

Position Statement of Korean Academic Society of Aesthetic and Reconstructive Breast Surgery: Concerning the Use of Aquafilling® for Breast Augmentation

Tai Suk Roh

President, Korean Academic Society of Aesthetic and Reconstructive Breast Surgery
Department of Plastic and Reconstructive Surgery, Gangnam Severance Hospital, Yonsei University College of Medicine, Seoul, Korea

In the article entitled 'Correcting shape and size using temporary filler after breast augmentation with silicone implants' published at October 2015 of the Archives of Aesthetic Plastic Surgery, Shin et al. [1] states that 'Aquafilling® is a new option for the correction of minor problems after breast augmentation surgery with implants.'

According to the article, Aquafilling® is composed of 98% of water and 2% of copolyamide. However, 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-bisacrylamide) and 98% of sodium chloride solution 0.9%.

Historically, there have been many attempts to augment breasts using injectable materials including paraffin, liquid silicone, polyacrylamide gel (PAAG) and so on [2]. Up-to-date, all materials resulted in some form of complications such as chronic inflammation, lumps due to foreign body granulomas and even skin ulcerations. For these reasons, U. S. Food and Drug Administration (FDA) unapproved use of fillers for breast augmentation [3].

There have been numerous reports that augmentation mammoplasty with PAAG filler injection results in serious adverse complications [2,4-6]. Specifically, it can result in local and systemic fever, breast swelling, redness, nipple bulging, tenderness and pain, asymmetry, deformity and even loss of ability for breastfeeding [7-9]. Although Shin et al. described that it is different from the previous

problematic PAAG fillers such as Amazing Gel or Aquamid, the major component of Aquafilling® is polyacrylamide in itself, no different from the existing fillers that have been commercially available. Furthermore, explanations in regards to how the same chemical constituents can be altered by some changes in the physical properties such as bonding reaction, are obscure if not totally lacking in evidence.

In this regard, members of the Korean Academic Society of Aesthetic and Reconstructive Breast Surgery express serious concerns over the use of Aquafilling® for breast augmentation, more so considering the short six months follow up from initial procedures. There have been previous reports that in the early period of PAAG use, it is well tolerated to breast, and migration resistant [10]. However, this report has become totally out of date and, unacceptable and abandoned at present. Especially, considering the late onset of serious complications after PAAG injection to breast, it is too hasty conclusion that Aquafilling® is new option for correction of unfavorably resulted augmentation mammoplasty.

KFDA only permitted the use of Aquafilling® for temporary improvement of facial wrinkle, asymmetry and shape and volume of lip. Not abiding by the permitted use as in augmentation of breasts requires much more volume, leading to potential complication and patients suffering where treatment is not easy [4]. Many cases of breast deformity after Aquafilling® injection is irreversible and even requires breast reconstruction [4].

The Korean Academic Society of Aesthetic and Reconstructive Breast Surgeons obviously opposes the use of Aquafilling® for breast augmentation until sufficient evidences of long term safety are accumulated, and verified. We also caution against commercial utilization of the unapproved filler relying on the preliminary report by Shin et al. More strict regulations must be applied in the human use of new or unproven injectable fillers. Only the highest standards of medical ethics can insure the health of our patients.

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Correspondence: Tai Suk Roh Department of Plastic and Reconstructive Surgery, Gangnam Severance Hospital, Yonsei University College of Medicine, 211 Eonju-ro, Gangnam-gu, Seoul 06273, Korea.
E-mail: rohts@yuhs.ac

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