

PATIENT FAQ'S FOR BREAST IMPLANT ASSOCIATED ALCL (BIA-ALCL)

Q: What is BIA-ALCL?

A: : *BIA-ALCL (Breast Implant-Associated Anaplastic Large Cell Lymphoma) is a rare spectrum of disorders that can range from a benign collection of fluids around the breast implant (seroma) to a rare lymphoma. BIA-ALCL is not a cancer of the breast tissue itself. When caught early, it is readily curable. If the disease is advanced, chemotherapy or radiation may be required.*

Q: What are the symptoms of BIA-ALCL?

A: *The first symptom of BIA-ALCL is usually a swelling of the breast between 2 to 28 years after the insertion of breast implants, with an average of about 8 years after implantation. The swelling is due to a collection of fluid surrounding the implant. This fluid can cause the breast to enlarge significantly over a period of days or weeks. It can also present as a lump in the breast or armpit, firmness of the breast, or pain. It is usually easily and completely treated if patients see their doctor at the first symptom.*

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

A: *Based on current data, the risk can be explained by the texture grade of the implants as follows:*

- *Grade 1 (Smooth only) - The current lifetime risk is zero.*
- *Grade 2 (e.g. Microtexture, Siltex and similar) – 1:82,000*
- *Grade 3 (e.g. Macrottexture, Biocell and similar) – 1:3,200*
- *Grade 4 (e.g. Polyurethane) – 1:2,800**

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

A. *There have been 16 confirmed deaths, (globally), attributed to BIA-ALCL since the disease was first reported nearly 20 years ago. However, when detected early before it becomes a lymphoma, BIA-ALCL is readily cured with removal of the implant and surrounding scar pocket or capsule.*

Q: Is it a problem with Saline or Silicone implants?

A: *Of the 414 reported cases of BIA-ALCL, 312 reports included information on the types of implants used. Of those, 234 reported implants with silicone gel and 119 reported implants filled with saline. **It appears to purely be related to the surface of the implant and not to what the implant is filled with.***

<https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm481899.htm>

As of September 30, 2017, the FDA has received a total of 414 medical device reports (MDRs) of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL), including 9 deaths¹. BIA-ALCL are counted for those with a confirmed pathology test, or ALK or CD30 biomarkers, or reported by health care professionals. There are 272 reports with data on surface information at the time of reporting. Of these, 242 were on textured implants and 30 on smooth implants. There are 413 reports with data on implant fill type. Of these, 234 reported the use of silicone gel-filled implants, and 179 reported the use of saline-filled implants.

Q: How does this impact those with breast implants?

A: *ASAPS and ASERF emphasize that the most important issue for women with breast implants is to screen for breast cancer with self-exam, a regular physician exam, and mammography/ultrasound/MRI as recommended by their physician. All women should see their plastic surgeon immediately if they note a change to the size, feel, or shape of their breasts.*

Q: Why would my surgeon have recommended textured implants for me?

A: There are two primary reasons your surgeon may have recommended textured surface breast implants. First is that some data has shown a lower rate of capsular contracture (firm scar tissue formation around the implant). Second, all teardrop or anatomic shaped implants have a textured surface to help hold them in place. Some surgeons believe these implants can offer an enhanced shape for certain patients, perhaps with a reduced risk of rippling.

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

A: *Current recommendations for the treatment of BIA-ALCL call for bilateral capsulectomy (removing all the scar tissue) and removal of the old breast implants. This is a very common procedure performed by plastic surgeons, identical to what is done when an implant has ruptured or capsular contracture has developed. Smooth implants can be put back in or the patient can choose not to have 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. However, if the disease has spread to lymph nodes or adjacent tissues, chemotherapy or radiation may be necessary. This has only been necessary in a small percentage of patients.*

Q: Should patients have their implants removed because of a risk of BIA-ALCL?

A: *Since BIA-ALCL has only been found with textured breast implants, smooth implant patients do not need to be concerned. For textured implant patients, neither the FDA nor any plastic surgery society currently recommends that women should preventatively remove textured breast implants to prevent BIA-ALCL. However there are women who have been concerned enough about BIA-ALCL and have chosen to have their implants removed. There are some women who were already considering a breast implant revision, and the BIA-ALCL issue gave them one more reason to decide to proceed.*

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

A: *There is no blood test to specifically screen for BIA-ALCL. The expert opinion is that asymptomatic women without breast changes do not require more than routine mammograms and breast exams. But if a patient experiences a change in her breasts – especially if there is swelling or a lump – she should undergo immediate examination, imaging, and consultation with a plastic surgeon. If there is fluid around the implant the fluid should be aspirated under ultrasound guidance and sent for analysis.*

Q: What causes BIA-ALCL?

A: *ASAPS, ASERF, the FDA, and the implant manufacturers are intensely studying 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. The best theory today is that a combination of four factors are required for the development of BIA-ALCL:*

- 1. Highly textured implant*
- 2. Chronic bacterial-inflammation*
- 3. Genetic pre-disposition*
- 4. Time*

The source of the chronic inflammation is thought to be bacteria that have been identified around the implants in affected breasts. Evidence is accumulating 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.

Genetic factors may play a role. 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: Does ASAPS 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.*

Every plastic surgeon offers patients options regarding breast implants in terms of sizing, shape, and surface. 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.