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. 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. 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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.
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.

REFERENCES

1. Kim JH, Paik NS, Nam SY, Cho Y, Park HK. The Emerging crisis of stakeholders in implant-based augmentation mammaplasty in Korea. J Korean Med Sci 2020;35(15):e103.
2. Unger JG, Carreras JM, Nagarkar P, Jeong HS, Carpenter W. Allergan style 410 implants for breast reconstruction: a prospective study in efficacy, safety, and symmetry. Plast Reconstr Surg 2016;138(3):548-55.
3. Panchapakesan V, Brown MH. Management of tuberous breast deformity with anatomic cohesive silicone gel breast implants. Aesthetic Plast Surg 2009;33(1):49-53.
4. Montemurro P, Cheema M, Heden P, Agko M, Quattrini Li A, Avedimento S. Do not fear an implant’s shape: a single surgeon’s experience of over 1200 round and shaped textured implants in primary breast augmentation. Aesthet Surg J 2018;38(3):254-61.
5. Montemurro P, Adams WP Jr, Mallucci P, De Vita R, Layt C, Calobrace MB, et al. Why do we need anatomical implants? The science and rationale for maintaining their availability and use in breast surgery. Aesthetic Plast Surg 2020;44(2):253-63.
6. McGuire P, Reisman NR, Murphy DK. Risk factor analysis for capsular contracture, malposition, and late seroma in subjects receiving natrelle 410 form-stable silicone breast implants. Plast Reconstr Surg 2017;139(1):1-9.
7. Listo F, Tutino R, Khan A, Ahmad J. Subglandular breast augmentation with textured, anatomic, cohesive silicone implants: a review of 440 consecutive patients. Plast Reconstr Surg 2013;132(2):295-303.
8. Ellabban MA, Nawar A, Milad H, Ellabban MG. Single-stage immediate breast reconstruction using anatomical silicone-based implant and the hammock technique of dermal-muscle flap in large and ptotic breasts: a multicenter study. World J Surg 2020;44(6):1925-31.
9. Duteille F, Perrot P, Bacheley MH, Stewart S. Eight-year safety data for round and anatomical silicone gel breast implants. Aesthet Surg J 2018;38(2):151-61.
10. Doren EL, Pierpont YN, Shivers SC, Berger LH. Comparison of allergan, mentor, and sientra contoured cohesive gel breast implants: a single surgeon’s 10-year experience. Plast Reconstr Surg 2015;136(5):957-66.
11. Danilla SV, Jara RP, Miranda F, Bencina F, Aguirre M, Troncoso E, et al. Is banning texturized implants to prevent Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) a rational decision? A meta-analysis and cost-effectiveness study. Aesthet Surg J 2019;39(5):343.
12. Bonomi S, Sala L, Gennaro M, Ricci C, Cortinovis U. Skin-reducing mastectomy and direct-to-implant breast reconstruction with submuscular-dermal-mesh pocket. Ann Plast Surg 2019;82(1):19-27.
13. Marra A, Viale G, Pileri SA, Pravettoni G, Viale G, De Lorenzi F, et al. Breast implant-associated anaplastic large cell lymphoma: a comprehensive review. Cancer Treat Rev 2020;84:101963.
14. Clemens MW, Jacobsen ED, Horwitz SM. 2019 NCCN consensus guidelines on the diagnosis and treatment of Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL). Aesthet Surg J 2019;39(Suppl. 1):S3-13.
15. Ministry of Food and Drug Safety. Comprehensive information for the patients with allergan textured breast implants. https://udiportal.mfds.go.kr/breastimplants/. Updated 2020. Accessed March 24, 2020.
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. 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. 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. In 2011, the FDA reported that there was a lack of MRI surveillance in association with the status of the post-FDA approval trials. 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.

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

Correspondence

Jeong Pil Jeong, Dong Seung Moon, Woo Sik Choi, Ho Chan Kim, and Jung Youp Sung

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

Jeong Pil Jeong, Dong Seung Moon, Woo Sik Choi, Ho Chan Kim, and Jung Youp Sung

1 Samsungyubang Breast Clinic, Busan, Korea
2 Goeun Lift Cosmetic Surgical Clinic, Busan, Korea
3 Lamar Clinic, Ulsan, Korea
4 Gangnam Picasso Clinic, Seoul, Korea
5 BBC Plastic Surgery Clinic, Changwon, Korea

Received: Apr 30, 2020
Accepted: May 6, 2020

Address for Correspondence:
Jung Youp Sung, MD, PhD
BBC Plastic Surgery Clinic, 3F Hapsung Medical Center, 775 3·15-daero, Masanhoewon-gu, Changwon 51209, Republic of Korea.
E-mail: jyhksr77@gmail.com

© 2020 The Korean Academy of Medical Sciences.
This is an Open Access article distributed under the terms of the Creative Commons Attribution Non-Commercial License (https://creativecommons.org/licenses/by-nc/4.0/) which permits unrestricted non-commercial use, distribution, and reproduction in any medium, provided the original work is properly cited.

ORCID IDs
Jeong Pil Jeong
https://orcid.org/0000-0001-8661-3315
Dong Seung Moon
https://orcid.org/0000-0002-7740-3514
We strongly agree with Kim et al. in that stakeholders in implant-based augmentation mammoplasty 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. Therefore, Kim JH et al.’s efforts and work should be appreciated and then treated as they deserve.

REFERENCES

1. Kim JH, Paik NS, Nam SY, Cho Y, Park HK. The emerging crisis of stakeholders in implant-based augmentation mammoplasty in Korea. J Korean Med Sci 2020;35(15):e103.
2. Tanne JH. FDA approves silicone breast implants 14 years after their withdrawal. BMJ 2006;333(7579):1139.
3. Handel N, Garcia ME, Wixtrom R. Breast implant rupture: causes, incidence, clinical impact, and management. Plast Reconstr Surg 2013;132(5):1128-37.
4. Elahi M, Eshera N, Bambata N, Barr H, Lyn-Cook B, Beitz J, et al. The food and drug administration office of women's health: impact of science on regulatory policy: an update. J Womens Health 2016;25(3):222-34.
5. Chung KC, Malay S, Shauver MJ, Kim HM. Economic analysis of screening strategies for rupture of silicone gel breast implants. Plast Reconstr Surg 2012;130(1):225-37.
6. Evans A, Trimboli RM, Athanasiou A, Balleyguier C, Baltzer PA, Bick U, et al.. Breast ultrasound: recommendations for information to women and referring physicians by the European Society of Breast Imaging. Insights Imaging 2018;9(4):449-61.
7. Chacko A, Lloyd T. Breast implant-associated anaplastic large cell lymphoma: a pictorial review. Insights Imaging 2018;9(5):683-6.
8. DePaola NEK, Coggins H. Breast implant-associated anaplastic large cell lymphoma: what we know. J Adv Pract Oncol 2019.10(1):54-61.
9. Gunawardana RT, Dessauvagie BF, Taylor DB. Breast implant-associated anaplastic large cell lymphoma, an under-recognised entity. J Med Imaging Radiat Oncol 2019;63(5):630-8.
10. Adrada BE, Miranda RN, Rauch GM, Arribas E, Kanagal-Shamanna R, Clemens MW, et al. Breast implant-associated anaplastic large cell lymphoma: sensitivity, specificity, and findings of imaging studies in 44 patients. Breast Cancer Res Treat 2014;147(1):1-14.
11. Dashevsky BZ, Gallagher KM, Grabenstetter A, Cordeiro PG, Dogan A, Morris EA, et al. Breast implant-associated anaplastic large cell lymphoma: Clinical and imaging findings at a large US cancer center. Breast J 2019;25(1):69-74.
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.

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.

Plastic surgeons’ favorable opinions towards a textured implant have also been described in the literature; Swanson 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. 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.
REFERENCES

1. Kim JH, Paik NS, Nam SY, Cho Y, Park HK. The emerging crisis of stakeholders in implant-based augmentation mammaplasty in Korea. J Korean Med Sci 2020;35(15):e103.  
   PUBMED | CROSSREF

2. Swanson E. Plastic surgeons defend textured breast implants at 2019 U.S. Food and Drug Administration Hearing: why it is time to reconsider. Plast Reconstr Surg Glob Open 2019;7(8):e2410.  
   PUBMED | CROSSREF

3. Sung JY, Jeong JP, Moon DS, Kim MS, Kim HC, Choi WS, et al. Short-term safety of augmentation mammaplasty using the BellaGel implants in Korean women. Plast Reconstr Surg Glob Open 2019;7(12):e2566.  
   CROSSREF