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The PIP mammary prosthesis: A product recall study☆

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Summary *Introduction:* Concerns about the durability of silicone breast implants manufactured by Poly Implant Prothèse (PIP) have been expressed for several years prior to their formal withdrawal from the market in March 2010. Although precise details of what elements were at fault remain unclear, concerns have been raised about both the elastomer and the filler gel. Media speculation has focussed on device safety, longevity and, recently, a possible association with lymphoma, specifically anaplastic large cell lymphoma (ALCL). There is however, no actual data concerning these implants with which to guide and inform when concerned patients seek advice.
Patients and methods: PIP mammary prostheses were used by the senior author for both primary and revision breast augmentation (BA) during the period January 2000—August 2005. A database of patients was constructed and attempts made to contact each patient offering a free consultation and referral for ultrasound scan (USS). Chief outcome measures included secondary surgery, the implant rupture rate and time to rupture.
Results: 453 consecutive patients with PIP devices were identified. Of this number 30 had already undergone implant exchange for a variety of reasons. 180 (39.7%) could not be contacted and 19 had undergone explantation elsewhere, including the NHS. Of those who could be contacted, 47 declined consultation as they had no concerns. 97 had neither clinical signs nor radiographic evidence of implant rupture and elected to remain under regular review. At the time of writing, 38 have undergone implant exchange after ultrasonographic indication of rupture and the overall patient rupture rate for the PIP implant is 15.9—33.8%. This cohort correlates reduced implant longevity with each successive year from 2000 and no cases of ALCL have been diagnosed.
Discussion: Long-term studies such as this are difficult to undertake for a number of reasons as they place a significant additional burden of resources on a practice. They are, however, essential from an industry perspective both for the provision of information and supporting

☆ Initial results from this study were presented at BODY Conference, Royal Society of Medicine, London November 2011.

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audit and professional standing. Being only a single-handed practice, this initial study is the tip of an iceberg that may affect 40,000 women in the UK with PIP implants, but it does provide some hard data with which to guide our patients. It is also believed to be the first independent product recall study in aesthetic breast surgery.

Introduction

On March 31st 2010, the Medicines and Healthcare products Regulatory Agency (MHRA) issued a warning leading to the immediate withdrawal of mammary implants from the French manufacturer, Poly Implant Prothèse (PIP), due to serious concerns about the quality of gel filler.[1] Subsequent tests by both the British MHRA[2] and French Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS)[3] have fortunately allayed fears of genotoxicity. There has been speculation about an unusually high rupture frequency of PIP's implants over recent years as recognised recently by AFSSAPS,[3] although the equivalent Australian body, the Therapeutic Goods Administration (TGA), did not show this on their supplied samples.[4] Whilst the senior author had ceased using these devices completely in August 2005 and other independent surgeons had followed suit,[5] many of the 'cosmetic companies' had been using PIP implants right up until the ban on account of their favourable cost. Most recently (December 21st 2011), the MHRA had to issue a further alert in response to the publicity surrounding the death from ALCL of a French patient with PIP devices. This same alert stated the rupture rate of PIP prostheses — as measured by reports to the MHRA — to be of the order 1%.[6]

PIP has had a somewhat chequered history with their earlier Hydrogel implant also withdrawn from the market because of late, inflammatory swelling.[7] With regard to PIP's high cohesive gel implant, loco-regional silicone spread was reported in 2006[8] and a case of systemic cutaneous dissemination in late 2011.[9] Whilst not considered injurious to health in the long-term,[10] presentation with either breast masses or palpable lymphadenopathy because of silicone dissemination, adds an additional emotional burden of the spectre of cancer, notwithstanding the extra resources involved in investigating this cancer-prone organ. Albeit rare, idiosyncratic granulomatous reactions requiring aggressive debridement and reconstruction have been reported.[11]

Whilst placing the present outcomes in perspective, published literature often combines different implant generations,[12] manufacturers and techniques including cosmetic admixed with reconstructive,[13,14] which serve to introduce bias and makes direct comparison difficult. Even device-specific studies generally involve either heterogeneous surgeons and/or techniques[15–18] so the clarity of the outcome may be clouded somewhat. With a single-surgeon, constant-technique cohort of several hundred patients since 2000, we present what is certainly homogeneous and may well be the first independent product recall study of a medical device.

Patients and methods

Women were eligible for inclusion in the study on the basis of having undergone breast augmentation with PIP mammary prostheses after January 2000. The senior author had evolved over more than 15 years a standard and reliable technique of trans-axillary, submuscular breast augmentation (TABA). Implant exchange utilised the axillary route except in cases either where rupture had been demonstrated radiologically to avoid silicone contamination of the axilla. An inframammary approach was also used where capsular surgery was anticipated. This took one of two forms: thin, pliable capsules were subjected to capsulotomy. On the other hand, thick, contracted, silicone-impregnated capsular tissue led to capsulectomy.

A part-time researcher appointed in July 2010 identified all patients who had undergone breast augmentation with PIP implants from January 2000—August 2005. The database constructed contained demographic and implant-specific details. Chief outcome measures included secondary surgery in general, implant integrity and time to rupture. Correlation of imaging at explantation was also evaluated and will be analysed and presented in a separate study. All patients identified were sent an initial letter detailing the MHRA guidance and offering a free, without-obligation, consultation. Non-responders were then approached to optimise the recall by telephone and/or email until all avenues were exhausted. At consultation, the patient's desire and/or clinical examination dictated further management, but all were encouraged to undergo an ultrasound scan (USS) with a breast-specialist team. Joint BAPRAS (British Association of Plastic Reconstructive and Aesthetic Surgeons) and BAAPS (British Association of Aesthetic Plastic Surgeons) guidance includes the following[18]:

- all patients being able to have an assessment by a surgeon, whether symptomatic or not
- implant removal should be undertaken upon patient request and adequate time for reflection should be allowed
- because radiological scans are not completely reliable, they should only be used as a tool to assist patients' decision-making
- advice to general practitioners on where to most appropriately refer patients

Results

Between January 2000 and July 2005, 453 consecutive patients underwent primary (209) or secondary (244) breast augmentation with PIP implants. The median age was 38