

# Complication of Ruptured Poly Implant Prothèse® Breast Implants Combined with AQUAfilling® Gel Injection: A Case Report and Literature Review



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## Abstract

**Introduction** We describe the first case of a patient who received AQUAfilling® gel (Biomedica, Prague, Czech Republic) after augmentation with Poly Implant Prothèse® (PIP) breast implants and later developed breast deformity with bilateral implant rupture.

**Case Report** A 49-year-old Korean female patient who received breast augmentation with PIP implants 18 years ago and subsequent insertion of AQUAfilling® gel 1 year ago visited our center with a chief complaint of pain and decreased implant sizes in both breasts. Breast implant and foreign body removal operation was performed for both breasts under general anesthesia. Intraoperative gross findings, pathologic findings, and tissue culture results were analyzed.

**Results** Our diagnosis included rupture of the implants in both breasts with leakage of injected material resulting in inflammation of the pericapsular area and pectoralis muscle. The intraoperative gross findings and results of the pathologic report showed that the implants were exposed with massive leakage of AQUAfilling® gel in the pericapsular space, and the pectoralis major was mixed with AQUAfilling® gel-like liquid and tissue with an inflammatory reaction.

**Conclusions** Surgeons should be careful in performing AQUAfilling® gel injection for breast augmentation, especially when combined with breast implant insertion.

AQUAfilling® gel itself is not yet proven safe in the long term, so more research on this topic is warranted. Additionally, surgeons should be aware of the comparatively high risk of implant rupture and foreign body reaction with PIP implants, and warn patients accordingly.

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**Keywords** Breast deformity · Implant rupture · Gel filler · Case report

## Introduction

Augmentation mammoplasty with breast implant insertion is a popular aesthetic surgery worldwide. Although there are still some implant-related complications or revision surgeries performed because of patient dissatisfaction, the procedure is considered safe and effective, with experienced surgeons choosing the appropriate type and size of implants from established manufacturers.

Recently, there was a scandal in Europe caused by a company that produced silicone gel breast implants. Since 2001, Poly Implant Prothèse® (PIP), a French company, was illegally manufacturing breast implants made from cheaper industrial-grade silicone instead of the mandated medical-grade silicone they had previously used. This resulted in a significant increased risk of breast implant rupture and leakage for patients and some rare cases of malignancies. The company was liquidated, and many case reports, reviews, and research papers were published

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worldwide and presented, especially to the European public [1].

In Korea, a filler injection was developed to be used for an alternative method of breast augmentation. It is promoted to be a less invasive technique than surgery. Among many types of fillers, AQUAfilling<sup>®</sup> gel (Biomedica, Prague, Czech Republic) was developed. It is a hydrophilic gel composed of 98% sodium chloride solution (0.9%) and 2% cation polyamide (acrylamide-co-*N,N'*-methylene-bisacrylamide), and it is described as a sterile synthetic material biocompatible with human tissues, offering stable results for approximately 8–10 years [2]. This product was first used as a dermal filler for the face and buttocks, but its use has been extended to serve as a body filler; now it has become popular in breast augmentation. AQUAfilling<sup>®</sup> gel products are manufactured and registered in Czech Republic, and now clinically used in the European Union, Turkey, Serbia, South Korea, Japan, and Malaysia, as cited on the company's official home page. South Korea, especially, where the public interest in filler use for body contouring is quite high, already has two published case reports regarding AQUAfilling<sup>®</sup> gel-related complications [3, 6]. Patients who want a simple, easier procedure choose to undergo injection of AQUAfilling<sup>®</sup> gel in primary breast augmentation, and some patients who previously received breast implant insertion choose AQUAfilling<sup>®</sup> gel to achieve more volume or breast contouring for correction of regional deformity.

Herein, we describe the first case of a patient who received AQUAfilling<sup>®</sup> gel injection in addition to undergoing breast augmentation with PIP breast implant insertion previously and later developed bilateral implant rupture with an inflammatory reaction.

## Case Report

A 49-year-old Korean female patient visited our plastic surgery department with a chief complaint of pain and feeling of decreased implant size in both breasts. She had received augmentation mammoplasty with implant insertion in both breasts at a local clinic approximately 18 years ago. She did not know the size and type of implants she received. She maintained the implants for about 15 years without any complications, and she decided to undergo additional breast augmentation with AQUAfilling<sup>®</sup> gel injection 1 year ago at a different local clinic. She did not know the total amount of gel injected, but she said that it was injected above, below, and inside of the pectoralis major of both breasts. Inflammatory signs, including redness, swelling, and fluid collection, were not seen during the physical examination, but she reported pain and tenderness, with more on the right side. Her breast size was

slightly smaller on the right side, the inferior mammary fold seemed symmetric, and no wound problem was identified (Fig. 1a–c).

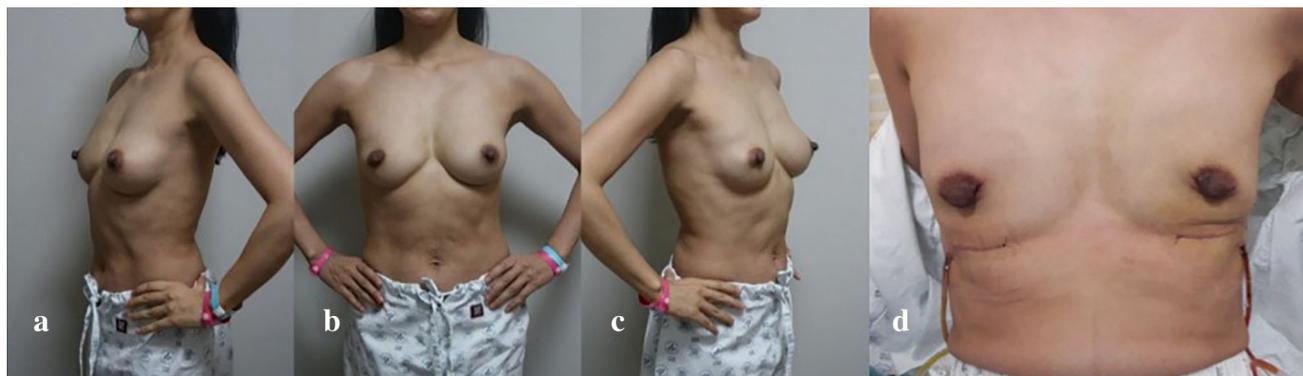
Breast sonography and contrast-enhanced magnetic resonance imaging (MRI) were performed, and findings of extracapsular rupture with an abundant amount of foreign bodies were found in both breasts. Additionally, sonography showed that the foreign body materials were mainly located in the retro-implant space, and they were involved in the superficial and deep layers of the pectoralis major (Fig. 2c, d). The MRI scan showed peri-implant fluid, which was presumed to be the AQUAfilling<sup>®</sup> gel rather than water or silicone, in the breast capsule pocket, outer interstitial area of the capsule, intramuscular portion of the pectoralis major, and partially extending into the axilla (Fig. 2a, b).

Our diagnosis included rupture of the implants in both breasts with leakage of the injected material, resulting in inflammation of the pericapsular area and pectoralis major. A breast implant and foreign body removal operation was performed for both breasts under general anesthesia with a 5-cm inferior mammary fold incision design. Partial capsulectomy was conducted, and the implants were exposed with massive leakage of the AQUAfilling<sup>®</sup> gel into the pericapsular space (Fig. 3a–d). After squeezing and suctioning the exposed AQUAfilling<sup>®</sup> gel, the ruptured implants and leakage of silicone were identified and removed carefully. Then the pectoralis major was exposed, and it was shown to be mixed with AQUAfilling<sup>®</sup> gel-like liquid and tissue with an inflammatory reaction. Residual foreign body and inflammatory tissue were removed with curettage and massive irrigation with Betadine and triple antibiotic solution consisting of 50,000 U of bacitracin, 1 g of cefazolin, 80 mg of gentamicin, and 500 ml of normal saline. Surgical biopsy and tissue culture were performed (Fig. 4a–c), and the wound was closed in layers with Hemovac drain insertion. We found that the previously inserted implants were both 150-cc PIP breast implants (Fig. 3b).

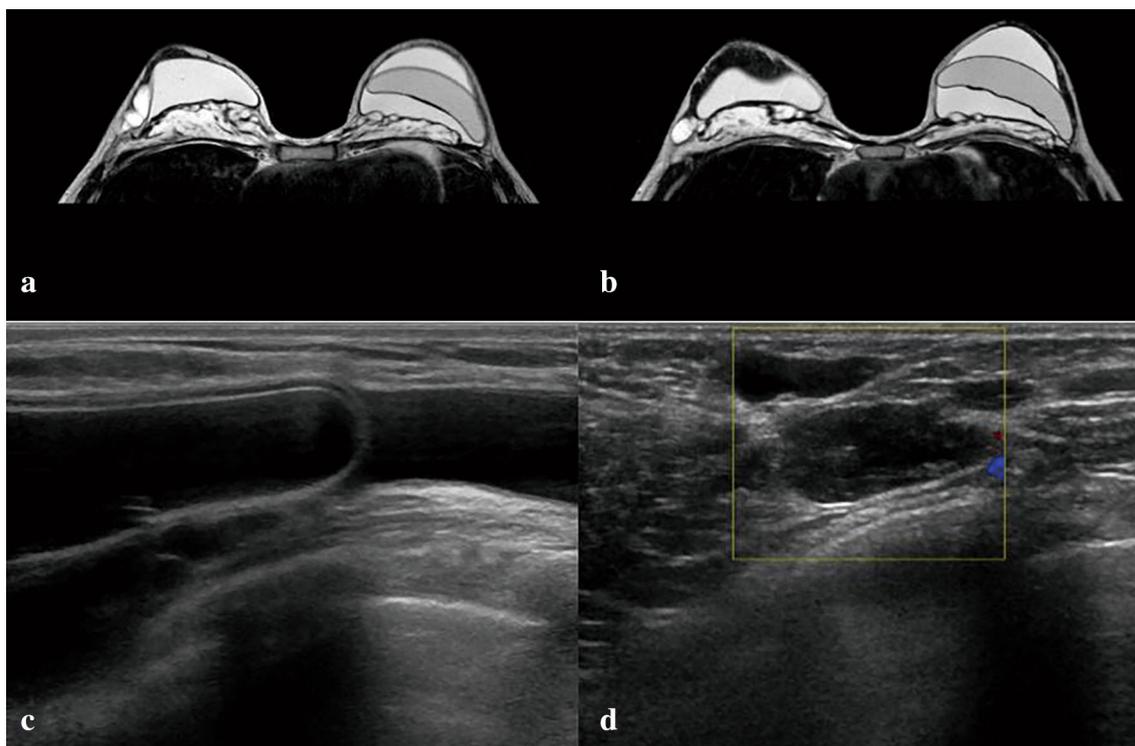
## Results

The patient was discharged on postoperative day 6 after Hemovac drain removal, and there were no acute postoperative complications (Fig. 1d). No growth of bacteria was found in the final tissue culture result, and inflammatory cells and synovial metaplasia with periprosthetic breast capsule and AQUAfilling<sup>®</sup> gel-associated change were indicated by the surgical biopsy result (Fig. 5a–d).

Periodic follow-up was performed in the outpatient clinic for 6 months. Breast deformity and recurrence of inflammation due to residual foreign body materials did not



**Fig. 1** Photographs of the patient **a–c** preoperatively in standing position and on **d** postoperative day 4 in sitting position, showing no complication



**Fig. 2** **a, b** Magnetic resonance imaging scans showing the peri-implant fluid in the breast capsule pocket, outer interstitial area of the capsule, intramuscular portion of pectoralis muscle, and partially

extending into the axilla. **c, d** Sonogram showing that the foreign body materials are mainly located in the retro-implant space, and involved in the superficial and deep layers of the pectoralis major

occur. The patient did not want her breasts re-augmented, so re-augmentation was not considered.

## Discussion

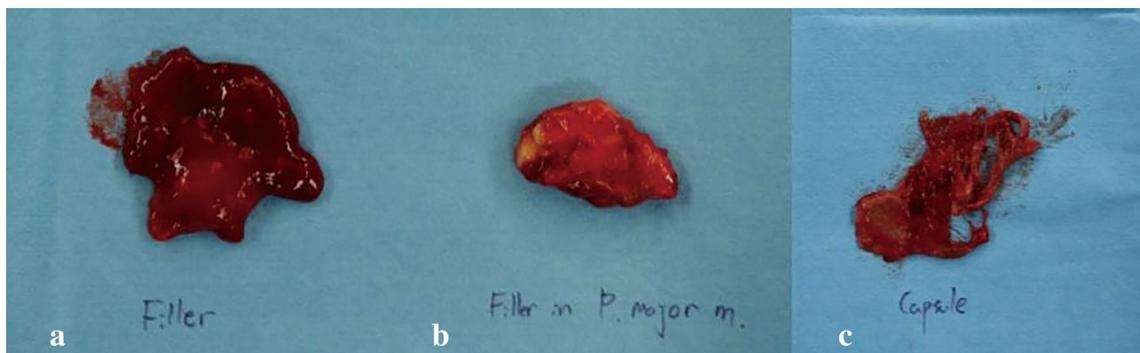
Augmentation mammoplasty with implant insertion is one of the most popular aesthetic operations in the world, but surgeons began to try alternative or adjuvant methods for breast augmentation using fillers and fat grafts. Fat grafts were the first method to be highlighted because they are

associated with minimal complications, although they lack longevity. In 2015, Shin et al. suggested injecting an adequate amount of filler in the space between the implant and skin to create a natural and satisfactory size and shape for revision purposes after breast augmentation using implants [2]. However, the use of this gel is prohibited in some countries because it is not yet approved by the United States Food and Drug Administration, and complications from the use of polyacrylamide hydrogel, which accounts for 2% of the AQUAfilling<sup>®</sup> gel, have been increasingly reported in many countries [3]. In 2017, Arslan reported



**Fig. 3** Intraoperative findings. **a** The capsular tissue is removed, and implant is exposed through the inframammary fold incision. **b** The 150-cc Poly Implant Prothèse® implant is removed. **c, d** Massive

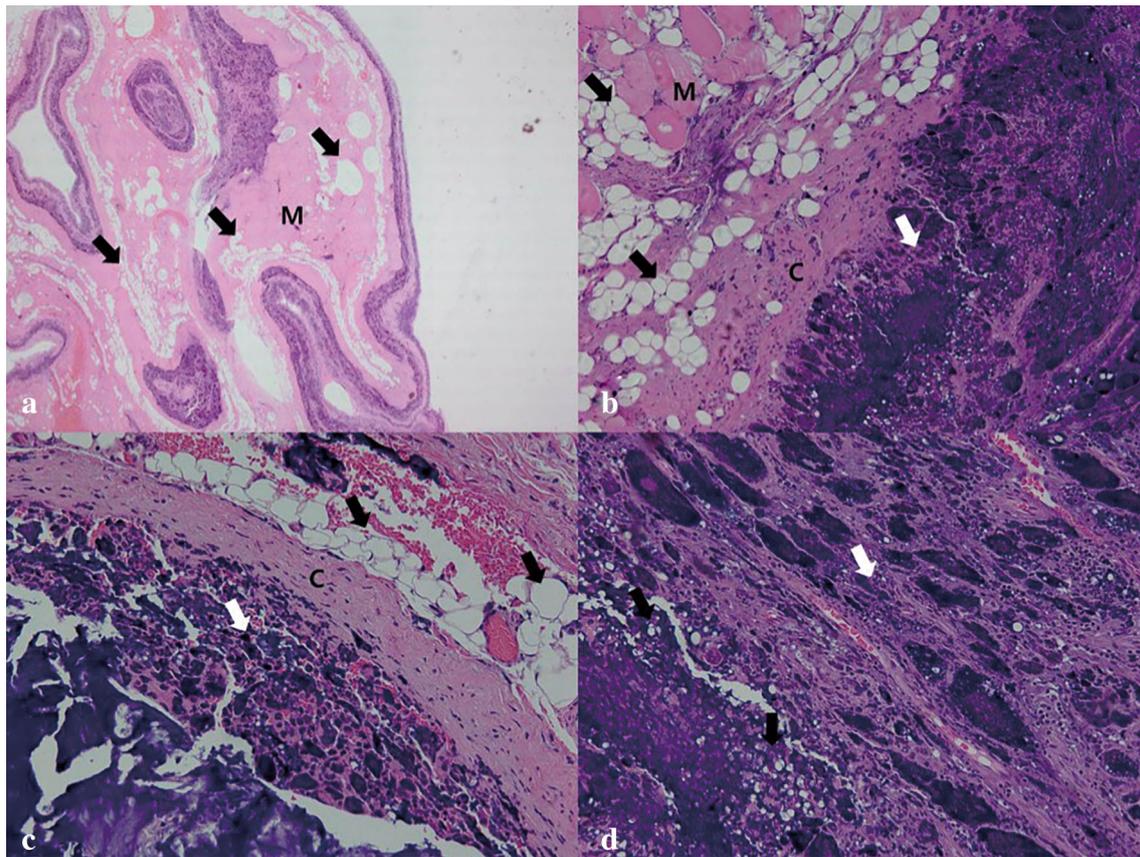
leakage of the AQUAfilling® gel is shown in the pericapsular space before implant removal



**Fig. 4** Gross photographs of the **a** filler, **b** filler in the pectoralis major muscle (p. major m.), and **c** capsule

complications of AQUAfilling® gel in breasts evaluated by ultrasonography and MRI [4]. Therefore, the efficacy of AQUAfilling® gel is not yet proven with long-term follow-up so surgeons need to use it cautiously and prepare for the possibility of long-term complications. Thus far in Korea, there has been one case report with a literature review of the complications associated with AQUAfilling® gel and one case series about the complications and radiologic features of breast augmentation with AQUAfilling® gel

injection. In 2018, Jung et al. concluded that corrective treatment is difficult when a complication occurs in breast augmentation with AQUAfilling® gel injection, and they mentioned concerns regarding toxicity of the gel material and its effect on surrounding tissues. Hence, they emphasized that sufficient evidence of its long-term safety must be accumulated and proven, until which time the aesthetic use of the unapproved filler must be restricted [5]. In 2017, Son et al. also reported concerns with the safety of



**Fig. 5** Pathology results of the AQUAfilling® gel in the pectoralis major and peri-implant tissue. **a** Diffuse distribution of the AQUAfilling® gel (black arrow) (hematoxylin and eosin (HE) stain,  $\times 12.5$ ). **b** AQUAfilling® gel (black arrow) in the muscle tissue, and severe

degenerative change (white arrow) of the filler and abutting connective tissue (HE stain,  $\times 100$ ). **c, d** Peri-implant AQUAfilling® gel (black arrow) and degenerative change of the tissue (white arrow) (HE stain,  $\times 200$ ; HE stain,  $\times 400$ ). **C** peri-implant capsule, **M** muscle

augmentation mammoplasty with AQUAfilling® gel, based on their experience with clinical complications observed in radiologic studies related to gel migration and recurrent infection. They recommended that the use of this gel, which contains polyacrylamide gel, a proven toxic substance, for whole breast mammoplasty be restricted until its long-term safety has been verified [6].

The illegally manufactured PIP implant was not widely known about in Korea. Patients with PIP implants require close and cautious follow-up. In 2012, Lampert et al. suggested some guidelines for patients with PIP implants because of the high risk of complications [7]. Although many patients have been warned about the implant and its complications, there are still some patients who have maintained the implant for 10–20 years with close follow-up. Surgeons should be aware of the known reported risks and complications, and the possibility that complications have not yet been reported for patients who have maintained the implant in the long term. There are many systematic reviews about PIP implants and retrospective analyses about implant rupture rates (Table 1) or other

complication rates, and some rare case reports, as shown in Table 2.

In our case, we are unsure whether the PIP implants previously inserted in the patient were illegally manufactured ones, but the possibility of this is high. The patient had never heard about the possible risk of complications with the PIP implant and did not undergo close follow-up over the past 15 years. Although she had no specific symptom, as referenced by some reports of abnormal findings shown on imaging studies preceding patients' complaint of symptoms, we cannot rule out that she already developed implant rupture or leakage before the AQUAfilling® gel injection procedure [8, 9]. She underwent the additional procedure without close evaluation to determine whether her previously inserted implants were intact. There was also a chance of implant injury during the procedure, which is performed with needle injection close to the implant. Additionally, there is a possibility that the inflammatory reaction in the pericapsular space or implant surface progressed after the AQUAfilling® gel was safely injected and then implant injury developed later. Another

**Table 1** Rupture rates of PIP implants

| Author               | Year of publication | No. of patients | Duration of follow-up (years) | Rupture rate per patient (%) | Specific note   |
|----------------------|---------------------|-----------------|-------------------------------|------------------------------|---|
| Khan [10]            | 2013                | 65              | 7.2                           | 27.7                         | Retrospective case–control study of patients with revision surgery<br>Non-PIP rupture rate, 7.6%<br>Grade 3 or 4 capsular contracture rate, 25%; this is similar to that in the non-PIP group |
| Santolo et al. [9]   | 2014                | 64              | 8                             | 36                           | Retrospective MR analysis of patients with PIP implants   |
| Oulharj et al. [11]  | 2014                | 455             | 6                             | 11.6                         | Single-center retrospective analysis of implant removal in patients   |
| Quaba and Quaba [12] | 2013                | 388             | 7.8                           | 35.2                         | Prospective analysis of patients with PIP implants who underwent implant removal  |
| Chummun et al. [13]  | 2013                | 44              | 7                             | 21.8                         | Retrospective analysis of patients with PIP implants who were invited to receive a non-obligatory, free consultation  |

PIP—Poly Implant Prothèse®, *no.*—number. MR—magnetic resonance

**Table 2** Unusual published cases of patients with ruptured PIP implants

| Author                            | Year of publication | Surgical purpose | Symptom  | Detection method       | Specific note  |
|-----------------------------------|---------------------|------------------|--|------------------------|--|
| Correia-Sa et al. [14] (Portugal) | 2013                | Aesthetic        | Breast deformity, enlarged axillary lymph node | Sonography             | Histologic findings of inflammation in the axillary conglomerate lymph nodes   |
| Dinets et al. [15] (Ukraine)      | 2016                | Aesthetic        | Asymptomatic                                   | Intraoperative finding | Xanthoma is found in the central lower part of the breast over the fascia of the pectoral major with microrupture of the PIP implant   |
| Mallon et al. [16] (France)       | 2013                | Reconstruction   | Erythematous rash                              | MRI                    | No symptoms except an erythematous rash on the anterior trunk below the breast   |
| Tafazal et al. [17] (the U.K.)    | 2014                | Aesthetic        | None   | MRI                    | Breast cancer is found with axillary silicone granulomas from the SLNB   |
| Kastner et al. [18] (Spain)       | 2018                | Aesthetic        | Breast pain, swelling                          | Mammography            | Recurrent 8-year painful seroma formation of the breast after implant removal, with histological exclusion of ALCL   |
| Mistry et al. [19] (Australia)    | 2015                | Aesthetic        | Breast pain                                    | MRI                    | 1 year after explantation, progressive locoregional lymphadenopathy involving cervical, axillary, and internal mammary groups developed, resulting in bilateral thoracic outlet syndrome |

PIP—Poly Implant Prothèse®, U.K.—United Kingdom, MRI—magnetic resonance imaging, SLNB—sentinel lymph node biopsy, ALCL—anaplastic large-cell lymphoma

possibility is that all these risk factors might have contributed to her condition.

This case report serves as a reminder of the potential issues with and history of PIP implants. Plastic surgeons should explain the possible complications and suggest close follow-up to the patients with previously inserted PIP implants. Furthermore, if some patients want an additional procedure, such as surgery, filler injection, or fat grafts,

plastic surgeons should warn patients before the procedure and perform the procedure carefully.

AQUAfilling® gel has been used in Korea but for only a short period. Some reports about complications are coming mainly from Korea, but systematic studies have not been published yet so more research and time are needed to conduct these types of studies. In our patient, we observed an inflammatory reaction and tissue changes through the

surgical biopsy results, but we could not prove which event, the AQUAfilling<sup>®</sup> gel injection or implant rupture, precipitated the inflammation. Although there was one report demonstrating the effectiveness of breast implant insertion combined with filler injection [2], we do not know the complication rate of implant injury during the needle procedure or long-term risk when the silicone implant and AQUAfilling<sup>®</sup> gel substance are used together in the body.

## Conclusions

With this case, we aimed to make plastic surgeons fully aware of the past PIP scandal in Europe, and we recommend they assume a critical attitude toward using silicone implants in combination with AQUAfilling<sup>®</sup> gel in aesthetic breast augmentation. Moreover, it is necessary to conduct further research on AQUAfilling<sup>®</sup> gel to determine its efficacy and safety, and whether performing breast augmentation combined with AQUAfilling<sup>®</sup> gel should be stopped.

## Compliance with Ethical Standards

**Conflict of interest** The authors have no financial or institutional interest in any of the drugs, materials, or devices described in this article.

**Ethical Approval** All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

**Informed Consent** Informed consent was obtained from the patient to publish the case and accompanying images.

## References

1. Greco C (2015) The poly implant prothèse breast prostheses scandal: embodied risk and social suffering. *Soc Sci Med* 147:150–157
2. Shin JH, Suh JS, Yang SG (2015) Correcting shape and size using temporary filler after breast augmentation with silicone implants. *Arch Aesthet Plast Surg* 21:124–126
3. Roh TS (2016) Position statement of Korean Academic Society of Aesthetic and Reconstructive Breast Surgery: concerning the use of AQUAfilling<sup>®</sup> for breast augmentation. *Arch Aesthet Plast Surg* 22:45–46
4. Gozde A, Levent C, Mahir AM, Levent C, Rahmi C (2017) Complication of non-US guided procedure of aquafilling breast gel. *Med Ultrason* 19:236–240
5. Jung BK, Yun IS, Kim YS, Roh TS (2018) Complication of AQUAfilling<sup>®</sup> gel injection for breast augmentation: case report of one case and review of literature. *Aesthet Plast Surg* 42:1252–1256
6. Son MJ, Ko KH, Jung HK, Koh JE, Park AY (2018) Complications and radiologic features of breast augmentation via injection of aquafilling gel. *J Ultrasound Med* 37:1835–1839
7. Lampert FM, Schwarz M, Grabin S, Stark GB (2012) The “PIP scandal”—complications in breast implants of inferior quality: state of knowledge, official recommendations and case report. *Geburtsh Frauenheilk* 72:243–246
8. Helyar V, Burke C, McWilliams S (2013) The ruptured PIP breast implant. *Clin Radiol* 68:845–850
9. Scotto di Santolo MS, Cusati B, Ragozzino A (2014) Poly implant prothèse incidence of rupture: a retrospective MR analysis in 64 patients. *Quant Imaging Med Surg* 4:462–468
10. Khan UD (2013) Poly implant prothèse (PIP) incidence of device failure and capsular contracture: a retrospective comparative analysis. *Aesthet Plast Surg* 37:906–913
11. Oulharj S, Pauchot J, Tropet Y (2014) PIP breast implant removal: a study of 828 cases. *J Plast Reconstr Aesthet Surg* 67:302–307
12. Quaba O, Quaba A (2013) PIP silicone breast implants: rupture rates based on the explantation of 676 implants in a single surgeon series. *J Plast Reconstr Aesthet Surg* 66:1182–1187
13. Chummun S (2013) PIP breast implants: our experience. *Surgeon* 11:241–245
14. Correia Sa I (2013) The “PIP problem”: clinical and histologic characteristics. *Aesthet Plast Surg* 37:936–940
15. Dinets A et al (2016) An unusual case of a ruptured poly implant prothèse breast implant associated with xanthoma. *Case Rep Plast Surg Hand Surg* 3(1):11–15
16. Mallon P et al (2013) Bilateral poly implant prothèse implant rupture: an uncommon presentation. *Plast Reconstr Surg Glob Open* 1:e29
17. Tafazal H et al (2014) Sentinel lymph node biopsy in a patient with ruptured poly implant prothèse (PIP) implants: a case report. *Int J Surg Case Rep* 5:992–994
18. Kastner S et al (2018) Recurrent 8-year ongoing unilateral breast seroma formation after pip implant removal—a case report and review of the literature. *Surg J* 4(1):e46–e51
19. Mistry R et al (2015) Thoracic outlet syndrome following breast implant rupture. *Plast Reconstr Surg Glob Open* 3:e331