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VIEWPOINT

Breast

Evaluating Risk versus Benefit When Advising Asymptomatic Women regarding Explantation of Textured Breast Implants

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Today, plastic surgeons regularly face questions from patients regarding the advisability of textured breast implant removal or replacement. Many factors influence this decision, and the data are still limited and evolving. The diagnosis and treatment of breast implant-associated anaplastic large-cell lymphoma (BIA-ALCL) involve considerable morbidity, expense, and risk. The advice we give to patients must be accurate and up-to-date.

The website of the American Society of Plastic Surgeons (ASPS) was recently updated. With regard to Allergan Biocell (Abbvie Inc., Lake Bluff, Ill.) implants, a sentence reads: "FDA [U.S. Food and Drug Administration] advises that patients who have no symptoms (*sic*), removal of these or other types of breast implants is not recommended, due to the low risk of developing BIA-ALCL."[1]

Under frequently asked questions for patients,[2] the first question on the ASPS website asks, "Do I need to have my implants removed?" The answer reads, "No, the FDA has specifically stated that implant removal is not necessary at this point unless you are diagnosed with BIA-ALCL." In response to the second question, "I have Allergan Biocell implants. What should I do?" the answer is, "Unless you are having the symptoms noted below, there is nothing to do at the present time other than routine continual breast examinations." The ASPS website continues: "However, patients should note that the current risks associated with any surgery are higher than the risk of developing BIA-ALCL." These points are reiterated by speakers on the website.

The ASPS website advises that the "current lifetime risk of BIA-ALCL is estimated to be 1:2207–1:86,029 based upon variable risk with different manufacturer types of implants."[1] Speakers on the website report a BIA-ALCL risk of 1:443–1:3345 for Allergan Biocell implants.[1]

In considering society guidelines, it is useful to revisit the FDA recommendations. The original communication released by the FDA on July 24, 2019 states: "The FDA does not recommend removal for patients without symptoms due to potential risks, but we provide helpful information for patients and providers to consider when discussing next steps."[3] Clearly, the FDA does not recommend explantation. However, the FDA does not recommend that women keep their textured implants either. The FDA is not affirmatively instructing patients not to have explantation. It defers to the patient and her surgeon to consider this information when discussing next steps, which would presumably include a discussion of explantation. The reason for the nonrecommendation was changed in a June 1, 2020 FDA release to "due to the low risk of developing BIA-ALCL."[4]

A risk/benefit analysis is needed when making an informed decision. The risk of explantation must be weighed against the risk of BIA-ALCL. This important subject was discussed by Santanelli di Pompeo,[5] at the 2021 3rd World Consensus Conference on BIA-ALCL.[6] This Italian plastic surgeon presented a retrospective study finding that there were zero deaths among almost 100,000 European breast implantation, explantation, and implant exchange patients treated over a period of 8 years. By comparison, Wixtrom et al[7] reported a 1:72,000 risk of death for cosmetic breast outpatients, not necessarily implant patients, based on the American Association for Accreditation of Ambulatory Surgical Facilities database.

How does the risk of explantation compare to the risk of BIA-ALCL? Estimates of the risk of BIA-ALCL in women with textured implants have increased dramatically in recent years.[6] In 2017, the calculated lifetime prevalence was 1:30,000.[8] Two large prospective studies by McGuire et al[9] and Cordeiro et al[10] report a risk of 1:2207 (supplemented with four postpublication diagnoses),[11] and 1:355, respectively, for women with Biocell implants. Both of these estimates are almost certainly too low because the average interval between implantation and diagnosis is 8–10 years.[12] In 2020, Cordeiro et al[10] estimated that the cumulative risk over 20 years in breast reconstruction patients

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implanted with Biocell devices is 1:100. According to the FDA, the risk associated with Biocell implants is six times greater than the risk of BIA-ALCL with textured implants marketed by other manufacturers in the United States,[4] although there are limited data. Clemens[6,13] reports a risk of 1:350–1:2200 for Allergan Biocell implants; the risk for other textured implants remains unknown.

The risk of death in a patient diagnosed with BIA-ALCL is not minuscule. In 2020, the FDA reported 733 medical device reports of BIA-ALCL and 36 deaths, for a mortality rate of 1:20 (5%).[14] According to the ASPS Global Network and European Taskforce, as summarized by Clemens,[13] there have been 1148 BIA-ALCL cases worldwide and 35 deaths (mortality rate, 1:32.8) as of October 9, 2021.[6] The evidence suggests that even if the risk of BIA-ALCL is as low as 1:2200, the risk of dying from BIA-ALCL exceeds the mortality of implant surgery. Moreover, the morbidity and expense associated with a BIA-ALCL diagnosis are likely to exceed the morbidity and cost associated with a complication from explantation.

According to core study data, between 22.3% (primary augmentation) and 71.5% (primary reconstruction) of women undergo implant replacement surgery within 10 years.[15–18] Santanelli di Pompeo[5] extrapolates that a woman first implanted at age 41 can expect to undergo as many as four future implant operations if she lives to the age of 85.[6] If a patient is very likely to have a reoperation, why not proceed with explantation or implant exchange sooner rather than later?

Identifying the benefit of explantation, if any, is not possible in the absence of any prospective studies. Similarly, any possible value from simultaneous removal of a normal-appearing capsule is unknown. In truth, no preventative treatment is known to eliminate the BIA-ALCL risk in exposed patients. It is difficult to prove the efficacy of implant removal because of the decade-long latency[12] between implantation and BIA-ALCL diagnosis. It is also true that there is no evidence that explantation is not effective in reducing risk. As Carl Sagan put it, "the absence of evidence is not the evidence of absence."[19] The textured breast implant is the trigger that sets in motion the path to BIA-ALCL.[6]

McGuire et al[20] report that BIA-ALCL has occurred in women who have undergone an explantation without a capsulectomy. However, these women had a seroma at the time of implant removal and were likely to have already developed BIA-ALCL.[20] Cases of BIA-ALCL have also occurred in women who previously underwent capsulectomies for capsular contracture with simultaneous replacement of textured implants with smooth devices.[21,22] Clemens[13] disputes the value of a "prophylactic capsulectomy"[5] and suggests that surgical treatment of a capsule that has occult disease might contribute to its dissemination.[21]

In view of the lack of evidence for efficacy, the author recommends explantation or implant exchange with smooth implants without capsulectomy in women who have no evidence of BIA-ALCL.[6,11,23,24] The patient risk, morbidity, and expense are much less when the capsules are preserved.[6,11,24] This risk/benefit analysis shifts strongly toward implant replacement.[11] Any theoretical benefit of capsulectomy is a moot point if the patient decides against replacement surgery because of the additional risk and expense.[11] If BIA-ALCL is diagnosed later, it is still treatable, especially if it is diagnosed early and is contained by an intact capsule.[11]

The ASPS website states that BIA-ALCL occurs "more frequently" in women with textured implants.[1] In October 2021, Clemens[13] confirmed that there are still no BIA-ALCL cases reported in women who received smooth implants in whom the device history is fully known.[6] Patients should be properly advised of this categorical, not relative, difference in risk when selecting an implant.

Considerable effort has been given to elucidate the connection (now considered causative[6,13]) between textured breast implants and BIA-ALCL. A bacterial cause has not been substantiated,[6] and sophisticated microbiological testing has not identified a microbiome specific for this disease.[25] Similar to most cancers, identifying the etiology, on a cellular, genetic, or molecular level, is likely to be difficult, very expensive, and possibly beyond our present capabilities. Chronic inflammation and silicone particle shedding are believed to be implicated.[5,6,11] Textured breast implants are categorically different from smooth implants in their surface treatment, unlike differences in bacterial counts, which are relative rather than absolute. These facts make a physical cause more compelling to investigators than an infective etiology.[5,6,11]

It would be helpful to know whether the risk increases with the length of exposure to the triggering influence (the textured breast implant). Cordeiro et al[10] have shown that the BIA-ALCL risk increases with time since implantation. Would these Kaplan–Meier curves appear differently if the textured breast implants were removed shortly after they were inserted?

It does seem puzzling to ban a defective device that may cause cancer, and at the same time instruct implanted women that there is no need to remove their defective devices. I have found that, when asking plastic surgeons and scientists at meetings what they would do if a loved one had Allergan Biocell implants, the answer is invariably, "they are coming out." Two of these individuals are Drs. Fabio Santanelli di Pompeo and Michael Atlan (personal communications, April 9, 2022). The way we advise our patients should be the same as how we would advise a family member. Plastic surgeons should not resist explantation in patients who request it. Such a response is arguably paternalistic and one they may regret if a woman returns years later with BIA-ALCL. To tell patients that "the FDA recommends against it" is not exactly true.

Some conclusions are clear. Women should not be instructed to do nothing. They should not be told that implant replacement is riskier than BIA-ALCL. Patients deserve to have realistic estimates of lifetime risk. In view of the drastically increasing risk estimates over the last decade,[6] and the increasing risk with implantation time,[10] it is prudent to give a lifetime risk estimate that may be too high (1:100),[10] as opposed to too low. Ultimately, a woman's decision regarding explantation is hers to make because it is one that could have life-or-death consequences. Our

responsibility is to give her the most accurate information on which to base this important decision.

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