

Breast Implant Surgery: An Overview of the Risks and Health Complications

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We present an overview of the risks and health complications associated with breast implant surgery with a focus on *breast implant illness* (BII), *breast implant-associated anaplastic large cell lymphoma* (BIA-ALCL), and *breast implant-associated squamous cell carcinoma* (BIA-SCC). BII is a constellation of systemic symptoms that can occur after breast implant devices are surgically implanted into the human body. BIA-ALCL is a T-cell lymphoma associated with the implantation of textured breast implant devices. BIA-SCC is a potentially aggressive epithelial-based tumor that can occur following implantation with smooth or textured breast implant devices. Nurses may lack awareness and knowledge regarding BII, BIA-ALCL, and BIA-SCC, and this can negatively affect patient safety. Therefore, it is essential that all nurses, especially members of the plastic and aesthetic nursing community,

understand these disease processes. Currently, it is not standard practice to screen every patient for the presence of an implantable device at every health care encounter. However, by not doing so, health care professionals may miss the opportunity to identify illness, disease, or cancer that could be related to an implanted device; therefore, practice changes to increase patient safety are both necessary and warranted. To identify those individuals at greatest risk for implant-related illness, disease, or cancer, we propose implementing universal screening of all individuals for implantable devices. We define *universal screening for implantable devices* as assessing all patients for the presence or absence of an implantable device at every health care encounter. We recommend using the IOWA model to guide our proposed evidence-based practice update.

Breast implant surgery, also known as *breast augmentation*, is the surgical placement of breast implant devices into the human body. Individuals undergo this type of surgery for various reasons, both cosmetic and reconstructive. Breast implant surgery is one of the most popular plastic surgery procedures performed worldwide, and there is a considerable global demand to undergo the procedure.

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Despite the popularity and market demand for undergoing the procedure, patients may experience health complications after undergoing breast implant surgery. Reports of *breast implant illness* (BII), *breast implant-associated anaplastic large cell lymphoma* (BIA-ALCL), and, most recently, *breast implant-associated squamous cell carcinoma* (BIA-SCC) have initiated worldwide concern over the safety of breast implant surgery (United States Food and Drug Administration [FDA], 2019a; FDA, 2022a).

In response to patient safety concerns, the FDA has taken action to increase the safety of individuals who choose to undergo breast implant surgery as well as those individuals who have already undergone breast implant surgery (FDA, 2021a). The FDA is spreading public awareness regarding the risks associated with breast implant surgery in the form of FDA news releases and safety announcements. The FDA is also implementing safety measures to protect patients undergoing breast implant surgery that include the requirement for a boxed warning on *all* breast implant devices, a decision checklist, and rupture-screening recommendations for silicone breast implant devices (FDA, 2021a; FDA, 2022a). Boxed warnings (formerly known as Black Box Warnings) are the highest safety-related warning that the FDA can assign to a medication or an implantable

device such as breast implant devices. The intent of these warnings is to bring attention to the major risks associated with either the medication or the implantable device (DeLong & Preuss, 2022). Boxed warnings are not meant to be an absolute contraindication but more of an *alert* to the potential risks associated with the product that the boxed warning is applied to (DeLong & Preuss, 2022).

The FDA protects the health of the public by assuring the safety, effectiveness, quality, and security of human and veterinary drugs, vaccines, other biological products, and medical devices (FDA, 2021b). When safety concerns arise, the FDA must alert the medical community and public to their concerns and disseminate their recommendations. In October 2019, the FDA shared their concerns about BIA-ALCL with the public and the health care community (FDA, 2019b). In September 2022, the FDA published their concerns about BIA-SCC (FDA, 2022b).

Given these efforts by the FDA to increase patient safety and promote public and health care community awareness about the risks and potential complications associated with breast implant devices, nurses, physicians, and other members of the health care community should be prepared to respond to patients who present with questions about or complications resulting from breast implant surgery. It is important for health care professionals to understand that breast implant surgery has been performed in the United States since the 1960s; therefore, this information may be relevant to current patients as well as to patients from the previous six decades.

BII is a constellation of systemic symptoms that can occur after breast implants have been surgically implanted into the human body (FDA, 2020). BIA-ALCL is a T-cell lymphoma associated with surgical implantation of textured breast implants (FDA, 2019b). BIA-SCC is a rare but potentially aggressive epithelial-based tumor that can occur following surgical implantation of both smooth and textured implant devices (FDA, 2022b).

There are substantial patient safety concerns for individuals undergoing breast implant surgery. A review of the research investigating the risks and potential health complications associated with breast implant surgery and breast implant devices reveals

- an absence of documented clinical trials studying specific types of breast implant devices (Zuckerman & Srinivasan, 2018);
- a shortage of quality, nonbiased long-term studies on the potential health effects associated with breast implant surgery and breast implant devices (Zuckerman & Srinivasan, 2018);
- an unknown prevalence of the risks and health complications associated with breast implant devices (Zuckerman & Srinivasan, 2018);

- a portion of research on breast implant surgery and breast implant devices that includes researcher bias and stakeholder influence (Zuckerman & Srinivasan, 2018); and
- a clinical shortage of health care providers who understand the risks and provide treatment for the health complications associated with breast implant surgery.

The clinical shortage of knowledgeable providers is evident when reviewing online support groups for patients with complications from breast implant surgery. Many patients are searching for doctors who understand the risks and potential health complications associated with breast implant devices.

Developing a nursing pathway may provide a safe and effective way for the nursing profession to respond to known patient safety concerns and provide a resolution for patients undergoing breast implant surgery. These steps establish the priorities for managing the risks and potential health complications associated with breast implant devices and breast implant surgery. This pathway includes patient and provider awareness, informed consent, and early intervention and illness-specific care.

Plastic surgeons and plastic surgical nurses must educate patients undergoing breast implant surgery about the specific risks associated with the surgery they are undergoing. Relative to breast implant surgery, these risks include

- infection;
- swelling;
- fluid collection (seroma);
- blood collection (hematoma);
- tissue death (necrosis);
- chronic pain; and
- inability to breastfeed (FDA, 2020).

In addition, all patients undergoing breast implant surgery must be fully educated about the potential risk for developing BII, BIA-ALCL, and BIA-SCC, as these are established health complications that may occur following breast implant surgery (FDA, 2019b; FDA, 2020; FDA, 2022b).

After the patient has been educated about breast implant surgery and the associated risks and potential health complications pertaining to breast implant devices, the surgeon must obtain informed consent from the patient. *Informed consent* involves the use of a formalized and documented decision checklist that provides the patient with education and knowledge about the possible risks and health complications that patients can experience after undergoing breast implant surgery (FDA, 2019b; FDA, 2020; FDA, 2022a). The FDA (2020) recommends that the body of the checklist include

- situations in which the device should not be used or implanted;
- considerations for a successful breast implant candidate;
- risks of undergoing breast implant surgery;
- importance of appropriate physician education, training, and experience;
- risk of BIA-ALCL;
- risk of systemic symptoms; and
- discussion of options other than breast implants, as appropriate.

The process of informed consent should be documented with a signature from both the patient and the surgeon (FDA, 2020). The FDA recommends that surgeons are fully transparent with their patients about the potential risks and health complications of breast implant surgery (FDA, 2022a). Full transparency enables the patient to understand the potential long-term health effects associated with breast implant devices.

When responding to the risks and health complications associated with breast implant devices, priorities for patient care include early intervention and illness-specific care as these interventions increase patient safety and can affect the patient's prognosis.

After providing education and obtaining and documenting informed consent, if the patient chooses to undergo breast implant surgery, immediately following the procedure, plastic surgical nurses should monitor the patient closely. The patient's plan of care team should include not only their plastic surgeon but also their primary care physician, as well as any and *all* other health care professionals involved in managing the patient's care. The FDA advises patients to monitor their breasts immediately after undergoing breast implant surgery and to promptly address any changes in their breasts or breast implant devices with their surgeon (FDA, 2022a).

The *nursing process* is defined as a systematic approach to patient care using the fundamental principles of critical thinking, client-centered approaches to treatment, goal-oriented tasks, evidence-based practice recommendations, and nursing intuition. The nursing process guides nursing practice and functions as a systematic guide to providing patient-centered care using the following five consecutive steps:

- Assessment
- Diagnosis
- Planning
- Implementation
- Evaluation (Toney-Butler & Thayer, 2022).

Notably, the nursing process begins with the *nursing assessment*. Unfortunately, many nurses have not been taught how to thoroughly assess a patient for the presence of an implantable device. In our facility, a team of

nurses identified this as a patient safety concern, and we initiated a formal call for nursing action. In response, key nurses at our facility developed a process for universal screening for implantable devices.

We define *universal screening for implantable devices* as assessing all patients for the presence or absence of an implantable device at *every* health care encounter. Universal screening for implantable devices helps determine which patients are at risk for implantable device-related illness, disease, or cancer. Using this screening tool enables nurses to initiate prompt illness-specific care, which is the ultimate goal in managing an illness, disease, or cancer potentially related to an implantable device.

Currently, it is not standard practice to screen every patient for the presence of an implantable device (most specifically breast implant devices). Health care professionals who do not implement universal screening for implantable devices could miss the opportunity to rapidly identify illness, disease, or cancer potentially related to an implantable device. This can negatively affect patient safety and further warrants the use of the suggested screening tool.

Universally screening all patients for implantable devices using the suggested screening tool allows for numerous possibilities. First and foremost, universally screening all patients for implantable devices lends itself to a mindset that comprehends the need for a complete physical assessment, including assessing for implantable devices. The importance of universal screening for implantable devices can also be formulated into a policy, procedure, or electronic medical record update. Notably, universal screening for implantable devices is intended not only for providers and nurses but also for patients. Patients are encouraged to self-advocate to increase their individual safety by providing this assessment data to their health care provider or other individuals involved in their medical care.

The health complications that can arise from breast implant surgery may be severe, and, as noted previously, prompt medical guidance and intervention are suggested (FDA, 2022a). It is important to note that historically, many physicians have treated health complications related to breast implant devices as a *diagnosis of exclusion* (i.e., the diagnosis is reached by a process of elimination). Clinically, this translates into ruling out all other potential causes for the patient's symptoms before concluding that the patient is symptomatic for illness, disease, or cancer related to an implantable device. This type of diagnosis can delay the implementation of appropriate illness-specific care and can negatively affect patient safety.

Initiating practice changes that increase safety for patients undergoing breast implant surgery is a priority; however, barriers and challenges to initiating practice changes have been identified. One notable barrier is stakeholder influence and researcher bias. When plastic surgeons and breast implant manufacturers conduct their own research,

there is a potential for *research bias* (i.e., a process in which the researcher influences the investigation to arrive at certain outcomes). Nurse researchers, especially plastic and aesthetic nurse researchers, should conduct research on breast implant surgery that omits stakeholder influence and research bias.

Another significant barrier to improving patient safety is that BII does not have a medical diagnosis code and, therefore, BII is not formally recognized as a disease process. However, the FDA requires a boxed warning on all breast implant devices stating that breast implant devices *have been associated with systemic symptoms* (FDA, 2022a). Notably, the FDA does not clarify the specific BII systemic symptoms, nor does it state that these systemic symptoms are related to the disease process of BII. However, to err on the side of caution, promote patient safety, and avoid unintentional patient dismissal and subsequent delayed medical intervention, plastic surgical nurses should assume that *systemic symptoms* could include *any or all* of the systemic symptoms that a patient with breast implant devices is experiencing.

In addition to the nursing process, evidence-based practice guides the nursing profession. Nurses can use the IOWA Model of Evidence-Based Practice (Iowa Model Collaborative, 2017) to implement new knowledge about BII, BIA-ALCL, and BIA-SCC, and the need for universal screening of all patients for implantable devices into current nursing practice. The steps of the IOWA Model include

- identifying an issue or opportunity;
- stating the purpose;
- forming a team;
- assembling, appraising, and synthesizing the body of evidence;
- designing and piloting the practice change;
- integrating and sustaining the practice change; and
- disseminating knowledge (Iowa Model Collaborative, 2017).

The scope of implementation may seem extensive, but the evidence can be broken down and implemented on a small scale and repeated until the new practice standard is obtained.

Successful practice change occurs when all health care providers, including the nursing profession as an entity and patients, have full knowledge of all risks and potential health complications associated with breast implant surgery, and the worldwide standard of care is to screen all patients for implantable devices at every health care

encounter. The risks and health complications associated with breast implant surgery can be serious and can severely compromise a patient's health and mental well-being; therefore, increasing awareness and implementing practices that increase patient safety regarding breast implant surgery are warranted and highly recommended.

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