In response to 'A late complication following the insertion of hydrogel breast implants'

The experience of Adams et al.[1] following explantation of a PIP Hydrogel implant is consistent with that of several other UK plastic surgeons who have reported problems to the Medicines and Healthcare products Regulatory Agency (MHRA). The product was recalled from the UK market in December 2000 following an MHRA investigation that revealed inadequate pre-clinical testing. At that time, there was no evidence of toxic effects that would indicate the need for prophylactic explantation and, prior to this, MHRA had received only one report of a problem with this implant. This concerned implant rupture associated with capsular contracture and the presence of approximately 30 ml of straw coloured fluid in the breast pocket. Since the product was withdrawn, around 50 cases have been reported to MHRA, in which breast swelling has typically been associated with the presence of fluid in the pocket surrounding the implant. The manufacturer, PIP, has carried out testing of the periprosthetic fluid, when it has been made available for investigation. However, to date, no new information of clinical significance has come to light either on the nature of the periprosthetic fluid or on any degradation products of the filler material.

On the other hand, reassurance has been obtained regarding the toxicity of the implant filler. Since recalling the product, the manufacturer has sponsored long-term toxicity studies in rats and MHRA has obtained advice on the results of these from the Committee on Toxicity.[2] This committee concluded that the results suggested that subcutaneous exposure to the hydrogel filler would not lead to toxic effects in women with these implants.[3] The Committee did, however, express concern about the lack of long-term follow up of women with hydrogel-filled breast implants.

MHRA continues to monitor the safety of PIP Hydrogel and other breast implants and, based on the currently available evidence, does not recommend that women with hydrogel-filled breast implants should have them removed unless they are experiencing problems.

Further information on the safety of breast implants and details of how to report adverse events are available from the MHRA website.[4]

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4. http://www.mhra.gov.uk/mhra/breastimplants

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Rupture of PIP breast implants

Further to the case report: Locoregional silicone spread after high cohesive gel silicone implant rupture (Lahiri and Waters, *J Plast Reconstr Aesthet Surg* 2006;**59**:885—6), I write to report a similar case, again involving an implant manufactured by Poly Implant Prostheses, France.

In this case, AP, a thirty-six-year old woman was referred by her GP to a breast surgeon with a lump in the right axilla. She had undergone bilateral augmentation with saline implants eight years previously and, following deflation on the right, these had been exchanged for PIP cohesive gel five years later.

The breast surgeon confirmed the presence of an enlarged right axillary lymph node and noted that the right breast was larger than the left. He performed excision biopsy of the node, histology of which showed vacuolated cells, foamy macrophages and multinucleated giant cells in keeping with a silicone lymphadenopathy.

She was referred to me and at exploration of the right breast I found, like Lahiri and Waters, that there was huge tear in the shell of the implant (Fig. 1).

The cohesive gel had remained in situ but the implant was surrounded by a considerable quantity — approximately 50 ml — of cloudy, viscous fluid, presumably serous in origin, which explained the enlargement of the breast.

That a high cohesive gel implant could have suffered such a massive failure only three years after implantation is very worrying and, in this case, not only had silicone migrated to a regional lymph node, but the exposed silicone gel appears

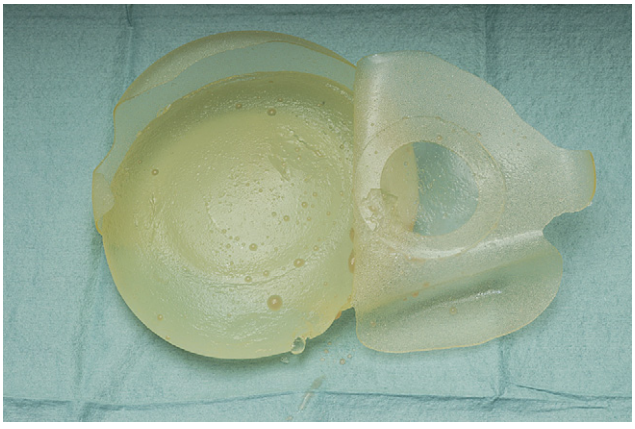

Figure 1 Implant removed from breast showing huge tear.

to have provoked an inflammatory response with the production of a significant quantity of serous exudate.
In view of these two reports the reliability of PIP implants must be questioned and, for myself, I intend to discontinue their use in favour of implants from other manufacturers.

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Tissue expanders in post-burn alopecia: supragaleal or subgaleal placement?
In response to: Prakash, Tandon, Mantri 'Supragaleal placement of tissue expander for post-burn alopecia' Journal of Plastic, Reconstructive & Aesthetic Surgery 2006;59:1102—1104

In your paper 'Supragaleal placement of tissue expanders for post-burn alopecia' you advocate, in three cases, that this technique gives the best results compared to those when the subgaleal plane is used,[1] as supported by most surgeons.[2—5] We believe that galeal tissue is important to protect the integrity of the hair follicles, preserving their circulation during the procedure and the expansion.[5]

We believe that your high incidence of dehiscence (10 out of 13) when placing expanders under the galea may be caused by the long incision made at the junction of the hair-bearing and nonhair-bearing scalp, as shown in your paper. We prefer to do two small incisions in the extremities of the area to be expanded from 0.5 to 1 cm inside the tissue with hair follicles[5] or in a distant area from the cicatricial tisssue or, as described by others,[2] in a perpendicular direction to the expander axis with no dehiscence out of 32 patients,[2] but never in the cicatricial área.

We prefer to do a slow expansion to preserve the integrity of the hair follicles[5] and to promote a nonpainful expansion. The excessive bleeding observed in your cases may lead to more reactive tissue around the prothesis; that is when the vessels need to be cauterised, causing injury to the hair follicles leading to local alopecias. Larger and comparative studies must be done to change the traditional procedure as you said in the paper.

We still use traditional procedures with good results.

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Comment on 'Reconstruction of pectus excavatum with silicone implants'

Margulis et al. are to be congratulated on the excellent aesthetic results which they have obtained using customised silicone implants for correction of the aesthetic abnormality associated with pectus excavatum in the adult population.[1]

It is, however, important to distinguish this group from a paediatric population whose chest walls are more amenable to correction of the anatomical abnormality due to the increased malleability of the paediatric chest. Historically, treatment for pectus deformities was mutilating, destructive of the thoracic skeleton and associated with significant morbidity. Good or excellent results can now be obtained in 90% of individuals using safe and established, minimally invasive techniques.

In this group there is no doubt that anatomical correction offers cosmetic and psychological benefit to the patient, but there is no reliable evidence to support a consistent improvement in respiratory or cardiac function. Despite this there is a widespread perception by parents that the child's stamina increases after successful repair of a pectus deformity and self-esteem improves dramatically.[2]

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