Capsular Contracture Rate in Augmentation Mammoplasty With Motiva Breast Implant Insertion: A Single-Center Experience in Korea

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Abstract

Background: Capsular contracture is the most common complication following breast implant surgery, and the implant shell characteristics are important in preventing this complication.

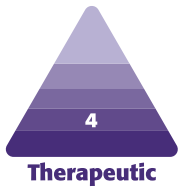
Objectives: The aim of this study was to evaluate the capsular contracture rate for SmoothSilk Motiva implants (Establishment Labs Holdings Inc., New York, NY) in females who underwent primary and revisional breast augmentation over a 3-year period.

Methods: A total of 1324 cases that took place from 2017 to 2020 were retrospectively analyzed, with 1027 being primary surgeries and 297 being revisional surgeries.

Results: In the 1324 cases of augmentation mammoplasty with SmoothSilk Motiva implants, the overall capsular contracture rate was 1.8% ($n = 24$). The capsular contracture rate in the 1027 primary surgery cases was 1.07% ($n = 11$), and the capsular contracture rate in the 297 revisional surgery cases was significantly different at 4.39% ($n = 13$, $P = .0001$). More specifically, the capsular contracture rate in 182 revisional surgery for cases without capsular contracture was 1.12% ($n = 2$), and it showed no statistically significant difference from the rate in primary surgery cases ($P = .965$). However, the rate in 115 revisional surgery for cases with capsular contracture was 9.57% ($n = 11$), and it showed a statistically significant difference from the rate in primary surgery cases ($P = .000$) and the rate in revisional surgery for cases without capsular contracture ($P = .001$).

Conclusions: Augmentation mammoplasty with SmoothSilk Motiva implants demonstrated a lower rate of capsular contracture than traditional smooth or textured implants. Revisional surgery for cases without capsular contracture showed a similar rate of capsular contracture to primary surgery cases, but the rates were higher in revisional surgery for cases with capsular contracture.

Level of Evidence: 4



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The first silicone breast implant was developed in 1962, and cohesive silicone gel implants were approved by the US Food and Drug Administration (FDA) in 2006. Complications associated with the use of implants include seroma, infection, rupture, leakage, double capsule, rippling, anaplastic large cell lymphoma (ALCL), and capsular

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contracture. Complications, such as infection and capsular contracture, also have associations with each other.[1,2]

Capsular contracture, the most common complication after augmentation mammoplasty, occurs due to excessive formation of capsule around the implants.[3] It is the most important potential adverse outcome of breast augmentation and the most common reason for revisional surgery.[4] The main reason for capsular contracture is bacterial growth on the implant surface. Therefore, implant surface characteristics are the key factor in preventing capsular contracture.[1,2,5,6]

Motiva implants (Establishment Labs Holdings Inc., New York, NY) represent a novel family of breast implants that include a variety of state-of-the-art technologies engineered to optimize the aesthetic and safety outcomes.[7] The implant has a unique surface designed to minimize reaction with host tissues.[8] Some articles have described improved results related to capsular contracture due to the preventive effect of SmoothSilk Motiva implants.[7-10]

To evaluate the capsular contracture rate for SmoothSilk Motiva implants, a single surgeon at a single center in Korea performed a 3-year retrospective study of females who underwent primary and revisional breast augmentation.

METHODS

A total of 1324 cases (2648 breasts) of augmentation mammoplasty with SmoothSilk Motiva implants performed by a single surgeon at the MD Clinic Breast Center from January 2017 to December 2020 were evaluated in a retrospective study. The study protocol was approved by the institutional review board (MD Clinic, no. P01-202208-01-006). Primary surgery was performed in 1027 cases, and revisional surgery was performed in 297 cases, consecutively. Capsular contracture was 1 of the main reasons for revisional surgery, accounting for 115 cases, or 38.7% of revisional surgery (Table 1).

The incision was made in 1 of 3 ways: axillary for 771, periareolar for 344, and inframammary for 209 cases. All cases had subpectoral insertion under general anesthesia. An endoscopic approach was employed in all cases with axillary incisions. For revisional surgery cases, subpectoral insertion was performed after removing the capsule via a periareolar or inframammary incision. Even with the endoscopic transaxillary approach, the implant was inserted with a Keller Funnel (Keller Medica, Stuart, FL) and compressed against the incisional entrance to facilitate implantation. This method was utilized in all cases.

All patients were treated with intravenous antibiotics (cefradine 1.0 g) during surgery. An oral antibiotic (cefradine 1.5 g) was then administered for 5 days after surgery. In all cases, a closed-suction drain was inserted in both breast pockets to prevent hematoma, and the drain was removed after 1 to 3 days, depending on the case status. The

Table 1. Reason for Revision

Reason for revision[a]	Patients (*n*)	%
Size	152	51.2
Shape (multiple)	132	44.5
asymmetry	77	
upper fullness	46	
bottoming down	12	
lateralization	15	
ptosis (aging)	21	
synmastia	6	
aesthetic	15	
Simple replacement (implant renewal)	17	5.7
Rippling, poor feeling	76	25.6
Capsular contracture	115	38.7
Rupture	69	23.2
Seroma	4	1.4

[a]Some patients had multiple (more than 1) reasons for revision. There were 297 revisional cases in total.

diagnosis of capsular contracture was performed by physical examination in December 2021, between 1 to 5 years after the operation by the same surgeon who performed the surgery. The diagnosis was based on Baker classification grades III and IV. Cases of capsular contracture on both sides of the breast were designated as a single case.

For statistical analysis, a 1-way analysis of variance (ANOVA) test was used to compare 3 data sets, including primary surgery, revisional surgery without capsular contracture, and revisional surgery with capsular contracture. For the capsular contracture rate, survival rates were calculated and compared with the Kaplan-Meier method and log-rank test. Statistical significance was set at $P < .05$.

RESULTS

The age of the patients ranged from 16 to 61 years. The mean age of patients was 34.4 years in primary surgery cases, 37.7 years in revisional surgery cases without capsular contracture, and 41.3 years in revisional surgery cases with capsular contracture. Compared to primary surgery cases, revisional surgery patients had a slightly higher age on average, and those with capsular contracture had a significantly higher mean age ($P = .000$). In primary surgery cases, an axillary incision was the most common incision site, with 755 cases (73.5%) compared to 127 cases

Table 2. Clinical Characteristics of Cases

Clinical characteristics	Description	Primary, *n* (%)	Revision, no CC, *n* (%)	Revision, with CC, *n* (%)	*P* value
Age (yrs)	Less than 30	354 (34.5)	30 (16.4)	12 (10.3)	.000
	30-39	413 (40.2)	78 (42.9)	42 (36.2)	
	40-49	218 (21.2)	56 (30.8)	47 (41.4)	
	50 or more	42 (4.1)	18 (9.9)	14 (12.1)	
	Total	1027 (100)	182 (100)	115(100)	
	Mean age, yrs (±SD, range)	34.4 (16-61)	37.7 (21-61)	41.3 (24-58)	
Location of incision	Axillary	755 (73.5)	13 (7.1)	3 (2.6)	.000
	Periareolar	127 (12.7)	123 (67.6)	94 (81.9)	
	Inframammary	145 (13.8)	46 (25.3)	18 (15.5)	
Volume of implants (cc)	Right mean vol (range)	322 (155-450)	331 (190-625)	319 (180-450)	.039
	Less than 250	28 (2.8)	12 (6.6)	11 (9.5)	
	250-299	128 (12.5)	36 (19.8)	26 (22.4)	
	300-349	525 (51.1)	67 (36.8)	44 (38.8)	
	350-399	292 (28.4)	42 (23.1)	22 (19.0)	
	400 or more	54 (5.2)	25 (13.7)	12 (10.3)	
	Left mean vol (range)	315 (155-450)	315 (150-625)	305 (155-450)	.123
	Less than 250	48 (4.7)	26 (14.3)	21 (18.3)	
	250-299	292 (28.4)	42 (23.1)	22 (19.1)	
	300-349	499 (48.6)	60 (32.9)	45 (39.1)	
	350-399	160 (15.6)	36 (19.8)	19 (16.6)	
	400 or more	28 (2.7)	18 (9.9)	8 (6.9)	
Follow-up	Median follow-up period, months (range)	35 (12-60)	35 (12-60)	33(12-60)	

cc, cubic centimeter; CC, capsular contracture; SD, standard deviation; vol, volume; yrs, years.

with a periareolar incision (12.7%) and 145 cases with an inframammary fold incision (13.8%). In contrast, an areolar incision accounted for most of the revisional surgery cases, especially those with capsular contracture, which constituted 81.9% of the cases ($P = .000$).

The mean volume of implants in primary surgery cases was 322 cc for the right side and 315 cc for the left side, whereas the mean volume of implants for revisional surgery cases without capsular contracture was slightly higher at 331 cc for the right side and 315 cc for the left side, and the volume of implants in revisional surgery cases with capsular contracture was slightly lower at 319 cc for the right side and 305 cc for the left side (right side: $P = .039$; left side: $P = .123$). The median follow-up period was 35 months in primary surgery cases, 35 months in revisional surgery for cases without capsular contracture, and 33 months for revisional surgery for cases with capsular contracture (Table 2).

In the 1324 cases of augmentation mammoplasty with SmoothSilk Motiva implants, the overall capsular contracture rate was 1.8% ($n = 24$). The capsular contracture rate in the 1027 primary surgery cases was 1.07% ($n = 11$), and the capsular contracture rate in the 297 revisional surgery cases was significantly different at 4.39% ($n = 13$; $P = .0001$). More specifically, the capsular contracture rate in 182 revisional surgery for cases without capsular contracture was 1.12% ($n = 2$), and it showed no statistically significant difference from the rate in primary surgery cases ($P = .965$).

However, the rate in the 115 revisional surgery for cases with capsular contracture was 9.57% ($n = 11$), and this was a statistically significant difference from the rate in both primary surgery cases ($P = .000$) and revisional surgery for cases without capsular contracture ($P = .001$). In the 24 cases that included capsulectomy due to capsular contracture, recurrence of capsular contracture was observed in 1 of 13 primary surgery cases (7.7%) and 0 of 2 revisional surgery cases without capsular contracture (0%), whereas recurrence of capsular contracture was found in 7 of 11 revisional surgery cases with capsular contracture (63.6%). However, there was no statistically significant difference between the recurrence rates ($P = .711$) (Figures 1, 2).

DISCUSSION

As augmentation mammoplasty has established itself as one of the most popular aesthetic surgical operations in the world, further improved breast implants have been developed. Since the first introduction of silicone implants in 1962, many implants have undergone multiple trial-and-error processes. Cohesive silicone gel implants finally became commercially available in 2006. Given the characteristics of their surface, these implants are divided into the smooth and textured types. Implant surfaces are characterized by their roughness, surface area, and potential for bacterial attachment.[11] Because the implant shell influences capsule formation on the surface area, it has been considered to have a close connection with capsular contracture, the most common complication after augmentation mammoplasty. Bergmann et al reported that bacterial contamination on the implant shell leads to a thicker capsule and increased tissue reaction, with a higher number of inflammatory cells.[5]

Many studies have reported a higher rate of capsular contracture with the smooth type of implant than the textured type.[12-15] Capsular contracture rates with smooth-type implants were reported to be around 9% to 20%, and the rates with textured-type implants were reported to be as low as 2.1% to 4.2%.[16-21] However, aggressive texturization has been associated with the risk of seroma, double capsule formation, and even rupture.[22] In 2018, the FDA banned the utilization of Biocell textured implants due to their connection with ALCL, a recurrent issue.

The SmoothSilk surface of Motiva implants is manufactured with micro-imprinting technology, which results in low roughness parameters, and therefore low friction.[23] The microscopic nanotextured surface inhibits bacterial growth and reduces chronic inflammation of the adjacent tissue, which reduces the occurrence of capsular contracture by inhibiting fibroblast adhesion activity.[24-26] Moreover, Motiva SmoothSilk implants have proprietary TrueMonobloc configuration, with similar durometer values for the patch and the shell, resulting in a single structure with uniform tensile strength.

Sforza et al reported zero cases of capsular contracture in their evaluation of 5813 consecutive breast augmentation cases with SmoothSilk Motiva implants.[8] This finding is particularly surprising given that their study included both primary and secondary cases. Similarly, Quiros et al did not find any cases of capsular contracture after 10 years of tracking and studying 35 primary cases.[7] Botti et al followed up 356 cases and reported only 2 cases of capsular contracture in 14 months and 2 years after surgery, which resulted in a capsular contracture rate of 0.28%.[9] Meanwhile, Hong et al reported 18 cases of capsular contracture (2.1%) in their 4-year follow-up study of 873 Korean females, but their study was conducted by multiple surgeons at multiple centers.[27] The complications included 18 cases of hematoma (2.1%) and 6 cases of infection (0.7%). Because these 2 complications are also causes for capsular contracture, it is possible that they may have influenced the research findings.

The authors of this study found 24 cases of capsular contracture (1.8%) among the 1324 cases of augmentation mammoplasty, whereas the 1027 primary surgery cases had 11 cases of capsular contracture (1.07%). They further divided the revisional surgery cases by the presence of capsular contracture before surgery and found that the capsular contracture rate in the 182 revisional surgery cases without capsular contracture was 1.12% ($n = 2$), indicating no statistical difference between this and the rate in primary surgery cases. However, the rate in 115 revisional surgery cases with capsular contracture was significantly higher at 9.57% ($n = 11$), and it suggests the possibility of recurrence due to the internal factor of capsular contracture.

In contrast to previous studies, this study focused on the cross-evaluation of cases of primary surgery, revisional surgery with capsular contracture, and revisional surgery without capsular contracture. It was also conducted by a single surgeon at a single center rather than multiple surgeons at multiple centers, thereby minimizing potential errors from variations in multiple studies. Furthermore, this study applied the same surgical technique, including subpectoral insertion through a Keller Funnel in all cases, the same treatments, such as 1 to 3 days of Hemovac (Zimmer Biomet, Dover, OH) placement to prevent hematoma and no recommendation for massage after surgery, as well as the same antibiotic treatment and the same level of postsurgical care, to exclude a number of factors that can affect the study results. In general, the incidence rate of capsular contracture is low with submuscular placement, primarily due to the elevated risk of infection associated with subglandular placement through the mammary duct.

Although there were some differences in the age of patients and the volume of implants, these are not factors known to affect capsular contracture. In fact, females

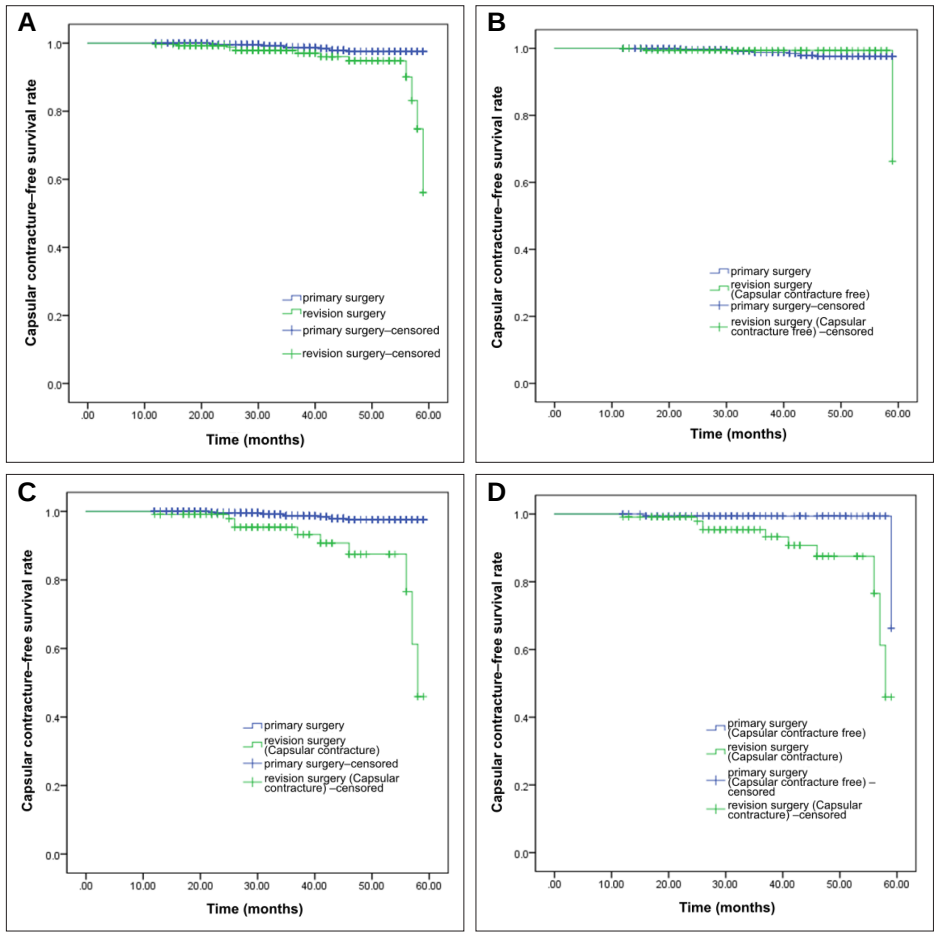

Figure 1. Capsular contracture–free survival curves according to the Kaplan-Meier method comparing (A) primary and revisional surgery cases overall, (B) primary and revisional surgery for cases without capsular contracture, (C) primary and revisional surgery for cases with capsular contracture, and (D) revisional surgery for cases without and with capsular contracture. The use of the term "censored" in this context means that the result was cut at the point of completion of the survey. As this figure describes survival analysis, an ongoing process, censored data has been included in the analysis.

undergoing revisional surgery tended to be older because they were some period from the first surgery. Many studies have shown that a periareolar incision method is a risk factor for capsular contracture.[28-30] This is because the infection risk, the main cause of capsular contracture, may be higher with the periareolar approach. However, Korean females prefer not to have inframammary incisions because of hypertrophic scar. Therefore, we made various attempts to prevent contamination, such as a subareolar vertical incision to prevent duct injuries, no-touch surgery, and adequate antibiotic irrigation. There were differences in the incision sites between primary and revisional surgery cases in this study. In our cases, more accurate capsulectomy was possible with a periareolar approach. Although revisional surgery cases without capsular contracture were mostly conducted with a periareolar approach, capsular contracture rates were not statistically different compared with the primary surgery cases done primarily with the axillary approach. This showed that the incision site did not significantly influence the occurrence of capsular contracture in this study. Moreover, this study was about the reduction in the incidence of capsular contracture with a new type of implant. The authors have previously reported a higher incidence of capsular contracture with round textured and anatomical textured implants, done by the same doctor with the same method.[18] Otherwise, the authors followed the 14-point plan to reduce the risk of associated implant surface infection.[31] Despite the fact that this was a retrospective study, the authors made efforts to mitigate errors by involving a single surgeon and utilizing a consistent methodology. However, due to the relatively short investigation period, it was challenging to determine the precise incidence of capsular contracture. The study included 383 cases in 2019 and 341 cases in 2020, making it a

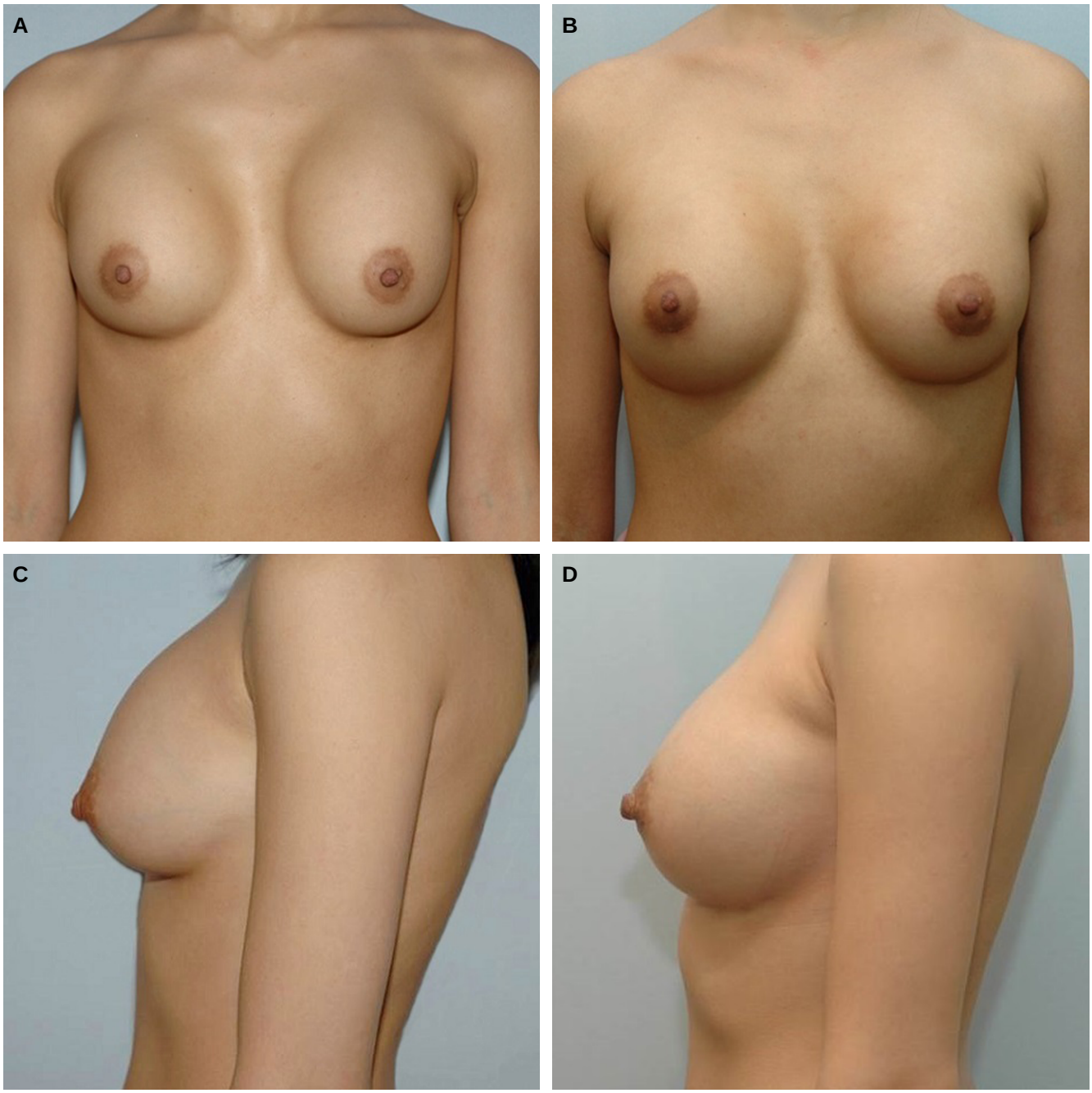

Figure 2. (A, C) Preoperative and (B, D) postoperative photographs of a revisional surgery case in a 35-year-old female in whom capsular contracture was cured.

regular follow-up report. Similar studies conducted by Mentor (Mentor Corp., Santa Barbara, CA) and Allergan (Allergan, Inc., Irvine, CA) have also presented interim survey results at 3 and 6 years before reporting 10-year survey results.[17,32] Additionally, the revisional cases were categorized as 2 groups: 1 comprising revisions due to capsular contracture, and the other involving revisions for other reasons. The findings for the latter group were consistent with those of the primary cases. To substantiate these findings, longer-term follow-up studies are required.

CONCLUSIONS

Augmentation mammoplasty with SmoothSilk Motiva implants demonstrated a lower rate of capsular contracture

than augmentation mammoplasty with traditional smooth or textured implants. Revisional surgery for cases without capsular contracture showed a similar rate of capsular contracture at follow-up to primary surgery cases, but the rates were higher in revisional surgery for cases with capsular contracture.

Disclosures

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REFERENCES

1. Ajdic D, Zoghbi Y, Gerth D, Panthaki Z, Thaller S. The relationship of bacterial biofilms and capsular contracture in breast implants. *Aesthet Surg J*. 2016;36(3):297-309. doi: 10.1093/asj/sjv177
2. Luvsannyam E, Patel D, Hassan Z, Nukala S, Somagutta MR, Hamid P. Overview of risk factors and prevention of capsular contracture following implant-based breast reconstruction and cosmetic surgery: a systematic review. *Cureus*. 2020;12(9):e10341. doi: 10.7759/cureus.10341
3. Handel N, Cordray T, Gutierrez J, Jensen JA. A long-term study of outcomes, complications, and patient satisfaction with breast implants. *Plast Reconstr Surg*. 2006;117(3):757-767. doi: 10.1097/01.prs.0000201457.00772.1d
4. Forster NA, Künzi W, Giovanoli P. The reoperation cascade after breast augmentation with implants: what the patient needs to know. *J Plast Reconstr Aesthet Surg*. 2013;66(3):313-322. doi: 10.1016/j.bjps.2012.09.033
5. Bergmann PA, Tamouridis G, Lohmeyer JA, et al. The effect of a bacterial contamination on the formation of capsular contracture with polyurethane breast implants in comparison with textured silicone implants: an animal study. *J Plast Reconstr Aesthet Surg*. 2014;67(10):1364-1370. doi: 10.1016/j.bjps.2014.05.040
6. Virden CP, Dobke MK, Stein P, Parsons CL, Frank DH. Subclinical infection of the silicone breast implant surface as a possible cause of capsular contracture. *Aesthetic Plast Surg*. 2020;44(4):1141-1147. doi: 10.1007/s00266-020-01816-w
7. Quirós MC, Bolaños MC, Fassero JJ. Six-year prospective outcomes of primary breast augmentation with nano surface implants. *Aesthet Surg J*. 2019;39(5):495-508. doi: 10.1093/asj/sjy196
8. Sforza M, Zaccheddu R, Alleruzzo A, et al. Preliminary 3-year evaluation of experience with SilkSurface and VelvetSurface Motiva silicone breast implants: a single-center experience with 5813 consecutive breast augmentation cases. *Aesthet Surg J*. 2018;38(suppl_2):S62-S73. doi: 10.1093/asj/sjx150
9. Botti G, Botti C, Ciancio F. A single center's clinical experience with Ergonomix breast implants. *Aesthet Surg J*. 2022;42(5):NP312-NP318. doi: 10.1093/asj/sjab422
10. Huemer GM, Wenny R, Aitzetmüller MM, Duscher D. Motiva Ergonomix round SilkSurface silicone breast implants: outcome analysis of 100 primary breast augmentations over 3 years and technical considerations. *Plast Reconstr Surg*. 2018;141(6):831e-842e. doi: 10.1097/prs.0000000000004367
11. Glicksman CA. Implant shell characteristics: the science behind the surface. *Clin Plast Surg*. 2021;48(1):79-86. doi: 10.1016/j.cps.2020.09.006
12. Stevens WG, Nahabedian MY, Calobrace MB, et al. Risk factor analysis for capsular contracture: a 5-year Sientra study analysis using round, smooth, and textured implants for breast augmentation. *Plast Reconstr Surg*. 2013;132(5):1115-1123. doi: 10.1097/01.prs.0000435317.76381.68
13. Spear SL, Murphy DK, Slicton A, Walker PS, Inamed Silicone Breast Implant U.S. Study Group. Inamed silicone breast implant core study results at 6 years. *Plast Reconstr Surg*. 2007; 120(7):8S-16S. doi: 10.1097/01.prs.0000286580.93214.df
14. Wong C-H, Samuel M, Tan B-K, Song C. Capsular contracture in subglandular breast augmentation with textured versus smooth breast implants: a systematic review. *Plast Reconstr Surg*. 2006;118(5):1224-1236. doi: 10.1097/01.prs.0000237013.50283.d2
15. Barnsley GP, Sigurdson LJ, Barnsley SE. Textured surface breast implants in the prevention of capsular contracture among breast augmentation patients: a meta-analysis of randomized controlled trials. *Plast Reconstr Surg*. 2006;117(7):2182-2190. doi: 10.1097/01.prs.0000218184.47372.d5
16. Seify H, Sullivan K, Hester TR. Preliminary (3 years) experience with smooth wall silicone gel implants for primary breast augmentation. *Ann Plast Surg*. 2005;54(3):231-235. doi: 10.1097/01.sap.0000153149.13912.e2
17. Cunningham B, McCue J. Safety and effectiveness of Mentor's MemoryGel implants at 6 years. *Aesthetic Plast Surg*. 2009;33(3):440-444. doi: 10.1007/s00266-009-9364-6
18. Wixtrom RN, Garadi V, Leopold J, Canady JW. Device-specific findings of imprinted-texture breast implants: characteristics, risks, and benefits. *Aesthet Surg J*. 2019;40(2):167-173. doi: 10.1093/asj/sjz155
19. Hammond DC, Canady JW, Love TR, Wixtrom RN, Caplin DA. Mentor Contour Profile gel implants: clinical outcomes at 10 years. *Plast Reconstr Surg*. 2017;140(6):1142-1150. doi: 10.1097/PRS.0000000000003846
20. 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;147(3):556-566. doi: 10.1097/PRS.0000000000007635
21. Lee S, Kim MK, Lee S, Ryu W, Back S. Capsular contracture rates in augmentation mammaplasty: comparison of round vs anatomical breast implants. *J Breast Dis*. 2020;8(2):115-120. doi: 10.14449/jbd.2020.8.2.115

22. Hall-Findlay EJ. Breast implant complication review: double capsules and late seromas. *Plast Reconstr Surg*. 2011;127(1):56-66. doi: 10.1097/PRS.0b013e3181fad34d
23. Munhoz AM, di Pompeo FS, De Mezerville R. Nanotechnology, nanosurfaces and silicone gel breast implants: current aspects. *Case Reports Plast Surg Hand Surg*. 2017;4(1):99-113. doi: 10.1080/23320885.2017.1407658
24. Barr S, Hill E, Bayat A. Current implant surface technology: an examination of their nanostructure and their influence on fibroblast alignment and biocompatibility. *Eplasty*. 2009;9:e22.
25. Barr S, Hill EW, Bayat A. Development, fabrication and evaluation of a novel biomimetic human breast tissue derived breast implant surface. *Acta Biomater*. 2017;49:260-271. doi: 10.1016/j.actbio.2016.11.052
26. Valencia-Lazcano AA, Alonso-Rasgado T, Bayat A. Characterisation of breast implant surfaces and correlation with fibroblast adhesion. *J Mech Behav Biomed Mater*. 2013;21:133-148. doi: 10.1016/j.jmbbm.2013.02.005
27. Hong P, Kim SS, Jeong C, et al. Four-year interim results of the safety of augmentation mammaplasty using the Motiva Ergonomix™ round SilkSurface: a multicenter, retrospective study. *Aesthetic Plast Surg*. 2021;45(3):895-903. doi: 10.1007/s00266-021-02152-3
28. Bartsich S, Ascherman JA, Whittier S, Yao CA, Rohde C. The breast: a clean-contaminated surgical site. *Aesthet Surg J*. 2011;31(7):802-806. doi: 10.1177/1090820X11417428
29. McGuire P, Reisman NR, Murphy DK. Risk factor analysis for capsular contracture, malposition, and late seroma in subjects receiving Natrelle 410 form-stable silicone breast implants. *Plast Reconstr Surg*. 2017;139(1):1-9. doi: 10.1097/PRS.0000000000002837
30. Calobrace MB, Stevens WG, Capizzi PJ, Cohen R, Godinez T, Beckstrand M. Risk factor analysis for capsular contracture: a 10-year Sientra study using round, smooth, and textured implants for breast augmentation. *Plast Reconstr Surg*. 2018;141(4S):20S-28S. doi: 10.1097/prs.0000000000004351
31. Deva AK, Adams WP Jr, Vickery K. The role of bacterial biofilms in device associated infection. *Plast Reconstr Surg* 2013;132(5):1319-1328. doi: 10.1097/PRS.0b013e3182a3c105
32. Maxwell GP, Van Natta BW, Murphy DK, Slicton A, Bengtson BP. Natrelle style 410 form-stable silicone breast implants: core study results at 6 years. *Aesthet Surg J*. 2012;32(6):709-717. doi: 10.1177/1090820 (12452423