

# Navigating Women's BIA-ALCL Information Needs: Group Seminars May Offer an Opportunity to Empower the Patient–Surgeon Team

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**Background:** Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) is a T-cell non-Hodgkin's lymphoma that has been linked to textured breast implants, and is an emerging concern within the plastic and reconstructive surgery community. Many surgeons are struggling with how best to inform their patients and manage BIA-ALCL care without overwhelming their standard clinical practice.

**Methods:** Five educational group seminars were held for 53 patients. A thematic analysis of the field notes taken at each seminar was conducted to identify recurring patient and surgeon behaviors.

**Results:** The thematic analysis identified 5 key themes: seeking, amplifying, framing, trusting, and empowering. *Seeking* describes the knowledge sought by patients and their varying engagement in their care. *Amplifying* underlines how the emotionally charged topic of BIA-ALCL impacted patient and surgeon behaviors. *Framing* presents surgeon efforts to help patients understand the risk level of BIA-ALCL. *Trusting* addresses the ways BIA-ALCL has impacted patient trust in the medical community and the mechanisms to rebuild this trust. *Empowering* outlines surgeon efforts to engage patients in shared decision-making.

**Conclusions:** Herein is presented a possible framework for efficient BIA-ALCL patient education that can be adapted to different surgical practices. Lessons learned are: (1) patients want information on BIA-ALCL's clinical features and prophylactic implant removal; (2) BIA-ALCL discussions are emotionally charged and surgeons must remain cognizant of group dynamics and that the physician–patient power differential may impact patient decision-making; (3) patient trust has been strained but can be restored; and (4) patient responses to BIA-ALCL are variable and subjective; thus, surgeons should emphasize patient-centered care. (*Plast Reconstr Surg Glob Open* 2020;8:e3142; doi: [10.1097/GOX.0000000000003142](https://doi.org/10.1097/GOX.0000000000003142); Published online 28 September 2020.)

## INTRODUCTION

Although the first case of BIA-ALCL was reported in 1997,<sup>1</sup> the US Food and Drug Administration did not link this T-cell non-Hodgkin's lymphoma to breast implants until 2011.<sup>2</sup> Early estimates found the risk of BIA-ALCL to be negligible with just 1–3 cases per million breast implant patients.<sup>3</sup> However, an increase in recognition of the disease and a change in denominator reflecting evidence

that textured implants are linked to BIA-ALCL now place the risk between 1:2,832 and 1:60,631.<sup>4</sup>

As evidence continues to emerge, the risk–benefit profile of textured implants has become increasingly concerning, and in April of 2019, Health Canada suspended the license of higher risk Allergan Biocell textured implants.<sup>5</sup> As a result, the Canadian Society of Plastic Surgeons encouraged its members to inform patients at risk of BIA-ALCL.<sup>6</sup> Many surgeons are grappling with how best to support their patients and are anxious about managing negative patient reactions.

Herein the authors present a structured patient education program that has been used to inform breast reconstruction patients about BIA-ALCL while balancing

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a regular clinical workload. In presenting the program's process, successes, and challenges, this report provides a framework that may be adapted to other surgical practices.

## METHODS

### Patient Population

Our surgical practice is based at an academic teaching center in Calgary, Alberta, Canada. All participating patients had a history of implant-based breast reconstructive surgery and many had a history of breast cancer.

### Patient Notification Letters

Prompted by emerging evidence and increasing media coverage of BIA-ALCL, letters were sent to all breast implant patients (see document, **Supplemental Digital Content 1**, which displays a sample patient notification letter, <http://links.lww.com/PRSGO/B481>). Using a practice-specific database, 358 patients with implant-based reconstruction were identified. Letters were sent from late 2018 to early 2019 using a staged approach, given the large volume and personalized nature of the letters, each requiring chart review to accurately include past and present implant details. This gradual approach served to regulate the flow of patient responses and consultation requests.

### Letter Content

- A brief description of BIA-ALCL and current recommendations;
- The American Society of Plastic Surgeons' BIA-ALCL information brochure<sup>7</sup>;
- A description (brand and texture) of implants the specific patient has or had in the past; and
- An invitation for patients to schedule a consult if they wished to discuss BIA-ALCL with or be examined by their surgeon.

### Group Seminar Format Rationale

The large volume of patients requesting BIA-ALCL consults and resulting time commitment of 45 minutes per consult, sometimes requiring further follow-up appointments, was starting to overload the administrative and clinical capacity of the practice. A group education framework was thus developed to systematically and efficiently inform patients about BIA-ALCL, while alleviating the workload that individual counseling would entail. All patients interested in learning more about BIA-ALCL were invited to group information seminars. If, after the seminar, patients still wished to have a one-on-one discussion, individual consults were held immediately afterward.

The seminar format was chosen because it enables information delivery to multiple patients at once, facilitating an efficient knowledge transfer of basic and general BIA-ALCL information. Patient-specific discussions were reserved for individual consults. Thus, fewer patients may request a consult, and consult time could be shortened to 10–15 minutes. Similar group-based patient education formats have previously been used in the breast cancer patient population.<sup>8–10</sup>

### Group Seminar Procedure

Patients were invited to 1 of the 5 one-hour group seminars held between July 15, 2019 and December 13, 2019, with each conducted 1 month apart. Attendees included the plastic surgeon, her research team, and patients with their companions. Between 9 and 16 patients were scheduled for each seminar.

Upon arrival, patients were provided with handouts about BIA-ALCL<sup>7</sup> and breast implant illness (BII)<sup>11</sup> to read while waiting for the seminar to start. Patients were asked to submit top-of-mind questions on supplied index cards and to complete a breast reconstruction history form. This form asked what type of reconstruction patients underwent, their implant brand and texture, whether they had nipples spared, and if they had a history of radiation therapy or implant replacement.

Seminars were led by the plastic surgeon, who began by welcoming participants, expressing empathy regarding the situation, and reading aloud the questions patients had submitted. While the surgeon was guided by a prepared list of topics (eg, reasons for textured implant use, BIA-ALCL risk, clinical presentation, monitoring, management, and prognosis), patient questions were used to tailor each seminar to attendees' concerns. Patients were invited to interject at any point with questions or comments.

### Data Collection

The content of each seminar was captured in field notes taken by an experienced qualitative researcher. These notes were detailed, recounting topics discussed, questions asked, emotional tone, and body language, but were not verbatim transcriptions. Although field notes may offer a less-detailed account of the seminars than verbatim transcriptions, they remain a valid qualitative data collection tool well suited to recording group discussions and non-verbal cues. Further, this method does not require audio or video recording that may influence participant behavior.<sup>12</sup>

Additional data included patients' answers to the breast reconstruction history form. These anonymized data were collected in real time at the start of each seminar to quickly survey attendees based on factors that influence their risk of BIA-ALCL, while also gauging patients' knowledge of their health history. This helped tailor each seminar to the patients in attendance.

### Data Analysis

All field notes were coded independently by the 3 researchers. NVivo 12 software (QRS International Pty Ltd., Chadstone, Australia) was used to aid data mining. Both inductive and deductive coding methods were used. Codes were then compared, and a collaborative and iterative thematic analysis was used to refine the coding. This analysis identified a mutually agreed upon framework of recurring themes among discussed topics, participant and surgeon behaviors, and patient responses to BIA-ALCL.

### Ethics

As per institutional protocol, this quality improvement project was scrutinized through ARECCI (A pRoject

Ethics Community Consensus Initiative) and underwent oversight via a second opinion review process.

## RESULTS

Qualitative analysis of the seminar field notes illuminated 5 key themes: seeking, amplifying, framing, trusting, and empowering. *Seeking* describes patient thirst for information and variability in knowledge of their breast reconstruction history. *Amplifying* outlines how patient and surgeon behaviors were driven by the emotionally charged topic of BIA-ALCL and by group dynamics. *Framing* illustrates surgeon efforts to contextualize patient perceptions of BIA-ALCL risk. *Trusting* underlines how BIA-ALCL has impacted patient trust in the medical community and how this trust may be repaired. *Empowering* outlines ways the surgeon encouraged patients to take ownership of their health information and engaged them in shared decision-making.

### Theme 1: Seeking

#### Patients Seek BIA-ALCL Education but Eagerness Varied

In response to the letters, the surgeon's office received multiple daily consult requests that were initially scheduled into routine clinical time. This began to preclude the ability to see new patients and was the impetus to invite patients to group seminars. A total of 63 patients signed up for the seminars and 53 (84%) attended. Fifteen (28%) attendees brought a companion, including partners, daughters, and mothers. Some patients arrived over half an hour early, while others arrived halfway through the seminar. Following the seminars, 6 attendees (11%) did not move forward with an individual consult; however, 3 of the 10 patients who did not attend their scheduled seminar came for their consult. [Table 1](#) summarizes these participation numbers.

#### Most Questions Pertained to BIA-ALCL Clinical Characteristics

The number of patient questions received varied by seminar. In some, every attendee submitted a written question; none did in others. Nevertheless, questions asked were ultimately very similar across seminars. The majority of questions pertained to BIA-ALCL characteristics and management. Patients asked about the risk of BIA-ALCL and factors that influence this risk. Many specifically wondered about an association with breast cancer and having undergone cancer treatments, such as radiation therapy or chemotherapy. Patients inquired about how they can self-monitor

for BIA-ALCL, relevant signs and symptoms, and how long after having implants placed these might appear. Patients were also curious about available BIA-ALCL tests, and if they could be used for screening or, rather, were reserved for symptomatic patients. They also wondered about which physicians would interpret these tests. Some expressed concern that certain physicians involved in their care, such as general practitioners and radiologists, may lack experience with BIA-ALCL. Finally, patients inquired about how BIA-ALCL is managed if diagnosed, but only 1 patient explicitly asked about BIA-ALCL's prognosis, although this was routinely covered during the presentation.

#### Patients Asked about Prophylactic Implant Removal

Patients also asked about prophylactic implant removal and whether removing one's textured implants would reduce or eliminate the risk of BIA-ALCL, and what the disadvantages of implant removal were. If patients did undergo implant removal, they were curious about the logistics of such a procedure such as whether nipples could be spared, if replacement implants would be smooth, and what aesthetic outcomes would be expected. Many patients asked if implants have a natural expiration date upon which they should be replaced, even in the absence of BIA-ALCL. A complete list of patient questions is included in [Table 2](#).

#### Patient Ownership of Their Health Information Varied

There was variability in the extent to which patients took ownership of their health information. The patient-completed implant history form demonstrated that, despite each patient receiving a detailed and personalized letter about their implant type, many did not recall specifics about implants they had in their bodies. No participant voiced recollection of discussion of BIA-ALCL pre-operatively, which had been a standard part of this surgeon's informed consent discussions for several years.

### Theme 2: Amplifying

#### *The surgeon emphasized common BIA-ALCL presentations with less emphasis on rarer variants*

There were occasions when the surgeon emphasized certain points in an effort to allay patient fear. When presenting signs and symptoms of BIA-ALCL, the visible presentation of a large, swollen breast was highlighted.<sup>13,14</sup> Although it is true that BIA-ALCL often presents with large, fairly rapid-onset swelling of the breast, surgeons should be clear about what constitutes otherwise subjective concepts such as "large" and "rapid." Also, less common presentations such as capsular contracture or skin changes were acknowledged by the surgeon and need to be stressed similarly.<sup>13</sup> Although it may appease patient anxiety to assure them that BIA-ALCL is generally readily apparent, it is important to ensure patients do not overlook presentation variations.

#### **The Surgeon Emphasized the Risks of *En Bloc* Capsulectomy**

BIA-ALCL management was described as almost exclusively surgical, involving implant removal and *en*

**Table 1. BIA-ALCL Education Program Participation Numbers**

Description	Value
BIA-ALCL patient notification letters sent	358
Patients who signed up for a seminar	63
Patients who attended a seminar	53
Seminar attendees who brought a companion	15
Patients who went on to an individual consult after their seminar	47
Patients who signed up for a seminar but only attended their individual consult	3

**Table 2. Common Patient Questions**

Question Topic	Specific Inquiries*
BIA-ALCL risk	What is the risk of BIA-ALCL? Can X change one's risk of BIA-ALCL? Does having a history of breast cancer increase the risk of BIA-ALCL? Does having a history of cancer treatments (eg, radiation therapy) increase the risk of BIA-ALCL?
BIA-ALCL signs and symptoms	What are the signs and symptoms of BIA-ALCL? What signs and symptoms can patients self-monitor for? How long after having implants placed does BIA-ALCL develop?
BIA-ALCL testing	What tests are used for BIA-ALCL monitoring? When and how often are asymptomatic patients screened for BIA-ALCL? What tests are used for BIA-ALCL diagnosis? What medical specialty is responsible for ordering and interpreting BIA-ALCL investigations? Are other medical specialties trained in BIA-ALCL monitoring and diagnosis?
BIA-ALCL management	What is the management for BIA-ALCL?
Prophylactic removal/exchange of implants	Does removing/replacing implants reduce or eliminate the risk of BIA-ALCL? What are the advantages of keeping one's implants? Can X (eg, nipple sparing, pectoral muscle repair) be done/avoided with implant removal/exchange? What are the aesthetic outcomes after implant removal/exchange?
Implant characteristics	Do implants have a natural expiry date upon which they need to be removed/replaced?
Medical device safety oversight	Why were textured implants still being used after BIA-ALCL was first recognized? How long were implants tested before being introduced?
Remediation	What are implant manufacturers doing for patients who are at risk of BIA-ALCL because of their implants?
Expert opinion	What do you think patients should do?

\*These represent a generic rephrasing of common questions and are not verbatim patient quotes.

*bloc* capsulectomy.<sup>13</sup> Some patients enquired about prophylactic *en bloc* capsulectomy. The surgeon explained that current recommendations do not support this, although patients may request it. The increased difficulty and risks of *en bloc* capsulectomy (eg, bleeding, possible removal of a portion of the ribs and muscle) were emphasized.<sup>15</sup> Again, the challenge of communicating the complexity and risk inherent in these procedures without over-dramatization is highlighted. Surgeons must balance unduly frightening patients about their preferred prophylactic management while still informing them of very real risks.

**Group Dynamics Amplify Affect and Attitudes**

Amplification was also noted in group dynamics. Each seminar had its own level of morale, collegiality, and engagement. Some seminars included patients making

jokes together, playfully exclaiming that they loved their surgeon, and asking multiple questions. Other seminars had little patient participation with some patients expressing overt animosity toward the medical community, which seemed to prompt other attendees to voice their own dissatisfaction with aspects of their care. Group dynamics were also seen to permeate the surgeon's behavior, who appeared less composed faced with the more disgruntled groups. In fact, the seminar with the most pointed questions and most confrontational patients was the only seminar in which the surgeon did not explicitly invite final patient questions at the end.

**Group Dynamics Should Be Considered When Developing Group Seminar Education**

Group dynamics are an important consideration when using a group seminar format. While this format may offer a sense of camaraderie between patients in a similarly difficult situation, if an attendee exhibits significant anxiety or hostility, this can detract from other attendees' experience. One possible solution could be to prescreen attendees for their anxiety level about BIA-ALCL to group patients with similar anxiety levels together; however, this risks losing the benefits attendees may draw from exposure to multiple perspectives, and high-anxiety patients may amplify each other's concerns. Another option would be to meet with the most anxious patients individually before the seminars, although this may single out patients and provide them with differential treatment. Surgeons should weigh the pros and cons of group dynamics when conducting BIA-ALCL patient education.

**Team Delivery of Educational Seminars May Attenuate Emotional Responses**

The emotional nature of BIA-ALCL puts into question whether the treating surgeon is the best person to deliver these seminars. Although surgeons have clinical knowledge and a personal relationship with their patients, their direct involvement with placing implants and thus exposing patients to risk may make it difficult to remain objective. One solution would be to have a team present BIA-ALCL seminars. This team may include members of the surgeon's support network (eg, surgical colleagues) and health professionals with BIA-ALCL knowledge but who lack direct involvement with patients in attendance (eg, nonclinical BIA-ALCL researchers or appropriately trained nurses).

**Theme 3: Framing**

*The changing denominator of BIA-ALCL risk contextualizes increasing risk estimates*

When presenting BIA-ALCL risk, the surgeon explained that, although this risk may appear to be increasing, this is largely due to refinement of the denominator as understanding of the disease has evolved. Early estimates looked at BIA-ALCL risk among all breast implant patients, while recent numbers have recognized that the risk is primarily from textured implants, and further stratify the risk by implant manufacturer and texturization process.<sup>16</sup>



### **BIA-ALCL Risk Should Be Framed in Relation to Other Risks and Practice Guidelines**

A significant effort was made to contextualize the risk posed by textured implants in relation to other regularly encountered risks. BIA-ALCL risk was compared with other risks known to be much higher, such as common everyday exposures (eg, driving, obesity), common malignancies including breast cancer, and risks of surgery and anesthesia. These risks were expressed as absolute numbers (eg, 1 in 3,000) rather than as relative risks, which, like everyday risk comparisons, has been shown to facilitate patient understanding of risk.<sup>17,18</sup> This risk communication may have been further improved by using a consistent denominator (eg, express all risks out of 1,000) or visual aids.<sup>18</sup> The relatively low risk of BIA-ALCL was further emphasized by noting that there is currently no medical indication to remove textured implants prophylactically, as evidence has yet to show any health or quality-of-life benefit.<sup>19</sup>

### **Textured Implant Benefits Should Be Weighed against BIA-ALCL Risk**

BIA-ALCL risk was also contextualized by describing the benefits textured implants offer. Textured implants were developed to reduce the risk of capsular contraction.<sup>16,20</sup> Compared with smooth, round, less-cohesive implants, textured implants also provide a more natural teardrop shape, less rippling, and avoid breast shape change arising from back-to-front flipping,<sup>20,21</sup> particularly in the breast reconstruction setting where patients lack endogenous breast tissue to mask the flipping. These benefits seemed reasonable for years when BIA-ALCL risk estimates were far below current reports. Surgeons can acknowledge textured implant benefits and why their use continued when BIA-ALCL risk seemed low, but these points may appear defensive.

### **Patient Risk Perceptions Are Subjective Yet Valid**

The surgeon acknowledged that risks associated with medical devices, such as implants, may be perceived uniquely since they are intentionally placed inside the body by a trusted medical expert, within a medical system wherein Health Canada monitors medical device safety. Further, the surgeon acknowledged the gap between physician and patient risk perceptions as physicians lack first-person patient experience. This helped recognize and validate patient risk perceptions.

### **Theme 4: Trusting**

#### **Patient Trust in the Medical Community Has Been Undermined**

BIA-ALCL is an issue whereby practitioners and the medical community at large have participated in patient exposure to an unforeseen risk. A common concern raised by patients was that of medical device safety oversight. Patients questioned the continued use of textured implants despite BIA-ALCL's recognition a decade ago. Many explicitly asked what implant manufacturers are doing to remediate patients for the risk and stress they have incurred.

### **Surgeons Must Acknowledge Persisting Knowledge Gaps**

It is important for surgeons to rebuild and maintain patient trust. One way the surgeon did this was by openly acknowledging that many knowledge gaps remain about BIA-ALCL and being careful not to dismiss patient concerns. BII was almost exclusively brought up by the surgeon, but once mentioned, patients asked various follow-up questions. It was acknowledged that there has been increasing media coverage of BII alongside coverage of BIA-ALCL and this has led to confusion. Although the lack of evidence for BII was outlined, discussions about BII were never dismissive as the surgeon again acknowledged persisting knowledge gaps on this disease entity.

### **Patients Continue to Trust Their Treating Surgeon**

Although trust has been tested by the emerging issue of BIA-ALCL, patients still value their surgeon's medical opinion when deciding how to proceed. On multiple occasions, patients directly asked the plastic surgeon for her personal opinion on what they should do.

### **Patients Appreciate BIA-ALCL Education Efforts**

Taking the initiative to address BIA-ALCL with patients and to acknowledge their concerns is beneficial. Generally, patient responses to the seminars were positive, and several voiced their appreciation for the seminars and their surgeon's care and concern. It should be noted that the project model did not explicitly seek patient feedback and thus any patient comments were offered voluntarily. Longitudinal data collected from individual consults and patient follow-up will be presented in future publications to elaborate on the impact and reception of this BIA-ALCL patient education program.

### **Theme 5: Empowering**

#### **Surgeons Should Emphasize that They Lack the Patient Experience**

The surgeon aimed to empower patients and level the physician-patient hierarchical relationship that may otherwise impede patient agency. The surgeon expressed empathy for patients and recognized that physicians cannot fully understand the patient perspective. Particularly, physicians cannot understand how the trauma of breast cancer may amplify BIA-ALCL risk perception. This helped empower patient voices in BIA-ALCL care decision-making.

#### **Patients Were Encouraged to Take Ownership of Their Health**

Patients were encouraged to remain engaged in their healthcare, keep themselves updated about emerging BIA-ALCL research and guidelines, and advocate for testing that might offer them peace of mind. This was, in part, a response to the higher than expected proportion of patients who arrived at the seminars uncertain of their breast implant surface (smooth or textured) or brand. While surgeons can offer patients BIA-ALCL information, this is an emerging issue with continually developing information that patients must ultimately weigh against their

personal risk profile and care objectives. Trusted websites for the latest BIA-ALCL information were provided.<sup>19,22,23</sup>

### Shared Patient-surgeon Decision-making Was Emphasized

Another key surgeon behavior was a repeated emphasis that patient goals and care decisions would be respected as much as possible. While the surgeon provided current evidence about which interventions were or were not recommended, over 20 times across the 5 seminars the surgeon emphasized a willingness to work with patients toward identifying and executing an individualized care plan. Every patient has a unique medical history, risk profile, and risk perception. Patient-centered care and shared decision-making were at the forefront at all times.

### Patients Were Encouraged to Initiate BIA-ALCL Monitoring

The surgeon encouraged patients to self-monitor for BIA-ALCL signs and symptoms. Annual ultrasounds were discussed as a possible management tool, though patients were alerted to not be unduly alarmed by imaging evidence of small amounts of fluid surrounding the implant, as this is normal.<sup>13</sup> Emphasis was placed on the current lack of BIA-ALCL screening guidelines.

### Patients Were Repeatedly Invited to Ask Questions

The surgeon invited patient questions and comments throughout the seminars. This modeled openness and respect toward maintaining patient engagement and trust. It also helped ensure that the seminars fulfilled the specific needs of attendees at a given seminar.

## CONCLUSIONS

This study outlines 1 possible framework for efficient patient education on BIA-ALCL. The group seminar format allowed for knowledge transfer to multiple patients at once, easing the load BIA-ALCL concerns may otherwise add to a standard surgical practice. Hopefully this account of 1 surgeon's experience can serve as a roadmap for other surgeons who may be unsure of how to address BIA-ALCL with their patients. This framework represents the state of BIA-ALCL knowledge in 2019 and should be updated as new research and guidelines are released. We also recognize that healthcare systems globally may differ from the Canadian system and that implementation of a similar program may be difficult or require local refinement.

Important lessons can be learned from delivery of this program. First, patients are seeking information on BIA-ALCL monitoring and management, and the risk-benefit trade-off of keeping versus removing implants. Second, emotions and group dynamics can amplify patient and surgeon behaviors and are both strengths and weaknesses of the group seminar format. Surgeons should prepare for a wide range of possible group sentiments, and contingency plans may be necessary in the event of high-anxiety patients. Third, there is a gap between physician and patient perceptions of risk. Surgeons can frame patient perceptions of BIA-ALCL risk by weighing

it against common risks and the advantage of avoiding risks of implant removal. Surgeons must remain cognizant that the physician–patient power differential may impact patients' decisions and work to present information objectively. Fourth, patient trust in the medical community and their treating surgeon can be supported by educating patients about BIA-ALCL and recognizing persisting knowledge gaps. Finally, reactions to BIA-ALCL are variable and surgeons should empower patients by engaging them in shared decision-making to determine the best course of action for each specific patient.

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