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Letter to the Editor: Discussion of the Article "The Emerging Crisis of Stakeholders in Implant-based Augmentation Mammaplasty in Korea"

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In the present article, the authors have tried to discuss the emerging crisis of stakeholders in implant-based breast augmentation mammoplasty and to propose a multidisciplinary approach for the early detection of complications.[1] However, the only finding with any basis of evidence in the "Methods" and the "Results" sections is that the awareness of patients regarding the information of breast implants was slightly different from the sonographic findings (78.95% vs. 85.09%). Based on this result, the authors have elaborated on their alarming claim, namely the alleged "conflict of interest" that plastic surgeons in Korea supposedly have ("something-for-something relationship" to quote the manuscript) and the "inappropriate approval process" of breast implants by the Korean Ministry of Food and Drug Safety (KMFDS). In addition, they have suggested a "multidisciplinary approach" to breast implant-associated anaplastic large cell lymphoma (BIA-ALCL). We fail to understand the relationship between the results of the study and the statements in the discussion. In other words, it is highly unclear what the authors intended to show in view of their study results. This manuscript causes confusion in the minds of readers by arriving at a completely different conclusion with no basis.

Conflict of interest is a critical issue and every physician should be aware of it. Surgeons should select the type of breast implant based on patients' pre-operative physical characteristics, personal preference, and legal availability and the decision should not be biased by the surgeons' tangible or intangible profits. However, in this article, the authors have rushed to accuse the plastic surgeons who have used textured implants, implying personal benefits. Too put this softly, this is a very serious claim. Respectfully, we would like to give the authors a chance to contemplate whether they really think plastic surgeons have used textured implants due to a "something-for-something" relationship with the manufacturers. We also question the authors' opinion on the abundant prospective and retrospective articles that have extensively studied the advantages of textured implants.[2-12] Have the studies reported these results on behalf of the manufacturers or considering their benefits? Above all, how do the results of the present study (the sonographic findings of breast implants) lead to the preposterous opinion on the conflict of interest?

Because we do not represent the KMFDS, we will not provide a detailed explanation about their approval process. However, it is unclear how the results of the present study (the sonographic findings of breast implants) lead to this claim against the KMFDS.

The authors have also attempted to discuss their multidisciplinary algorithm for BIA-ALCL. However, we cannot find nothing new from it. As recommended by many nations that have years of experience in treating BIA-ALCL before us, BIA-ALCL should be approached with the involvement of professionals from multiple disciplines including oncologists, pathologists, surgical oncologists, radiation oncologists, and plastic surgeons, since the treatment strategy can vary depending on the stage and unlike other types of lymphoma, the mainstay of treatment for BIA-ALCL is surgical excision (en bloc capsulectomy), especially for early-stage patients.[13,14] However, in the present article, the aforementioned points are not discussed. We would like to know what the authors' multidisciplinary algorithm means.

In addition to the aforementioned inquiries, we would like to provide our readers with some refreshing facts. In collaboration with the KMFDS, the Korean Society of Plastic and Reconstructive Surgery has been sharing safety information about textured implants in a variety of forms. They have formulated an informed consent, which describes the potential benefits and risks of textured breast implants including the risk of BIA-ALCL. They have also set up a web portal, which has comprehensive information on BIA-ALCL open for anyone to see.[15] From this website, patients can obtain extensive information on BIA-ALCL including what BIA-ALCL is, its presentation in patients, follow-up guidelines, the current status of BIA-ALCL occurrence in Korea, lists of regional centers that patients with suspicious symptoms can visit, and even compensation information provided by the manufacturers. They have also established an early reporting system for patients with suspicious symptoms of BIA-ALCL.[16] In this system, plastic surgeons can report the clinical information of patients with suspected BIA-ALCL before and after the final diagnosis. All confirmed cases in South Korea (n = 2) have been reported and can be tracked within this system from the initial diagnosis to the postoperative follow-up.

Finally, we would like to point out that the indication for ultrasonography in the present study is very vague. The authors have stated that the majority of patients (82.46%) underwent ultrasonographic evaluation as a “routine check-up.” What does “routine check-up” mean? Is it for the early detection of breast cancer or that of BIA-ALCL? If it is for breast cancer, it is a completely different issue. If it is for BIA-ALCL, the benefit of screening ultrasonography for asymptomatic patients lacks clinical evidence. According to the current National Comprehensive Cancer Network guidelines, sonographic evaluation is recommended for patients with suspicious symptoms (effusion, enlargement, mass, and ulceration) on physical examination.[17] The most common presentation of BIA-ALCL is a large periprosthetic fluid collection (seroma), and to confirm the diagnosis, a minimum of 50 cc of seroma should be collected.[14] Patients with this amount of seroma usually experience a change in the size and the shape of their breasts. Hence, many prior clinical studies have recommended follow-up of asymptomatic patients without further evaluation. With “routine” sonographic evaluation, small collections of seroma can be detected in many asymptomatic patients. However, its clinical significance is questionable, as benign seroma is not rare after breast augmentation or reconstruction and the diagnosis of BIA-ALCL cannot be made with inadequate specimens.

In conclusion, the only tangible result of the present article is that the patients' awareness of the information of breast implants was slightly different from the sonographic findings.

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The assertions following the result are neither logical nor grounded. Routine sonography to evaluate breast implant status cannot be justified solely on the basis of these results. The completely unrelated claims involving conflict of interest and the approval process of medical devices are even more concerning.

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Letter to the Editor: The Emerging Crisis of Stakeholders in Implant-based Augmentation Mammaplasty in Korea

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Dear editor,

We're interested to read the article titled “The Emerging Crisis of Stakeholders in Implant-based Augmentation Mammaplasty in Korea” by Kim et al.[1] They emphasized the importance of breast ultrasound as a component of a multi-disciplinary, algorithm-based approach to an early detection of complications of an implant-based augmentation mammaplasty.

A silicone gel-filled breast implant was first approved by the US Food and Drug Administration (FDA) in November 2006.[2] But it was approved on condition that the corresponding manufacturers would have conduct six post-FDA approval trials, for which enrolled patients should be evaluated for integrity of a breast implant on magnetic resonance imaging (MRI) scans at a 3-year interval postoperatively and every two years thereafter.[3] In 2011, the FDA reported that there was a lack of MRI surveillance in association with the status of the post-FDA approval trials.[4] It remains a challenge, however, that an MRI is not a cost-effective, convenient imaging modality in postoperatively assessing a breast implant. Moreover, its disadvantages include possibility of false-negative results that may cause unnecessary surgery in asymptomatic cases.[5]

To overcome demerits of an MRI, the use of breast ultrasound (US) has been considered in the postoperative assessment of a breast implant.[3] Its advantages include non-invasiveness, cost-effectiveness and a high level of availability.[6]

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The authors have no potential conflicts of interest to disclose.

We strongly agree with Kim et al. in that stakeholders in implant-based augmentation mammaplasty face the crisis arising from the recent onset of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL). In this regard, it is imperative that a safe, rapid, cost-effective, user-friendly, accurate imaging modality be used as a screening, diagnostic regimen in patients receiving a silicone gel-filled breast implant. Therefore, the use of breast US is a recommendable surveillance strategy for them. Its usefulness in the context of BIA-ALCL has been well described in the literature.[7-11] Therefore, Kim JH et al.'s efforts and work should be appreciated and then treated as they deserve.

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Response

The Author's Response: The Emerging Crisis of Stakeholders in Implant-based Augmentation Mammaplasty in Korea

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The authors have no potential conflicts of interest to disclose.

We would like to thank the authors for their comments on our article which reported that there was a difference in the distribution of a textured implant between the patients' subject awareness and their objective findings on breast ultrasound. We also added that it would be mandatory to make a multidisciplinary, algorithm-based approach to an early detection of complications of an implant-based augmentation mammaplasty.[1]

We placed an emphasis on the fact that patients receiving an implant-based augmentation mammaplasty have been exposed to a textured implant, and they should be meticulously monitored through a patient-registry.[1] Plastic surgeons' favorable opinions towards a textured implant have also been described in the literature; Swanson[2] noted that many plastic surgeons in the US had a relationship with an industry and defended a textured implant at 2019 US Food and Drug Administration (FDA) hearing.

Some of co-authors of our article were involved in the first evidence-based study to assess the short-term safety of breast implants, including a textured one, from a Korean manufacturer. All of the authors of the corresponding article had no financial relationship with the manufacturer.[3] Moreover, we have also submitted other studies about other brands of a silicone gel-filled breast implant to medical journals and they are currently under review. Furthermore, we conducted a case-control study to assess the feasibility of a multidisciplinary, algorithm-based approach to an early detection of complications of an implant-based augmentation mammaplasty and are currently preparing it for submission to a peer-reviewed journal.

We admit that further studies are warranted to establish the usefulness of breast ultrasound as a component of the above-mentioned approach. But we have conducted studies to assess it; one of our efforts is to make an accurate diagnosis of capsular contracture based on the ultrasound-guided measurement of capsule thickness after an implant-based augmentation mammaplasty.

Finally, it would be greatly appreciated if readers of our article consider it a brief report showing patients have been exposed to a textured implant.

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