

Style 410 Highly Cohesive Silicone Breast Implant Core Study Results at 3 Years

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Background: In February of 2001, Allergan (formerly Inamed) began an Investigational Device Exemption study of a shaped breast implant: the Style 410 highly cohesive silicone-filled breast implant.

Methods: Forty-eight plastic surgeons across the United States performed implantation on 941 subjects enrolled in a 10-year study. This prospective, non-randomized study provided 3-year follow-up data, clinical outcomes, and satisfaction rates from this cohort of 492 primary augmentation, 225 breast reconstruction, and 224 breast revision subjects. Complications were reported and compared with those from current standard gel and saline implant studies.

Results: With greater than 85 percent follow-up compliance at 3 years, complication rates were low among augmentation subjects, with implant malposition being the most common (2.6 percent) and all other complications occurring in less than 2 percent of subjects. In the revision-augmentation group, the most common complications were capsular contracture (4.8 percent) and implant malposition (4.7 percent), with all other complications occurring in less than 4 percent. Asymmetry (8.7 percent) and capsular contracture (5.9 percent) were the only complications that occurred in more than 5 percent of reconstruction subjects. The overall risk of rupture across all cohorts was 1.0 percent by subject and 0.8 percent by implant. Subject satisfaction with implants was 98 percent for augmentation and 90 percent or higher for all other cohorts.

Conclusions: The Style 410 highly cohesive silicone implant has low complication rates and high satisfaction rates through 3 years after implantation. These results are significant in introducing more evidence-based medicine that will allow plastic surgeons and patients to make better informed decisions regarding implant options. (*Plast. Reconstr. Surg.* 120 (Suppl. 1): 40S, 2007.)

The Inamed Style 410 breast implant marketed in Europe since 1993 contains a highly cohesive silicone gel filler. A prospective study was begun in February of 2001 to support a premarket approval application. The 3-year data contained in this article documents the clinical outcomes from the use of the Inamed Style 410 highly cohesive silicone breast implant in an Investigational Device Exemption study. In particular, the results of this study are important in bringing forth more evidence-based medicine, to allow women to make better informed decisions regarding their implant options in primary breast augmentation, breast reconstruction, and breast revision surgery.

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SUBJECTS AND METHODS

Study Design

To support a premarket approval application for Style 410 highly cohesive silicone breast implants in the United States and a medical device licensing application in Canada, a prospective, multicenter study is currently being conducted to investigate the safety and effectiveness of these devices. The devices included in the study are Style 410 implants with full or moderate height and projection (styles FM, FF,

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MM, and MF). This pivotal study involves a total of 941 subjects (50 percent augmentation, 25 percent reconstruction, and 25 percent revision) with follow-up intervals at 0 to 4 weeks, 6 months, 1 year, and annually through 10 years. In addition to the annual office visits, approximately one-third of subjects receive silent rupture screening by means of magnetic resonance imaging at 1, 3, 5, 7, and 9 years after implantation. This article reports data collected through the first 3 years of the study.

All investigational sites were required to have surgeons certified by the American Board of Plastic Surgery with experience placing silicone-filled implants. Because the Style 410 is a shaped implant, investigational sites were recruited on the basis of experience specifically with shaped (non-round) breast implants. Informed consent was obtained from all subjects, as was approval from the relevant institutional review boards.

Local complications, reoperations, and implant removals were documented and gauged as the primary safety measurements. Effectiveness measurements included investigator and subject satisfaction with the implants, quality of life, and breast size change. Quality-of-life results will be reserved for future articles because of space constraints (see **Table, Supplemental Digital Content 1**, which displays the complete Style 410 Study Investigator List, <http://links.lww.com/A203>).

Subjects

The inclusion criteria for subjects were female sex, age 18 years or older, adequate tissue to cover the implants, and willingness to follow all study requirements. Exclusion criteria were advanced fibrocystic disease considered to be premalignant without accompanying subcutaneous mastectomy; breast cancer without mastectomy; abscess or infection at the time of enrollment; pregnant or nursing; any disease including uncontrolled diabetes (hemoglobin A1c >8 percent) that impacts wound-healing ability; tissue characteristics that are clinically incompatible with mammoplasty, such as tissue damage resulting from irradiation,

inadequate tissue, compromised vascularity, or ulceration; any condition that constitutes an unwarranted surgical risk (e.g., unstable cardiac or pulmonary problems); psychological characteristics that may be incompatible with the surgical procedure and the prosthesis, such as inappropriate attitude or motivation (e.g., body dysmorphic disorder); and unwillingness to undergo further surgery for revision if medically required.

Based on the indication for implantation, subjects were classified into one of three cohorts as follows: augmentation (subject dissatisfaction with breast size or shape, asymmetry, ptosis, aplasia), reconstruction (for the affected breast, mastectomy for cancer or trauma, or prophylactic mastectomy; for the unaffected breast, contralateral asymmetry), and revision (previous augmentation or reconstruction with silicone-filled or saline-filled breast implants). No prior breast implants were allowed for subjects in the augmentation or reconstruction cohorts.

Statistical Analyses

Investigators used standardized case report forms to collect data prospectively before implantation and at scheduled follow-up visits and at unscheduled office visits. Complications were reported by means of check boxes for 38 possible complications including “other” and included ranking the severity on a five-point scale. The complications with *very mild* or *mild* severities or Baker grade I or II for capsular contracture were not considered to be clinically significant problems and thus were not included in the analysis. All reported occurrences of implant rupture, implant extrusion, gel fracture, and pneumothorax are included in the analysis regardless of the severity rating.

For silent rupture screening results, the magnetic resonance imaging films were reviewed by both a central reviewer radiologist and a radiologist at the screening facility, with data analysis based on the worst case rupture status reported by either reviewer. Neither reviewer was aware of the other’s evaluation or of any suspicion of rupture identified by clinical examination. Magnetic resonance imaging results were classified as either evidence of rupture, no evidence of rupture, or indeterminate or unreadable film (because of inadequate views or flawed film).

To determine the effect of implantation on breast size for augmentation subjects, lateral breast measurements and bra size information were collected at baseline and at 6 months after implantation. If a valid measurement was not obtained at 6 months, the 1 year measurement was used for anal-

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ysis. At each follow-up visit, subjects and physicians provided ratings of implant satisfaction using a five-point scale.

Safety and breast size analyses included only the data on original devices implanted at baseline. Satisfaction analyses included both original and replacement devices because having an implant replaced could have an impact on satisfaction. Rupture rate analyses were based on the implants undergoing serial magnetic resonance imaging screening to capture both silent and symptomatic ruptures. Kaplan-Meier survivorship was the primary analysis method for the safety data, and frequency distributions were used for satisfaction data and reasons for reoperation and explantation. Descriptive statistics and a paired *t* test were used for breast size change results.

RESULTS

Subjects and Surgical Characteristics

Subjects were recruited through 48 investigational sites across the United States, with enrollment completed between February of 2001 and February of 2002. A total of 941 subjects were enrolled: 492 augmentation subjects, 225 reconstruction subjects, and 224 revision subjects (later stratified as 156 revision-augmentation subjects and 68 revision-reconstruction subjects at the request of the U.S. Food and Drug Administration).

Demographic data revealed that most subjects were Caucasian, married, and attended college

(Table 1). Median age was 36 years for augmentation subjects, 44 years for revision-augmentation subjects, 48 years for reconstruction subjects, and 52 years for revision-reconstruction subjects. The majority of subjects were implanted with full-height Style 410 devices placed in a partial or complete submuscular position (Table 2). The most commonly used implant was full height/moderate projection (FM), 310 g, for augmentation subjects and full height/full projection (FF), 475 g, for the other cohorts. The incision site was most frequently inframammary for augmentation and revision-augmentation subjects versus a mastectomy scar incision for reconstruction and revision-reconstruction subjects. General anesthesia was used predominantly, with surgical facilities used for the majority of augmentation and revision-augmentation procedures and hospitals for reconstruction and revision-reconstruction procedures.

Subject compliance with the follow-up schedule was excellent through the first 3 years of the study completed. Of those subjects expected to be seen at the 3-year visit, excluding the less than 4 percent who discontinued because of explantation or death, compliance rates were 87 percent for augmentation, 85 percent for revision-augmentation, 89 percent for reconstruction, and 92 percent for revision-reconstruction. Follow-up rates for the year-3 serial magnetic resonance imaging were 84 percent for augmentation, 82 percent for revision-

Table 1. Demographic Data

Demographic	Augmentation (%)	Revision-Augmentation (%)	Reconstruction (%)	Revision-Reconstruction (%)
No. of subjects	492	156	225	68
Median age, years	36	44	48	52
Age range, years	18–60	22–66	18–80	24–72
Race				
Caucasian	448 (91.1)	148 (94.9)	204 (90.7)	64 (94.1)
African American	4 (0.8)	1 (0.6)	9 (4.0)	0
Asian	15 (3.0)	0	7 (3.1)	0
Hispanic	20 (4.1)	4 (2.6)	1 (0.4)	3 (4.4)
Other	8 (1.6)	1 (0.6)	2 (0.9)	1 (1.5)
Not provided	0	2 (1.3)	2 (0.9)	0
Marital status				
Single	95 (19.3)	10 (6.4)	17 (7.6)	2 (2.9)
Married	294 (59.8)	108 (69.2)	161 (71.6)	50 (73.5)
Widowed	5 (1.0)	5 (3.2)	11 (4.9)	1 (1.5)
Separated	12 (2.4)	4 (2.6)	4 (1.8)	0
Divorced	86 (17.5)	29 (18.6)	32 (14.2)	15 (22.1)
Education				
Less than high school	4 (0.8)	0	2 (0.9)	1 (1.5)
High school graduate	86 (17.5)	30 (19.2)	38 (16.9)	9 (13.2)
Some college	172 (35.0)	55 (35.3)	68 (30.2)	21 (30.9)
College graduate	173 (35.2)	50 (32.1)	80 (35.6)	21 (30.9)
Postgraduate	57 (11.6)	21 (13.5)	36 (16.0)	16 (23.5)
Not provided	0	0	1 (0.4)	0

Table 2. Device and Surgical Characteristics

Characteristic	Augmentation (%)	Revision-Augmentation (%)	Reconstruction (%)	Revision-Reconstruction (%)
Device characteristics				
No. of devices	983	310	351	112
Product style				
Full height/moderate projection	485 (49.3)	97 (31.3)	83 (23.6)	10 (8.9)
Full height/full projection	215 (21.9)	115 (37.1)	141 (40.2)	70 (62.5)
Moderate height/moderate projection	215 (21.9)	71 (22.9)	52 (14.8)	12 (10.7)
Moderate height/full projection	68 (6.9)	27 (8.7)	75 (21.4)	20 (17.9)
Incision site				
Periareolar	120 (12.2)	48 (15.5)	16 (4.6)	3 (2.7)
Inframammary	853 (86.8)	234 (75.5)	73 (20.8)	47 (42.0)
Mastectomy scar	0	16 (5.2)	262 (74.6)	60 (53.6)
Axillary	4 (0.4)	0	0	0
Breast scar	0	4 (1.3)	0	0
Mastopexy incision	6 (0.6)	8 (2.6)	0	1 (0.9)
Other	0	0	0	1 (0.9)
Implant location				
Subcutaneous	0	0	0	2 (1.8)
Subglandular	154 (15.7)	88 (28.4)	1 (0.3)	3 (2.7)
Submuscular (partial or complete)	829 (84.3)	222 (71.6)	307 (87.5)	103 (92.0)
Subtissue flap	0	0	43 (12.3)	4 (3.6)
Surgical characteristics				
No. of subjects	492	156	225	68
Anesthesia				
General	403 (81.9)	135 (86.5)	224 (99.6)	63 (92.6)
Local	89 (18.1)	21 (13.5)	1 (0.4)	5 (7.4)
Surgical facility				
Physician's office	138 (28.0)	33 (21.2)	0	4 (5.9)
Hospital	120 (24.4)	40 (25.6)	144 (64.0)	33 (48.5)
Freestanding surgical facility	234 (47.6)	83 (53.2)	83 (36.9)	31 (45.6)

augmentation, 87 percent for reconstruction, and 100 percent for revision-reconstruction.

Safety

Complication rates were low among augmentation subjects, with implant malposition the most common at 2.6 percent and all other complications occurring in less than 2 percent of subjects (Table 3). The Baker grade III and IV capsular contracture rate was 1.9 percent in the augmentation cohort. For revision-augmentation subjects, the most common local complications were capsular contracture (4.8 percent) and implant malposition (4.7 percent), with all other complications constituting less than 4 percent. Asymmetry (8.7 percent) and capsular contracture (5.9 percent) were the only complications above 5 percent for reconstruction subjects and were two of the three complications, at 7.7 percent and 6.1 percent, respectively, along with wrinkling/rippling (7.7 percent), in excess of 5 percent for revision-reconstruction subjects. The overall risk of suspected or confirmed rupture across all cohorts was 1.0 percent by subject and 0.8 percent by implant.

Aside from local complications, the other key safety endpoints are the reoperation and explantation rates. The risk of reoperation ranged from 12.5 percent for augmentation subjects to 31.8 percent for reconstruction, with the two revision cohorts falling squarely in the middle of the range at 21.1 percent (revision-augmentation) and 19.8 percent (revision-reconstruction). Approximately 80 percent of subjects underwent only one reoperation. The primary reason for reoperation was implant malposition for augmentation subjects, scarring for revision-augmentation and reconstruction subjects, and capsular contracture for revision-reconstruction subjects (Table 4).

More than half of the augmentation subjects having their implants removed did so to change the size or style. This was also the most common reason for explantation among reconstruction and revision-reconstruction subjects. Capsular contracture was the most common reason for explantation in revision-augmentation subjects and was tied with size and style change as the primary reason that revision-reconstruction subjects underwent explantation.

Table 3. Kaplan-Meier Key Risk Rates* by Patient through 3 Yearst

Complication	Augmentation (n = 492)	Revision- Augmentation (n = 156)	Reconstruction (n = 225)	Revision- Reconstruction (n = 68)
Key risk rates				
Reoperation	12.5 (9.5–15.4)	21.1 (14.4–27.7)	31.8 (25.6–38.1)	19.8 (10.1–29.5)
Implant removal with replacement	4.7 (2.8–6.6)	8.3 (3.8–12.8)	13.8 (9.1–18.5)	15.4 (6.6–24.2)
Implant removal without replacement	0.7 (0.0–1.4)	2.7 (0.1–5.4)	3.5 (0.9–6.1)	0
Implant rupture	0.7 (0.0–2.1)	2.2 (0.0–6.5)	1.3 (0.0–3.9)	0
Capsular contracture Baker grade III/IV	1.9 (1.0–3.7)	4.8 (1.3–8.2)	5.9 (3.4–10.2)	6.1 (0.3–11.9)
Additional risk rates occurring in $\geq 2.0\%$ of subjects				
Implant malposition	2.6 (1.5–4.5)	4.7 (1.3–8.0)	4.9 (2.7–9.0)	3.0 (0.0–7.1)
Swelling	1.8 (1.0–3.5)	2.0 (0.0–4.1)	2.8 (1.3–6.2)	1.5 (0.0–4.3)
Infection	1.3 (0.6–2.8)	1.3 (0.0–3.1)	4.3 (2.3–8.2)	4.5 (0.0–9.4)
Breast pain	1.2 (0.6–2.7)	1.3 (0.0–3.1)	3.1 (1.4–6.7)	1.7 (0.0–5.0)
Delayed wound healing	1.0 (0.4–2.5)	1.3 (0.0–3.1)	0.5 (0.1–3.3)	2.9 (0.0–7.0)
Hypertrophic/abnormal scarring	0.9 (0.3–2.4)	2.8 (0.1–5.5)	4.2 (2.2–8.0)	1.5 (0.0–4.5)
Asymmetry	0.8 (0.3–2.2)	3.4 (0.5–6.3)	8.7 (5.6–13.4)	7.7 (1.2–14.3)
Hematoma	0.8 (0.3–2.2)	2.0 (0.0–4.2)	1.1 (0.3–4.3)	0
Seroma/fluid accumulation	0.8 (0.3–2.2)	1.5 (0.0–3.5)	1.4 (0.5–4.4)	4.4 (0.0–9.3)
Wrinkling/rippling	0.5 (0.1–1.8)	2.1 (0.0–4.4)	2.0 (0.8–5.3)	7.7 (1.2–14.2)
Upper pole fullness	0	0.7 (0.0–2.0)	4.2 (2.2–7.9)	1.5 (0.0–4.4)

*Kaplan-Meier is a more accurate risk rate than raw percentages in that it gives the complication percentage with a 95% confidence level ($\pm 2.5\%$) for how likely a complication is to occur.

†Values are given as percentages, with 95% confidence intervals in parentheses.

Table 4. Reasons for Reoperation and Explantation

Reason	Augmentation	Revision- Augmentation	Reconstruction	Revision- Reconstruction
For reoperation occurring in $>8\%$ of reoperations				
No. of reoperations	72	40	89	16
Implant malposition	18.1%	12.5%	14.6%	12.5%
Patient request for style/size change	16.7%	2.5%	12.4%	6.3%
Scarring	12.5%	17.5%	27.0%	0
Hematoma/seroma	12.5%	7.5%	2.2%	6.3%
Ptosis	8.3%	12.5%	5.6%	0
Capsular contracture	6.9%	15.0%	9.0%	25.0%
Need for biopsy	5.6%	10.0%	1.1%	0
Infection	2.8%	7.5%	9.0%	6.3%
Delayed wound healing	4.2%	2.5%	0	18.8%
For implant removal (with or without replacement) occurring in $>8\%$ of explantations				
No. of explantations	44	27	49	15
Patient request for style/size change	54.6%	11.1%	36.7%	20.0%
Asymmetry	13.6%	7.4%	10.2%	0
Ptosis	9.1%	7.4%	2.0%	0
Implant malposition	4.6%	14.8%	10.2%	13.3%
Infection	4.6%	11.1%	10.2%	6.7%
Capsular contracture	4.6%	25.9%	10.2%	20.0%
Suspected rupture*	0	3.7%	0	13.3%
Wrinkling/rippling	0	0	6.1%	13.3%

*One revision-augmentation and two revision-reconstruction devices were removed because of suspected rupture, and all were found to be intact.

tation. The vast majority of subjects (83 percent) who had their implants removed opted to have them replaced at the same time, and most of the replacement Style 410 implants were selected to be larger than the original implants.

Effectiveness

A comparison of preimplantation and postimplantation bra sizes for augmentation

subjects found that a majority of subjects (53 percent) had an increase of two cup sizes, and the second most common outcome was an increase of one cup size (38 percent). Breast size, as measured from the point at which the breast mound begins laterally across the nipple to where it ends medially, increased from a mean of 16.8 cm before implantation to 22.7 cm after implantation ($p < 0.001$).

Table 5. Comparison of Kaplan-Meier By-Patient Risk Rates

Complication	Augmentation with Style 410 Highly Cohesive Silicone Gel Implants through 3 Years (n = 492) (%)	Augmentation with Current Standard Silicone Gel Implants through 4 Years (n = 455) (%)	Augmentation with Current Saline Implants through 3 Years (n = 901) (%)
Reoperation	12.5	23.5	21.1
Implant removal with replacement	4.7	7.5	↑ 7.6 combined ↓
Implant removal without replacement	0.7	2.3	
Implant rupture/deflation	0.7	2.7	5.0
Capsular contracture Baker grade III/IV	1.9	13.2	8.7

Implant satisfaction was high for augmentation subjects at 98 percent (satisfied or definitely satisfied on the five-point scale) for the 3-year assessment. The other cohorts also had high satisfaction rates: 90 percent for revision-augmentation subjects, 94 percent for reconstruction subjects, and 93 percent for revision-reconstruction subjects, with investigator assessments mirroring those of the subjects.

DISCUSSION

The importance of these data is best understood when put into perspective with those of the other Allergan U.S. Food and Drug Administration–approved implants currently available in the United States (Table 5). Although the current standard gel implant data are reported through 4 years,¹ compared with 3 years for Style 410 and saline implant data,² the lower incidence of complications for Style 410 implants is clearly evident. There are lower rates of capsular contracture and reoperation in particular. An analysis of the characteristics of the 410 implant and the possible reasons for these improved data follows.

As described by Maxwell and Hartley,³ the currently available, U.S. Food and Drug Administration–approved, standard cohesive silicone gel implants are considered fourth-generation silicone implants and are differentiated from the prematorium (before 1992) silicone implants by refined manufacturing processes. The evolution of silicone implants has been further characterized by Maxwell and Baker,⁴ establishing the 410 implant as the first fifth-generation implant, distinguished by its highly cohesive, form-stable, silicone gel filler (Table 6).

The extent of crosslinking of the silicone polymers during the manufacturing process is what determines the firmness of the silicone gel. When the filler crosslinking occurs to the degree that the sili-

cone gel breast implant will maintain its dimensions and form (i.e., gel distribution within the shell) in any position, the cohesive gel implant is said to be form-stable³⁻⁵ (Figs. 1 and 2). If the upper pole collapses significantly, the implant is said to be non-form-stable (i.e., the gel distribution within the shell is not maintained).^{3,4} All breast implants developed before the 1993 introduction of the Style 410 are non-form-stable (Table 6).⁴

The 410 implant is not a single implant but a matrix of shaped, textured implants of varying width, height, and projection options or cells, all

Table 6. Evolution of Silicone Gel-Filled Breast Implants

Implant	Description
First generation (1962–1970)	Thick, two-piece shell Smooth surface with Dacron fixation patches Anatomically shaped (teardrop) Viscous silicone gel
Second generation (1970–1982)	Thin, slightly permeable shell Smooth surface (no Dacron patches) Round shape Less viscous silicone gel
Third generation (1982–1992)	Thick, strong, low-bleed shell Smooth and textured surface Round shape More viscous silicone gel
Fourth generation (1993–present)	Thick, strong, low-bleed shell* Smooth and textured surfaces Round shape More viscous (cohesive) silicone gel Refined manufacturing processes
Fifth generation (1993–present)	Thick, strong, low-bleed shell* Smooth and textured surfaces Round and diverse anatomical shapes Enhanced cohesive and form-stable silicone gel

*In accordance with technical parameters established by the American Society for Testing and Materials.

Reprinted with permission from Maxwell, G. P., and Baker, M. R. Augmentation mammoplasty: General considerations. In S. L. Spear (Ed.), *Surgery of the Breast*, 2nd Ed. Baltimore: Lippincott Williams & Wilkins, 2006. P. 1237.



Fig. 1. The silicone implants (of similar volume) are placed vertically (in an upright position) on a flat surface. On the *left* is an Inamed Style 410 implant and on the *right* is a fourth-generation gel implant. Note upper pole collapse in the fourth-generation device but not in the Style 410.



Fig. 2. The Style 410 and fourth-generation gel devices appear somewhat similar when held from above, whether intact or (below) when cut into. Thus, neither of these positions is representative of the clinically significant properties of these implants.

filled with a highly cohesive gel (Fig. 3). This matrix of shaped implants allows a customized approach to breast aesthetic enhancement and reconstruction with flexibility to match the implant to the individual patient's needs.⁴⁻⁷

The Biocell surface covering these implants is an "aggressive open-pore textured surface" with an irregular distribution of depressions on the implant surface⁸ and a pore diameter of 100 to 600 μm (typically 300 μm) (Fig. 4). Developed in the mid 1980s and introduced clinically in 1987,^{9,10} it has been shown to facilitate a stable implant position.¹⁰ In both animal⁹ and human⁸ studies, the Biocell surface has demonstrated an ability to propagate tissue ingrowth and subsequent tissue adherence to the implant surface.

This adhesive effect⁸ of the Biocell surface promotes tissue adherence¹¹ and reduces rotation.^{9,12} Tissue adherence may be further enhanced by the creation of a precise, bloodless surgical pocket.¹⁰ Fluid formation around the Biocell is undesirable and is one potential cause of capsular contracture. Although 100 percent tissue adherence may not always occur or only be partial, the friction coefficient of the surface in the surgically precise pocket generally maintains position and softness.³ The resultant soft breast is described frequently as a "one-breast feel," in which the implant and surrounding breast tissue feel like a single entity.⁵ Despite the slightly firmer nature of the highly cohesive gel to palpation, the resultant breast implant in combination with the surrounding soft-tissue interface yields a soft feel clinically.

Before this report, the most positive effect of the Biocell texture has been documented with Biocell-covered tissue expanders.¹⁰ It has been thought that the mechanical advantage of pushing the Biocell surface into the developing capsular surface by means of rapid expansion facilitates adherence.⁹ The same may be true with the pressure from Style 410 highly cohesive gel when placed in a tight pocket,¹³ which may account for the decreased incidence of capsular contracture seen with Style 410 Biocell implants versus standard cohesive gel implants.⁵

The clinical study results are further supported by previously published clinical series using the 410 Matrix with larger numbers of patients and longer follow-up. The largest North American series of Style 410 implants was published by Brown et al. in 2005, in which 117 women underwent 235 implantations for aesthetic and reconstructive indications.⁵ In their series, there were no rotations, no Baker grade III or IV capsular contractures, and no implant ruptures reported. Cur-

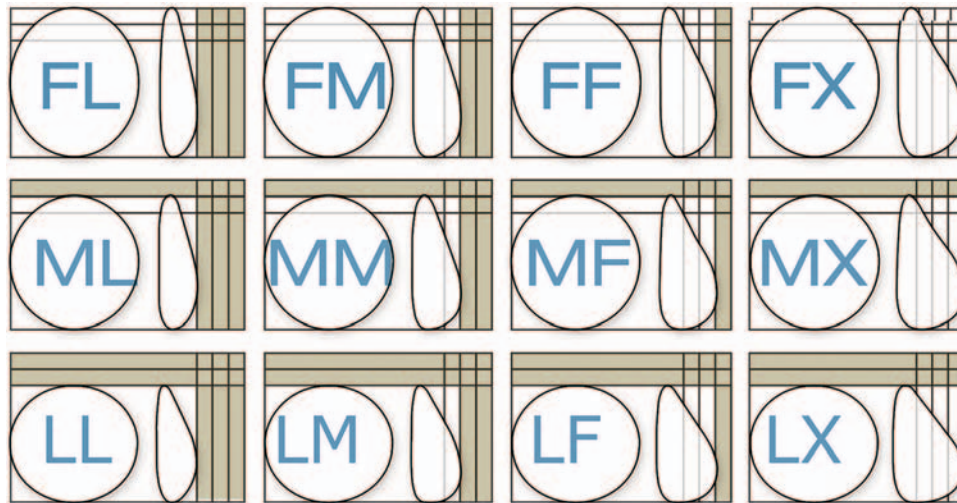


Fig. 3. The 12 “cells” of dimension options are created by low, medium, and full heights (x axis) and low, medium, full, and extra full projections (y axis). Only four cells (FM, FF, MM, and FF) were used in this study.

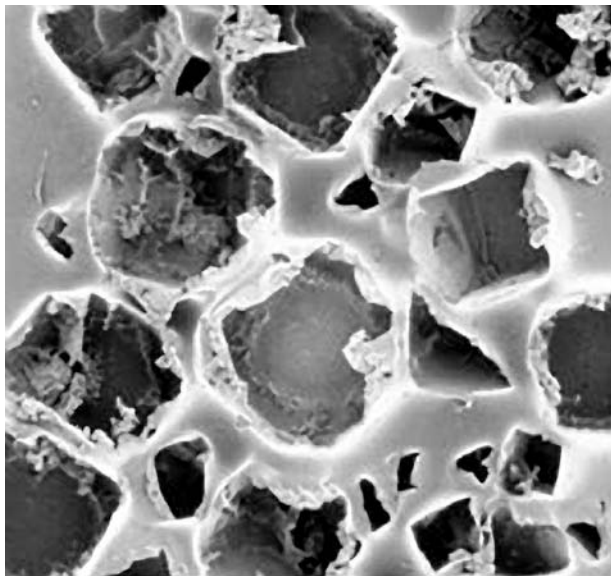


Fig. 4. The Biocell textured surface has an irregular distribution of pores (typically 300 μm in diameter) facilitating an “adhesive effect” and tissue adherence. (Reprinted with permission from Maxwell, G. P., and Baker, M. R. Augmentation mammoplasty: General considerations. In S. L. Spear (Ed.), *Surgery of the Breast*, 2nd Ed. Baltimore: Lippincott Williams & Wilkins, 2006. P. 1237.)

rently, their series includes 467 patients with 885 Style 410 implants with up to 4-year follow-up. Including both augmentation and reconstruction patients, they note one Baker grade IV capsular contracture (<1 percent), three malpositions (<1 percent), no implant ruptures, and 20 reoperations (4.3 percent).¹⁴

The largest series in the world using the Style 410 Matrix implant system was reported by Hedén et al. in 2001.⁶ One thousand six hundred seventy-six Style 410 implants studied showed excellent clinical results for all indications with a low complication rate, including 4.2 percent capsular contracture, less than 1 percent rotation, and less than 1 percent device ruptures. They currently have implanted more than 7000 Style 410 devices, and complications remain at comparable levels with up to 12 years’ follow-up.¹⁵

Of equal importance to the aesthetic outcomes and the lower incidence of capsular contracture is the documentation of the low incidence of 410 device rupture. In our study, magnetic resonance imaging analysis at 3 years demonstrated an 0.8 percent overall suspected implant rupture rate. Only one rupture was confirmed at explanation, with no extracapsular gel and a thin silicone film on the surface of the implant. Device analysis confirmed rupture, with a sharp-edged opening of unknown cause. These results are in line with previously published retrospective magnetic resonance imaging analysis of 286 Style 410 implants with a 0.3 percent incidence of rupture found at 6 years’ average follow-up¹⁶ and substantially lower than magnetic resonance imaging analysis of 199 standard cohesive implants with a rupture incidence rate of 8.0 percent at 11 years.¹⁷

There are clinical differences in the use of the Style 410 implant compared with round devices. Careful dimensionally based patient analysis is mandatory.¹⁸ Implant selection should not exceed tissue characteristics and breast dimen-

sions. Accordingly, both implant dimensions and volume should be individualized.⁶ Pocket selection should be based on soft-tissue thickness and characteristics, and pocket dissection should be bloodless and precise, taking care to avoid pocket overdissection.⁵ The incision must be of an appropriate length to allow ease of implant insertion without fracturing the gel (reported by Brown et al.⁵ as 5 cm and by Hedén et al.⁶ as 5.5 cm). Although periareolar and transaxillary incisions are possible, most subjects in our study had inframammary incisions.

In addition to longer incisions, other potential disadvantages to the use of this implant are greater initial cost and requirements for exact surgical technique. Finally, it should be noted that, despite the outcomes reported, the Style 410 implants are merely one part of an overall breast surgery process. This process should include extensive preoperative patient education and informed consent,¹⁹ focused preoperative planning, precise surgical technique, defined postoperative care, and long-term follow-up and evaluation.

SUMMARY

This clinical study provided 3-year safety and effectiveness data for the Style 410 highly cohesive silicone breast implant to Health Canada and secured approval in that country. These data are also currently under review by the U.S. Food and Drug Administration for U.S. access to the Style 410 device. These next generation, highly cohesive implants will offer surgeons additional options for providing patients with their desired aesthetic outcome, using a device with low complication rates and high satisfaction rates.

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