CASE REPORT

https://doi.org/10.14730/aaps.2022.00458
Arch Aesthetic Plast Surg 2022;28(3):107-110
pISSN: 2234-0831 eISSN: 2288-9337

aaps
Archives of Aesthetic Plastic Surgery

Atypical rupture of a Poly Implant Prothése implant and fluid shifting: a case report

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Women have undergone augmentation mammoplasty for decades, and if implant rupture is suspected, imaging modalities such as magnetic resonance imaging (MRI) and ultrasonography are available. The linguine sign, keyhole sign, and noose sign are all suggestive of rupture. However, earlier-generation implants with alternative filler materials demonstrate rupture signs that differ from those of today's better-known implant materials. A 60-year-old female patient who had undergone augmentation mammoplasty 20 years ago presented with left breast swelling and pain in the lower-outer quadrant. Ultrasonography and MRI confirmed extracapsular diffuse wall enhancement with suspected, but not apparent, discontinuity in the patient's left breast implant. Therefore, both implants were removed. It was determined that these were Poly Implant Prothése implants. The left breast implant differed from the contralateral implant in that it contained fluctuating fluid. This could be attributed to an osmotic gradient that caused the implant to swell and weakened the elastomer shell, resulting in micro rupture without a gross tear. Patients who undergo augmentation mammoplasty should have regular follow-up examinations, even if there are no symptoms. Furthermore, clinicians should be aware that some patients who have had breast augmentation mammoplasty may experience atypical symptoms and signs if the implant ruptures.

Keywords Mammaplasty / Breast implants / Hydrogels / Magnetic resonance imaging / Case reports

INTRODUCTION

Since the 1960s, when silicone implants were first used, they have evolved with increased strength, reduced gel bleeding, and improved durability. The so-called third-generation silicone implants were developed with these improved properties. However, the U.S. Food and Drug Administration (FDA) called for the temporary removal of third-generation implants from the market in 1992, citing insufficient data to demonstrate the safety and effectiveness of breast implants. As alternatives, implants made of hydrogel or triglyceride appeared on the market. However, the severe side effects of these newly manufactured implants (e.g., Misti Gold and Novagold) caused them to be withdrawn from the market. The U.S. FDA finally lifted restrictions on silicone implants in 2006. The use of silicone implants was not permitted in Korea from 1992 to July 2007. However, regulation of implantable agents was lax at the time and many patients underwent implantation of the various injectable filler materials or alternative implants mentioned above, resulting in social and medical issues that persist to this day.

Poly Implant Prothése (PIP) is a French breast implant manufacturer. When the use of silicone implants for cosmetic purposes was prohibited in 1992, they began producing saline-filled and hydrogel-filled implants encapsulated in a silicone shell. In 1999, the FDA refused to approve PIP's saline-filled implants, and in December 2002, the Medical Devices Agency of the United Kingdom's Department of Health withdrew its hydrogel implants from the

Received: Apr 8, 2022 **Revised:** Jun 8, 2022 **Accepted:** Jul 5, 2022
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market for precautionary reasons. Hydrogel implants were widely used in Korea from 1999 until 2002, when they were outlawed. Later, silicone implants were reapproved by the U.S. FDA and the Korean Ministry of Food and Drug Safety (MFDS) in 2006 and 2007, respectively. However, in 2010 it was discovered that PIP had been using unapproved industrial-grade silicone in their implants since 2001. These implants had a higher rate of rupture that resulted in legal issues for the company and eventual bankruptcy. After the French medical safety agency recalled its implants, PIP was put into liquidation. There have been other reports of PIP implants identified after implant removal that presented with various clinical courses and imaging reports.

Several implant rupture cases have been reported with variable findings. Some implants had a peri-implant fluid collection, while others had gross tears on the surface of the implant. Herein, we present a case of atypical implant rupture and fluid shifting without a significant gross tear of the shell. We also examined studies on PIP implant rupture cases as well as specific radiologic findings in PIP implant rupture.

CASE REPORT

A 60-year-old female patient who had gone augmentation mammoplasty 20 years ago had been experiencing left breast swelling and pain in the lower-outer quadrant (LOQ) for several months. Ultrasonography of the breasts indicated rupture of both breast implants. The patient was referred to our center, where she underwent a magnetic resonance imaging (MRI) examination as well as breast ultrasonography.

MRI showed diffuse wall enhancement on the extracapsular diffuse wall enhancement and the outer portion of the left implant was suspected to be discontinuous. A 1.2×3.2-cm non-mass enhancement with T2 high signal intensity was discovered 3.7 cm from the nipple in the 5 o'clock direction (Fig. 1A). This finding suggested that the extracapsular rupture was associated with inflammation. On ultrasonography, both breasts showed diffuse heterogeneous parenchymal echotexture with subglandular implant insertion (Fig. 2). Diffuse peri-implant fluid collection was found in both breasts, especially in the LOQ of the left breast. Irregular contours on the prominent folds of both implants were discovered, implying the possibility of intracapsular rupture. There were several prominent lymph nodes in the left axillary level I, whereas there were no abnormal focal lesions on the right breast parenchyma and no prominent lymph nodes in the right axilla. On silicone suppression view, the signal intensity of the inner material was still high (Fig. 1B). The radiologist who dictated the MRI view stated that the implant might be a hydrogel implant.

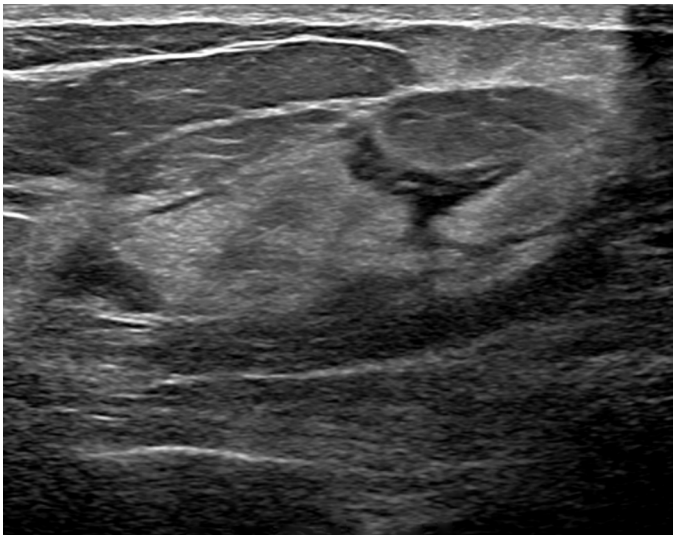

Fig. 2. Ultrasonography of the left lower-outer quadrant. Diffuse heterogeneous parenchymal echotexture was observed.

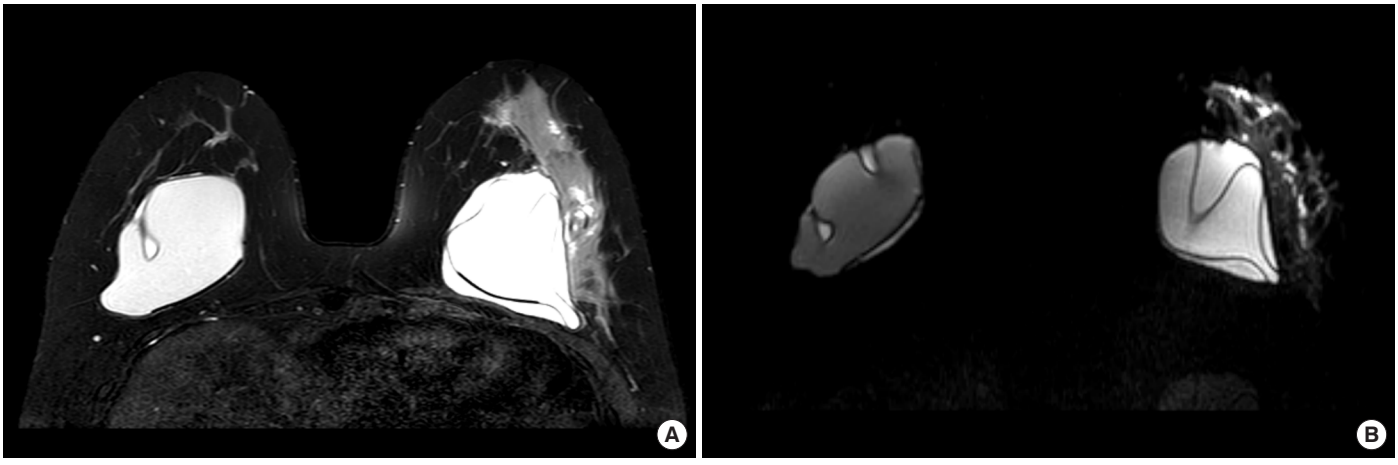

Fig. 1. Magnetic resonance image of the patient's breasts. (A) Diffuse wall enhancement is noted on the lateral side of the left breast. (B) Silicone suppression showed that the signal intensity of the inner material was still high, indicating that the implant might be a hydrogel implant.

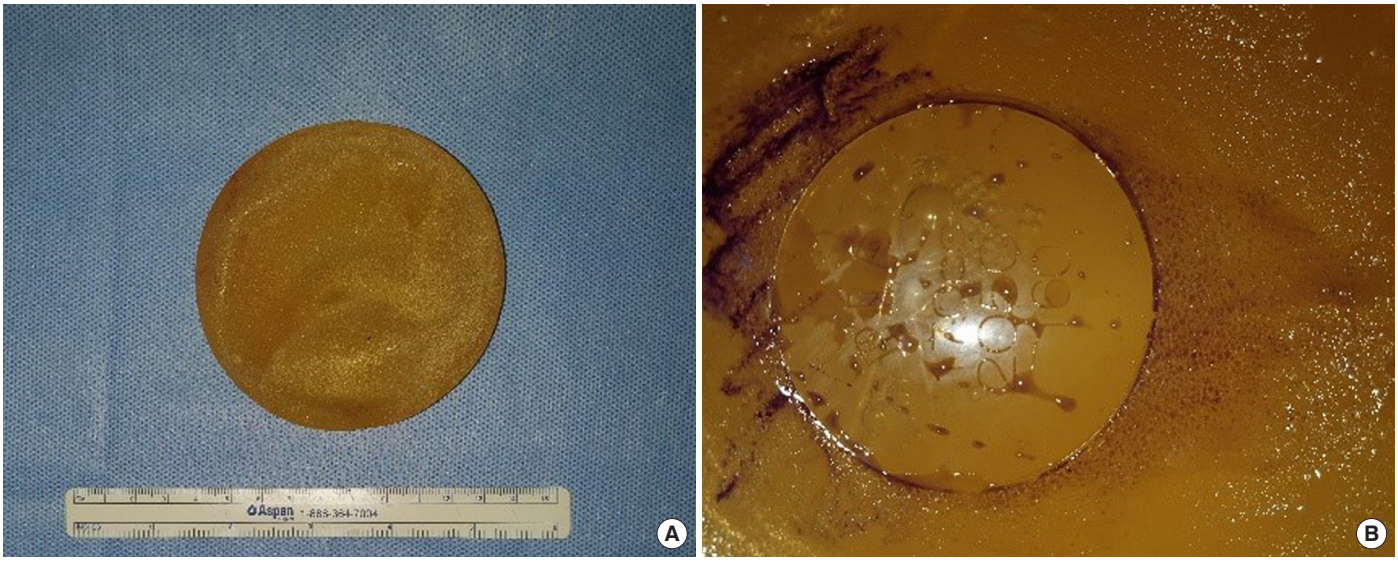

Fig. 3. Explanted left breast implant. (A) There was no remarkable tear in the shell. (B) A yellowish fluctuating sticky fluid was observed within the shell, which was not mixed with the remaining hydrogel.

Both implants were removed through inframammary incisions. It was determined that the implants used for this mammoplasty augmentation were manufactured by PIP. Within the silicone shell, a yellowish fluctuating sticky fluid was observed that had not mixed with the remaining hydrogel, and no remarkable tear was found in the shell (Fig. 3). The right implant had no fluid inside the intact capsule. Following fluid culture, cytology, and biopsy of the left breast tissue, copious irrigation was performed. Mastopexy with an inverted T scar design was performed on both breasts. Cultures of the fluid from both breasts detected no bacteria or fungal growth, and the cytology test came back negative for malignant cells. A biopsy of the left breast tissue revealed foamy histiocytic infiltration and clinical implant rupture. No complications related to the operation have been noted for several months postoperatively.

DISCUSSION

Multiple efforts have been made to develop an implant with a natural shape and feel. Although there is no absolute standard for the ideal breast, certain female breast characteristics, such as a full, sloping upper pole that leads to a fuller, gently curving lower pole, are widely recognized as aesthetically favorable.

Silicone implants were removed from the market in 1992 because of safety concerns [1], leading to the use of alternative filler materials for breast augmentation such as hydrogel and saline. At the time, the advantages of hydrogel implants were thought to be their high viscoelasticity and natural feel. However, they were withdrawn from the United Kingdom market in December 2000 due to insufficient preclinical testing of the filling material's metabolic fate [2]. Hydrogel implants were used in Korea from 1999 to 2002 and there are some records of the official import of hydrogel PIP implants [1]. However, due to the short time frame of their use, there has been no extensive research on PIP hydrogel implants. Furthermore, there is almost no information on long-term outcomes, and only a few case reports have been published. Unfortunately, patients are unaware of the different types of implants due to the lack of reporting and the absence of an implant registry.

In one case report, 12 patients presented to an outpatient clinic with swelling, size change, and changes in sensation [3]. The patients underwent implant removal, and seven of them were found to have an intracapsular rupture, while five were found to have an extracapsular rupture. Another study discussed the imaging characteristics and clinical outcomes of the PIP hydrogel implant [4] and reported several cases of peri-implant fluid collection without a gross tear, as in our study. Those cases presented with intracapsular rupture findings on MRI. In contrast, where MRI revealed extracapsular rupture, there was a gross tear in the implants but no peri-implant fluid collection. More research is needed to determine whether peri-implant fluid collection without a gross tear can be considered a classic rupture finding. It has been proposed that hydrogel implants degrade spontaneously due to osmotic hydrogel filler leakage into the surrounding capsule [4]. A foreign body reaction to the hydrogel substance results in the formation of a seroma collection as well as issues associated with increased osmotic pressure that can lead to implant rupture. However, not all implant ruptures result in capsular collapse, as in our case. The intracapsular fluid collection was formed by the hydrogel coming out from the implant and spreading out. The fluid and hydrogel diffused through an osmotic pressure gradient, and when the osmotic pressure became equivalent the capsule did not collapse, creating a so-

called "intracapsular rupture" [3].

In our case, the patient complained of left breast swelling and pain. She underwent MRI and ultrasonography, both of which revealed abnormalities. MRI depicted diffuse wall enhancement on the left extracapsular space, and there was non-mass enhancement with T2 high signal intensity around the implant at 5 o'clock (Fig. 1A) that suggested extracapsular rupture with inflammation. Extracapsular rupture of hydrogel breast implants is characterized by high signal foci in the silicone suppression view, which differs from silicone implants (Fig. 1B). The MRI finding was consistent with the intraoperative finding, demonstrating the predictive value of MRI in detecting implant rupture, as well as the filler material of the implant. In the current case, the implant was minimally collapsed without a gross tear, but serous fluctuating fluid was discovered inside. The fact that most of the fluid did not flow out of the implant distinguishes it from other implant rupture cases [1,5-9].

Many social issues concerning breast implants have recently been raised. Because of a critical complication (i.e., breast implant-associated anaplastic large cell lymphoma), Allergan Biocell textured implants were withdrawn from the market. The BellaGel microtexture implant has been halted following the discovery of the illegal use of unapproved materials. Some patients even complain of a cluster of symptoms such as fatigue, memory loss, and joint pain after receiving breast implants that improves after the implants are removed, a condition known as breast implant illness [4]. Breast implants are receiving more attention than ever. Most patients want to confirm their safety by undergoing imaging tests, and some even demand that their implants be removed.

Before the official approval of silicone implants by the Korean MFDS in 2007, many other implants such as hydrogel and triglyceride implants had been used. Even though the hydrogel PIP implant was removed from the Korean market in 2002, there have been reports of PIP hydrogel implants being used during this period. Those patients who had augmentation mammoplasty with PIP hydrogel implants may still have them in their breasts. Several reports describe the rupture of PIP hydrogel implants [3,5] and it should be noted that while some of these cases exhibited typical signs such as the linguine sign, keyhole sign, and noose sign, others were suspected based on atypical signs.

NOTES

Conflict of interest

No potential conflict of interest relevant to this article was reported

Patient consent

The patient provided written informed consent for the publication and the use of her images.

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