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Clinical Experience with the Fifth-Generation of a Breast Implant with a Smooth, Fine Surface from a Korean Manufacturer in Asian Women

Dong Yeon Hwang[1], Sang Wha Kim[2], Joon Yong Jung[3], Robert Kim[4]*

[1]NANA Plastic Surgery, Seoul, Korea
[2]Department of Plastic and Reconstructive Surgery, Seoul National University Hospital, College of Medicine, Seoul National University, Seoul, Korea
[3]Department of Radiology, Seoul St. Mary's Hospital, College of Medicine, The Catholic University of Korea, Seoul, Korea
[4]Department of Medical and Pharmaceutical Affairs, Doctor CONSULT, Seoul, Korea
Email: *mcgcompany@naver.com

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Abstract

Background: In this study, we describe our clinical experience with the fifth-generation of a breast implant with a smooth, fine surface from a Korean manufacturer (BellaGel® SmoothFine; HansBiomed Co. Ltd., Seoul, Korea) in Asian women. **Methods:** We analyzed 223 women (mean age = 35.28 ± 9.45 years and mean follow-up period = 12.03 ± 2.48 months), comprising 118 bilateral cases and 109 unilateral ones, who received breast augmentation using the BellaGel® SmoothFine at our hospital between June 4, 2018 and February 28, 2019. For safety assessment, we analyzed frequencies of postoperative complications and overall survival of the BellaGel® SmoothFine. **Results:** Postoperatively, complications (12 cases, 5.38%) include asymmetry (3 cases, 1.35%), hematoma (2 cases, 0.90%), hypertrophic scars (2 cases, 0.90%), wound disruption (2 cases, 0.90%), rippling (1 case, 0.45%), capsular contracture (1 case, 0.45%), stretch deformities with skin excess (1 case, 0.45%). In addition, time-to-events were calculated as 10.94 ± 0.64 months (95% CI 9.69 - 12.19) and the survival rate reached 0.290 ± 0.168 (95% CI 0.094 - 0.901) at 12 months postoperatively. **Conclusions:** Here, we describe our clinical experience with the BellaGel® SmoothFine. Our results are of significance in that this is the first report about the fifth-generation of a breast implant with a smooth, fine surface from a Korean manufacturer for Asian women.

Keywords

Clinical Study, Retrospective Studies, Surgical Procedures, Operative, Postoperative Period, Follow-Up Studies

1. Introduction

In the US in 2018, breast augmentation using 313,735 implants was performed. Of these, 29,236 and 19,149 were removed from patients following aesthetic and reconstructive surgeries, respectively [1]. Nevertheless, such patients are vulnerable to postoperative complications, including breast implant-associated anaplastic large cell lymphoma (BIA-ALCL). It is an extremely rare, fatal condition with a causal relationship with a textured device. In addition, it is characterized by formation of scar tissue, known as a tissue capsule, around a device; it occurs at approximately 7 - 10 years postoperatively on average [2] [3] [4]. In 2018, de Boer *et al.* reported that there was an age-dependent increase in its risk in women receiving a breast implant; it was estimated at 1/35,000, 1/12,000 and 1/7000 in patients aged 50, 70 and 75, respectively [5]. Nevertheless, a lack of safety studies in the US remains problematic; two representative breast implant manufacturers received a warning letter from the Food and Drug Administration (FDA) in March of 2019 because they failed to conduct long-term follow-up studies required for the regulatory approval [6]. Therefore, safety studies evaluating breast augmentation using an implant in Korea are also warranted [7].

The BellaGel® SmoothFine (HansBiomed Co. Ltd., Seoul, Korea) was the fifth-generation of a breast implant with a smooth, fine surface from a Korean manufacturer. Its manufacturing process entails an analysis of physical features of Korean women [8].

The BellaGel® implants, including the BellaGel® SmoothFine, were exported to 30 countries worldwide since they were first developed in 2005 [9]. It is noteworthy that their efficacy and safety have been described through evidence-based studies [8] [9] [10] [11] [12].

Here, we describe our clinical experience with the BellaGel® SmoothFine in Asian women.

2. Patients and Methods

2.1. Study Design

We evaluated a total of 223 women (446 breasts) who received breast augmentation using the BellaGel® SmoothFine and were followed up for more than one year at our hospital between June 4, 2018 and February 28, 2019. We adhered to the relevant ethics guidelines and the Declaration of Helsinki. The current study was approved by the Internal Institutional Review Board (IRB) of the Korea National Institute of Bioethics Policy (IRB approval # 2020-03-634-168).

2.2. Study Material

The BellaGel® SmoothFine is manufactured through a process where the mandrel surface is treated with sandblast and its fine structure is transferred to the surface of shell. The mobility of cell and tissue varies depending on the surface topography. This is associated with variability in the occurrence of complications of breast augmentation using an implant [13].

It is equipped with a softness *as well as* a refined, smooth surface with a roughness of 5.96 mm, which is a different feature from traditional smooth surface, according to the International Organization for Standardization (ISO) 14,607 Annex H Test for surface characteristics (**Figure 1** and **Figure 2**) [14].

Figure 1. The BellaGel® SmoothFine based on the international organization for standardization classification. The BellaGel® SmoothFine is equipped with a refined, smooth surface with a roughness of 5.96 mm, which is a different feature from traditional smooth surface.

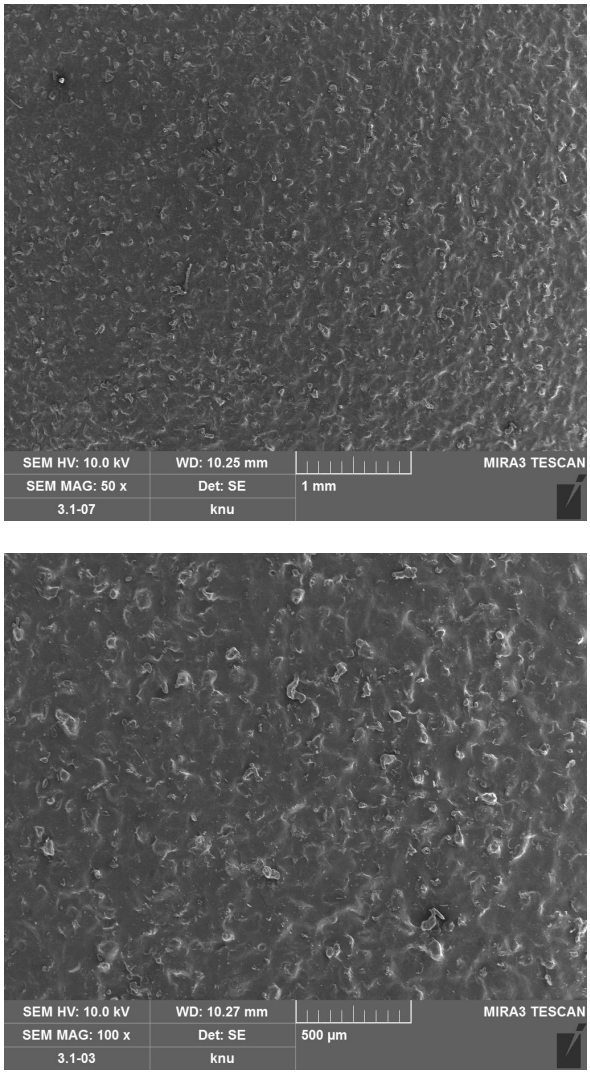


Figure 2. Surface characteristics of the BellaGel® SmoothFine. The surface of the BellaGel® SmoothFine was coated with platinum for 60 seconds and then examined using a scanning electron microscope (MIRA3 LM; TESCAN, Kohoutovice, Czech) at magnifications of (a) ×50 and (b) ×200.

It is covered with five layers of shell, within which there is a barrier layer that efficiently prevents the leakage of a gel due to a rupture (Figure 3). In addition, it is equipped with a round shape, a high degree of viscoelasticity and excellent gel properties; it is advantageous in creating a natural breast silhouette (Figure 4).

A previous study reported that the BellaGel® SmoothFine showed a relatively lower incidence of complications [10].

2.3. Treatment Protocol

Evidence-based treatment protocol for breast augmentation using the BellaGel® SmootFine has been previously described in detail [8] [11]. Our treatment protocol is schematically illustrated in Figure 5.

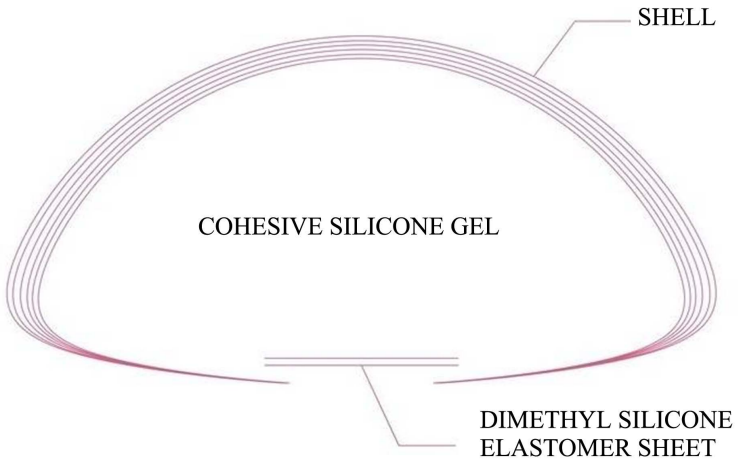


Figure 3. The structure of the BellaGel® SmoothFine. The BellaGel SmoothFine® is covered with a five layers of shell, within which there is a barrier layer that efficiently prevents the leakage of a gel due to a rupture.

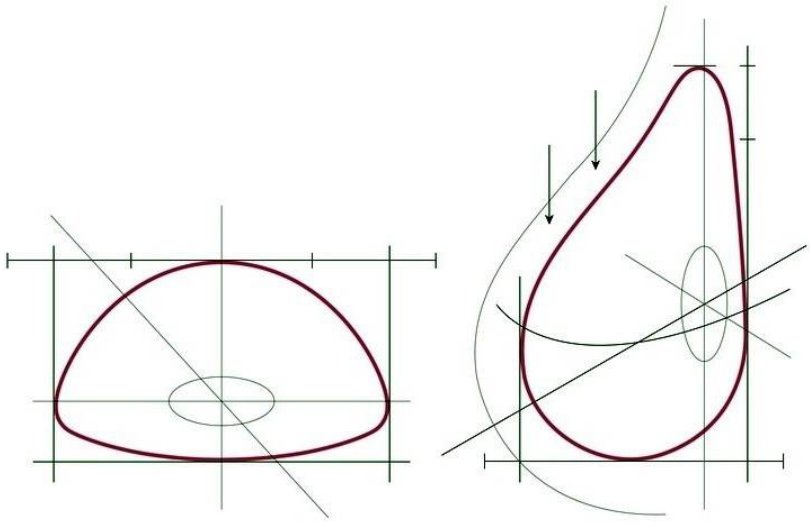


Figure 4. The advantages of the BellaGel® SmoothFine. The BellaGel® SmoothFine has a round surface, a high degree of viscoelasticity and excellent gel properties; it is advantageous in creating a natural breast silhouette.

Figure 5. A multi-disciplinary approach to an implant-based augmentation mammaplasty using the BellaGel® SmoothFine. A multi-disciplinary approach to an implant-based augmentation mammaplasty using the BellaGel® SmoothFine was developed for the purposes of maximizing its safety outcomes.

Postoperatively, the patients were regularly followed up at a 1-week interval for the first three weeks, a 3-month interval for the next one year and thereafter. In addition, they were also examined on magnetic resonance imaging (MRI) studies at 3 years after surgery and at a 2-year interval thereafter, as recommended by the FDA [8] [11].

2.4. Criteria for Assessing the Patients' Postoperative Course and Analyzing Their Data

The patients' demographic and clinical characteristics were analyzed using their medical records, as previously described [8] [11]. In more detail, we assessed the safety based on frequencies of postoperative complications and survival of the BellaGel® SmoothFine, as previously described [8] [11].

After presenting the data as mean ± standard deviation or standard error or the number with percentage, we performed a data analysis with the SPSS ver. 23 (IBM Corp., Armonk, NY). Statistical significance was defined as $P < 0.05$. The Kaplan-Meier survival was estimated.

3. Results

3.1. Demographic and Clinical Characteristics of the Patients

In the current study, 223 women (446 breasts) were evaluated; they comprise 118 bilateral cases and 109 unilateral ones. As presented in **Table 1**, their mean

Table 1. Baseline characteristics of the patients (n = 223; 446 breasts).

Variables	Values	
Age (years)	35.28 ± 9.45 (23 - 47)	
Follow-up period (months)	12.03 ± 2.48 (12 - 16)	
Sex		
Men	0 (0.00%)	
Women	223 (100.00%)	
Height (cm)	162.92 ± 20.78 (158 - 173)	
Weight (kg)	51.37 ± 5.84 (46 - 68)	
Operation time (hours)	1.09 ± 0.38 (0.75 - 2.00)	
Round of surgery		
Primary augmentation mammaplasty	214 (95.96%)	
Revision augmentation mammaplasty	9 (4.04%)	
Profile and volume of breast implant (cc)		
Right side (n = 223)	H275	2 (0.90%)
	H300	4 (1.79%)
	H325	16 (7.17%)
	H350	10 (4.48%)
	H375	3 (1.35%)
	H400	3 (1.35%)
	M150	1 (0.45%)
	M225	4 (1.79%)
	M250	12 (5.38%)
	M275	43 (19.28%)
	M300	48 (21.52%)
	M325	58 (26.01%)
	M350	13 (5.83%)
Left side (n = 105)*	H275	2 (0.90%)
	H300	4 (1.79%)
	H325	10 (4.48%)
	H350	11 (4.93%)
	H375	3 (1.35%)
	M225	2 (0.90%)
	M250	9 (4.04%)
	M275	14 (6.28%)
	M300	26 (11.66%)
	M325	18 (8.07%)
	M350	5 (2.24%)
	M375	1 (0.45%)

Continued

Type of surgical methods	
Dual-plane augmentation mastopexy	6 (2.69%)
Dual-plane technique	211 (94.62%)
Neo-subpectoral technique	3 (1.35%)
Neo-subpectotal technique with ADM	1 (0.45%)
Subglandular technique	2 (0.89%)
Type of surgical incision	
Axillary incision	148 (66.37%)
IMF incision	75 (33.63%)

Abbreviations: ADM, acellular dermal matrix; IMF, inframammary fold. Values are mean ± standard deviation with the range in parenthesis or the number of the patients with percentage, where appropriate. *The remaining 118 patients received other brands of a breast implant on the left side for correction of the asymmetry.

age was 35.28 ± 9.45 years (range, 23 - 47) and mean follow-up period was 12.03 ± 2.48 months.

Illustrative cases are shown in **Figure 6** and **Figure 7**.

3.2. Safety Outcomes

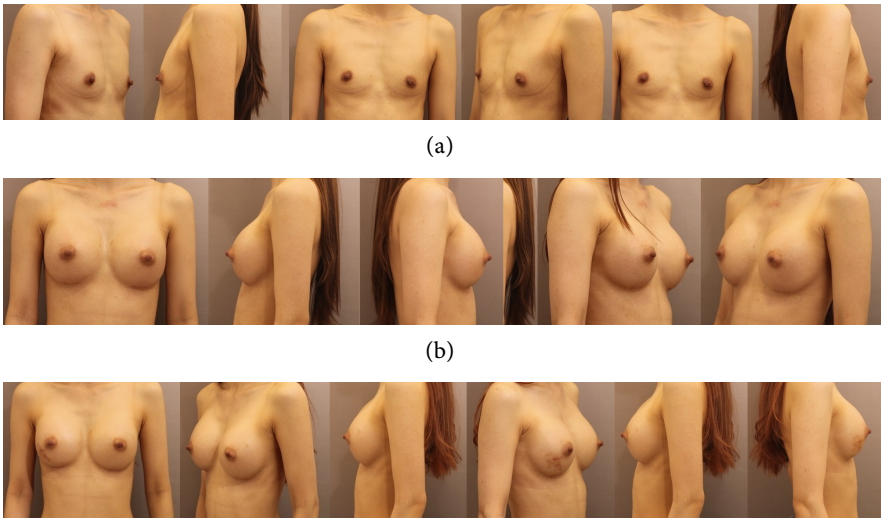
Postoperatively, complications (12 cases, 5.38%) include asymmetry (3 cases, 1.35%), hematoma (2 cases, 0.90%), hypertrophic scars (2 cases, 0.90%), wound disruption (2 cases, 0.90%), rippling (1 case, 0.45%), capsular contracture (1 case, 0.45%), stretch deformities with skin excess (1 case, 0.45%) (**Table 2**).

In addition, time-to-events (TTEs) were calculated as 10.94 ± 0.64 months (95% CI 9.69 - 12.19) (**Table 3** and **Figure 8**). Furthermore, the survival rate reached 0.290 ± 0.168 (95% CI 0.094 - 0.901) at 12 months postoperatively (**Table 4** and **Figure 9**).

4. Discussion

To date, anatomical implants have become available to maximally imitate a natural shape of the breast by providing a more fullness in the lower pole. But their availability has been greatly decreased. Currently, a balance between the width and volume of a breast implant therefore serves as a determinant of aesthetic outcomes of a silicone gel-filled breast implant [15] [16].

Korean women with a breast width of approximately 11 - 12 cm require both a full B- or C-cup size and a natural feel [10] [17]. The BellaGel® SmoothFine is a silicone gel-filled breast implant whose manufacturing process encompasses the consideration of physical characteristics of Korean women, such as the size of chest and skin features, and their westernized life style and then compensates the disadvantages of other brands of the breast implant [8].

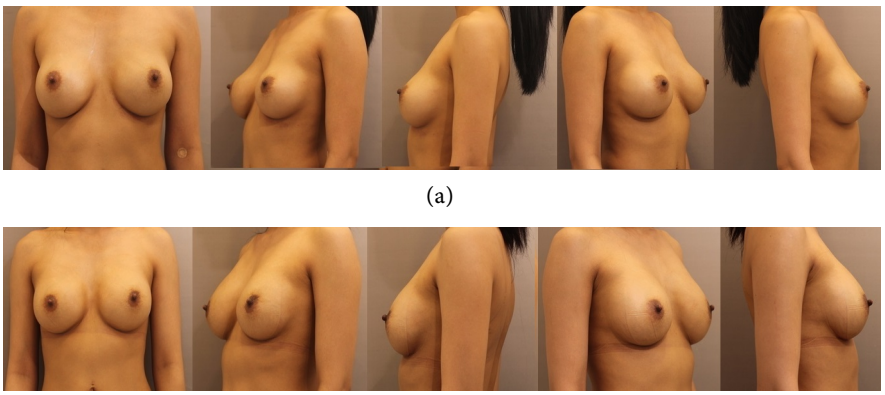


(a)

(b)

(c)

Figure 6. Primary augmentation mammaplasty using the BellaGel® SmoothFine. (a) Preoperatively, a 25-year-old woman visited us with a chief complaint of small breast size. The patient received the BellaGel® SmoothFine at a volume of 350 and 325 cc for the right and left sides, respectively, *via* an inframammary fold incision using a modified dual-plane type 1 technique. (b) At 1 month postoperatively, the patient achieved an improvement in the size of the breast. (c) At 3 months postoperatively, the patient was satisfied with the external appearance of the breast.



(a)

(b)

Figure 7. Reoperation using the BellaGel® SmoothFine. (a) Preoperatively, a 34-year-old woman had a 7-year-history of receiving an 300-cc implant of unknown brand *via* an axillary incision. Due to dissatisfaction with the size and shape of the breast, the patient underwent inferolateral capsulorrhaphy with superomedial "mirror image" capsulotomy. The pre-existing implant was replaced with the BellaGel® SmoothFine at a volume of 350 cc for both sides. (b) At 1 month postoperatively, the patient was satisfied with the external appearance of the breast.

Conventional types of anatomical breast implants equipped with a thick shell and a highly-viscous silicone gel are vulnerable to decreased tensile strength of the shell despite its thickness; they do not adjust to the stress due to continuous exercise. This may lead to fracture due to the increased fatigue [18] [19]. It can therefore be inferred that women receiving anatomical implants are at increased

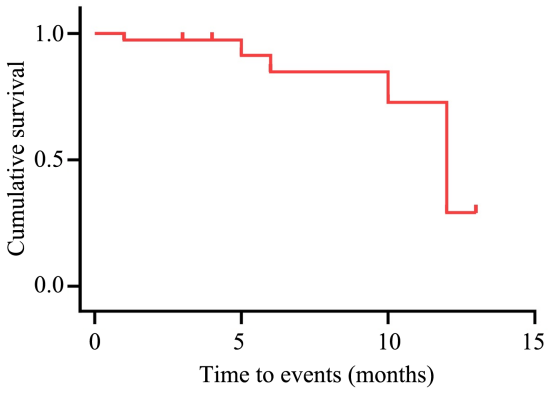


Figure 8. Kaplan-Meier cumulative survival. In our series, time-to-events were calculated as 10.94 ± 0.64 months (95% CI 9.69 - 12.19).

Table 2. Postoperative complications.

Variables	Values
Asymmetry	3 (1.35%)
Hematoma	2 (0.90%)
Hypertrophic scars	2 (0.90%)
Wound disruption	2 (0.90%)
Rippling	1 (0.45%)
Capsular contracture	1 (0.45%)
Stretch deformities with skin excess	1 (0.45%)

Values are the number of the patients with percentage.

Table 3. Overall complication-free survival.

N	n	Censored value	Time-to-events (months)	95% CI
223	12	211 (94.62%)	10.94 ± 0.64	9.69 - 12.19

Note: N, total number of cases; n, incidences of postoperative complications; CI, confidence intervals. Values are mean ± standard error or the number of the patients with percentage, where appropriate.

Table 4. Cumulative complication-free survival.

FU (months)	N	n	Survival rate	95% CI
1	223	6	0.973 ± 0.011	0.952 - 0.995
5	16	1	0.912 ± 0.060	0.802 - 1.000
6	14	1	0.847 ± 0.084	0.698 - 1.000
10	7	1	0.726 ± 0.133	0.507 - 1.000
12	5	3	0.290 ± 0.168	0.094 - 0.901

Note: FU, follow-up; N, total number of cases; n, incidences of postoperative complications; CI, confidence intervals. Values are mean ± standard error.

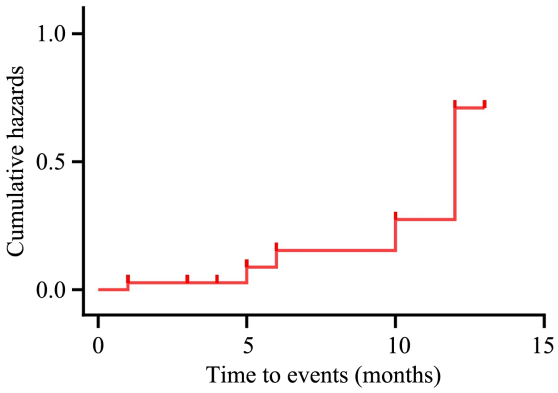


Figure 9. Kaplan-Meier cumulative hazards. The survival rate reached 0.290 ± 0.168 (95% CI 0.094 - 0.901) at 12 months postoperatively.

risks of derangement in the integrity of a silicone gel and the resulting shape deformity [20] [21]. In addition, a breast implant with a thick shell and a soft silicone gel reveals its disadvantages such as an insufficient level of tensile strength [22] [23]. Therefore, such breast implants cannot retain their integrity in a standing posture after a considerable length of time postoperatively. This may cause serious problems in women with ptotic or elastic breast with thin overlying skin. Tensile force and strength of the shell as well as the softness and viscosity of a silicone gel are therefore key determinants of biomechanical properties of a breast implant [23].

To summarize, we found a total of 12 cases (5.38%) of postoperative complications. We also showed that TTEs were calculated as 10.94 ± 0.64 months (95% CI 9.69 - 12.19) and the survival rate reached 0.290 ± 0.168 (95% CI 0.094 - 0.901) at 12 months postoperatively.

Our results cannot be generally interpreted due to the following reasons:

1) We failed to clarify a relationship between physico-chemical properties and surface characteristics of the BellaGel® SmoothFine and its short-term safety.

2) We failed to identify associations of rheological and biomechanical properties of the BellaGel® SmoothFine with westernized life style of Korean women who are much interested in pilates, Yoga or fitness.

3) We could not completely rule out the possibility of a study design bias because this is a manufacturer-sponsored, retrospective study [11].

Nevertheless, we recommend that surgeons use the BellaGel® SmoothFine in performing an implant-based augmentation mammaplasty for Korean women. The cost of surgery using the BellaGel® SmoothFine is estimated at approximately USD 4577.33; it is lower as compared with the Motiva Ergonomix™ (USD 7323.73) [24] [25].

5. Conclusion

Here, we describe our clinical experience with breast augmentation using the BellaGel® SmoothFine. Our results are of significance in that this is the first report about the fifth-generation of a breast implant with a smooth, fine surface

from a Korean manufacturer in Asian women.

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Conflicts of Interest

Robert Kim was a paid consultant for key opinion leaders of the HansBiomed Co., Ltd. (Seoul, Korea) between November of 2018 and February of 2020; the other authors had no conflicts of interest in relation to the current work.

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