Allergan Suspends Sales of Its Textured Breast Implants in Europe, Breast Implants Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)

Breast Reconstruction Specialist Dr. Constance M. Chen with important information and tips for patients concerned about their breast implants.

NEW YORK (PRWEB) January 22, 2019 -- In December 2018, Allergan, one of the world's largest manufacturer of breast implants, suspended sales of its textured implants in Europe after the implants were denied renewed safety certificates in France because of concerns about BIA-ALCL. The French regulatory agency and a British association of plastic surgeons have recommended the use of smooth-surface implants in place of textured-surface products. Both European regulators and the U.S. FDA will hold meetings in 2019 to review further the safety of all breast implants but for now, textured implants remain approved for use in the U.S. *

“ALCL is a extremely rare cancer of the immune system, and questions have been raised about whether the incidence is higher in women undergoing breast reconstruction with breast implants,” says Dr. Constance M. Chen, board-certified plastic surgeon and breast reconstruction specialist. The incidence of ALCL in the breast is 3 cases of ALCL in 100 million women (0.000003%). Dr. Chen adds that “BIA-ALCL has been associated in women who have breast implants for both cosmetic and reconstructive reasons. Women who have breast implants for breast reconstruction due to mastectomy or for cosmetic breast augmentation are at equal risk for developing BIA-ALCL. The simple fact of having a breast implant - of any type, for any reason - in her body places a woman at higher risk of developing BIA-ALCL.” Dr. Chen adds that the current literature estimates that BIA-ALCL may develop in 1 in 3,817 to 30,000 women with textured breast implants.

“While attention has been focused on textured breast implants, BIA-ALCL has actually been found in all types of breast implants: textured, smooth, silicone, saline,” says Dr. Chen. As of 30 September 2017, the FDA had received 414 medical device reports of BIA-ALCL, including the death of 9 patients. Only 272 of the 414 reports included information on the implant surface. Of these cases, BIA-ALCL was found associated with 242 implants with textured surfaces and 30 implants with smooth surfaces. With regard to implant filling, BIA-ALCL was found associated with 234 implants filled with silicone gel and 179 implants filled with saline. About half of the reported cases were diagnosed within 7-8 years of breast implantation.

The backstory:
In 2011, the U.S. Food and Drug Administration (FDA) first noted that the incidence of ALCL seemed slightly higher in patients with breast implants, but it was still very rare even in this population with 60 cases of ALCL worldwide in 5-10 million women (0.0006-0.0012%). Dr. Chen adds, “that at the time, many healthcare professionals believed that the incidence of ALCL in women with breast implants might have even been overestimated because some of the data collected may have been duplicate cases.” However, in 2016 data collection improved due to an increased attention to ALCL and breast implants, and the World Health Organization (WHO) designated breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) as a T-cell lymphoma that can develop following breast implants.

Several recent journal articles explore risk factors for developing BIA-ALCL, including the role of biofilm. Dr. Chen notes that “textured implants have significantly more surface area than smooth implants, which may explain why there is a higher incidence of BIA-ALCL in textured implants than smooth implants.” However, BIA-ALCL has clearly been found associated with every type of breast implant. Textured implants may be at
slightly greater risk for ALCL than smooth implants, but findings are not conclusive. Dr. Chen points out that “this is important to note because many plastic surgeons have stopped using textured breast implants, but they continue using smooth breast implants. It is clearly not true that BIA-ALCL is limited to textured breast implants only. Since every type of breast implant has been associated with BIA-ALCL, it is a false sense of security to limit breast implant use to smooth breast implants. In reality, all types of breast implants can lead to BIA-ALCL.”

Tips for Patients:
When ALCL occurs with breast implants, it is identified most frequently in patients undergoing implant revisions for late onset, persistent seroma (a fluid collection that develops around the implant), or other symptoms such as pain, lumps, swelling, or breast asymmetry. Dr. Chen advises that “any women experiencing these symptoms should see a plastic surgeon to be evaluated for BIA-ALCL.”

The FDA already recommends that women with silicone breast implants undergo breast MRI every 2-3 years to evaluate for silent rupture of her silicone breast implants. Dr. Chen advises that if a patient with breast implants feels a change in her breasts, breast imaging can be obtained to evaluate for seroma. If a seroma is found, an interventional radiologist or a skilled breast radiologist can aspirate the seroma fluid to test for CD30 markers and lymphoma. If the cytology is positive, the patient will need to be treated.

Treatment of BIA-ALCL includes removal of the implant and capsule surrounding the implant and sometimes chemotherapy and radiation. If ALCL is diagnosed through imaging and testing of the fluid around the breast, treatment is generally the surgical removal of the implant and the entire capsule that surrounds it. In its early stages, all traces of cancer are generally removed by surgery. Further treatment is necessary only if all the cancer could not be removed or if the disease has spread to the lymph nodes or other parts of the body.

Dr. Chen clarifies that the FDA does not currently recommend prophylactic breast implant removal in patients without symptoms or other abnormalities. At present, breast implants are still approved in the USA when used as labeled for breast augmentation or breast reconstruction, as the risk of ALCL is still considered to be small and inconclusive. All of this may soon change, however, as new and better data is collected on BIA-ALCL.

“Women with breast implants who want to have their breast implants removed have options,” says Dr. Chen. A woman facing breast reconstruction after mastectomy can consider autologous reconstruction, in which a new breast is created from her own tissue. If she is not a candidate for autologous reconstruction or if she prefers implants, she must be aware of the risk of BIA-ALCL. A woman who had breast implants for cosmetic breast augmentation can have her breast implants removed and undergo natural breast augmentation or accept a smaller size breast. Dr. Chen concludes, “even though breast implants of all types are still approved for use in the United States, any woman who has breast implants or is considering breast implants should be aware of BIA-ALCL so that she can be fully educated and consider the potential repercussions of breast implants on her health and well-being.”

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