INTRODUCTION

A natural appearance of the breast is an essential goal of augmentation mammoplasty, and it is subjectively assessed based on the size, shape, and proportion of the breast. But lack of objective, quantifiable determinants of breast esthetics poses challenging problems for plastic surgeons. 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. 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.

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, the 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. 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...
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 mammoplasty 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 mammoplasty. 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 mammoplasty 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 mammoplasty using the BellaGel in Korean women.

METHODS

Study Setting

A total of 672 patients (n = 672) underwent esthetic augmentation mammoplasty 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 mammoplasty 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 H2O2 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 ampule 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 1.0g. 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, non-steroidal anti-inflammatory drugs, and antacid 3 times daily for a week. Moreover, they were also recommended to take montelukast sodium 10mg (Lucastr tab.; Wooridul Pharmaceutical Ltd., Seoul, Korea) for a month in the prevention of CC and to wear a compressive garment for 3 months. Furthermore, they were also recommended to use an upper or lower hand, 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 mammoplasty; 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.\textsuperscript{28–31}

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.\textsuperscript{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.

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 (χ² = 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.\textsuperscript{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\textsuperscript{34} conducted a 10-year follow-up study to assess the efficacy and safety of augmentation mammoplasty 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.\textsuperscript{34} Spear et al\textsuperscript{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 mammoplasty; there was a significant increase in the

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 mammoplasty  | 594 (93.2%) |
| Revision augmentation mammoplasty | 43 (6.8%)  |
| Causes of revision surgery        |        |
| Postoperative complications       | 19 (44.2%) |
| Disatisfaction with the shape     | 19 (44.2%) |
| Dissatisfaction with the softness  | 3 (7.0%)   |
| Dissatisfaction with the shape     | 2 (4.5%)   |
| Smoking status                    |        |
| Never smokers                     | 541 (84.9%) |
| Former smokers                    | 43 (6.8%)  |
| Current smokers                   | 53 (8.3%)  |
| BMI (kg/m²)                       |        |
| 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 mammoplasty | 2 (0.3%)    |
| Sub glandular augmentation mammoplasty | 0 (0.0%) |
| Dual-plane augmentation mammoplasty | 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.
risk of CC over time despite its relatively lower incidence (56.2%). 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. 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. 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 and Sforza et al, respectively. These 2 studies showed that patients receiving the Motiva Implants presented with no CC as a postoperative complication. Of note, there were also no cases of CC in our clinical series of the patients. Its efficacy and safety has been recently documented. But lack of CC in our series is closely associated with a short period of follow-up; Maxwell et al 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 ± 0.005). Second, there was no significant difference in the cumulative complication-free survival between the 4 types of the BellaGel implants (χ² = 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 mammoplasty 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.

**REFERENCES**

1. Kim MS, Shbalchiero JC, Reece GP, et al. Assessment of breast aesthetics. *Plast Reconstr Surg.* 2008;121:186e–194e.
2. Hudson DA. Factors determining shape and symmetry in immediate breast reconstruction. *Ann Plast Surg.* 2004;52:15–21.
3. Hsia HC, Thomson JG. Differences in breast shape preferences between plastic surgeons and patients seeking breast augmentation. *Plast Reconstr Surg.* 2003;112:312–320; discussion 321.
4. Sarwer DB, Cash TF, Magee L, et al. Female college students and cosmetic surgery: an investigation of experiences, attitudes, and body image. *Plast Reconstr Surg.* 2005;115:931–938.
5. von Soest T, Kvalem HI, Skolleborg KC, et al. Psychosocial factors predicting the motivation to undergo cosmetic surgery. *Plast Reconstr Surg.* 2006;117:51–62; discussion 63.
6. Alderman AK, Collins ED, Stree R, et al. Benchmarking outcomes in plastic surgery: national complication rates for abdominoplasty and breast augmentation. *Plast Reconstr Surg.* 2009;124:2127–2133.
7. Khavanin N, Jordan SW, Vieira BL, et al. Combining abdominal and cosmetic breast surgery does not increase short-term complication rates: a comparison of each individual procedure and pre-treatment risk stratification tool. *Aesthet Surg J.* 2015;35:999–1006.
8. Barnsley GP, Sigurdson L, 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;117:2182–2190.
9. Wong CH, Samuel M, Tan BK, et al. Capsular contracture in subglandular breast augmentation with textured versus smooth breast implants: a systematic review. *Plast Reconstr Surg.* 2006;118:1224–1236.
10. Chung KC, Malay S, Shauver MJ, et al. Economic analysis of screening strategies for rupture of silicone gel breast implants. *Plast Reconstr Surg.* 2012;130:225–237.
11. Noone RB. A review of the possible health implications of silicone breast implants. *Cancer.* 1997;79:1747–1756.
12. Cheng MH, Huang JJ. Augmentation mammoplasty in Asian women. *Semin Plast Surg.* 2009;23:48–54.
13. Brown TP, Ringrose C, Hyland RE, et al. A method of assessing female breast morphology and its clinical application. *Br J Plast Surg.* 1999;52:355–359.
14. Park IV, Kim MR, Jo HH, et al. Association of the nipple-areola complexes with age, parity, and breastfeeding in Korean premenopausal women. *J Hum Lact.* 2014;30:474–479.
15. Takayangi S, Nakagawa C, Sugimoto Y. Augmentation mammoplasty: where should the implant be placed? *Aesthetic Plast Surg.* 2004;28:83–88.
16. Kim S, Choi TH, Liu W, et al. Update on scar management: guidelines for treating Asian patients. *Plast Reconstr Surg.* 2013;132:1580–1589.
17. McCurdy JA Jr. Considerations in Asian cosmetic surgery. *Facial Plast Surg Clin North Am.* 2007;15:387–397, vi.
18. Sun J, Liu C, Mu D, et al. Chinese women’s preferences and concerns regarding incision location for breast augmentation surgery: a survey of 216 patients. *Aesthetic Plast Surg.* 2015;39:214–226.
19. Thorne CH. An evidence-based approach to augmentation mammoplasty. *Plast Reconstr Surg.* 2016;126:2184–2188.

20. Lista F, Ahmad J. Evidence-based medicine: augmentation mammoplasty. *Plast Reconstr Surg.* 2013;132:1684–1696.
21. Schwartz MR. Evidence-based medicine: breast augmentation. *Plast Reconstr Surg.* 2017;140:109e–119e.
22. Sieber DA, Stark RY, Chase S, et al. Clinical evaluation of shaped gel implant rotation using high-resolution ultrasound. *Aesthet Surg J.* 2017;37:290–296.
23. Quiroz MC, Balboa MC, Fassero JJ. Six-year prospective outcomes of primary breast augmentation with nano surface implants. *Aesthet Surg J.* 2019;39:495–508.
24. Nava MB, Rancati A, Angirgiani C, et al. How to prevent complications in breast augmentation. *Gland Surg.* 2017;6:210–217.
25. Duteille F, Rouif M, Laurent S, et al. Five-year safety data for eurosilicone’s round and anatomical silicone gel breast implants. *Plast Reconstr Surg Glob Open.* 2014;2:e138.
26. Mazzocchi M, Desy LA, Corrias F, et al. A clinical study of late seroma in breast implantation surgery. *Aesthetic Plast Surg.* 2012;36:97–104.
27. Wong T, Lo LW, Fung PY, et al. Magnetic resonance imaging of breast augmentation: a pictorial review. *Insights Imaging.* 2016;7:399–410.
28. Back YW, Lew DH, Lee DW. A retrospective analysis of ruptured breast implants. *Arch Plast Surg.* 2014;41:734–739.
29. Hvilson GB, Friis S, Frederiksen K, et al. The clinical course of immediate breast implant reconstruction after breast cancer. *Acta Oncol.* 2011;50:1045–1052.
30. Clemens MW, Nava MB, Rocco N, et al. Understanding rare adverse sequelae of breast implants: anaplastic large-cell lymphoma, late seromas, and double capsules. *Gland Surg.* 2017;6:169–184.
31. Lee WS, Kang SG. Upside-down rotation of a breast implant with double capsule formation after aesthetic breast augmentation: a case report. *Arch Aesthetic Plast Surg.* 2018;24:75–77. https://doi.org/10.14730/aaps.2018.24.2.75.
32. Harvey N, Ahlmann ER, Allison DC, et al. Endoprosthesis lasts longer than intramedullary devices in proximal femur metastases. *Clin Orthop Relat Res.* 2012;470:684–691.
33. El-Haddad R, Lafarge-Clauoue B, Garabedian C, et al. A 10-year prospective study of implant-based breast augmentation and reconstruction. *Eplasty.* 2018;18:e7.
34. Maxwell GP, Van Natta BW, Bengtson BP, et al. Ten-year results from the natrelle 410 anatomical form-stable silicone breast implant core study. *Aesthet Surg J.* 2015;35:145–155.
35. Spear SL, Murphy DK. Allergan Silicone Breast Implant U.S. Core Clinical Study Group. Natrelle round silicone breast implants: core study results at 10 years. *Plast Reconstr Surg.* 2014;133:1354–1361.
36. Hammond DC, Migliori MM, Caplin DA, et al. Mentor contour profile gel implants: clinical outcomes at 6 years. *Plast Reconstr Surg.* 2012;129:1381–1391.
37. Cunningham B, McCue J. Safety and effectiveness of mentor jellygel implants at 6 years. *Aesthetic Plast Surg.* 2009;33:140–144.
38. Hammond DC, Canady JW, Love TR, et al. Mentor contour profile gel implants: clinical outcomes at 10 years. *Plast Reconstr Surg.* 2017;140:1142–1150.
39. Sforza M, Zacchelli 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.
40. Han J, Jeong JH, Bang SI, et al. BellaGel breast implant: 4-year results of a prospective cohort study. *J Plast Surg Hand Surg.* 2019;53:225–229.
41. Maxwell GP, Van Natta BW, Murphy DK, et al. Natrelle style 410 form-stable silicone breast implants: core study results at 6 years. *Aesthet Surg J.* 2012;32:709–717.