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Breast

Short-term Safety of Augmentation Mammaplasty Using the BellaGel Implants in Korean Women

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Background: Asian women are stereotypically characterized by a slim body, smaller breasts and areolae, and larger nipples when compared with White women. They would therefore be vulnerable to displacement of a breast implant if they receive larger implants. They are also prone to hypertrophic and prolonged hyperemic scars. Surgeons should therefore be aware of Asian women's breast anatomy, healing tendency, and preferences. We conducted this multicenter, retrospective study to assess the short-term safety of the BellaGel implants in Korean women.

Methods: We evaluated a total of 637 women (n = 637; 1,274 breasts) for incidences of postoperative complications and the cumulative Kaplan–Meier complication-free survival.

Results: Overall, there were 12 cases (1.9%) of postoperative complications; these include 6 cases (0.9%) of hematoma, 2 cases (0.3%) of infection, and 4 cases (0.6%) of seroma. Moreover, there was no significant difference in the cumulative complication-free survival at 120 weeks between the 4 types of the BellaGel implants ($\chi^2 = 2.289$, $P = 0.513$).

Conclusion: In conclusion, we describe the short-term safety of augmentation mammaplasty using the BellaGel implants in Korean women. But further prospective, large-scale, multicenter studies with a long period of follow-up are warranted to establish our results. *(Plast Reconstr Surg Glob Open 2019;7:e2566; doi: 10.1097/GOX.0000000000002566; Published online 24 December 2019.)*

INTRODUCTION

A natural appearance of the breast is an essential goal of augmentation mammaplasty, and it is subjectively assessed based on the size, shape, and proportion of the breast.[1] But lack of objective, quantifiable determinants of breast esthetics poses challenging problems for plastic surgeons.[2] This causes a discrepancy in evaluation of esthetic outcomes between a plastic surgeon and a patient; there is a considerable difference in understanding of body image associated with attractiveness and natural appearance of the breast between the 2 parties.[3] Surgeons should not therefore neglect the association between breast esthetics and psychological body image, both of which are closely related to patients' quality of life.[4,5]

Tracking outcomes and complications of elective cosmetic surgery is essential for ensuring high-quality care and safety and informed selection of patients. Therefore, surgeons should be knowledgeable about reliable data regarding outcomes and potential complications that may be transferrable to their own patients. It remains problematic, however, that such data have been derived from a single surgeon or single-center studies; their applicability may be limited because the efficacy of a surgical procedure performed by a single surgeon cannot be interpreted as that by different surgeons. To overcome this, the use of national registries or health insurance claims data has been attempted. Therefore, American Society of Plastic Surgeons and the American Board of Plastic Surgery created the Tracking Operations and Outcomes for Plastic Surgeons database for the purposes of promoting a monitoring of the quality of plastic surgical care.[6] But the utility of the Tracking Operations and Outcomes for Plastic Surgeons may also be limited because it captures complications occurring within only 30 days postoperatively. It is therefore probable that

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the actual incidence of long-term complications, such as implant-related infections, loss of breast implants, and capsular contracture (CC), might be underestimated.[7]

To date, few medical devices have been assessed for their safety profile more strictly than silicone gel–filled breast implants. Despite great advances in their design over the past decades, such as cohesiveness of silicone gel and texturing of the shell, there are only a few randomized, controlled clinical trials that have provided evidence in esthetic augmentation mammaplasty through a comparison between diverse types of silicone gel–filled implants and techniques.[8,9] It remains unanswered, however, whether certain types of implants and surgical techniques are associated with best outcomes of esthetic augmentation mammaplasty. Data from the US Food and Drug Administration have been therefore analyzed to derive the best evidence about the safety of silicone gel–filled breast implants.[10,11]

Currently, 8 different brands of silicone gel–filled breast implants compete with each other in the Korean market. Of these, the BellaGel (HansBiomed Co. Ltd., Seoul, Korea) is the only product from a Korean manufacturer; it has been manufactured to cater for the need of Korean women through a rigorous analysis of their anatomical and anthropometric characteristics. Three types of shape (round, anatomical, and conical) and another 3 types of surface texture (smooth, textured, and microtextured) are therefore available. This enables Korean women to receive augmentation mammaplasty using approximately 300 different subtypes of the BellaGel implants. Asian women are stereotypically characterized by a slim body, smaller breasts and areolae, and larger nipples when compared with their White counterparts.[12–14] They would therefore be vulnerable to displacement of a larger breast implant.[15] They are also prone to hypertrophic and prolonged hyperemic scars.[16,17] Surgeons should therefore be aware of Asian women's breast anatomy, healing tendency, and preferences.[16,18]

Given the above background, we conducted this multicenter, retrospective study to assess the short-term safety of augmentation mammaplasty using the BellaGel in Korean women.

METHODS

Study Setting

A total of 672 patients (n = 672) underwent esthetic augmentation mammaplasty using the BellaGel implants at our hospitals during a 2-year period from April 1, 2017, to March 30, 2019. We included the patients who were followed up for up to 12 months, those without underlying diseases (eg, hypertension and diabetes mellitus), those without depression or anxiety, and those with availability of follow-up data. But we excluded the patients who had received autologous fat grafting within 6 months before taking surgeries at our hospitals (n = 11), those lost to follow-up (n = 21), and those who are deemed to be ineligible for the current analysis according to our judgment (n = 3). Therefore, we finally evaluated a total of 637 patients (n = 637) in the current study; it was conducted in compliance with the relevant ethics guidelines, and informed consent was waived due to its retrospective nature.

Treatment Protocol

An evidence-based implant-based augmentation mammaplasty was performed, as previously described.[19–21]

Periareolar, inframammary fold, and axillary incisions were made under general anesthesia and intravenous sedation for the purposes of preventing visible scarring. Selection of surgical incision is based on our desired outcomes, types of breast implants, the degree of augmentation, the anatomical characteristics of patients, and patient–surgeon preference. Based on the Ranquist formula, we determined the distance extending from the nipple to the inframammary fold, the size of breast implant, and the scope of dissection. After the dissection, each breast was irrigated using a 100 mL of normal saline mixed with H_2O_2 solution at a ratio of 1:1, followed by the use of betadine 100 cc. Then, a breast implant was immersed in a normal saline mixed with ceftezole 1 vial and gentamicin 1 ample and then inserted in a pocket either under the pectoralis major muscle (a submuscular placement) or in the retromammary space above it (a subglandular/submammary placement). Methods for inserting and positioning a breast implant in the pocket were dependent on its types, the degree of augmentation, characteristics of a patient's body, and our recommendations. Thus, we performed a dual-plane I/II augmentation on a case-by-case basis. Intraoperatively, the patients were intravenously given ceftezole 1.0 g. Incisions were closed using layered sutures in the breast tissue. In addition, skin adhesive or surgical tape were used to close the skin.

Postoperatively, the patients were given cefaclor, nonsteroidal anti-inflammatory drugs, and antacid 3 times daily for a week. Moreover, they were also recommended to take montelukast sodium 10 mg (Lucast tab.; Wooridul Pharmaceutical Ltd., Seoul, Korea) for a month for the prevention of CC and to wear a compressive garment for 3 months. Furthermore, they were also recommended to use an upper or lower band, if necessary, and most of them used an upper one for 1–2 months.

Postoperative course was meticulously monitored during a regular follow-up at 1, 2, 3, and 4 weeks; 3, 6, 9, and 12 months; and thereafter. Moreover, the patients were also recommended to be further evaluated on magnetic resonance imaging scans at 3 years and at a 2-year interval thereafter in accordance with the US Food and Drug Administration labeling recommendation.[22]

Patient Evaluation and Criteria

We performed a retrospective review of baseline characteristics of the patients; these include age, sex, round of surgery (primary and revision breast augmentation), smoking status (never, current, and former smokers), body mass index, the type and volume of breast implant, and the type of surgical approach.

For safety assessment, we analyzed incidences of complications after an implant-based augmentation mammaplasty; potential complications include CC, implant malposition or rippling, breast deformation or asymmetry, wound or skin problems, infection, hematoma or hemorrhage, implant rupture, seroma, abscess, silicone granuloma or implant extrusion, double capsule, folding,

upside-down rotation, and breast implant–associated anaplastic large cell lymphoma.[23–31]

Analysis of Implant Survival

In the current study, we analyzed complication-free survival; it is defined as survivorship of the patients without any complications. It was calculated as percentage of functional implants that remain without undergoing revision or removal of them without revision.[32]

Statistical Analysis of the Patient Data

All data of our clinical series of the patients were expressed as the number of patients with percentage, mean ± SD, or mean ± standard error, where appropriate. The cumulative overall complication-free survival was estimated, for which 95% confidence intervals (CIs) were provided. Moreover, differences in complication-free survival between the 4 types of the BellaGel implants were tested for statistical significance using the repeated measures analysis of variance and Duncan's post hoc analysis. Furthermore, the corresponding cumulative complication-free Kaplan–Meier survival curve was plotted. Statistical analysis was done using the SPSS ver. 18.0 for windows (SPSS Inc., Chicago, Ill.). A P value of <0.05 was considered statistically significant.

RESULTS

Baseline Characteristics of the Patients

A total of 637 patients (n = 637; 1,274 breasts) were evaluated, all of whom were women with a mean age of 33.2 ± 7.2 years old. The patients were followed up during a mean period of 25.8 ± 7.2 months. Their baseline characteristics are represented in Table 1.

Table 1. Baseline Characteristics of the Patients (n = 637; 1,274 Breasts)

Variables	Values
Age, y	33.2 ± 7.2
Sex (male:female ratio)	0:637
Round of surgery	
Primary augmentation mammaplasty	594 (93.2%)
Revision augmentation mammaplasty	43 (6.8%)
Causes of revision surgery	
Postoperative complications	19 (44.2%)
Dissatisfaction with the shape	19 (44.2%)
Dissatisfaction with the softness	3 (7.0%)
Dissatisfaction with the shape	2 (4.6%)
Smoking status	
Never smokers	541 (84.9%)
Former smokers	43 (6.8%)
Current smokers	53 (8.3%)
BMI (kg/m^2)	
Lower body weight (<18.5)	200 (31.4%)
Normal body weight (18.5–24.9)	432 (67.8%)
Overweight (25–29.9)	5 (0.8%)
Obesity (>30)	0 (0.0%)
Type of breast implant	
Round microtextured	315 (49.5%)
Anatomical textured	272 (42.7%)
Round textured	48 (7.5%)
Round smooth	2 (0.3%)
Volume of breast prosthesis (cc)	
200–245	27 (4.3%)
250–295	227 (35.6%)
300–345	347 (54.5%)
350–395	34 (5.3%)
≥400	2 (0.3%)
Type of surgery	
Subpectoral augmentation mammaplasty	2 (0.3%)
Subglandular augmentation mammaplasty	0 (0.0%)
Dual-plane augmentation mammaplasty	635 (99.7%)
Surgical approach	
Axillary approach	104 (16.3%)
Inframammary fold approach	520 (81.6%)
Periareolar approach	5 (0.8%)
Others	8 (1.3%)

Values are mean ± SD with range or the number of patients with percentage, where appropriate.
BMI, body mass index.

Safety Outcomes

Overall, there were 12 cases (1.9%) of postoperative complications in our series; these include 6 cases (0.9%) of hematoma, 2 cases (0.3%) of infection, and 4 cases (0.6%) of seroma. Incidences of postoperative complications are represented in Table 2.

As shown in Table 3, cumulative overall complication-free survival reached the highest level at 120 weeks postoperatively (0.981 [95% CI, 0.971–0.992]). Moreover, as shown in Table 4, there was no significant difference in cumulative complication-free survival at 120 weeks between the 4 types of the BellaGel implants (χ^2 = 2.289, P = 0.513). The corresponding Kaplan–Meier complication-free survival curve was plotted in **Supplemental Figure 1** (**Supplemental Digital Content 1,** which displays the Kaplan–Meier complication-free survival curve, **http://links.lww.com/PRSGO/B260**).

DISCUSSION

According to the 2015 International Society of Aesthetic Plastic Surgery report, esthetic breast augmentation surgery is performed more prevalently when compared with liposuction and blepharoplasty. Moreover, the number of patients undergoing implant-based breast augmentation is estimated at >220,000 based on the 2014 International Society of Aesthetic Plastic Surgery data.[33] But concerns have been raised regarding the safety of esthetic breast augmentation using implant prostheses.

Currently, diverse types of silicone gel–filled breast implants are commercially available in a clinical setting. Studies have been conducted to assess their safety profile, whose results are well documented. First, Maxwell et al[34] conducted a 10-year follow-up study to assess the efficacy and safety of augmentation mammaplasty using the Natrelle 410 anatomical form-stable silicone-filled breast implants (Allergan Inc., Irvine, Calif.), for which a 10-year incidence of postoperative complications and a 10-year cumulative risk of them served as outcome measures. These authors reported that CC of Baker scale grades III/IV occurred at an incidence of 9.2%. According to these authors, other complications also include rupture (9.4%), malposition (4.7%), asymmetry (6.9%), and seroma (1.6%). Of note, there was a case of breast implant–associated anaplastic large cell lymphoma.[34] Spear et al[35] conducted another 10-year follow-up study to evaluate the safety profile of the 410 Allergan core study, thus showing that CC was the most frequent complication after augmentation mammaplasty; there was a significant increase in the

Table 2. Incidences of Postoperative Complications

Variables	Values				
	Total (n = 637)	Round Microtextured (n = 315)	Anatomical Textured (n = 272)	Round Textured (n = 48)	Round Smooth (n = 2)
CC	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Implant malposition or rippling	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Breast deformation or asymmetry	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Wound or skin problems	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Infection	2 (0.3%)	0 (0.0%)	0 (0.0%)	2 (4.2%)	0 (0.0%)
Hematoma or hemorrhage	6 (0.9%)	0 (0.0%)	6 (2.2%)	0 (0.0%)	0 (0.0%)
Implant rupture	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Seroma	4 (0.6%)	0 (0.0%)	4 (1.5%)	0 (0.0%)	0 (0.0%)
Abscess	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Silicone granuloma or implant extrusion	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Double capsule	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Folding	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Upside-down rotation	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
BIA-ALCL	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Values are the number of patients with percentage.
BIA-ALCL, breast implant–associated anaplastic large cell lymphoma.

Table 3. Cumulative Overall Complication-free Survival

Duration (wk)	N	n	Complication-free Survival	95% CI
1	637	1	0.998 ± 0.002	0.995–1.000
3	636	1	0.997 ± 0.002	0.993–1.000
4	635	1	0.995 ± 0.003	0.990–1.000
5	634	2	0.992 ± 0.004	0.985–0.999
7	632	1	0.991 ± 0.004	0.983–0.998
8	631	1	0.989 ± 0.004	0.981–0.997
9	630	1	0.987 ± 0.005	0.979–0.996
11	629	1	0.986 ± 0.005	0.977–0.995
13	628	1	0.984 ± 0.005	0.975–0.994
14	627	1	0.983 ± 0.005	0.973–0.993
120	626	1	0.981 ± 0.005	0.971–0.992

N, total number of cases; n, incidences of postoperative complications.

Table 4. Cumulative Complication-free Survival at 120 Weeks Depending on the Type of the BellaGel Implants

Type of the BellaGel Implants	N	n	Censored Values
Round microtextured	315	0	315 (100.0%)
Anatomical textured	272	10	262 (96.3%)
Round textured	48	2	46 (95.8%)
Round smooth	2	0	2 (100.0%)

N, total number of cases; n, incidence of postoperative complications.

risk of CC over time despite its relatively lower incidence (56.2%).[35] From the similar context, 2 studies about the form-stable Mentor Contour Profile Gel implants (Mentor Worldwide LLC, Santa Barbara, CA, USA) showed a lower incidence of CC when compared with smooth-surface round gel breast implants.[36,37] It deserves special attention that the implant rippling or wrinkling occurred at a very low rate of 0.9% at a 10-year follow-up.[38] Finally, the safety of the Motiva Implants (Establishment Labs Holdings Inc., Alajuela, Costa Rica) was also evaluated at a 6- and 3-year follow-up by Quirós et al[23] and Sforza et al,[39] respectively. These 2 studies showed that patients receiving the Motiva Implants presented with no CC as a postoperative complication.[23,39] Of note, there were also no cases of CC in our clinical series of the patients. Its efficacy and safety has been recently documented.[40] But lack of CC in our series is closely associated with a short period of follow-up; Maxwell et al[34,41] formerly reported an approximately 1% annual increase in the incidence of CC of Baker grade III/IV from the previously reported 6-year incidences.

To summarize, our results are as follows: First, cumulative overall complication-free survival reached the highest level at 120 weeks postoperatively (0.981 [95% CI, 0.971–0.992]). Second, there was no significant difference in the cumulative complication-free survival between the 4 types of the BellaGel implants ($\chi^2 = 2.289$, $P = 0.513$).

But limitations of the current study are as follows: First, we evaluated a small series of the patients under the retrospective design. Second, we followed up our clinical series of the patients for short periods of time. Third, we conducted the current study at 6 local clinics only. The possibility of selection bias could not therefore be completely ruled out. Fourth, we failed to eliminate a bias that might arise from differences in surgical methods between the study centers. Fifth, we failed to quantify esthetic outcomes using anthropometric measurements. Sixth, the patients receiving either of 2 types of the BellaGel implants (round microtextured [n = 315] and anatomical textured [n = 272]) accounted for more than 90% of total cases. Therefore, the possibility of comparison bias could not also be completely ruled out.

CONCLUSIONS

In conclusion, we describe the short-term safety of augmentation mammaplasty using the BellaGel implants in Korean women. But further prospective, large-scale,

multicenter studies with a long period of follow-up are warranted to establish our results.

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