Mentor Contour Profile Gel Implants: Clinical Outcomes at 6 Years

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Background: MemoryShape (Contour Profile Gel) is a textured contoured implant filled with a cohesive silicone gel intended for use in aesthetic and reconstructive breast surgery. The 6-year summary of the clinical outcomes and satisfaction rates for this device from a 10-year, prospective, open-label, multicenter clinical trial is presented.

Methods: According to 2006 guidelines set forth by the U.S. Food and Drug Administration, 955 women were enrolled: 572 undergoing primary augmentation, 124 undergoing revision-augmentation, 191 undergoing primary reconstruction, and 68 undergoing revision-reconstruction. The cumulative incidence of selected complications was estimated using the Kaplan-Meier method.

Results: For the primary augmentation cohort, Kaplan-Meier estimated 6-year cumulative incidence rates for key complications by patient were as follows: 2.4 percent Baker grade III/IV capsular contracture, 0.9 percent infection, 7.0 percent explantation, and 18.1 percent any reoperation. Corresponding rates were 9.7, 2.1, 13.6, and 24.1 percent for revision-augmentation; 10.1, 1.6, 21.8, and 44.5 percent for primary reconstruction; and 16.4, 3.0, 34.2, and 45.4 percent for revision-reconstruction. The Kaplan-Meier estimated rupture rate at 6 years was 2.1 percent for primary augmentation, 2.9 percent for revision-augmentation, 1.5 percent for primary reconstruction, and 0 percent for revision-reconstruction. Implantation of Contour Profile Gel breast implants resulted in a significant increase in circumferential chest size in the overall population (mean change, 1.5 inches; $p < 0.0001$), and 96.6 percent of patients would make the same decision to have Contour Profile Gel breast implant surgery.

Conclusions: At 6 years postoperatively, Contour Profile Gel breast implants were found to be effective and have an acceptable safety profile in women undergoing breast augmentation, reconstruction, and revision surgery. (*Plast. Reconstr. Surg.* 129: 1381, 2012.)

CLINICAL QUESTION/LEVEL OF EVIDENCE: Therapeutic, II.

Continuing efforts to enhance the performance of breast implants have led to the development of several different styles of contoured implants. The MemoryShape Breast Implant (formerly known as Contour Profile Gel) is one such device (Fig. 1). The shell is constructed with a barrier layer creating a low-bleed elastomer shell, and is filled with a more cohesive, tightly cross-linked gel as compared with Mentor round gel implants (MemoryGel). The increased density of the gel supports the contoured shell, enhancing the ability of the surgeon to control the shape of the breast.

In accordance with 2006 guidelines for industry set forth by the U.S. Food and Drug Administration, a 10-year, prospective, open-label, multi-

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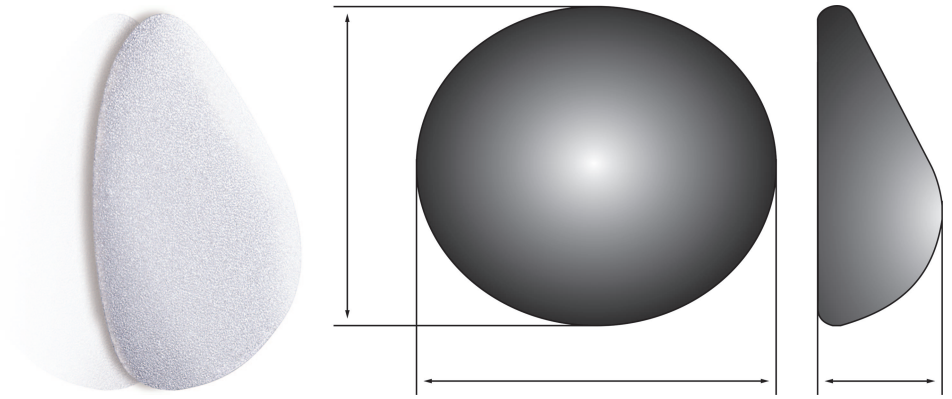

Fig. 1. The Mentor MemoryShape (Contour Profile Gel) implant.

center clinical trial was initiated to examine the safety and effectiveness of the Contour Profile Gel implant for both primary and revision breast augmentation and reconstruction. Initial 2-year results reported by Cunningham provided encouraging data regarding the performance of this device.[1] This report extends these findings by presenting key safety and effectiveness data through 6 years.

PATIENTS AND METHODS

Study Design

This prospective, multicenter, 10-year clinical trial of 955 patients was composed of four cohorts, which were assigned at entry: primary augmentation ($n = 572$), revision-augmentation ($n = 124$), primary reconstruction ($n = 191$), and revision-reconstruction ($n = 68$).[1] Each investigator participated in an innovative structured presurgical educational program and investigators' meeting that outlined the complexities and technical aspects of the Contour Profile Gel breast implant. (**See Document, Supplemental Digital Content 1**, which displays the Mentor Contour Profile Gel Study investigator list, ***http://links.lww.com/PRS/A498***.) Informed consent was obtained from each patient before enrollment and the study was conducted in compliance with the principles of the International Conference on Harmonization, adhering to Good Clinical Practice according to the Declaration of Helsinki.

Serial safety variables (e.g., infection, capsular contracture, explantation, rupture, and reoperation to the breast or surrounding areas) and efficacy data (e.g., chest circumference) were collected at five time points (10 ± 2 weeks, 1 year ± 6 weeks, 2 years ± 8 weeks, 5 years ± 4 months, and 6 years ± 4 months relative to the date of initial implant surgery). Detailed efficacy and quality-of-life results will be reserved for future publications because of space restraints. Connective tissue/autoimmune/rheumatic disease evaluations were performed at baseline and at 1, 2, 4, and 6 years after implantation.

A magnetic resonance imaging substudy of 419 patients (252 primary augmentations, 56 revision-augmentations, 74 primary reconstructions, and 37 revision-reconstructions) was conducted to detect silent ruptures, and magnetic resonance imaging scans were obtained at 1, 2, 4, and 6 years. This population of patients was used as the basis for estimating the overall rupture rate because it is only in this sample that, in general, both silent ruptures and overt ruptures would have been detected. Only the original study implants were considered in the analysis.

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Entry Criteria

Women aged 18 years or older who were candidates for primary breast augmentation (to increase breast size), primary breast reconstruction (for cancer, trauma, or severe breast abnormality), or revision surgery (previous augmentation or reconstruction with saline-filled or silicone gel-filled implants) were eligible for enrollment. The following confirmed conditions were primary reasons for exclusion from the trial: pregnancy at time of implant surgery, lactation within 3 months

of implant surgery, previous implantation with any silicone implant other than breast implants, confirmed diagnosis of rheumatic diseases or syndromes, condition that could compromise or complicate wound healing (except reconstruction subjects), diagnosis of active cancer of any type in the augmentation group (an exception is low-grade nonmetastasizing skin cancer), any infection or abscess, tissue characteristics that were clinically incompatible with implant (e.g., tissue damage resulting from irradiation, inadequate tissue, or compromised vascularity), premalignant breast disease without a subcutaneous mastectomy, and human immunodeficiency virus seropositivity.

Statistical Analysis

For demographic and operative characteristics, continuous variables were summarized using descriptive statistics. Categorical data were summarized using frequency counts and percentages. All statistical tests were performed at the 0.05 significance level.

Postoperative complication and reoperation incidence rates, including new connective tissue/autoimmune/rheumatologic disease, were calculated at the patient, implant, and event levels for each cohort and overall. The cumulative incidence of selected complications and reoperations at 10 weeks and annually through 6 years was estimated using the Kaplan-Meier method. The Kaplan-Meier method is specifically designed to take into account loss to follow-up (e.g., if a patient does not return for a follow-up visit or withdraws from the study). The rupture rate analyses were based on follow-up of the magnetic resonance imaging substudy patients through their last office visit or magnetic resonance imaging examination. Kaplan-Meier estimates were compared between Contour Profile Gel and round gel using the log-rank test.

For the primary effectiveness endpoints, overall mean changes from the preoperative assessment and the standard deviations of the overall mean changes were calculated for circumferential chest size. The Wilcoxon signed rank test was performed to test whether the overall mean change equals 0.

RESULTS

Patient Demographic and Surgical Characteristics

A total of 955 patients (572 primary augmentation patients, 124 revision-augmentation patients, 191 primary reconstruction patients, and 68 revision-reconstruction patients) were enrolled and implanted with 1831 devices between February of 2002 and September of 2004. Overall, 70 percent of patients provided follow-up data at 6 years postoperatively as of the database cutoff date (69 percent primary augmentation patients, 66 percent revision-augmentation patients, 73 percent primary reconstruction patients, and 76 percent revision-reconstruction patients). Demographic and operative characteristics are summarized in Tables 1 and 2, respectively.

Safety Outcomes

The cumulative 6-year Kaplan-Meier estimated incidence rates for complications by patient per cohort are presented in Tables 3 through 6. Overall, the primary augmentation cohort had the lowest rate of key complications: 2.4 percent Baker grade III/IV capsular contracture, 7.0 percent explantation with or without replacement, and 18.1 percent any reoperation (Table 3). Notably, subglandular placement of the device compared with submuscular/subpectoral was associated with a significantly (Cox regression, $p < 0.05$) higher risk of Baker grade III/IV capsular contracture in the primary augmentation group. Women undergoing primary or revision reconstruction (Tables 5 and 6) had higher rates of each complication compared with those having augmentation procedures (Tables 3 and 4).

The Kaplan-Meier estimated 6-year cumulative incidence rates of reoperation (excluding planned secondary operations) were 18.1, 24.1, 44.5, and 45.4 percent for the primary augmentation, revision-augmentation, primary reconstruction, and revision-reconstruction cohorts, respectively (Tables 5 and 6 and Fig. 2). The primary reasons for reoperation that occurred at a rate of greater than or equal to 10 percent for any cohort are summarized in Figure 3.

The Kaplan-Meier estimated 6-year cumulative incidence rates of explantation for any reason were 7.0, 13.6, 21.8, and 34.2 percent for the primary augmentation, revision-augmentation, primary reconstruction, and revision-reconstruction cohorts, respectively (Tables 5 and 6 and Fig. 4). The primary reasons for explanation that occurred at a rate of greater than or equal to 10 percent for any cohort are summarized in Figure 5.

Among 419 patients who had an initial magnetic resonance imaging scan as part of the magnetic resonance imaging substudy, six (four primary augmentation, one revision-augmentation, and one primary reconstruction) had evidence of a rupture of the original study implant. One implant was removed and confirmed as ruptured; five of the implants were not removed, according to the decision of the patient and/or surgeon involved. The Kaplan-Meier estimated rupture

Table 1. Demographic Characteristics

Characteristic	Primary Augmentation (%)	Revision-Augmentation (%)	Primary Reconstruction (%)	Revision-Reconstruction (%)
No. of subjects	572	124	191	68
Median age, yr	36.0	45.6	47.4	52.7
Age range, yr	18.0–66.2	20.1–65.8	19.4–72.3	29.4–77.4
Race				
African American	6 (1.0)	0 (0.0)	9 (4.7)	1 (1.5)
Asian	13 (2.3)	2 (1.6)	1 (0.5)	0 (0.0)
Caucasian	518 (90.6)	119 (96.0)	179 (93.7)	65 (95.6)
Other	30 (5.2)	3 (2.4)	2 (1.0)	1 (1.5)
Missing	5 (0.9)	0 (0.0)	0 (0.0)	1 (1.5)
Marital status				
Single	129 (22.6)	12 (9.7)	22 (11.5)	11 (16.2)
Married	361 (63.1)	88 (71.0)	146 (76.4)	47 (69.1)
Separated	10 (1.7)	3 (2.4)	0 (0.0)	1 (1.5)
Divorced	65 (11.4)	21 (16.9)	18 (9.4)	5 (7.4)
Widowed	5 (0.9)	0 (0.0)	5 (2.6)	4 (5.9)
Missing	2 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
Educational level				
<12 yr	4 (0.7)	1 (0.8)	3 (1.6)	2 (2.9)
High school graduate	48 (8.4)	15 (12.1)	25 (13.1)	9 (13.2)
Some college	199 (34.8)	44 (35.5)	49 (25.7)	22 (32.4)
College graduate	255 (44.6)	44 (35.5)	73 (38.2)	18 (26.5)
Postgraduate	58 (10.1)	18 (14.5)	37 (19.4)	15 (22.1)
Missing	8 (1.4)	2 (1.6)	4 (2.1)	2 (2.9)
Previous breast surgery (excluding mastectomy)				
Yes	13 (2.3)	124 (100.0)	123 (64.4)	63 (92.6)
No	559 (97.7)	0 (0.0)	68 (35.6)	5 (7.4)
Smoking history				
Never smoked	374 (65.4)	73 (58.9)	108 (56.5)	40 (58.8)
Currently smoker	86 (15.0)	19 (15.3)	17 (8.9)	5 (7.4)
Former smoker	112 (19.6)	32 (25.8)	66 (34.6)	23 (33.8)

Table 2. Summary of Operative Characteristics

Characteristic	Primary Augmentation (%)	Revision-Augmentation (%)	Primary Reconstruction (%)	Revision-Reconstruction (%)
No. of implants	1143	247	328	113
Surgical approach				
Periareolar	67 (5.9)	36 (14.6)	15 (4.6)	0
Inframammary	1046 (91.5)	204 (82.6)	78 (23.8)	35 (31.0)
Transaxillary	0	0	1 (0.3)	0
Mastectomy scar	0	3 (1.2)	225 (68.6)	78 (69.6)
Other*	30 (2.6)	4 (1.6)	9 (2.7)	0
Implant location†				
Subglandular	154 (13.5)	80 (32.4)	22 (6.7)	2 (1.8)
Submuscular/subpectoral	985 (86.2)	165 (66.8)	306 (93.3)	111 (98.2)
Other‡	4 (0.3)	2 (0.8)	0	0
Incision size, cm				
Median	5.0	6.0	6.0	6.0
Range	3–29	3–28	4–15	4–16
Pocket irrigation (not mutually exclusive)				
Saline	781 (68.3)	152 (61.5)	173 (52.7)	50 (44.6)
Steroid	49 (4.3)	20 (8.1)	33 (10.1)	8 (7.1)
Antibiotic	779 (68.2)	196 (79.4)	273 (83.2)	81 (71.7)
Drug	44 (3.8)	30 (12.1)	45 (13.7)	13 (11.5)
Other§	186 (16.3)	26 (10.5)	34 (10.4)	15 (13.3)
Missing	0	2 (0.8)	0	0

*Other surgical approaches include circumareolar, inverted-T, reduction scar, standard Wise keyhole mastopexy, and transverse rectus abdominis myocutaneous scar.

†Subglandular placement of the device compared with submuscular/subpectoral placement was associated with a significantly (Cox regression, $p < 0.05$) higher risk of Baker grade III/IV capsular contracture in the primary augmentation group.

‡Other implant locations include partial retropectoral and prepectoral.

§Other pocket irrigations include various povidone-iodine dilutions, Marcaine (AstraZeneca, London, United Kingdom), epinephrine-soaked sponges, and Techni-Care (Care-Tech Laboratories, St. Louis, Mo.).

Table 3. Kaplan-Meier Estimated 6-Year Cumulative Incidence Rates of Adverse Events for Primary Augmentation Patients (*n* = 572)

	%	95% CI
Key complications		
Any reoperation	18.1	15.1–21.6
Explantation with or without replacement	7.0	5.1–9.5
Baker grade III/IV capsular contracture	2.4	1.4–4.2
Infection	0.9	0.4–2.1
Other complications ≥1%		
Mass/cyst	5.9	4.1–8.3
Nipple sensation changes*	4.4	3.0–6.6
Breast sensation changes*	3.6	2.3–5.6
Patient dissatisfied with aesthetic appearance of breast	2.8	1.7–4.6
Scarring	2.4	1.4–4.1
Breast pain*	2.4	1.4–4.1
Position dissatisfaction*	2.0	1.1–3.7
Miscarriage	1.6	0.8–3.3
New diagnosis of rheumatic disease†	1.4	0.7–3.0
Hematoma	1.2	0.6–2.6
Patient dissatisfied with feel of implant	1.1	0.5–2.5
Implant rotation	1.1	0.5–2.4
Hypertrophic scarring	2.5	1.5–4.3
Ptosis	14.6	11.7–18.0
Size change (patient request)	3.7	2.4–5.7
Wrinkling*	2.7	1.6–4.5

CI, confidence interval.
*Mild occurrences were excluded.
†There were 10 new diagnoses of rheumatic disease in seven primary augmentation patients: spondyloarthropathies (25 months), other connective tissue diseases (35 months), Sjögren syndrome (35 and 42 months), systemic lupus erythematosus (35, 42, and 44 months), fibromyalgia (36 and 37 months), and undifferentiated connective tissue disease (41 months).

Table 4. Kaplan-Meier Estimated 6-Year Cumulative Incidence Rates of Adverse Events for Revision-Augmentation Patients (*n* = 124)

	Rate (%)	95% CI (%)
Key complications		
Any reoperation	24.1	17.2–33.0
Explantation with or without replacement	13.6	8.6–21.3
Baker grade III/IV capsular contracture	9.7	5.3–17.5
Infection	2.1	0.5–8.7
Other complications ≥1%*		
Patient dissatisfied with aesthetic appearance of breast	8.1	4.1–15.7
Mass/cyst	6.6	3.2–13.5
Nipple sensation changes†	5.3	2.4–11.4
Patient dissatisfied with feel of implant	4.6	1.9–10.7
Position dissatisfaction†	3.7	1.4–9.7
Palpability of implant†	3.5	1.3–9.2
Breast sensation changes†	2.7	0.9–8.2
Implant rotation	2.6	0.9–8.0
Wound dehiscence	2.4	0.8–7.4
Scarring	2.2	0.6–8.5
Baker grade II capsular contracture with surgical intervention	1.7	0.4–6.5
Tenderness/soreness	1.3	0.2–9.1
Delayed wound healing†	1.2	0.2–8.5
Fibrocystic disease	1.2	0.2–8.4
Patient would not have surgery again	1.2	0.2–8.3
Calcification†	1.1	0.2–7.7
Miscarriage	1.1	0.2–7.7
Skin lesion	1.1	0.2–7.5
Nipple complication	1.1	0.2–7.4
Asymmetry†	1.7	0.4–6.6
Hypertrophic scarring	3.5	1.3–8.9
Ptosis	14.4	8.7–23.4
Size change		
Patient request	6.6	3.4–12.8
Physician assessment only	1.7	0.4–6.5
Wrinkling†	5.9	2.9–12.0

CI, confidence interval.
*There was one (<1%) new diagnosis of rheumatic disease: rheumatoid arthritis (11 mo).
†Mild occurrences were excluded.

rates based on magnetic resonance imaging substudy patients followed through their last office visit or magnetic resonance imaging examination were 2.1 percent (95 percent confidence interval, 1.0 to 6.9 percent) for primary augmentation, 2.9 percent (95 percent confidence interval, 0.5 to 22.8 percent) for revision-augmentation, 1.5 percent (95 percent confidence interval, 0.2 to 11.1 percent) for the primary reconstruction, and 0 percent for revision-reconstruction.

In the overall study population (955 patients), there were three additional reports of rupture: one in the primary augmentation non–magnetic resonance imaging cohort (suspected by means of mammogram; removed but not returned for evaluation), one in the revision-augmentation non–magnetic resonance imaging cohort (suspected based on abnormal appearance; removed and confirmed as ruptured), and one in the primary reconstruction magnetic resonance imaging cohort (removed and confirmed as ruptured; however, it was not the original study device and therefore was not included in Kaplan-Meier analysis). In one patient in the primary augmentation cohort, a rupture identified with magnetic resonance imaging was noted to be associated with evidence of extracapsular silicone.

Fourteen new rheumatologist-confirmed diagnoses of connective tissue, autoimmune, or rheumatic disease were reported in 11 patients through 6 years. These included 10 diagnoses in seven primary augmentation patients, one diagnosis in a revision-augmentation patient, and three diagnoses in three primary reconstruction patients (Tables 3 and 5). There were no new diagnoses of rheumatic disease in the revision-reconstruction cohort.

Table 5. Kaplan-Meier Estimated 6-Year Cumulative Incidence Rates of Adverse Events for Primary Reconstruction Patients (*n* = 191)

	Rate (%)	95% CI (%)
Key complications		
Any reoperation	44.5	37.5–52.2
Explantation with or without replacement	21.8	16.4–28.7
Baker grade III/IV capsular contracture	10.1	6.2–16.0
Infection	1.6	0.5–5.0
Other complications ≥1%		
Lack of projection	8.5	5.1–14.1
Patient dissatisfied with aesthetic appearance of breast	5.1	2.6–10.2
Implant rotation	5.1	2.5–10.0
Mass/cyst	4.6	2.2–9.8
Excess skin/tissue	4.3	2.2–8.5
Baker grade II capsular contracture with surgical intervention	4.2	2.0–8.7
Implant immobility	3.8	1.7–8.2
Seroma	3.4	1.5–7.4
Nipple sensation changes*	2.9	1.2–6.9
Scarring	2.9	1.2–6.8
Breast pain*	2.8	1.2–6.6
Recurrent breast cancer	2.5	0.9–6.5
Loss of definition of inframammary fold	2.3	0.9–6.1
Metastatic disease	2.3	0.9–5.9
Miscarriage	2.1	0.7–6.6
Position dissatisfaction*	2.1	0.7–6.6
Irritation/inflammation	2.1	0.8–5.6
Skin lesion	1.8	0.6–5.5
Patient dissatisfied with feel of implant	1.7	0.6–5.3
Suture complication	1.7	0.6–5.3
New diagnosis of rheumatic disease†	1.7	0.6–5.1
Shape distortion	1.6	0.4–6.5
Other: missing	1.6	0.4–6.3
Death as a result of metastatic disease	1.4	0.4–5.5
Tenderness/soreness	1.4	0.3–5.7
Itching	1.3	0.3–5.2
Breast sensation changes*	1.1	0.3–4.5
Delayed wound healing*	1.0	0.3–4.1
Asymmetry*	10.6	6.7–16.7
Hypertrophic scarring	2.5	0.9–6.4
Ptosis	5.8	3.0–10.8
Size change		
Patient request	5.0	2.6–9.4
Physician assessment only	2.2	0.8–5.6
Wrinkling*	4.0	1.9–8.2

CI, confidence interval.
*Mild occurrences were excluded.
†There were three new diagnoses of rheumatic disease in three primary reconstruction patients: rheumatoid arthritis (10 months), other inflammatory arthritis (11 months), and other mechanical/degenerative condition (16 months).

Table 6. Kaplan-Meier Estimated 6-Year Cumulative Incidence Rates of Adverse Events for Revision-Reconstruction Patients (*n* = 68)

	Rate (%)	95% CI (%)
Key complications		
Any reoperation	45.4	34.0–58.5
Explantation with or without replacement	34.2	24.0–47.3
Baker grade III/IV capsular contracture	16.4	8.7–29.8
Infection	3.0	0.8–11.4
Other complications ≥1%		
Lack of projection	13.7	7.1–25.6
Patient dissatisfied with aesthetic appearance of breast	8.4	3.5–19.1
Scarring	6.5	2.1–19.6
Position dissatisfaction*	4.9	1.6–14.4
Seroma	4.6	1.5–13.5
Skin lesion	4.3	1.1–16.3
Patient dissatisfied with feel of implant	3.8	0.9–14.6
Baker grade II capsular contracture with surgical intervention	3.7	0.9–14.2
Recurrent breast cancer	3.6	0.9–13.9
Palpability of implant*	3.5	0.9–13.4
Paresthesia	3.4	0.9–12.9
Breast pain*	3.3	0.8–12.8
Irritation/inflammation	3.0	0.8–11.3
Implant immobility	1.9	0.3–12.9
Excess skin/tissue	1.6	0.2–11.1
Metastatic disease	1.6	0.2–10.9
Implant rotation	1.5	0.2–10.4
Muscle atrophy	1.5	0.2–10.1
Hematoma	1.5	0.2–10.0
Swelling (excessive)	1.5	0.2–10.0
Erythema	1.5	0.2–10.0
Loss of definition of inframammary fold	1.5	0.2–10.0
Silicone from previous rupture	1.5	0.2–10.0
Asymmetry*	6.1	2.3–15.6
Ptosis	12.2	5.5–25.6
Size change		
Patient request	9.9	4.5–20.8
Physician assessment only	4.8	1.2–17.8
Wrinkling*	12.2	5.9–24.5

CI, confidence interval.
*Mild occurrences were excluded.

Through 6 years postoperatively, a total of six patients had at least one new diagnosis of breast cancer, including four patients (0.7 percent) in the primary augmentation cohort, one patient (0.8 percent) in the revision-augmentation cohort, and one patient (0.5 percent) in the primary reconstruction cohort. No new cases of breast cancer were reported in the revision-reconstruction cohort. Four primary reconstruction patients (2.1 percent) and two revision-reconstruction patients (2.9 percent) had a diagnosis of recurrent breast cancer.

Effectiveness

Implantation of Contour Profile Gel breast implants resulted in a significant increase in circumferential chest size in the overall population (mean change, 1.5 inches; $p < 0.0001$). High satisfaction was observed in that 96.6 percent (562 of

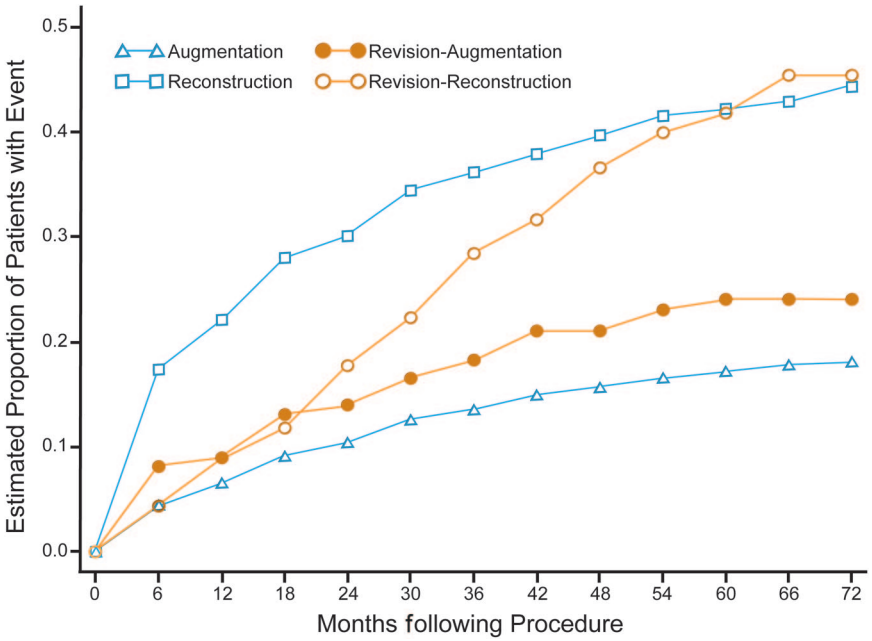

Fig. 2. Kaplan-Meier estimated cumulative incidence of any reoperation: 6-year follow-up data.

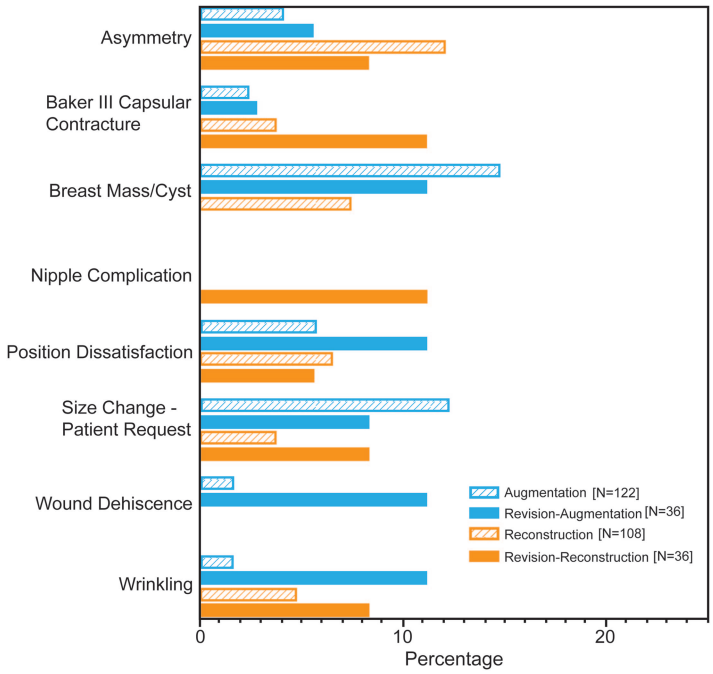

Fig. 3. Primary reason for reoperation (>10 percent for any cohort): 6-year follow-up data.

582) of women stated they would "make the same decision to have this breast surgery."

DISCUSSION

Silicone gel–filled breast implants are one of the most studied devices in medical history. However, long-term safety and effectiveness data for the newer generation highly cohesive, form-stable breast implants are just beginning to emerge.[1–5] This article confirms and extends to 6 years the 2-year postimplantation findings by Cunningham[1] that Contour Profile Gel breast implants are safe

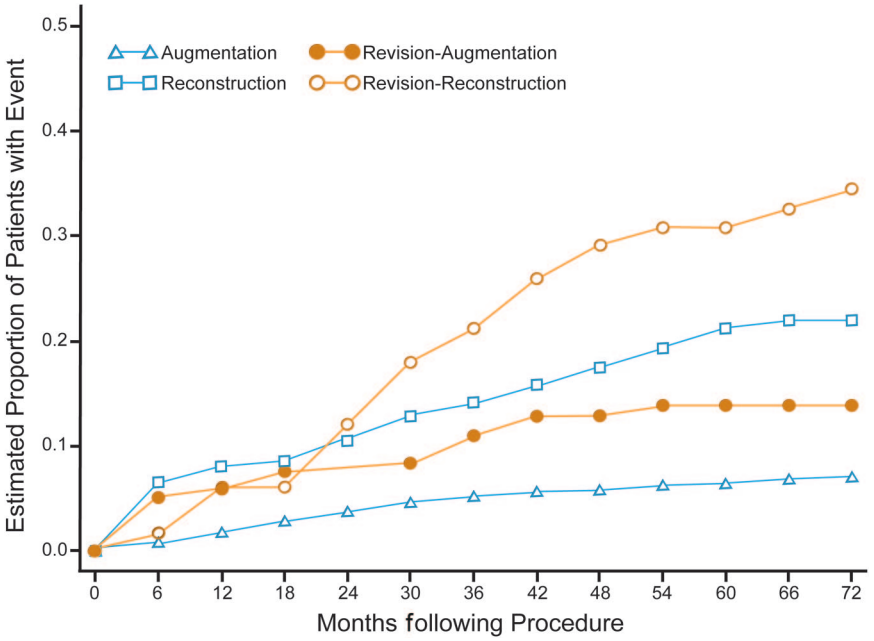

Fig. 4. Kaplan-Meier estimated cumulative incidence of explantation, with or without replacement: 6-year follow-up data.

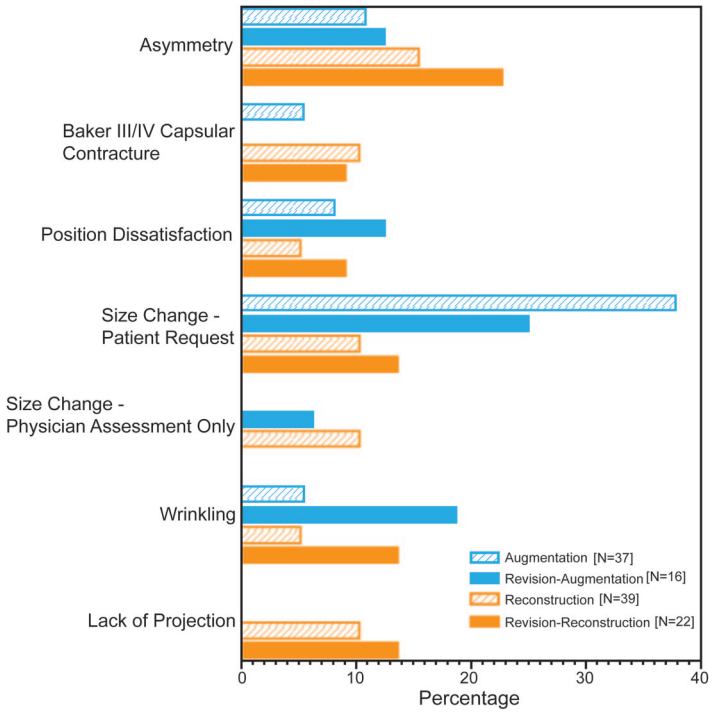

Fig. 5. Primary reason for explantation (>10 percent for any cohort): 6-year follow-up data.

and effective following breast augmentation and reconstruction. The demographics of the women who participated in this 6-year follow-up (e.g., majority ≥30 years old) are comparable to the profile of women who participated in the Core Round Gel Study[6,7] and to the general U.S. population of women undergoing augmentation and reconstruction breast implant procedures.[8] Notably, 6-year cu-

mulative postoperative complication incidence rates with Contour Profile Gel breast implants for Baker grade III/IV capsular contracture, infection, reoperation, and explantation with or without replacement were often lower than the rates for Mentor's Round Gel breast implants.[6,7] Importantly, the overwhelming majority of women who underwent surgery with Contour Profile Gel breast implants (>96 percent) claimed they would make the same decision to have the surgery, indicating a high level of satisfaction.

For more than 40 years, capsular contracture has plagued plastic surgery as one of the most common complications of aesthetic and reconstructive breast surgery.[9] However, only a few studies have included large enough sample sizes and a prospective and randomized design, and achieved adequate follow-up, to obtain a true measure of rates of capsular contracture occurrence.[10] Although it is possible that the Contour Profile Gel form stabilized shape and more cohesive gel may mask mild degrees of capsular contracture, the 6-year data reported in this article found that the Contour Profile Gel implant provided statistically lower estimated cumulative incidence rates when compared with the Core Round Gel implant for Baker grade II/III/IV capsular contracture. The improved contracture rates with the Contour Profile Gel implant are likely the result of the multifaceted education program that focused on meticulous preoperative preparation and precise operative technique specifically developed in an attempt to avoid complications such as rotation and malposition. The obvious advantages of a decrease in capsular contracture are fewer reoperations for implant removal/replacement and a better aesthetic result.

Infection can be a cause of significant morbidity following breast implantation, with a reported incidence of 2.0 to 2.5 percent.[11,12] Low-grade subclinical infections with biofilm formation are also speculated to be a potential cause for capsular contracture.[11,13] The estimated cumulative incidence rate for infection 6 years after implantation of the Contour Profile Gel device ranged from 0.9 to 3.0 percent across cohorts, compared with 0 to 5.7 percent across cohorts in the Core Round Gel Study (data on file; Mentor Worldwide LLC, Santa Barbara, Calif.).

Over the past two decades, reoperation rates have remained between 13 and 20 percent at 3 years postoperatively in three different premarket approval studies for three different types of implant devices, indicating that reoperation rates are not device dependent.[14] In this 6-year follow-up, the Kaplan-Meier estimated cumulative reoperation incidence rates for the Contour Profile Gel implant compared with the Core Round Gel implant were 18.1 percent versus 18.7 percent for the primary augmentation cohort, 24.1 percent versus 34.2 percent for the revision-augmentation cohort, 44.5 percent versus 32.9 percent for the primary reconstruction cohort, and 45.4 percent versus 37.0 percent for the revision-reconstruction cohort. The higher incidence rates of reoperations in the reconstruction versus the augmentation cohorts are expected because the reconstruction process typically involves multiple procedures to achieve the intended aesthetic result. The primary reasons for reoperations varied by cohort; the five most frequent across cohorts included breast mass/cyst, size change, asymmetry, position dissatisfaction, and capsular contracture.

Removal of a silicone gel implant may be requested for a variety of reasons, including aesthetic concerns related to capsular contracture, systemic symptoms, rupture determined by mammography, and fear of interference with mammography or clinical examination for breast cancer.[15] Although no deaths have been attributed to explantation, an overall morbidity incidence of 20 percent has been reported.[16] The estimated cumulative incidence rates of Contour Profile Gel implant removal at the 6-year follow-up ranged from 7.0 to 34.2 percent across cohorts and were similar to rates observed with the Mentor Core Round Gel implant (6.9 to 24.0 percent across cohorts) (data on file; Mentor).

Although information about silicone gel implant longevity is sparse, sequelae of rupture may include migration of gel accompanied by inflammation and silicone granuloma formation[17] and autoimmune or related diseases.[18] The escape of silicone gel from the implant shell typically occurs following intracapsular rupture; however, the event is often unrecognized because of a lack of patient complaints or physical changes in breast configuration. Extracapsular rupture (leakage of gel outside the fibrous capsule surrounding an implant) may also occur.[19] Studies that examined an actual incidence rate of breast implant rupture for newer generation round cohesive implants after repeated magnetic resonance imaging scans cited a rupture rate of 12 to 17 percent after 10 years.[20,21] Based on magnetic resonance imaging data in the current study (i.e., 213 patients with a repeated scan at year 6), the estimated rupture rate for the Contour Profile Gel breast implant was low (0 to 2.9 percent across cohorts) and less than those observed in the Core Round Gel Study at the

6-year evaluation (2.7 to 7.2 percent across cohorts; data on file, Mentor).

Breast augmentation has been associated with a higher incidence of lactation insufficiency when compared with women who have not undergone breast augmentation.[22] Damage to milk ducts during surgery and possible long-term complications, such as persistent breast pain, capsular contracture, and pressure effects on the breast from implant devices, may compromise a woman's future lactation potential. Postoperatively, through the 6-year Contour Profile Gel evaluation, 41 of the 48 patients (85.4 percent) who attempted to breastfeed reported that they had adequate milk and three (6.3 percent) reported that they did not. These rates appear similar to the general U.S. population,[23] suggesting that women with Contour Profile Gel breast implants are not likely to experience lactation problems after implantation.

There is little convincing evidence that silicone gel–filled breast implants alter the risk of nonbreast malignancies[24,25] or that the incidence of breast cancer among women who had breast augmentation is significantly higher or lower than the general population.[26] Also, augmented patients do not experience delayed detection or poorer post–breast cancer survival.[27,28] At the end of the 6-year Contour Profile Gel postoperative period, six new occurrences of breast cancer (in four patients) were reported in the primary augmentation cohort, translating to an annual incidence rate of 2.0 occurrences per 1000. There was one new occurrence of breast cancer reported in the revision-augmentation cohort, which represents an annual incidence rate of 2.0 per 1000. By comparison, among plastic surgery control patients in the Brinton et al. study,[29] there were 60 cases of breast cancer observed in 26,151 person-years of follow-up, amounting to a similar annual incidence rate of 2.3 per 1000. In the Contour Profile Gel primary reconstruction cohort, one new occurrence of breast cancer was reported 6 years postoperatively, representing an annual incidence rate of 1.1 per 1000. There were no new cases of breast cancer reported in the revision-reconstruction cohorts. Overall, a recurrence rate of as high as 30 percent has been reported during the first 5 years after the initial breast cancer diagnosis,[30] suggesting that reconstructive surgery does not negatively affect outcome.

The association between silicone gel–filled breast implants and connective tissue disease has been extensively studied. Validated data unanimously suggest that there is no evidence that breast implants exacerbate any traditional connective tissue disorders or cause an excess of atypical or undefined disease.[18,19,31,32] Although the Contour Profile Gel results reported in this analysis generally support these findings, they should be interpreted with caution because there was no comparison group of similar women without implants. In addition, patients were excluded from being implanted with a Contour Profile Gel breast device if they had a preoperatively confirmed diagnosis of a rheumatic disease. Fourteen newly confirmed diagnoses of connective tissue, autoimmune, or rheumatic disease were reported in 11 patients during the 6-year follow-up period. With 4789 person-years of follow-up across all four cohorts, this represents an annual incidence rate of 0.6 per 1000. By comparison, among the plastic surgery control patients in the study by Brinton et al.,[32] there were 49 cases of rheumatoid arthritis observed in 23,724 person-years of follow-up, corresponding to an annual incidence rate of 2.1 per 1000.

SUMMARY

At the 6-year evaluation point, Contour Profile Gel breast implants have been shown to be safe and effective and have provided high satisfaction rates in women undergoing breast augmentation, reconstruction, and revisionary procedures. The rates for key complications (i.e., contracture, infection, reoperation, explantation, and rupture) were generally comparable to or lower than those reported in Mentor's Core Round Gel Study. There was no new evidence to support a causal association between the Contour Profile Gel breast implants and breast cancer and definite or atypical connective tissue disease. Continued safety tracking through 10 years postoperatively is ongoing.

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