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# Leak rate of faulty implants is 1 in 3 in the UK

*Sarah-Kate Templeton and John Follain* Published: 8 January 2012



The rupture rate of faulty PIP breast

Claire Quinn paid £4,000 last summer to have her PIP implants replaced (Bob Collier)

implants is as high as one in three, according to a new survey — at least 16 times higher than the rate previously claimed by the industry.

Two British surgeons carried out an audit of 453 patients and found between 16% and 34% of the French-made PIP brand ruptured. This compares with a failure rate of 0.9% among the new implants the surgeons are using.

The study, by Jan Stanek and Miles Berry, submitted to the *Journal of Plastic, Reconstructive & Aesthetic Surgery*, comes as the government said it could not obtain reliable data and as the cosmetic industry trade body claimed a failure rate of PIP implants of just 1%-2%.

The new figures will put pressure on the government to follow the recommendations of ministers in France, Germany, the Czech Republic and Belgium and to advise removal of the PIP implants.

Women who received the implants on the National Health Service will be able to have them removed without charge, with private firms expected to offer the same deal, the government has said.

If a private clinic does not carry out the procedure, the woman can have it done on the NHS — but will not be given replacement implants if the original surgery was for cosmetic reasons.

Mel Braham, of Harley Medical Group, which has given PIP implants to more than 10,000 women, said he would pay the cost of a new implant for patients but only if the NHS undertook to do the surgery.

Braham said: “The party responsible is the government and they do hold a responsibility to all the females. They have the ability to correct the situation; they have all of these hospitals at their fingertips.”

Stanek, a fellow of the Royal College of Surgeons and who runs a Harley Street clinic, said his study revealed that the failures were not simply a breach in the outer membrane. “It is not just a simple tear which allows silicone to leak outside the shell but a complete disintegration of the whole thing, a falling apart,” he said.

The new statistics come at the same time as an admission by Thierry Binon, former head of research and development at PIP (Poly Implant Prothèses) that he knew the implants were dangerous but his warnings were ignored.

PIP saved €10 (£8) on each implant by using its own home-made gel with industrial silicone rather than the medically approved silicone. At one point it was selling 100,000 implants a year.

Binon carried out his own tests which highlighted the gel’s unsuitability. When he told Jean-Claude Mas, the company’s founder, about the results, Mas said they were “rubbish”. Mas told police: “I knew that this gel wasn’t officially registered, but I did it knowingly because the PIP gel was less expensive . . . and of much higher quality.”

The fact that PIP went bankrupt in 2010 and that Mas, 72, faces criminal charges is small consolation to the 40,000 British women who have the implants. It also raises profound questions about how the cosmetic surgery industry is regulated in Britain.

Even at a time of crisis, some practitioners seem to view the PIP scandal as less of a medical problem and more of a business opportunity. Some are offering cut-price deals for the removal of the faulty implants and replacement with a respected brand.

Professor James Frame, president of the UK Association of Aesthetic Plastic Surgery, said: “There are still surgeons charging a consulting fee and full upfront payment for removal and exchange [of PIP implants they inserted].

“If women are having to pay a lot of money to these people, they should not go back to them. They should go to an accredited plastic surgeon.”

If the patients tend to blame the cosmetic surgery clinics for their predicament, the clinics, in turn, blame the Medicines and Healthcare products Regulatory Authority (MHRA).

Nigel Robertson, chief executive of Transform, one of Britain’s largest cosmetic surgery chains, said: “The MHRA has failed in its duty to monitor and . . . audit their [the implants’] use and must bear responsibility for this situation.”

Whoever is to blame, the human cost for the women involved is high. Anntina Moughan, 39, from

Crawley, West Sussex, faces having to breastfeed her baby in the knowledge that the implants have ruptured.

Moughan had heard about the worries over PIP implants 18 months ago and contacted the clinic that had carried out her surgery. "They told me not to worry, that these implants were the best in the business," she said.

She discovered her implants had ruptured in the same week she found out she was pregnant again. She has been advised that the implants cannot be removed until after the birth of the baby and fears for the health of the infant.

For other women, the pressure on cosmetic clinics to replace the implants without charge has come too late. Claire Quinn, 35, from South Yorkshire, paid £4,000 last summer to Birkdale Clinic in Rotherham to replace the PIP implants it had given her.

Quinn, who has a 15-year-old daughter and a six-year-old son, decided to have implants in 2006. In 2007 lumps appeared under her arms and she had pain in one of her breasts. Eventually the pain went away but last summer a friend mentioned the unfolding PIP scandal and she was immediately worried.

"I was just terrified by the idea of having this poison inside me which could leak at any moment," Quinn said. "In the end I felt so beaten down and frightened I just agreed to pay to have them removed."

Dr Promod Bhatnagar, owner of the Birkdale Clinic, said he could not afford to give free treatment. "Out of the goodness of my heart I have been replacing free implants, because I care about people," he said. "Now the government says they will pay for it, so the government should. In this case they were all approved implants. Everything was right. No one is going to die.

"If you need a liver transplant we don't go to the alcohol industry. If you need a gastric band we don't go to Burger King. I have no legal responsibility, I'm more than fulfilling my moral responsibility."

A number of clinics which carried out implant surgery have gone out of business. Becky Jones, 37, of Muswell Hill, north London, cannot find out whether her implants are PIP ones or not because the clinic she used, Rubicon, went into liquidation in December.

At his home on the Riviera, Mas is dismissive of the complainants. They are "fragile" money-grabbers, he says, and France's privacy laws mean he does not have to say anything.

That silence will have to end one day soon, though, when he appears in court on charges of aggravated fraud and manslaughter after a woman died following the rupture of an implant.

*Additional reporting: Kate Spicer, Kevin Dowling*