

The Manufacturer's Deliberate Modification of the Shell Structure of the BellaGel® SmoothFine in Violation of the Regulatory Requirement

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Abstract

The BellaGel® SmoothFine (HansBiomed Co. Ltd., Seoul, Korea) is the only fifth-generation of a silicone gel-filled breast implant from a Korean manufacturer. The BellaGel® SmoothFine with a 5-layered shell structure was approved for clinical use, but the manufacturer deliberately modified the shell structure in violation of the regulatory requirement of the Korean Ministry of Food and Drug Safety. This was hidden by both plastic surgeons and the manufacturer. With the use of high-resolution ultrasound, however, we confirmed that both 4-layered and 5-layered devices were circulated in the Korean market. Further investigations are warranted to disclose a relationship between plastic surgeons and the manufacturer.

Keywords: Equipment and supplies; Breast implants; Fraud; Whistleblowing; Ultrasonography

Introduction

Since the introduction of the first-generation of a breast implant in the 1960s, manufacturers of a device and plastic surgeons have experienced great advancements in the technology and surgical skills, which has focused on the modification of gel cohesivity, the thickness and surface topography and gel fill [1-4].

With continued improvements in the design of a silicone gel-filled breast implant, round and anatomical devices have emerged in the market. The latter has been developed to overcome demerits of the former. That is, anatomical devices are advantageous in providing a more natural appearance as compared with round ones. But their disadvantages limit their applicability to an implant-based breast augmentation. First, patients receiving an anatomical device are vulnerable to rotation and displacement. Therefore, they need to undergo revision surgery or reoperation. Second, the adherence of a device to the tissue has been improved due to the introduction of a macrotextured surface. However, patients are at increased risks of developing double capsule or late seroma. Third, the firmness and rigidity of an implant make it difficult to adjust to the natural movement of human breast. It has been therefore imperative that a novel type of a silicone gel-filled breast implant be developed [5]. Thus, a silicone gel-filled breast implant with a microtextured shell surface has been developed to reduce a risk of both capsular contracture and Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) [6]. It is allegedly known that the Motiva Ergonomix™ (Establishment Labs Holdings Inc., Alajuela, Costa Rica)

and the BellaGel® SmoothFine (HansBiomed Co. Ltd., Seoul, Korea) are two representative brands of a microtextured device. The Motiva Ergonomix™ was commercially released in the Korean market in June 20, 2016, which opened the era of a microtextured device in Korea. This was followed by commercial release of the BellaGel® SmoothFine in July 19, 2017 [7,8].

In our previous article, we first reported the BellaGel® breast implant scandal, thus describing a possible association of a Korean manufacturer of a silicone gel-filled breast implant with the Poly Implant Prothèse fraud [7]. But the story continues; the manufacturer deliberately modified the shell structure of the only microtextured breast implant from a Korean manufacturer, the BellaGel® SmoothFine, in violation of the regulatory requirement.

The Manufacturer's Description of the BellaGel® Smoothfine

The BellaGel® is the only silicone gel-filled breast implant from a Korean manufacturer; the BellaGel® implants are manufactured using Polydimethylsiloxane (PDMS), and they are available with diverse shape (round, anatomical and conical), surface texture (smooth, textured and microtextured), volume, height and diameter [9,10]. Of these, the BellaGel® SmoothFine (formerly BellaGel® Micro) 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 an implant-based augmentation mammoplasty [11]. It is equipped with softness as well as a refined, smooth surface with a roughness of 5.96 μm , which is a different feature from traditional smooth surface, according to the International Organization for Standardization (ISO) 14607 Annex H Test for surface characteristics (Figure 1) [12]. Its silicone gel is covered with five layers of shell. Within the shell, there is a barrier layer that efficiently prevents the leakage of a gel due to a rupture (Figure 2) [13-15]. Moreover, 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 3) [14].

Deliberate Modification of the Shell Structure of the BellaGel® SmoothFine in Violation of the Regulatory Requirement Enforced by the Korean Ministry of Food and Drug Safety (KMFDS)

As reported by a Korean news media in December 2, 2020, a whistleblower revealed that the manufacturer deliberately modified the structure of the shell layer of the BellaGel® SmoothFine in violation of the regulatory requirement enforced by the KMFDS. The KMFDS approved the BellaGel® SmoothFine with a 5-layered shell structure, as supported by a manufacturer-sponsored study [14,16].

The news media reported that the manufacturer first discussed reducing the shell thickness of the device in late 2016, when its tensile strength was superior to its global competitors, such as the Allergan Inc. (Irvine, CA) or the Mentor Worldwide LLC. (Santa Barbara, CA) (25 N versus 15 N, respectively). In the early stage of development, a greater shell thickness of the BellaGel® SmoothFine compared to

its competitors has remained problematic although it showed no significant difference from that described in a product brochure (0.73 mm) (approximately 0.8 mm versus 0.6-0.7 mm, respectively). Therefore, considering the possibility that a thick shell might impair a soft feel, the manufacturer discussed preparing a test sample with a thin shell while maintaining the standard strength mandated by the KMFDS [16].

In January of 2017, the manufacturer implemented a plan; it prepared samples of the device with a 4-layered shell and then sent it to plastic surgeons to obtain their opinion on how soft it feels. According to the manufacturer's internal meeting report, plastic surgeons had a favorable opinion about a soft feel of the sample with a 4-layered shell. Then, sales team of the HansBiomed Co. Ltd. opined that it would be necessary to identify a method for commercializing the BellaGel® SmoothFine with a 4-layered shell structure. Thereafter, the shell structure of the BellaGel® SmoothFine was deliberately modified into a 4-layered one during the manufacturing process. As a result, the shell thickness was decreased to 0.37-0.39 mm; it was smaller as compared with previous models of the BellaGel® implants by 35-48%. Indeed, both sonographic and microscopic findings confirmed a 4-layered shell structure whose thickness was measured as 0.5 ± 0.1 mm [16] (Figures 4 and 5).

According to the ISO 14607, a breast implant should be equipped with a shell with a tensile strength of >11.12 N. In June of 2017, according to the manufacturer's own test, the tensile strength of the BellaGel® SmoothFine with a 4-layered shell structure was decreased by 35-48% as compared with previous models of the BellaGel® implants (26-31 N) and then measured as approximately 16 N. But this met the



Figure 1: The surface roughness of the BellaGel® SmoothFine based on the International Organization for Standardization classification [12].

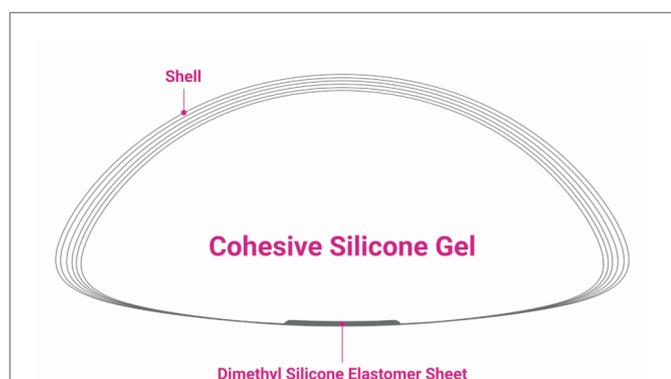


Figure 2: The structure of the BellaGel® SmoothFine [13-15].

According to the manufacturer, the BellaGel® SmoothFine is covered with five layers of shell. In addition, a barrier layer within the shell efficiently prevents the leakage of a gel due to a rupture.

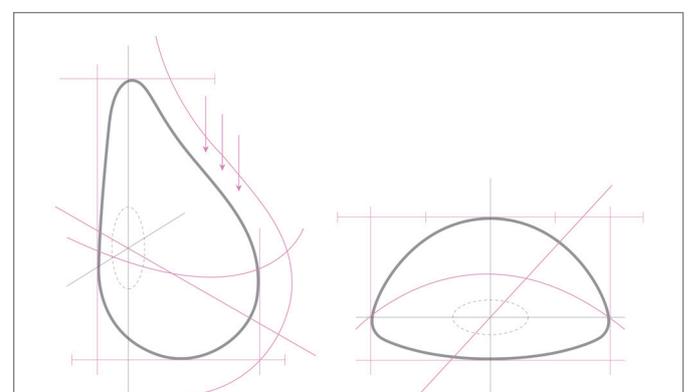


Figure 3: The advantages of the BellaGel® SmoothFine [14].

According to the manufacturer, 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.

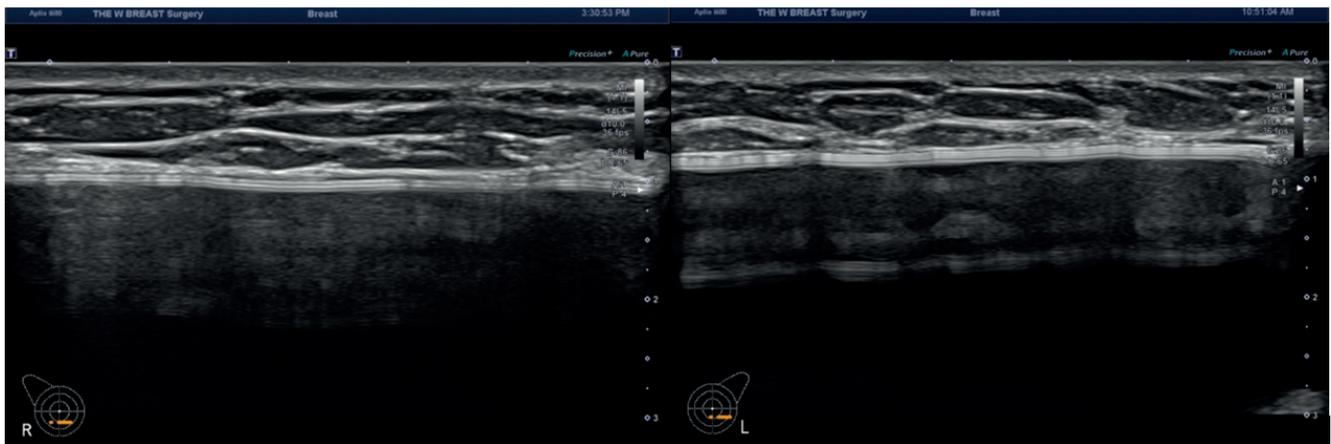


Figure 4: Sonographic images showing two different shell structures of the BellaGel® SmoothFine.

(A) In July 28, 2018, a 31-year-old woman (height: 158 cm, weight: 50 kg) received dual-plane type I aesthetic augmentation mammoplasty using the BellaGel® SmoothFine (profile: high, volume: 325 cc for both sides) via a trans-axillary incision in the subpectoral pocket at our hospital. In December 28, 2020, the patient was evaluated using breast ultrasound (Aplio i600 [Canon Medical System, Otawara, Tochigi, Japan] system with a 7-18-MHz linear transducer). A sonographic image shows a 4-layered shell structure of the device, which is characterized by three hyperechoic lines. (B) In December of 2019, a 32-year-old woman (height: 159 cm, weight: 47 kg) received aesthetic augmentation mammoplasty using the BellaGel® SmoothFine in the subpectoral pocket at other hospital. In December 3, 2020, the patient visited us and was evaluated using breast ultrasound (Aplio i600 [Canon Medical System, Otawara, Tochigi, Japan] system with a 7-18-MHz linear transducer). A sonographic image shows a 5-layered shell structure of the device, which is characterized by four hyperechoic lines.

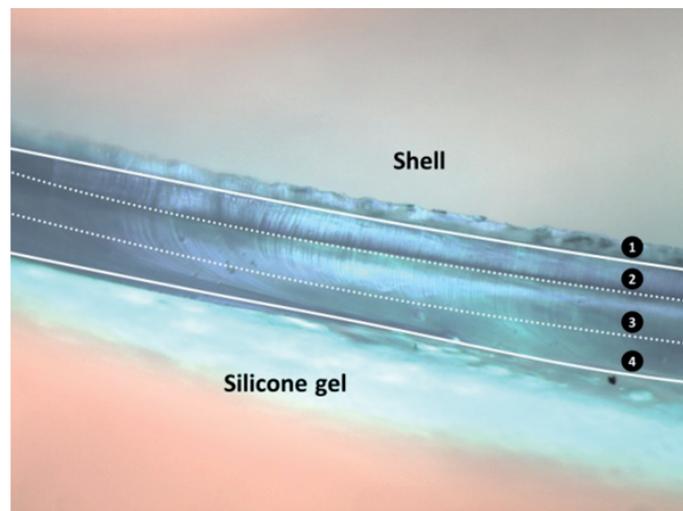


Figure 5: A microscopic image showing a 4-layered shell structure of the BellaGel® SmoothFine.

A longitudinal section of the BellaGel® SmoothFine was prepared and then examined using a stereomicroscope (Olympus SZ61; Olympus Optical Co., Tokyo, Japan). The resulting photograph was taken using the TUCSEN H series digital camera (Fuzhou Tucsen Photonics Co., Fuzhou, Fujian, China) (1,000 ×).

ISO 14607 standards. But some samples of the device showed problems that their tensile strength was measured to be relatively lower (9-10 N). The manufacturer performed its own test by cutting the device into several forms to prepare samples for the measurement of the tensile strength. It was required, however, that all the samples should meet the ISO 14607 standards. However, the manufacturer did not resolve the issue that some samples failed to meet the ISO 14607 standards before commercially releasing the BellaGel® SmoothFine. Thus, the

manufacturer decided to first release the BellaGel® SmoothFine with a 4-layered shell structure and to later do that with a 5-layered one, as evidenced by sonographic findings showing two different shell layers of the BellaGel® SmoothFine. According to the manufacturer's internal report dated January of 2018, the upper and lateral parts of the BellaGel® SmoothFine were vulnerable to damages. It can therefore be inferred that patients receiving a 4-layered device might be at increased risks of rupture due to its decreased thickness [16].

Discussion

Both patients' safety and health-related quality of life are essential factors forming the highest priority in an implant-based augmentation mammoplasty [17]. Therefore, plastic surgeons, patients and manufacturers of a breast implant should be aware of detrimental effects of the device [18]. With the onset of three Korean cases of BIA-ALCL occurring in August 16 and December 24, 2019 and October 5, 2020, they have faced a crisis that may lead to a withdrawal of a breast implant [19-21]. Indeed, the clinical use of textured breast implants was prohibited by the KMFDS [19]. Therefore, plastic surgeons and manufacturers of a breast implant were forced to respond to a question regarding a possible causal relationship between a microtextured surface of the device and a risk of BIA-ALCL in Korea, "Who's next?" Actually, the HansBiomed Co. Ltd. has sponsored studies to display superiority or non-inferiority of the BellaGel® SmoothFine to its competitors [22-24]. This explains why the manufacturer tried to improve a soft feel by deliberately modifying the shell structure of the BellaGel® SmoothFine.

The manufacturer's deliberate modification of the shell structure should be considered serious in that both plastic surgeons and the manufacturer were involved in an attempt to increase a soft feel in violation of the regulatory requirement enforced by the KMFDS [16]. Two authors of two manufacturer-sponsored studies were reported to participate in the development of the BellaGel® SmoothFine [9,23,25,26]. According to Choi MS, et al. [26], a consecutive series of 239 patients (478 breasts) received an implant-based augmentation mammoplasty using the BellaGel® implants at three hospitals in Korea between December 1, 2015 and January 31, 2018. These authors noted that 49.4% (118/239) of total patients received the BellaGel® SmoothFine. Interestingly, they described the BellaGel® SmoothFine as a nanotextured device rather than a microtextured one; one of its competitors, the Motiva Ergonomix™, has been commonly described as a breast implant with a nanotextured surface [6,27,28]. Kang SH, et al. [23] reported that 53.1% (530/621) of total cases received the BellaGel® SmoothFine between November 27, 2015 and April 30, 2018. Therefore, plastic surgeons who conducted two manufacturer-sponsored studies neglected clinicians' duty by failing to disclose the exact number of the patients receiving the 4-layered device between July 19, 2017 and April 30, 2018 [9,23]. Moreover, according to the news interview with the director of research and development of the HansBiomed Co. Ltd., there was also no mention about a 4-layered shell structure of the BellaGel® SmoothFine [29].

The use of high-resolution ultrasound is an efficient modality in investigating a medical device fraud as well as protecting the safety of patients receiving an implant-based augmentation mammoplasty in cases of deliberate modification of the shell structure of the BellaGel® SmoothFine. To date, ultrasound has played a role in examining the integrity and rotation of a breast implant [3,30-37]. Moreover, its role has been expanded to manage patients who are suspected of having breast implant-associated anaplastic large cell lymphoma as well as to evaluate a breast mass [38,39]. For the appropriate management of a patient receiving an implant-based augmentation mammoplasty, surgeons should perform an ultrasound-guided assessment of two matters: (1) Information about a breast implant (e.g., location, constituents, shell, shape and manufacturer) and (2) Possible occurrence of implant-related complications (e.g., folding with or without detachment, periprosthetic fluid collection, thickened capsule, rupture, capsular mass, malrotation of an anatomical device, upside-down rotation and foreign body reactions).

Conclusions

We, at the Korean Society of Breast Implant Research, reviewed literatures about the manufacturer's deliberate modification of the shell structure of the BellaGel® SmoothFine in violation of the regulatory requirement enforced by the KMFDS. We propose that patients receiving the BellaGel® SmoothFine be meticulously evaluated for possible detrimental effects due to an unknown number of those with the 4-layered device. Moreover, further investigations are warranted to disclose a relationship between plastic surgeons and the manufacturer.

Disclosure

The author has nothing to declare in relation to this manuscript.

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