

Correcting Shape and Size Using Temporary Filler after Breast Augmentation with Silicone Implants

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We write in response to the editorial by Jun Ho Shin and colleagues [1] in the October 2015 issue of Archives of Aesthetic Plastic Surgery. The authors of this paper report the relatively satisfactory results using a filler to improve the size and shape of the implant that has already been inserted into the breast based on only 6 month follow-up. The authors say that they used temporary filler in the title, but they describe in the discussion, "We used Aquafilling[®] filler, which is composed of 98% water and 2% copolyamide. Since it is homogeneous and soft, this hyaluronic acid (HA) monophasic filler has excellent lifting capacity and viscoelasticity compared to an HA biphasic filler or calcium filler, and thus can modify the form instantly through molding as well as properly maintain a natural form in a narrow space between the implant and the skin."

However, HAs are broken down by enzymes, absorbed, or phagocytized slowly, with minimal histologic reaction. They can be used as temporary fillers which can last generally from 12 to 18 months. HA monophasic filler is totally different from Aquafilling[®] that authors used. In the document submitted to Korean Food and Drug Administration (KFDA), the exact ingredient of Aquafilling[®] is 2% of poly (acrylamide-co-N,N'-methylene-bis-acrylamide) and 98% of sodium chloride solution 0.9%. And it lasts longer than 3 years, which means it can be classified as semi- or permanent filler.

The injection method using liquid silicone and paraffin for breast augmentation has been performed for more than 3 decades. But many complications after breast augmentation using the injection method were also reported [2].

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HA which is known to be safer than permanent fillers has come to represent the most widely used injectable cosmetic product in the world. Brought into being by the Swedish company Q-Med AB, Macrolane[™] was authorized for use in France in 2007, and the year after, it received official European approval as a mean of breast augmentation. Since then, however, numerous controversies pertaining to its side effects have led to its withdrawal from the worldwide breast augmentation market. That is because the restrictive measure was predicated on four main arguments. First, repeated product injection in the retroglandular region creates a risk of inflammatory breast cancer. Second, the injected product can migrate and contribute to the formation of nodules. Third, the product may interfere with clinical and image-based examination and occasion delay in the screening and diagnosis of mammary pathologies. Finally, screening and early diagnosis of breast cancer are considered to be nation-wide public health priorities. To sum matters up, Macrolane[™] deposits in the breast are liable to mask breast cancer, delay diagnosis and complicate surgery [3].

As described above, Aquafilling[®] filler consists of mainly polyacrylamide. Since 1995, polyacrylamide hydrogel (PAAG), which is same element as polyacrylamide, has been used as an injectable material in plastic and aesthetic surgery in China but was banned by the State Food and Drug Administration of China in 2006 because its safety is questionable. In a comparison study in the rat, PAAG appeared to be highly bioactive, undergoing cell infiltration and integration into tissues, even if the low-dose injection in the animal experiment did not show any systemic or local complication. In recent clinical reports of PAAG complications, the major manifestations were localized lumps, asymmetry, mastodynia, diffuse stiffness, infections, hematomas, myalgia, limitation of movement of the upper extremity, and gel migrations [2,4,5]. Furthermore, like silicone, polyacrylamide is reported to cause a rather high incidence of late complications if injected in large quantities [6]. There is also a report that a group of patients show late hematoma, seroma, and galactocele appearing 3 months to 10 years after breast

augmentation by PAAG injection [7].

In addition, polyacrylamide gel, when it is a form of polymer, is considered to be nontoxic, nonbiodegradable, and nonteratogenic. Although the polymer does not appreciably degrade into single molecules, the acrylamide monomer has been shown to be a neurotoxin and teratogen [8].

It is off-label use for the authors to use Aquafilling[®] filler for breast augmentation. The standard of meaning and limitation of off-label use should be based on 'safety'. Therefore, the authors need to provide the evidence to prove that safe features of Aquafilling[®] filler which differentiate from PAAG filler, and that it can be safely used in breast augmentation.

If safety isn't proven for now, it should be banned to use Aquafilling[®] filler for aesthetic use on breast considering several arguments. This is because breast tissues have high incidence of breast cancer and it is risky to use a large amount of Aquafilling[®] filler before long-term safety is acquired.

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