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CASE REPORT

A late complication following the insertion of hydrogel breast implants

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Summary This case report draws attention to an unusual presentation and subsequent complication following the insertion of a PIP Hydrogel[®] implant for breast augmentation. A cutaneous and capsular foreign body giant cell reaction was identified, and was preceded by the development of a notable increase in breast volume prior to spontaneous discharge. We believe that this was caused by subclinical leakage of the implant contents through a degrading shell. The biodegradability of hydrogel makes it impossible to ascertain the precise nature of the material that leaked out. Given this demonstrable leakage, the adverse clinical effects and the potential for toxicity that is currently unknown, we question whether this product (and other hydrogel breast implants like it) should be formally recalled for the benefit of patient safety.

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The controversy concerning silicone gel implants in the 1990s, followed by the recall of trilucent breast implants in 2000, has encouraged alternative solutions for breast implant fillers. Hydrogel[®] breast implants, manufactured by Poly Implant Prosthesis (PIP) in France and supplied in the UK by Clover Leaf Products, were first

introduced on to the market for their use in breast augmentation in 1994.¹ Approximately 4000 women in the UK have undergone breast augmentation with these implants.² Hydrogel[®] breast implants have a silicone elastomer shell and are filled with a hydroxypropyl cellulose polysaccharide gel. As a result of a series of investigations into the safety of implant fill materials, a Medical Devices Agency (MDA) review identified inadequacies relating to the manufacturer's biological safety standards, long-term toxicity data collection and clinical follow-up studies. Particular

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concerns were raised over the metabolic fate of the filling material, and the pathological effects following implantation of this hydrogel directly into experimental animals.¹

After accepting those concerns, and as a precautionary measure, the manufacturer voluntarily withdrew PIP Hydrogel breast implants from sale in the UK market in December 2000 until sufficient data are made available on their longevity and overall safety, although there is no evidence at this stage to recommend explantation on health grounds. At the time of writing, only one adverse incident (involving filler leakage) has been reported and no specific risks have been identified concerning their use.¹ Indeed despite these precautions, a number of European authors have commended the use of hydrogel implants, citing low risks of capsular contracture and the absence of major complications in their series studied.^{3,4}

The following case report highlights a complication using PIP Hydrogel[®] breast implants and reviews the literature surrounding possible complications of the use of hydrogel implants in breast augmentation.

A 44-year-old female underwent bilateral breast augmentation in 1999 for cosmetic reasons. The bilateral, sub-glandular, placement of 240 cc Hydrogel[®] breast implants (PIP/Clover Leaf Products Ltd.) were used at the patient's request. Follow-up six months later was unremarkable other than minimal capsule formation, which was asymptomatic.

Four years later, she re-presented to her General Practitioner complaining of a non-tender "lumpiness" in the lower aspect of her right breast and concern about the change in breast size. She was referred to her local breast surgeon who noted on examination that her right breast was significantly larger than her left side, despite symmetry immediately post-operatively. She described some non-specific discomfort from the right breast. The breast showed no fluctuation in size in relation to menstruation and the patient was systemically well at all times. An ultrasound scan of the breasts at this time illustrated some fluid surrounding the implant on the right side, and subsequent MRI demonstrated cystic changes within the right breast with the suspicion of implant rupture. The patient was re-referred back to her original plastic surgeon.

Two weeks prior to her plastic surgery appointment, the patient developed a discharging, nodular sinus from the inferior aspect of the right breast along the original infra-mammary scar (Fig. 1). On examination, both breasts were soft and non-tender and the patient was afebrile.



Figure 1 Right breast infra-mammary scar with discharging sinus of hydrogel implant contents.

Her white cell count was $8.0 \times 10^9/l$ (range: 4.0–11.0). Following these findings, both hydrogel implants were removed and found to be intact, capsulectomies performed, and bilateral replacements with silicone gel implants.

The right infra-mammary scar was excised and sent for histology. On removal of the intact implant, copious amounts of yellow/green, non-purulent fluid was collected from the right breast pocket (Fig. 2). Histologically, the lumpy



Figure 2 Contents of hydrogel implant drained from within capsule.

infra-mammary scar revealed extensive foreign body giant cell reaction and fat necrosis, consistent with a foreign body giant cell reaction to leakage of hydrogel material through the intact wall. The adjacent fibrous capsule contained large numbers of foamy histiocytes. The patient went on to make an uneventful post-operative recovery.

Discussion

Many different types of hydrogels are used in a wide variety of products including pharmaceuticals, foods and medical devices, such as contact lenses and surgical dressings. As polymeric materials, hydrogels have the ability to swell in water without dissolving and are able to retain water within their structures.² This particular phenomenon made injectable hydrogel, directly into breast tissue, a cheap and easily performed alternative to breast augmentation for more than 10 years in some countries including Russia and China.^{5,6} Christensen et al.⁵ examined breast tissue samples from a total of 27 women who had polyacrylamide hydrogel injected for aesthetic purposes at Kiev City Hospital over an eight-year period. Histological findings of the breast tissue revealed collections of macrophages and foreign body giant cell reactions in the surrounding tissue of 19 patients, with granulomas seen in up to six patients.⁵ This observation would appear to support our findings in which there was evidence of exposure of hydrogel directly to both the capsule and subcutaneous tissues giving rise to a foreign body giant cell reaction. One study did evaluate the tolerability of 20 hydrogel breast implants and reported no complications, but this was in only 12 consecutive patients followed up for a limited period of 3.5 years.⁴

This case report also highlights the patient's anxiety concerning the apparent increase in the size of her right breast on presentation, four years after her original surgery, and before the onset of the spontaneous discharge from the sinus at the

infra-mammary scar. This phenomenon may be explained by the leakage of the osmotic hydrogel filler from the implant into the surrounding capsule. A number of studies have shown that hydrogel breast implants can swell in vivo^{7,8} with some implants increasing in volume up to 38%, which was cited as the main reason for their removal after an average of four years.⁹ It is likely that the increase in the patient's right breast in this case was caused by her Hydrogel[®] implant undergoing spontaneous, direct degradation with content leakage into the surrounding capsule. There is no data in the literature concerning the degradation potential of hydrogel implants or to the potential toxicity of any degradation products on the surrounding silicone shell or biological tissues.

We believe that, despite the lack of evidence in support of its safety, these types of implants should be formally recalled.

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