This letter is written regarding the recently published case report, ‘Correcting shape and size using temporary filler after breast augmentation with silicone implants’ [1] written by the Editorial Board of Archives of Aesthetic Plastic Surgery (AAPS). After publication of this article in recent issues of AAPS, many members of Korean Society for Aesthetic Plastic Surgery (KSAPS) express concern regarding safety of the injected material; major issue being that Aquafilling is not approved for breast augmentation by the Korean Food and Drug Administration (KFDA). They also point out that there have been numerous literatures concerning the disastrous effects of injectable materials including polyacrylamide gel (PAAG), same ingredient as Aquafilling® (although the authors describe that Aquafilling® is different from PAAG), previously used for breast augmentation.

Editorial Board of AAPS clearly recognized that the material used in this article is approved only for the face in small volume injections, and is not for the body in large volume usage. We also want to make it clear that this manuscript is just a case report involving two patients under the authors’ responsibility and patients’ consent, and not a confirmative article by a well-designed clinical trial with Institutional Review Board (IRB) approval.

Based on these facts, we want to present our position on the use of Aquafilling® for breast augmentation as stated below;

First, we admit there can be opposing opinions about this article and encourage that such be expressed in the forms of article or letter, based on clinical and scientific evidence. We will positively review and publish those manuscripts so that an open and fair debate be provided through the journal.

Second, the most important factor in dealing with the current situation lies in determining adequate compliance with the publication ethics outlined in the Helsinki declaration. Helsinki declaration is a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data [2]. It contains many basic principles, and some important statements are as below; all studies involving human subjects should include informed consent of volunteers and be conducted under generally accepted scientific principles. Every medical research project involving human subjects should be preceded by careful assessment of predictable risks and burdens in comparison with foreseeable benefits to the subject or to others. Nowadays, medical ethics is just as important as the originality of manuscript. The AAPS equally expect the authors to submit their manuscript abiding to the declaration of Helsinki.

We recently requested the authors of the particular article to refrain from commercial advertisement using the published article, especially considering the fact that this was a preliminary case report. This is in light of the fact that the general public lack medical knowledge enabling them to judge right from wrong amidst the overwhelming medical advertisement that we face today. Therefore, providing the right medical information is a duty of medical professionals, hence commercial advertisement using medical articles should be limited and performed carefully if at all. Moreover, the copyright of the all published articles in the AAPS journal is possessed by the AAPS. Therefore, commercial utilization such as insertion in magazine or internet news of partially captured article or the whole text without permission of the AAPS is considered illegal. We caution that legal litigations will be applied on these actions.

Consequently, the article by Shin et al. [1] is just a case report with only two patients. It is a preliminary report and, therefore, it is
far from concluding that Aquafilling® is safe and effective material for breast use. KFDA has no record of approving the use of Aquafilling for breast augmentation. Nevertheless, since it can be used under the author’s responsibility and patient’s consent if the benefits are expected to far outweigh the harms, there is no ethical problem in its off-label use. If the authors really want to prove that Aquafilling® is safe and effective material for breast augmentation and obtain a consensus about its use in the breasts, a proper clinical trial with approval of IRB is mandatory. Lacking such data as of today, the Editorial Board of AAPS express serious concern in Aquafilling® being accepted as ordinary method for breast augmentation, and in the recent commercial advertisement using the particular article written by Shin et al.

We plan on proper and necessary action based on the current situation soon after consulting with the Ministry of Health and Welfare and the KFDA. We hope this situation comes to a resolution at the earliest time possible and it gives us an opportunity to go one step forward in the meaningful evolution of the AAPS.

REFERENCES