A review of PIP implant ruptures

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Introduction
Poly Implant Prothèses (PIP) breast implants were manufactured by a French company between 2001 and 2010. Concerns raised in March 2010 regarding the product ingredients, and a higher observed rate of implant rupture in comparison to the other third generation implants, resulted in cessation of their manufacture and subsequent company closure. The main concerns with PIP implants relate to the use of lower molecular weight industrial-grade silicone rather than the advocated medical-grade silicone, and also a variability in the thickness of the implant shell leading to increased permeability and rupture. Several studies since have demonstrated a significantly weaker mechanical strength of the PIP implant capsule, with some studies also suggesting possible in vivo implant capsule degradation over time.

It is estimated that approximately 400,000 PIP implants have been sold worldwide. In the UK, around 47,000 women had these implanted, the majority being in the private sector for cosmetic breast augmentation. Following the PIP scandal, an expert panel chaired by Sir Bruce Keogh was appointed by the Department of Health to assess the situation. In June 2012, the panel concluded in their final report that “PIP implants have not shown any evidence of significant risk to human health.”

However, the Medicines and Healthcare Products Regulatory Agency (MHRA) has since advised clinicians to contact all women with PIP implants, including those who are asymptomatic, for a specialist consultation and “appropriate investigation” of the implants. This, along with significant patient anxiety, has resulted in an unexpected increase in PIP implant imaging. Media attention focussing on a possible link with a rare form of cancer, anaplastic increase in PIP implant imaging. Mammography has a limited role to play in implant assessment. It can be useful if an ECR is suspected when mammography, especially the Eklund views, can demonstrate gel leakage as a high density area similar to silicone density seen in the breast parenchyma surrounding the implant (silicoma, figure 1). Due to the compression required with mammography it does, however, carry a risk of causing an implant rupture or converting an ICR to an ECR. Mammography is therefore not routinely advocated in implant assessment.

Ultrasound
Ultrasound (US) is a good first-line investigation, especially in symptomatic women, as it is readily available and cost-efficient. The sensitivity of US in implant rupture is 77% with a specificity of 69%. The main limitations of US are reverberation artefact and the inability to see the posterior aspect of a very large implant.

ICR is often seen as the linguine sign where the collapsed implant shell is seen as multiple echogenic lines within the silicone gel. Occasionally in PIP implants, subtle ICR can be seen as a thin echogenic line along the outer aspect of the implant shell.

Pitfalls: Radial folds can sometimes mimic an ICR, and US reverberation artefact may be misinterpreted as a subtle ICR.

ECR is often identified as an area of diffuse echogenic shadowing (‘snowstorm’ appearance, figure 2) within the breast tissue corresponding to the site of gel leak (silicoma). In the axilla, similar appearances are seen where the involved lymph nodes demonstrate increased echogenicity.

Pitfalls: Normal lymph nodes with a prominent fatty hilum occasionally demonstrate higher echogenicity and this should not be misinterpreted as silicone uptake.

Magnetic resonance imaging
Magnetic resonance imaging (MRI) is considered the gold standard, with a sensitivity of 96% and a specificity of 78%, and is the investigation of choice when assessing implant integrity. While it has the advantage of assessing both breasts and axillae simultaneously, the implant-selective MRI sequences do not help in excluding other breast pathology. Issues with MRI availability and higher patient costs are other limiting factors.

STIR and selective silicone sequences are the most useful in implant assessment. By adding water suppression to the STIR images, a selective silicone-bright sequence can be achieved, which is often diagnostic.

ICR is usually seen as the linguine sign (figure 3), similar to that seen on ultrasound. Subtle ICR is seen as the keyhole or noose sign where silicone signal is seen on either side of an opposing implant shell. Occasionally water droplets are seen mixed with the silicone in the implant (figure 4), which is again indicative of breach of the implant shell especially when there are no overt signs of ICR. ICR is frequently associated with an increase in peri-implant fluid, especially when compared to the normal opposite breast.

Pitfalls: Radial folds often mimic ICR, but in the former they are usually seen to extend to the periphery of the implant with none of the other signs of ICR. Incomplete water suppression can also lead to misinterpretation as leaked silicone.
ECR is often identified as high signal foci similar to silicone, which are seen within the breast parenchyma (figure 5). It is often associated with features of ICR. Similar bright silicone signal is seen in the axillary lymph nodes when there is silicone adenitis.

**Pitfalls:** Cysts also appear as high signal foci on the STIR sequence but these are suppressed on the silicone-selective sequences.

**Conclusion**

Due to the difference in the thickness of the implant shell in PIP implants, identification of subtle intracapsular rupture on US can often be challenging. A lower threshold for further investigation with MR imaging is strongly recommended, especially if surgical removal is being contemplated. With a higher chance of medicolegal implications, it is essential to be aware of potential pitfalls to avoid any misinterpretation in these cases. Due to the inadequacies in their construction, the lifespan of PIP implants is likely to be shorter than that of their counterparts, which is estimated at ten years. This should therefore be considered carefully when imaging asymptomatic women, as intracapsular rupture can often remain silent.

In spite of no reported instances specific to PIP implants, it is worth being aware of rare but known association between anaplastic large cell lymphoma (ALCL) and breast implants.

Although media interest appears to have lessened since the initial scandal in 2011, it only takes one mistake to bring the issue back into the spotlight. National guidance would therefore be helpful to standardise the imaging and management of these women to avoid any future problems, as we are likely to be imaging the existing PIP implants for at least another ten years.

**References**

Figure 4
MRI STIR with silicone-suppressed sequence, showing left ICR as multiple high signal water droplets (thin arrow) seen within the low signal silicone, often associated with increased peri-implant fluid (thick arrow) on the ruptured side.

Figure 5
MRI STIR with silicone bright sequence demonstrating features of both ICR and ECR. High signal silicone is seen outside the implant shell but within the fibrous capsule (black arrow) and areas of high signal free silicone are seen within the breast parenchyma (thick white arrows). Silicon uptake is also seen as high signal within a right internal mammary lymph node (thin white arrow).