

Update on Breast Implants : ALCL, and Breast Implant Illness

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ALCL

ALCL is not a breast cancer. It is a type of cancer of the immune system found in the fluid and scar tissue (capsule) around an implant. The disease is associated with textured and polyurethane covered implants, and has not occurred around smooth surfaced implants. Textured implants have the advantage of enabling the use of breast shaped devices (anatomic or teardrop), and also have reduced risk of capsule contracture.

Please visit my website www.davidglasson.co.nz for more information about ALCL.

There has been recent publicity about the **suspension of Allergan Biocell textured breast implants.**

These implants have now been **recalled**. What does that mean? A recall means that any Allergan Biocell textured implants held in stock by surgeons or hospitals must be returned to the distributor. This is to prevent any further use of the implants.

A recall does NOT mean that implants should be removed from patients who have them.

Why have Allergan textured implants been recalled? These implants have been identified as having a 6 times higher risk of Breast Implant Associated Anaplastic Large Cell Lymphoma (ALCL) than those made by other manufacturers . Therefore, health authorities in NZ, Australia, USA, France, and some other countries, have moved to suspend their further use.

Because ALCL is rare, no country has recommended the preventive removal of implants for patients who already have them. If you have no symptoms then no surgery is required to remove implants. Regular screening (checking) for ALCL is not recommended.

(The most common reasons for breast implant removal are unrelated to ALCL, e.g. implant rupture, capsule contracture, implant movement/displacement, and deterioration of the cosmetic result.)

The key message for patients is to be aware of any obvious changes in the breasts, and to report early for review. Plastic Surgeons know how to respond and investigate to exclude ALCL.

Most cases of ALCL occur many years after breast implant surgery. However, cases have occurred as early as 1 year after surgery, and at 30+ years later.

The first sign of ALCL is an obvious SWELLING of one breast. This is due to a large volume of fluid around the implant, inside the capsule. Most implants have a little fluid around them, seen on ultrasound. But ALCL causes a very obvious size increase. In that case, some fluid will be removed and tested for ALCL. Large fluid collections around implants are not always ALCL.

Women should consult their surgeon if they notice any swelling, a new lump, persistent pain, or any changes in the augmented or reconstructed breast.

In most cases ALCL is successfully treated with surgery to remove the implant and surrounding capsule. If the signs of ALCL are neglected, and the disease advances, then chemotherapy and radiotherapy may be required. Deaths have occurred.

To date, the FDA in the USA reports 573 cases worldwide, with the majority associated with Allergan implants.

What is the risk? The Australian TGA puts it this way :

Based on the currently available data, it is not possible to provide an accurate estimate of risk. Current expert opinion puts the risk of ALCL at between 1-in-1,000 and 1-in-10,000. Most (95%) of cases of breast implant-associated ALCL occur between 3 and 14 years after the implant (median: 8 years; range: 1-37 years).

It can be difficult to express this risk in a concrete way, such that you can make a fully informed decision about whether or not to have a breast implant. Some different ways of expressing the risk are given below:

- One woman will be diagnosed with breast implant-associated ALCL for every 1000 to 10,000 women with breast implants.
- Suppose we took 1-in-5000 women, the middle of the experts' range, as the best estimate of risk of ALCL in women who have breast implants. This would mean that, of 5000 women with implants, one woman will develop ALCL over a period of about 3-14 years following an implant; the other 4999 women will not develop ALCL.

The actual risk of ALCL for each individual patient with implants is low.

To give some perspective : the **lifetime risk** of a woman developing one of the **common types of breast cancer** is approximately 1 in 8.

For a **30 year old woman**, the risk of developing breast cancer in the following 10 years is 1 in 227; and from age 40 it is 1 in 68 (National Cancer Institute USA).

Useful links

1. www.davidglasson.co.nz
2. TGA Australia : <http://www.tga.gov.au/alert/breast-implants>
3. NZ Association of Plastic Surgeons : <http://plasticsurgery.org.nz/consumer-information/issues/breast-implant-associated-anaplastic-large-cell-lymphoma-alcl-fags/>
4. FDA, USA : <https://www.fda.gov/news-events/press-announcements/fda-takes-action-protect-patients-risk-certain-textured-breast-implants-requests-allergan>
5. American Society of Plastic Surgeons : <https://www1.plasticsurgery.org/search/?ref=/&q=alcl>

How do I find out about my implants? What type are they?

At the time of surgery you may have received information about your implant type, size and manufacturer. If you do not have this information, you can contact my practice and all the details are recorded in the operation note. The email address is info@davidglasson.co.nz.

The key message is :

Women should consult their surgeon if they notice any swelling, a new lump, persistent pain, or any changes in the augmented or reconstructed breast. If the surgeon is no longer in practice, or you live elsewhere, contact a GP for referral to a surgeon involved with implant surgery.

Breast Implant Illness : NZ Association of Plastic Surgeons statement 25 July 2019

A statement on breast implant illness

Breast implant illness is a term used by women who have breast implants and who describe symptoms of illness. These symptoms may include tiredness, chest pain, difficulty sleeping and depression. Women feel these symptoms are related to their breast implants.

A large number of studies have been carried out on the safety of silicone breast implants. To date, silicone has not been proven to cause any disease. Research into the safety of silicone breast implants has found no clear link between the implants and illness. Many of the symptoms described by women who have had implants are also experienced by the general public who do not have implants.

An article published in the journal of the American Society of Plastic Surgeons in July 2019¹ states there is presently 'overwhelming evidence to support the safety of silicone breast implants.... To the best of our body of scientific knowledge to date, there have not been any concrete or evidence-based studies or peer-reviewed data concerning the formation of a new syndrome: "silicone implant illness".'

There is currently no way to test for breast implant illness – which means whether it exists cannot be proved or disproved. There is therefore no known 'risk' for breast implant illness.

It is important that women with concerns about potential breast implant illness discuss these with their plastic surgeon to decide together about the best thing to do. Options might include doing nothing, monitoring the situation, or removing the implants. However, removal of implants may not mean the symptoms go away, as they may not have been linked to the implant. Ultimately, it is the woman's decision whether to keep or remove breast implants.

Risks associated with breast implants

There are some risks associated with breast implants, including breast implant associated anaplastic large cell lymphoma (BIA-ALCL). This is a rare form of lymphatic cancer that can develop near breast implants. Please see our separate statement on this condition.

¹ Rohrich, Rod J. M.D.; Kaplan, Jordan M.D.; Dayan, Erez M.D. Silicone Implant Illness: Science versus Myth? *Plastic and Reconstructive Surgery*: [July 2019 - Volume 144 - Issue 1 - p 98-109](#), doi: 10.1097/PRS.00000000000005710

I have seen some patients who are worried they have breast implant illness. After consultation, if they wish, surgery is done to remove the devices and surrounding capsule. There is no evidence to prove that there is a therapeutic benefit, but it is the woman's decision to make.