

BREAST IMPLANT CONTROVERSY: AN UPDATE

Dr Michael Yunaev, Oncoplastic Breast, General and Cosmetic Surgeon

MBBS, FRACS, MS Breast Surgery, BMedSci (Hons), MPH

Recently, TGA has made some important changes to the Australian Breast market. As you're probably aware, there has been ongoing controversy around the safety of some of these implants in relation to the risk of Breast Implant Associated - Anaplastic Large Cell Lymphoma (BIA-ALCL).

This condition has been around for a long time, in extremely small numbers. However, in the recent decade, there has been a steady increase in the incidence of this condition identified worldwide, with Australia being one of the main centres in the world with this problem relative to its population.

Due to the rising incidence, which has not yet plateaued, TGA has made a decision to assess the safety of the implants currently in use in Australia and has come up with guidelines and directions for the near future. The background to this is the growing body of evidence which identified several factors that seem to correlate with the rising incidence.



These included factors such as surgical technique (i.e. steps taken to minimise bacterial load on implants), the type of implants used and the surface coarseness (texturing) of these implants and the genetic makeup of the patients with some genetic subtypes being more predisposed to this, as well as other less defined factors.

The two things we can do something about are of course surgical technique, which has been evolving thanks to the 14 point plan devised to reduce implant bacterial colonisation. The second thing is the type of implants that are being used.

The evidence suggests that the more heavily textured (rougher surface) macro textured implants are, the higher incidence of this condition they have. Saying that, it is still extremely low by comparison to other common conditions, somewhere in the order of one in 2-3000.

Whilst the less coarse implants, the so called micro textured, have an incidence between 1 in 30-80000, an order of magnitude less than the rougher implants. Note that smooth (non-textured) implants are yet to have any cases associated with them, however over 90% of all implanted breast implants worldwide are textured, so we may or may not see some developments in this category in the future.

As a result, TGA has advised that there has been a voluntary withdrawal from Australian market of macro textured Allergan breast implants (one of the most commonly used devices worldwide), as well as a six months suspension of use for a number of other well known breast device companies, especially their macro and some microtextured products. This included Sebbin, Eurosilicone, Polytech and Nagor.

In six months, TGA will rule whether to allow them to return to the market, to prolong that suspension or to proceed to a complete removal from Australia.

It is important to note that some devices such as Mentor micro textured implants have been allowed to be used, due to their low incidence, as well as a range of smooth or nanotextured products from the companies listed above, as well as Motiva.



What does this mean to your patients. There are a couple of important take-home points:

1. Patients with existing implants do not require removal, unless they exhibit symptoms of BIA-ALCL (breast swelling, breast pain in this setting, fluid around implant, a lump in the breast capsule/breast tissue, regional lymphadenopathy, etc), have other complications related to implants or have a preference for explanation.
2. Patients who need breast reconstruction/revision can still use expanders and implants from Mentor, one of the most commonly used devices in this setting at the moment.
3. Patients undergoing primary breast augmentation, breast reconstruction or revision need to understand that this is an evolving field and that more evidence may come to light in the future, which may direct further decision making at that time, and therefore they need to be aware of their alternative choices, if available.

Finally, over the next six months, TGA is going to be rigorously collecting data from implant manufacturers about any adverse events relating to this scenario and will be providing further updates on this thereafter, which may affect the layout of the Australian device market in the years to come.

If you have any questions or concerns relating to your patient situation, feel free to contact us for further guidance or discussion. I can be contacted via our practice number **(02) 98197449** or via our email **info@bbclinic.com.au**

References:

1. <https://www.tga.gov.au/alert/breast-implants-and-anaplastic-large-cell-lymphoma>



Dr Michael Yunaev

Oncoplastic Breast, General and Cosmetic Surgeon
MBBS, FRACS, MS Breast Surgery, BMedSci (Hons), MPH

Dr Michael Yunaev is an Oncoplastic Breast, General and Cosmetic Surgeon. He provides patients with a Comprehensive Breast Surgery Service.

Areas of interest include:

- Breast Cancer Surgery, including Oncoplastic Surgery
- Breast Cancer Reconstruction
- Aesthetic Breast Surgery, including Augmentation/Reduction/Lifts
- Male Gynaecomastia and Cancer Surgery
- Abdominoplasty
- Mummy Makeovers
- Liposuction/Fat Grafting
- General Surgery (Hernia/Gall Bladder/Skin Cancer)



St Luke's Clinic: Hemsley House, 20 Roslyn Street, Potts Point NSW 2011
Norwest Private Hospital: Suite G5B, 9 Norbrik Drive, Bella Vista NSW 2153
St Jude Street Specialist Centre: 21 St Jude Street, Bowral NSW 2576
The Chris O'Brien Lifehouse: 119-143 Missenden Rd, Camperdown NSW 2050
Sydney Specialist Suites: 670B Darling St, Rozelle NSW 2039

p: (02) 9819 7449
f: (02) 9356 0460
e: info@bbclinic.com.au
w: bbclinic.com.au
w: dryunaev.com.au