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## The PIP mammary prosthesis: A product recall study<sup>☆</sup>

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### KEYWORDS

Breast augmentation;  
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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

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

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