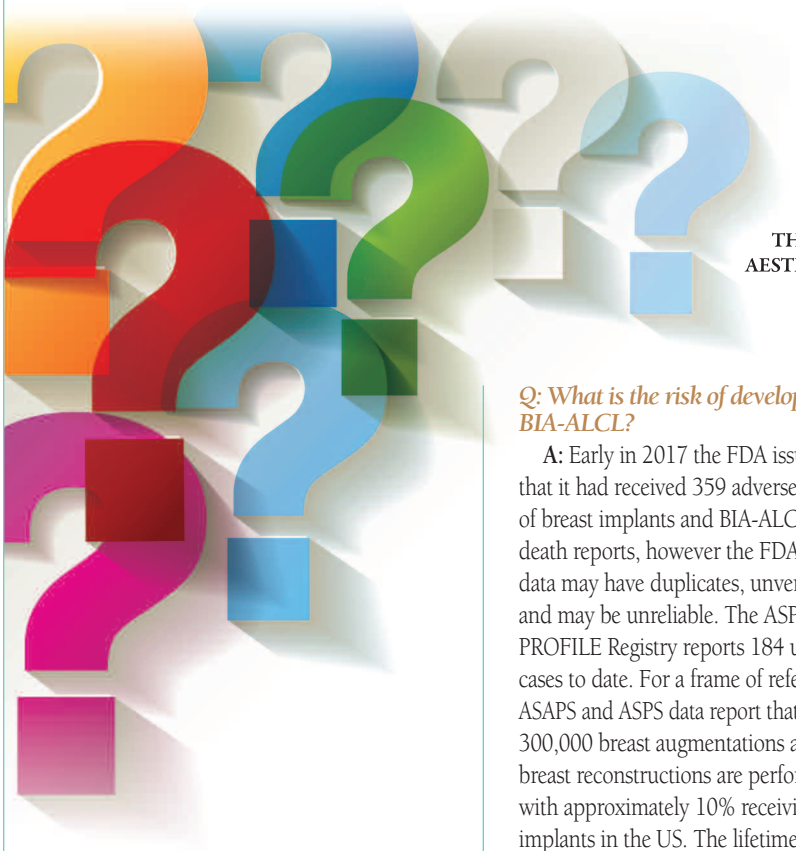
BIA-ALCL Frequently Asked Questions

A Joint Project from the American Society for Aesthetic Plastic Surgery and the American Society of Plastic Surgeons



THE AMERICAN SOCIETY FOR AESTHETIC PLASTIC SURGERY, INC.

AMERICAN SOCIETY OF PLASTIC SURGEONS

Q: What is BIA-ALCL?

A: BIA-ALCL (Breast Implant-Associated Anaplastic Large Cell Lymphoma) is a rare lymphoma that to date has only been noted to occur in patients with a history of a textured breast implant device—and when caught early, it is curable in most patients. BIA-ALCL is not a cancer of the breast tissue itself. All government authorities and oncology organizations currently classify BIA-ALCL as a lymphoma. On-going research continues to best understand and define BIA-ALCL, which consists of a spectrum of stages from a CD30+ seromas/effusions to capsular tumors to lymph node involvement and even distant metastasis.

Q: What are the symptoms of BIA-ALCL?

A: BIA-ALCL usually develops as a delayed swelling of the breast (Average 8 years, range 2 to 28 years) after the insertion of textured breast implants, which may present as fluid collecting around the implant or marked breast asymmetry. It can also present as a lump in the breast or armpit.

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

A: Early in 2017 the FDA issued a report that it had received 359 adverse event reports of breast implants and BIA-ALCL and nine death reports, however the FDA warns this data may have duplicates, unverified cases, and may be unreliable. The ASPS/FDA PROFILE Registry reports 184 unique US cases to date. For a frame of reference, both ASAPS and ASPS data report that approximately 300,000 breast augmentations and 150,000 breast reconstructions are performed annually with approximately 10% receiving textured implants in the US. The lifetime risk for BIA-ALCL in previous epidemiological studies ranges from 1:1000 to 1:30,000 for those with textured implants based on implant sales data from the U.S., Canada, Netherlands, and Australia. Currently the lifetime risk of developing BIA-ALCL for a smooth-only implant is zero, as there are no reported cases to date of BIA-ALCL in patients exposed to only smooth implants. The risk for different types of textured implants may be different with proportionally more cases of higher surface-area textured implants, such as Biocell and polyurethane, although all textured implants with a sufficient time of follow up have attributable cases to date.

Q: What did the latest FDA statement say in regards to BIA-ALCL?

A: BIA-ALCL is a rare and highly treatable condition that can develop around textured breast implants. The FDA advocated for surgical management in the majority of patients as well as specifically recommended all confirmed BIA-ALCL cases be reported to the PROFILE registry (www.thepsf.org/PROFILE) for detailed tracking of cases. In October 2017, the European Commission's Scientific Committee on Health, Environmental, and Emerging Risks (SCHEER) released a scientific advice report on BIA-ALCL and also stressed the importance of future research and reporting to prospective patient registries.

Q: What is the significance of the latest FDA statement?

A: The 2017 FDA statement emphasized that this disease was predominantly associated with textured implants. The FDA acknowledged and agreed with the World Health Organization classification of BIA-ALCL as a lymphoma and treatment guidelines established by the National Comprehensive Cancer Network (NCCN). Both ASAPS and ASPS fund research to ascertain what might be the underlying issues causing this cancer, and to try to find a solution so that the disease may be eradicated.

Q: Is BIA-ALCL a major concern?

A: Although the incidence is rare, any procedure that may lead to the death of a patient must be considered a major concern, and something that patients should be made aware of prior to undergoing breast implant surgery. They should be advised of that risk, as well as the risks that surgery itself poses including additional financial costs.

As of December 1, 2017, the PROFILE registry has received 183 unique cases of BIA-ALCL in the U.S., 56% had a history of cosmetic breast augmentation; 44% had a history of post-mastectomy reconstruction. Worldwide, approximately 500 unique cases have been reported which includes 17 disease-related deaths. PROFILE data is regularly updated and available by contacting

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www.thepsf.org/PROFILE for additional data and information. ASAPS and ASPS continue to work on patient education tools that will help breast implant patients put this disease in perspective. In simple terms, the relative risk of capsular contracture versus BIA-ALCL is approximately 100–3000 times higher for a given patient. Patients often desire more tangible terms for patient education on BIA-ALCL, and consultation talking points can be found in a July 2017 *Micromort Analysis*, although these data are in constant evolution as more information is gathered Although the risk is small, patient safety is the primary focus of our societies, and we strive to educate and inform our members and the public about the symptoms and any risk of BIA-ALCL.

Q: Can you explain the differences in implant texture and what role that factor plays in the research?

A: Although it is rare, BIA-ALCL appears to currently develop exclusively in women with textured implants. To date there has not been a confirmed case of BIA-ALCL in a patient with only smooth implants. Proposed theories of the primary potentiator of BIA-ALCL include textured implant particulate, mechanical friction, and/or bacteria/biofilm. Of the 183 unique reported cases of BIA-ALCL to PROFILE as well as world reported cases, silicone and saline fill implants and reconstructive versus cosmetic patients are evenly represented.

Q: How does this impact those with breast implants?

A: ASAPS and ASPS advocate following the FDA recommendation that all women, including those with breast implants follow their normal routine in medical care and follow up, including mammography when appropriate and should immediately contact their physician if they sense any abnormalities within the breast or notice any significant changes. There is no recommended screening for asymptomatic patients. Suspicious fluid collections after one year of implantation should be aspirated and tested for CD30 immunohistochemistry. The FDA recommends all confirmed BIA-ALCL cases be reported to the PROFILE registry. (www.thepsf.org/PROFILE)

Q: What about those considering breast implants?

A: Physicians should include BIA-ALCL in breast implant patient education materials and informed consent so that patients can determine the right procedure for them. Furthermore, breast implants remain among the most studied medical devices available—and the incidence of BIA-ALCL is low.

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

A: Diagnosis and treatment follow standardized guidelines established by the National Comprehensive Cancer Network (NCCN). (Algorithm available on ASAPS and ASPS website). Current recommendations for the treatment of BIA-ALCL call for bilateral capsulectomy and removal of the breast implants. All cases of BIA-ALCL with disease confined to the capsule that have been diagnosed and treated with total capsulectomy have been cured to date. In the 16 known deaths from the disease, all patients either received chemotherapy/XRT alone, died of the treatment itself, had incomplete resection/partial capsule removal, or distant metastasis. The majority of early stage patients treated with total capsulectomy require no additional treatment. Chemotherapy is required for unresectable disease and lymph node and organ metastasis.

Q: Are some patients at greater risk than others?

A: It is not possible to predict who will develop BIA-ALCL. It has occurred in women who have a history of textured breast devices for both cosmetic and reconstructive purposes and has occurred in women with both saline and silicone implants. The following are the current risk factors for BIA-ALCL based on published data and research:

1. **Device.** Textured surface devices. There have been no reported pure smooth-walled device cases at this time.
2. **Genetics.** There has been one published report that there may be a genetic predisposition (germ line mutations in JAK1 and STAT3 genes). Further investigation is required.
3. **Inflammation.** Chronic inflammation either triggered by bacteria or another factor, has been implicated.
4. **Time.** BIA-ALCL mean presentation is 8–9 years post-operative.

Q: Should healthy patients have their implants removed prophylactically?

A: The FDA does not suggest additional screening or prophylactic removal of implants for asymptomatic women.

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

A: The FDA recommends 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, and the FDA are working proactively to study BIA-ALCL. Bacteriologic contamination, long-term allergic inflammation, implant texturing, and genetic factors have been theorized and are undergoing further study. Research is ongoing and cases are being monitored. Genetic predisposition may play a role. Concentrations of reported cases vary widely across the globe, with some geographic areas reporting very few cases. Ongoing data collection worldwide will help to determine any genetic propensities for this disease.

Q: Does the FDA recommend against the use of textured implants?

A: The FDA affirms that all breast implants carry a reasonable assurance of safety and efficacy. 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 including BIA-ALCL, capsular contracture, implant malposition, and rates of reoperation. 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. It is critical that the patient makes a

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fully informed decision following a full discussion of the risks and benefits. For clinical situations where use of a smooth versus textured device is equivocal, surgeons should consider a smooth device.

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

A: There have been 16 confirmed deaths globally, which includes 5 U.S. cases, attributed to BIA-ALCL to date. Disease related deaths have now been reported in Australia, Brazil, France, Netherlands, New Zealand, Sweden, Italy, and the US. Deaths and advanced disease cases emphasize the importance of disease recognition and proper treatment in a timely fashion.

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

A: In July 2016, ASAPS and ASPS issued a joint "Tear Sheet" describing the recommended clinical protocol for patients presenting with symptoms that could be attributable to BIA-ALCL. For a copy of the ASAPS/ASPS tear sheet, please visit http://www.surgery.org/professionals.

ASPS members can find a copy of the ASAPS/ASPS tear sheet at https://cdn.plasticsurgery.org/doc/Joint-ASPS-ASAPS-Statement-On-Breast-Implant-Associated-ALCL.pdf.

This protocol formed the framework for the international recommendations by the National Comprehensive Cancer Network (NCCN) for the diagnosis of BIA-ALCL. Following NCCN guidelines, a swollen breast can be evaluated with ultrasound for either a fluid collection, capsular mass, or lymph node swelling.

Fluid collections should be aspirated percutaneously.

Aspirate (minimum 25–50ml) should be sent for:

1. CD30 immunohistochemistry
2. Cell block cytology evaluation and labelled to "rule out BIA-ALCL."

CD30 testing is critical to direct pathologists and help establish a diagnosis prior to any surgical intervention.

Q: How is BIA-ALCL diagnosed?

A: Diagnosis should be made by fluid aspiration in a clinic or by interventional radiology prior to any surgical intervention. Diagnosis requires large anaplastic cells on cytology and CD30+ immunohistochemistry. Mammograms are not useful in diagnosing BIA-ALCL. In confirmed cases, PET/CT scans are performed to help stage the disease, evaluate for associated capsule masses (20–40% of cases), lymph node metastasis (5–15%) or organ metastasis (1–3%). Confirmation of diagnosis allows for oncologist consultation and oncology workup prior to surgical intervention.

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

A: Additional information, downloadable manuscripts, and resources on BIA-ALCL are available online at www.thepsf.org/PROFILE and at www.plasticsurgery.org/alcl and by searching "ALCL" on RADAR.

This tear sheet represents the data known as of December 2017. Updates to this document will be provided as warranted and as more information is known.

Please visit the organizations websites for additional info:

ASAPS
surgery.org/professionals

RADAR (search "ALCL")
radarresource.org

FDA
https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm239995.htm

ASPS
plasticsurgery.org/alcl

Plastic and Reconstructive Surgery
http://journals.lww.com/plasreconsurg/pages/collectiondetails.aspx?TopicalCollectionId=45