UPDATE May 2019 : FOR PATIENTS WITH BREAST IMPLANTS

ASSOCIATION WITH A TYPE OF LYMPHOMA (ALCL)

David Glasson, Plastic Surgeon

Useful links :

1. TGA Australia :
http://www.tga.gov.au/alert/breast-implants

2. NZ Association of Plastic Surgeons :
http://plasticsurgery.org.nz/consumer-information/issues/breast-implant-associated-anaplastic-large-cell-lymphoma-alcl-faqs/

What are implants made of? Implants have a silicone rubber shell (smooth or textured) which contains a soft silicone gel filling. Silicone is probably the most studied implantable material used in medicine.
Long term effects of silicone breast implants remain a subject of ongoing monitoring and study.
It is accepted that women with implants have **no increased risk of the common types of breast cancer**.

This update is about breast implants and the risk of developing a rare lymphoma around the implant - ALCL

Lymphoma is a cancer of the immune system, with many subtypes.
Anaplastic large cell lymphoma (**ALCL**) is a rare T cell lymphoma, non-Hodgkins type.
In women **without** implants, it occurs in an estimated 1 in 500,000 women per year.
ALCL can occur anywhere in the body, and the breast is one of the least common sites.

But, having breast implants does increase the risk of ALCL.

Breast Implant Associated ALCL (BIA-ALCL) :
This cancer may occur in **fluid** around implants, or in the capsule (layer of scar tissue) that naturally forms around a breast implant.
Patients may develop a **swelling due to excess fluid**, or **lumps**, causing asymmetry of the breasts, some years after their implant surgery. BIA-ALCL has occurred as soon as 1 year after the operation, and as late as 37 years.

Diagnosis : The disease is **diagnosed** when fluid from around the implant is removed and sent for analysis. Lymphoma cells may be identified floating in this fluid. The lymphoma may also grow on the capsule tissue which surrounds the implant pocket. Most fluid collections are not ALCL, but it is important to check for it.

Mammograms are not helpful. But, if ALCL is diagnosed, then CT and MRI scans are done.

Treatment of ALCL is mainly with surgery, but chemotherapy and radiation may also be required if lumps have developed.
Surgery involves removal of the implant and surrounding capsule tissue. Removal of the implant and capsule from the **other breast** is also recommended. This is usually curative.

For women who have developed ALCL, the **prognosis** after treatment has been good. But it is possible that there will be serious or even fatal outcomes, if the disease is not recognized early.
After treatment of BIA-ALCL, long term surveillance is required for 5 years.

What is the risk?
This is still unclear. The NZ Association of Plastic Surgeons reports 10 known cases in this country. Some of these women had the surgery overseas. Australia has had more than 70 cases.
The Therapeutic Goods Administration (TGA) in Australia states : "Current expert opinion puts the risk at between 1 in 1000, to 1 in 10,000. Most cases of ALCL have occurred between 3 and 14 years after surgery, with a median of 8 years."

As the TGA states : Using 1 in 5000 as the mid range risk – this would mean that out of 5000 women with implants, 1 would develop ALCL and 4999 would not.

To date, there have been about 700 reported cases of ALCL in women with breast implants, in the world. The problem is that the exact number is uncertain because not all cases are reported or published, and it is a recent clinical entity. Some countries have had no cases at all.

However, the number of cases is very small compared with the estimated 5-10 million women who have received breast implants worldwide.

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).

There have been cases of ALCL associated with all **types and brands of implants**.
The disease almost always occurs around **textured or polyurethane covered** implants. In Australia and NZ, no cases have occurred where **smooth** implants have been used.

Why are implants textured on the surface? Texturing of the implant surface has advantages. Texturing is done so that shaped implants stick to the tissues and do not rotate out of position. Texturing also reduces the rate of capsule contracture (tight scar around the implant).
It is thought that texturing may provide an environment where certain bacteria can thrive, causing low grade chronic inflammation, which triggers this disease. The answers are still not clear.

What do the authorities say?
In Europe, UK and USA, regulatory agencies (FDA, ANSM, MHRA) do not recommend any changes to current best practice. Textured implants are still recommended to be available as a choice for patients, a view supported by the European Commission BIA-ALCL Task Force.
In France , an expert committee has recommended that one type of implant, Allergan Biocell, be no longer sold, as the risk is higher with that type of textured implant.

Regular screening (checking) for ALCL is not recommended. Women should report to their surgeon if a swelling of one or both breasts, or a lump, is noticed.

What is happening?
Doctors will continue to gather data about this rare cancer and search for the relationship with breast implants.
The manufacturers of implants will continue to monitor reports of ALCL, as well as other rare events.

What is the significance?
The number of cases is small compared with the total number of women with implants.
No definite cause and effect relationship has been established yet.

The possibility of **ALCL** occurring must be considered when surgeons treat the complications of implants. **If a fluid collection should develop around an implant, or a lump near the implant, then tests such as Ultrasound, MRI and fluid aspiration for cytology should be done.**

Should breast implants be removed because of the risk of ALCL?

At present, the FDA (Food and Drug Administration) in the USA, and the NZ Association of Plastic Surgeons do **not** recommend "preventive" breast implant removal in patients without symptoms or any abnormality associated with their implants.

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

The most important message is this :

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.

There is no reason to contact the surgeon if you have no symptoms.