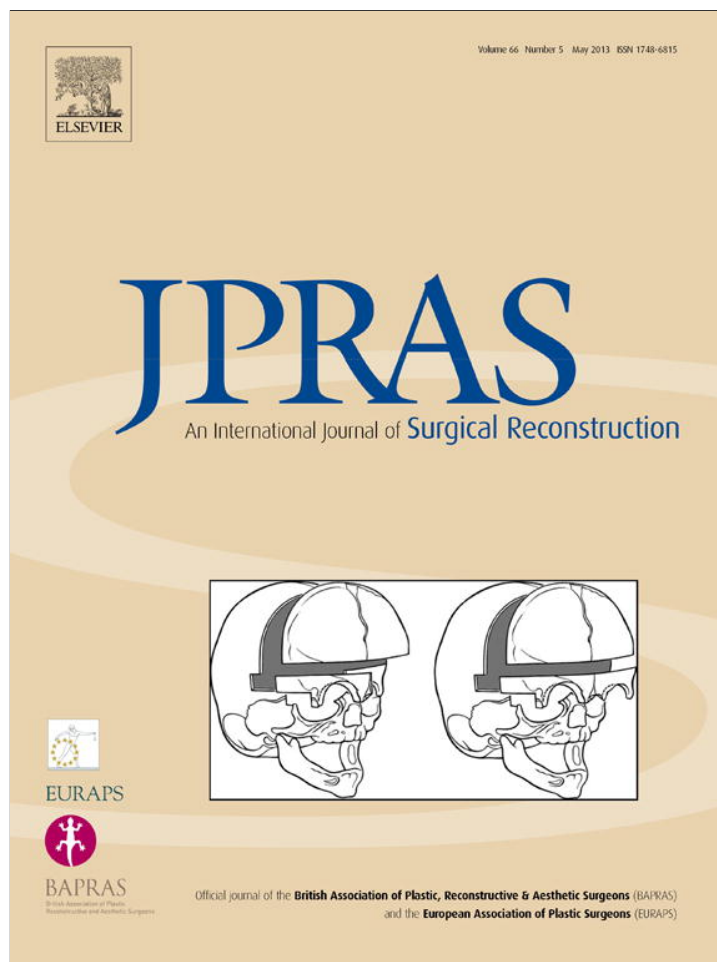


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## CORRESPONDENCE AND COMMUNICATION

### A single surgeon's experience of the PIP breast implant "saga": Indications for surgery and treatment options

Dear Sir,

The French company Poly Implant Prothèse (PIP) has recently been at the centre of international outcry having fraudulently used industrial grade silicone in the manufacture of their implants which are more prone to rupture.<sup>1</sup> Approximately 47,000 women in the UK and 400,000 worldwide have had these devices implanted.<sup>2</sup> As a consequence of the anxiety created by the PIP implant scandal, increasing numbers of patients have presented to plastic surgeons seeking assistance.

#### Methods

We identified six consecutive private patients with ruptured PIP implants and reviewed their medical notes to determine the presentation, mechanism for identifying implant rupture, the in-situ duration of the implants and the revision operation undertaken.

#### Results

##### Presentation

The average age of the six patients was 42.5 years (range 34–59) and median duration of PIP implant being in-situ was just over five years (range 2–11). All primary procedures had been performed in cosmetic clinics in the UK by practitioners who were not plastic surgery accredited. All patients had at least two of the following five features: (i) breast discomfort (ii) axillary discomfort, (iii) breast swelling (iv) axillary swelling, or (v) change in breast consistency (Table 1).

##### Investigations

Two patients underwent breast ultrasound imaging while four had MRI scans. All investigations identified extracapsular

implant shell rupture with a positive "linguini" sign. Silicone granulomata were also visualised with MRI.

#### Intraoperative findings and management

Intraoperative findings were:

- Implant rupture; unilateral in five patients, bilateral in one (B)
- Purulent material in pockets; five patients (A,B,C,D,F)
- Thickened capsules; five patients (B,C,D,E,F)
- Enlarged lymph nodes; four patients (B,C,D,F)
- Granulomata; three patients (B,C,D)

Intraoperative findings revealed at least one ruptured implant in every patient while five had severe bilateral capsular contracture with silicone extravasation with purulent material in the pockets. Half of the patients presented with soft tissue silicone granulomata. A series of intraoperative findings are shown in Figure 1C.

All patients required bilateral total capsulectomies. Five of the six requested implant exchange, and these all were placed in a different pocket, from subglandular to subpectoral to ensure improved cosmesis and reduce the risk of recurrent capsular contracture (Figure 1A). Three patients underwent ancillary procedures comprising excision of enlarged silicone-filled lymph nodes from the axilla, and silicone granulomata from the breast.

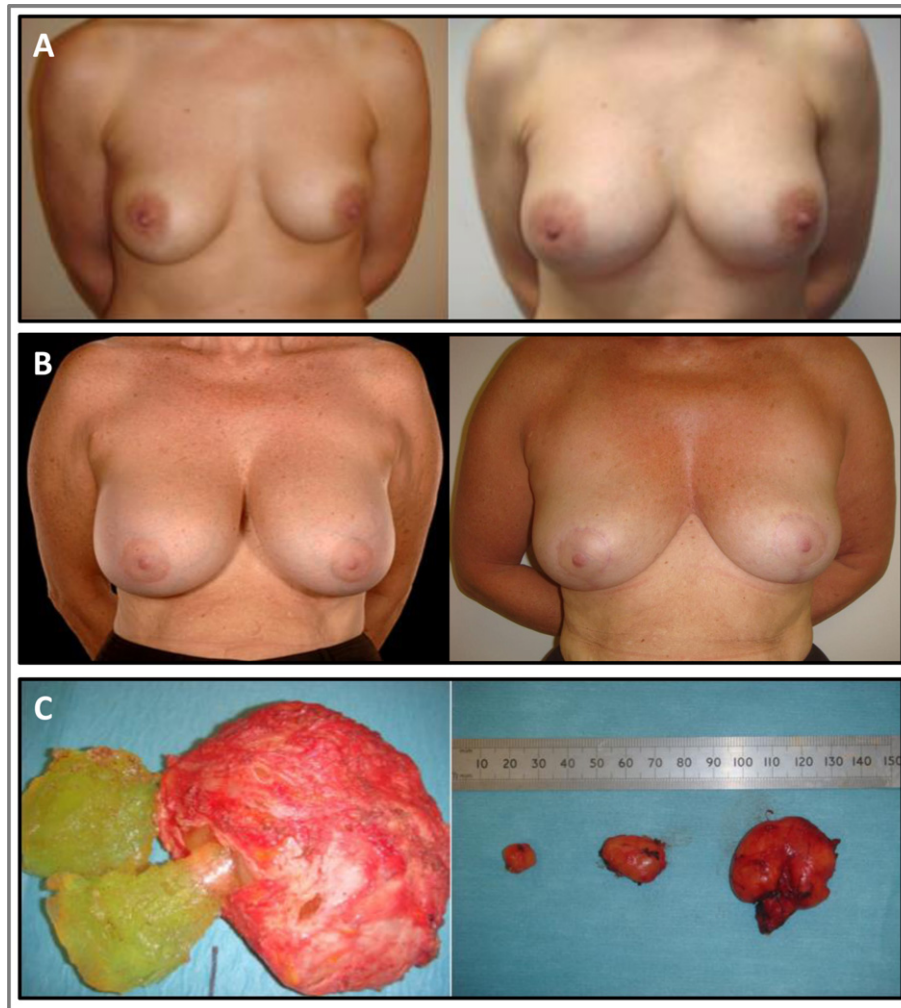
Due to severe anxiety, one patient specifically requested insertion of saline implants. Another patient declined implant exchange as she attributed her Parkinson's disease and Chronic Fatigue Syndrome to silicone despite reassurance to the contrary. She went onto have a mastopexy to ensure the cosmetic results of explantation were acceptable (Figure 1B).

#### Discussion

All patients presented with pain or discomfort, swelling or changes in appearance of their breasts and axillae. Almost all required further investigations prior to corrective surgery. Investigations confirmed ruptured implants and silicone granulomas in the breast and axilla.

**Table 1** Summary of presentation, investigations and management of the six PIP implant rupture patients.

Patient	In-situ duration (months)	Presentation					Clinical diagnosis	Investigations		Intraoperative findings correlation with clinical diagnosis	Management				
		Breast discomfort	Axillary discomfort	Breast swelling	Axillary swelling	Change in breast consistency		USS	MRI		Capsule	Implant	Pocket	Ancillary	Skin
A-45 years	60	Y	—	Y	—	—	Ruptured R Soft capsule	—	—	Y	-ectomy bilateral	Exchange (anatomical, silicone)	Subglandular to subpectoral	—	—
B-44 years	69	Y	Y	—	Y	—	Ruptured R/L Capsular contracture R/L Silicone lymphadenopathy	Y	—	Y	-ectomy bilateral	Exchange (anatomical, silicone)	Subglandular to subpectoral	Axillary granulomata excision	—
C-38 years	51	—	—	Y	—	Y	Ruptured R Capsular contracture R/L	—	Y	Y	-ectomy bilateral	Exchange (round, silicone)	Subglandular to subpectoral	Axillary granulomata excision	—
D-34 years	87	—	Y	—	Y	Y	Ruptured R Capsular contracture R/L Silicone lymphadenopathy and granulomata	Y	Y	Y	-ectomy bilateral	Exchange (round, saline)	Subglandular to subpectoral	Axillary and nipple areola complex granulomata excision	—
E-35 years	24	—	—	Y	—	Y	Ruptured L Capsular contracture R/L	—	Y	Y	-ectomy bilateral	Exchange (round, silicone)	Subglandular to subpectoral	—	—
F-59 years	132	Y	Y	Y	Y	Y	Ruptured L Capsular contracture R/L	Y	Y	Y	-ectomy bilateral	Removal	—	—	Mastopexy



**Figure 1** (A) This 44 year-old (Patient B in Table 1) presented with capsular contracture and changes in consistency of her breasts and was unhappy about their poor aesthetics. Post-operative photographs following bilateral total capsulectomies and implant exchange show improved symmetry and cosmesis despite the intraoperative finding of implants in different pockets. (B) Pre- and post-operative photographs of a 59 years old patient (Patient F) who had her implants in-situ for 11 years. She presented with systemic symptoms and radiologically ruptured implants and requested implant removal. Following bilateral total capsulectomies a superomedial 'T' scar mastopexy was needed to maintain good breast aesthetics. She is shown 8 months post-surgery. (C) Intra-operative findings from Patient B. Ruptured implants were found with disintegrated shells and thickened, contracted capsules and silicone-filled lymph nodes measuring up to 35 mm were excised from the axilla.

Surgery was necessarily more complicated than a typical revision requiring a total capsulectomies and replacement of the implants with pocket change or mastopexy to ensure acceptable cosmesis. Additional procedures included local granuloma excision, resection of clinically enlarged silicone-filled lymph nodes and wash-outs of extravasated silicone. The operations were therefore prolonged and technically challenging, while patients were required to stay in hospital for at least 48 h with drains in-situ. The cost to the patient rose in parallel with this degree of surgical complexity.

Based on our experience, we have devised an algorithm to manage patients with PIP implants (Figure 2). After clinical evaluation, we categorise the patients into one of three groups; those with and those without implant-related complications, and those with separate breast pathology. The latter group require urgent referral to breast cancer

services. The remaining groups may require breast imaging should they wish to keep their clinically intact devices. The surgical management can be divided into five operative components relating to the; (1) capsule, (2) implant, (3) pocket, (4) skin envelope and (5) ancillary procedures.

We recommend that all PIP implant patients have a total capsulectomy rather than a capsulotomy given the presence of extravasated silicone, the markedly thickened capsule and the florid tissue reaction observed intra-operatively with these devices. Depending on patient preference, the implant should be explanted or exchanged. On the assumption that most PIP implants were placed in the subglandular pocket, we advocate placement of the new implant into the subpectoral pocket. Use of this pocket will improve cosmesis by reducing implant visibility, rippling and the appearance of empty upper poles. It also reduces the rate of future capsular contracture.<sup>3</sup>

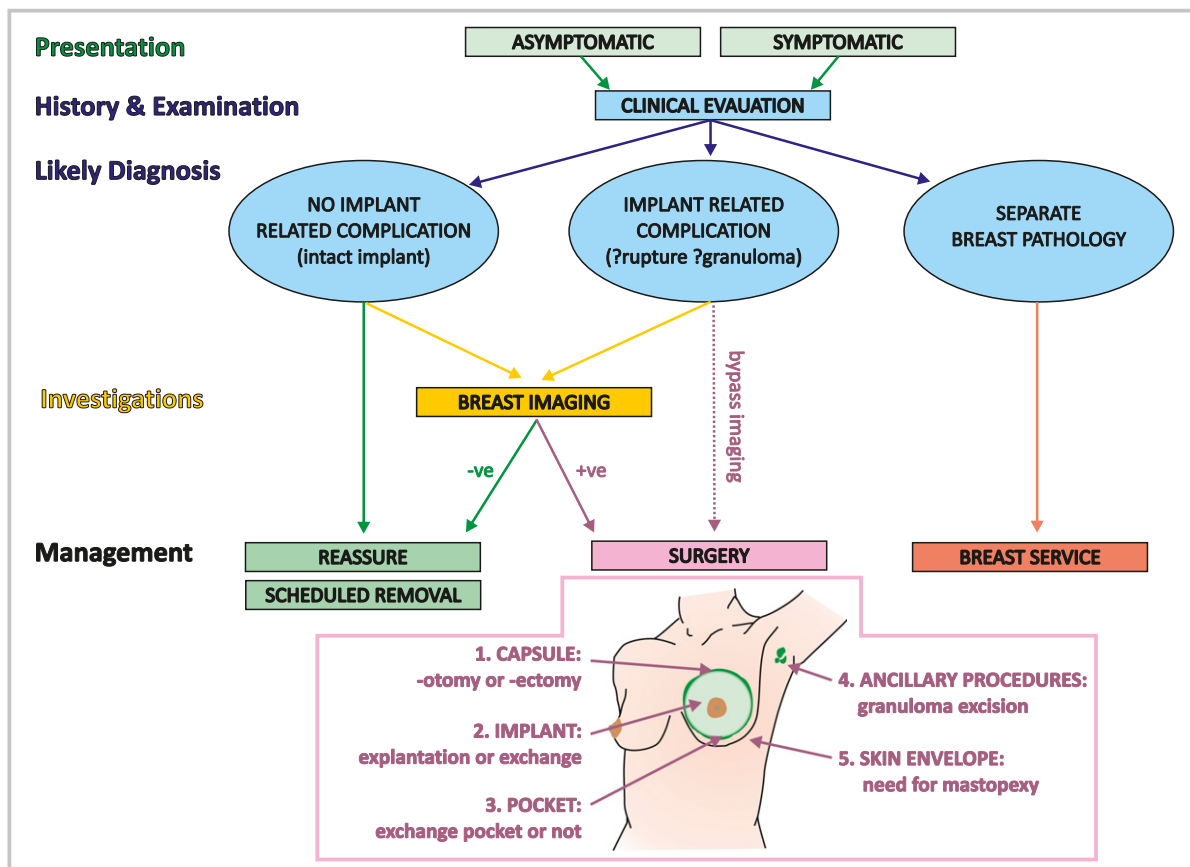


Figure 2 Proposed PIP implant management algorithm.

Mastopexy can be useful in countering the ptotic, deflated appearance seen if patients opt for explantation alone. This is especially so with the older patient. Lastly, ancillary procedures maybe required such as excision of symptomatic silicone granulomata in the breast, and enlarged lymph nodes in the axilla.

The PIP scandal has raised many issues for the government, regulators and clinicians. We look forward to improved regulation of the manufacturers, cosmetic surgery industry, and re-establishment of a National Registry of devices.

**Disclosures**

The patients were fully consented for the surgery and provided both verbal and written consent for the use of case histories in this article.

This article is not being considered for publication elsewhere nor has it been published by any other medical journal.

The senior author (CMM) received an honorarium for his advisory role to Allergan Medical Systems in October 2010. The authors have no other financial interests or commercial associations to declare in relation to the contents of this article. The senior author is also the President of the European Society for Surgical Research (2011–2013).

**Conflict of interest**

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C.M. Malata  
 Department of Plastic & Reconstructive Surgery,  
 Addenbrooke's Hospital, Hills Road,  
 Cambridge University  
 Hospitals NHS Foundation Trust,  
 United Kingdom

*Cambridge Breast Unit, Addenbrooke's Hospital,  
Cambridge University Hospitals NHS Foundation Trust,  
United Kingdom  
E-mail address: [cmalata@hotmail.com](mailto:cmalata@hotmail.com)*

*N.G. Cunniffe  
A.M. Blake  
School of Clinical Medicine, University of Cambridge,  
United Kingdom*

*N.G. Patel  
Department of Plastic & Reconstructive Surgery,  
Addenbrooke's Hospital, Hills Road,  
Cambridge University  
Hospitals NHS Foundation Trust,  
United Kingdom*

30 June 2012