

ASPS-ASAPS UPDATE

BIA-ALCL SUMMARY AND QUICK FACTS

In December 2016, the Australian Government's Therapeutic Goods Administration (TGA) issued a report about Breast Implant-Associated ALCL (BIA-ALCL). The new information contained in the TGA report suggests a higher incidence of BIA-ALCL in textured (which includes polyurethane) implants, relative to all types of implants. The TGA-reported incidence rate was in the range of 1:1,000-10,000 for patients with textured implants. However, neither ASPS nor ASAPS has had the opportunity to review the underlying, unpublished data behind this new suggested incidence rate.

The following provides a summary of what is currently known about BIA-ALCL.

- Breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) is a rare and treatable type of T-cell lymphoma that can develop around breast implants.
- BIA-ALCL is not a cancer of the breast tissue itself.
- BIA-ALCL should continue to be discussed with any patient considering breast implants as part of the informed-consent process. (1)
- The lag time between implant insertion to diagnosis of BIA-ALCL has been from 2 to 28 years, with a median of 8 years.
- No cases of BIA-ALCL have been definitively associated with patients who have only had smooth implants. However, it is not possible to exclude the appearance of BIA-ALCL in association with smooth implants at this time.
- The association of BIA-ALCL textured implants may be related to the increased surface area of the texturing; however, this has not yet been definitively proven. The variation in surface texturing among manufacturers may mean there are variable risks for the development of BIA-ALCL, although the number of cases to date remain too low to make any significant distinctions between the various forms of texturing.
- The disease has been associated with both silicone and saline implants in aesthetic as well as reconstructive patients.
- The majority of patients present as a delayed seroma. Diagnosis is based on ultrasound-guided fine needle aspiration of the peri-implant fluid, which is assessed with immunohistochemistry for CD 30-positive and ALK-negative T-cell lymphocytes.
- PET-CT and MRI scans are investigations performed following a positive diagnosis. Mammograms are not helpful
- Consideration should be given to a multidisciplinary approach including, when required, an oncological breast surgeon and an oncologist specializing in lymphoma.
- Incomplete capsular resection has been associated with both recurrence and significantly lower survival.
- The majority of patients can be cured of their disease by bilateral total capsulectomy and implant removal. Rare patients will present with a mass and have an increased risk of requiring radiotherapy and chemotherapy. Treatment approach should follow international guidelines established by the National Comprehensive Cancer Network (NCCN) for BIA-ALCL, available at nccn.org.

- Current treatment recommendation is for bilateral complete capsulectomy and implant removal, as a small number of women have had contralateral disease found incidentally. (2)
- The FDA recommends that any suspected or confirmed cases of BIA-ALCL be reported to the PROFILE registry, the MAUDE database, and the device manufacturer. To submit a case to PROFILE, go to ThePSF.org/PROFILE. To submit a case to the FDA’s Manufacturer and User Facility Device Experience (MAUDE) database, which collects medical device reports (MDRs) of suspected device-associated deaths, serious injuries and malfunctions, visit <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm>.
- For more information: visit www.plasticsurgery.org/alcl or search “ALCL” on RADAR.

1. Clemens, M. W., Miranda, R. N., & Butler, C. E. (2016). Breast Implant Informed Consent Should Include the Risk of Anaplastic Large Cell Lymphoma. *Plastic and Reconstructive Surgery*, 137(4), 1117–1122. <http://doi.org/10.1097/01.prs.0000481103.45976.b1>

2. Clemens, M. W., Medeiros, L. J., Butler, C. E., Hunt, K. K., Fanale, M. A., Horwitz, S., et al. (2016).

Complete Surgical Excision Is Essential for the Management of Patients With Breast Implant-Associated Anaplastic Large-Cell Lymphoma. *Journal of Clinical Oncology : Official Journal of the American Society of Clinical Oncology*, 34(2), 160–168. <http://doi.org/10.1200/JCO.2015.63.3412>

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BIA-ALCL Frequently Asked Questions

Q: What is BIA-ALCL?

A: BIA-ALCL is a rare type of lymphoma that has been found in proximity to breast implants. BIA-ALCL is not a cancer of the breast tissue itself.

Q: What are the symptoms of BIA-ALCL?

A: BIA-ALCL usually develops as a swelling of the breast 2 to 28 years after the insertion of breast implants, which may present as fluid collecting around the implant. It can also present as a lump in the breast or armpit.

Q: What is the risk of developing BIA-ALCL?

A: Early in 2016 the FDA issued a report that it had received 258 adverse event reports of breast implants and ALCL. For a frame of reference, both ASPS and ASAPS data report that approximately 300,000 breast augmentations are performed annually.

A: The lifetime risk for BIA-ALCL in previous epidemiological studies ranges from 1:30,000 to 1:50,000

A: The figure derived and issued by the Australian government was in the range of 1:1,000 to 1:10,000 for Australian/New Zealand patients with textured/polyurethane implants. Polyurethane implants are not available in the United States.

Q. How is BIA-ALCL treated and what is the prognosis?

A: Current recommendations for the treatment of BIA-ALCL call for bilateral capsulectomy and removal of the breast implants. In all but a few cases, the disease has been fully resolved by this surgery alone. The majority of patients require no additional treatment.

Q: Are some patients at greater risk than others?

A: It is not possible to predict who will develop BIA-ALCL, and while the Australian Government reports a higher risk of BIA-ALCL in those patients with textured/polyurethane implants, the data is not yet well established. This risk remains far less than that other known risks, such as capsular contracture.

A: It has occurred in women who have breast implants for both cosmetic and reconstructive purposes.

A: BIA-ALCL has occurred in women with both saline and silicone implants

Q: Should patients have their implants removed?

A: Neither the FDA nor the Australian Government's report suggest additional screening or removal of implants for asymptomatic women.

Q: Should women with breast implants be screened for BIA-ALCL?

A: Expert opinion is that asymptomatic women without breast changes do not require more than routine follow-up. If a patient experiences a change in her breasts – especially if there is swelling or a lump – she should undergo examination and appropriate imaging, including ultrasound and fine needle aspiration of any peri-implant fluid.

Q: What causes BIA-ALCL?

A: ASPS, ASERF, the FDA, and the implant manufacturers are working proactively to study BIA-ALCL. To date, no specific causal factors have been identified. Implant texturing, bacteriologic contamination, and genetic factors have been implicated and are undergoing further study.

A: Bacteria have been identified within the lymphoma and around implants in affected breasts, and there is accumulating evidence that a long-term inflammatory response to the presence of these bacteria is one of the factors that may cause BIA-ALCL. Research is ongoing and cases are being monitored through the PROFILE registry.

A: Genetic factors may play a role. The Australia/New Zealand risk appears higher than other studies have indicated. Some geographic areas have reported very few cases. Ongoing data collection worldwide will help to determine whether or not there are any genetic propensities for this disease.

Q: Do ASAPS and ASPS recommend against the use of textured implants?

A: The available data does not support discontinuance of textured implants. The best practice is always for the physician to discuss with each patient the known risks and potential complications associated with any procedure. It is important for the patient and her doctor to frankly discuss all options available, and the risks involved.

A: Every plastic surgeon offers patients options regarding breast implants in terms of sizing, shape, and surface. Textured implants may offer advantages when placed subglandularly (lower risk of capsular contracture), and when an anatomically shaped implant is utilized (lower risk of malrotation).

Depending on a particular patient's needs, a textured implant may be preferable. The plastic surgeon must provide a frank and transparent discussion regarding the benefits and risks of implants, both

smooth and textured. The patient must then make an informed decision, based upon her own assessment of her needs and the risks involved.

A: Every plastic surgeon needs to help each individual patient make her own decision about which implant she prefers in a fully transparent manner. This involves weighing any possible increased risks against the advantages offered by a particular type of implant. It is critical that the patient makes a fully informed decision following a full discussion of the risks and benefits.

Q. Have there been any deaths due to BIA-ALCL?

A. There have been 12 confirmed deaths, including 6 in the United States, attributed to BIA-ALCL since the disease was first reported nearly 20 years ago.

Q. What is the recommended clinical response to a patient presenting with symptoms that could be attributable to ALCL?

A. In July 2016, ASPS and ASAPS issued a joint "Tear Sheet" describing the recommended clinical protocol for patients presenting with symptoms that could be attributable to BI-ALCL. For a copy of the ASPS/ASAPS Tear Sheet please go to:

<https://cdn.plasticsurgery.org/doc/Joint-ASPS-ASAPS-Statement-On-Breast-Implant-Associated-ALCL.pdf>

Access on the ASAPS website at: <http://www.surgery.org/professionals>

This protocol formed the framework for the international recommendations by the National Comprehensive Cancer Network (NCCN) for the diagnosis of BIA-ALCL and can be accessed at www.nccn.org.

Q: How is BIA-ALCL diagnosed?

A: If a woman develops swelling in an augmented breast, she should undergo an ultrasound scan. If fluid is detected, it should be drained and tested with CD30 immunohistochemistry to diagnose BIA-ALCL. Mammograms are not useful in diagnosing BIA-ALCL. In confirmed cases MRI and PET/CT scans may be performed to help stage the disease.

Q: How is organized plastic surgery working with the FDA to study BIA-ALCL?

A: The Plastic Surgery Foundation (PSF) created PROFILE (Patient Registry and Outcomes for Breast Implants and Anaplastic Large Cell Lymphoma, Etiology and Epidemiology) in 2012, a collaboration with the FDA. Any suspected or confirmed cases of BIA-ALCL should be reported for inclusion in the PROFILE registry at ThePSF.org/PROFILE.

A: PROFILE is collecting data both retrospectively and prospectively on confirmed cases of BIA-ALCL.

A: The primary goal of PROFILE is to better understand the role of the breast implants in the etiology of BIA-ALCL. The research hopes to identify potential risk factors, diagnostic predictors, and the best ways to manage this disease. In addition to providing health care practitioners and patients with information about the diagnosis and treatment of ALCL, the confirmed cases will assist with further analytical epidemiological studies.

Q: Where can I find more information on BIA-ALCL?

A: Additional information and resources on BIA-ALCL are available online at www.plasticsurgery.org/alcl and by searching "ALCL" on RADAR at www.radarresource.com.

Reporters seeking information or plastic surgeons contacted by a member of the media are encouraged to forward inquiries to Adam Ross, ASPS integrated communications manager at aross@plasticsurgery.org or 847-228-3361. ASAPS members are encouraged to contact Leigh Hope Fountain, ASAPS Director of Public Relations at leigh@surgery.org or 561-799-2356.