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.

**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...

**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.
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, 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.

In 2012, the Food and Drug Administration approved the Sientra portfolio of High-Strength Cohesive silicone gel implants including HSC+ shaped implants, 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. 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.

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

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.8 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.

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 mamorpexy 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 surgery, 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 sub-muscular approach is the technique of choice and sub-glandular 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 overinflate 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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