THE CENTER FOR COSMETIC SURGERY & medi Spa

DEAN P KANE, MD, FACS, PA
LAURI P KANE, RD, MPH, SCD

EXECUTIVE CENTRE AT HOOKS LANE
1 RESERVOIR CIRCLE, SUITE 201 • BALTIMORE, MD 21208
DeanKane@DrDeanKane.com • www.DrDeanKane.com
410.602.3322

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Dear Breast-implant Patient,

You are receiving this letter as you had been a prior breast-implant patient of Dr. Dean Kane.

Over the past several months textured breast implants have been in the news because patients with this kind of prosthesis seem to have a higher risk of developing a condition known as Breast Implant Associated-Anaplastic Large Cell Lymphoma (BIA-ALCL). As your surgeon, I am writing to provide additional information and to discuss what actions, if any, are appropriate.

What is BIA-ALCL? It is a type of lymphoma which develops within the capsule that forms naturally around the implant. It is a very rare condition and if it occurs, is very treatable in its early stages. Until now, BIA-ALCL has been relatively unexplored and is not considered to be breast cancer. Approximately 35 million implants have been sold since 1997, with fewer than 600 cases of this disease documented.

Are specific implants affected? Many breast implants have a textured surface and have been used by surgeons worldwide. Only textured implants have been reported to be associated with the risk of BIA-ALCL among all types of implants manufactured by different companies. It is important to know that there have been no confirmed cases of BIA-ALCL associated with patients with smooth-surface implants. The reasons remain unclear.

Of the 573 cases of BIA-ALCL, 481 are reported to have Allergan BioCell textured breast implants at the time of diagnosis, according to the FDA. Allergan has stopped the production of this implant envelope.

Is the health ministry asking me to have my implants removed? NO, just the opposite. ***It has been specifically stated that removal or replacement of textured implants in patients who have no symptoms is not recommended or suggested due to the low risk of developing BIA-ALCL.***

How serious is BIA-ALCL? When BIA-ALCL is diagnosed and treated early, it is usually curable. Of the 573 cases in the world, there have been 33 deaths. Deaths associated with BIA-ALCL are thought to have resulted from delayed diagnosis or inappropriate treatment. The single most important intervention to prevent advanced BIA-ALCL is regular monitoring and early detection.

What symptoms should I be looking for? Unlike breast cancer, BIA-ALCL most commonly presents with swelling of one breast. Other less common symptoms include hardening of the breast, an unusually persistent rash or a palpable mass in the breast or armpit – all easily identified by you. If you have any of these symptoms, please call to schedule an appointment for an examination and if needed, further tests. An ultrasound can detect the presence of fluid, and if present, a small amount can be aspirated with a needle and tested. Should tests called CD30 and ALK be positive, a diagnosis of BIA-ALCL will be considered. If the tests are negative, the fluid collection is considered benign. Benign fluid collections, known as seromas, are not uncommon around breast implants. It is important to differentiate them from those associated with ALCL.

What if the tests confirm BIA-ALCL? In most patients, BIA-ALCL is curable with surgery alone – removing the textured implants and the capsule. Consultations with other medical specialists may be recommended, but in most cases, there is no need for radiation or chemotherapy.

What if I do not have any symptoms? To our knowledge, there is no medical agency or health ministry that recommends removal of your textured breast implants at this time. Should you develop any signs or symptoms mentioned above, you should make an appointment for evaluation.

FAQS:

What is the most up-to-date assessment of overall risk of BIA-ALCL?

The reported risk and incidence of BIA-ALCL in patients with Allergan BIOCELL textured implants ranges from 1:443 (median of 7 years) to 1:3345. The overall risk of BIA-ALCL in the US is 1:30,000 which is an average of several high and lower risk textured implants. There is currently no identified risk-reducing procedures. Patients have developed BIA-ALCL with a history of a retained scar capsule, a history of only simple implant exchange, and some patients have been told they received a total capsulectomy and ultimately developed disease. However*, patients should note that the current risks associated with surgery are higher than the risk of developing BIA-ALCL.*

Other textured implants exist and they are not recalled. While their incidence of BIA-ALCL is not yet measured, it is far less than Allergan BIOCELL.

Do I need to have my implants removed?

No, the FDA has specifically stated that implant removal is not necessary at this point unless you are diagnosed with BIA-ALCL. Having symptoms such as breast swelling, a lump in your breast or armpit, persistent breast pain, a rash or any change in your implants should be investigated by your physician. If you have any of these symptoms you should make an appointment to see a board-certified plastic surgeon and member of the American Society of Plastic Surgeons. To find a plastic surgeon in your area, visit Find.PlasticSurgery.org.

Do all BIA-ALCL cases involve/present with a seroma? Are there other symptoms I need to be looking for?

No, although seroma is by far the most common presentation for BIA-ALCL, only roughly 70% of cases of BIA-ALCL present with a delayed, unilateral seroma. Twenty percent of cases present with a breast mass, adjacent to the implant capsule. The remainder, <5%, present with regional lymphadenopathy, distant metastasis, an aggressive capsular contracture, breast pain and/or a breast rash. Very few cases of BIA-ALCL have been asymptomatic and only found incidentally at time of mastectomy, implant exchange, or other unrelated procedure.

Have there been any cases of BIA-ALCL where a patient had at one time, but does not currently have implants or expanders at the time of diagnosis?

Yes. There are a few reported cases of patients who have had textured implants or expanders in the past, who had their devices removed and later developed BIA-ALCL.

Trace fluid around the breast implant was identified on routine breast imaging. Do I need to aspirate and send for evaluation?

Patients with BIA-ALCL typically present with a large volume seroma around a textured implant. "Trace fluid" seen around a breast implant is a common finding and likely benign. If the amount of fluid is symptomatic and allows for aspiration, then this fluid can be sent to pathology for CD30 immunohistochemistry, especially if found around a textured implant. Note that volumes of aspirate less than 50 ml are unreliable for detecting disease. For a patient presenting with symptoms of BIA-ALCL, if the amount of fluid seen does not allow for aspiration and suspicion of disease remains high, consider close clinical follow up with repeat imaging with ultrasound or MRI in 3-6 months.

I have symptoms of BIA-ALCL. What should I do?

The most common sign of BIA-ALCL is fluid or swelling around a breast implant. This usually happens many years after the implant was originally placed. BIA-ALCL can also cause tumors that arise from the scar capsule around the implant. Less commonly, BIA-ALCL can cause a breast to become lumpy or misshapen with the development of thick scar capsule around an implant.

If you have any of these symptoms of BIA-ALCL or other changes in your breast(s), your health care provider should evaluate you promptly. It is important to note that these signs and symptoms do not necessarily mean a diagnosis of BIA-ALCL. These changes, for example, can also result from a leaking implant or trauma to the breast area. To evaluate for BIA-ALCL, your health care provider will take your history, perform a physical exam and may order imaging or an assessment of any fluid or tissue around your implant.

Is there a screening test for BIA-ALCL?

At present there is no screening test or tool for BIA-ALCL. The best course of action is careful routine breast examination. If you have symptoms such as breast swelling, a mass in your breast or armpit, a new rash on your breast or persistent breast pain, or any change whatsoever in your breasts, you should see your plastic surgeon for evaluation.

I have a BIOCELL implant and / or expander. I am very concerned about BIA-ALCL. What should I do?

Each patient should be informed about the low risk of BIA-ALCL as well as the signs and symptoms of the disease. The patient should have a thorough history and physical examination performed*. If no abnormality is found on physical exam, the patient should be informed that the FDA is not recommending removal of BIOCELL implants.* A patient may choose, however, to proceed with explantation and capsulectomy. It is important to know that having a total capsulectomy may lower the risk, but there is no data to confirm the future risk of developing the disease. Patients should be reminded that the risk of a surgical capsulectomy and implant exchange is significantly greater than the incidence of developing BIA-ALCL. A total capsulectomy in an undiagnosed BIA-ALCL patient may still leave residual mass which has been reported to lead to hyperprogression of disease with adverse sequelae. Reconstruction patients should also be advised that their breast shape may change following a complete capsulectomy and that this procedure may devascularize overlying skin and/or flaps. Thoroughly discuss all benefits and risks with your patient to help her make an informed decision that is best for her and her health.

I developed a new mass / new aggressive capsule / new breast asymmetry and I want to rule out BIA-ALCL. What is the next step?

A proper clinical exam is required to determine next steps. If there is fluid around the implant, this should be sent for CD30 immunohistochemistry. Patients should undergo imaging with ultrasound or (MRI) to further evaluate any clinical abnormal findings. Breast MRI is particularly helpful in patients with suspicion for a mass. The presence of a mass and/or lymphadenopathy should prompt a biopsy and surgeons may consider referral to breast oncology for workup. For core biopsy, fine needle aspiration, or tissue biopsy, the pathologist should be alerted to the suspicion for BIA-ALCL as a specific work-up for that disease may not typically be included in the more common work up of a breast mass.

I have received and are now again receiving information that the FDA is not recommending prophylactic implant removal. What should I do?

Return to your implant surgeon and receive the risks of explantation surgery. I may elects to proceed with surgery and as with all procedures, proper informed consent is required. The patient should be informed that there is no data to indicate any effect on the future risk of developing BIA-ALCL.

I have Allergan BIOCELL implants. What should I do?

Unless you are having the symptoms noted below, there is nothing to do at the present time other than routine continual breast examinations. Any changes in your breast should be examined and discussed with a board-certified plastic surgeon. The current recommendation from the FDA is that women with Allergan BIOCELL implants that do not have symptoms do not require removal. If you have Allergan BIOCELL implants, you should understand that textured surface implants are associated with a low but real risk of BIA-ALCL, a cancer of the lymphatic system. You should know the signs and symptoms of the disease. As long as you have your breast implant(s), you should monitor your breast area for any changes.

It is important to note that on September 12, 2019 the FDA released an update identifying Allergan BIOCELL Textured Breast Implant(s) as a Class I recall, the most serious type of recall. If changes to your breast(s) arise, you should seek evaluation promptly. More information about BIA-ALCL can be found at:

1. FDA Frequently asked questions

   https://www.fda.gov/medical-devices/breast-implants/questions-and-answers-about-%20breast-implant-associated-anaplastic-large-cell-lymphoma-bia-alcl

2. FDA Statement on Allergan Recall

   https://www.fda.gov/medical-devices/safety-communications/fda-requests-allergan-voluntarily-recall-natrelle-biocell-textured-breast-implants-and-tissue

3. ASPS Resources

   https://www.plasticsurgery.org/patient-safety/breast-implant-safety

I have a textured implant(s) but my implant(s) have not been recalled. What is my risk for developing BIA-ALCL?

At the present time, your exact risk is not known. However, it appears to be significantly less than the risk noted below in question 4. The FDA and a 2017 study of US epidemiology of BIA-ALCL noted that Allergan BIOCELL implants appeared to be 6x more likely to be associated with the development of BIA-ALCL than other textured implants currently on the market.

What is my risk of BIA-ALCL? Is my risk of BIA-ALCL lower if I remove my implants and do not have them replaced?

The risk and incidence of BIA-ALCL in patients with Allergan BIOCELL textured implants ranges from 1:443 (median of 7 years) to 1:3345. The overall risk of BIA-ALCL in the US is 1:30,000 which is an average of several high and lower risk textured implants. *There is no known procedure that can*

reduce risk for the development of the disease in the future. Patients have developed BIA-ALCL with a history of a retained scar capsule and a history of only simple implant exchange. However, patients should note that the current risks associated with any surgery are higher than the risk of developing BIA-ALCL. Discuss all benefits and risks with your board-certified plastic surgeon. Understanding all potential risk factors will help with better decision-making that is best for you and your health.

I had (or currently have) textured tissue expanders. Should I be worried? What is my risk of BIA-ALCL?

Risk of disease with tissue expanders has not been determined at this time. It is important to stay vigilant and upon noticing any changes in your breasts, consult a board-certified plastic surgeon.

If I choose to have my implants removed and/or replaced, do I need to have the capsule (scar around my implant) removed? What is an En-Bloc resection?

If you choose to have your breast implant(s) removed out of concern for BIA-ALCL, you should have a discussion with your surgeon about implant removal, implant exchange, and partial or total scar capsule removal. The surgical removal of the scar capsule around your implant is called a "capsulectomy" in an otherwise healthy patient. Having a total capsulectomy at the time of implant removal is not known to change the risk of developing BIA-ALCL. The risk of performing a capsulectomy includes, but is not limited to, bleeding and other wound complications. For reconstruction patients, a capsulectomy could result in a change of shape to your breast or loss of the reconstruction.

En-Bloc resection is often a misused term that means a cancer removal in a BIA-ALCL diagnosed patient with removal of the implant, complete capsule in conjunction with any associated mass and a rim or margin of surrounding healthy tissue.

I didn't receive an implant card. How do I find out what kind of implant I have?

The best and easiest way is to contact the surgeon who performed your surgery or the hospital where you had your surgery performed and ask for your medical records. If your surgeon is no longer in practice or a significant time has elapsed since your surgery, the implant manufacturers may have this information through their device tracking mechanisms. Call the medical information division at one of the companies to find out about your implants.

Am I in the NBIR/PROFILE registries?

The aggregate NBIR and PROFILE registry datasets do not contain any personal identifying information. Contact your plastic surgeon and/or treating physician to determine whether or not your information was entered in either registry.

Where can I find more information?

https://www.plasticsurgery.org/patient-safety/breast-implant-safety/bia-alcl-summary/frequently-asked-questions?utm_source=Adestra&utm_medium=email&utm_campaign=ASPS-BIA-ALCL-Update_09.25.19&utm_term=Varies&utm_content=Patient%20FAQs

Please continue to have your breast implants checked routinely, usually every other year. You may schedule a consultation at any time.

If you have any further concerns or would like to schedule an evaluation, please contact my office for an appointment.

Most sincerely,

Dean Kane, MD, FACS