

Safety and Effectiveness of Silicone Gel-Filled Breast Implants in Primary Augmentation Patients

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Abstract

Background: Results from the MemoryGel Breast Implants Core Clinical Study suggest these devices are safe and effective at 10 years after implantation. Although clinical trials are essential for measuring the safety and effectiveness of a device, real-world evidence can supplement clinical trials by providing information on outcomes observed in diverse clinical settings for a more heterogeneous population, without fixed treatment patterns, and without continuous patient monitoring, such that follow-up is more representative of normal clinical practice.

Objectives: The aim of this study was to measure real-world outcomes, including safety and effectiveness, in patients who underwent primary breast augmentation with smooth MemoryGel implants.

Methods: This was a case series looking at patients, age 22 years and older, who underwent primary breast augmentation at a single site between December 2006 and December 2016 and who had a minimum of 2 years of follow-up. Descriptive statistics were used to summarize baseline characteristics and outcomes. Kaplan-Meier models were used to estimate safety outcomes for capsular contracture (Baker grade III/IV), infection, and rupture.

Results: A total of 50/777 (6.4%) patients reported a complication, with an average time to complication of 3.9 years (range, 19 days–11.8 years) postprocedure. Kaplan-Meier estimates of the 10-year cumulative incidence of capsular contracture (Baker grade III/IV), infection, and rupture were 4.7%, 0.1%, and 1.6%, respectively.

Conclusions: Analyses of a large population from a single site provide further support for the long-term safety and effectiveness of MemoryGel breast implants in a primary augmentation cohort.

Level of Evidence: 4

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MemoryGel silicone gel-filled breast implants (Mentor Worldwide LLC, Irvine, CA) were approved by the Food and Drug Administration on November 17, 2006 for breast augmentation for women at least 22 years old and for breast reconstruction for women of any age, based on data from the Core Gel Study of the Safety and Effectiveness of Mentor Round Low Bleed Silicone Gel-Filled Mammary Prosthesis (NCT00753922). Caplin et al¹ recently reported Kaplan-Meier estimated rates at 10 years for the primary augmentation cohort for capsular contracture (Baker grade III/IV; 12.1%), infection (1.6%), and rupture (24.2%).

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Although clinical trials are essential for measuring the safety and effectiveness of a device, real-world evidence can supplement clinical trials by providing information on outcomes observed in diverse clinical settings for a more heterogeneous population, without fixed treatment patterns, and without continuous patient monitoring, such that follow-up and adherence to therapy is more representative of normal clinical practice.² In an attempt to measure real-world outcomes, including safety and effectiveness associated with MemoryGel breast implants, we analyzed data from patients who underwent primary breast augmentation with smooth MemoryGel implants by 2 surgeons at a single site.

METHODS

This study was a case series analysis of data from patients age 22 years and older who underwent primary breast augmentation and were implanted with MemoryGel breast implants at a single site between December 2006 and December 2016, and who had a minimum of 2 years of follow-up. All patients were treated according to normal clinical practice per the following summary. Cefazolin was administered prior to surgery per Surgical Care Improvement Project recommendations.³ After chlorhexidine preparation and antibiotic prophylaxis, incision was made at the inframammary or lateral areolar border. Dissection was carried down to the inferior border of the pectoralis muscle. For a prepectoral placement plane, dissection was carried out medially, superiorly, and laterally in the prepectoral tissue. For a subpectoral placement plane, the inferior border of pectoralis major was attenuated and elevated with electrocautery until 1 finger breadth could fit underneath. A small pocket was created with conservative electrocautery dissection and vessel ligation followed by placement of an implant sizer which was inflated to the desired size, further facilitating blunt dissection of the pocket. The same was performed on the contralateral side. Sizers were removed and hemostasis was achieved again with electrocautery followed by copious irrigation with saline, then triple antibiotic solution, then intrapocket bupivacaine for analgesia. Implants were placed with a 2-hand approach up until 2009; after 2009 a no-touch approach with a funnel was used. Closure was performed in 3 layers with 2-0 vicryl, 3-0 monocryl, and 4-0 barbed monocryl sutures.

Patients were scheduled for in-office follow-up visits at 1 week, 2 weeks, 1 month, 2 months, 6 months, and 1 year postoperatively. Beginning postoperative week 3, patients were instructed to begin implant massage if no wound-healing issues were present. Additional telephone and e-mail follow-up were performed for all patients at 2 years or more after their final implant by the first author (D.M.). All

eligible patients received a telephone call and follow-up e-mail questionnaire over a period of 1 to 2 months. Patients who did not respond to either telephone calls or e-mails were contacted again for a total of 3 times. Telephone follow-up consisted of the following 3 questions, supplemented by specific descriptors: (1) Have you experienced any problems or complications (eg, hematoma, bleeding, pulmonary embolism, cellulitis, infection, abscess, hospitalization, hardening of breast, capsular contracture)? (2) Have you had any surgeries or breast procedures (eg, biopsies, implant exchange, explant, breast lift/mastopexy) at an outside practice? (3) What is your overall satisfaction with your breasts' appearance? (This question excludes consideration of how the patient feels about the surgeon or practice team.) Patients were asked to elaborate and were provided with directed questioning if they indicated that a problem had occurred or if they had a satisfaction score of <8. All patients with possible complications or problems were asked to come into the office for evaluation and verification of potential complications.

Descriptive statistics were used to summarize baseline characteristics and outcomes. All data were deidentified by the clinic prior to analysis. Deidentified data received in Excel format were imported into SAS data files for analysis. Tabulation of summary statistics, graphical presentations, and data analyses were performed with SAS/STAT software, version 9.4 (SAS Institute Inc, Cary, NC). Kaplan-Meier models were performed with dependent variables of time to first capsular contracture (Baker grade III/IV), time to first infection, time to first rupture, and time to any complication. Cox multivariable regression models were used to explore whether patient characteristics or procedural details were statistically significant predictors of the overall complication outcome. The Northside Hospital Institutional Review Board determined this project to be exempt from institutional review board oversight according to federal regulations (45 CFR 46.104(d)).

RESULTS

A total of 1,595 women who underwent primary breast augmentation at Artisan Plastic Surgery, LLC (Atlanta, GA) were eligible for inclusion in the study. Of these eligible women, 777 (48.7%) responded. The majority of patients (70%) reporting a complication were evaluated in the office. Average follow-up time was 6.2 years (range, 2.0-12.2 years). Of the 777 patients included, 191 underwent surgery in 2009 or earlier, allowing for at least 10 years of follow-up. Baseline characteristics and medical history are presented in [Table 1](#). Briefly, the mean [standard deviation] age of the women at the time of their first surgery was 37.1 [9.0] years (range,

Table 1. Baseline Characteristics and Medical History

Total patients	777 (100%)
Baseline characteristics	
Age at first surgery (years)	37.1 [9.0]
History of smoking	85 (10.9%)
Body mass index (kg/m ²)	22.3 [2.6]
Antidepressant medication	128 (16.5%)
Birth control medication	131 (16.9%)
Hormone replacement therapy	28 (3.6%)
Medical history	
Number of children	1.3 [1.3]
Number of pregnancies	1.5 [1.4]
Family history of breast cancer	88 (11.3%)
Diabetes	10 (1.3%)
Hypertension	34 (4.4%)
Coronary artery disease	4 (0.5%)
Hypothyroid	46 (5.9%)
Other cancer ^a	3 (0.4%)

Values are n (%) or mean [standard deviation]. ^aOther cancer is defined as any cancer, excluding basal cell and squamous cell skin cancers.

22-68 years). Average implant size was 349.5 [65.8] cc (range 175-650 cc), with the vast majority of implants being placed in the subpectoral plane (97.4%).

A total of 50 (6.4%) patients reported a complication, with an average time to complication of 3.9 years (range, 19 days-11.8 years) postprocedure. The frequencies of postoperative complications are summarized in [Table 2](#) and expanded to include methods of correction in [Table 3](#). Kaplan-Meier estimates of the 10-year cumulative incidence of capsular contracture (Baker grade III/IV), infection, and rupture were 4.7% (95% confidence interval (CI): 3.0%, 7.4%), 0.1% (95% CI: 0.0%, 0.9%), and 1.6% (95% CI: 0.7%, 3.6%), respectively ([Figure 1A-C](#)).

Multivariable Cox regression analysis of any complication showed that larger average implant size (per 25-cc increase in size, averaged across left and right implants) increased the likelihood of a complication (hazard ratio (HR): 1.12; 95% CI: 1.01, 1.24; $P = 0.033$). Other predictor variables with significance levels <0.15 are listed in [Table 4](#).

Patient-reported satisfaction scores at last follow-up were high, averaging 9.3 [1.5] out of 10, with 551 of 776 (70.9%) women reporting a score of 10.

DISCUSSION

This analysis from a single site provides support for the long-term safety and effectiveness of MemoryGel breast implants in a primary augmentation cohort. Specifically, patients included in the current analysis had relatively low rates of capsular contracture, infection, and rupture, coupled with high patient satisfaction.

Capsular contracture is one of the more commonly reported complications associated with breast augmentation, with rates from individual studies, including various implant types from multiple manufacturers, ranging from 2.8% to 20.4% over 1.24 to 8 years of follow-up.⁴ In the current study, the estimated 10-year cumulative incidence of capsular contracture is 4.7% (95% CI: 3.0%, 7.4%), representing the lower end of the range provided above. Alternatively, the MemoryGel Core Study 10-year Kaplan-Meier estimated the cumulative incidence rate of capsular contracture Baker grade III/IV to be 12.1% (95% CI: 9.6%, 15.2%) in the primary augmentation cohort.¹ It is possible that this difference is due, in part, to changes in the standard of care from the period 2000 to 2002, when the MemoryGel Core Study participants underwent breast augmentation, to 2006 to 2016, when participants of the current study underwent augmentation procedures.⁵ Another factor contributing to this improvement is a better understanding of preventative strategies to minimize the risk of biofilm, a factor thought to be associated with capsular contracture; these strategies include the use of antibiotic mesh and nipple shields, irrigation of the breast pocket with antibiotic solution, standard prophylaxis for surgical site infections, atraumatic technique, and the “no touch” technique with a Keller funnel.⁶ As previously mentioned, use of a Keller funnel was implemented in all procedures at this site beginning in 2010. To better understand the effect of Keller funnel use on capsular contracture rates, capsular contracture data were partitioned based on whether the implants were inserted with or without a funnel. Whereas unadjusted percentages are lower in the 2010 and later group compared with the earlier group (2.4% vs 5.2%), the median follow-up time is also shorter (4.9 years vs 10.5 years). A Kaplan-Meier time-to-event analysis shows no statistical difference in rates between the 2 groups over time, with 5-year estimates of 2.4% (2010 and later) and 2.1% (2009 and earlier).

The incidence of infection reported in this study (0.1%; 95% CI: 0.0%, 0.9%) is similar to that reported in the Core Study (1.6%; 95% CI: 0.9%, 3.1%). A study from 2010 suggests the incidence of bacterial infection to be between 2.0% and 2.5% for augmentation procedures and substantially higher (20%) for reconstructive procedures,⁷ suggesting a relatively low rate of infection for both the present study and the Core Study.

Table 2. Postoperative Self-Reported Complications

Postoperative self-reported complications	Frequency	Percentage of total complications (N = 58)	Percentage of total patients (N = 777)
Capsular contracture Baker grade II ^a	17	29.3	2.2
Capsular contracture Baker grade III	16	27.6	2.1
Ruptured implant	9	15.5	1.2
Capsular contracture Baker grade IV	8	13.8	1.0
Seroma	2	3.4	0.3
Implant exchange outside office (one had mastopexy)	2	3.4	0.3
Breast cancer	1	1.7	0.1
Asymmetry	1	1.7	0.1
Double bubble	1	1.7	0.1
Cellulitis	1	1.7	0.1
Any one or more complication(s) above ^b	50		

^aDue to the self-report nature of the study and the fact that Baker grade II capsular contracture is often asymptomatic, rates may be underestimated. ^bNote that some patients reported >1 complication.

Table 3. Correction Methods for Postoperative Complications

Complication	Correction method	Count (%)
Capsular contracture Baker grade II	Medical	17 (100)
Capsular contracture Baker grade III	Surgical	11 (68.8)
	Implant removal	1 (6.3)
	Removal at outside hospital	1 (6.3)
	Scheduled for surgery, but canceled	1 (6.3)
	None	1 (6.3)
	Missing	1 (6.3)
Ruptured implant	Surgical	7 (77.8)
	None	2 (22.2)
Capsular contracture Baker grade IV	Surgical	6 (75.0)
	Never scheduled for surgery	1 (12.5)
	None	1 (12.5)
Seroma	Aspiration, office	2 (100)
Breast cancer	Reconstruction at outside hospital	1 (100)
Asymmetry	Surgical	1 (100)
Double bubble	Surgical	1 (100)
Cellulitis	Surgical	1 (100)

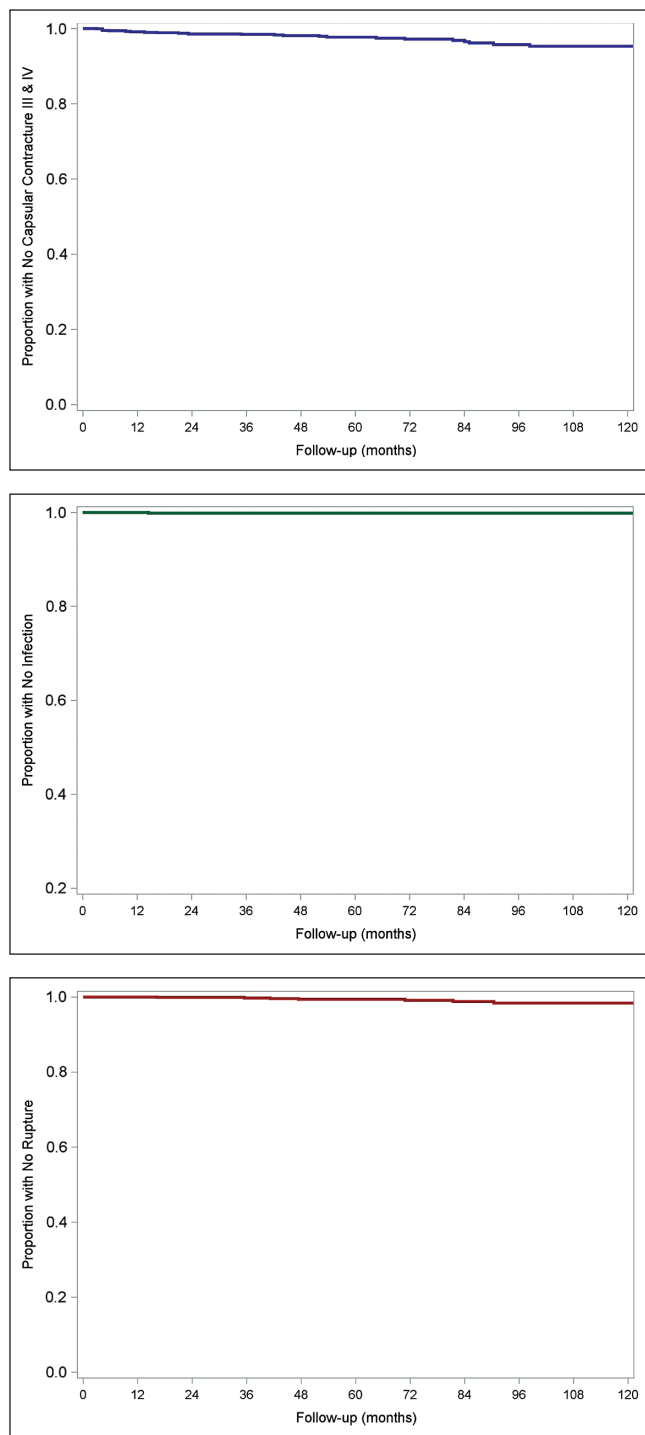


Figure 1. Ten-year Kaplan-Meier survival from (A) capsular contracture (Baker grade III/IV), (B) infection (infection composite created from complications containing "abscess," "cellulitis," or "infection"), and (C) rupture.

The rupture rate reported here is comparable to the overall rupture complaint rate from November 2006 to December 2017, which is 0.7% for over 2 million MemoryGel breast implants implanted in the United States (US Mentor

MemoryGel Complaint Data statistics from November 2006 to December 2019). This rate is substantially lower than the 24.2% 10-year Kaplan-Meier estimated cumulative incidence rate of suspected or confirmed ruptures reported in the MemoryGel Core Study,¹ likely due to the lack of magnetic resonance imaging (MRI) screening leading to an underestimation of silent rupture. Whereas MRI screening was required in the Core Study, in normal clinical practice, physicians are merely advised to encourage regular MRI screenings. For example, in the MemoryGel Product Insert Data Sheet, it is recommended that the first MRI be performed 3 years postoperatively and every 2 years thereafter. A recent study that surveyed members of the American Society of Plastic Surgeons found that 55.0% of respondents (427/776 surgeons) reported that they do not follow up the MRI evaluations at the recommended intervals described in the Product Insert Data Sheet unless an issue arises.⁸ Just over one-third of respondents (293/776 surgeons; 37.8%) reported that they do follow the recommended guidelines. Possible reasons for the low rate of compliance include the low prevalence of rupture in asymptomatic patients, cost, and availability of resources. For instance, 1 study estimated the prevalence of rupture in asymptomatic women to be around 8%,⁹ and the average cost of an MRI to be \$1197;¹⁰ hence, the guidelines are often not followed. Current literature also suggests that silent ruptures do not always exhibit clinically relevant symptoms; therefore, many women diagnosed with silent ruptures forgo surgery and opt for observation only.^{11,12} Due to the lack of required MRI screening in the present analysis population, it is likely that the rate presented here largely represents only symptomatic ruptures. In support of this theory, the Kaplan-Meier rupture rate in this analysis (1.6%) is much closer to the Core Study rate of symptomatic ruptures (0.6%) than to the rupture rate that included both suspected and confirmed ruptures.¹

Given the high incidence of asymptomatic ruptures reported in the literature, and because the significant costs associated with MRI lead to a high rate of noncompliance with the current recommended Food and Drug Administration guidelines, high-resolution ultrasound should be considered as an alternative method for detecting silent ruptures to provide a more accurate assessment of silicone gel breast implant shell failure.¹³ Bengtson and Eaves¹³ assessed the accuracy of detecting asymptomatic and symptomatic ruptures in 29 breasts with MRI, surgeon-performed high-resolution ultrasound, or radiologist-performed high-resolution ultrasound compared to surgical findings. They found that all 3 techniques were able to accurately identify ruptured implants. Because high-resolution ultrasound is noninvasive, safe, widely available, and accurate, and the 2011 Medicare Global Diagnostic Service Fee for bilateral MRI is 8.2 times that of a breast ultrasound, surgeons should consider utilizing this technology to detect silent ruptures.

Table 4. Multivariable Cox Regression Model of Any Self-Reported Complication

Predictor variable	P value	Hazard ratio estimate (95% confidence interval)
Average size of left and right implant (per 25-cc increase)	0.033	1.12 (1.01, 1.24)
Subpectoral placement vs prepectoral placement	0.109	0.30 (0.07, 1.30)
Concurrent body procedure (yes vs no)	0.065	1.92 (0.96, 3.85)
History of hypertension (yes vs no)	0.124	2.26 (0.80, 6.37)

Multivariable Cox regression analysis showed that implant size was the most significant predictor of a complication, despite several studies demonstrating no correlation between implant size and complication rate.^{14,15} One study showed the opposite effect in a Kaplan-Meier analysis, reporting that times to reoperation, rupture, and capsular contracture were significantly less in implants ≤ 350 cc compared with those in implants >350 cc ($P < 0.001$), but this study included patient requests for size change as reoperations, thus confounding the effect of size on true complications with the effect due to preference for a larger implant.¹⁴ The statistical significance of this result will require further investigation in a larger population that is powered to detect an effect size of this magnitude.

The multivariable Cox regression model of any self-reported complication (Table 4) also provides information on the difference in complication rates between subpectoral and prepectoral augmentation. Subpectoral placement resulted in a relatively lower rate of complications than found with prepectoral placement (HR: 0.30; 95% CI: 0.07, 1.30); however, the results are not statistically significant ($P = 0.109$). Care should be taken in interpreting these results given that the majority of patients included in this analysis had their implants placed in the subpectoral plane ($n = 757$; 97.4%), with only 20 patients having their implants placed in the prepectoral plane (2.6%).

Patients undergoing a concurrent body procedure trended towards having more complications than those who did not (HR: 1.92; 95% CI: 0.96, 3.85; $P = 0.065$). Of the 777 patients, 97 (12.5%) underwent a concurrent body procedure; abdominoplasty was most common (93/97). The percentage of capsular contracture grade II was similar in the 2 groups: 2.1% in the concurrent procedure group and 2.2% in the no concurrent procedure group. However, 2 other complications were higher in the concurrent procedure group: capsular contracture grade III (3.1% vs 1.9%) and capsular contracture grade IV (2.1% vs 0.9%).

Real-world evidence studies can be extremely beneficial and informative when considered as complementary to randomized clinical trials.¹⁶ Specifically, large case series, or other cohorts that are treated per routine standard

of care, can increase the generalizability of clinical trial results, which alone can lack external validity due to their strict inclusion and exclusion criteria. For example, clinical trials may exclude concomitant use of medication or certain procedures to decrease confounding variables and more confidently attribute the effect to the intervention of interest. Observational studies typically do not have such strict restrictions imposed, and therefore additional insights can be gained regarding risk factors, contraindications, etc, that might otherwise not be uncovered. Costs associated with real-world evidence studies compared with those in randomized clinical trials can be considerably lower when they are based on the use of devices, medical visits, and laboratory tests per standard clinical practice such that the associated costs are covered by the patient and/or insurance provider.¹⁷ As discussed above, continuous monitoring is not required.

Due to the inherent limitations of case series and other observational study designs, it is essential for real-world findings to be considered complementary to, as opposed to a replacement for, clinical trials. Internal validity for real-world studies can be lower due to the inability to control for biases due to unknown confounders, insufficient sample size to control for the full spectrum of heterogeneity in the population, lack of a valid control treatment, and missing data due to a lack of continuous patient monitoring.¹⁸ In addition to the general classes of bias that must be considered based on the study design, there are potential limitations specific to the current study, including data from a single site that may not be representative of all practices. In addition, there could be a selection bias in the subset of patients who agreed to participate in the study. Finally, there could be some clinical biases based on the fact that some of the complications were patient reported without physician confirmation or due to the absence of regular MRI screening for rupture. It is important to acknowledge that available studies with higher levels of evidence are also needed to make appropriate conclusions. However, considering the importance of patient satisfaction, quality of life, and expected outcomes in plastic surgery, patient-reported outcomes provide clinically meaningful adjunctive evidence regarding risks and benefits of novel

procedures, patients' perception of surgical results, and cost effectiveness.¹⁹

CONCLUSIONS

These data provide support for the long-term safety and effectiveness of MemoryGel breast implants in a primary augmentation cohort. Specifically, the low rate of capsular contracture, infection, and rupture rate coupled with the high patient-reported satisfaction illustrates the favorable safety profile and clinical benefits of these devices.

Disclosures

Dr. Estes, Dr. Walcott, and Dr. Canady are employees of Mentor Worldwide, LLC (Irvine, CA). Dr. Hunter and Dr. Gache are employees of CTI Clinical Trial and Consulting Services (Raleigh, NC), which is a consultant to Mentor Worldwide, LLC.

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REFERENCES

1. Caplin DA, Calobrace MB, Wixtrom RN, Estes MM, Canady JW. MemoryGel breast implants: final safety and efficacy results after 10 years of follow-up. *Plast Reconstr Surg*. 2021. In press.
2. Sherman RE, Anderson SA, Dal Pan GJ, et al. Real-world evidence—what is it and what can it tell us? *N Engl J Med*. 2016;375(23):2293-2297.
3. Rosenberger LH, Politano AD, Sawyer RG. The surgical care improvement project and prevention of post-operative infection, including surgical site infection. *Surg Infect (Larchmt)*. 2011;12(3):163-168.
4. Headon H, Kasem A, Mokbel K. Capsular contracture after breast augmentation: an update for clinical practice. *Arch Plast Surg*. 2015;42(5):532-543.
5. Nava MB, Rancati A, Angrigiani C, Catanuto G, Rocco N. How to prevent complications in breast augmentation. *Gland Surg*. 2017;6(2):210-217.
6. Ajdic D, Zoghbi Y, Gerth D, Panthaki ZJ, Thaller S. The relationship of bacterial biofilms and capsular contracture in breast implants. *Aesthet Surg J*. 2016;36(3):297-309.
7. Feldman EM, Kontoyiannis DP, Sharabi SE, Lee E, Kaufman Y, Heller L. Breast implant infections: is cefazolin enough? *Plast Reconstr Surg*. 2010;126(3):779-785.
8. Carr LW, Roberts J, Mericli AF, Liu J, Arribas EM, Clemens MW. Breast implant imaging surveillance among US plastic surgeons: US Food and Drug Administration recommendations versus clinical reality. *Plast Reconstr Surg*. 2020;145(6):1381-1387.
9. Heden P, Nava MB, van Tetering JP, et al. Prevalence of rupture in inamed silicone breast implants. *Plast Reconstr Surg*. 2006;118(2):303-308; discussion 309-312.
10. Vlahiotis A, Griffin B, Stavros AT, Margolis J. Analysis of utilization patterns and associated costs of the breast imaging and diagnostic procedures after screening mammography. *Clinicoecon Outcomes Res*. 2018;10:157-167.
11. Hillard C, Fowler JD, Barta R, Cunningham B. Silicone breast implant rupture: a review. *Gland Surg*. 2017;6(2):163-168.
12. Hölmich LR, Vejborg IM, Conrad C, et al. Untreated silicone breast implant rupture. *Plast Reconstr Surg*. 2004;114(1):204-214; discussion 215.
13. Bengtson BP, Eaves FF 3rd. High-resolution ultrasound in the detection of silicone gel breast implant shell failure: background, in vitro studies, and early clinical results. *Aesthet Surg J*. 2012;32(2):157-174.
14. Huang GJ, Wichmann JL, Mills DC. Transaxillary subpectoral augmentation mammoplasty: a single surgeon's 20-year experience. *Aesthet Surg J*. 2011;31(7):781-801.
15. Swanson E. Prospective comparative clinical evaluation of 784 consecutive cases of breast augmentation and vertical mammoplasty, performed individually and in combination. *Plast Reconstr Surg*. 2013;132(1): 30e-45e.
16. Kim HS, Lee S, Kim JH. Real-world evidence versus randomized controlled trial: clinical research based on electronic medical records. *J Korean Med Sci*. 2018;33(34):e213.
17. Suvarna VR. Real world evidence (RWE)—are we (RWE) ready? *Perspect Clin Res*. 2018;9(2):61-63.
18. Kim HS, Kim JH. Proceed with caution when using real world data and real world evidence. *J Korean Med Sci*. 2019;34(4):e28.
19. Pusic AL, Lemaine V, Klassen AF, Scott AM, Cano SJ. Patient-reported outcome measures in plastic surgery: use and interpretation in evidence-based medicine. *Plast Reconstr Surg*. 2011;127(3):1361-1367.