Mentor Contour Profile Gel Implants: Clinical Outcomes at 10 Years

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Background: Contour Profile Gel/MemoryShape breast implants consist of a textured silicone elastomer shell filled with silicone gel. The objective of this clinical study was to assess the safety and effectiveness of Contour Profile Gel/MemoryShape breast implants in women who were undergoing primary breast augmentation, primary breast reconstruction, or revision surgery (revision-augmentation or revision-reconstruction).

Methods: This was a prospective, open-label, multicenter clinical study involving Contour Profile Gel/MemoryShape breast implants in 955 female subjects, including 572 primary augmentation, 124 revision-augmentation, 190 primary reconstruction, and 69 revision-reconstruction subjects. Safety was assessed based on the incidence, severity, and method of resolution of all complications. Endpoints were examined on both a per-subject and a per-implant basis.

Results: For the primary augmentation, revision-augmentation, primary reconstruction, and revision-reconstruction cohorts, the Kaplan-Meier estimated 10-year cumulative incidence rates for the key complications at the subject level were as follows: Baker grade III/IV capsular contracture, 3.6 (primary augmentation), 15.5 (revision-augmentation), 14.3 (primary reconstruction), and 16.4 (revision-reconstruction) percent; infection, 0.7 (primary augmentation), 1.9 (revision-augmentation), 1.6 (primary reconstruction), and 2.9 (revision-reconstruction) percent; explantation with or without replacement, 9.2 (primary augmentation), 25.9 (revision-augmentation), 34.1 (primary reconstruction), and 49.0 (revision-reconstruction) percent; explantation with replacement with study device, 4.0 (primary augmentation), 10.8 (revision-augmentation), 16.7 (primary reconstruction), and 27.9 (revision-reconstruction) percent; and any reoperation, 22.3 (primary augmentation), 35.0 (revision-augmentation), 52.7 (primary reconstruction), and 59.7 (revision-reconstruction) percent.

Conclusion: The results of this study demonstrate that Contour Profile Gel/MemoryShape breast implants are safe and effective for primary and revision breast augmentation and reconstruction for women at least 22 years old. (*Plast. Reconstr. Surg.* 140: 1142, 2017.)

Anatomically shaped silicone gel breast implants were introduced to improve the safety profile associated with silicone gel breast implants and enhance aesthetic results. Mentor's Contour Profile Gel implant (Mentor Worldwide LLC, Irvine, Calif.), known as the MemoryShape breast implant in the United States, is a device filled with a more cohesive gel than round devices, and which concentrates

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the fill volume in the lower pole with a tapered upper pole. The firmer gel allows the implant to resist deformation and is intended to shape the breast rather than the breast shaping the implant, as is the case with round devices. Thus, by using a properly chosen implant, the Contour Profile Gel/MemoryShape device is designed to fit synergistically with the patient's soft tissue. The Contour Profile Gel/MemoryShape breast implant is textured using microtexture (Siltex; Mentor) designed to reduce the rate of capsular contracture and to providing sufficient friction between the implant and the capsule to retain proper orientation. This 10-year, open-label, multicenter, prospective study was designed to collect safety and efficacy data on the Contour Profile Gel/MemoryShape breast implant. These findings extend the previously reported 2-, 6-, and 9-year results.[1–3]

PATIENTS AND METHODS

Study Design

The current study was conducted in accordance with U.S. Food and Drug Administration Breast Implant Guidance.[4] Inclusion and exclusion criteria, along with study endpoints and schedule of visits, were described previously.[2] The medium-height, moderate-profile breast implant was used in this study. Informed consent was obtained from patients before study enrollment in compliance with the principles of the International Conference on Harmonization and Good Clinical Practice according to the Declaration of Helsinki. The supplemental material provides details on (1) the Contour Profile Gel/MemoryShape Post Approval Continued Access Study and (2) the Contour Profile Gel/MemoryShape Styles Study, both initiated after enrollment into the Core Study was completed. (**See Document, Supplemental Digital Content 1**, which shows Methods and Results from the Contour Profile Gel/MemoryShape PostApproval Continued Access Study and the Contour Profile Gel/MemoryShape Styles Study, ***http://links.lww.com/PRS/C438***.)

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Statistical Analysis

Demographic variables and baseline and operative characteristics were summarized by cohort using descriptive statistics for continuous variables and frequency counts and percentages for categorical variables. Safety analyses were based on events having an onset date calculated to be within 120 months of the initial implant surgery. The cumulative incidences of complications and reoperations through each of the scheduled follow-up visits were estimated using the Kaplan-Meier method. Subjects were censored as of the date of their last office visit, the 120-month time point, or the date of explantation of all initial study devices, whichever was earliest. A subject was counted only once regardless of whether the subject had bilateral or unilateral implants. In addition, if a subject or implant experienced more than one event of the same type over the course of the study, only the first event was considered in the analyses.

Kaplan-Meier survival analyses of time to rupture was calculated as the number of days from surgery to the earliest of the following dates: (1) the investigator-reported onset date, (2) the nominal date of the earliest scheduled magnetic resonance imaging at which the rupture was detected, and (3) the actual date of the earliest interim magnetic resonance imaging at which the rupture was detected. These analyses were conducted using only subjects who underwent magnetic resonance imaging evaluation. Verification of rupture, identified either directly by study investigator or through magnetic resonance imaging screening, also included visual examination of explanted and retrieved devices by Mentor Product Evaluation, whenever possible. The overall mean in circumferential chest and bra cup size change from the preoperative assessment was calculated. The Wilcoxon signed rank test was performed to test whether the overall mean change equals 0.

Percentages were tabulated and reported according to responses for global subject satisfaction ("Would subject make the same decision to have this breast surgery?"), investigator satisfaction ("Are you satisfied with implant results?"), and the Breast Evaluation Questionnaire ("How satisfied with the general appearance of your breasts are you?"). Response options were very satisfied, somewhat satisfied, neither satisfied nor dissatisfied, somewhat dissatisfied, or very dissatisfied.

RESULTS

Patient Demographic and Surgical Characteristics

A total of 1831 devices (Contour Profile Gel/MemoryShape textured, medium-height,

moderate-profile) were implanted in 955 study patients including 572 primary augmentation, 124 revision-augmentation, 190 primary reconstruction, and 69 revision-reconstruction patients between February of 2002 and September of 2004. Demographic and operative characteristics were previously published (note: one patient was reclassified from primary to revision-reconstruction, and although we acknowledge there is a clear difference between submuscular and subpectoral implant placement, through further investigation, we discovered these terms were used interchangeably among physicians and therefore have combined them into one category).[3]

Overall, 63 percent of patients completed follow-up at 10 years after implantation (equivalent to 95.5 percent follow-up each year of patients from the prior year). Follow-up rates at 10 years were 60 (primary augmentation), 63 (revision-augmentation), 67 (primary reconstruction), and 74 (revision-reconstruction) percent. The primary reasons for discontinuation were subject noncompliance (31.1 percent), subject lost to follow-up (29.9 percent), and explantation without study device reimplantation (21.4 percent).

Safety Outcomes

The vast majority (93.9 percent) of postoperative complications among all cohorts were considered mild (e.g., breast sensation changes) or moderate (e.g., infection) in severity, with only 5.8 percent of complications categorized as severe (e.g., Baker grade IV capsular contracture; 0.3 percent of data were missing). Per cohort, 4.6 (primary augmentation), 5.3 (revision-augmentation), 7.7 (primary reconstruction), and 10.5 (revision-reconstruction) percent of complications were categorized as severe at the event level (Table 1).

Reoperation was required in 22.3 (primary augmentation), 35.0 (revision-augmentation), 52.7 (primary reconstruction), and 59.7 (revision-reconstruction) percent of patients (Fig. 1). The most commonly reported reasons for reoperation included breast mass/cyst, asymmetry, lack of projection, size change, wrinkling, and Baker grade III capsular contracture (Fig. 2). Although breast masses/cysts requiring biopsy count toward reoperations in the present study, it is important to note that women with implants continue to undergo routine breast cancer surveillance including biopsy of any suspicious masses.

The rates of explantation among patients, with or without replacement of study device, were 9.2 (primary augmentation), 25.9 (revision-augmentation), 34.1 (primary reconstruction), and 49.0 (revision-reconstruction) percent (Fig. 3). The rates of explantation among patients with replacement of the study device were 4.0 (primary augmentation), 10.8 (revision-augmentation), 16.7 (primary reconstruction), and 27.9 (revision-reconstruction) percent. Patients without replacement of study devices underwent implantation with a Mentor nonstudy device (i.e., MemoryGel), Mentor saline device, other gel device, other saline device, or did not undergo reimplantation with any device. The most common reasons for implant removal included size change, lack of projection, asymmetry, wrinkling, and position dissatisfaction (Fig. 4).

Postoperative Complications

The Kaplan-Meier estimated 10-year cumulative incidence rates of Baker grade III/IV capsular contracture, at the subject level, were 3.6 (primary augmentation), 15.5 (revision-augmentation), 14.3 (primary reconstruction), and 16.4 (revision-reconstruction) percent (Fig. 5). Capsular contracture was measured by the investigator at 10 weeks and annually until 10-year follow-up and was graded in severity on a scale of I to IV according to the Baker classification. Capsular contracture among primary augmentation patients at 10 years for patients with subglandular placement (7.7 percent) compared to those with submuscular/subpectoral placement (3.05 percent) was not significantly different ($p = 0.0625$, log-rank test). To further test this finding, a proportional hazards

Table 1. Postoperative Complications through 10 Years after Implantation by Severity (Event Level)*

	Severity			
Subject Cohort	**Mild (%)**	**Moderate (%)**	**Severe (%)**	**Missing (%)**
Primary augmentation	1089 (71.4)	362 (23.7)	70 (4.6)	5 (0.3)
Revision-augmentation	286 (65.7)	125 (28.7)	23 (5.3)	1 (0.2)
Primary reconstruction	353 (62.0)	170 (29.9)	44 (7.7)	2 (0.4)
Revision-reconstruction	119 (59.5)	60 (30.0)	21 (10.5)	0 (0.0)
Overall accounting	1847/2730	717/2730	158/2730	8/2730

*Adverse events that were noticed by the subject were mild, those noted by both the subject and/or doctor were moderate, and those requiring treatment/intervention were severe.

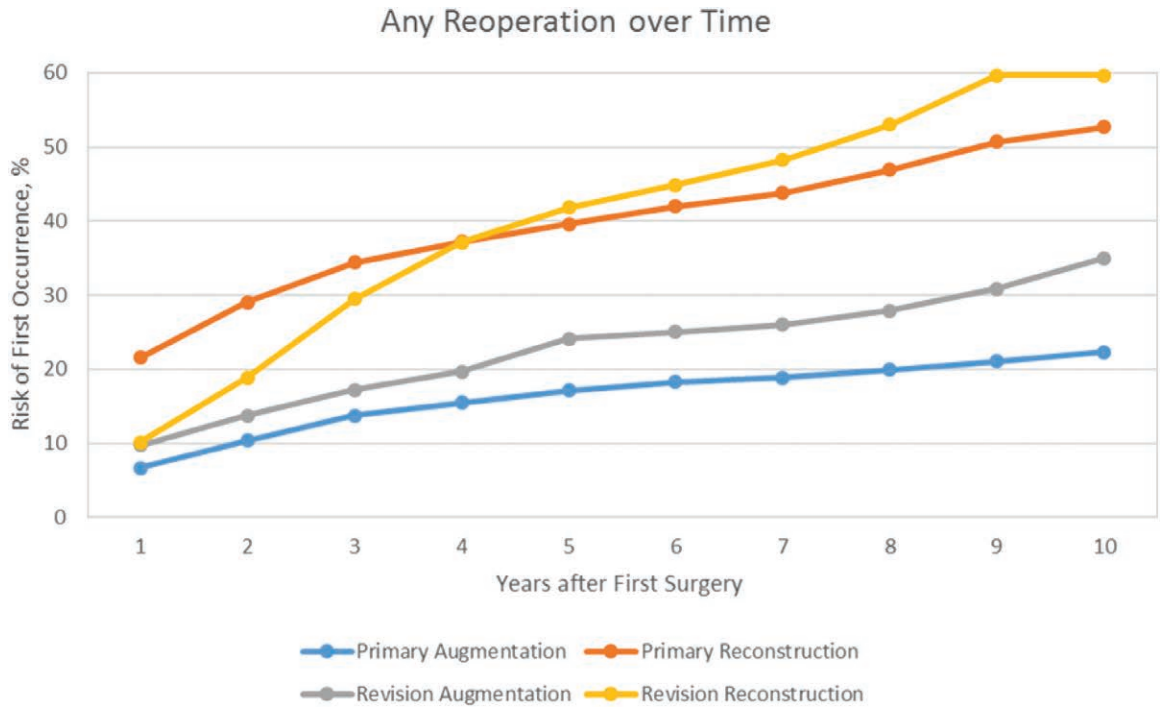

Fig. 1. Kaplan-Meier estimated cumulative incidence of any reoperation at the subject level.

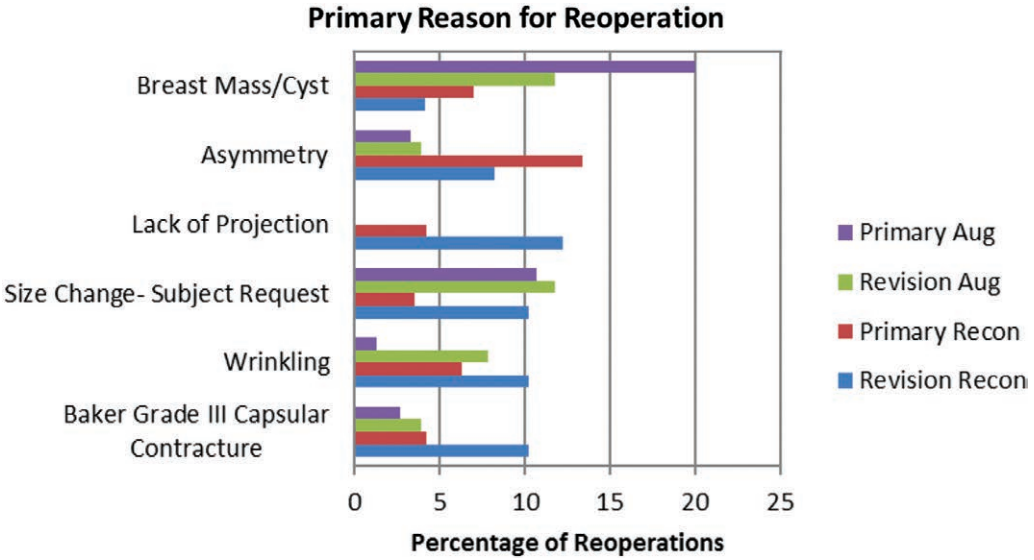

Fig. 2. Reasons for reoperation (includes only those that occurred at a rate ≥10 percent in each cohort).

regression model was fit to compare device placement while controlling for surgical approach, prior occurrence of a hematoma or seroma, and clinical site. Sites with fewer than 10 patients were pooled and included as a random effect. The proportional hazards assumption was satisfied. After controlling for these effects, the capsular contracture rate associated with subglandular device placement was significantly higher (hazard ratio, 3.1; 95 percent CI, 1.0 to 9.8; $p = 0.0358$).

The Kaplan-Meier estimated 10-year cumulative incidence rates of implant rotation were 1.3 (primary augmentation), 3.6 (revision-augmentation), 6.3 (primary reconstruction), and 5.7 (revision-reconstruction) percent. The cumulative rate of moderate and severe wrinkling among primary augmentation patients at 10 years was 2.82 percent overall, 5.37 percent for subglandular placement, and 2.46 percent for submuscular/subpectoral placement. This difference by

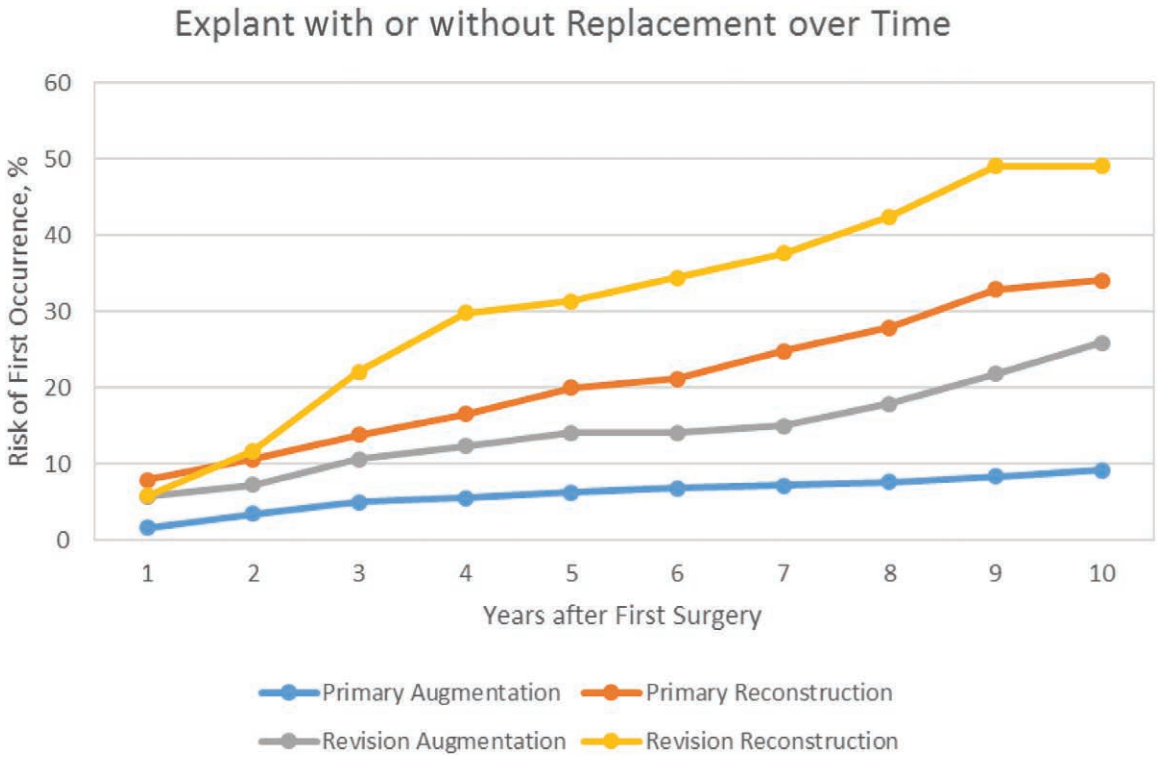

Fig. 3. Kaplan-Meier estimated cumulative incidence of explantation with or without replacement at the subject level.

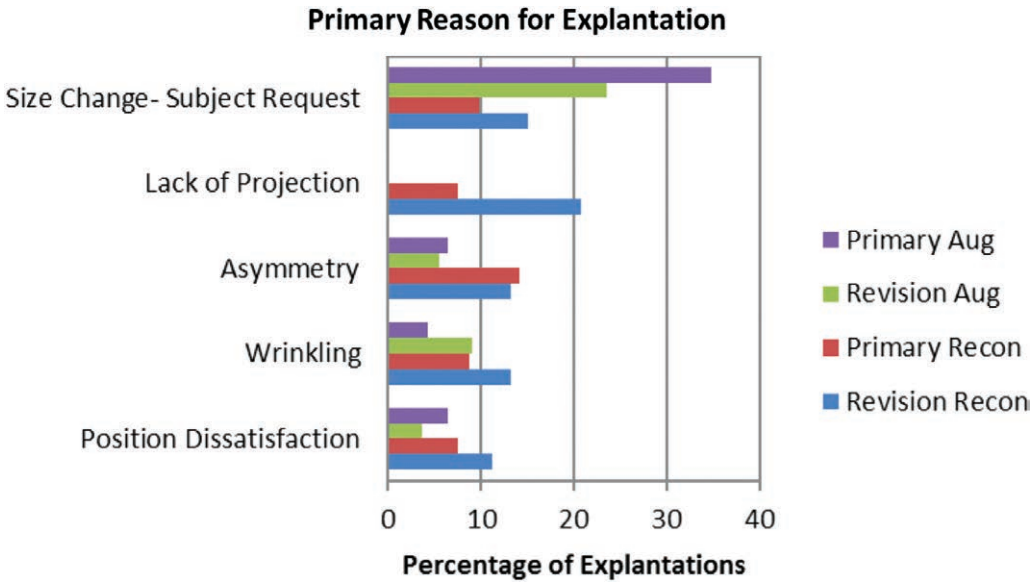

Fig. 4. Reasons for explantation (reasons include only those that occurred at a rate ≥10 percent in each cohort).

device placement was not statistically significant ($p = 0.1136$, log-rank test). Again, to further test this finding, a proportional hazards regression model was fit to compare device placement while controlling for surgical approach, prior occurrence of a hematoma or seroma, and clinical site. Sites with fewer than 10 patients were pooled and included as a random effect. The proportional hazards assumption was satisfied. Significant variation was observed between sites. Various sensitivity models were also performed to investigate the significant site effect. One site was identified as

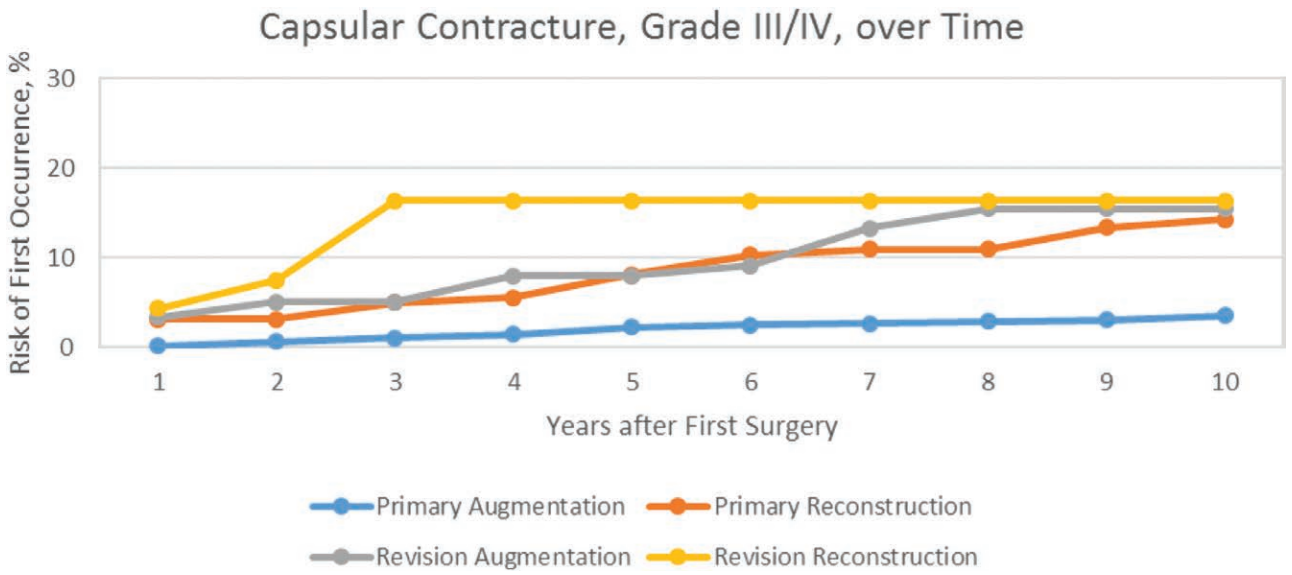

Fig. 5. Kaplan-Meier estimated cumulative incidence of Baker grade III/IV capsular contracture at the subject level.

having higher than anticipated rates of wrinkling compared with all other sites. The outlying site had high rates of wrinkling within both device placement options. When this site was removed, the cumulative rate of wrinkling was 2.17 percent at 10 years, and there was still no significant difference in wrinkling rates by device placement observed (hazard ratio, 1.66; 95 percent CI, 0.35 to 7.82; $p = 0.5219$), controlling for site variation.

Four hundred patients were initially enrolled in the magnetic resonance imaging portion of the study, as that was determined to be an adequate number to detect a silent rupture rate of 5 percent. In 2010, the protocol was modified and magnetic resonance imaging screening was implemented for all study patients. At 1, 2, 4, 6, 8, and 10 years, the respective overall follow-up rates of all patients who passed the follow-up anniversary minus deaths and discontinuations because of explantation for the magnetic resonance imaging cohort were 71, 86, 72, 63, 56, and 45 percent, respectively. Figure 6 presents the estimated rupture rates through 1, 2, 4, 6, 8, and 10 years. Overall, there were 17 suspected or confirmed reports of implant rupture for 17 patients in the original magnetic resonance imaging cohort and

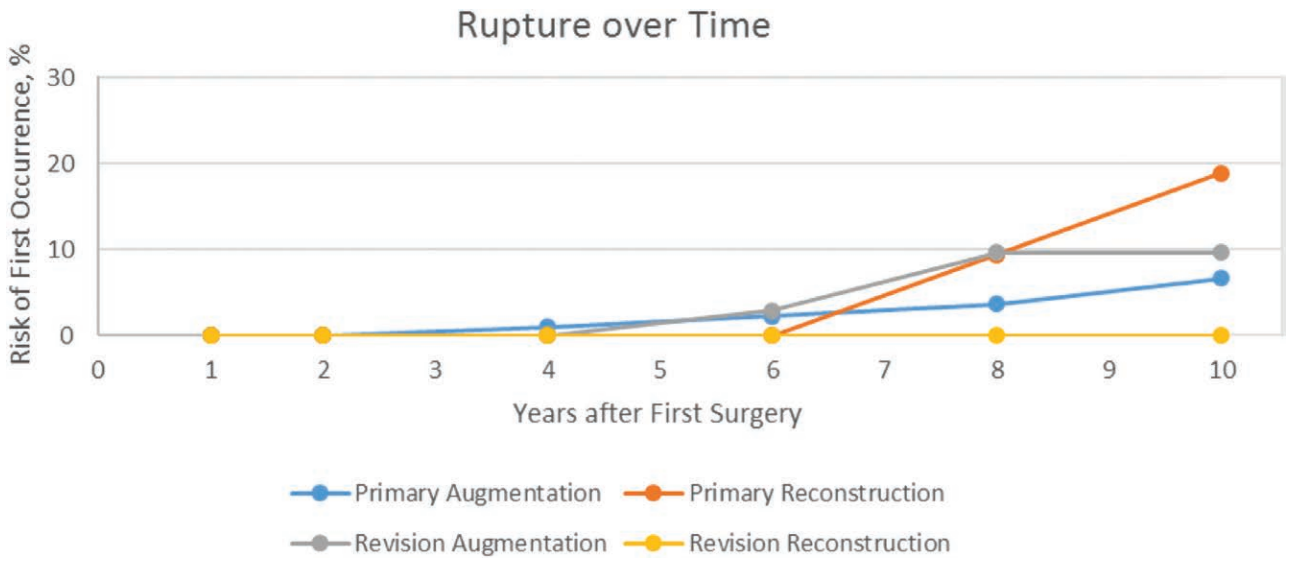

Fig. 6. Kaplan-Meier estimated cumulative incidence rates for rupture for magnetic resonance imaging substudy patients at the subject level.

20 suspected or confirmed reports of implant rupture for 18 patients in the original cohort of patients who did not undergo scheduled magnetic resonance imaging screening before 2010. A suspected rupture was identified by investigator adverse event report or magnetic resonance imaging finding. Of the 37 suspected or confirmed ruptured implants in the overall study, four cases showed definite extracapsular silicone by magnetic resonance imaging and four cases were indeterminate for extracapsular silicone. Kaplan-Meier estimated cumulative incidence rates of suspected or confirmed rupture for the magnetic resonance imaging substudy subjects at 10 years (on an implant level) were 3.3 (primary augmentation), 4.7 (revision-augmentation), 11.2 (primary reconstruction), and 0 (revision-reconstruction) percent. At the subject level, 10-year rates of suspected or confirmed rupture were 6.6 (primary augmentation), 9.6 (revision-augmentation), 18.9 (primary reconstruction), and 0 (revision-reconstruction) percent.

Through 10 years after implantation, six patients (1.0 percent) in the primary augmentation cohort had seven new diagnoses of breast cancer and one patient (0.8 percent) in the revision-augmentation cohort had one new diagnosis of breast cancer. There were no new cases of breast cancer in the primary reconstruction and revision-reconstruction cohorts. There were four incidences of late seroma at 10-year follow-up, one in the primary augmentation cohort, two in the primary reconstruction cohort, and one in the revision-reconstruction cohort. No subject was diagnosed with anaplastic large cell lymphoma (ALCL).

Efficacy Outcomes

For the primary augmentation cohort, the overall mean change in circumferential chest size through 10 years was 2.1 inches, with a mean increase of 2.2 cup sizes from baseline ($p < 0.0001$). At the 10-year follow-up visit, 96.9 percent of patients who responded to the global satisfaction question (total respondents: $n = 322$ primary augmentation patients, $n = 87$ primary reconstruction patients, $n = 66$ revision-augmentation patients, and $n = 34$ revision-reconstruction patients) indicated they would make the same decision to undergo breast implant surgery. Similarly, when asked about satisfaction with breast appearance, 86.2 percent (total respondents: $n = 299$ primary augmentation patients, $n = 93$ primary reconstruction patients, $n = 60$ revision-augmentation patients, and $n = 33$ revision-reconstruction patients) of patients indicated they were very satisfied or somewhat satisfied at 10 years, compared with only 20.7 percent at baseline (total respondents: $n = 569$ primary augmentation patients, $n = 187$ primary reconstruction patients, $n = 124$ revision-augmentation patients, and $n = 68$ revision-reconstruction patients). Investigator satisfaction was 97.6 percent ($n = 1728$).

DISCUSSION

When evaluating the results of this study, two important aspects merit emphasis: the documented safety profile and the quality of the aesthetic results as evidenced by patient satisfaction. When viewed alongside results associated with round implants[3] and even other types of anatomical implants,[5] not only do shaped implants have a superior safety profile, but the results of this study demonstrate an encouraging performance history that translates into effective results. To place the results of this study into context, it is helpful to reemphasize why shaped implants were initially developed. A typical, round, silicone gel implant merges with the overlying soft-tissue framework to create the external three-dimensional result the human eye evaluates aesthetically. When the patient is upright, the gel in a round implant can settle to the bottom of the device, causing a variable, irregular folding in the shell.[6] The result is a trend toward a teardrop shape, with the now underfilled upper pole shell variably folding and wrinkling. If there is enough soft tissue to mask these contour irregularities, this is an aesthetically tolerable event. However, the long-term sequelae of such sharply defined stress points along the fold may result in weakening of the shell, ultimately leading to fold flaw failure and rupture.[7] In cases where a proportionately higher volume round implant provides most of the volume to a smaller breast, the round implant can tend to overfill the upper pole, creating a distracting and, in many instances, undesirable amount of upper pole breast fullness.[8] The design of the Contour Profile Gel/MemoryShape device was strategically developed to address both concerns. By creating the teardrop shape initially with the anatomically shaped shell, and then filling this shell with a firmer, more cohesive gel, a stable shape is created directly by the device. Rather than the breast shaping the implant, now with the Contour Profile Gel/MemoryShape device, it is most decidedly the implant that is shaping the breast. Because the shape of the implant is stable secondary to

the presence of a more cohesive gel, the tendency for the shell to fold is reduced, leading to fewer creases in the implant, less chance for fold flaw failure, and, theoretically, a reduced rupture rate (Fig. 7). This becomes important, as long-term rupture is a common complication associated with silicone breast implants. The 10-year data reported here show a favorable rupture rate in the primary augmentation cohort, which lends support to the initial premise that limiting the propensity of the shell to fold will translate into improved long-term device performance. The reported rupture rates for the other cohorts are higher, possibly because of the more challenging surgical environments posed by revision or reconstructive procedures, where the incidence of capsular contracture and shell folding might occur more frequently. It is also important to note that there were no cases of breast implant-associated ALCL in the current study. Although, to date, all patients with breast implant-associated ALCL have had prolonged exposure to textured implants, a recent study suggests that the implant-specific risk of developing breast implant-associated ALCL per 10,000 implant years is 1:60,631 with Siltex texturing.[9]

The data confirm that the Contour Profile Gel/MemoryShape device is associated with a relatively low rate of capsular contracture that compares very favorably with reported rates for other devices.[3,5] Siltex texture is created by pressing a sheet of foam into an uncured sheet of silicone and then bonding this thin sheet to the surface of the implant, thereby creating a microtextured relief on the outer implant shell. This roughed surface then assists in maintaining the orientation of the implant because of the friction that is subsequently present between the implant surface and capsule. More importantly, this texture has been noted to reduce the rate of capsular contracture in textured versus smooth implants.[10] The precise mechanism of action for the reduction in the rate of capsular contracture with shaped implants remains poorly understood.[10] Another but perhaps small contribution to observed differences relates to these implants being firmer and more resistant to shape change than a traditional round device; therefore, a mild amount of capsular contracture can develop without any appreciable change in the overall feel or shape of the breast.

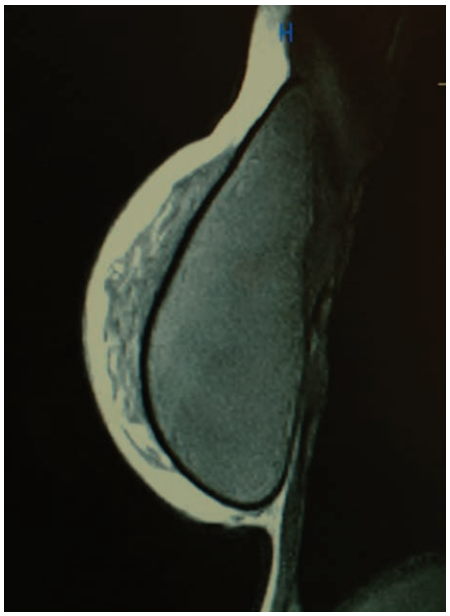

Fig. 7. Upright magnetic resonance imaging scan of a MemoryShape implant.

This study also supports the overall effectiveness of the implant. Both patient and surgeon satisfaction rates are high, implying overall aesthetic success with the device. It is difficult to assess the aesthetic performance of the implant more definitively than what has been reported because of patient body type, breast size, implant size, implant location, and varying aesthetic goals. Based on the personal experience of the surgeon authors of this article, Contour Profile Gel/MemoryShape implants offer aesthetic advantages related to control of the upper pole contour and the creation of an overall pleasing shape to the breast.

Although this study has documented both safety and effectiveness associated with the use of Contour Profile Gel/MemoryShape devices, certain modifications in technique must be incorporated into the overall surgical plan for the implants to function effectively. Perhaps the most important concern associated with the use of anatomical devices relates to the risk of postoperative rotation with distortion of the breast shape. The incidence of rotation in this study ranged from 1.3 percent in the primary augmentation cohort to 6.3 percent in the primary reconstruction cohort. Contributing to these low rotation rates are the technical modifications relating to pocket development that are required to limit the potential for rotation. Specifically, the dimensions of the pocket should closely match the dimensions of the chosen implant. In this fashion, the soft-tissue–supporting framework along with the textured surface can reliably combine to hold the implant in position until the pocket stabilizes. In any surgical situation where the implant pocket and the base diameter of the pocket exceed those of the chosen implant, the risk for rotation increases.

Therefore, in cases of total capsulectomy, or implant-based reconstruction after mastectomy, it may be difficult to control pocket base diameter, and Contour Profile Gel/MemoryShape implants should be used only with great care in such cases. It should be pointed out to the patient that the breast will have a firmer palpability because of the more highly cohesive gel, and if this feature of the operative strategy is deemed to be problematic, a more traditional, round, less cohesive implant could avoid this potential problem.

Although the present study has many strengths, limitations included the open-label nature, lack of a control group, and lower than desired follow-up rate to optimally minimize potential bias. Also, the sample size determined to prove acceptable precision in the estimation of commonly occurring complications following breast implantation does not allow for the detection of rare events.

CONCLUSION

Given appropriate surgical technique, the results from this study suggest that Contour Profile Gel/MemoryShape implants provide for safe and effective use in a variety of clinical situations.

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