

# A Comparison of Outcomes Involving Highly Cohesive, Form-Stable Breast Implants From Two Manufacturers in Patients Undergoing Primary Breast Augmentation

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## Abstract

**Background:** Although there have been reports of single-surgeon outcomes with highly cohesive, form-stable silicone gel implants in women undergoing primary breast augmentation, there has been only one study published that compares the outcomes between the Allergan 410 and the Mentor CPG devices.

**Objectives:** The goal of the study is to compare outcomes in each cohort and to determine if quality systems and processes would have an impact on lowering the surgical revision rate, as compared to published reports for round gel implants and form-stable implants.

**Methods:** Patients selected for the study were required to meet predefined inclusion criteria and general indications for breast augmentation. All subjects were treated uniformly with extensive informed consent prior to surgery. The entire process of breast augmentation (patient assessment, informed consent, the surgical procedure itself and postoperative instructions) was identical between the two groups. Patients were not randomized, as the studies did not start at the same time. The process for management of each patient was based on adaptation of the Toyota Production System and Lean Manufacturing, with emphasis on achieving operational excellence in the use of planning templates for surgery, including accurate management of patient expectations regarding size outcome.

**Results:** Outcomes data included physical breast measurements, quality of life metrics, and patient/surgeon satisfaction assessment. Adverse events were compared against published data for breast implants. Follow-up ranged between 20–77 months (Allergan 410) and 16–77 months (Mentor CPG). The outcome data indicate that these devices produce natural-appearing breasts with extremely low aggregate reoperation rate (4.2%). Only 0.8% of the reoperations were attributable to surgeon-related factors. There were no reoperations to correct mismanaged size expectations during the course of each study. There were 13 pregnancies and no difficulties with lactation were reported. Rippling (lateral/medial, palpable and/or visible) was encountered in both cohorts. The Mentor CPG cohort had a fivefold greater incidence of rippling (37.3% versus 7.6% in Allergan 410 cohort). This was highly statistically significant ( $P < .001$ ).

**Conclusions:** Provided that there is adherence to core principles and avoidance of errors in planning, patient expectations, and surgery, highly cohesive, form-stable breast implants can deliver excellent long term outcomes in primary breast augmentation in a diverse patient population. The impact of quality processes such as Toyota Production System and Lean Manufacturing was substantive in delivering operational excellence in primary breast augmentation.

## Keywords

breast augmentation, form-stable silicone gel breast implants, reoperation following breast augmentation, patient satisfaction with breast augmentation, complications of breast augmentation

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Published reports involving patient outcomes with highly cohesive, form-stable breast implants (Allergan Natrelle 410; Allergan, Irvine, California) and Mentor Contour Profile Gel (CPG; Mentor, Santa Barbara, California) have covered the clinical outcomes of a single brand of devices. To date, there has been only one other study published regarding a population of women undergoing form-stable primary breast augmentation with similar devices from the two current US implant manufacturers.<sup>1</sup> The goal of this study is to compare outcomes between two cohorts, one from each manufacturer, and to determine if quality systems and processes would have an impact on lowering the surgical revision rate, as compared to published reports for

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**Table 1.** Inclusion and Exclusion Criteria

	Inclusion Criteria	Exclusion Criteria
<b>Allergan 410</b>	Female, age 18 or older Adequate tissue to cover implants Patient willing to follow study requirements and signed informed consent Primary augmentation—no previous breast implants Reconstructed breast—no history of breast implant, other than tissue expander Contralateral breast augmentation for asymmetry following mastectomy Revision of previous augmentation Revision of previous reconstructions	Pregnant or nursing Advanced fibrocystic disease Existing carcinoma without mastectomy Presence of active infection anywhere in the body Had any disease including diabetes with A1C > 8% that would negatively affect wound healing Tissue characteristic incompatible with mammaplasty Has a condition that would be considered an unwarranted surgical risk Psychological characteristics incompatible with surgery Willing to undergo further surgery for revision
<b>Mentor CPG</b>	Genetic female, aged 18 years or older Candidate for primary breast augmentation or primary reconstruction (for cancer, trauma, surgical loss of breast, or congenital deformity) or revision surgery involving breast implants Agree to return device to Mentor if explant is necessary Agree to comply with follow-up procedures, including follow-up visits	Pregnant or nursing mother History of nursing within three months of study enrollment Presence of any other silicone implant other than a breast implant Confirmed diagnosis of rheumatic diseases or syndromes or inflammatory arthritic condition Any condition that would inhibit wound healing Active cancer of any type Presence of an infection or abscess anywhere in the body Tissue characteristics incompatible with implant placement Condition that would be considered an unwarranted surgical risk Anatomic or physiologic anomaly that could lead to significant postoperative complications Inappropriate attitude or motivation that is unreasonable/unrealistic with surgical risks, in the opinion of the investigator Presence of premalignant breast disease Untreated or inappropriately treated breast malignancy HIV positive Relative of study site personnel or the investigator or any employee of study site or sponsor

round gel implants and form-stable implants. We identify clinical processes to lower the revision rates previously cited in published data on third- and fourth-generation breast implants and examine the differences in outcome between highly cohesive, form-stable breast implants.

## METHODS

The study was conducted with institutional review board oversight and monitoring by clinical research staff from both sponsors. Access to outcomes data was restricted to respective clinical monitors and was not shared between sponsors.

The Allergan cohort of 118 consecutive patients began in April 2001 and concluded in September 2007. The Mentor cohort of 117 consecutive patients began in

December 2002 and concluded in January 2008. Patients selected for the respective study protocols met inclusion criteria (outlined in Table 1) and general indications for breast augmentation. All patients were treated uniformly and informed consent was extensively discussed prior to surgery. Each participant completed baseline personal inventory information regarding health, quality-of-life metrics, and body image. All patients were women 18 years of age or older. Individuals with ptosis of a severity that would require a mastopexy (ie, nipples >1 cm below the fold) were excluded. The entire process of breast augmentation—patient assessment, informed consent, the surgical procedure itself, and postoperative instructions—were identical between the two groups. Patients were not randomized, as the studies did not start at the same time.

All devices (Allergan Natrelle 410 and Mentor CPG) were purchased from the respective manufacturer. Patients paid for the procedure but received stipends from both manufacturers to return for follow-up visits during the 10-year duration of the studies. Devices were treated uniformly, according to established office policies and protocols for primary breast augmentation.

Tissue-based planning guided device selection, with consideration given to patient input regarding size outcome. Breast history, parity, preaugmentation size, and desired outcome data were all recorded on templates. Sternal-nipple (SN) distance, nipple-nipple (NN) distance, breast width (BW), breast height (BH), and upper pole pinch thickness (UPP) measurements were made using tape and calipers. The tone of the breast envelope was assessed but not measured in terms of skin stretch. Device location was determined to be either retromammary (RM) or biplanar (BP), according to patient preference or an upper pole tissue thickness greater than 35 mm. Device selection did not exceed the measured base diameter of the breast by more than 5 mm.

Within the Allergan Natrelle 410 cohort, there were several options for device selection, including MM styles (moderate height, moderate projection), FM styles (full height, moderate projection), FF (full height, full projection), and MF (moderate height-full projection). SN distance determined selection among these options. For example, individuals with an SN distance of 18 cm or less received MM or MF styles. Individuals with an SN distance of 18 to 21 cm had taller breast height, and the FM style devices were thus selected. Individuals with an SN distance of greater than 21 cm or with skin envelope looseness received FF style devices. The Mentor cohort largely comprised style 321 CPG implants (99 patients), with a small number of 321 and 332 devices. When other configurations became available, style 322 devices were used (nine patients).

Surgery was performed by the senior author (MLJ) via an inframammary incision. Incision planning was performed in a way similar to that described by Adams<sup>1</sup> and Tebbetts and Adams.<sup>2</sup> Sterile occlusive adhesive plastic dressings (OP Site, Smith and Nephew, Tuttlingen, Germany) were applied to the nipple areolar complex in all cases, following application of chlorhexidine-based surgical prep (Hibiclens, Mölnlycke Health Care US, LLC, Norcross, Georgia) and placement of surgical drape. Emphasis was placed on precise, atraumatic dissection to produce a tight-fitting pocket for the implant.<sup>3-5</sup> All incisions were 5 cm or greater in length. Every patient received parenteral cefazolin or cefotaxime and oral antibiotics during the perioperative period. All implant pockets were irrigated with either cefazolin or cefotaxime. Implants were inserted with the least amount of force necessary and oriented according to alignment marks on the devices. Closed suction drains were used in all cases and were generally removed 48 hours after surgery. Surgical wounds were closed with three layers of Monocryl (Ethicon, Somerville, New Jersey) and Dermabond (Ethicon, Somerville, New Jersey).

The process for management of each patient was based on an adapted version of the Toyota Production System

(TPS) and Lean Manufacturing plan.<sup>6-11</sup> Emphasis was placed on achieving operational excellence in the use of planning templates for surgery, including accurate management of patient expectations regarding size outcome. There was a focus in surgery on precise, bloodless dissection to create the pocket for form-stable devices via inframammary access and the use of closed suction drains for 48 hours after surgery. The surgical technique for implant placement/location was identical for both cohorts. If it was necessary to lengthen the nipple-to-fold distance, the new breast fold was reinforced with sutures attaching the superficial fascia inferiorly to the chest wall.

Patients were instructed to purchase and wear soft-cup, underwire-style bras starting at seven days postsurgery. They were restricted from upper extremity exercise and strenuous activities for six weeks following surgery. Each patient was evaluated at follow-up visits at day one, day seven, 10 weeks, six months, and annually thereafter. Serial measurements were recorded on template forms, and postoperative photographs were taken at each visit. Situations involving adverse events (AE) were documented in the patient's chart and reported to sponsors with designated forms. Explanted devices were returned to the manufacturer. Some members of each cohort were selected for magnetic resonance imaging (MRI) studies.

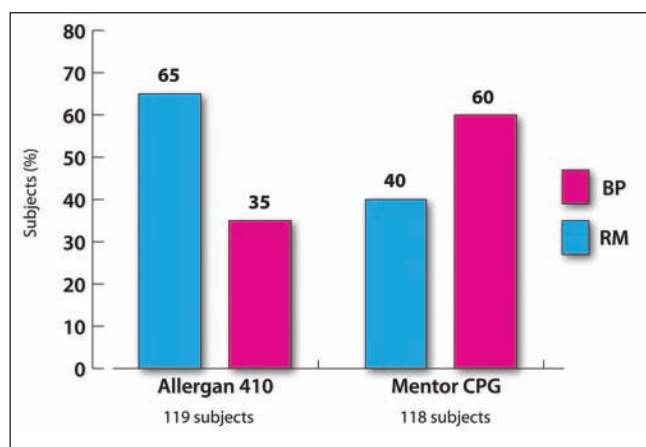
Outcomes involving each patient were assessed during follow-up visits. Data collected were analyzed for physical breast measurements, quality-of-life metrics, and patient/surgeon assessment of outcome quality. The data collection forms called for information about breast measurements, patient satisfaction, bra size, intervening pregnancies, and occurrence of adverse event (AE). If AE or patient dissatisfaction with the outcome occurred, there were processes in place for managing these situations. In the case of AE, the root cause was determined. AE that were logged during the study were compared against published data for breast implants. Other normal occurrences, such as pregnancy and lactation, were also logged.

## RESULTS

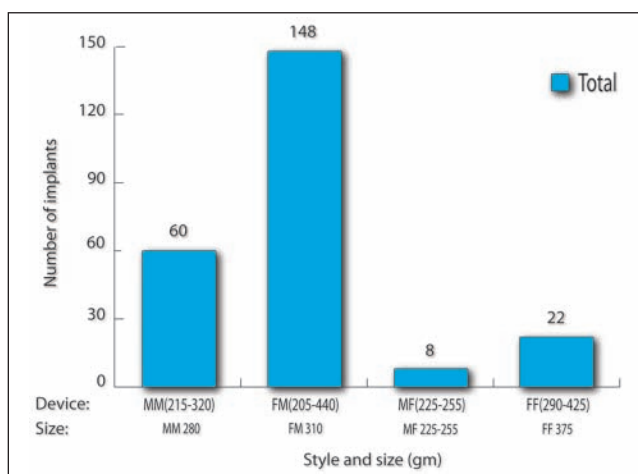
Excellent results were achieved in both device cohorts in terms of aesthetic outcome, low rates of surgical revision, and infrequent occurrence of AE. There was excellent (90%) compliance with patients returning for scheduled visits. The range of follow-up is shown in Figure 1.

### Device Allocation and Location

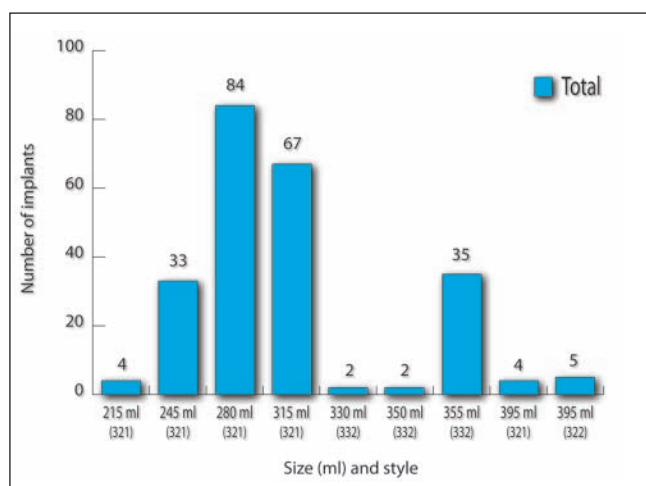
The Allergan 410 Natrelle cohort of 118 patients included 60% retromammary placement ( $n = 71$ ) and 40% biplanar placement ( $n = 47$ ). Device placement was determined through tissue measurements and patient preferences, when possible. The Mentor CPG cohort of 117 patients included 60% with biplanar implants ( $n = 70$ ) and 40% with retromammary placement ( $n = 47$ ). All patients underwent surgery using an inframammary approach. The allocation of devices is detailed in Figures 2 and 3 and Table 2. Patient results are shown in Figures 4 to 9.



**Figure 1.** Implant pocket plane location, retromammary (RM) and biplanar (BP).



**Figure 3.** Allergan 410 device allocation (119 patients, 238 devices).



**Figure 2.** Mentor CPG device allocation (118 patients, 236 devices).

## Adverse Events

As mentioned above, the instances of AE were studied. Data regarding the incidence of infection, Baker III-IV capsular contracture (CC), implant malposition, implant rotation, breast cancer, rippling, seroma, loss of nipple sensation, surgical revision (along with the root cause), and device rupture are detailed in Table 3.

### Infection

There were no reports of infection in either cohort.

### Capsular contracture

The rate of Baker III CC was 2.5% in the Allergan 410 cohort and 0.8% in the Mentor CPG cohort. There was no Baker IV CC noted in either cohort. None of the patients who developed CC underwent revision to correct this

**Table 2.** Range of Follow-Up

Follow-Up, mo	Allergan Natrelle 410 Cohort	Mentor CPG Cohort
Mean (average) for series	42.5	51.8
Mean biplanar	46	62.8
Mean retromammary	40.6	36.1
Median for series	37	51
Median for biplanar	27	65.5
Median for retromammary	38	37
Range of follow-up	20-97	16-77

The Allergan 210 cohort began in April 2001 and concluded in September 2007; the Mentor CPG cohort began in December 2002 and concluded in January 2008.

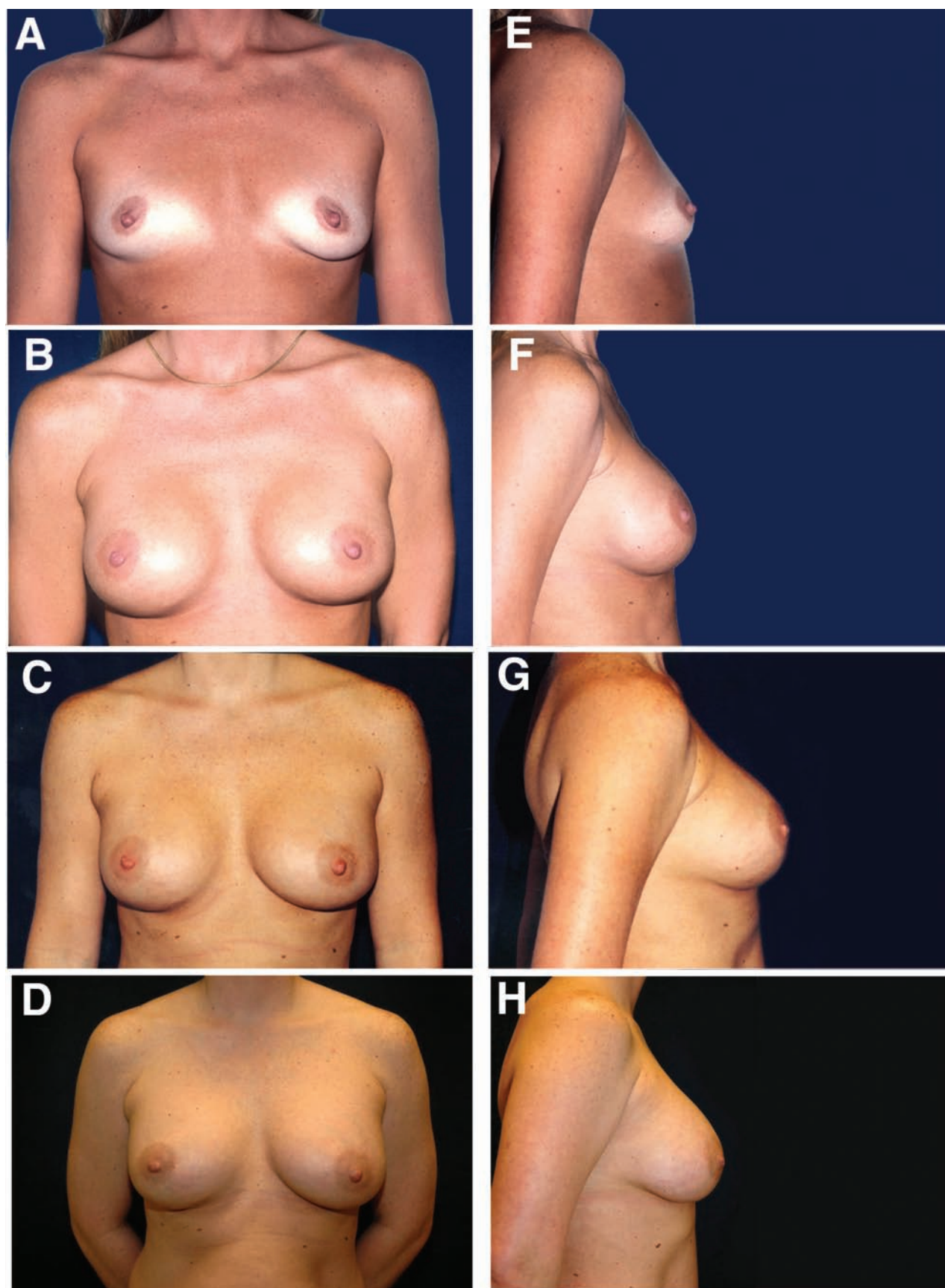
problem. There did not appear to be a progression of the severity of the CC noted over time or a trend toward increasing incidence over time.

### Implant malposition

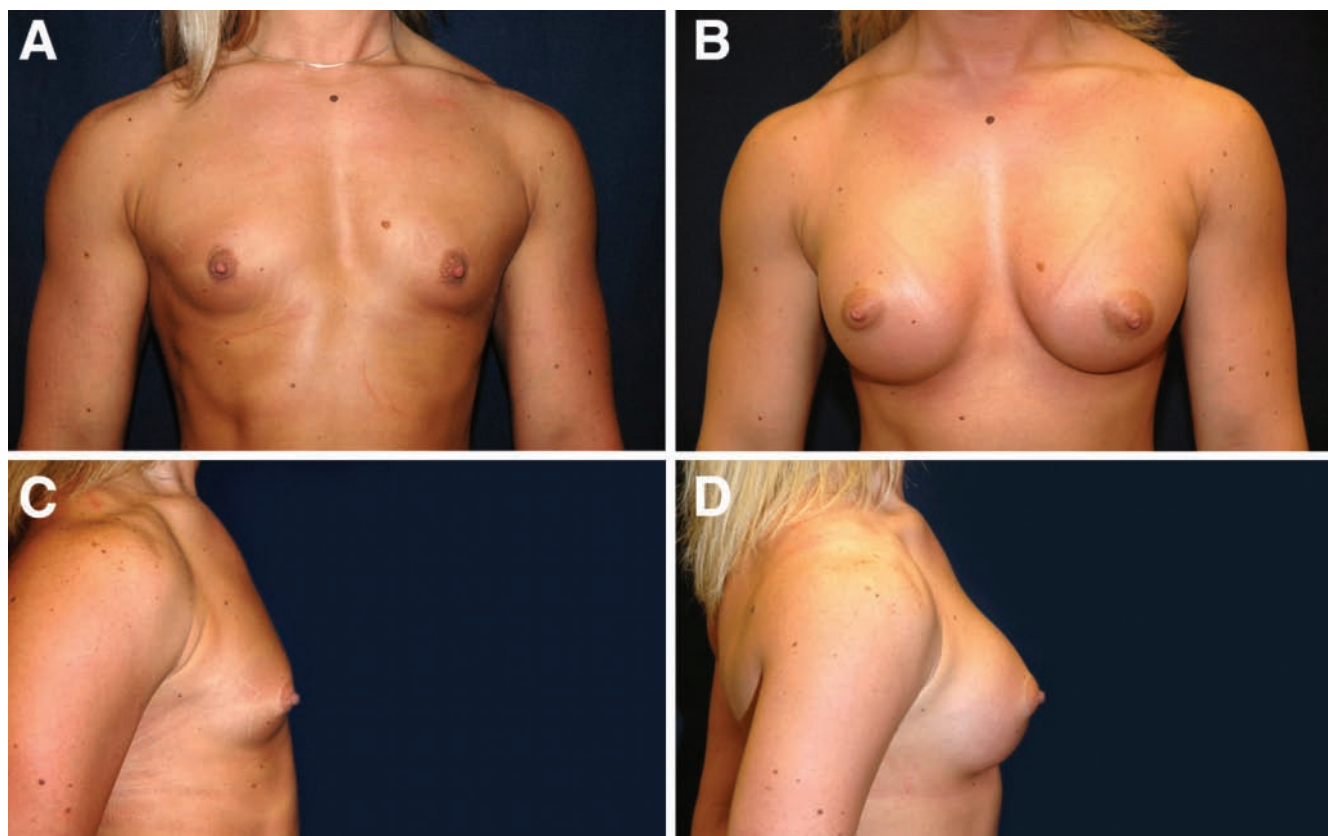
There were two instances of implant malposition in the Allergan 410 cohort. One of the patients required a lateral capsulotomy to enlarge the implant space. In this case, the cause of implant malposition was attributable to technical errors in pocket dissection. In the other patient, an inferior fold malposition was noted but was minor enough that the patient did not request correction. There were no "double bubble" deformities encountered in situations where the inframammary fold was lowered and then reinforced with sutures to attach the superficial fascia inferiorly to the chest wall.

### Implant rotation

The noted incidence of implant rotation was 1.7% in the Allergan 410 cohort; none were noted in the Mentor



**Figure 4.** A 34-year-old woman is shown preoperatively (A, E), one year (B, F), three years (C, G), and five years (D, H) after biplanar placement of Allergan 410 devices, MM 320 g.



**Figure 5.** (A, C) This 22-year-old presented a specific surgical challenge because of her workout regimen; she was a female bodybuilder. The patient is shown one year (B, D) after retromammary placement of Allergan 410 devices, MM 280 g.

CPG cohort. Both instances of rotation in the Allergan group were manually reduced, so no surgical revision was necessary. Rotation appeared to be related to strenuous physical activities on the part of the patient.

#### **Incidence of breast cancer**

Three of the patients in the Mentor CPG cohort developed invasive breast cancer following augmentation mammoplasty. All three were treated with segmental mastectomies and sentinel lymph node dissections. One patient required chemotherapy; one patient was treated with adjunctive radiation therapy. There was successful salvage of implants in all three patients. Two patients required the use of acellular dermal matrix as a replacement for anterior capsular tissue removed at the time of the segmental mastectomy. Two patients required a second revision for implant size change, to correct a volume loss caused by the segmental mastectomy. There were six total revisions attributable to segmental mastectomies and implant size change.

#### **Seroma**

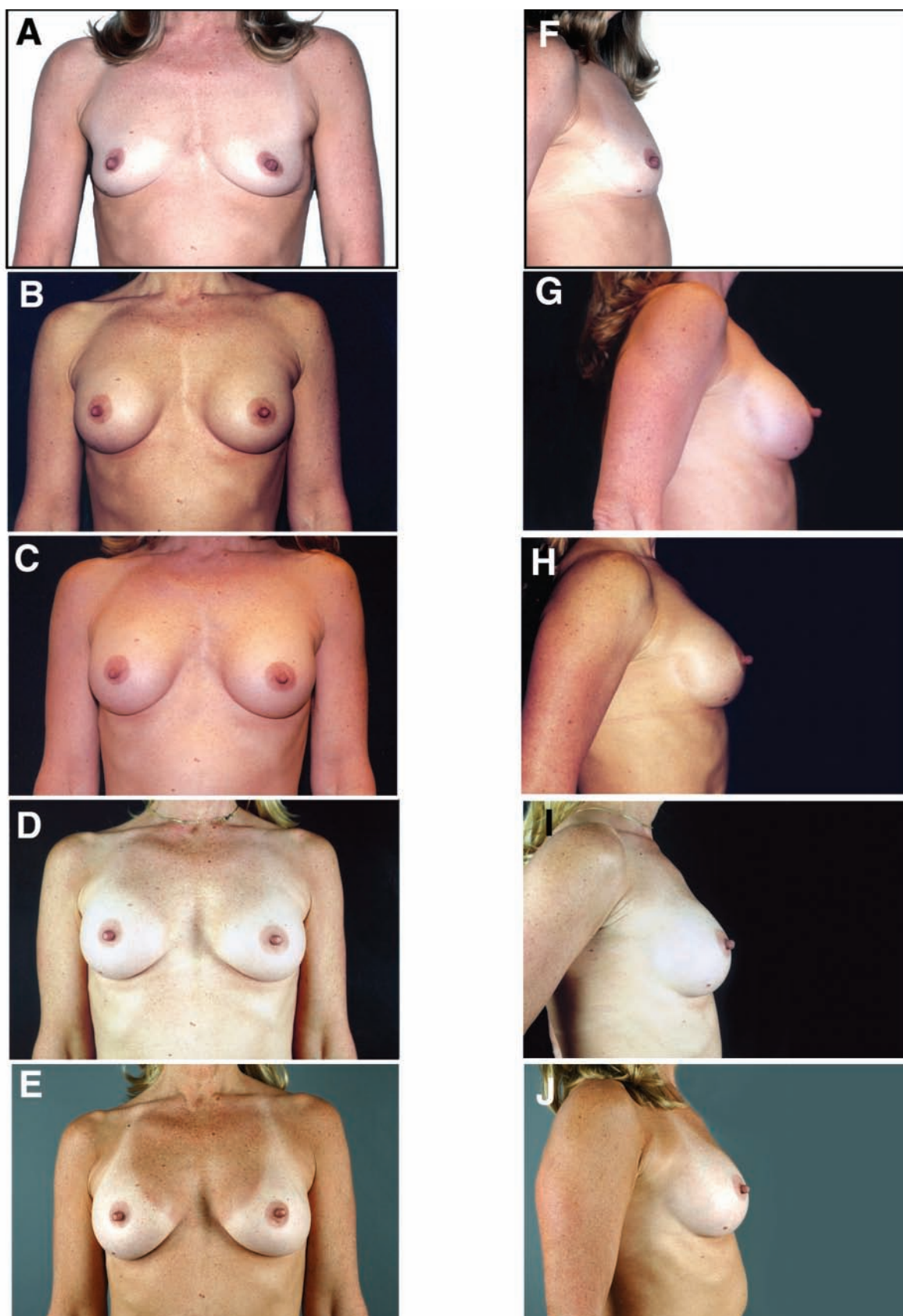
There was one seroma in the Mentor CPG cohort; it occurred at nine months postoperatively and required bilateral implant removal without replacement. The root cause of the seroma appeared to be trauma sustained

during intimate relations. The seroma fluid appeared quite cloudy yet did not grow organisms on culture.

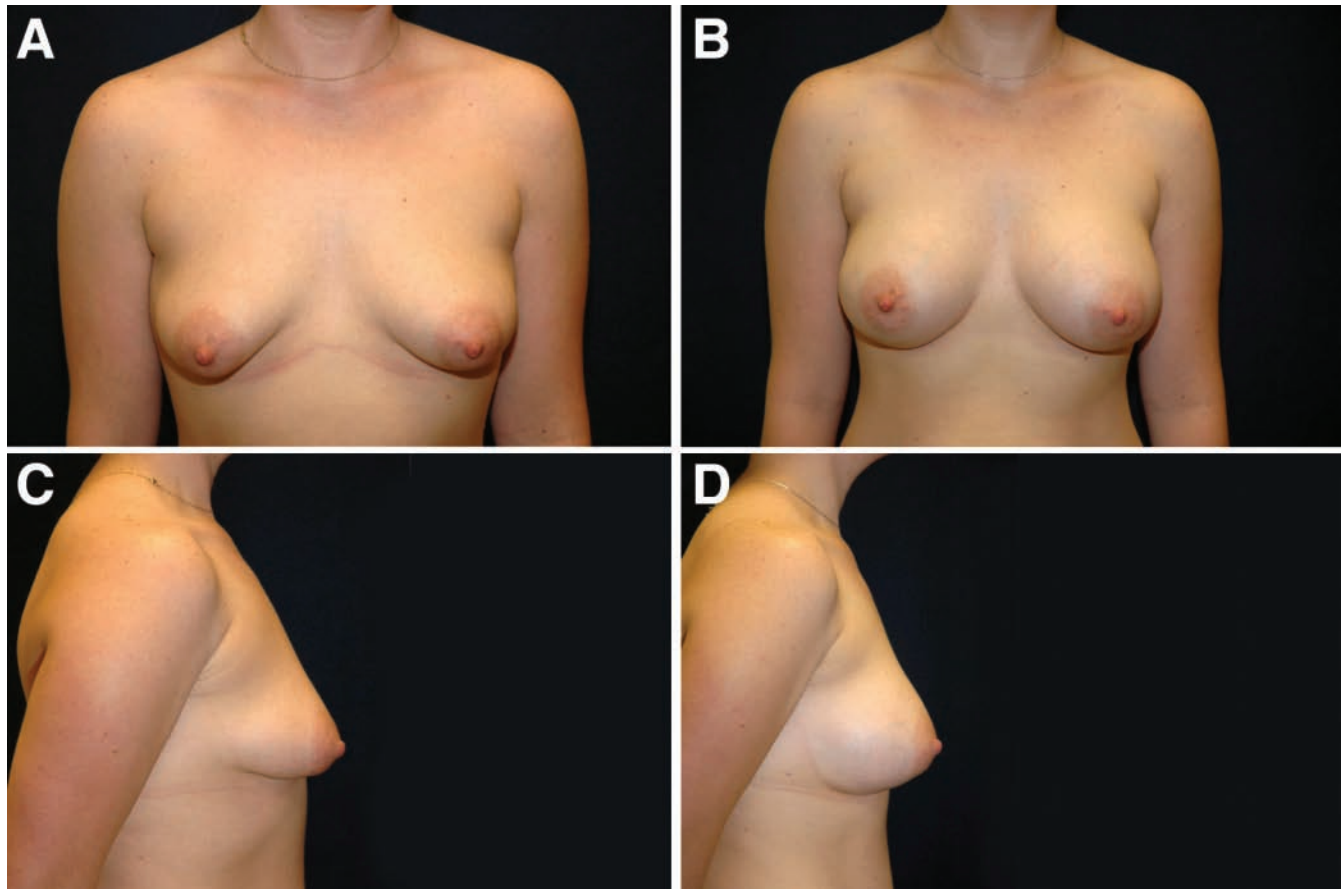
#### **Rippling**

Instances of visible or palpable rippling were noted in both cohorts in the lateral or medial breast regions (Table 4). The Mentor CPG cohort had a 37.3% incidence of rippling; approximately 72% of the Mentor patients who experienced rippling had implants in the biplanar position and 28% had them in the retromammary location. The Allergan 410 cohort showed a 7.6% incidence of rippling, with approximately 33% of the rippling occurring with implants in the biplanar location and 66% in the retromammary location. Instances of rippling were discovered by the patient, surgeon, or clinical nursing staff during follow-up visits. Occurrence of rippling and device palpability was logged in the data forms used to record outcomes after surgery. There was no incidence of visible or palpable upper pole traction rippling noted in either cohort.

Multivariate logistic regression showed that even after controlling for differences between groups and other potential risk factors (eg, body mass index, breast base diameter, device base diameter, CC, and procedure/location), the rippling difference between the two cohorts remained statistically significant ( $P \leq .001$ ; Table 5).



**Figure 6.** A 44-year old woman is shown preoperatively (A, F), one year (B, G), three years (C, H), five years (D, I), and seven years (E, J) after retromammary placement of Allergan 410 devices, FM 310 g.



**Figure 7.** A 31-year-old woman with tubular breasts (A, C). The patient is shown one year (B, D) after retromammary placement of Mentor CPG devices, 315 cc.

Analysis of base diameters of implanted devices was compared and was also statistically significant ( $P = .03$ ) for both cohorts.

#### **Loss of nipple sensation**

This AE was reported in two patients, one from each cohort. One patient reported some improvement in sensation over the course of 12 months.

#### **Pregnancy and lactation**

There were 13 total pregnancies reported, seven from the Allergan 410 cohort and six from the Mentor CPG cohort. All patients successfully breastfed their infants.

#### **Patient satisfaction**

Most patients (95%) indicated that they were highly satisfied with their outcomes in terms of size increase and a natural-appearing shape. Dissatisfaction with breast firmness was reported in patients who developed Baker III CC. Some patients who also developed rippling expressed dissatisfaction. Other patients expressed dissatisfaction with size outcome because they desired a larger size than originally agreed upon. (Most patients experienced increases to a C or D bra cup size: US sizes 32, 34, and 36.) There were

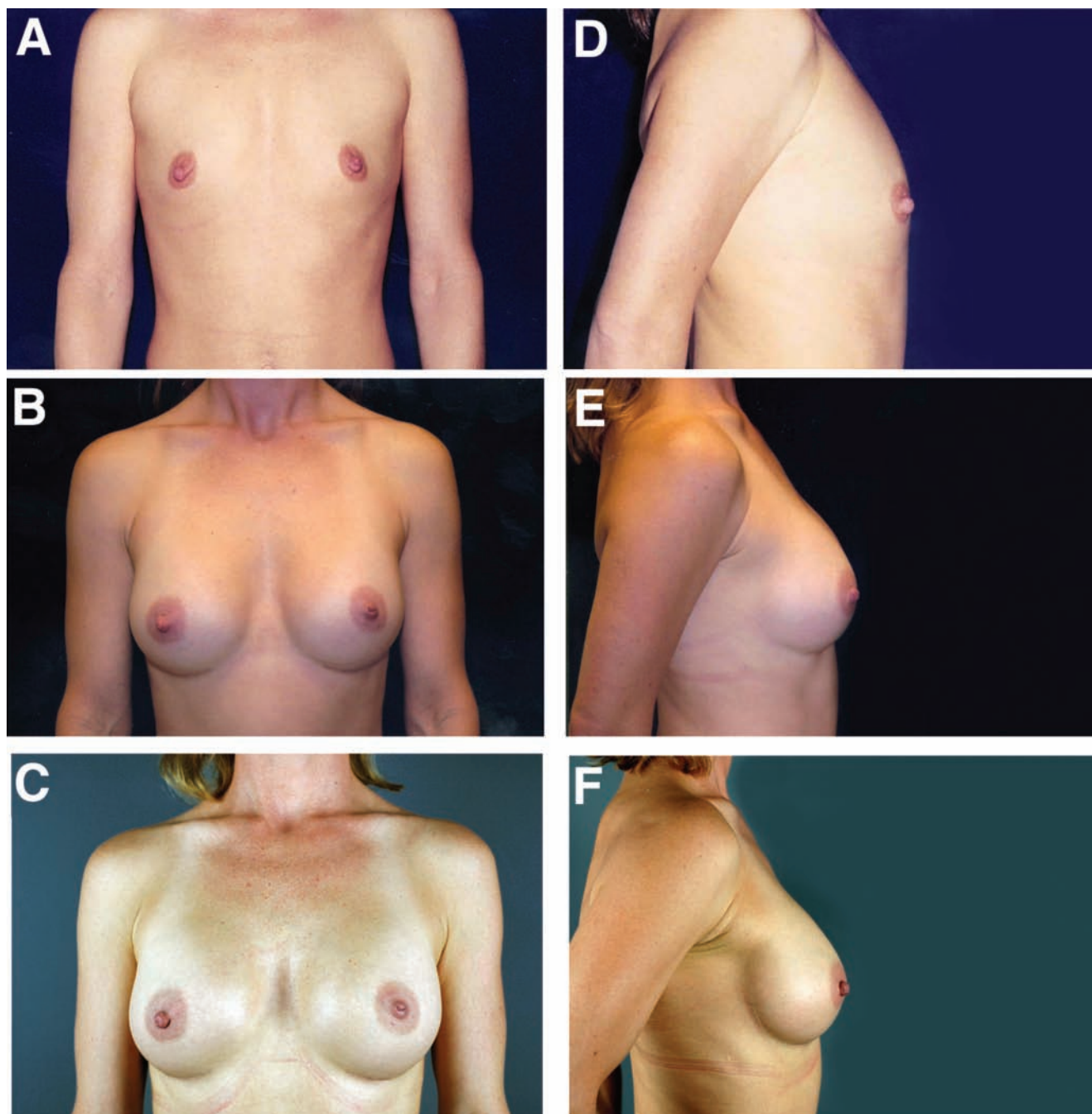
no revisions during the duration of the study to correct size due to mismanaged expectations in either cohort.

#### **Rupture**

No ruptures were encountered in either cohort. As noted earlier, some of the patients in the Mentor CPG cohort underwent MRI; none of the results demonstrated rupture or equivocal findings suggestive of rupture.

#### **Surgical Revision**

A surgical revision was defined as a surgical procedure performed on a patient's breasts following the initial surgical procedure in which the form-stable device was placed. One such revision occurred in the immediate perioperative period to correct surgical bleeding. Others ( $n = 3$ ) occurred later to correct surgical scarring, explant devices following a seroma, or correct implant malposition from pocket underdissection. Three patients developed breast cancer and required segmental mastectomies ( $n = 4$ ; one patient had bilateral segmental mastectomies performed at different time intervals) with sentinel lymph node dissections. Two patients who developed breast cancer underwent a size change with a larger implant to reconstruct

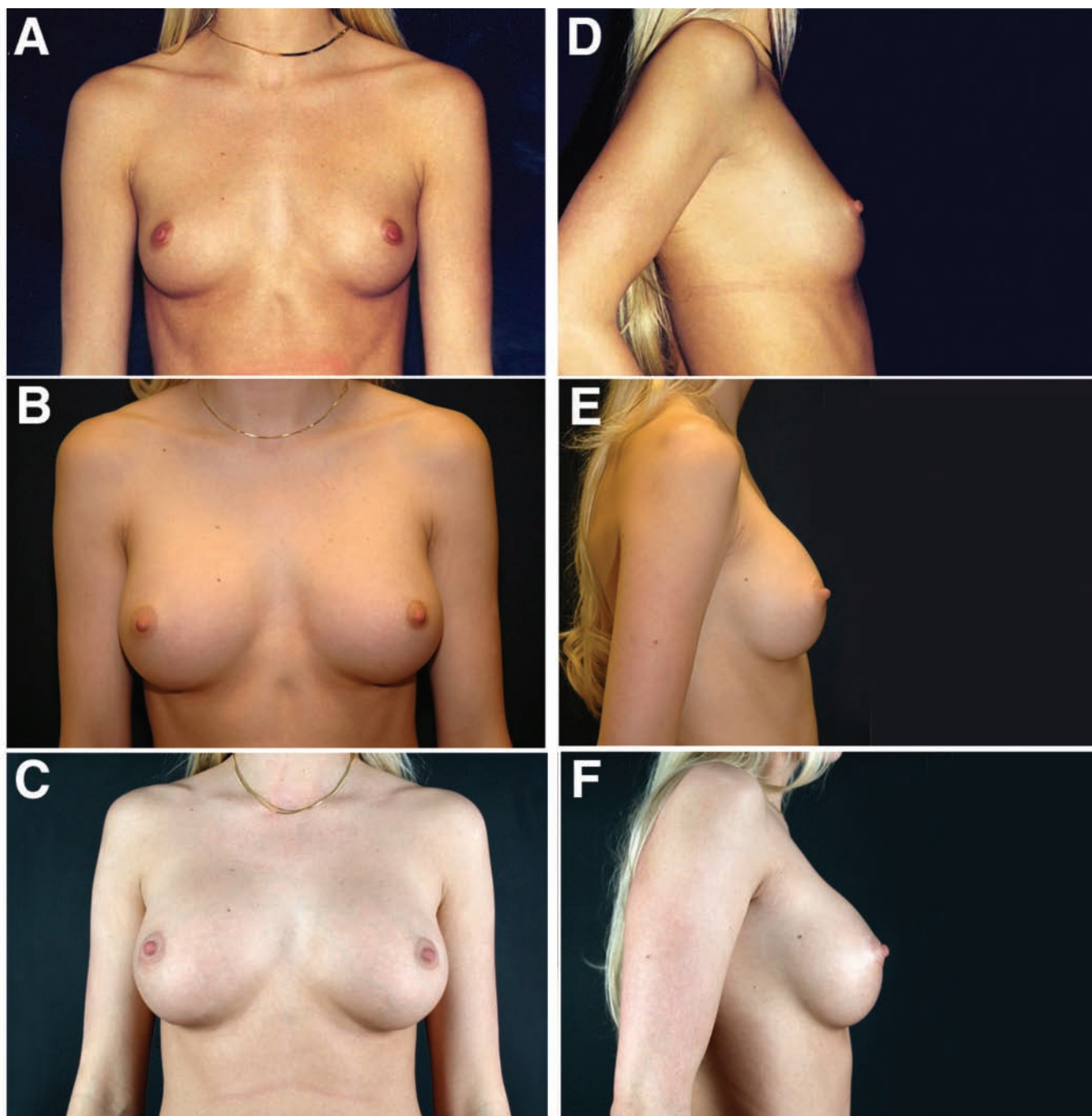


**Figure 8.** A 34-year old woman is shown preoperatively (A, D), one year (B, E), and five years (C, F) after biplanar placement of Mentor CPG devices, 315 cc.

volume loss resulting from the segmental mastectomy. There were a total of 10 revisions (4.2%) noted between the two cohorts as of May 2009 (Allergan 410, 2.5%; Mentor CPG, 5.9%). Surgeon-related factors accounted for 0.8% of the aggregate total and other factors outside the control of the surgeon accounted for 3.4%.

## DISCUSSION

The use of highly cohesive, form-stable breast implants and specific processes for their placement heralds a new era in breast aesthetics. Given the wide range of shapes and sizes available from both manufacturers involved in this study, it is possible to customize each procedure—



**Figure 9.** A 20-year old woman is shown preoperatively (A, D), two years (B, E), and four years (C, F) after biplanar placement of Mentor CPG devices, 315 cc.

including device selection—based on patient measurements and expectations. Follow-up data from this study revealed stability in shape and breast dimensions, without evidence of implant malposition (inferior displacement) or upper pole traction rippling. Successful use of form-stable, highly cohesive gel breast implants requires emphasis on planning, precise surgery, and accurate management of patient expectations.<sup>6</sup>

Patients from both cohorts were highly satisfied with their outcomes. They reported satisfaction with size and shape, including a natural appearance without the upper pole roundness noted with round devices. In a few situations where patients expressed concerns over size outcome, the senior author reviewed preoperative/postoperative photos and measurements with them; they subsequently appeared satisfied with their outcome and declined

**Table 3.** Adverse Events (Food and Drug Administration and *Plastic and Reconstructive Surgery* [PRS])

Adverse Event	Allergan 410 (n = 119)	Mentor CPG (n = 118)	Comparison Data
Malposition	1.7%	0%	0.74% Adams <sup>1</sup> 2.6% Bengtson et al <sup>16</sup> 410 three years
Rotation	0.8%	0.8%	0.58% Adams <sup>1</sup> 1.1% CPG 2 years
Infection	0%	0%	0.58% Adams <sup>1</sup> 1.3% Bengtson et al <sup>16</sup> 410 1.6% CPG 2 years
1.69% capsular contracture (Baker III-IV)	2.5% Baker III 0.0% Baker IV No reoperations	0.8% Baker III 0.0% Baker IV No reoperations	0% Brown et al <sup>14</sup> 0.58% Adams <sup>1</sup> 0.8% CPG 2 years 1.9% Bengtson et al <sup>16</sup> 3 years 4.2% Hedén et al <sup>17</sup> (CL PS) 8.2% MNT gel PMA 13.2% AGN gel PMA
4.2% surgical revision	2.5% 1 (malposition)	5.9% 1 (seroma-explant)	3.7% CPG, 0% 410 cohort w/mean follow-up 1.7 years Adams <sup>1</sup>
0.8% Surgeon related	1 (surgical bleed)	4 (segmental mastectomies in three patients)	9.4% CPG 2 years 12.5% Bengtson et al <sup>16</sup> 3 years
3.4% other causes	1 (scar revision)	2 (size change after segmental mastectomy)	15.4% MNT gel PMA 23.5% AGN gel PMA 28.0% AGN gel 6 years

PMA, premarket approval.

**Table 4.** Statistical Analysis of Palpable/Visible Rippling in Form-Stable Cohorts

Rippling	Incidence, %
Allergan 410 (Jewell <sup>6</sup> )	7.6
Mentor CPG (Jewell <sup>6</sup> )	37.3
Allergan 410 (Adams <sup>1</sup> )	2.7
Mentor CPG (Adams <sup>1</sup> )	10.37
Mentor CPG 2 years	Not addressed
Allergan round gel 3 years <sup>a</sup>	< 1
Allergan round gel 6 years <sup>a</sup>	1.2
Mentor round gel 3 years <sup>a</sup>	< 1
Allergan round saline 3 years <sup>a</sup>	10.5
Allergan round saline 5 years <sup>a</sup>	12.2
Mentor round saline 3 years <sup>a</sup>	20.8

<sup>a</sup>Premarket approval data.

revision. The rippling noted in both cohorts was generally accepted, with dissatisfaction expressed only if it was visible medially and/or laterally on the breast. There appeared to be no substantive differences in the firmness or softness between cohorts. This is in contrast to a report by Niechajev et al,<sup>12</sup> who compared outcomes with the Allergan 410 and Eurosilicone Vertex breast implants, both of which are form-stable devices.

An operative process was designed that utilized principles from the TPS Lean Manufacturing manual,<sup>6-9,11</sup> a

**Table 5.** Comparison of Benchmark Data for the Rate of Breast Implant Rippling

	Mentor CPG	Allergan 410	P Value
Rippling incidence	37.3% (44/117)	7.6% (9/119)	< .001 <sup>a</sup>
Location	32 biplanar 12 retromammary	3 biplanar 6 retromammary	
Baker class	Baker I-II	Baker I-II	
Base diameters of devices in cohort	Mean ± SD: 12.0 ± 0.06 cm Median: 12.0 cm Range: 11-13.5 cm	Mean ± SD: 12.0 ± 0.53 cm Median: 12.0 cm Range: 10.5-13.5 cm	.03

<sup>a</sup>Multivariate logistic regression showed that even after controlling for differences between groups and other potential risk factors (ie, body mass index, breast base diameter, device base diameter, capsular contracture, procedure/location), rippling incidence between the two cohorts remained statistically significant ( $P < .001$ ).

health care adaptation of which was previously reported by Cohen<sup>8</sup> and Graban.<sup>9</sup> Accordingly, our breast augmentation plans were mapped in terms of service requirements and fail points, defined by staff interactions, requisite

supplies, and patient interactions. Our approach relied heavily upon the concept of *kaizen* (systematic thinking), as elaborated upon in the TPS manual.<sup>7-9</sup> Breast augmentation was viewed as a manufacturing concept—specifically, as a sequence of events that are all connected. The consequence of disconnecting these events through “workarounds” would diminish the quality of outcomes. For example, we believe that form-stable implants cannot be effectively used if there is an incorrect process by which decisions are made about implant volume without consideration being given to breast dimensions.

The TPS concept of *muda*, the elimination of waste in the process, was also used. Steps were taken to diminish the excess that occurs when ordering multiple implant sizes for a surgery, instead relying upon measurements to define which device would be optimal. Service mapping was helpful in defining exactly which resources and supplies were needed at each point in time for each step of the process. Operational effectiveness in the process greatly reduced the cost to patients and the necessity of surgical revisions to correct mistakes in planning, technical mistakes, or mismanaged size expectations.

Finally, the TPS concepts of *poka-yoke* and *jidoka* were incorporated into the process in an effort to eliminate mistakes and workarounds. Mistakes in planning for surgery can lead to the need for surgical revisions. Expectations for size outcome must be correctly managed, or patient dissatisfaction that demands surgical revision will result. Workaround practices, which are an effort to bypass a problem area without correction, were eliminated. In breast augmentation, typical workarounds include the utilization of a large-volume implant to correct ptosis or high-projecting implants to achieve size outcome in breasts with a small diameter. In short, attention was paid to eliminating common mistakes of overly large or overly wide implants, as well as technical mistakes that might require surgical revisions.<sup>13</sup>

The following core principles regarding the use of form-stable implants were followed<sup>6</sup>:

1. Based on the TPS guidelines, a process was instituted by which decisions were made on device size, style, and location.
2. Implant selections were made based on data from measurements, including reasonable patient wishes for size outcome. Large-volume augmentation with devices that exceeded the breast base diameter was avoided.
3. Precision was paramount in surgery, and over-dissection of the pocket was avoided.
4. Data were collected in the postoperative period regarding outcomes and patient satisfaction.
5. The process was continually improved through analysis and reflection on what caused both the excellent outcomes and the suboptimal ones. The participation of office and nursing staff in the process was essential in preventing the

occurrence of disconnected events, mistakes, and workarounds that could adversely affect the outcomes in our form-stable anatomic-shaped breast augmentations.

A previous study by Tebbetts and Adams<sup>2</sup> described the process of breast augmentation as a series of connected events versus just a single surgical procedure. We particularly credit Dr. Adams for describing the four sequential steps that optimize surgical outcomes. On the basis of our data, we expanded upon his concept, proposing that the process actually involves hundreds of steps that contribute to overall surgical success. We agree with Adams that the incidence of surgical revisions and patient satisfaction are key quality markers for breast augmentation. However, our approach differed from his in our use of the TPS manual to define the entire patient selection, consultation, and surgical process. Great reliance was placed on staff training to manage situations that normally occur pre- and postoperatively and could have a negative impact on quality of outcomes and patient satisfaction. Terminology that describes processes and situations where mistakes and underperformance could occur—such as the terminology outlined in the TPS manual and described in the Methods section—allowed staff to better address these situations because they had an improved understanding of the connections between the steps of the process and the possible fail points.

Outcomes data from both cohorts were gleaned from a general population of women seeking primary breast augmentation. No attempt was made to “cherry-pick” specific cases that would potentially be considered to benefit from form-stable implants more than others. The only exclusions were made for inadequate tissue coverage, severe asymmetry, or ptosis that would require mastopexy correction with a vertical or keyhole pattern. Individuals with borderline ptosis, tubular breast deformities, and short nipple-fold distance were included in the cohort. We achieved excellent outcomes in these patients with the use of form-stable devices that would shape the breast versus filling the envelope.

The aggregate and device-specific outcomes from each of the cohorts in this study revealed data that demonstrated a substantial improvement over previously published benchmark data for saline, conventional gel, and form-stable gel devices.<sup>2,14-20</sup> When data comparisons are made, there can be differences in the outcomes of pre-market approval studies resulting from the work of multiple surgeons, individualized techniques, and different protocols/criteria. The results reported in this study most closely parallel the single surgeon/similar process used by Tebbetts and Adams,<sup>2</sup> with the exception of substantially longer follow-up (mean and median; Table 2).

Implant malposition as an aggregate number was lower than reported by Bengtson et al.<sup>16</sup> One patient with malposition required revision to correct capsulotomy. No implant infections were encountered in either cohort during the duration of the study, which is an improvement upon the

**Table 6.** Factors Known to Produce Rippling

Patient Factors	Device Factors	Surgeon Factors
Device location	Amount of fill	Pocket
Body mass index	Gel cohesivity	underdissected
Base diameter of breast	Texture	
	Capsular	
Base diameter of device	contracture	

1.3% also reported by Bengtson et al. Brown et al<sup>14</sup> reported a 0% infection rate in their series.

Data from the individual cohorts revealed that there were statistically significant differences in the outcomes concerning the incidence of visible and/or palpable rippling in the medial or lateral breast regions (37.3% incidence for Mentor CPG; 7.6% for Allergan 410). The matter of rippling incidence was considered from multiple dimensions. Factors known to produce rippling are displayed in Table 6.<sup>21,22</sup>

Careful statistical analysis with multivariate logistic regression showed that, even after controlling for differences between groups and other potential risk factors, the rippling incidence between the two cohorts remained statistically significant ( $P \leq .001$ ). This is of importance as it points to the root cause of rippling being device-related. There are differences noted between the two devices in terms of the apparent fill-to-shell volume and firmness of the gel, as noted by upper pole collapse when held in the vertical position. Texture may also be involved, as the Allergan 410 tended to have a “one-breast feel” in which the implant and breast tissue felt like a single unit, rather than breast tissue envelope with a palpable device inside. The Mentor CPG was noted to be more palpable, especially in the inferior breast pole, even in situations where there was no rippling encountered otherwise.

Another intriguing explanation for rippling is the matter of the mandrel curve used to mold the shells of the respective devices. There is the possibility that the simple act of placing implants on the curvilinear surface of the ribs alters the edge curve geometry enough to produce side pleating due to increased side wall stress from anterior compressive forces.

The CPG cohort showed more rippling than reported for Mentor saline devices.<sup>23</sup> The Allergan 410 cohort had more rippling than reported for conventional gel devices but less than reported for all saline devices.<sup>24</sup> Rippling rates in both devices were noted to be greater in both cohorts than data reported elsewhere. Following statistical analysis that controlled for other variables, the fivefold difference in the reported rate of visible/palpable rippling between the two cohorts appears to be related to differences that are device specific. Other investigators have encountered CPG rippling<sup>2,25</sup>; it is of interest that, in the data reported by Tebbetts and Adams,<sup>2</sup> there was a four-fold greater incidence of rippling reported in the CPG cohort than in the Natrelle 410 cohort.

**Table 7.** Revision Rate of 0% in Consecutive Cases, Incidence/Interval

	Incidence (Number of Cases)	Interval, mo
Allergan 410 (Jewell <sup>6</sup> )	87	40
Mentor CPG (Jewell <sup>6</sup> )	73	31
Tebbetts 410 (Tebbetts <sup>5</sup> )	50	36

Device rotation has been discussed as occurring with form-stable devices. Data from the cohorts demonstrated that the 0.8% rotation rate was very low in comparison to previously published figures.<sup>15,26,27</sup> Accurate pocket dissection and avoidance of overdissection, along with the use of closed suction drains, are important factors that will promote device-tissue contact. Device rotation has been touted as problematic with shaped implants.<sup>26</sup>

The incidence of CC in both cohorts was low. There is general agreement between the data generated from both cohorts from this study and data on CC incidence reported by other investigators using form-stable devices.<sup>14-16,19</sup> Contracture data for all form-stable devices appear better than what has been reported for saline and conventional gel devices.

Both cohorts were classified as Baker I-II soft. The Natrelle 410 had a greater incidence of Baker III CC (at 2.5%) as compared with the Mentor CPG (at 0.8%). There were no revisions to correct CC. There was no progression noted in terms of a Baker III becoming a Baker IV contracture during the duration of the study.<sup>12</sup> It is believed that measures taken to reduce biofilm contamination of implants, parenteral/oral antibiotics, and drains were effective.<sup>28,29</sup> Both cohorts had lower incidence of CC than the 5.6% reported by Hedén et al.<sup>17</sup>

There were 13 pregnancies in the two cohorts. All patients were able to successfully breastfeed their babies without reported problems. Patients were satisfied with the appearance of their breasts after weaning and normal involution occurred. Seven of the 13 had biplanar implant placement; six were in the retromammary location.

Surgical revisions occurred in both cohorts for a variety of root causes. Some occurred as a result of surgeon-related factors, such as inadequate pocket dissection that produced a malposition problem or inadequate hemostasis from the inferior medial perforator vessel that produced surgical bleeding requiring revision five minutes after the patient was transferred to the recovery area. Other factors contributing to a need for scar revision are indeterminate. One patient required revision for a seroma because of “bedroom trauma” that occurred nine months after the initial surgery. The majority of the aggregate number of revisions (82%) resulted from factors that were beyond the control of the surgeon (eg, scarring, seroma, and breast cancer). The importance of having defined processes to manage AEs associated with breast augmentation was helpful in defining management options.<sup>30</sup>

Three patients in the Mentor CPG cohort developed stage one (T1N0M0) breast cancer (two unilateral, one bilateral). Segmental mastectomies with sentinel node dissections were counted as revisions ( $n = 4$ ). One patient developed cancer in the contralateral breast, accounting for a total of four revisions (two segmental mastectomies with implant salvage in which the anterior capsule was replaced with acellular dermal matrix and two size exchanges to compensate for volume loss). Another patient accounted for two revisions—a segmental mastectomy with sentinel node biopsy that was combined with acellular dermal matrix, followed by a later size exchange to compensate for volume loss. One patient underwent a segmental mastectomy with sentinel node biopsy that was followed by radiation only. None of the sentinel node biopsies were positive for metastatic cancer. None of the patients who developed breast cancer have required explantation.

The impact of using a quality process derived from the TPS manual was substantive in terms of reducing the incidence of revisions while producing a high degree of patient satisfaction with the aesthetic outcome. These processes appeared to offer reproducibility in outcomes and substantially longer intervals of consecutive cases between revisions. It was possible to improve upon published data regarding the rate and interval between revisions (Table 7).<sup>31,32</sup> Our data reinforced the relevancy of quality initiatives in which there is an emphasis on the concept of breast augmentation as a series of events that are all connected.<sup>2</sup> With the use of carefully considered protocols throughout the augmentation process, we believe that mistakes that would necessitate surgical revision can be reduced or even eliminated.

## CONCLUSIONS

Provided that there is adherence to the core principles outlined in this study—which are directed toward avoidance of mistakes in planning, patient expectations, or surgery—highly cohesive, form-stable breast implants can deliver excellent long-term outcomes in primary breast augmentation in a diverse patient population. We considered breast augmentation with form-stable anatomic breast implants as a manufacturing process and determined that substantive improvements could be made to ensure predictable long-term outcomes, a very low rate of revision, and high degree of patient satisfaction. The impact of quality processes such as those described in the Toyota Production System and Lean Manufacturing manual was substantive in delivering operational excellence in primary breast augmentation.

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## Disclosures

Mark L. Jewell, MD, is a consultant for Mentor, Allergan, Mediscis, Kythera, Sound Surgical, and Excaliard. He advises Allergan, Mediscis, COAPT, Sound Surgical, AorTech, Keller Medical, and *New Beauty Magazine*. James L. Jewell has nothing to disclose.

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