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ORIGINAL PAPER

A multi-center, retrospective, preliminary observational study to assess the safety of BellaGel® after augmentation mammaplasty

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Abstract

Background BellaGel® is the only cohesive silicone gel-filled breast implant from a Korean manufacturer, and it was first developed in 2005. It was approved by the CE in 2008, thus becoming the first Asian breast implant available in the EU. We conducted this study to assess the safety of BellaGel® in patients receiving augmentation mammaplasty.

Methods We evaluated a consecutive series of 239 patients (478 breasts) who received esthetic augmentation mammaplasty using the BellaGel® (round smooth, round textured, round nanotextured, and anatomical textured types of implant) (HansBiomed Co. Ltd., Seoul, Korea) at three clinics in Korea (JW Plastic Surgery Center, BS The Body Plastic Surgery Clinic and Grace Plastic Surgery Clinic) during a period from December 1, 2015 to January 31, 2018.

Results A total of 239 patients with a mean age of 33.1 ± 8.5 years old were followed up during a mean period of 399.58 ± 232.71 days, where there were no cases of capsular contracture in our clinical series of the patients. Other complications include one case (0.4%) of seroma, three cases (1.3%) of hematoma, and one case (0.4%) of infection. Moreover, there were no significant differences in the cumulative incidences of complications between the four types of the BellaGel® ($\chi^2 = 2.322$, $df = 3$, $P = 0.508$). Furthermore, the cumulative Kaplan-Meier survival rate was estimated at 0.979 (95% CI 0.961–0.997).

Conclusions Our results indicate that the BellaGel® is such a safe breast implant that surgeons might consider using it for esthetic augmentation mammaplasty.

Level of evidence: Level III, risk/prognostic study.

Keywords Breast · Breast implants · Augmentation mammaplasty · Safety

Introduction

A silicone gel-filled breast implant was first introduced by Cronin and Gerow in 1963. Since then, there has been an evolution in implant manufacturing up to present [1, 2]. That is, the second-generation silicone gel-filled breast implants are equipped with a low viscosity gel covered with a thin, slightly permeable shell; their gel is vulnerable to leakage into the adjacent tissue if they are ruptured. The third-generation silicone gel-filled breast implants containing a cohesive gel are characterized by a decrease in occurrence of gel leakage. This is followed by the development of the fourth-generation silicone gel-filled breast implants; their advantages include a high viscosity of gel arising from an increased silicone cross-linking. Finally, the fifth-generation silicone gel-filled breast implants are characterized by a more cohesive, form-stable gel [2–5].

With technological advancements in the manufacturing of a silicone gel-filled breast implant, its safety has been scrutinized worldwide [6]. But controversial opinions exist regarding the safety of a silicone gel-filled breast implant; it eventually resulted in a moratorium of breast implants in the USA from 1992 to 2000 [7]. Since then, manufacturers of a silicone gel-filled breast implant were mandated to submit both premarket approval (PMA) safety data and efficacy data obtained from a large-scale prospective "Core" study [8–10].

Cohesive silicone gel-filled breast implants are characterized by a high degree of softness [11, 12]. Their clinical use was approved by the Korean Ministry of Food and Drug Safety (KMFDS) in 2007. Since then, diverse brands of cohesive silicone gel-filled breast implants have become commercially

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available in Korea. Of these, the BellaGel® (HansBiomed Co. Ltd., Seoul, Korea) is the only cohesive silicone gel-filled breast implant from a Korean manufacturer, and it was first developed in 2005. It was approved by the CE in 2008, thus becoming the first Asian breast implant available in the EU. Moreover, its clinical use was also approved by the KMFDS. Currently, diverse types of the BellaGel® implants (round smooth, round textured, round nanotextured, and anatomical extured ones) are available in 30 countries worldwide. According to a recent prospective cohort study, the BellaGel® was found to be an effective, safe implant [13].

Given the above background, we conducted this multi-center, retrospective, preliminary observational study to compare the short-term safety between the four types of the BellaGel® implants in Korean women.

Patients and methods

Study patients and setting

Between December 1, 2015 and January 31, 2018, a consecutive series of 239 patients (478 breasts) underwent esthetic augmentation mammaplasty using the BellaGel® implants at three clinics in Korea (JW Plastic Surgery Center, BS The Body Plastic Surgery Clinic and Grace Plastic Surgery Clinic). We evaluated the patients with available medical records. But we excluded the patients with a follow-up period of < 6 months. The current study was conducted in compliance with the relevant ethics guidelines. But informed consent was waived due to its retrospective nature.

Criteria for evaluating the patients

In the current study, we performed a retrospective review of medical records. Thus, we evaluated baseline characteristics of the patients; these include age, sex, round of surgery, smoking history, body mass index (BMI), the shape (round and anatomical shape), surface texture (smooth, textured and nanotextured surface) and volume (< 200, 200–249, 250–299, 300–349, 350–399, and ≥ 400 cc) of breast implant, the type of implant pocket, the type of surgical incision, and the method of pocket irrigation.

The patients were evaluated for the safety of augmentation mammaplasty using the BellaGel®. We compared cumulative incidences of postoperative complications between the four types of the BellaGel® (round smooth, round textured, round nanotextured, and anatomical textured implants). Moreover, we estimated cumulative survival depending on the types of the BellaGel® implants. Differences in cumulative incidences of postoperative complications between the four types of the BellaGel® served as primary safety outcome measure. Differences in cumulative survival between the four types of the BellaGel® served as secondary safety outcome measure.

Statistical analysis of the patient data

Data was expressed as the number of the patients with percentage, mean ± standard deviation or mean ± standard error, where appropriate. Both primary and secondary outcome measures were analyzed using the repeated measures analysis of variance (ANOVA) and Duncan's post hoc analysis. The cumulative overall survival rate was estimated using the

Table 1 Baseline characteristics of the patients

Variables	Values
Age (years)	33.1 ± 8.5
Sex (male-to-female ratio)	0:239
Round of surgery	
Primary augmentation mammaplasty	223 (93.3%)
Revision augmentation mammaplasty	16 (6.7%)
Smoking history	
Never smokers	203 (84.9%)
Former smokers	16 (6.7%)
Current smokers	20 (8.4%)
BMI (kg/m^2)	
Lower body weight (< 18.5)	75 (31.4%)
Normal body weight (18.5–24.9)	162 (67.8%)
Overweight (25–29.9)	2 (0.8%)
Obesity (> 30)	0 (0.0%)
Type of breast implant	
Round smooth type	1 (0.4%)
Round textured type	18 (7.5%)
Round nanotextured type	118 (49.4%)
Anatomical textured type	102 (42.7%)
Volume of breast implant (cc)	
< 200	0 (0.0%)
200–249	10 (4.2%)
250–299	85 (35.6%)
300–349	130 (54.4%)
350–399	13 (5.4%)
≥ 400	1 (0.4%)
Implant pocket	
Subpectoral	1 (0.4%)
Subglandular	0 (0.0%)
Dual-plane	238 (99.6%)
Surgical incision	
Axillary	39 (16.3%)
Inframammary fold	195 (81.6%)
Periareolar	2 (0.8%)
Others	3 (1.3%)
Method of pocket irrigation	
Saline + betadine	94 (39.3%)
Saline + betadine + antibiotics	77 (32.2%)
Antibiotics	68 (28.5%)

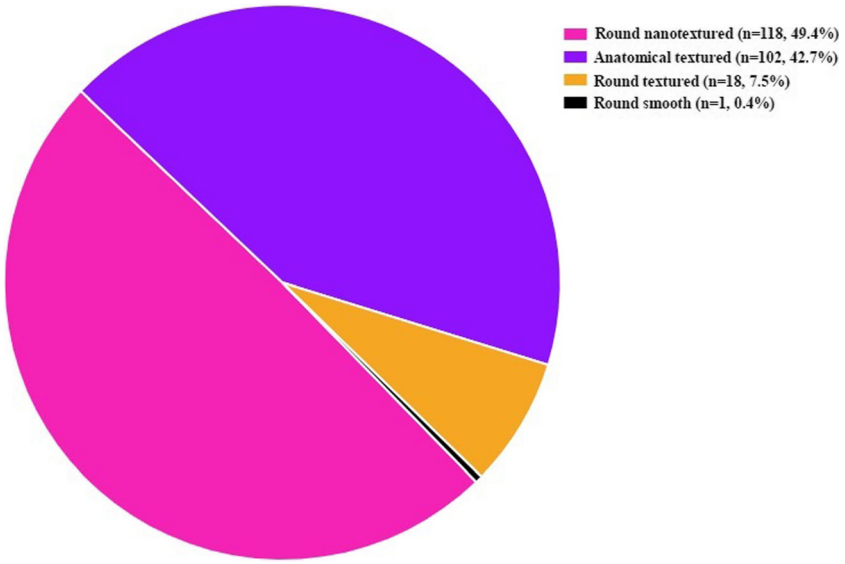

Fig. 1 Distribution of the BellaGel® implants

Kaplan-Meier method, for which 95% confidence intervals (CIs) were provided. Statistical analysis of the patient data was performed using the SPSS ver. 26.0 for windows (SPSS Inc., Chicago, IL). Statistical significance was set at $P < 0.05$.

Results

Baseline characteristics of the patients

A total of 239 patients ($n = 239$; 478 breasts) were evaluated in the current study, all of whom were women with a mean age of 33.1 ± 8.5 years old. They were followed up during a mean period of 399.58 ± 232.71 days. Their baseline characteristics are represented in Table 1.

Our clinical series of the patients include 223 cases (93.3%) of primary augmentation mammaplasty and 16 cases (6.7%) of revision one. Causes of revision augmentation mammaplasty include postoperative complications ($n = 7$, 43.8%), dissatisfaction with the shape ($n = 7$, 43.8%), that with the softness ($n = 1$, 6.2%), and that with the size ($n = 1$, 6.2%).

The patients underwent augmentation mammaplasty using a round nanotextured implant ($n = 118$, 49.4%), an anatomical textured one ($n = 102$, 42.7%), a round textured one ($n = 18$, 7.5%), or a round smooth one ($n = 1$, 0.4%). Distribution of the BellaGel® implants is shown in Fig. 1.

Safety outcomes

Overall, there were five cases (2.1%) of complications in our series; these include three cases (1.3%) of hematoma, one case (0.4%) of infection, and one case (0.4%) of seroma. By the type of the BellaGel® implants, the incidence of postoperative complications is summarized in Table 2.

In our series, complications occurred at 7, 13, 16, 21, and 35 days postoperatively, based on which the overall survival was estimated at 0.979 ± 0.009 (95% CI 0.961–0.997) (Table 3).

As shown in Table 4, there were no significant differences in the cumulative survival between the four types of the BellaGel® ($\chi^2 = 2.322$, $df = 3$, $P = 0.508$).

Table 2 Complications depending on the type of the BellaGel®

Variables	Values			
	Round smooth type ($n = 1$)	Round textured type ($n = 18$)	Round nanotextured type ($n = 118$)	Anatomical textured type ($n = 102$)
Hematoma	1	0	0	2
Infection	0	1	0	0
Seroma	0	0	0	1
Capsular contracture	0	0	0	0

Discussion

Numerous options are available for use of a breast implant in plastic surgery settings, such as augmentation mammaplasty, revision surgery, and breast reconstruction, and they include shape, size, the type and properties of gel material, fill ratio, and surface texture of shell. Esthetic outcomes and safety of surgery as well as performance of a breast implant may depend on such options [14, 15]. Multiple factors are closely associated with selection of a breast implant; these include breast anatomy and tissue measurements, a surgeon's experience, specific application of surgery, and preference of a patient and a surgeon [16–18]. Although contemporary surgeons emphasize the importance of the shape and fill material of a breast implant in deciding on it, they should also consider other physical properties [14].

Since breast implants are placed in a human body, their safety should be rigorously assessed. Therefore, the FDA mandated manufacturers of a breast implant to conduct large-scale post-approval studies for the purposes of monitoring long-term safety outcomes. Such studies include approximately 100,000 patients receiving a silicone gel-filled breast implant during a follow-up period of 10 years [19]. It remains problematic; however, their database has yet to be completely analyzed. The currently available database has been derived from industry-sponsored studies [19–23]. Of these, relatively smaller-scale "Core" studies have been analyzed [19, 20, 22–24]. Our results are of significance in that the BellaGel® is the only cohesive silicone gel-filled breast implant whose safety has been assessed in Korea. Recently, its nanotextured type (BellaGel SmoothFine®) was released; it is advantageous in lowering capsular contracture (CC) rates and providing more softness. These properties might arise from the surface interaction that can decrease macrophage activities and enhance the elasticity of the gel [25].

Of the most common complications of augmentation mammaplasty, CC is a pathologic hardening and tightening of the capsule around the implant. Still, little is known about its exact etiologic and pathophysiologic mechanisms, for which various hypotheses have been proposed [26–28].

Table 3 Cumulative survival at time points of follow-up

Time point of FU	*N*	*n*	SR	SE	95% CI
At 7 days	239	1	0.996	0.004	0.988–1.000
At 13 days	238	1	0.992	0.006	0.980–1.000
At 16 days	237	1	0.987	0.007	0.973–1.000
At 21 days	236	1	0.983	0.008	0.967–1.000
At 35 days	235	1	0.979	0.009	0.961–0.997

FU, follow-up; *N*, number of total cases; *n*, incidence of postoperative complications; *SR*, survival rate; *SE*, standard error; *CI*, confidence interval

Previous published studies have shown that the incidence of CC is relatively lower in patients undergoing augmentation mammaplasty using textured implants [29, 30]. But this remains controversial; the use of smooth implants has also been advocated based on reports that there is no significant difference in the incidence of CC between the textured and smooth types [31–34]. Textured implants are characterized by an ability to modify the host response to wound healing. Tissue ingrowth may not only stabilize the interface of implants but also increase compatibility. This leads to an inhibition of the formation of CC [35]. In more detail, irregular surface properties of textured implants promote the growth of fibroblasts into and around their interface. The resulting contact inhibition effect may lead to the formation of a thinner capsule around the implant [36, 37]. By contrast, smooth implants promote the fibrosis characterized by the deposition of collagen fibrils in a capsule composed of the connective tissue around the implant [38, 39]. Of note, we found no cases of CC in our series. Presumably, this might be not only because we used anatomical textured or round nanotextured implants in 92% of total cases but also because we followed up our clinical series of the patients for relatively shorter periods of time. Therefore, there is a possibility that the number of cases of CC might rise over time. Indeed, a previous experimental research using the BellaGel® nanotextured implant showed that there were significant decreases in the thickness of capsule as well as collagen density with inhibition of transforming growth factor (TGF)-ß-induced fibrosis [40].

In addition to the formation of CC, patients undergoing augmentation mammaplasty using prosthetic implants are also vulnerable to other complications, such as infection, hematoma, seroma, rupture, malposition, and rippling deformity [41, 42]. In the current study, our clinical series of the patients exhibited one case (0.4%) of seroma, three cases (1.3%) of hematoma, and one case (0.4%) of infection.

Our results cannot be generalized not only because we followed up our clinical series of the patients for relatively short periods of time but also because we conducted the current study at three local clinics only. The possibility of selection bias could not therefore be completely ruled out.

Table 4 Cumulative survival depending on the type of the BellaGel®

Type of breast implant	*N*	*n*	Censored values
Round smooth type	1	0	1 (100.0%)
Round textured type	18	1	17 (94.4%)
Round nanotextured type	118	1	117 (99.2%)
Anatomical textured type	102	3	99 (97.1%)

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

Conclusions

In conclusion, our results indicate that the BellaGel® is such a safe breast implant that surgeons might consider using it for augmentation mammaplasty. The current study provides the latest update on the first breast implant from the Asian manufacturer and describes its safety outcomes in Asian patients, which may differ from results obtained from Western countries. Further prospective, large-scale, multi-center studies with a long-term follow-up period are warranted to establish our results.

Compliance with ethical standards

Funding The current study was sponsored by the HansBiomed Co. Ltd.

Conflict of interest Dr. Chul Hwan Seul is a non-executive medical director of the HansBiomed Co., Ltd. But Drs. Moon Seop Choi and Jae Hoon Chang declare that they have no conflict of interest.

Ethical approval The current study was conducted in compliance with the relevant ethics guidelines; all procedures performed in it were in accordance with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

Informed consent Written informed consent was waived due to the retrospective nature of the current study.

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