



## Breast implants and BIA-ALC Lymphoma

In light of the recent focus on breast implants and their association with Anaplastic Large Cell Lymphoma (ALCL), Dr Gahankari answers some commonly asked questions regarding risk, treatment, cure and what to do if you have concerns.

### What is BIA-ALCL?

Anaplastic Large Cell Lymphoma (ALCL) is a rare type of Non-Hodgkin's Lymphoma, usually found in children or young people. Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) is, as the name suggests, the same type of Lymphoma, also rare, which has been specifically linked to breast implants. BIA-ALCL is believed to arise from capsules formed around breast implants over number of years.

### Is BIA-ALCL the same as breast cancer?

Even though BIA-ALCL occurs in the breast, it is not a breast cancer (breast cancer is much more common in women, with incidence of 1 in 8 or 9 women, and has a higher risk of spreading to Lymph nodes or elsewhere).

### How common is BIA-ALCL?

Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) is considered to be rare - there are under 1000 known cases of BIA-ALCL worldwide, among the approximately 30 million women with breast implants. TGA advises the incidence of ALCL in breast implant patients from 1 in 1000 to 1 in 10000 and this is believed to average around one in 2700 patients. This can occur 7-10 years after breast implant surgery.

### How does it happen?

BIA-ALCL (Breast Implant Associated ALCL) is mostly seen in macro-textured implants (those with thicker texturing) and polyurathane implants. It has not been conclusively proven in smooth implants.

It is considered that more than just one factor is involved in the cause of BIA-ALCL. There is substantial research – some notably from Australia – suggesting a link of bacterial contamination possibly at the time of surgery. In this instance it is thought the contamination forms a 'shell' or 'bio-film' which makes these bacteria difficult to be attacked by the antibiotics.

Australian research resulted in a [14 Point Plan](#) during surgery to minimise the risk of contamination during implant surgery. This involves steps such as using intravenous antibiotics at the time of surgery and washing the implant in these antibiotics prior to being inserted.

I use meticulous techniques for all surgeries, including breast augmentation, and I am a signatory on the register of Plastic Surgeons who follow this plan.

### Can it be cured?

Most cases of BIA-ALCL (Breast Implant Associated ALCL) are cured by removal of the implant and the capsule surrounding the implant.

On July 11, the **Therapeutic Goods Administration (TGA)**, Australia's medical device regulator, proposed regulatory action in relation to a number of textured implants only, pending submissions on July 24. The proposed regulatory actions are either 'a proposal to cancel' or 'a proposal to suspend'

The TGA has asked that by July 24, manufacturers Allergan, Nagor, Polytech Health & Aesthetics, Airxpander, Eurosilicone and Mentor Medical Systems supply further submissions regarding certain textured breast implants, and some temporary breast prostheses such as tissue expanders.

Once the submissions are received, the TGA says it "will, as a matter of priority, consider the sponsor's submissions before reaching any decision on whether to proceed to the proposed regulatory action".

If the proposed cancellations or suspensions did go ahead, any associated recall would only apply to product that is waiting to be implanted. There is not a recommendation to surgeons to remove implants in the absence of a BIA-ALCL diagnosis

Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) is considered to be rare - there are under 1000 known cases of BIA-ALCL worldwide, among the approximately 30 million women with breast implants.

### What are the symptoms of BIA-ALCL?

The most common symptom of BIA-ALCL is swelling of the breasts, due to fluid collection around the implant or a lump, or both.

### How do I test for BIA-ALCL?

If there is swelling of the breast, an ultrasound may be used to assess the swelling, and if any fluid is detected, it is removed under ultra-sound guidance and tested for lymphoma cells. (an MRI scan may also be required if the ultrasound is not conclusive).

If a lump is detected, a biopsy may be required. If the tests are positive, further scans and tests may be required and an opinion from an Oncologist is also sought.

Most cases of BIA-ALCL can be potentially curable with removal of the implant and the capsule without any need for chemo or radiation therapy.

## What about Breast Implant Illness?

In recent years, there has been growing number of women who have unexplained constitutional or breast related symptoms. These symptoms are commonly known as Breast Implant Illness (BII).

Exact diagnostic criteria for BII do not currently exist, and there are no tests to prove or disprove this diagnosis.

I regularly treat patients with presumed BII who seek removal of their implants and en-bloc capsulectomy (removal of the implant and the surrounding capsule).

## Removing implants

Removal of implants is a big decision with many factors. Many times, removal of implants leaves behind flat breasts, which may not be aesthetically pleasing.

The alternatives to this approach is to have a "lift" and fat transfer for adding more volume to the breasts. The fat is obtained from liposuction and with careful technique, it is reinjected meticulously into the breast tissues.

However, fat transfer can only provide a modest increase in the bust size and generally speaking cannot match the augmentation possible with breast implants.

## When should I have my implants checked?

I advise my clients to monitor their implants every two years or so with an ultra-sound scan.

Concerns about breast implants may be about the implants themselves or about the actual breasts, that change over the life span of implants.

Some women have their implants removed and replaced. Common reasons for change of implants are capsule formation, which can form hardening or deformity of the breasts, and or loosening of the breast implant pockets with gravity, sagging of breast tissue over the implants. Many women simply wish to have larger or smaller breasts after a time. Typically, most women with implants who have a replacement procedure, do so within 10-15 years.

## Where should I have my implants checked?

You can return to your original surgeon, or any Plastic Surgeon, such as myself, who offers Implant Checks.

## Choosing an implant

Like most surgeons, I have used various brands of implants of over the past 15 years of my practice – and some of these have been macro-textured implants.

Fortunately, as far as I am aware, there have been no cases of BIA-ALCL in any of my patients.

As BIA-ALCL has not been linked to smooth implants, it may be logical to think, that these are the most appropriate implants to use. I certainly use these implants if my patient wishes to have them.

However, smooth implants have their own specific risks and short- and long-term concerns. They have been associated with a slightly higher risk of capsular contracture because of their smoothness. And, being smooth, they are also more mobile within the breast implant cavity and therefore have risk of flipping (back to front – causing breast deformity).

Since 2017, I have used micro-textured or nano-textured Motiva implants, as this texture seems to be a good balance between the much-reduced (if at all) risk of ALCL and less of the risks associated with smooth implants.

Motiva implants are relatively new and have been in use for about 10 years, and as far as I am aware, these implants have not been associated with BIA-ALCL.

These implants have been backed by manufacturer's guarantee and most come with a chip inside the implant which carries the information about the implant. This information can be accessed by any Plastic Surgeon, who has a simple Motiva scanner.

## What do the proposed regulatory actions 'to cancel' or 'to suspend' mean?

The [TGA's advisory statement](#) of July 11 says:

"If the entries of the above products are **cancelled**, the products would no longer be able to be imported, manufactured or exported from Australia by the sponsor. The TGA is also proposing to require the sponsor to recall the products to remove all remaining products from the market. **The recall would only apply to product that is waiting to be implanted. There is not a recommendation to surgeons to remove implants in the absence of a BIA-ALCL diagnosis.**

"If the entries of the above products are **suspended**, the products would no longer be able to be imported, manufactured or exported from Australia by the sponsor for the duration of the suspension. A suspension can be revoked if concerns about the products are addressed to the TGA's satisfaction. Alternatively, where concerns persist the duration of the suspension may be extended or the entries of the products may be cancelled. If any of the products are suspended, it is proposed to recall all remaining product to remove it from the market. **The recall would only apply to product that is waiting to be implanted surgically. There is not a recommendation to surgeons to remove implants in the absence of a BIA-ALCL diagnosis.**"



### Dr Dilip Gahankari

Dr Dilip is an Australian qualified specialist Plastic Surgeon. With over two decades of experience, Dr Gahankari is a skilled surgeon with a commitment to the highest standards of surgical techniques and quality patient care.

**Keep up to date:** The [TGA website](#) has a table of the specific manufacturers and products involved. The TGA is proactive in keeping Australian consumers informed about breast implants and ALCL related updates, and their regulatory activities and advice. Further information about breast implants and regular updates can be accessed via [TGA website](#).