

Silicone Gel Breast Implants: Science and Testing

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Background: Since the first generation of breast implants, major design innovations, including consistency of the gel, palpability and thickness of the shell, and barrier materials in the shell, have been introduced. Surgeons have not had metrics to assess and compare available implants.

Methods: Research at independent laboratories included 4 tests: gel elasticity (the gel's ability to retain its shape), gel compression fracture (the resistance to permanent gel deformation), gel-shell peel (the integration of the gel with shell as a cohesive unit), and morphological analysis.

Results: Sientra's round High-Strength Cohesive (HSC) experienced the least gel elasticity (5.805 mm), whereas Allergan's round implants experienced the most (7.465 mm). Among shaped implants, Allergan 410 experienced the least gel elasticity (3.242 mm), whereas the Sientra HSC+ implant experienced the most (4.270 mm). Sientra's round (36.32 lbf) and shaped (44.16 lbf) implants demonstrated the highest resistance to gel fracture, with Allergan's implants demonstrating the least among round (23.06 lbf) implants and Mentor Contour Profile Gel (CPG) among shaped (30.45 lbf) implants. For the gel-shell peel test, Sientra's implant required over 26% greater force than Allergan's implant and over 35% greater force than Mentor's implant. Sientra's shaped implants required more than double the peel force than Allergan 410 (119% greater) and Mentor CPG (130% greater). Morphological results showed Sientra's implants preserved structural integrity (-1.10% change).

Conclusions: The initial findings show that these implant characteristics are individual factors to be considered separately and are not necessarily correlative. Further study of implants using these and other testing techniques will help clinicians choose between implants. (*Plast. Reconstr. Surg.* 134: 47S, 2014.)

Before 1963, implants of any type were rarely used to augment the breast. Cronin and Gerow introduced a first-generation breast implant, and since these were brought to market, many iterations of the original product have been developed.¹ From January 1992 to November 2006, the use of silicone implants was highly restricted and not available to first-time and non-reconstructive patients.² Major design innovations have addressed clinical challenges from previous generations—natural feel and softness of the gel, palpability and thickness of the shell, barrier

materials in the shell reducing gel diffusion, and creation of textured surfaces, to name a few.

The current “shaped” devices, commonly deemed fifth generation, have increased structural stability and cohesion of the gel to retain a teardrop shape in vivo.³ Two design features, silicone gel filler and a silicone elastomer shell, have survived generational variations and remain the core components of current Food and Drug Administration–approved implants. Thus, the material testing of these devices has remained consistent, with slow evolution of specifications in concert with adjustments in materials. Biocompatibility, validated designs, and mechanical integrity are required under current Food and Drug Administration and

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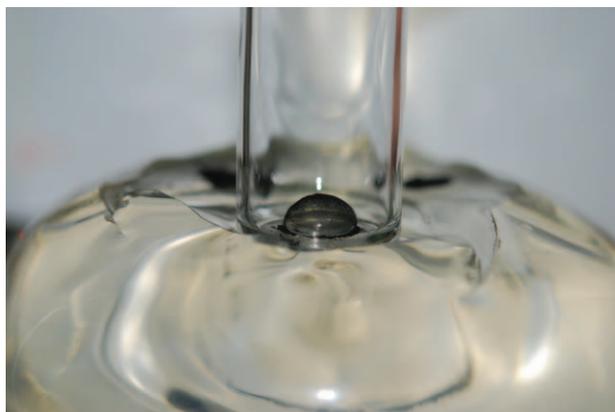


Fig. 1. Implant gel under vacuum pressure in BTC-2000 test chamber.

international standards in the preclinical phase before premarket approval. Additionally, extensive clinical studies are required of manufacturers to verify the safety and effectiveness of devices before approval and in the largest post-approval studies ever required by the Food and Drug Administration.

In the quest for optimal results, surgeons try to determine how to compare the various implants, whether it is comparing different products offered by a single company or implants designed by competing companies. Areas of interest include the cohesiveness of the gel, texturing of the surface, and the relative merits of round, oval, or teardrop shapes. However, the current standards and guidelines that govern the parameters of preclinical and clinical studies, which include ASTM F 703 07 and others,⁴⁻⁶ do not address surgeons' questions about these differentiating factors. Recently, the 3 major implant manufacturers in the United States, who have met Food and Drug Administration standards and received approval to market their implants, have initiated postapproval and retrieval studies to evaluate the performance of their products.⁷⁻⁹ The primary emphasis of these studies relates to the safety and clinical effectiveness of the implants.

Although this research is valuable, it does not address all of the questions that surgeons and patients have about the plethora of implant styles available to them.

Sientra has addressed many of these unanswered questions by conducting independent testing to scientifically compare devices offered by the 3 approved manufacturers. New and modified methodologies were developed and implemented, which help evaluate intact, sterilized implants. This testing not only addresses the primary components of the implant, the gel, and the shell but also considers their collective properties as a finished device in a clinical setting. This approach seeks to assist surgeons to better characterize how implants perform in a clinical setting to aid surgeons in selecting the implants that best serve specific needs of individual patients.

Tests employed, modified, or developed include gel deformation testing to measure the gel's ability to retain its shape, gel compression fracture testing to measure the resistance to permanent gel deformation, gel-shell peel testing to measure the integration of the gel with shell as a cohesive unit, and morphological analysis of shaped implants. The development of these tests and the results for various implant types are presented here.

METHODS

Gel Elasticity Testing

Gel elasticity testing quantifies the ability of the gel to retain its shape under force—that is, firmness versus softness. The BTC-2000 System (SRLI Technologies, Nashville, Tenn.) was employed to test the ability of a gel to retain shape under load. This well-described system for mechanical characterization of skin, connective tissue, and biological implants incorporates analysis of stress-strain relationships of viscoelastic materials such as silicone gel polymers. Based on 20-year-old research^{10,11} originally designed to evaluate the implant shell,

Table 1. Implants Analyzed in Gel Deformation Testing

Manufacturer	Type of Implant	Model	cc
Round			
Sientra	Silicone gel breast implant	Smooth Round Moderate Profile	380
Mentor	Silicone gel breast implant	Smooth Round Moderate Plus Profile	375
Allergan	Silicone gel breast implant	Smooth Round Midrange Profile	339, 371, 397
Shaped			
Sientra	Silicone gel breast implant HSC+	Oval Base Moderate Profile	330
Mentor	CPG 321 gel breast implant	Medium Height, Moderate Profile	315
Allergan	Natrelle 410	MM	320

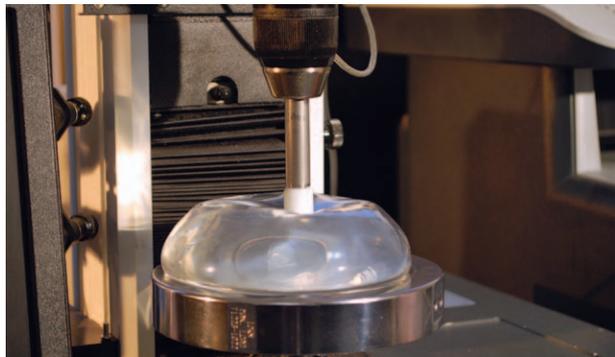


Fig. 2. Compression fracture setup comprised a penetrometer foot and a compression platen.

it tests the ability of the gel in round and shaped implants to retain shape under load. The basic principle is to place a portion of the implant gel under negative pressure inside a cylindrical chamber and measure the deformation of the gel with a laser.

A 1-cm circle of implant shell is removed from the apex of the implant, and the gel is dusted with laser toner to enhance laser tracking of the surface. A cylindrical BTC test chamber is lowered onto the surface with 5 g of force applied to create a vacuum (Fig. 1). Negative pressure of 1 millimeter of mercury (mm Hg) per second is applied until 15 mm Hg is reached. Deformation (mm) and pressure (mm Hg) readings are collected. The resulting value “elastic deformation” is defined as the amount of deformation measured up to the point of maximum negative pressure, which represents the elastic response to the applied pressure. Higher values represent “softness,” and lower deformation represents “firmness.”

Devices tested were Sientra (High-Strength Cohesive [HSC] and HSC+), Mentor (Memory-Gel and Contour Profile Gel [CPG]), and Allergan (Natrele and 410) as shown in Table 1. Eight implants from each company of each type, round and shaped, at similar volumes, were tested 3 times each, totaling 24 tests for round and 24 tests for shaped devices.

Table 2. Implants Analyzed in Gel Compression Fracture Testing

Manufacturer	Type of Implant	Model	cc
Round			
Sientra	Silicone gel breast implant	Smooth Round Moderate Profile	380
Mentor	Silicone gel breast implant	Smooth Round Moderate Plus Profile	375
Allergan	Silicone gel breast implant	Smooth Round Midrange Profile	371
Shaped			
Sientra	Silicone gel breast implant HSC+	Oval Base Moderate Profile	330
Mentor	CPG 321 gel breast implant	Medium Height, Moderate Profile	315
Allergan	Natrele 410	MM	320

Table 3. Gel-Shell Peel Testing Definitions

Term	Definition
Gel/shell failure	The elastomer shell membrane peels away from gel. Integration of the shell to gel fails
Sustained gel/shell integration	Integration of shell and gel is intact; thus, the disruption is at the gel level. After separation, gel coats the entire surface of the shell
Mixed gel/shell failure and integration	A combination of gel/shell failure and gel/shell integration is found in the same sample

Gel Compression Fracture Testing

Gel compression fracture testing measures the strength of the implant to quantify forces it can withstand before permanent deformity. The gel fracture testing method used employs an Instron 3345 tensiometer device equipped with a 15-mm-diameter penetrometer with a 500 N load cell (Fig. 2).

Compression is applied at 1"/min. Compression force applied against the gel is measured until a drop in force signifies the point of gel fracture. Greater compression force suggests increased resistance to gel fracture.

Three implants each in the following categories were tested 5 times for each lot number, 90 in total (Table 2).

Shell-Gel Peel Testing

To understand the bond between the gel and the shell, a new test was developed. The strength of the adhesion of the cohesive gel to the shell represents an evolved method of evaluating implant performance. The method employs an Instron 3345 tensiometer equipped with a 15-mm-diameter penetrometer foot and 500 N load cell. Lines are drawn 1" apart on the shell with a permanent marker, and a razor blade is used to cut along the lines drawn on the implant. The test sample is placed on the compression plate, and 1" of the elastomer shell membrane is peeled away from the gel. The free end of the shell is clamped into the grips of the tensile tester and adjusted to uniformly distribute over



Fig. 3. Images of 3 types of peel test failures: gel/shell failure (*above*), gel/shell integration (*center*), and mixed gel/shell failure and integration (*below*).

the cross section of the specimen. The load is set to zero, and the elastomer shell is pulled at a rate of 20"/min. The maximum force applied to separate the shell from the gel is measured. Triplicate measurements are recorded to obtain an average value. The terms for gel-shell peel testing are defined in Table 3 and depicted in Figure 3.

Table 4. Morphological Analysis Definitions

Term	Definition
Point of maximal projection	Point along short axis where the most projecting point of the implant is found, expressed as a percentage of total vertical length
Upper-pole dimension	Portion of lateral profile extending outward from the line drawn from the outer radius of the implant to the point of maximal projection. This is expressed as a percentage of the total cross-sectional area of the lateral profile

Table 5. Shaped Implants Analyzed in Morphological Testing

Sientra HSC+ Round Base 425 cc
Sientra HSC+ Classic Base 400 cc
Allergan Style 410 MF 375 cc
Allergan Style 410 FF 425 cc

Morphological Analysis of Shaped Silicone Gel Implants

Morphological analysis analyzes how the implant acts as a whole unit in the body. The reference standard for morphological analysis was originally developed for tissue-expander shape using a biomechanical model.¹²⁻¹⁴ The 1993 article has been adapted for evaluation of current-generation gel implants when oriented in the horizontal and vertical planes analogous to the supine and upright breast (Table 4). This test was designed to be conducted on expanders; however, claims of stability in the shape of the implants, especially in the upper poles, leave this as an area of interest lacking objective data for silicone breast implants. The rationale is to apply forces on a device to simulate clinical conditions and evaluate shape and shift of the device when the patient moves from a supine to upright position.

Changes in upper-pole dimension between the horizontal and vertical positions indicate movement of gel material within the implant, generally in the caudad direction with gravity. In this series, upper-pole dimension change from horizontal to vertical is described as a percentage decrease in area. Sientra's and Allergan's textured shaped implants (Table 5) were analyzed.

RESULTS

Gel Elasticity of Round and Shaped Implants

With the round implants tested, the Sientra devices experienced the least gel elasticity, whereas the Allergan midrange profile implants experienced the highest elasticity (Fig. 4). Statistically

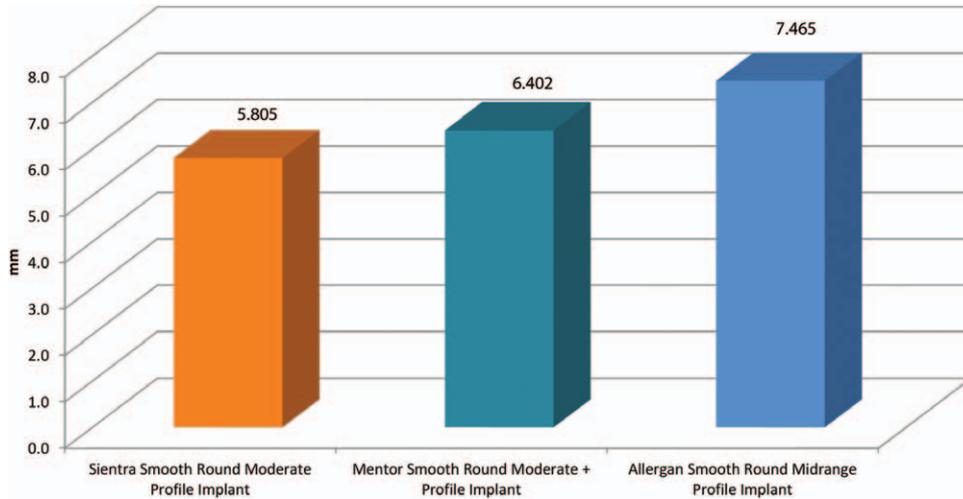


Fig. 4. Gel elastic stretch in round implants. The higher the elastic stretch, the softer the implant ($N=8$).

significant differences were noted in comparison of all round implant study groups. In the shaped category, Allergan Style 410 MM experienced the least gel elasticity, whereas the Sientra shaped oval-base, moderate-profile implant experienced the most (Fig. 5). Statistical significance was observed for Sientra’s shaped implant in comparison to Allergan’s and Mentor’s shaped implants. No statistical significance was found between Allergan’s and Mentor’s shaped implants.

Gel Compression Fracture of Implants

With the round implants tested, Sientra implants demonstrated the highest resistance to gel compression fracture, with the Allergan mid-range profile demonstrating the least resistance (Fig. 6). In the shaped category, Mentor CPG demonstrated the least resistance, whereas the Sientra

shaped oval-base, moderate-profile implant demonstrated the highest resistance (Fig. 7).

Gel-Shell Peel Testing

Results of the gel-shell peel testing show that the force needed for separation was higher for Sientra implants than for the other manufacturers. When the adherence between the gels could not be disrupted, the implant behaved more like a single unit and required much more force to disrupt (Fig. 8). When integration/adherence was poor between the shell and the gel such as in Mentor CPG, the force required was much less, resulting in delamination (Fig. 9), and thus the shell and the gel were found to behave as independent entities.

Among the round implants tested, the Sientra implant had over 26% greater peel force than the

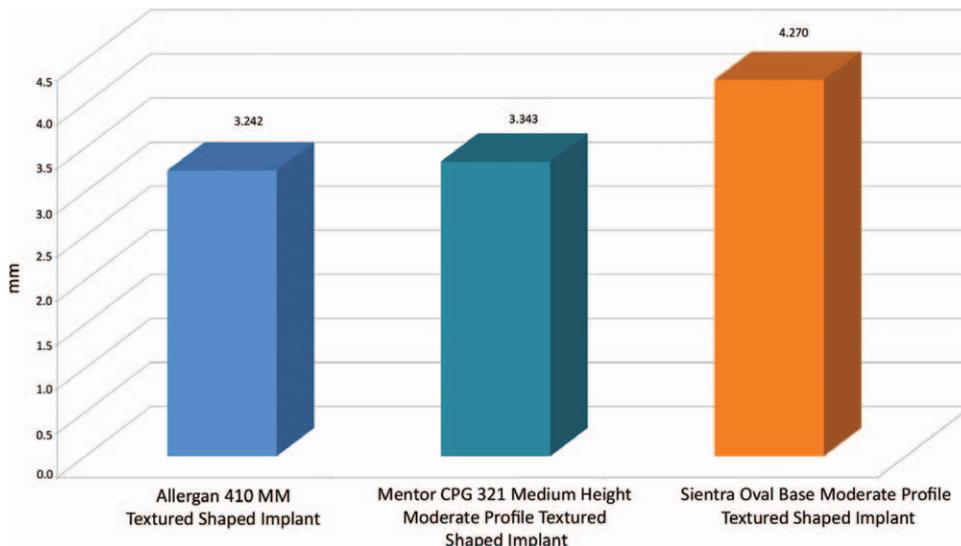


Fig. 5. Gel elastic stretch in shaped implants. The higher the stretch, the softer the implant ($N=8$).

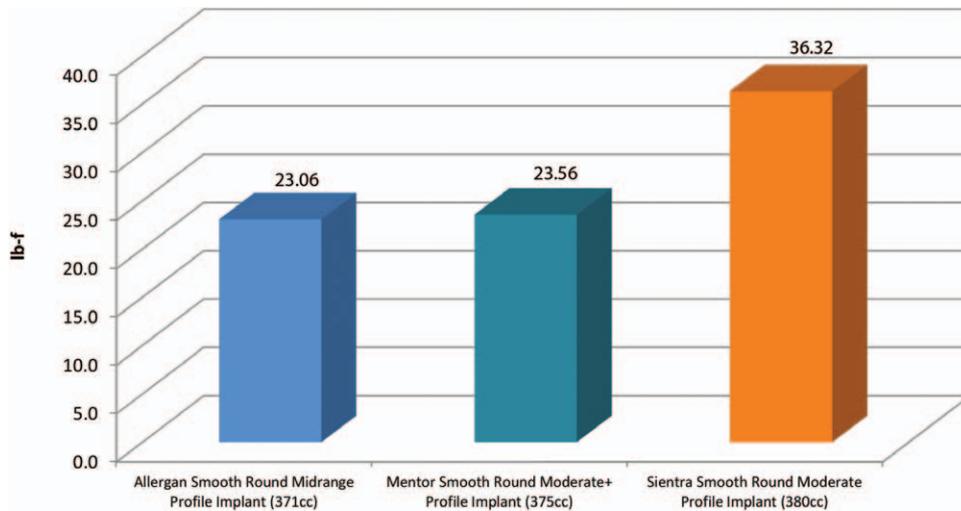


Fig. 6. Gel compression fracture of smooth round implants. The higher the force needed to fracture the gel, the stronger the gel.

Allergan implant and over 35% greater peel force than the Mentor implant (Fig. 10).

Likewise, with the shaped implants tested, the Sientra HSC+ implants have more than double (119% greater) the peel force than Allergan 410 and double (130% greater) the peel force than Mentor CPG (Fig. 11).

Morphological Analysis of Textured Shaped Silicone Gel Implants

Within the shaped implants, upper-pole dimension and structural integrity are better preserved in the Sientra implants than in the Allergan implants when moved from a horizontal position to a vertical position (Table 6 and Figs. 12 and 13). Test results for the Mentor CPG implants are

unavailable as they were not approved at the time of testing.

DISCUSSION

Clinically, the perfect implant (1) would be a strong but soft implant that resists both rupture and gel fracture, (2) has a balanced cohesiveness to allow the implant to maintain shape, and (3) functions as a cohesive unit with the breast, and thus is not palpable or visible to either the patient or the surgeon. In the search for the ideal breast implant, the ability to objectively measure and quantify material properties of breast implant materials assists surgeons in evaluating clinical outcomes¹⁵⁻¹⁹ and gives patients the opportunity to place context around the subjective results they experience.

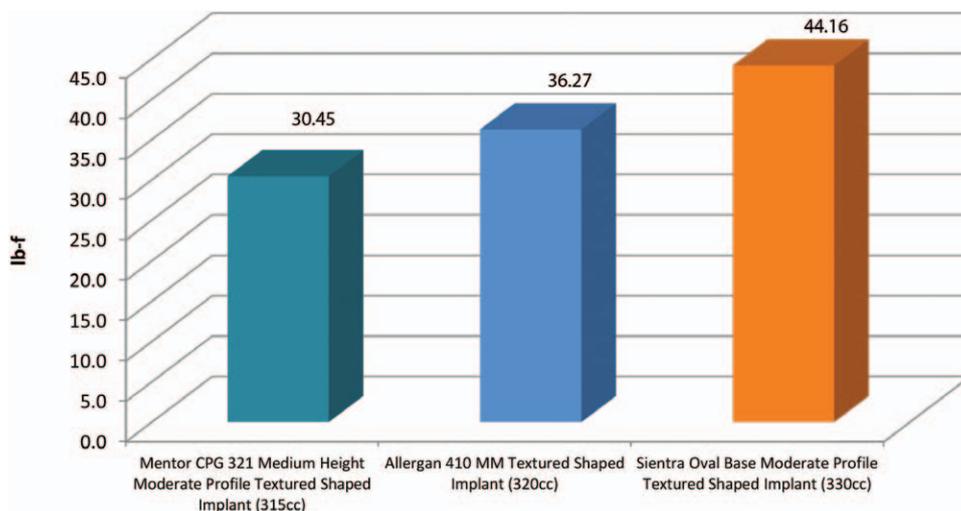


Fig. 7. Gel compression fracture of textured shaped implants. The higher the force needed to fracture the gel, the stronger the gel.

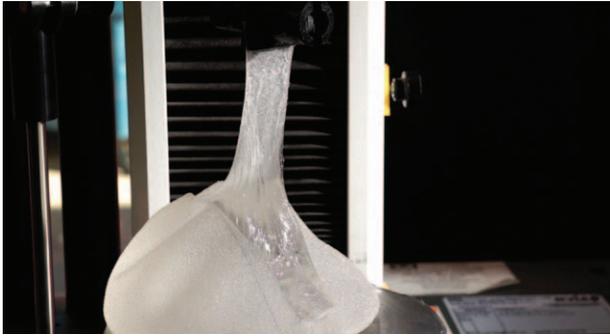


Fig. 8. Gel-shell integration of the Sientra HSC+ RB.



Fig. 9. Gel/shell failure of the Mentor CPG.

Gel Elasticity Test—Softness

Gel elasticity testing quantifies the ability of the gel to retain its shape under force—that is, firmness versus softness. Clinically, this may translate into less implant palpability by the patient. Not surprisingly, all round implants score softer than shaped implants, as evidenced in higher

elastic deformation testing. Shaped implants require more cohesion to help maintain implant shape in vivo and are designed accordingly with more resistance to tensile forces. In the round implant group, Sientra HSC round was the firmest compared with Allergan Natrelle, which was the softest. In the shaped implant group, the Sientra oval base was the softest followed by Mentor CPG, and the Allergan Style 410 MM gel was the firmest of the 3 shaped devices.

Gel Compressive Fracture Tests—Strength

Gel compressive fracture testing quantifies the force an implant gel can sustain without permanent deformity—that is, the strength of the implant. It correlates to structural integrity, gel cohesion, and shell/gel adhesion, all desirable qualities in a modern gel implant. Because the structural integrity and the shape of firmer gels can be irreversibly misshapened under twisting and compression forces during and after implantation, it is important to have a predictive test that allows surgeons to know the resilience of implants under compressive load for reference. In this study, Sientra’s smooth round and shaped textured implants are more resistant to compressive force—that is, stronger—than the implants of the other 2 companies, whether textured or smooth. Because of increased cross-link density, gel cohesion, gel-shell integration, or a combination of these factors, the fracture test showed that shaped implants are more resistant than standard round implants for each company’s devices.

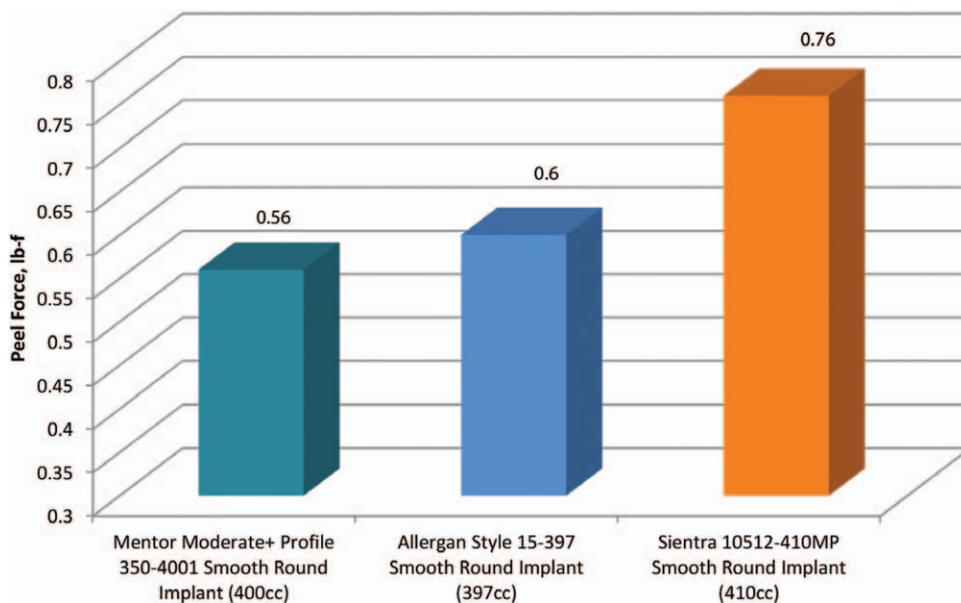


Fig. 10. Results of round implant gel-shell peel testing. The greater the force required, the greater the integration between shell and gel.

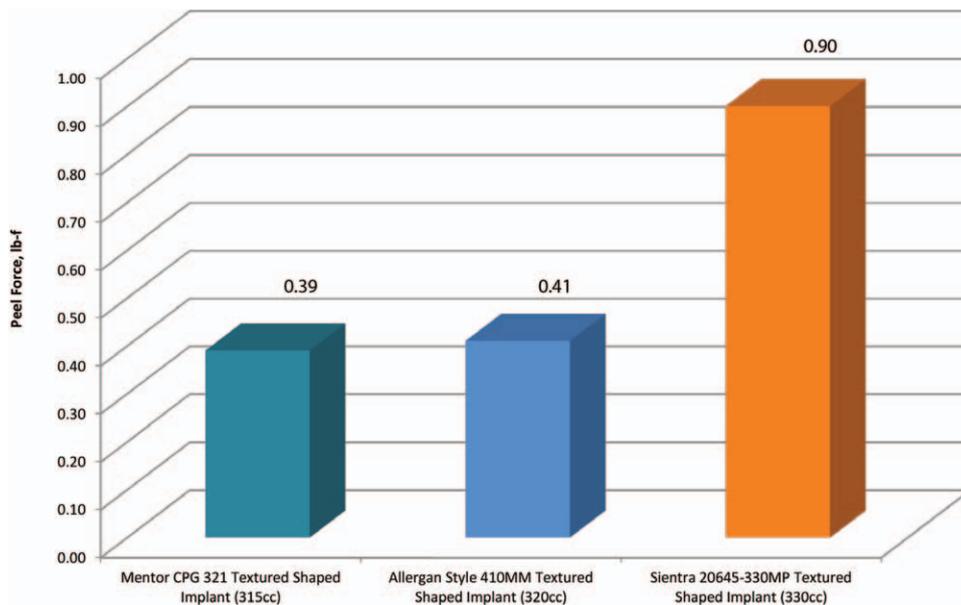


Fig. 11. Results of shaped implant gel-shell peel testing. The greater the force required, the greater the integration between shell and gel.

Interestingly, the gel elasticity and gel compression fracture test results were not inversely related as one might think—that is, softness did not necessarily correlate with decreased strength. This indicates that gel compressive fracture and gel elasticity tests are independent characteristics and may be helpful to the clinician in choosing an implant.

Shell-Gel Peel Testing—Integration

The gel-shell peel testing measures the integration of the gel with the shell. The test showed integration both quantitatively (force needed for disruption) and qualitatively (coating of gel on the shell after disruption). The nature of the adhesion may contribute to the implants’ delamination or failure in vivo and its characteristics within the patient as a unit as opposed to separate components. Sientra’s gel-shell interaction is reported to be more integrated than that of other companies’ devices, an important consideration when understanding implant mechanics. The gel does not act as just “filler” but instead supports the shell and creates a 2-component firm, but elastic implant designed to act as an integral unit with

the goal of mimicking motions seen by clinicians in the breast.

Morphological Analysis of Implants—Shape Retention

A morphological analysis analyzes how the implant acts as a whole unit in the body. Change in the upper pole indicates shifting of the gel that simulates the implant in the body. This test was previously described by Hammond, Perry, Maxwell, and Fisher in 1993. These tests show that Sientra HSC+ implants maintain the shape in the upper pole without downward migration into the lower poles as well or better than the other implants tested. It seems that the shape of the implant itself also affected the percentage shift in gel—that is, round base versus classic base; moderate height, full projection versus full height, full projection. Further studies may indicate optimal implant shape for shape retention. Again, interestingly, since Sientra’s shaped implants had the most shape retention while having higher softness and least gel fracturing, it seems that shape retention testing did not necessarily correlate with gel softness, or gel strength, showing that this is

Table 6. Morphological Analysis of Textured Implants

	Sientra HSC+ Round Base 425 cc	Sientra HSC+ Classic Base 400 cc	Allergan MF 375 cc	Allergan FF 425 cc
Horizontal UPD (%)	14.77	15.95	17.10	18.74
Vertical UPD (%)	14.61	15.39	16.42	17.40
Change (%)	-1.10	-3.57	-3.98	-7.15

UPD, upper-pole dimension.

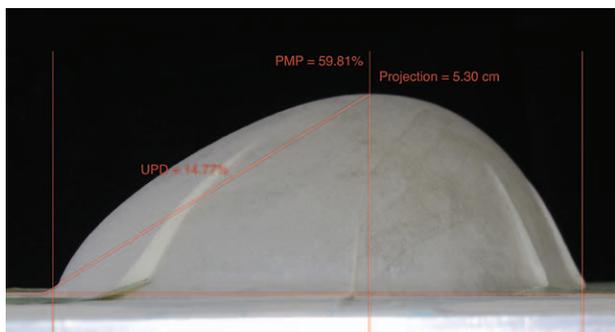


Fig. 12. Sientra HSC+ Round Base HP 425-cc implant in horizontal orientation. PMP, point of maximal projection; UPD, upper-pole dimension.

another separate characteristic to be considered in choosing an implant and that one does not necessarily need to be sacrificed proportionately for the other characteristics.

SUMMARY

Until recently, most surgeons chose implants solely on base diameter, volume, and projection. There was no definitive evidence that a specific brand held any significant advantage in outcomes or characteristics. Within the last several years,

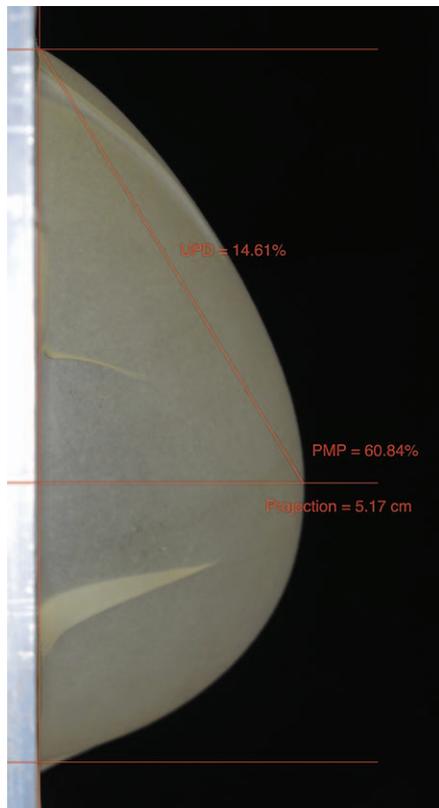


Fig. 13. Sientra HSC+ Round Base HP 425-cc implant in vertical orientation. PMP, point of maximal projection; UPD, upper-pole dimension.

not only were new shapes introduced, but new types of cohesive silicone and new texturing have emerged. Although each company positioned its product to be superior, clinicians had no objective measure in which to evaluate implants and their relevance to behavior in vivo. Confusion existed between whether it was better for the implant to be firmer or softer, with implications being that firmness was linked to strength and shape retention and thus one must sacrifice feel for strength and shape.

This article presents 4 tests that quantify characteristics of implants that are relevant to clinicians trying to choose between implants: softness (gel elasticity), strength (gel compressive fracture), integration (gel-shell peel), and shape retention (morphological analysis of shaped implants). The initial findings show that these characteristics are each factors to be considered separately and are not necessarily correlative—that is, an implant can be both softer than others, stronger than others, and hold shape better than others at the same time. Shell integration may play a role in failure and implant behavior, which has not previously been studied and requires further investigation. Further study of implants using these testing techniques will help clinicians choose between current and future implants based on quantifiable data and not solely on marketing conjecture.

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