

# An Update On Breast Implant-Associated Anaplastic Large Cell Lymphoma

The plastic surgery field is confronting renewed focus on risks for a rare cancer. Here's an update.

>> The FDA earlier this year issued a letter to healthcare providers in an effort “to increase awareness about an association between all breast implants, regardless of filling or texture, and Breast Implant Associated-Anaplastic Large Cell Lymphoma (BIA-ALCL).” The letter states that FDA, “received reports indicating that patients with breast implants have an increased risk of developing this disease within the scar capsule adjacent to the implant.”

The warning has raised some eyebrows because the thinking to date has been that the risk for BIA-ALCL is primarily associated with textured breast implants. In fact, late last year Allergan suspended sales of textured breast implants and tissue expanders in European markets at the request of the Agence Nationale de Sécurité du Médicament (ANSM).

“We want all healthcare providers to be aware of BIA-ALCL, particularly in patients with new swelling, lumps, or pain around breast implants, to expedite diagnosis of this malignancy,” FDA says in its letter. “We are also asking health care providers to report to the FDA cases of BIA-ALCL in patients with breast implants. This includes reporting individual cases as well as rates you may have experienced during your practice.”

“Some surgeons have gotten in front of the news and urged patients with textured implants to seek explantation. This is not supported by the data. It is important to remember that the vast majority of our patients will not have a problem, and that BIA-ALCL is easily treated and cured when diagnosed early.”

According to FDA, current literature reports various estimates for the incidence of BIA-ALCL, with ranges from a high of one per 3,817 patients to a low of one in 30,000. The majority of patients who develop BIA-ALCL have had textured implants, however, FDA says there have been reports of BIA-ALCL in patients with smooth-surfaced implants and reports where the texture of the implants is not known.

This fall, prior to the FDA letter, *Practical Dermatology*<sup>®</sup> magazine's sister publication, *Modern Aesthetics*<sup>®</sup> magazine spoke with William P. Adams, Jr., MD, a plastic surgeon in Dallas and an Associate Clinical Professor of Plastic Surgery at UT Southwestern Medical Center. Dr. Adams also serves as Treasurer of the

American Society for Aesthetic Plastic Surgery's Board of Directors.

He assessed the risk and urged prudence and proactivity, not paranoia when it comes to addressing BIA-ALCL risk.

## What is BIA-ALCL?

**William P. Adams, Jr., MD:** BIA-ALCL is a rare and treatable type of T-cell lymphoma that can develop around breast implants. It is not a breast cancer. Clinically, the disease is typically very indolent and ongoing research is being done to determine if it is better classified as a lymphoproliferative disorder, a spectrum of disease from indolent/non-malignant to full-blown advanced lymphoma.

The FDA estimates that the lifetime risk of developing BIA-ALCL for

patients with textured breast implants ranges from one in 3,817 to one in 30,000.

### Are there any common denominators?

**Dr. Adams:** The condition has only been seen in textured implants thus far. There have been no confirmed smooth surface-only cases of BIA-ALCL reported. The condition has been diagnosed with both silicone gel- and saline-filled implants.

### Is there a differential risk when it comes to degrees of texture in breast implants?

**Dr. Adams:** Yes, there appears to be a differential risk based on the grade of texture. The more heavily textured the implant, the greater the ALCL risk. It is about one in 3,000 for Grade 3/macro-textured implants and one in 82,000 for Grade 2/micro-textured implants. This is largely due to the surface area on the devices.

In the US, we mainly use smooth breast implants (>90 percent). In other countries, textured implants are the norm.

### Do we know what causes BIA-ALCL?

**Dr. Adams:** Exactly what causes BIA-ALCL is not fully understood yet, but the best science points to a combination of four requirements: 1. Chronic bacterial inflammation with a gram-negative microbiome, 2. Textured implant, 3. Genetic predisposition, 4. Time (mean 8.5 years).

### What are the symptoms of BIA-ALCL? Is it Treatable?

**Dr. Adams:** Symptoms may include breast enlargement and/or seroma around the implant. It is an indolent disease in most cases, and all of those individuals who have been diagnosed early and treated appropriately have been cured. We take out the capsule and the implant (the same treatment as for capsular contracture). Early diagnosis equals a great prognosis and a 100 percent cure rate.

### What are obstacles to early diagnoses?

**Dr. Adams:** This is such a rare problem. Awareness is key for both physicians and surgeons. Any breast implant patient that notices any abnormality, especially enlargement, firmness, shape changes should go be evaluated by their plastic surgeon. Some of these patients end up seeing their internists or emergency care centers where they are not aware of BIA-ALCL.

The most common presentation is a seroma around the implant. Any patient with an enlarged breast should have ultrasound performed and fluid sent for analysis. We collect fresh seroma fluid and part of the capsule and send for

## by the numbers

**1** Breast Augmentation was the number 1 surgical cosmetic procedure in 2017 (333,392 procedures) —up 6.6% from 2016.

**67** % of all patients who had implants removed had them replaced with new implants

**18.3** % of all patients who had implants removed had no further surgical intervention

**11.9** % of all patients who had implants removed had a breast lift only

**2.3** % of all patients who had implants removed had fat grafting to increase volume

—ASAPS 2017 Statistics

cytology and to test for CD30. CD30 is not diagnostic for BIA-ALCL; it is a marker of T-cell activation.

### What type of follow-up is recommended for breast implant patients?

**Dr. Adams:** All breast implant patients should have long-term follow-up with their surgeons. If a patient who has textured implants is doing fine, they don't need any treatment. That said, some people will decide textured breast implants should be removed. All patients should connect with their plastic surgeon and get personal recommendations.

Some proactive plastic surgeons have elected to reach out to their breast implant patients and let them know about BIA-ALCL and its signs and symptoms as well as stress that any patient with concerns come in for a full evaluation. Some surgeons have gotten in front of the news and urged patients with textured implants to seek explanation. This is not supported by the data. It is important to remember that the vast majority of our patients will not have a problem, and that BIA-ALCL is easily treated and cured when diagnosed early.

All cases should be reported to the Patient Registry and Outcomes for Breast Implants and Anaplastic Large Cell Lymphoma Etiology and Epidemiology (PROFILE) Registry. ■

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