JOURNAL OF PLASTIC SURGERY AND HAND SURGERY
2021, VOL. 55, NO. 6, 345–353
https://doi.org/10.1080/2000656X.2021.1888744

ARTICLE

Short-term treatment outcomes and safety of two representative brands of the fifth-generation silicone gel-filled breast implants in Korea

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ABSTRACT

It is allegedly reported that the BellaGel® SmoothFine (HansBiomed Co. Ltd., Seoul, Korea) and Motiva Ergonomix™ (Establishment Labs Holdings Inc., Alajuela, Costa Rica) are representative brands of a microtextured breast implant in Korea. We compared short-term safety outcomes between them. We evaluated the patients who received breast augmentation using the BellaGel® SmoothFine ($n = 264$) or the Motiva Ergonomix™ ($n = 76$) for aesthetic purposes and those with available medical records. They were followed up during a mean period of 122.11 ± 95.37 (4–477) and 126.80 ± 116.29 (13–534) days in the corresponding order. Early seroma occurred at an incidence of 1.89 and 5.26% following breast augmentation using the BellaGel® SmoothFine and the Motiva Ergonomix™, respectively. This difference reached statistical significance ($p < 0.05$). Of note, CC occurred at an incidence of 2.27 and 0.00% in the corresponding order. Cumulative incidences of postoperative complications depending on the type of breast implants showed no significant difference; statistical significance was analyzed using the log-rank test ($\chi^2 = 1.71$, $df = 1$, $p = 0.19$). Cumulative survival of the breast implant is shown in Table 3; the Motiva Ergonomix™ showed a longer survival as compared with the BellaGel® SmoothFine (130.13 ± 13.70 vs. 120.45 ± 5.76 days). In conclusion, we describe short-term treatment outcomes and safety of an implant-based breast augmentation using two representative brands of the fifth-generation silicone gel-filled breast implants in Korean women.

ARTICLE HISTORY
Received 22 June 2020
Revised 9 January 2021
Accepted 6 February 2021

KEYWORDS
Breast; surgical procedures; operative; esthetics; reconstructive surgical procedures; breast implants; ultrasonography

Introduction

The emergence of the fifth-generation breast implant has been justified based on demerits of conventional anatomical devices [1,2]. As compared with round breast implants, anatomical devices are advantageous in providing a more natural appearance. But their disadvantages limit their applicability to an implant-based breast augmentation [3,4]. First, patients receiving an anatomical breast implant are vulnerable to rotation and displacement, for which they should undergo revision surgery or reoperation [1,3,5,6]. Second, with the introduction of a macrotextured surface, there have been improvements in the adherence of a device to the tissue. But patients are at increased risks of developing double capsule or late seroma [7–10]. Third, the firmness and rigidity of an implant make it difficult to adjust to the natural movement of human breast [11,12]. It has been therefore imperative that a novel type of the fifth-generation silicone gel-filled breast implant be developed.

It is allegedly reported that the BellaGel® SmoothFine (formerly BellaGel® Micro) (HansBiomed Co. Ltd., Seoul, Korea) and Motiva Ergonomix™ (Establishment Labs Holdings Inc., Alajuela, Costa Rica) are two representative brands of the fifth-generation silicone gel-filled breast implants that are commercially available in Korea (Figure 1). The Motiva Ergonomix™ was commercially released in the Korean market in 17 June 2016, which opened the era of a microtextured device in Korea. This was followed by commercial release of the BellaGel® SmoothFine in 19 July 2017 [13]. Interestingly, there have been two manufacturer-sponsored studies comparing 1-year incidences of complications and complication-free survival as well as surface characterization [14,15]. Still, however, there are no manufacturer-sponsored studies to perform a direct comparison between the two devices.

Given the above background, we conducted this non-manufacturer-sponsored study to compare the short-term treatment outcomes and safety between the BellaGel® SmoothFine and the Motiva Ergonomix™ in Korean women.

Patients and methods

Study patients and setting

In the current study, we evaluated a total of 343 patients ($n = 343$, 686 breasts) who received breast augmentation using the BellaGel® SmoothFine or the Motiva Ergonomix™ for aesthetic or reconstructive purposes at our hospitals between 26 September 2017 and 30 April 2019 and those with available medical records. But we excluded the patients with missing data. The current study was conducted in compliance with the relevant ethics guidelines. Written informed consent was waived due to its retrospective nature.

Treatment protocol

Surgery was performed by the senior author (JH Kim), which is based on an evidence-based approach to an implant-based breast augmentation, as previously described [16].

Peri-areolar, inframammary fold (IMF) and axillary incisions were made under general anesthesia and intravenous sedation for the purposes of preventing visible scarring. Selection of

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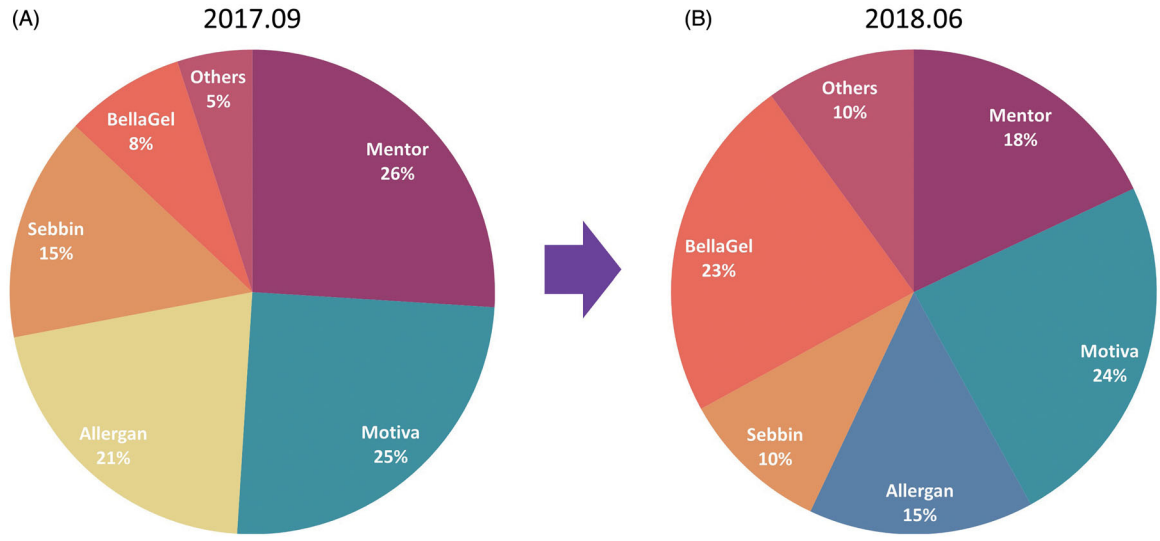

Figure 1. Market share of the BellaGel® in Korea. The market share of the BellaGel® was increased from 8% in (A) November of 2017 to 23% in (B) June of 2018.

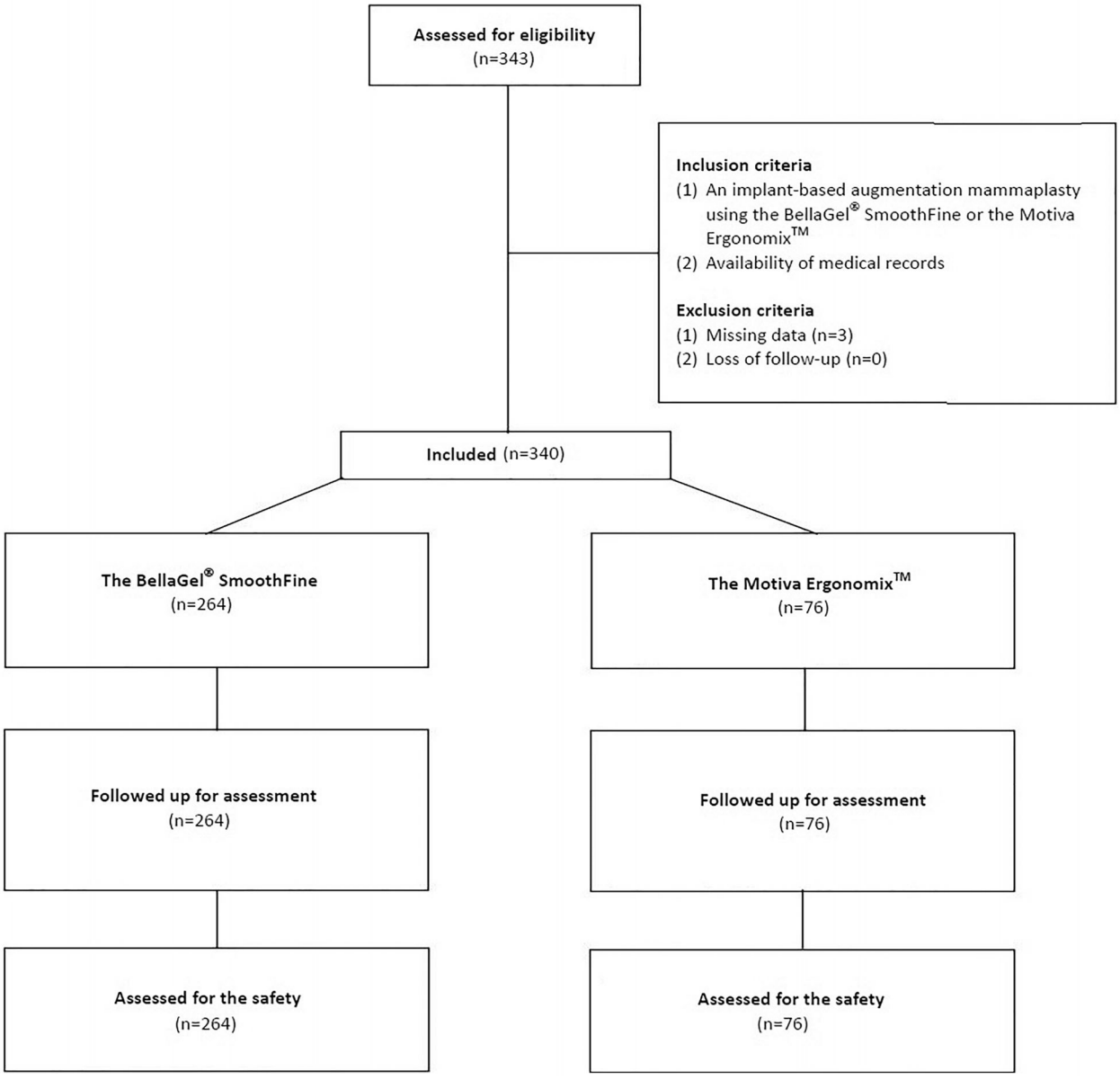

Figure 2. Disposition of the study patients. Initially, a total of 343 patients ($n = 343$; 686 breasts) were evaluated through a retrospective review of their medical records. Of these, 340 patients ($n = 340$) met eligibility criteria and were included in the current study. Finally, 264 and 76 patients were assigned to the BellaGel® SmoothFine and the Motiva Ergonomix™.

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 IMF, the size of breast implant and the scope of dissection. After the dissection, each breast was irrigated using a 100 cc 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 gentamycin 1 ample and then inserted in a pocket either under the pectoralis muscle (a submuscular placement) or in the retromammary space above the pectoralis major muscle (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, non-steroidal anti-inflammatory drugs and antacid three 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 three 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 [16].

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 [16].

Patient evaluation and criteria

All the patients received breast augmentation for aesthetic or reconstructive purposes. Their baseline characteristics include age, sex, height, weight, purposes of surgery (aesthetic and reconstructive breast augmentation), volume (<250, 250–300, 300–350, 350–400 and ≥400 cc) and profile (ultra-high, high, medium and low profiles) of breast implants and the type of incision (axillary, inframammary fold and peri-areolar incision).

For safety assessment, the patients were evaluated for complications. Potential postoperative complications include capsular contracture (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 (BIA-ALCL) [16].

To estimate time to occurrence of complications of an implant-based breast augmentation, we analyzed complication-free survival that is defined as survivorship of the patients exhibiting complications. It was expressed as percentage of the patients who survived without undergoing revision to or removal of a breast implant [16].

Statistical analysis of the patient data

Data was expressed as the number of patients with percentage, mean ± SD (SD: standard deviation) or mean ± SE (standard error). The cumulative complication-free survival was estimated, for which 95% confidence intervals (CIs) were provided. Moreover, a difference in it between the two breast implants was also

Table 1. Baseline characteristics of the patients ($n = 340$).

Variables	Values: BellaGel® SmoothFine ($n = 264$)	Values: Motiva Ergonomix™ ($n = 76$)
Age (years old)	32.44 ± 7.19	35.84 ± 8.60
Sex		
Men	0 (0.0%)	0 (0.0%)
Women	264 (100.0%)	76 (100.0%)
Height (cm)	162.67 ± 4.99	163.67 ± 5.12
Weight (kg)	51.08 ± 5.52	52.45 ± 5.72
Follow-up period (days)	122.11 ± 95.37 (4–477)	126.80 ± 116.29 (13–534)
Purpose of surgery		
Aesthetic augmentation mammoplasty	263 (99.62%)	75 (98.68%)
Reconstructive augmentation mammoplasty	1 (0.38%)	1 (1.32%)
Type of incision		
Right side		
Axillary incision	257 (97.35%)	65 (85.53%)
IMF incision	4 (1.52%)	7 (10.94%)
Peri-areolar incision	1 (0.37%)	4 (3.53%)
Others	2 (0.76%)	0 (0.00%)
Left side		
Axillary incision	257 (97.35%)	65 (85.53%)
IMF incision	3 (0.76%)	7 (10.94%)
Peri-areolar incision	1 (0.37%)	4 (3.53%)
Others	4 (1.52%)	0 (0.00%)
Volume of breast implant (cc)		
Right side		
<250	4 (1.52%)	3 (3.94%)
250–300	34 (12.88%)	15 (19.74%)
300–350	145 (54.92%)	26 (34.21%)
350–400	66 (25.00%)	17 (22.37%)
≥400	15 (5.68%)	15 (19.74%)
Left side		
<250	5 (1.89%)	3 (3.95%)
250–300	60 (22.73%)	16 (21.05%)
300–350	147 (55.68%)	29 (38.16%)
350–400	42 (15.91%)	19 (25.00%)
≥400	9 (3.40%)	9 (11.84%)
Non-applicable	1 (0.39%)	0 (0.00%)
Profile of breast implant		
Right side		
Ultra-high	0 (0.00%)	0 (0.00%)
High	257 (97.35%)	67 (88.16%)
Medium	7 (2.65%)	9 (11.84%)
Non-applicable	0 (0.00%)	0 (0.00%)
Left side		
Ultra-high	0 (0.00%)	0 (0.00%)
High	246 (93.18%)	63 (82.90%)
Medium	17 (6.44%)	13 (17.10%)
Non-applicable	1 (0.38%)	0 (0.00%)

Abbreviations: IMF: inframammary fold.
Values are mean ± standard deviation or the number of cases with percentage, where appropriate.

Table 2. Distribution of postoperative complications by the breast implant.

Variables	Values: BellaGel® SmoothFine ($n = 264$)	Values: Motiva Ergonomix™ ($n = 76$)
Total number of cases	35 (13.26%)	11 (14.47%)
Early hematoma	5 (1.89%)	1 (1.32%)
Early seroma	5 (1.89%)	4 (5.26%)
Delayed seroma	1 (0.38%)	0 (0.00%)
CC	6 (2.27%)	0 (0.00%)
TC	9 (3.41%)	1 (1.32%)
Shape deformation	7 (2.65%)	4 (5.26%)
Infection	4 (1.52%)	0 (0.00%)
Redness	0 (0.00%)	0 (0.00%)
Sliding	6 (2.27%)	1 (1.32%)
Others	1 (0.38%)	1 (1.32%)

Abbreviations: CC: capsular contracture; TC: thickened capsule.
Values are the number of cases with percentage.

Table 3. Cumulative incidences of postoperative complications and time-to-events by the breast implant.

			Censored values			95% CI	
Breast implants	*N*	*n*	*N*	%	TTE (days)	LL	UL
Total	340	10	330	97.1%	122.61 ± 5.41	111.97	133.26
BellaGel® SmoothFine	264	9	255	96.6%	120.45 ± 5.76	109.11	131.78
Motiva Ergonomix™	76	1	75	98.7%	130.13 ± 13.70	102.84	157.43

Note: *N*: total number of cases; *n*: incidence of postoperative complications.
Abbreviations: TTE: time to events; CI: confidence interval; LL: lower limit; UL: upper limit.
Values are mean ± standard error, the number of cases or percentage, where appropriate.

analyzed using the log-rank test. Furthermore, the corresponding Kaplan–Meier survival and hazard were plotted. Statistical analysis was done using the SPSS ver. 18.0 for windows (SPSS Inc., Chicago, IL, USA). A *p*-value of <0.05 was considered statistically significant.

Results

Baseline characteristics of the patients

A total of 340 patients ($n = 340$, 680 breasts) met eligibility criteria and were evaluated in the current study, 264 and 76 of whom received breast augmentation using the BellaGel® SmoothFine and the Motiva Ergonomix™, respectively. All the patients were women with a mean age of 33.20 ± 7.65 years old and they were followed up during a mean period of 123.71 ± 100.26 days (range, 4–534). The patients receiving the BellaGel® SmoothFine comprise 263 bilateral cases and one unilateral case. But all the patients receiving the Motiva Ergonomix™ were bilateral cases. Disposition of the patients is shown in Figure 2. Baseline characteristics of the patients are represented in Table 1.

Difference in the safety profile between the two breast implants

Early seroma occurred at an incidence of 1.89 and 5.26% following breast augmentation using the BellaGel® SmoothFine and the Motiva Ergonomix™, respectively. This difference reached statistical significance ($p < 0.05$). Of note, CC occurred at an incidence of 2.27 and 0.00% in the corresponding order (Table 2).

Cumulative incidences of postoperative complications depending on the type of breast implants showed no significant difference; statistical significance was analyzed using the log-rank test ($\chi^2 = 1.71$, $df = 1$, $p = 0.19$).

Cumulative survival of the breast implant is shown in Table 3; the Motiva Ergonomix™ showed a longer survival as compared with the BellaGel® SmoothFine (130.13 ± 13.70 vs. 120.45 ± 5.76 days). The Kaplan–Meier survival and hazard are plotted as shown in Figures 3 and 4.

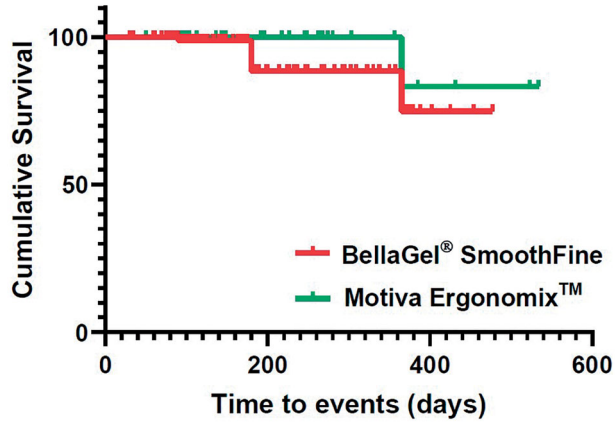

Figure 3. Kaplan-Meier survival by the breast implant. The Motiva Ergonomix™ showed a longer survival as compared with the BellaGel® SmoothFine (130.13 ± 13.70 vs. 120.45 ± 5.76 days).

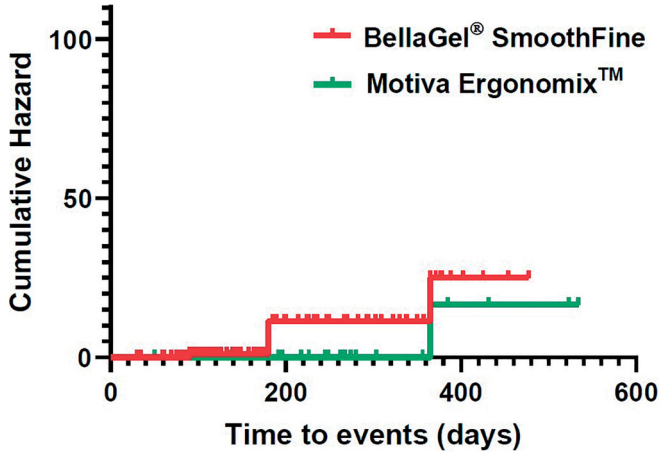

Figure 4. Kaplan-Meier hazards by the breast implant. There were no significant differences in cumulative incidences of postoperative complications between the BellaGel® SmoothFine and the Motiva Ergonomix™ on the log-rank test ($\chi^2 = 1.71$, $df = 1$, $p = 0.19$).

Discussion

With technological advancements in nanotechnology, new biomaterials with individual properties regulating cellular functions have emerged [17]. Nanotechnology has also been applied to the improvement of the surface of a commercially-available breast implant for the purposes of increasing its roughness [8]. This is followed by many published *in vitro* and clinical studies showing positive and satisfactory outcomes of texturization [18,19]. Further, the microtexturization and nanotexturization have also been applied to clinical practice. The Motiva Ergonomix™ VelvetSurface® is equipped with 1800–2200 contact points of 40,000–100,000 nm depth, being much narrower as compared with a macrotextured device. Moreover, the Motiva Ergonomix™ SilkSurface® is equipped with 49,000 contact points per 16,000 nm, being much smaller and shallower depressions as compared with a macrotextured or microtextured device [8].

The Motiva Ergonomix™ and the BellaGel® SmoothFine share the similar characteristics, both of which are equipped with a softness as well as a refined, smooth surface with a roughness of 3.18 and 5.96 μm, respectively, according to the International Organization for Standardization (ISO) 14607 Annex H Test for surface characteristics [14,20].

In our series, there were six cases (6.27%) of CC following the placement of the BellaGel® SmoothFine, although no CC occurred

Table 4. Cumulative survival by the breast implant.

				Survival rate		95% CI	
Breast implants	FU (days)	N	n	M	SE	LL	UL
BellaGel® SmoothFine	4	264	0	1			
	6	263	0	1			
	7	261	0	1			
	10	260	0	1			
	13	259	0	1			
	15	257	0	1			
	16	256	0	1			
	18	255	0	1			
	21	254	0	1			
	23	252	0	1			
	24	251	0	1			
	25	250	0	1			
	27	249	0	1			
	28	245	0	1			
	29	240	0	1			
	30	236	0	1			
	31	230	0	1			
	32	228	0	1			
	33	226	0	1			
	34	224	0	1			
	36	222	0	1			
	37	221	0	1			
	40	218	0	1			
	41	217	0	1			
	42	216	0	1			
	44	214	0	1			
	47	213	0	1			
	48	212	0	1			
	49	211	0	1			
	50	210	0	1			
	56	209	0	1			
	59	208	0	1			
	61	207	0	1			
	63	206	0	1			
	67	205	0	1			
	69	204	0	1			
	75	203	0	1			
	76	202	0	1			
	78	201	0	1			
	79	199	0	1			
	80	198	0	1			
	83	197	0	1			
	84	196	0	1			
	85	195	0	1			
	86	194	0	1			
	87	192	0	1			
	88	188	0	1			
	89	183	0	1			
	90	176	2	0.9886	0.008	0.9553	0.9971
	91	167	0	0.9886	0.008	0.9553	0.9971
	92	149	0	0.9886	0.008	0.9553	0.9971
	93	142	0	0.9886	0.008	0.9553	0.9971
	94	135	0	0.9886	0.008	0.9553	0.9971
	95	129	0	0.9886	0.008	0.9553	0.9971
	96	128	0	0.9886	0.008	0.9553	0.9971
	97	122	0	0.9886	0.008	0.9553	0.9971
	98	115	0	0.9886	0.008	0.9553	0.9971
	99	108	0	0.9886	0.008	0.9553	0.9971
	100	105	0	0.9886	0.008	0.9553	0.9971
	101	101	0	0.9886	0.008	0.9553	0.9971
	103	98	0	0.9886	0.008	0.9553	0.9971
	105	94	0	0.9886	0.008	0.9553	0.9971
	106	91	0	0.9886	0.008	0.9553	0.9971
	107	88	0	0.9886	0.008	0.9553	0.9971
	108	86	0	0.9886	0.008	0.9553	0.9971
	110	85	0	0.9886	0.008	0.9553	0.9971
	115	84	0	0.9886	0.008	0.9553	0.9971
	116	81	0	0.9886	0.008	0.9553	0.9971
	118	79	0	0.9886	0.008	0.9553	0.9971
	119	78	0	0.9886	0.008	0.9553	0.9971
	120	72	0	0.9886	0.008	0.9553	0.9971
	121	71	0	0.9886	0.008	0.9553	0.9971

(*continued*)

Table 4. Continued.

				Survival rate		95% CI	
Breast implants	FU (days)	N	n	M	SE	LL	UL
	122	69	0	0.9886	0.008	0.9553	0.9971
	126	68	0	0.9886	0.008	0.9553	0.9971
	132	67	0	0.9886	0.008	0.9553	0.9971
	133	66	0	0.9886	0.008	0.9553	0.9971
	139	63	0	0.9886	0.008	0.9553	0.9971
	140	62	0	0.9886	0.008	0.9553	0.9971
	141	61	0	0.9886	0.008	0.9553	0.9971
	143	59	0	0.9886	0.008	0.9553	0.9971
	144	58	0	0.9886	0.008	0.9553	0.9971
	146	57	0	0.9886	0.008	0.9553	0.9971
	147	56	0	0.9886	0.008	0.9553	0.9971
	148	55	0	0.9886	0.008	0.9553	0.9971
	157	54	0	0.9886	0.008	0.9553	0.9971
	163	53	0	0.9886	0.008	0.9553	0.9971
	167	52	0	0.9886	0.008	0.9553	0.9971
	168	51	0	0.9886	0.008	0.9553	0.9971
	171	50	0	0.9886	0.008	0.9553	0.9971
	175	49	0	0.9886	0.008	0.9553	0.9971
	180	48	5	0.8857	0.0442	0.7621	0.9472
	185	43	0	0.8857	0.0442	0.7621	0.9472
	186	42	0	0.8857	0.0442	0.7621	0.9472
	189	41	0	0.8857	0.0442	0.7621	0.9472
	198	38	0	0.8857	0.0442	0.7621	0.9472
	200	37	0	0.8857	0.0442	0.7621	0.9472
	214	36	0	0.8857	0.0442	0.7621	0.9472
	224	35	0	0.8857	0.0442	0.7621	0.9472
	226	34	0	0.8857	0.0442	0.7621	0.9472
	232	33	0	0.8857	0.0442	0.7621	0.9472
	233	32	0	0.8857	0.0442	0.7621	0.9472
	236	31	0	0.8857	0.0442	0.7621	0.9472
	246	30	0	0.8857	0.0442	0.7621	0.9472
	249	29	0	0.8857	0.0442	0.7621	0.9472
	266	28	0	0.8857	0.0442	0.7621	0.9472
	270	27	0	0.8857	0.0442	0.7621	0.9472
	282	26	0	0.8857	0.0442	0.7621	0.9472
	292	25	0	0.8857	0.0442	0.7621	0.9472
	294	24	0	0.8857	0.0442	0.7621	0.9472
	295	23	0	0.8857	0.0442	0.7621	0.9472
	302	22	0	0.8857	0.0442	0.7621	0.9472
	309	21	0	0.8857	0.0442	0.7621	0.9472
	322	20	0	0.8857	0.0442	0.7621	0.9472
	323	19	0	0.8857	0.0442	0.7621	0.9472
	330	18	0	0.8857	0.0442	0.7621	0.9472
	337	17	0	0.8857	0.0442	0.7621	0.9472
	338	16	0	0.8857	0.0442	0.7621	0.9472
	350	15	0	0.8857	0.0442	0.7621	0.9472
	357	14	0	0.8857	0.0442	0.7621	0.9472
	365	13	2	0.7494	0.0962	0.5016	0.8864
	371	10	0	0.7494	0.0962	0.5016	0.8864
	376	9	0	0.7494	0.0962	0.5016	0.8864
	378	8	0	0.7494	0.0962	0.5016	0.8864
	379	6	0	0.7494	0.0962	0.5016	0.8864
	388	5	0	0.7494	0.0962	0.5016	0.8864
	402	4	0	0.7494	0.0962	0.5016	0.8864
	425	3	0	0.7494	0.0962	0.5016	0.8864
	454	2	0	0.7494	0.0962	0.5016	0.8864
	477	1	0	0.7494	0.0962	0.5016	0.8864
Motiva Ergonomix™	13	76	0	1			
	16	75	0	1			
	22	74	0	1			
	24	73	0	1			
	25	72	0	1			
	26	71	0	1			
	27	69	0	1			
	28	67	0	1			
	29	66	0	1			
	33	64	0	1			
	35	63	0	1			
	36	61	0	1			
	38	59	0	1			
	40	57	0	1			
	41	56	0	1			

(*continued*)

Table 4. Continued.

Breast implants	FU (days)	N	n	Survival rate		95% CI	
				M	SE	LL	UL
	50	55	0	1			
	64	54	0	1			
	66	53	0	1			
	80	52	0	1			
	87	51	0	1			
	88	49	0	1			
	90	47	0	1			
	91	45	0	1			
	92	38	0	1			
	93	33	0	1			
	95	30	0	1			
	96	29	0	1			
	98	27	0	1			
	103	25	0	1			
	112	24	0	1			
	136	22	0	1			
	143	21	0	1			
	148	20	0	1			
	191	19	0	1			
	195	18	0	1			
	196	17	0	1			
	217	16	0	1			
	226	15	0	1			
	245	14	0	1			
	248	13	0	1			
	262	12	0	1			
	267	11	0	1			
	274	10	0	1			
	280	9	0	1			
	303	8	0	1			
	356	7	0	1			
	365	6	1	0.8333	0.1521	0.2731	0.9747
	385	4	0	0.8333	0.1521	0.2731	0.9747
	431	3	0	0.8333	0.1521	0.2731	0.9747
	523	2	0	0.8333	0.1521	0.2731	0.9747
	534	1	0	0.8333	0.1521	0.2731	0.9747

Note: FU: time points of follow-up; N: number of risks; n: incidence of postoperative complications; M: mean; SE: standard error; CI: confidence interval; LL: lower limit; UL: upper limit.

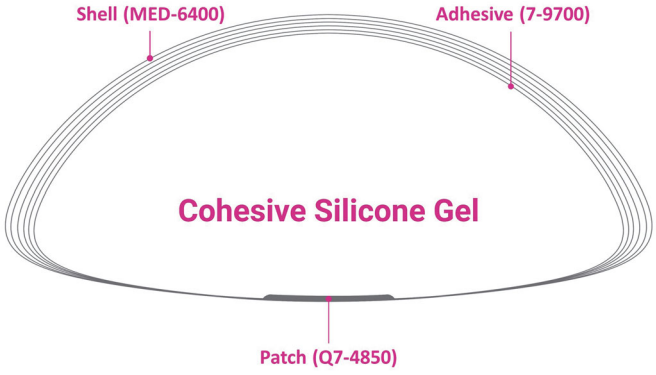

Figure 5. Use of unapproved materials for manufacturing of the BellaGel®. A total of five constituents were not approved for use for manufacturing of the BellaGel® implants; these include 7-9700 (soft skin adhesive), Q7- 4850 (liquid silicone rubber), MED2-6300 (silicone gel), MED-6400 (silicone dispersion) and MED2-4213 (skin adhesive).

in association with the use of the Motiva Ergonomix™. Lack of CC in patients receiving the Motiva Ergonomix™ can also be seen in previous published studies [6,21,22].

Early seroma occurred at a significantly higher incidence following the placement of the Motiva Ergonomix™ as compared with that of the BellaGel® SmoothFine (5.26 vs. 1.89%; $p < 0.05$). According to Sforza et al., the formation of early seroma had a significant correlation with a high body mass index, large implant size, submammary pocket and smoking [23]. These authors advocated the involvement of the frictional force in the pathogenesis of seroma, including delayed one in particular. But a higher incidence of early seroma following the use of the Motiva Ergonomix™ deserves further experimental and clinical studies.

In our series, delayed seroma occurred at an incidence of 0.38% and 0.00% following the placement of the BellaGel® SmoothFine and the Motiva Ergonomix™, respectively. This difference reached no statistical significance, based on which it can be inferred that there is no significant difference in the possibility of causing the BIA-ALCL following an implant-based breast augmentation between the BellaGel® SmoothFine and the Motiva Ergonomix™. But this deserves further long-term follow-up studies.

Finally, despite a lack of statistical significance, the Motiva Ergonomix™ showed a longer survival as compared with the BellaGel® SmoothFine (130.13 ± 13.70 vs. 120.45 ± 5.76 days).

In conclusion, we describe short-term treatment outcomes and safety of an implant-based breast augmentation using two representative brands of the fifth-generation silicone gel-filled breast implants in Korean women. From our empirical experience, the BellaGel® SmoothFine is not preferable to the Motiva Ergonomix™; the former shows a higher rate of CC, as shown in the current study, and its profile is lower as compared with the latter.

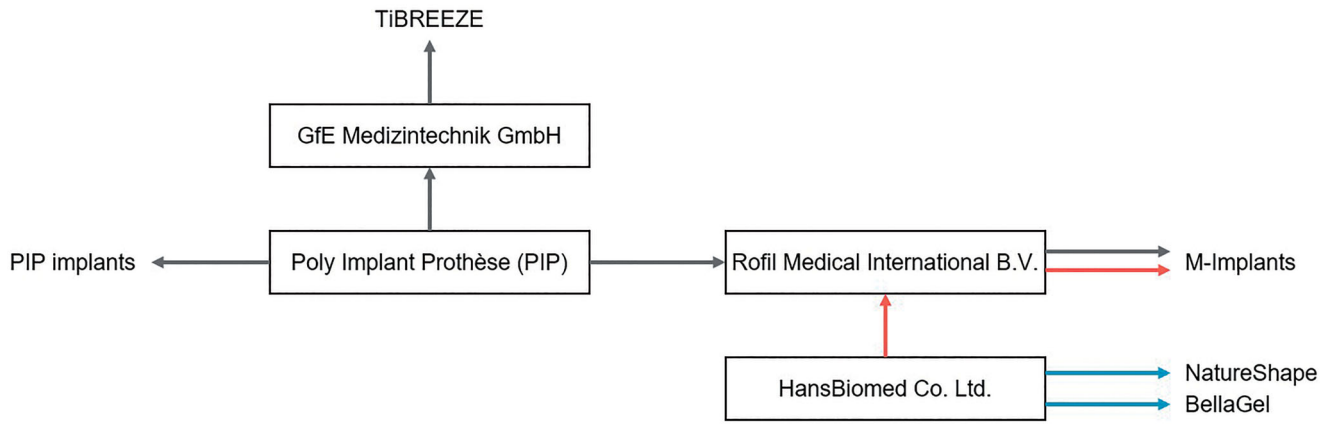

Figure 6. Involvement of the HansBiomed Co. Ltd. in the Poly Implant Prothèse fraud.

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 local clinics located in Korea only. The possibility of selection bias could not therefore be completely ruled out. Fourth, there was a great difference in the number of the patients between the two devices. Presumably, this might be because there is a great difference in the cost of surgery between the BellaGel® SmoothFine and the Motiva Ergonomix™; it amounts to approximately USD 4,577.33 and approximately USD 7,323.73, respectively [24,25]. A relatively higher cost of surgery using the Motiva Ergonomix™ is closely associated with high-price strategy of the Motiva Korea [26]. Therefore, the possibility of comparison bias could not also be completely ruled out. Fifth, we failed to control factors affecting the occurrence of CC, such as incision choice; a periareolar incision is closely associated with a higher rate of CC and the risk of CC is significantly higher with an axillary one as compared with a periareolar or IMF ones [27–29]. Further prospective, multi-center, randomized, controlled studies with long periods of follow-up are therefore warranted to establish our results. Moreover, differences in the quality of life of the patients between the two devices also deserve further studies using the BREAST-Q [30]. Sixth, we failed to analyze constituents of the BellaGel® SmoothFine that may affect its safety. Kim JH recently reported that the HansBiomed Co. Ltd., the manufacturer of the BellaGel® SmoothFine, illegally used unapproved substances, such as 7-9700 and Q7-4850, for manufacturing of it. The HansBiomed Co. Ltd. illegally used 7-9700 to overcome the detachment between the shell and silicone gel since 2009. It was originally designed for use for a wearable monitoring device or wound dressing. Although its biocompatibility was tested for cytotoxicity, skin irritation and skin sensitization, there were no tests for mutagenicity/genotoxicity, pyrogenicity and system toxicity because it was not designed for *in vivo* use in humans. It can therefore be inferred that the safety of a long-term *in vivo* presence of 7-9700 cannot be established. Moreover, illegal use of Q7-4850 in the manufacturing process for the BellaGel® implants should also be considered serious in that its *in vivo* use for >30 days was prohibited (Figure 5) [19]. It is therefore impossible to completely rule out the possibility that patients receiving the BellaGel® SmoothFine containing hazardous substances. The Korean Ministry of Food and Drug Safety initiated the mandatory recall of the BellaGel® breast implants, including the BellaGel® SmoothFine in November 13, 2020 [13].

Finally, Kim JH provided evidence suggesting that the HansBiomed Co. Ltd. previously participated in the Poly Implant Prothèse fraud in Europe (Figure 6). It would therefore be mandatory to consider the manufacturer's previous involvement in a medical device fraud in assessing the long-term safety outcomes of the BellaGel® SmoothFine [13].

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

Disclosure statement

No potential conflict of interest was reported by the author(s).

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