

BIA-ALCL: This is not 1992 all over again

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Many of us remember the FDA ban on the use of silicone-filled breast implants in 1992 like it was yesterday. It was a dark time in plastic surgery and a traumatic experience for physicians and patients alike. Patients were concerned about developing systemic diseases and malignancies from their breast implants. Physicians were concerned about the health of their patients. We all wanted what was best for our patients, but we did not have enough information to know exactly what that was.

Fortunately, over the ensuing 14 years, a series of high-quality epidemiological studies were performed to evaluate the safety of silicone-filled breast implants. Those studies determined that the device was safe for use in humans for both reconstructive and aesthetic purposes. As a result of these extensive research efforts, silicone-filled breast implants were approved for use in November 2006.

It was a remarkable turn of events and an important demonstration of the value of data and high-quality research in answering the most challenging questions.

BIA-ALCL and new questions

We're now faced with new concerns regarding the safety of breast implants: breast implant-associated anaplastic large-cell lymphoma (BIA-ALCL). BIA-ALCL is a rare T-cell lymphoma that arises in the fluid around breast implants. The original diagnosis of a peripheral T-cell lymphoma associated with breast implants was made in 1994. Since that time, there have been approximately 170 cases documented in the literature.

This seems like a relatively low number of cases, considering the millions of patients with breast implants worldwide. However, without more information about the relative risk and prognosis, this still could represent a health risk for our patients and is certainly worthy of further investigation and scrutiny.

For those who lived through the prior implant crisis, this may seem strangely reminiscent of 1992. But it's not. What makes this situation different is that over the past 25

years, we've developed strong working relationships and strategic alliances with our plastic surgery partners at ASAPS and with the FDA to respond to this issue in a comprehensive and thoughtful way. We have created partnerships with the worldwide plastic surgery community to bring our entire specialty together during this critical time. We have created a database to collect as much information as possible about BIA-ALCL. We have supported basic science and clinical research to gain a more comprehensive understanding of the disease process, prevention and treatment strategies. All of this taken together makes this situation substantially different than 1992.

Strong relationship with the FDA

In 2009, a multispecialty conference on facial soft-tissue fillers was convened for the purpose of assessing the "State of the Science" on dermal fillers. This meeting was conceptualized and developed by ASPS/PSF and the American Academy of Dermatology, in conjunction with the FDA. Representatives from ASAPS, dermatology, otorhinolaryngology, and ophthalmology also contributed substantially to this meeting. It was an important event because it represented the first time ASPS/PSF and ASAPS developed an open, bidirectional dialogue with the FDA for the stated purpose of enhancing patient care and patient safety in plastic surgery.

A year later, the FDA prepared a safety communication based on the first 34 reported cases of BIA-ALCL. Due to the strong relationship that had been built during the prior years, ASPS/PSF and ASAPS assembled a scientific advisory panel and convened a working group conference with the RAND Corporation to understand this rare condition more completely. The FDA was involved in the meeting's design and was present during the deliberations. To date, ASPS has a strong working relationship with the FDA and is a member of the FDA's Network of Experts program.

Data is power/knowledge is king

It quickly became clear that we needed more information to be able to address more comprehensively the concerns regarding BIA-ALCL. There simply was not enough published data on BIA-ALCL.

As a result, the decision was made in 2012 to build a database to collect as much data as possible on every case of BIA-ALCL in the United States. This was the genesis of the Patient Registry and Outcomes for Breast Implants and Anaplastic Large Cell Lymphoma Etiology and Epidemiology (PROFILE) registry.

It is true that data is power and without it, decisions are made based on conjecture and anecdotal observations. The data we collect and analyze from PROFILE will be invaluable as we make critical decisions about the prevention and treatment of BIA-ALCL. Additionally, as the PROFILE registry was being developed, we established a Cooperative Research and Development Agreement (CRADA) with the FDA. This agreement established a formal working relationship with the FDA to enhance our exchange of information, data and sharing of our expertise with them to ensure that the decisions being made are optimal for the health and well-being of our patients. In essence, we locked arms with the FDA to pursue information and knowledge with the singular focus on outcomes and safety related to BIA-ALCL.

With the PROFILE registry and FDA CRADA in place, we have been working hand-in-hand with the agency to answer the most difficult questions. We work together with them, and we have shared with them everything we know. All with a common goal. All with common interests.

This is also what makes our situation very different today than it was in 1992. We are not fighting the FDA. We are not in conflict with our partners. Instead, we are focused on one goal: to provide safe and effective care for our patients.

More questions than answers

To date, there are more than 170 cases of BIA-ALCL reported in the literature. Not all of these cases have complete data or a confirmed diagnosis. With such a rare disease process and so little data, it is difficult to calculate relative risks, determine underlying etiologies, or define measures to reduce overall incidence. Even though there are a number of additional cases that have been reported through the FDA's Manufacturer and User Facility Device Experience (MAUDE) database and additional cases reported world-

wide, there still remains a relatively limited database to perform subgroup analysis for in-depth determination of risk.

To the best of our knowledge, the lifetime risk of developing BIA-ALCL appears to be about 1:30,000 for women with textured implants. However, recent prospective studies are suggesting a risk which may be as high as 1:3,000. However, more data is required to answer this question. There are also many theories about why BIA-ALCL develops, how it develops and ways to prevent it – but without more data, the answers to these questions will remain elusive.

A great deal of work to do

We have been working very closely with ASAPS President Dan Mills II, MD, and his entire team to determine the best way to inform our patients, surgeons and the FDA. We have developed the ALCL subcommittee, headed by Mark Clemens, MD, to work aggressively to understand BIA-ALCL more comprehensively and help guide potential interventions in the future. We continue to work closely with our international colleagues to capture as much data as possible.

Of course, we have maintained an outstanding relationship with the FDA through our CRADA to help each other in our common goal of protecting patients and providing safe care.

To return to the original question of whether this is 1992 all over again, my answer is an emphatic "No." We are on top of it. We're working collaboratively with our colleagues at ASAPS and the FDA to learn as much as possible about this disease process and define interventions that are appropriate and reasonable. We're collecting data through PROFILE to understand the cases more comprehensively. We're supporting research efforts to more clearly define the underlying causes of this condition.

It's difficult to know what will happen in the future, but what I do know is that we have the right team and the right process to ensure that our surgeons are armed with the appropriate information to guide the care of their patients. As always, our patients' safety is our No. 1 priority. [PSW](#)

For additional resources on BIA-ALCL, visit plasticsurgery.org/ALCL.