Physician Questions

Presentation and Diagnosis

1. **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.

2. **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.

3. **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.

4. **My patient presents with 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.

5. **I'm in private practice and do not have easy access to pathology to test for CD30 and ALK. Can I just use a microscope and skip the immunohistochemistry?**
   Absolutely not, CD30 immunohistochemistry is essential as a screen for the disease. CD30 positivity coupled with large anaplastic cells on cytology, ALK negativity, and a single T-cell clone on flow cytometry is pathognomonic for BIA-ALCL. If the lab that you usually work with does not perform CD30 testing, know that specimens can be sent out to tertiary centers for testing and evaluation. Please note, however, there is a small incidence of CD30 cells in 'normal' seroma

specimens. Note that, CD30 positivity is not completely diagnostic as false positives do occur. Therefore, low or scant CD30 positivity of normal shaped lymphocytes by itself is not reflective of disease.

6. **My patient has BIOCELL implants and is 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.

   It is important to note that on September 12, 2019, the FDA has identified BIOCELL Textured Implants as a Class I recall; this means that the use of these devices may cause serious injuries or death. For additional information about this FDA update, visit https://www.fda.gov/medical-devices/medical-device-recalls/allergan-recalls-natrelle-biocell-textured-breast-implants-due-risk-bia-alcl-cancer

Surgical Treatment

1. **After I have explained that the FDA is not recommending prophylactic implant removal, my patient still wants her implants out. What should I do?**
   If you have explained the risks of explantation surgery and the patient elects to proceeds with surgery, 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.

2. **My patient has elected to proceed with explantation of her textured implants out of concern for BIA-ALCL. What do I do with the capsule? Does the capsule need to be sent for pathology?**
   Some patients may express an interest in explantation and complete capsulectomy with or without replacement. Most states require that anything removed from a breast must be sent for pathology. In this case especially, the implant and capsule should be sent for pathology to adequately assess for any occult finding. If there is anything of suspicion for BIA-ALCL found on the capsule, then any fluid and/or residual tissue should be sent for CD30 immunohistochemistry.

3. **What is the difference between an En-Bloc resection and a complete capsulectomy? (When should one be performed over another?)**
   En-Bloc capsulectomy is a commonly misused term when dealing with breast implants. Patients may incorrectly refer to *en bloc* as only removing the implant with the entire capsule intact. An

en bloc resection is an oncologic term performed to remove a cancer specimen in whole. For BIA-ALCL, this would include explantation, capsulectomy, ablation of associated masses surrounded by a contiguous rim of healthy tissue margin.

There is no data to suggest that partial, total capsulectomy or an "en bloc" of a healthy patient is any better than no surgery.

General

1. **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.

2. **Should I send a letter to my breast implant patients about BIA-ALCL**
   With the current recall of BIOCELL implants, the FDA has recommended that all patients with a history of these implants and expanders should be contacted. Obviously, patient addresses and phone numbers can change, so a reasonable effort is what is expected. ASPS developed a sample letter that can be found here (login required). Allergan is currently contacting all patients within their device tracking system. It is up to the surgeon, at this point in time, as to whether to contact patients with Mentor and Sientra textured implants.