

FAQs - Breast implant-associated ALCL

Background

Breast implant-associated anaplastic large cell lymphoma (ALCL) is a rare type of lymphoma that develops near breast implants.

In November 2016, Australia's Therapeutic Goods Administration (TGA) – a division of the Australian Department of Health – convened an expert advisory panel to discuss the issue of anaplastic large cell lymphoma (ALCL) as part of its ongoing monitoring of the association between breast implants and ALCL.

The expert advisory panel included representation from plastic, cosmetic and breast cancer surgeons, cancer epidemiologists, data analysts and public health practitioners.

In December 2016, the TGA advised that 46 cases of breast implant-associated ALCL have been confirmed in Australia since 2007, including three that resulted in death. The TGA said it was also aware of a small number of unconfirmed cases, which were being investigated.

The TGA said it would:

- work with research groups to obtain better estimates of the risk of breast implant-associated ALCL
- work with manufacturers, Australian experts on breast implant-associated ALCL and Australian experts on breast augmentation and reconstructive surgery to evaluate the benefit-risk balance of the various types of breast implants
- continue to liaise with major overseas regulatory partners and collaborate in international working groups.

The New Zealand Association of Plastic Surgeons has been kept up-to-date with the work of the TGA and the expert advisory panel. The Association has had regular discussions about the latest information on breast implant-associated ALCL with Medsafe, which is responsible for the regulation of medicines and medical devices in New Zealand.

The following FAQs take into account the advice provided by the TGA's expert advisory panel, with some additional information for New Zealand women.

What is breast implant-associated ALCL?

Breast implant-associated ALCL is a rare type of non-Hodgkin's lymphoma, which is a cancer of the cells of the immune system. Most cases of breast implant-associated ALCL are cured by removal of the implant and the capsule surrounding the implant.

What are the symptoms of breast implant-associated ALCL?

The most common symptom is a swelling of the breast, typically 3 to 14 years after the operation to insert the breast implant. This swelling is due to an accumulation of fluid. Breast implant-associated ALCL has been known to occur as soon as 1 year after the operation and as late as 37 years after the operation.

Less commonly, breast implant-associated ALCL can take the form of a lump in the breast or a lump in the armpit.

What should New Zealand women with breast implants, or who are considering breast implants, who are concerned about ALCL do?

Women who experience sudden, unexplained changes, such as lumps or swelling in the breast, or who have any concerns about their implants should see their general practitioner for referral to a specialist with knowledge of breast implants, or the surgeon who carried out their breast implant surgery.

Women who have no symptoms have no cause for concern.

Women who are considering breast implant surgery should discuss the risks and benefits of the procedure with their surgeon.

What about women who had their breast implant surgery overseas or whose surgeon is no longer practicing?

Women who are unable to contact their implant surgeon should see their general practitioner for a referral to a surgeon experienced in implant surgery.

How is breast implant-associated ALCL diagnosed?

If a woman develops swelling of an implanted breast her doctor will send her for an ultrasound scan to see if this is due to a fluid collection. If fluid is present it will be removed and sent to the laboratory for analysis. Most fluid collections are not ALCL, but the laboratory test will be able to tell for sure.

Other investigations such as MRI and CT-scans would typically be done if the laboratory analysis of the fluid confirms a diagnosis of ALCL.

Mammograms are not helpful for diagnosing ALCL

What causes breast implant-associated ALCL?

One current theory is that chronic, low grade, non-clinical bacterial contamination possibly contracted at the time of implant placement, or in the immediate postoperative period can develop into breast implant-associated ALCL in the long term. The theory is that because the body can't get rid itself of the contaminated implant, there is chronic irritation over a period of time that stimulates the immune system, causing some of the cells to potentially transform into ALCL. However, this theory has not been proven.

There are many potential sources of bacteria that may contaminate an implant and while surgeons do many things to prevent bacterial contamination, such as washing out the breast cavity with antibiotic solution, re-prepping or covering the skin and only using a new pair of sterile gloves to touch the implant, it is not possible to completely eliminate this risk.

How is breast implant-associated ALCL treated?

Most cases of breast implant-associated ALCL are cured by removal of the implant and the capsule surrounding the implant. Usually both implants will be removed, even if breast implant-associated ALCL has only occurred in one breast. This is because there is a small but real risk that breast implant-associated ALCL can develop in the opposite breast.

Sometimes there is a solid lump (not just fluid). In these cases, chemotherapy or radiotherapy may be required.

The management of breast implant-associated-ALCL is multidisciplinary, with all patients requiring a referral to a surgeon experienced with breast implants and the involvement of a

haematologist who specialises in lymphoma for initial and ongoing investigations and management.

How many cases of breast implant-associated ALCL have there been in New Zealand?

There have been 10 known cases of breast implant-associated ALCL in New Zealand. Some of these cases are women who have had breast implant surgery overseas.

How many New Zealand women have died from breast implant-associated ALCL?

There has been one New Zealand death as a complication of the treatment of breast implant-associated ALCL.

What is the risk of breast implant-associated ALCL?

Based on the currently available data, it is not possible to provide an accurate estimate of the risk of breast implant-associated ALCL. 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. The average time for cases to appear is 8 years after implant surgery. Other ways of expressing the risk are:

- One woman will be diagnosed with breast implant-associated ALCL for every 1000 to 10,000 women with breast implants.
- Taking the middle of the experts' range as the best estimate of risk of ALCL in women who have breast implants of 1-in-5000 women, this would mean that one woman in 5000 with breast implants will develop ALCL over a period of about 3-14 years following an implant.

Should women have their breast implants removed, just in case?

Because breast implant-associated ALCL is rare, experts do not recommend removal of breast implants for women who have no problems with their implants.

Generally, breast implants are not lifetime devices regardless of breast implant-associated ALCL. The longer a woman has the implant, the more likely it will need to be removed. Common reasons for removal are capsular contracture (hardening of the scar tissue around the implant that causes physical deformity and pain) or movement of the implant.

Should women with implants be screened for ALCL?

Based on external expert clinical advice received by the TGA, regular screening is not recommended at this time.

Are some women more at risk of breast implant-associated ALCL than others?

Breast implant-associated ALCL can develop regardless of whether the implant is inserted for cosmetic reasons or for reconstruction of the breast following breast cancer. It can occur with both saline- and silicone gel-filled implants.

All Australian and New Zealand cases of breast implant-associated ALCL have occurred in women who have had textured or polyurethane implants. No Australian or New Zealand cases have been reported in women who have only had smooth implants. Based on the currently available data:

- It is uncertain whether textured (either micro or macro) and polyurethane implants carry different risks.
- It is uncertain whether different brands of textured and polyurethane implants carry different risks.

- It is not possible to predict which women with textured or polyurethane implants will develop breast implant-associated ALCL.

However, there are sound clinical reasons to use textured implants – in particular to reduce the incidence of capsular contracture (hardening of the scar tissue around the implant that causes physical deformity and pain), and to enable the use of anatomical (shaped) implants for breast reconstruction.

Is there a higher incidence of in New Zealand (and Australia) or is the world-wide incidence of it being under-reported?

While it's likely that the worldwide incidence of breast implant-associated ALCL is under reported, the reason this was looked at in New Zealand and Australia is because we have good reporting. There appeared to be a higher incidence rate in Australia and New Zealand, so there was a need to know as much about it as possible. Data collection suggests that New Zealand's rate of breast implant-associated ALCL could be higher than that published so far. However, everything about the incidence of breast implant-associated ALCL to date is a 'best guess'.

In New Zealand and Australia, we were able to obtain anonymised breast implant sales data from 1999. It's the best data available internationally and important because the average time for cases of breast implant-associated ALCL to appear is eight years after implant surgery and as much as 14 years.

No one knows how many New Zealand women have breast implants. Breast implant surgery is not regulated here and not all breast implant surgery is carried out by plastic surgeons. Some general surgeons and cosmetic surgeons also do breast implant surgery. Some New Zealand women have had breast implant surgery overseas.

The 46 patients in the recently-presented research paper had 56 sets of implants. While a lot of the patients had only had one set of implants, several had had two or more sets and one patient had had five sets of implants over several years.

Are there clusters of breast implant-associated ALCL related to individual surgeons?

While some surgeons and surgical groups have reported higher numbers of breast implant-associated ALCL than others, there is a difference between surgeons identifying cases of breast implant-associated ALCL and surgeons doing the original implant surgery. For example, one surgeon in New Zealand identified four women with breast implant-associated ALCL, but had only performed the implant surgery on one of them.

One of the two cases identified more recently is a woman who had her breast implant surgery in another country three years ago.

The research appears to implicate high surface area textured implants. Are these used in New Zealand?

All cases of breast implant-associated ALCL have involved textured implants rather than smooth surfaced implants, including those where a woman may have originally had smooth surfaced implants that were later replaced by textured implants.

The vast majority of breast implants used in New Zealand are textured. One possible issue with breast implants is capsular contracture (hardening of the scar tissue around the implant – that causes physical deformity and pain). A couple of decades ago it was determined that textured implants greatly reduced the risk of capsular contracture, with the result that most of those doing breast implant surgery switched to using textured implants.

Additionally, anatomically shaped implants widely used for reconstruction are all textured.

What has the New Zealand Association of Plastic Surgeons done to educate its members about breast implant-associated ALCL?

The New Zealand Association of Plastic Surgeons has continued to provide its members with the latest information about breast implant-associated ALCL, including how to manage patients with suspected or proven breast implant-associated ALCL. The Association has also developed a guide for patients about breast implant-associated ALCL.

The Association has also asked its members to pledge their support to a 14-point plan – a suggested set of steps that surgeons can undertake to reduce contamination on breast implants – as a sign of their commitment to reducing implant contamination using the best available evidence. The pledge represents a proactive way Association members can demonstrate they are applying science and knowledge to improve the safety and reliability of breast implant surgery for patients.

The Association will continue to evaluate all available information to better understand the nature and possible factors contributing to breast implant-associated ALCL and work with researchers and regulatory authorities to reduce its incidence.

Why doesn't New Zealand have a breast implant registry like Australia?

While there is a breast implant registry in Australia, it is a voluntary, opt-in system for hospitals and other facilities doing breast implant surgery, rather than individual surgeons, and has only a 60 percent participation rate. It also relies on these facilities providing breast implant information to the registry.

The New Zealand Association of Plastic Surgeons would like to see a breast implant surgery registry in New Zealand and has been working towards this with the regulatory authorities for some time. New Zealand privacy laws are the biggest barrier to establishing a comprehensive register. There would also need to be a commitment to participate by all those providing breast implant surgery for it to be of any real value. It would also be useful for breast implant manufacturers to provide sales data to help with data matching.

Not all breast implant surgery in New Zealand is carried out by plastic surgeons. Some general surgeons and cosmetic surgeons also do breast implant surgery.