



Australian Government

Department of Health and Ageing

Advice from the Chief Medical Officer on PIP silicone breast implants and breastfeeding

In 2010, French authorities announced that the manufacturer of PIP silicone breast implants had been fraudulently substituting the silicone gel that had been authorised by regulators as being suitable for use in these implants, with another gel that had not been approved for this use.

Women with PIP silicone breast implants who have breastfed, are currently breastfeeding, or are contemplating breastfeeding their baby will understandably be concerned about whether there are any health risks to themselves or their baby from their implants.

Silicone is widely used – most teats on babies' bottles are made from silicone, silicone is used in nappy rash creams, children's medicines for colic and reflux, and silicone is also present in many cosmetics, hair shampoos, perfumes, and deodorants used by breastfeeding women.

Silicone compounds, including those found in PIP breast implants, have been the subject of intense scientific study for over 50 years, and are generally accepted as being safe for a wide variety of medical and other uses.

A major review of the safety of silicone breast implants published by the US Institute of Medicine in 1999¹ concluded that "there do not appear to be long-term systemic toxic effects from silicone gel implants or from unsuspected compounds in these gels or elastomers". A more recent (2007)² review again found no evidence that silicone breast implants had any toxic effects in pregnant or breast-feeding women.

Following the worldwide recall of these implants in 2010, the unauthorised gel used in PIP implants has been subjected to a considerable amount of scientific testing both in Australia and in other countries. Fortunately, none of the tests undertaken to date has shown the presence of any chemicals that are likely to pose a health risk for either a woman with the implants, or her baby during pregnancy or breastfeeding.

Analysis of the silicone used in PIP implants has to date only revealed the same chemicals that are present in other silicone implants, and biological testing has not shown any toxic effects on living cells of the silicone used in PIP implants. It is not uncommon for some silicone to remain in breast tissue following removal of any ruptured implant, but there is no evidence that this is a health risk, or that the risk would be any greater with PIP implants compared to others.

¹ <http://www.iom.edu/Reports/1999/Safety-of-Silicone-Breast-Implants.aspx>

² McLaughlin JK, Lipworth L, Murphy DK, Walker PS. The safety of silicone gel-filled breast implants: a review of the epidemiologic evidence. *Ann Plast Surg*. 2007;59(5):569-580

Consistent with current (May 2012) advice to Australian women with PIP implants from the Australian Chief Medical Officer³, the Medical Director of the National Health Service (NHS) in the UK has also recently (June 2012)⁴ released a report on this issue which noted that “Rigorous world-wide chemical and toxicological analyses of a wide variety of PIP implants have not shown any evidence of significant risk to human health”.

The recent NHS report also noted that “Silicone polymers of high molecular weight are considered highly unlikely to cross the barrier into breast milk and current advice from the MHRA [the UK regulator] is that women with PIP breast implants should continue to breast feed their infants. In theory it is possible that the lower molecular weight siloxanes could migrate into breast milk; the MHRA have therefore arranged for chemical analysis of a sample of breast milk from a patient with ruptured PIP implants and we will publish the results as soon as they are available. In the meanwhile we consider that there is no reason to depart from the current MHRA advice.”

In summary, most silicone compounds used in breast implants are too large to enter breast milk, and even if the implant ruptured and silicone directly entered a milk duct in the breast, the silicone is unlikely to have any effect on a breastfed baby. Although no specific studies of the smaller silicone compounds in breastfeeding women have yet been published using the PIP brand of silicone breast implants, studies of breast milk from women with other silicone breast implants have shown levels of silicone that are no higher than those found in breast milk from women without breast implants, most commercial infant formulas, and in supermarket milk.

There is no evidence that there is an increased risk to the child from breast feeding with a ruptured implant compared to an intact implant. Although the current advice is to have an implant removed if it has ruptured, this does not need to be done urgently unless the ruptured implant is causing symptoms. Decisions about when to cease breastfeeding and when to remove a ruptured implant are individual decisions that should be made by a woman in consultation with her surgeon.

Overall, these concerns underline the importance of informed consent prior to having breast implants - a woman contemplating this procedure who may wish to become pregnant or breastfeed should discuss these concerns with her surgeon prior to the operation, and ensure that she fully understands all the risks of the procedure, as well as its benefits.

In conclusion, the benefits of breastfeeding are well known, and extensive testing has not revealed any additional risks to a woman or her baby if PIP implants remain in her body during breast feeding without causing symptoms, whether or not the implants have ruptured.

Professor Chris Baggoley
Chief Medical Officer
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³ <http://www.health.gov.au/internet/publications/publishing.nsf/Content/PIP-breast-implants-report-CMO-toc>

⁴ <http://www.dh.gov.uk/health/2012/06/pip-report/>