MIA TALMOR: For young, thin women I prefer the Round Base implant. The ratio of base width to projection in this implant is close to ideal. In a patient with less than ideal body habitus, the Oval Base high-projecting implant fills the pocket better.

MIKE SCHWARTZ: I typically prefer the Classic Base for most patients. My exception is that I have found utility in the Oval Base implants because of their ability to create both lateral sweep and medial fullness of the breast. They also prevent upper pole fullness in the patient with a full pectoral muscle or axillary fat/breast tissue.

What Types of Postoperative Complications Have You Encountered with the Shaped Implant? Have You Had Any Rotations? How Have You Mitigated Them?

KIYA MOVASSAGHI: My complication rate has been within the range of published data for textured implants. When comparing the smooth implants with the textured implants, the most noticeable drops in complications have been in the rate of capsular contracture and pocket instability (loss of IMF control, lateral migration) which I attribute to the textured surface. I have seen two minor cases of implant rotation, both with the shaped oval base implants. Neither of these patients wished to have a revision. I do not use any drains and have only seen one case of seroma that presented three weeks postoperatively, which was successfully managed with drainage. I also advise my patients not to...
wear a bra for six weeks to minimize the capsular contracture rate in primary augmentation cases.

MIA TALMOR: Tight and precise pocket control is the only way to mitigate the complication of rotation. For this reason, if the pocket is over-stretched or an extensive capsulorraphy is required I will choose a textured round implant as opposed to a shaped device. A big challenge for me was distinguishing between capsular contracture and rotation of the implant, which can be a difficult differentiation on clinical

Figure 3. Dr Capizzi’s breakthrough case. (A, C, E) This 36-year-old woman desired to improve the shape and size of her breasts after having children, with a natural result that would not hinder athletic activities. She underwent bilateral submuscular breast augmentation with Sientra Round Base 255 cc implants placed through the inframammary fold. (B, D, F) Photographs obtained 10 months postoperatively offer a natural feel, shape, and performance.
exam. I am more enthusiastic about revising a patient with a rotation than a contracture because the result of the correction is immediate and guaranteed. I have replaced my rotation patients with both textured round and larger shaped implants, but have not simply rotated the implant back for fear of encountering a recurrence of the rotation.

MIKE SCHWARTZ: I have had two patients with implant rotation. For the first patient, I chose too large an implant for her base diameter. Her initial result was good, but because I selected a round based implant and her pocket stretched, it was easy for the device to rotate. The second was in an augmentation mastopexy and again the pocket was not ideal. Initially the result was good, but with time and pocket laxity the implant rotated and was replaced with a round device. These problems can be reduced with better implant selection and pocket dissection.

What Is Your Experience and Impression of the Shaped Implant in Revision Cases?

MIA TALMOR: I am less likely to use a shaped device on a patient who has already been operated on because it is more difficult to precisely shape the pockets in these patients, and the rotation risk is higher. That being said, if improved shape is the primary goal of the revision (ie, someone who has too much superior pole fullness or a round appearance) I will do the revision with ADM to better control the pocket.

PETER CAPIZZI: Psychologically, cosmetic revisions are very challenging for the patient and require a high level of surgical expertise and appropriate devices. The patient may be downsizing, have implants that are displaced inferiorly and laterally, the fold may be displaced, the original implant size and type may be unknown, or all of the above. Additionally, the skin most often has aged and has an excess or paucity. The consultation reviews their concerns, goals, and various implant types available now and historically. Generally, round implants appear larger than shaped, as do saline implants, which actually appear larger than round or shaped gels. In reconstruction surgeries, the tissue around the implant is the limiting factor and therefore restricts size options. The patient’s’ body makes the choice for the surgeon. More projection and smaller reconstructions with a medially placed implant at the crease usually will result in an excellent appearance.

KIYA MOVASSAGHI: As my experience with these devices increased, I found they are well suited for revision augmentation and reconstruction. In many of these cases, there is a lack of pocket control and paucity of soft tissue coverage. The use of a textured device in a neo-pocket (typically seen in revision) or a tall anatomic implant in a mastectomy case greatly improves the outcome. In many cases where I previously used ADM in addition to creating a neo-pocket, I no longer use the ADM because the textured device provides better stability and pocket control.

MIKE SCHWARTZ: The key point in revision cases is pocket control. I have found great success with these because of the True Texture. This allows me to use absorbable sutures for my capsulorrhaphy, and avoid ADM completely, as Dr Movassaghi mentioned, therefore eliminating the need for drains except in cases of capsular contracture, where I always use them. The shaped implant in the neo-pocket is exceptionally stable and a great option. I agree with Dr Capizzi that silicone implants in general, and shaped specifically, seem smaller to patients who have had either saline implants or capsular contracture. These patients are used to the firm, full projection of their old device, even if it looked or felt abnormal. You must be very careful in size selection with these revisions to be sure they are not disappointed at being too small.

SURGICAL PEARLS

Have You Modified Any of Your Operative Techniques with this Implant (Figure 4)?

PETER CAPIZZI: Surgical technique is a matter of continual refinement. For breast reconstruction surgery, my technique has been modified over the years, as reconstructive patients have less blood supply acutely than cosmetic patients, which puts reconstruction patients at a higher risk of infection. For the reconstructive revision patients, radiation is also a consideration. For both of these conditions, the implants are opened only within minutes of placement, gloves are changed, and an Ioban Drape (3M, St. Paul, MN) is placed over the chest.

I do not lower the fold. I have seen cases with smooth displaced implants with double bubbles and malposition. If the fold needs to be lowered, most often a different style, size, and model implant needs to be considered. Dual plane is utilized in grade 2-3 ptotic patients. Most often the submuscular approach is the technique of choice and subglandular is used rarely for those patients requesting an unnatural appearance and concerned for animation. I have not found animation to be an issue as long as expectations are discussed at length. I use Elastoplast (Beiersdorf, Hamburg, Germany) for 72 hours.

KIYA MOVASSAGHI: There is a greater need for accuracy in surgical planning. The new inframammary fold (IMF) location and accurate pocket development are the keys to success. The most important measurement is the base width, where it may vary by 1 cm from the patient’s native breast width. Lowering of the fold is a function of the width of the
implant and the distance from the nipple to IMF on stretch. The new IMF (hence, the inframammary incision site) is then determined based on the ABC algorithm. I use a monopolar cautery to cut the muscle and develop the pocket, and never use finger dissection in order to achieve a dry pocket. I rarely use a subglandular pocket. I mostly use dual plane 1, unless I am dealing with a tuberous breast, tight lower pole, or ptotic breast, where I may use dual plane 2 (Figure 5).

MIA TALMOR: If the patient will undergo placement of a tissue expander prior to placement of the shaped device, I will choose a tissue expander with a base width that is at least one centimeter narrower than the base width of the implant that I ultimately intend to use. I will under-inflate, or inflate to full (50% delivered intra-operatively), but never overinflated the tissue expander. The key to success with these implants is maintaining a tight pocket.

MIKE SCHWARTZ: I think this is where my experience with shaped implants has most dramatically affected my practice. I have shortened my operating room time because for straightforward cases, there are no sizers and no sitting up, which is all facilitated by 3D imaging and accurate preoperative planning. Data from both my cases, and all three companies' FDA-published data for shaped and textured devices, drives my primary choices to only textured devices, primarily submuscular placement, and inframammary incisions. I use nipple shields and triple antibiotic irrigation on every case. Because of the stability of the cohesive gel, I aggressively lower the IMF with both textured round and especially shaped implants.

**Do You Have Any Final Tips You Would Recommend to New Shaped Users? What Is the Best Way to Transition from Round to Shaped Devices?**

KIYA MOVASSAGHI: With education and experience, I can offer my patient a treatment that is customized to their individual needs. Introduction of new breast implants is not a new concept. We experienced the same resistance with the smooth gel implant when it first entered the market, but it now has become the main player. I suspect that with more data and education, the anatomic implants will also take on a bigger role in the US market. With access to all the new implants, the practice of “volumizing” the breast must be replaced with the practice of “shaping” the breast. This is an exciting time to be a plastic surgeon.
PETER CAPIZZI:
(1) Let go of the fear. Recognize that failure only means removing an implant at the time of the procedure if you determine it’s wrong.
(2) Get started with best-candidate cosmetic patients. Consider a small-breasted, symmetrical, no ptosis patient that desires a natural, full breast result.
(3) In reconstruction, try and place an implant within 60 cc of the expander volume used. Perform a medial and superior capsulotomy, leaving the lateral area intact. Limit the amount of acellular dermis utilized.

MIKE SCHWARTZ: My advice is to use a classic shape device. I feel the non-round shape is more protective from rotation. If your pocket dissection is inaccurate, then the implant can rotate. The taller shape protects you more. Photograph your preoperative markings on every case to allow yourself to review and critically evaluate your results, preoperative planning, and surgical technique.

CLOSING THOUGHTS
MIKE SCHWARTZ: I would like to thank the panelists for their wonderful insights and experience. As demonstrated by this group of surgeons, the future of breast surgery lies in the diversity of options available to the thinking, planning, and elegant breast surgeon of today. With the ability to use 3D imaging, accurate preoperative planning, a wide selection of implants, and better surgical techniques, we are providing the safest, best results our patients have ever been able to expect. The Sientra

Figure 5. Dr Movassaghi’s breakthrough case. (A, C) This 32-year-old woman with tuberous breast deformity and asymmetry desired natural-looking breasts. She underwent bilateral submuscular dual-plane two-breast augmentation with Sientra Classic Base 350 cc implants. (B, D) Photographs obtained six months postoperatively show a new inframammary fold with controlled tissue expansion of lower pockets and a natural result.
profile of HSC+ implants is now a significant addition to our armamentarium.

I encourage any surgeon who wants to obtain better results to consider the use of the shaped implants available today. Your transition will be easier than you expect, your results better than you expect, and your patients even happier than you expect.

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**REFERENCES**

Sientra Primary and Revision Augmentation Rupture Trending and Analysis with Magnetic Resonance Imaging

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Abstract

**Background:** Rupture of silicone gel breast implants is a rare occurrence but remains one of the key surgical concerns. The objective of this article was to provide visibility and information on trends for the impact that patient and surgical characteristics play in the occurrence of rupture.

**Objectives:** Examine trends in surgical techniques to better understand the etiology of implant rupture.

**Methods:** Analysis was based on Sientra’s prospective, open-label, U.S.-based clinical study of High-Strength Cohesive silicone breast implants. Patient and surgical characteristics were compared between ruptured and intact implants.

**Results:** The subset of data used for this analysis included 1792 implants in 935 primary and revision augmentation patients implanted by 31 plastic surgeons, with an average follow-up of 6.6 years. The results confirm that rupture remains a rare adverse event. Overall, the rupture prevalence for this study was 2.4%. Rupture prevalence was lower among textured devices (0.8%) compared to smooth devices (3.8%). The prevalence of rupture was 7.8% among devices placed with a transaxillary incision site compared to 1.6% and 3.0% when placed with an inframammary or periareolar incision site, respectively. Rupture was reported in 5.5% of the devices that received steroid pocket irrigation, compared to 1.8% of the devices that did not.

**Conclusions:** Although ruptures in the Sientra study with the High-Strength Cohesive silicone gel implants were an uncommon occurrence, the authors were able to identify strong trends for the association of certain surgical factors and characteristics. The results show among other factors that an inframammary approach and a textured device were found to be protective against rupture.

**Level of Evidence:** 2

Rupture of silicone gel breast implants remains one of the least understood complications following breast augmentation. The etiology is variable and includes such modes as fold fatigue and flex fatigue, as well as iatrogenic occurrences during surgery. Silent rupture presents a challenging situation for plastic surgeons and often requires sophisticated imaging modalities. Although rupture is relatively low in terms of actual occurrence, it is one of patients’ key concerns when considering breast implant surgery.

This study incorporates data obtained from the Sientra clinical trial based in the United States, evaluating women following primary and revision breast augmentation. The goal of this analysis was to examine trends in surgical techniques and to further understand the etiology and diagnosis of silicone gel implant rupture.

**METHODS**

**Patients**

Analysis was based on Sientra’s Food and Drug Administration-approved large prospective, open-label, U.S.-based clinical study of its high-strength cohesive silicone gel breast...
implants. Patients were enrolled based on defined inclusion and exclusion criteria and informed consent was obtained for all patients by the study surgeons under an IRB approved protocol. The subset of data for this analysis included 1792 implants in 935 primary and revision augmentation patients implanted by 31 plastic surgeons (median 63 implants).

**Data Collection**

All patients were monitored per protocol by their surgeons at postoperative intervals that included six weeks, one-year, and annually through 10 years of study follow-up. The occurrence of rupture was documented on explant and MRI case report forms. Fifty-five percent of the analysis population was enrolled in an additional MRI substudy and underwent MRI scans every two years. The distribution of scans in the MRI cohort was: no MRIs (5%), 1-2 MRIs (43%), 3-4 MRIs (49%), and 5-6 MRIs (3%). MRI scans were independently interpreted by two radiologists. One was a local radiologist and the other was a blinded central expert radiologist. Both radiologists reported their findings and these findings were classified into three categories: no evidence of rupture, indeterminate evidence of rupture, and definitive evidence of rupture. Although not required by protocol, some non-MRI cohort patients included in this analysis underwent MRIs.

Patient and device-related characteristics were collected on the study case report forms. Patient characteristics included: age at implantation, body mass index, and indication for surgery (primary augmentation or revision augmentation). Device characteristics included type of implant surface (textured or smooth), device size (cc), and if round or shaped. Surgery-related characteristics included: method of anesthesia (general or local), incision site (transaxillary, periareolar or inframammary), surgical facility (surgeon’s office or hospital/surgical center), and implant pocket placement (submuscular or subglandular). Submuscular device placement included various dual-plane techniques. Some of the subglandular devices were placed in the subfascial position. The various irrigation solutions included antibiotic, dilute povidone-iodine, or steroid solutions alone or in combination.

Postoperative characteristics collected were capsular contracture formation prior to rupture as well as the recommendation of a surgical bra and/or massage protocols.

**Device Retrieval**

Retrieval analysis was performed on explanted devices that were returned through the study. Extensive mechanical and physical testing is performed along with microscopic analysis, which includes scanning electronic microscopy when required. Ruptures are generally categorized into three main types of shell failure: flex fatigue/fold flaw failure, surgical instrument damage, and unknown local stress (Figure 1). Flex fatigue/fold flaw can be a cause or result of shell failure and is characterized by “feather lines” on the surface of the explanted device, which can advance to pronounced surface cracking. Surgical instrument damage is typically characterized by parallel striation lines on the cut surface of the shell, caused by a surgical instrument such as a scalpel or needle. Local stress of unknown origin is caused by an unknown stress applied to the implant that causes shell failure; these types of rupture do not have any obvious signs of another failure cause.

**Statistical Methods**

All devices were categorized as either ruptured or non-ruptured. Categorization of rupture was defined as rupture at explantation or MRI evidence of definitive rupture by both radiologists. Categorization of non-rupture was defined as a non-ruptured device at explantation or MRI evidence of an intact implant by both radiologists. Devices with inconsistent or indeterminate MRI results that were not yet explanted were excluded from this analysis.

All ruptured devices were included in the analysis. These devices were compared to a non-ruptured group, which was limited to devices where explantation/MRI date was greater than 146 days. This timeframe was selected because it aligned with the earliest number of days to occurrence within the ruptured group. The purpose was to have comparable data whereby there was a minimum implantation time prior to the diagnosis of rupture. The prevalence of rupture was evaluated for each patient as well as surgical and post-surgical characteristics. Statistical association was determined using a GEE model adjusted for variables found to be individually significant. The difference between clinical and statistical significance has been widely discussed. It is important to note, “clinically significant” is not dependent on the amount of the p-value; correlations and findings are often “clinically significant” without being “statistically significant”. For the purposes of this article, clinical significance has been defined as a difference ≥2%, and the threshold for statistical significance was set at p ≤ .05. The distribution of prior MRI results within the ruptured group was also assessed using a frequency distribution. Finally, the prevalence of rupture and various patient/surgical characteristics were calculated by individual surgeon to examine surgeon-specific techniques.

**RESULTS**

**Patients**

The median patient age at the time of enrollment was 38 years (range: 18-71) with the majority of patients being Caucasian and married, and 37% having an annual household income that exceeded $80,000. The median body mass index was 20.8 (range: 15.9-35.0). The majority of
patients had completed some college education with 45% holding at least a Bachelor’s degree and 8% having completed postgraduate level education.

The implants included in this analysis (Table 1) had a median size of 360 cc (range: 175 cc-700 cc). Surface characteristics included a smooth shell (52%) and a textured shell (48%). Round devices were used in 86% and shaped devices in 14%. The incision site was inframammary in 64% and periareolar in 30%. Device location was submuscular in 56% and subglandular in 44%. The majority of surgeons (21/31) placed smooth surface devices through an inframammary incision. Four surgeons completed implant placement with the transaxillary approach.

The ruptured devices (N = 43) identified in these patients were implanted a median time of 7.0 years (range: 147 days-10.2 years). The non-ruptured devices (N = 1749) were implanted a median time of 6.6 years (range: 148 days-10.6 years).

Identification of Ruptures

Sixteen of the 31 investigators identified 43 ruptured devices. Ten of the devices were identified via MRI and have not yet been explanted. Nine of the ruptured devices were identified at explantation and did not have MRIs prior to explantation. The remaining 24 devices underwent MRI prior to explantation. Table 2 reports the MRI findings for these explants. Almost half of the MRI scans within the ruptured group (45.8%) were read by both radiologists as having definitive evidence of rupture. Seven MRI scans had inconsistent radiologist findings prior to explantation of the ruptured device. Of the 43 device ruptures, 21 were in the MRI cohort and 22 were in the non-MRI cohort.

Two of the 43 ruptured devices were classified as symptomatic. One patient reported that her breast implant “felt different” and the other reported pain. These implants were found to be ruptured at explantation.

Figure 1. Scanning electron microscope images of a flex fatigue failure, photograph taken at 50 × magnification (A), striations from surgical instrument damage, photograph taken at 35 × magnification (B), and unknown local stress, photograph taken at 75 × magnification (C). Reprinted with permission from Sientra, Inc. (Santa Barbara, CA).
on the implant with minimal presence of gel outside the shell within the capsule. Figure 4 shows this device as a pictorial example of one of the modes of failure. The analysis from device retrieval suggests flex fatigue as the likely cause of failure as there are no definitive striations, uniform markings, or any other features that suggest otherwise.

**Characteristics of Ruptured vs Non-Ruptured Implants**

Table 3 describes the incidence of rupture. Overall the rupture prevalence for this study was 2.4% through an average follow-up of 6.6 years. Rupture was reported in 0.4% of the shaped devices and 2.7% of the round devices. Rupture was also reported in 0.8% of textured surface devices (round and shaped) and in 3.8% of smooth surface devices. Rupture was reported in 5.5% of the devices that received steroid pocket irrigation compared to 1.8% of the devices that did not receive steroid pocket irrigation. Rupture was reported in 1.1% of devices that were placed in the subglandular position while for those in the submuscular position rupture was reported at 3.4%. Other variables that resulted in a difference >2% were: incision site, incision size, and massage. Although multivariate analysis did not identify any statistically significant associations \( (p > .05) \), the following characteristics had the strongest association with ruptured devices: steroid pocket irrigation \( (p = .0520) \), device surface \( (p = .0549) \), and device placement \( (p = .2650) \). The remaining characteristics had \( p \)-values >.3463.

**Surgeon-Focused Analyses**

The surgeon-specific incidence of rupture as related to surgical and postoperative practices was reviewed. Three surgeons accounted for over 51% of the reported ruptures but enrolled only 15% of the devices (Table 4). Each of these three surgeons reported a greater than 8% rupture, while all other remaining surgeons reported rates of 6.3% or less. This review revealed differences in device/surgical practices between these three surgeons and the remaining 28 surgeons with less rupture. These three surgeons employed only round devices (100%) and utilized smooth devices for over 99% of their implantations. Regarding the remaining characteristics that were identified as having an impact (>2% in Table 3), these surgeons more often employed techniques associated with higher rupture. Specifically, pocket irrigation with steroid was done with 61% of the devices implanted by these surgeons compared to 9% usage by other surgeons. The surgeons with higher rupture employed submuscular placement with over 93% of their devices, whereas the other surgeons employed submuscular placement with only 49% of their devices. Similarly, the surgeons with higher rupture recommended massage (99%) more often than other surgeons (41%).

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**Table 1. Device and Surgical Characteristics**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device attributes</td>
<td></td>
</tr>
<tr>
<td>Surface characteristics</td>
<td></td>
</tr>
<tr>
<td>Smooth</td>
<td>52%</td>
</tr>
<tr>
<td>Textured</td>
<td>48%</td>
</tr>
<tr>
<td>Shape characteristics</td>
<td></td>
</tr>
<tr>
<td>Round</td>
<td>86%</td>
</tr>
<tr>
<td>Shaped</td>
<td>14%</td>
</tr>
<tr>
<td>Device size</td>
<td></td>
</tr>
<tr>
<td>Median size</td>
<td>360 cc</td>
</tr>
<tr>
<td>Range</td>
<td>175-700 cc</td>
</tr>
<tr>
<td>Surgery characteristics</td>
<td></td>
</tr>
<tr>
<td>Incision site</td>
<td></td>
</tr>
<tr>
<td>Periareolar</td>
<td>30%</td>
</tr>
<tr>
<td>Inframammary</td>
<td>64%</td>
</tr>
<tr>
<td>Transaxillary</td>
<td>6%</td>
</tr>
<tr>
<td>Device placement</td>
<td></td>
</tr>
<tr>
<td>Subglandular</td>
<td>44%</td>
</tr>
<tr>
<td>Submuscular</td>
<td>56%</td>
</tr>
</tbody>
</table>

**Table 2. MRI Findings for 24 Devices Prior to Explantation of Ruptured Device**

<table>
<thead>
<tr>
<th>MRI Findings</th>
<th>Ruptures n (% of 24)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consistent finding between two radiologists</td>
<td></td>
</tr>
<tr>
<td>No evidence of rupture</td>
<td>3 (12.5%)</td>
</tr>
<tr>
<td>Definitive evidence of rupture</td>
<td>11 (45.8%)</td>
</tr>
<tr>
<td>Inconsistent finding between two radiologists</td>
<td></td>
</tr>
<tr>
<td>No evidence &amp; indeterminate evidence</td>
<td>2 (8.3%)</td>
</tr>
<tr>
<td>No evidence &amp; definitive evidence</td>
<td>2 (8.3%)</td>
</tr>
<tr>
<td>Indeterminate evidence &amp; definitive evidence</td>
<td>3 (12.5%)</td>
</tr>
<tr>
<td>Definitive evidence &amp; inconclusive</td>
<td>3 (12.5%)</td>
</tr>
</tbody>
</table>

Figure 2 depicts an MRI scan read by both radiologists as having definitive evidence of rupture; the devices were explanted 49 days after the scan and rupture was confirmed.

Figure 3 depicts an MRI scan first read by both radiologists as ruptured and later cleared of rupture on the second scan. Upon removal, the physician noted a small puncture.
Figure 2. Progression to Rupture. Fifty-one year-old primary augmentation patient implanted in with Smooth Round High Profile 385 cc implants placed submuscularly through a transaxillary incision. (A) MRI scan of right breast 3 years postoperative with a consistent finding of No Rupture between radiologists. (B) MRI scan of right breast 4 years postoperative with a consistent finding of Definitive Rupture on right side between radiologists. The arrow indicates the spot of suspected rupture. Explantation 5 years postoperative revealed rupture on right. Reprinted with permission from Sientra, Inc. (Santa Barbara, CA).

Figure 3. Multiple MRIs with varying radiology findings prior to explantation. Forty-year-old primary augmentation patient implanted with Smooth Round Moderate Profile 390 cc implants placed submuscularly through a periareolar incision. (A) MRI scan 9 years postoperative with a consistent finding of Indeterminate Rupture on the right side between radiologists. The arrow indicates the spot of suspected rupture. (B) MRI scan three months after the first scan with a consistent finding of No Rupture between radiologists. The arrow indicates the area initially suspected of rupture cleared in this read. Explantation three months subsequently revealed a small shell tear on right. Reprinted with permission from Sientra, Inc. (Santa Barbara, CA).
Regarding incision site and size, these surgeons did transaxillary incisions (37%) and 0-3 cm incisions (26%) more often than other surgeons (<1% and 15%, respectively). Almost all transaxillary incisions in this study were done by the surgeons with higher rupture rates; surgeons with lower rates only placed five total devices using transaxillary incisions. Furthermore, 88% of the devices placed with transaxillary incisions were round, smooth, and placed submuscularly and with general anesthesia, betadine, and steroids. Massage and surgical bra was also recommended for over 90% of these patients.

**DISCUSSION**

This study demonstrates that rupture is relatively a rare occurrence and likely due to its various etiologies. It is not associated with the factors that are typically investigated to determine relationships between breast implants and other studied adverse events (ie, infection, capsular contracture). These fifth generation implants are inert and consist of High-Strength Cohesive silicone gel and a low bleed barrier elastomer shell.\(^5\) The shells are designed to be unaffected by patient tissue characteristics, operative technique, and operative solutions (ie, antibiotics, steroids). However, the results from this analysis demonstrate that certain surgical characteristics are related to device rupture.

Although the characteristics investigated were not statistically significant, some are considered clinically significant. Some specific characteristics emerged as correlated with higher rupture in the overall results and were also confirmed within the subset of surgeons with greater than 8% rupture rates. Rupture prevalence was lower among textured devices compared to smooth (0.8% vs 3.8%, respectively). This is consistent with the protective effect that the TrueTexture™ surface has demonstrated against capsular contracture.\(^2\)

Contrary to the current school of thought, rupture was not more common among patients with prior capsular contracture compared to patients without previous capsular contracture (3.4% vs 2.3%, respectively). However, further study of the correlation of capsular contracture as a precursor to rupture is warranted.

The results found a lower prevalence of rupture among devices placed subglandularly (1.1%) compared to those placed submuscularly (3.4%). The authors hypothesize that implants placed subglandularly are not subject to the deforming force of the muscle and, therefore, may sustain...
less folding of the implant edge. The muscle inherently contracts over the implant exerting more force across the device and causing more fold wear over time. It would then be expected that fold fatigue in the submuscular position would occur more often than in the subglandular plane.

However, with both placements, a highly cohesive fifth generation gel adds to implant stability, which should result in less folding overall, hence less wear areas and a lower rupture rate. The low rupture rates seen in this study may in part be attributed to the High-Strength Cohesive silicone gel fill which has been shown to be the strongest currently available on the market in the United States.

The prevalence of rupture was 7.8% among devices placed with a transaxillary incision site compared to 1.6%
and 3.0% when an inframammary or periareolar approach was utilized. Although a large difference in prevalence is apparent, the transaxillary sample size was small (N = 102 out of 1792) and possibly influenced by the four surgeons who employed this technique (97 implanted devices by a single surgeon). Although an impact analysis was not within the scope of this study, it is likely that exclusion of the transaxillary approaches would only have a minimal impact among characteristics with large sample sizes (eg, round (n = 1539), smooth (n = 936)), yet the impact is unknown for characteristics with smaller sample sizes (eg, betadine (n = 287) and steroids (n = 292)). Povidone-iodine is contraindicated for all three U.S. manufacturers, though there is research to suggest that povidone-iodine has no significant impact on tensile strength.

Regarding the surgeon-focused analysis, an important finding of this study is that three surgeons accounted for over 51% of the ruptures and enrolled only 15% of the patients. This largely disproportionate distribution of rupture further supports the technique-dependent variable of this

<table>
<thead>
<tr>
<th>Table 4: Comparison of Patient, Device, and Surgical Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Characteristic</strong></td>
</tr>
<tr>
<td>---------------------</td>
</tr>
<tr>
<td><strong>Device attributes</strong></td>
</tr>
<tr>
<td>Size ≤360 cc</td>
</tr>
<tr>
<td>Round</td>
</tr>
<tr>
<td>Smooth</td>
</tr>
<tr>
<td><strong>Patient characteristics</strong></td>
</tr>
<tr>
<td>Age &gt;37 years</td>
</tr>
<tr>
<td>BMI ≤21</td>
</tr>
<tr>
<td><strong>Pocket irrigation</strong></td>
</tr>
<tr>
<td>Antibiotic</td>
</tr>
<tr>
<td>Betadine</td>
</tr>
<tr>
<td>Steroid</td>
</tr>
<tr>
<td><strong>Surgical characteristics</strong></td>
</tr>
<tr>
<td>General anasthesia</td>
</tr>
<tr>
<td><strong>Incision site</strong></td>
</tr>
<tr>
<td>Transaxillary</td>
</tr>
<tr>
<td>Periareolar</td>
</tr>
<tr>
<td>Inframammary</td>
</tr>
<tr>
<td><strong>Incision size</strong></td>
</tr>
<tr>
<td>0-3 cm</td>
</tr>
<tr>
<td>3-6 cm</td>
</tr>
<tr>
<td>6-9 cm</td>
</tr>
<tr>
<td><strong>Surgical indication</strong></td>
</tr>
<tr>
<td>Augmentation</td>
</tr>
<tr>
<td>Revision-Augmentation</td>
</tr>
<tr>
<td><strong>Device placement</strong></td>
</tr>
<tr>
<td>Subglandular</td>
</tr>
<tr>
<td>Submuscular</td>
</tr>
<tr>
<td><strong>Post-Surgical characteristics</strong></td>
</tr>
<tr>
<td>Surgical bra used</td>
</tr>
<tr>
<td>Prior capsular contracture</td>
</tr>
<tr>
<td>Massage recommended</td>
</tr>
</tbody>
</table>
complication. This highlights the need for further analysis/assessment as some of these factors are controllable via best surgical practices.

It is important to highlight that of the 43 ruptured devices only two were classified as symptomatic (“felt different” and pain). The remaining 41 ruptured devices were asymptomatic (95.3%) and include 10 devices (24.4%) that have not yet been explanted. The large number of asymptomatic patients in this sample corroborates studies on long-term untreated silicone implant rupture, which have found that implant rupture is rarely symptomatic.11,12 Although manufacturer’s guidance is to remove any device suspected of rupture, the surgeon’s clinical determination to explant an asymptomatic rupture is widely variable depending on patient preference with the consideration that implant rupture may be relatively harmless.12

Figure 5 depicts a patient’s MRI scan read as ruptured by both local and central radiologists, but confirmed non-ruptured at explant. The surgeon noted and removed free-floating silicone from the patients’ previous implant in the pocket, which led to the false positive read. The dependence on MRI diagnosis remains a paradoxical discussion because the high cost can be prohibitive to many breast implant patients.13,14 While the potential for false positive reads and MRI costs remain a consideration, MRIs are currently the most accurate diagnostic tool for silent rupture13,15,16 and are recommended by all U.S. manufacturers.7-9

Limitations

Interpretations of the results in this analysis should be considered with care due to sample size and study design limitations. Despite the large overall study population, the sample included very few ruptures and, therefore, the sample was not powered sufficiently to detect statistical differences. Regarding study design, this prospective cohort did not stratify to enroll specific surgical characteristic randomly or equally across surgeons. Therefore, only a small number of the implants in this analysis were placed with a transaxillary incision, and over 95% were placed by a single surgeon. This limitation causes results from analyses regarding the transaxillary incision site to possibly be biased due to the single surgeon. Regarding other possible biases introduced by specific surgeons, the authors
recognize that an impact analysis, excluding the three surgeons that accounted for over 50% of ruptures, may have been beneficial. However, the analysis was not performed due to the smaller rupture sample size that would have resulted from the exclusion. Lastly, while MRI scans are one of the best diagnostic tools for silent rupture, the variability in read interpretations as well as the small potential for false positives, may limit the conclusions of this analysis.

CONCLUSION

The occurrence of rupture is relatively uncommon but continues to concern both patients and plastic surgeons. Even with a very large sample size, the number of ruptures that occurred with the Sientra fifth generation devices was too low to detect statistically significant associations between factors and rupture. However, a strong trend for association with certain factors emerged. Lower rupture rates were seen with the utilization of textured devices, an inframammary approach, and subglandular placement. Future research is needed to help definitively determine characteristics that may affect implant rupture, however the results presented here provide visibility and demonstrate trends for the impacts that patient, device, and surgical characteristics play in the occurrence of rupture.

Disclosures

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REFERENCES