

**CASE AND COMMENTARY: PEER-REVIEWED ARTICLE****What Do Clinicians and Organizations Owe Patients With Recalled Implanted Devices or Materials?**

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**Abstract**

Placement of prosthetic breast implants for augmentation or reconstruction is common. Two specific safety concerns are considered in this article: breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) and complexes of symptoms known as breast implant illness. In response to a case involving a patient with concerns about BIA-ALCL, this commentary notes that triage, counseling, and treatment are guided in practice by available data in the literature. The commentary also discusses ethical considerations regarding breast implants and related illnesses.

**Case**

As of January 2020, 733 cases of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) had been reported to the US Food and Drug Administration (FDA), with a large majority of those cases involving textured breast implants manufactured by one company.<sup>1</sup> In response, the FDA requested that the company voluntarily withdraw its textured breast implants and tissue expanders from the market.<sup>2,3</sup> The company sent Urgent Medical Device Recall letters to US customer surgeons, instructing them to return all unused products to a third-party recall provider, and sent notification letters to patients.<sup>2,3</sup>

Dr W is a plastic surgeon who has implanted textured breast implants in patients, but not those manufactured by the company in question. Dr W's retired practice partner and friend, Dr X, did implant this company's textured breast implants in patients, many of whom still live locally. Stimulated by local news coverage of the textured breast implant recall, hundreds of her own and Dr X's patients have been calling to request appointments to discuss the risks and benefits of implant removal and replacement and whether they require increased monitoring.

**Commentary**

Implantation of devices in the breast for augmentation or **reconstruction** is common, and concerns have been raised over time regarding safety. Currently, BIA-ALCL<sup>4</sup> and complexes of symptoms termed *breast implant illness* (BII) are being most prominently

considered<sup>1</sup> in hopes that available data will guide triage, counseling, and treatment. The case highlights ethical issues related to triage, patient education, patient satisfaction and management, and balancing patients' financial worries and fears, which are considered in this article as best addressed through shared decision making among physicians, patients, and caregivers.

### **Triage**

Understanding patients' psychological as well as physical reactions to the risk of breast implant-associated illnesses like BIA-ALCL and BII will affect triage. The intensity or severity of patients' concerns, symptoms, or signs, as well as the resources of the practice, will all inform how surgeons prioritize new and returning patients' needs. Severe clinical presentations or extreme psychological distress (eg, intrusive thoughts, mood changes, sleep disruption) warrant urgent response and appropriate management. Physicians and clinic staff members should also be prepared to field calls from patients whose implants were not recalled but who are concerned and seeking information.

Well-informed surgeons will be aware of the clinical issues and prepare office staff to respond appropriately and responsively to potential patient misconceptions.<sup>5</sup> Advanced preparation of all team members with whom patients communicate can affect patients' experiences of device recalls. Much of the impetus for advanced preparation has arisen beyond clinical spaces—for example, on social media sites where patients get information of varying quality about BIA-ALCL and BII.<sup>5</sup> Regardless of information and knowledge gaps between patients and physicians, physicians should validate patients' concerns.<sup>6</sup>

### **Patient Education**

When the patient and physician begin discussing clinical implications of recalled breast implants, the nature of a recall, symptoms and signs, risks and benefits of and alternatives to explantation, limitations of present knowledge, and financial considerations must be carefully considered.

*Recall.* A good discussion starting point is the recall, which, in this case and in actual recalls, does not apply at present to breast implants that have already been implanted.<sup>2,3,7</sup> While insufficiently reassuring to some patients, **accurate information** from physicians should remain a priority.

*Symptoms and signs.* Plastic surgeons likely will also carefully discuss the nature of symptoms and signs that may be associated with implants. These discussions may include not only rare events but also more common, less media-publicized phenomena like appearance changes over time, chest discomfort, and implant firmness. Physician counseling regarding warning signs and **symptoms of complications** could help patients to be vigilant about their health. Moreover, validation of patients' own health concerns could strengthen patient-clinician relationships. Building trust could also encourage patients to seek care about their future concerns, regardless of whether they are presently predictable.<sup>8</sup>

*Risks and benefits.* Explantation of breast implants, as with any surgical procedure, carries potential risks that must be balanced with proposed and hoped-for benefits. In addition to surgical risk, explantation of breast implants has implications for chest aesthetics. Clinicians should thoroughly describe potential postexplantation appearance changes to help patients understand that their breasts' appearance might be

suboptimal and present them with potential solutions. Techniques to address native breast or chest soft tissue changes postexplantation include no management, tissue rearrangement, and autologous augmentation. Some authors propose algorithms to guide application of these strategies.<sup>9,10,11</sup> Patients must understand each of these choices, and physicians must be prepared for variable patient reactions to postexplantation management.<sup>12,13,14,15</sup> Sharing knowledge of patient-reported outcomes in different clinical scenarios might help patients make decisions; however, the absence of consensus recommendations can be expected to add to the burden of the patients' decision making.

*Limitations of present knowledge.* Discussing what is not known with patients, including the nascent literature guiding practice decisions, remains essential. For example, estimates of BIA-ALCL risk vary tenfold.<sup>16</sup> Many barriers exist to clinicians obtaining accurate information about the incidence and risk of BIA-ALCL.<sup>17</sup> The existence of other difficult-to-define-and-treat conditions associated with breast implants, such as BII, further complicates patient-physician conversations.<sup>18</sup> Debates remain about other technical aspects of explantation in asymptomatic patients, such as management of the capsule (the internal tissue surrounding the implant).<sup>19</sup> However, while strong scientific evidence unequivocally supporting certain interventions (eg, en bloc capsulectomy for conditions other than BIA-ALCL) is lacking, social media connections among patients are driving treatments, especially surgery.<sup>5,6</sup> Patients should understand that current counseling cannot incorporate future discoveries or fully address all possible outcomes. As such, patients' trusting relationships with their physicians will hopefully lead patients to return for further assessment and treatment as their circumstances change over time.

*Insurance.* Financial considerations affect decision making in many ways. Counseling about financial responsibility for complications associated with breast implants has long-standing roots in plastic surgery, since this challenge long predates recognition of BIA-ALCL. Patients who have undergone procedures without insurance coverage, like aesthetic breast augmentation, might find that insurers do not cover subsequent costs related to a recall. Vieira et al suggest that appropriate plastic surgery care can be considered independently of insurers' decisions.<sup>20</sup>

In sum, education about a recall can enhance patients' sense of ownership about seeking further consultation aside from routine monitoring and can help patients develop actionable plans and a sense of agency if they need to respond to explantation complications. Patients should be invited to engage their physicians in standard clinical follow-up and in additional appointments as needed. Patient education can also build trust by demonstrating physician concern, knowledge, and interest in patients' concerns.

### **Patient Satisfaction**

Consideration of the entire patient remains essential to patient satisfaction.<sup>9</sup> And it does seem that surgical management of breast implant concerns through explantation is associated with patient satisfaction.<sup>21</sup> Lee et al reported that, in their sample of 50 patients with explantation due to BII symptoms, none would reconsider breast implants.<sup>22</sup> Of 345 BII Facebook support group posts examined by Tang et al, none expressed explantation regret.<sup>6</sup> In Slavin and Goldwyn's words: "Satisfying the needs in these patients emphasizes the importance and necessity of the surgeon taking the time to understand what the patient wants,"<sup>23</sup> which remains as true today as when these words were written to address a prior surge in breast implant safety concerns.<sup>13,23</sup>

### **Multidisciplinary Management**

When diagnosed with life-altering or life-threatening conditions, patients deserve timely access to appropriate care. National Comprehensive Cancer Network guidelines exist to guide diagnosis and management of BIA-ALCL, for which multidisciplinary management is recommended.<sup>24</sup> **Multidisciplinary involvement** can benefit patients with breast implant concerns, even when BIA-ALCL is not the likely diagnosis. Ongoing health monitoring and surveillance, including routine breast cancer surveillance, can be managed by nonsurgical clinicians and coordination of care beyond the perioperative period.

### **Shared Decision Making**

Specific communication strategies useful in decision sharing with patients after a recall are modeled here in an extension of the case.

*Patient Z calls Dr W's office to arrange an urgent follow-up with Dr X. Upon hearing of Dr X's retirement, she begins to cry, relating to the receptionist that she has been so worried since hearing of the implant recall yesterday that she hasn't felt like eating and spent the night awake, worrying that she is going to need more surgery. The receptionist reassures the patient that Dr W has heard about the recall and has instructed the staff to make sure that Patient Z, and others like her, can be added to the schedule for an urgent appointment.*

*When Dr W and Patient Z meet, Patient Z appears distraught and begins the conversation by explaining that she feels lost and alone. Dr W explains that many patients are experiencing similar reactions to the news. Dr W suggests that Patient Z allow her to share her knowledge to help Patient Z decide on the next steps related to the implants. After a thorough discussion of the topics elucidated above, Dr W helps the asymptomatic Patient Z understand her choices. Dr W suggests that the patient consider the options for a period of time before making a decision, since Patient Z had been happy with her results until learning of the recall and is asymptomatic and the recall does not require removal of existing implants. Dr W reminds Patient Z that she can continue to work with her health care team to monitor the situation and stay up-to-date as knowledge evolves. Patient Z plans to talk to her family members and schedules another appointment to further discuss potential surgery when they can be present also.*

Respect, education, and shared decision making can be empowering for patients concerned about breast implants, especially in the case of a recall. Physicians can promote patient satisfaction by optimizing the quality of the care they offer patients, expressing respect for patients, and cultivating ongoing awareness of clinical practice changes.

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#### Editor's Note

The case to which this commentary is a response was developed by the editorial staff.

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#### Conflict of Interest Disclosure

Dr Manahan serves on committees of several national plastic surgery specialty societies.

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