Discussion: Breast Implant–Associated Anaplastic Large Cell Lymphoma in Australia and New Zealand: High-Surface-Area Textured Implants Are Associated with Increased Risk

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What's obvious to me, isn't always obvious to other people.

—Mike Watt

There is nothing more deceptive than obvious facts, and I would like to highlight some important aspects of this article that further define what we know about breast implant–associated anaplastic large cell lymphoma (BIA-ALCL). The biggest issue we have struggled with over the past 6 to 7 years is defining the exact risk of this disorder. The number of worldwide implants has continually been frequently misquoted as 7 to 9 million implants, and calculations are naturally distorted based on this misnomer. Recent analysis has found that there are probably over 35 million patients with breast implants worldwide, and 60 to 70 million implants globally.[1]

One of the most important contributions of this article is that it has a proven numerator and denominator when calculating risk. The authors should be congratulated for their diligence in tracking cases and obtaining sales data, which is likely the most accurate method of determining the actual numbers of breast implants implanted. The reader should be clear these data apply *uniquely* to the Australian and New Zealand geographic location with regard to population; however, despite the geographic specifics of the data, the important concepts presented apply to all patients (and surgeons) globally.

The concept detailed by the authors of the unification theory of breast implant–associated BIA-ALCL is a good one. It consists of the following:

1. Textured implant.
2. Specific type of bacterial chronic inflammation.
3. Unique genetic disposition.
4. Time.

The important takeaway is that there are really only two factors a surgeon can control (items 1 and 2 in the list above), and given that surgeons clearly have indications for textured devices in specific clinical situation, item 2 (bacteria load) is the target that surgeons can influence.

I would like to emphasize the following three points:

1. Breast implant–associated BIA-ALCL needs to be reclassified as a lymphoproliferative disorder.
2. Breast implant–associated BIA-ALCL is a bacteria-mediated process.
3. Surgeons should be aware of this disorder, know how to diagnose and treat it, and also know how to minimize risk through state-of-the-art surgical technique.

BIA-ALCL Needs to Be Reclassified as a Lymphoproliferative Disorder (LPD)

The disease was initially classified as BIA-ALCL by the World Health Organization; however, the members of the World Health Organization are largely people who never have seen a breast implant patient. Initially, when there was quite a bit less understood about this entity, the World Health Organization made the decision to conservatively classify this as BIA-ALCL; however, now with a lot more knowledge of the disease, this should be reconsidered, as breast implant–associated BIA-ALCL generally behaves as an indolent and benign process. If it looks like a dog, smells like a dog, barks like a dog...IT'S A Dog. The data from this study demonstrate that 80 percent present with a seroma and 60 percent of these on final pathologic evaluation have abnormal cells only

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in the seroma and have a clean, normal capsule. How in the world can you call that BIA-ALCL? In fact, this is clearly a regression of the disease—a hallmark for a lymphoproliferative disorder. Unless the cells spontaneously and magically arise de novo; how else would tumor cells end up in seroma fluid unless they originally began in and were stimulated by a process from the living tissue? Reclassification is the first change we need to make, because patients, the U.S. Food and Drug Administration, and media are getting the wrong message. The science supports this as well, with breast implant–associated BIA-ALCL expressing the exact same biomarkers as primary cutaneous BIA-ALCL, which is an LPD.[2] Furthermore, nonmalignant $CD30^+$ seromas have been described that further elucidate the typical proven pathway known for lymphoproliferative disorders.[3]

Reclassification is essential, as patients currently hear "cancer" and "deaths," which are misleading terms. Understand that this LPD does have an end-stage expression that is a full-blown lymphoma; however, similar to primary cutaneous BIA-ALCL, that is not the typical presentation, and with accurate diagnosis and treatment, the cure rate is currently 100 percent. Furthermore, the relative risk of breast implant–associated BIA-ALCL is far less than reported in the media. One report has demonstrated the micromort risk increase of a woman with textured implants over her lifetime is one-third of the micromort increase of skiing for 1 day, 40 times less than driving a car for 8 hours, and 670 times less than having a basal cell skin cancer.[1] Because of the unique proven facts that we know regarding breast implant–associated BIA-ALCL, it must be reclassified as a lymphoproliferative disorder, and we submit it should be called Brody's disease, as Garry Brody is the person who initially brought this to light. *Seems quite obvious to me.*

BIA-ALCL Is a Bacteria-Mediated Process

The concept of a shift in the microbiome that results in a pathologic process is not new. In fact, it is proven in mucosa-associated lymphoid tissue–associated gastric lymphoma,[4] breast cancer,[5] oral cancer,[6] and colorectal malignancies.[7] We have debated ill-informed naysayers who claim that this association is not proven; however, one simply needs to take a closer look at the data and what we know and have observed clinically with breast implant–associated BIA-ALCL patients. Without a bacterially mediated process we would not be able to logically explain what we know is true clinically. Both the geographic distribution and the case clusters are the sine qua non for the presence of an infective trigger. In addition, the timeframe for development fits with a chronic bacterial/ biofilm infection. The increased risk with textured implants should come as a surprise to no one. This is a pure phenomenon related to the surface area of the implant resulting in higher numbers of bacteria,[8] and specific pathogens (typically Gram-negative) that when present in sufficient numbers produce a transformative host response. We are finished with the notion that this is caused simply by a specific implant type. The implant is merely a passenger in this event. The data in this study demonstrate a higher risk in the macrotextured implants. The study found a 14-fold higher risk for Biocell and an 11-fold higher risk for polyurethane compared with the more microtextured Siltex devices.

These data logically make sense and would certainly be consistent with the larger data set that we know worldwide. *Seems quite obvious to me.*

Table 1. Surgical 14-Point Plan for Breast Implant Placement

1.	Use intravenous antibiotic prophylaxis at the time of anesthetic induction.
2.	Avoid periareolar/transaxillary incisions; these have been shown in both laboratory and clinical studies to lead to a higher rate of contracture.
3.	Use nipple shields to prevent spillage of bacteria into the pocket.
4.	Perform careful atraumatic dissection to minimize devascularized tissue.
5.	Perform careful hemostasis.
6.	Avoid dissection into the breast parenchyma.
7.	The use of a dual-plane pocket.
8.	Perform pocket irrigation with correct proven betadine triple- or non-betadine triple-antibiotic solutions or 50% (1:1 dilution) or stronger povidone-iodine.
9.	Take steps to minimize skin contamination (e.g., re-prep/ wipe skin, barriers, sleeves).
10.	Minimize implant open time and replacement of implant or sizers.
11.	Change surgical gloves before handling and use new or cleaned instruments and drapes.
12.	Avoid using a drainage tube, which can be a potential site of entry for bacteria.
13.	Use a layered closure.
14.	Use antibiotic prophylaxis to cover subsequent procedures that breach skin or mucosa.

Surgeons Should Be Aware of This Disorder, Know How to Diagnose and Treat It, and Know How to Minimize Risk through State-of-the-Art Surgical Technique

Given the association with chronic biofilm infection and breast implant–associated BIA-ALCL, surgeons can optimize their surgical technique by minimizing the bacterial load around implants and subsequent adverse outcome.[9–16] This benefit has been proven over the past 20 years and has resulted in the capsular contracture rate falling from 50 percent to 1 percent.[17] We strongly believe that the risk for breast implant–associated BIA-ALCL can be commensurately reduced with high-level surgical technique as well. The 14-point plan (Table 1) is evidence-based practice that all surgeons can consider implementing as they see fit.[10] Not only are the steps important in concept, but practicing these intraoperatively as a systematic, templated process has been shown time and time again to increase efficiency and improve outcomes in all areas of surgery. In this *Journal* last month, a publication demonstrated a series of 42,000 macrotextured implants all treated with the 14-point plan steps and zero cases of breast implant–associated BIA-ALCL.[18]

I would like to congratulate the authors for an important contribution to the literature and for their efforts to really better define this entity. None of us has a crystal ball; however, we think that in 5 years, using the current research data we have produced, we will be able to not only identify patients at risk for Brody's disease but also easily diagnose and optimize treatment. More importantly, on the front end, using these processes and state-of-the-art surgical techniques, the risk for patients for this disorder will be infinitesimal. *Seems quite obvious to me.*

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