Clinical Experience With a Fourth-Generation Textured Silicone Gel Breast Implant: A Review of 1012 Mentor MemoryGel Breast Implants

W. Grant Stevens, MD; Salvatore J. Pacella, MD; Andrew J. L. Gear, MD; Mark E. Freeman, MD; Celeste McWhorter; Marissa J. Tenenbaum, MD; and David A. Stoker, MD

Background: Since the introduction of fourth- and fifth-generation silicone gel implants, manufacturers have conducted several prospective, multicenter trials to examine their safety and efficacy. However, these studies were not standardized with regard to surgeon skill, pocket placement, operative technique, adjunct therapies, or postoperative management.

Objective: The purpose of this study was to examine the surgical outcomes of a single surgeon (WGS) in a consecutive series of breast augmentation cases using a fourth-generation cohesive silicone MemoryGel breast implant (Mentor, Santa Barbara, CA).

Methods: A retrospective chart review was conducted to identify all patients who underwent silicone breast augmentation within the Mentor Adjunct Silicone MemoryGel breast implant by a single surgeon (WGS) within a single free-standing outpatient surgical center over a 13-year period (1992 to 2006). For each patient, demographic information, comorbidities, and surgical information (implant size and concomitant surgery) were recorded. In addition, outcomes were analyzed to identify complications and the need for surgical revision.

Results: A total of 1012 fourth-generation, textured, cohesive silicone gel implants were placed in 511 patients during the 13-year study period. The overall complication rate per implant was 5.5% (n = 56 implants in 43 patients). The most common complication was capsular contracture (n = 26; 2.6 %) followed by abnormal scarring (n = 11; 1.1%). The overall revision rates per patient and per implant were 8.0% (n = 41 patients) and 6.8% (n = 69 implants), respectively. The average time interval between initial implantation and revision was 18.5 months (range, 2 weeks to 26 months). The most common indication for surgical revision was patient desire for implant size change (n = 15 patients) followed by Baker class III or IV capsular contracture (n = 13 patients). The presence of previous surgery for capsular contracture was not statistically correlated to the need for revision ($P = .326$). Age ($P = .568$), previous history of breast surgery ($P = .704$), and history of smoking ($P = .138$) were also not statistically correlated to revision. Placement of the implant in the subglandular position (n = 30 implants), however, was statistically correlated with need for revision ($P < .01$).

Conclusions: Mentor fourth-generation cohesive silicone gel implants possess a complication and revision profile that is superior to earlier-generation silicone gel implants. Implantation with MemoryGel implants, when standardized with regard to surgeon and operative technique, can have significantly reduced complication and revision rates compared to the Mentor Core Data. (*Aesthetic Surg J 2008;28:642–647.*)

Since the United States Food and Drug Administration (FDA) moratorium on silicone breast implants in 1992, outcomes data within the United States on newer generations of silicone implants have been relatively sparse. As third-generation devices were removed from the American market, implant manufacturers began developing fourth-generation silicone implants that had increased silicone cross-linking to create a more viscous gel. These so-called "cohesive gel" implants were a significant technological advance in reducing systematic leakage or "gel bleed."[1] Almost in parallel to the fourth-generation implants, a fifth generation was also created that had a more cohesive, form-stable gel. This

Drs. Stevens and Stoker are in private practice in Marina Del Rey, CA. Dr. Pacella is in private practice in La Jolla, CA. Dr. Gear is in practice in Sauk Rapids, MN. Dr. Freeman is in practice in Idaho Falls, ID. Ms. McWhorter is an undergraduate student in Los Angeles, CA. Dr. Tenenbaum is from the Division of Plastic and Reconstructive Surgery, Department of Surgery, Washington University School of Medicine, St. Louis, MO.

technology allowed for the construction of anatomically shaped implants in an attempt to create a more natural breast shape and fewer ripples.

Since the inception of fourth- and fifth-generation implants, manufacturers have conducted prospective, multicenter trials to examine their safety and efficacy. Examples include the Mentor Adjunct Study (1992), Mentor Contour Profile Gel Study (1993), and Mentor Core Gel Study (2000). While these studies have the benefit of being multicenter, they are not standardized with regard to surgeon skill, pocket placement, operative technique, adjunct therapies, or postoperative management.

As the popularity of silicone gel implants for breast augmentation grows, they are having an ever-increasing role in reconstruction, revision augmentation, and augmentation with mastopexy.[2-4] As recent editorials in leading plastic surgery journals iterate, plastic surgeons and investigators alike have a duty to ensure the safety and efficacy of these devices.[5] The purpose of this investigation was to examine a single surgeon (WGS) and surgical center experience with a fourth-generation textured cohesive MemoryGel implant (Mentor, Santa Barbara, CA) within the context of the Mentor Adjunct Study.

METHODS

A retrospective chart review was conducted to identify all patients who underwent breast augmentation within the Mentor Adjunct MemoryGel Silicone Breast Implant Study by a single surgeon (WGS) at a single free-standing outpatient surgical center over a 13-year period (1992 to 2006).

Inclusion criteria included patients within the Mentor Adjunct Study who had implants placed for the following indications: (1) delayed or immediate postmastectomy reconstruction; (2) posttraumatic reconstruction; (3) congenital breast anomalies requiring reconstruction (ie, tubular breasts and Poland syndrome); (4) severe breast involution with ptosis requiring a mastopexy in addition to augmentation; (5) reconstructive or aesthetic revision breast implant surgery; or (6) patients who were inappropriate candidates for saline implants because of thin skin, insufficient tissue, or severe wrinkling.[6,7]

Exclusion criteria included the following: (1) failure to have at least 1 of the diagnoses identified in the Mentor Adjunct Study inclusion criteria; (2) abscess or infection; (3) currently pregnant or nursing; (4) diagnosed as having lupus defined as systemic lupus erythematosus or discoid lupus, or scleroderma defined as progressive systemic sclerosis; (5) currently have uncontrolled diabetes; (6) demonstrating tissue characteristics that are clinically incompatible with mammaplasty; (7) any condition that in the opinion of the investigator may constitute unwarranted surgical risk; (8) demonstration of psychological characteristics such as inappropriate attitude or motivation; or (9) having an unwillingness to undergo any further surgery for revision (if required).[7]

All implants included within the study were fourth-generation, textured, round, cohesive silicone gel (MemoryGel; Mentor) and were placed under general anesthesia. Mentor defines these implants as highly cross-linked silicone gel with a multilayered barrier to inhibit silicone gel bleed.[8] Prophylactic intravenous antibiotics and betadine irrigation of the surgical pocket were performed in all cases, and the implants were placed using a minimal-touch technique. Surgical drains and Foley catheters were not used. All patients were instructed on early mobilization of their implants after surgery and were given vitamin E for a period of 1 year.

For each patient, basic demographic information, comorbidities, and surgical information (implant size and concomitant surgery) were recorded. In addition, outcomes were analyzed to identify complications and the need for surgical revision. Data were organized and tabulated using Excel (Microsoft Corp., Redmond, WA). Statistical analysis was calculated using the χ^2 test (for qualitative, independent variables) and linear regression (for age).

RESULTS

A total of 1012 fourth-generation, textured Mentor MemoryGel cohesive silicone gel implants were placed in 511 patients during the 13-year study period. The mean patient age was 32.2 years (range, 19 to 72 years). A majority of the patients were healthy with few comorbidities; 2.3% (n = 12) had preoperative rheumatologic conditions, including well controlled rheumatoid arthritis, lupus (but not defined as systemic lupus erythematosus or discoid lupus), Lyme disease, or Raynaud disease. Seven percent (n = 34) of patients were active smokers. These patients all fit within the inclusion and exclusion criteria for the Mentor Adjunct Study as mentioned in the Methods section.

The average clinical follow-up during the study was 32 months (range, 8 to 47 months). Patient demographics and breast surgical history are illustrated in Figure 1. A total of 64.6% (n = 330) of patients had previous breast surgery; 35.4% (n = 181) were primary breast patients (primary augmentation or augmentation mastopexy). Of those patients who had secondary breast surgery (ie, secondary augmentation or secondary augmentation mastopexy), 6.7% (n = 34) required a capsulotomy.

Surgical implant approaches and volume distribution are illustrated in Figures 2 and 3, respectively. Of all implants, 81.7% (n = 827) were placed in the submuscular position. The remainder were placed in the subglandular position.

Complications data are illustrated in Table 1. The overall complication rate per implant was 5.5% (n = 56 implants in 43 patients). The most common complication was capsular contracture (n = 26) followed by abnormal scarring defined as widened or hypertrophic scars (n = 11).

Patient surgical revisions are listed in Table 2. The overall revision rates per patient and per implant were 8.0% (n = 41 patients) and 6.8% (n = 69 implants), respectively. The average time interval between initial

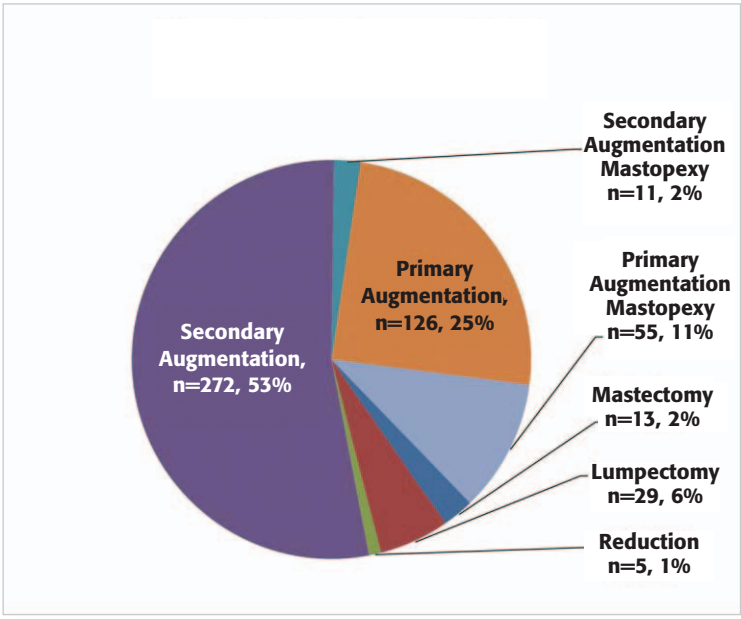

Figure 1. Percentage of patients with differing breast surgical history. Primary versus secondary patients and augmentation versus reconstructive patients are compared.

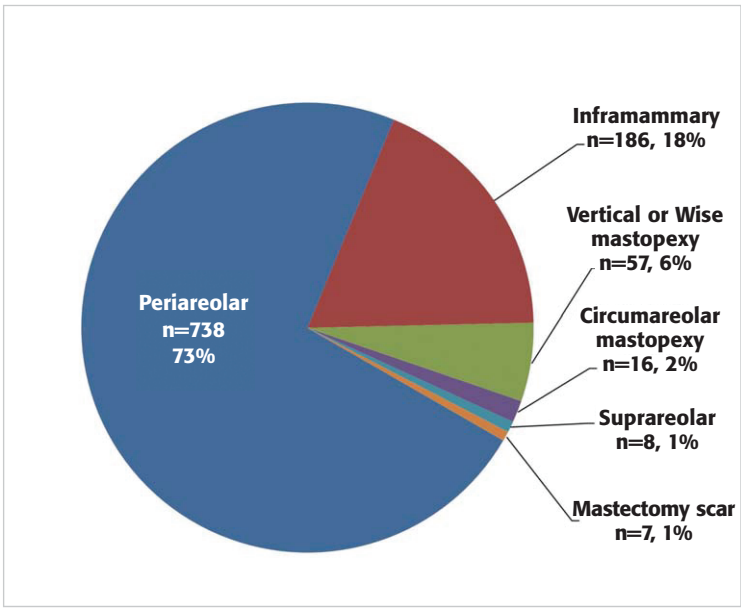

Figure 2. Surgical implant approaches. The vast majority of patients were augmented through the periareolar approach.

implantation and revision was 18.5 months (range, 2 weeks to 26 months). The most common indication for surgical revision was patient desire for implant size change (n = 15 patients). The capsular contracture rate requiring revision was 2.6% (n = 13 patients). Within the subset requiring revision surgery for capsular contracture, 62% had previous breast surgery (n = 8), and 15% (n = 2) had previous procedures related to capsular contracture. The presence of previous surgery for capsular contracture was not statistically correlated to the need for revision (P = .326). Age (P = .568), history of breast surgery (P = .704), and history of smoking (P = .138) were also not statistically correlated to revision. However, placement of the implant in the subglandular position (n = 30 implants) was statistically correlated with a need for revision (P < .01).

DISCUSSION

Since the FDA moratorium on silicone breast implants in 1992, outcome data involving silicone breast augmentation in the United States have been limited. Nonetheless, the clinical experience with silicone implants in regards to safety and complication rates in Europe has been well documented.[9-12] While several of these recent European

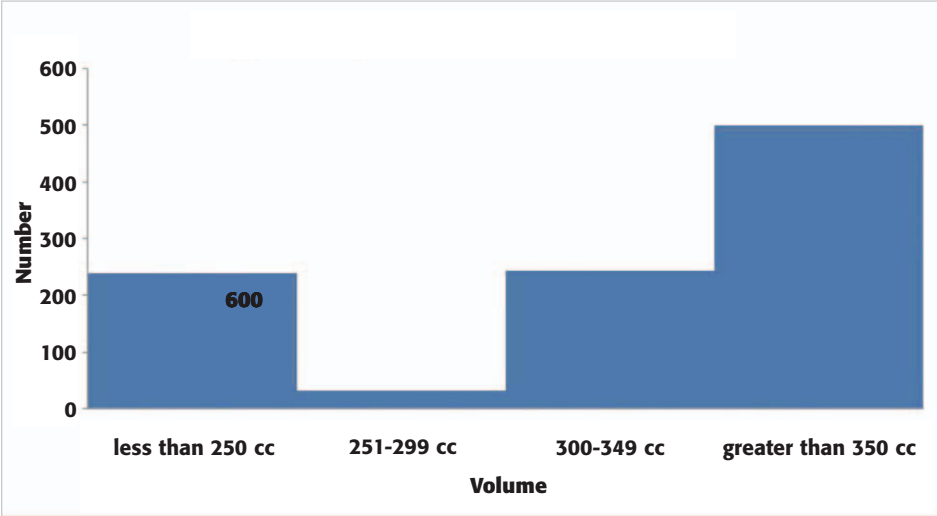

Figure 3. A breakdown of the distribution of implant volumes.

studies indicate that patient satisfaction with newer generation (both form-stable anatomic and gel-filled round) is high, multicenter premarket studies by several implant manufacturers demonstrate significant reoperation rates (13% to 20%).[13-18]

The Mentor Adjunct Study, which began in 1992, was never officially published in its entirety for comparison; however, the Mentor Core Study, which began in 2000, represents a 10-year study of round, cohesive silicone gel implants placed for breast augmentation, reconstruction, and revision breast surgery. The recent FDA published data from the Mentor Core Study indicate that the risk of any complication (including reoperation/revision, infection, nonoperative complications, etc.) at a 3-year follow-up is high, with rates of 36.6% for primary augmentation patients and 50.1% for revision-augmentation patients.[19] Of all complications, the most common was the need for revision (15.4% for primary augmentation and 28% for revision augmentation). In a majority of these patients, capsular contracture (Baker grades III and IV) was the most common reason for revision (8.1% for primary augmentation, 18.9% for revision augmentation). One recent peer-reviewed study examined the 3-year clinical experience of Mentor smooth-walled cohesive silicone implants in a group of 44 patients and found comparable revision (13.6%) and capsular contracture rates (20%).[20]

Table 1. Implant complications

Complication	No. of patients	Percent
Capsular contracture (Baker grade III or IV)	26	2.6%
Hypertrophic scar or keloid	11	1.1%
Asymmetry (compared to contralateral side)	6	0.6%
Rupture	4	0.4%
Implant wrinkling	4	0.4%
Infection	4	0.4%
Ptosis	1	0.1%
Hematoma	0	0.0%
Total	56	5.5%

In our study of 1012 textured cohesive silicone implants placed in 511 patients, total operative and nonoperative implant complications were low (5.5%). In addition, surgical revision rates (6.8% per implant, 8.0% per patient) and capsular contracture rates (2.5% of patients) were considerably lower than the aforementioned studies and the FDA Mentor Core Study data. Both our study (n = 511 patients) and the Mentor Core Study (n = 1007 patients) are large-volume studies that had adequate follow-up times (2.6 versus 3 years). We believe that there are several reasons for these lower complication and revision rates.

First, our study represents a case sample that is standardized in regards to a single surgeon, consistent operative technique (ie, minimal touch of the implant, no drains, bloodless electrocautery), a single center, and standardized postoperative care. Although large multicenter trials have significant value by providing large numbers of study participants that could never be gathered by a single source, the nature of the multicenter aspect of the Mentor Core Study means that there is no standardization of these variables. Therefore, one can certainly assume that results may vary greatly among surgeons, techniques, and centers within the study.

With regard to operative technique, there may be several reasons for our reduced rate of capsular contracture compared to the Mentor Core Study: in our study, betadine was used in all patients for pocket irrigation. Classic studies by Burkhardt et al[21] and Burkhardt and Demas[22] have affirmed the utility of betadine in reducing capsular contracture; however, this has fallen out of favor because of the reported potential effect on deflation rates. Recent studies sug-

Table 2. Surgical revisions

Reason for revision	No. of implants	No. of patients	Percentage per implant	Percentage per patient
Patient desire for size change	30	15	3.0%	2.9%
Capsular contracture (Baker grade III or IV)	26	13	2.6%	2.5%
Asymmetry	6	6	0.6%	1.2%
Rupture	4	4	0.4%	0.8%
Periprosthetic Infection	2	2	0.2%	0.4%
Implant wrinkling	1	1	0.1%	0.2%
Hematoma, seroma or wound dehiscence	0	0	0.0%	0.0%
Total	69	41	6.8%	8.0%

gest that the use of betadine irrigant does appear to have a significant effect on reducing capsular contracture in vitro.[23] Most recently, several clinical studies have challenged the effect of betadine on deflation rates and affirmed the significant reduction in capsular contracture formation with the use of betadine irrigant.[24] Findings such as these suggest that the reimplementation of betadine irrigation as a standard modality may prove beneficial.

Secondly, the vast majority of patients in this study (82%) had implants placed in the submuscular position. Classically, this has been postulated to reduce the rate of capsular contracture.[25] Within the Mentor Core Study, there is no information on implant position as a variable in the study. We certainly believe that this is a key factor with regard to complication and revision rates. If submuscular placement is consistent with patient desires for a natural, anatomic slope to the superior pole of the breast, we continue to advocate submuscular placement.

In our study, a history of previous surgery for capsular contracture, history of previous breast surgery, and a history of smoking were not clinically correlated to the need for revision. Placing of the implant in the subglandular position, however, was statistically correlated to the need for revision. If we remove the subset of patients that desired implant size change, capsular contracture was the most common reason for revision.

Compared to studies involving smooth silicone implants, an additional reason for the reduction of capsular contracture rates may involve the use of surface texturing in the MemoryGel Siltex (Mentor) implant. Several early studies demonstrated that textured silicone implants following subglandular augmentation nearly halved the capsular contracture rates in comparison to smooth silicone implants.[26-28] Indeed, Spear[29] advocates that textured implants be placed submuscularly to avoid capsular contracture. Early data from Mentor's Adjunct Study have shown a capsular contracture rate of 5% after placement of more than 15,000 Siltex textured gel implants, while the Inamed (Irvine, CA; now Allergan) multicenter trial has produced a 5.5% contracture rate after 4 years.[30] These rates are significantly lower than those reported for smooth, silicone implants, which have ranged from 15% to 45%, in both older- and newer-generation silicone preliminary studies.[12,31] All patients within our study had textured implants placed, which may be an additional reason for the reduction in capsular contracture and revision rates.

Handel et al[32] reported that the risk of capsular contracture increases with follow-up time despite differences in surface texture (smooth or textured) or filler material (saline or silicone).[32] Long-term follow-up within the group of patients in this study will likely increase capsular contracture and revision rates. Nonetheless, our data suggest that fourth-generation textured MemoryGel silicone implants may have a superior risk profile for capsular contracture, complications and revisions as compared to the FDA Mentor Core Study.

The senior author feels that intravenous antibiotics, pocket irrigation with betadine, and operative technique (minimal touch with bloodless dissection, no drains) may contribute to these results. Furthermore, this study also indicates that revision rates with cohesive gel implants can certainly be low in a diverse group of reconstructive and secondary augmentation revision patients, as it is in the primary augmentation patient.[16]

CONCLUSIONS

This large series demonstrates that fourth-generation textured cohesive silicone MemoryGel implants possess a complication profile that is clearly superior to previous generation silicone gel implants. The placement of these implants in the subglandular position significantly increases revision rates. In addition, our study illustrates that MemoryGel implants, when standardized with regard to surgeon and operative technique, can have significantly reduced complication and revision rates compared to the Mentor Core Study data. As aftermarket data and follow-up continue to grow, implantation with late-generation cohesive silicone gel implants may continue to demonstrate superior results. ◗

DISCLOSURES

The authors have no disclosures with respect to manufacturers of products mentioned in this article.

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Reprint requests: W. Grant Stevens, MD, FACS, 4644 Lincoln Blvd., Ste. 552, Marina Del Rey, CA 90292. E-mail: drstevens@hotmail.com.

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