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REVIEW

Recognizing and Managing Breast Implant Complications: A Review for Healthcare Providers Who Treat Women Who Underwent Breast Implant–Based Surgery

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Abstract: Given the prevalence of breast implants, healthcare providers treating women should be familiar with potential complications that may result from breast augmentation and implant-based reconstruction surgeries and the appropriate management strategies to adopt for each. Familiarity with risk factors and variables involved in complications and an understanding of the patient's surgical history and implant type/characteristics is key. This article provides an overview of implant types and surgical approaches and potential complications related to surgery that physicians treating women may encounter during routine clinical practice. It describes potential implant complications such as hematoma, implant rupture, infection, seroma, rare capsular lymphomas, capsular contracture, implant malposition, rippling, and animation deformity. This article also describes systemic symptoms that patients sometimes attribute to breast implants, such as fatigue, brain fog, joint pain, anxiety, hair loss, depression, rash, autoimmune diseases, inflammation, or gastrointestinal symptoms. Rare conditions, such as breast implant–associated anaplastic large cell lymphoma and squamous cell carcinoma in the capsule around breast implants, are also presented. Diagnostic criteria are summarized, with photographic examples, and management strategies and referral recommendations across the range of potential complications are provided. This article provides information to support healthcare providers who treat women in detecting breast implant complications and guiding their patients to an appropriate treatment and referral strategy.

Plain Language Summary: Breast implants are used to increase breast size or to restore shape following surgical removal of the breast due to cancer. The use of breast implants is growing, increasing the likelihood of doctors providing care for women who have breast implants. As a result, it is important for doctors who treat women to recognize problems that may occur following breast implant surgery and how to manage them. Knowing the factors that increase the likelihood of problems that may be related to breast implants, the medical history of the patient, and the type of breast implant are important. This article reviews the types of breast implants, the types of implant surgeries, and the problems that can result from those surgeries. For each potential breast implant problem identified, example photographs are provided, along with details on how to diagnose and manage the problem and when to refer the patient to a specialist. This article provides information to doctors to aid in identifying and treating women who encounter problems that may be related to their breast implants.

Keywords: contracture, hematoma, referral and consultation, mammaplasty, seroma

Introduction

Approximately 1.6 million breast augmentations were performed worldwide in 2020,[1] and implant-based breast reconstruction procedures increased 75% from 2000 to 2021 in the United States.[2] Given the popularity of augmentation and

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the growing number of reconstruction procedures related to breast cancer management, it is highly probable that healthcare providers (HCPs) who treat women (eg, obstetrician-gynecologists, family practitioners, primary care providers) will provide care to patients with breast implants. During routine visits with an HCP, patients with breast implants may ask questions or express concerns about complications or symptoms possibly related to their implants instead of returning to the surgeon who performed their augmentation or reconstruction. This scenario is especially likely if a patient's postsurgical monitoring period has passed or insurance-related hurdles have made obtaining specialty care difficult. Therefore, all HCPs who treat women should be familiar with breast implant types, implant surgical approaches, potential complications and symptoms arising from breast augmentation and reconstruction surgeries, and the appropriate management strategies to pursue, such as diagnostic testing and/or timely referral to a specialist. The existing literature on this topic for HCPs in the primary care setting is limited, and this paper aims to fill the void.

Methods

A literature search was performed to gather clinical data and information about issues and practices surrounding breast implants, breast augmentation surgery, and breast reconstructive surgery that would be relevant to HCPs for optimizing the care of affected patients. Resultant publications were reviewed and summarized along with the expert opinion of the lead author, who collaborated with the other authors on the development of guidance for the HCP on implant types, implant surgical approaches, potential complications, and appropriate management strategies.

Discussion

The first step in assessing and managing implant-related concerns is knowing the type of breast implant the patient received.

Breast Implant Types

Differences in the types of available breast implants may have bearing on the potential for certain complications. Patients uncertain about the implant used in their surgery should be directed to the implant registry/warranty card that is customarily provided after surgery and identifies the implant manufacturer, style, and serial number.[3] The HCP may also request surgical records to obtain the information.

Differences in implant types include the material used to fill the implant, the surface texture of the implant's outer shell, and the shape of the implant. All breast implants have a silicone outer shell that is filled with either saline solution or silicone gel. In silicone gel implants, the gel may be more or less cohesive (firm or soft).[4–6] The level of cohesivity affects the implant's ability to preserve its shape under pressure.[4,6] Silicone implants, which are more commonly used than saline implants,[1] are considered to have a more natural look and feel.[7] Saline implants are filled after insertion, which allows for small and sometimes hidden incision sites.[7] Silicone implants have reportedly lower short-term rates of rupture,[7,8] but their cohesiveness also makes rupture less detectable, and imaging may be necessary for further evaluation.[5,9] Saline naturally lacks the cohesivity of silicone and drains upon rupture.[9] Texturization of the outer shell of breast implants is aimed at promoting tissue ingrowth and increasing the stability and longevity of the implant.[10] The degree of texture may range from smooth (no texture) to nanotextured to highly textured. Highly textured implants are not presently in use in the United States due to an increased risk of breast implant–associated anaplastic large-cell lymphoma (BIA-ALCL).[11] Polyurethane-coated implants, also considered highly textured,[10] were withdrawn from the US market in 1991 due to safety concerns, but remain popular in both Europe and South America due to the lower risk of capsular contracture.[12] However, clinicians may still encounter patients with these implants from a less recent surgery or from a procedure abroad. Breast implants may be round or anatomical (projected at the base and tapered at the top for a natural contour).[10] Anatomical implants simulate the natural teardrop shape of the breast, but they require surface texture to encourage stability and tissue ingrowth; if the surface texture fails in this aspect, implant rotation and subsequent distortion of the breast shape may occur. Round implants are linked to positive outcomes when existing breast volume, cohesivity, and soft tissue coverage are sufficient, but may be less suitable for augmentation in patients who are thin or undergoing reconstruction because tissue coverage may be inadequate in these patients and may make the implant more noticeable, rippled, or wrinkled.[6,10,13–15]

Types of Implant-Based Surgeries

HCPs should be aware that a patient's experience with breast implants may vary not only based on the type of implant used, but also depending on the surgical indication (aesthetic or reconstructive) or the surgical technique used to place the implant. Certain complications may be more often associated with postmastectomy reconstruction than with aesthetic augmentation surgery.[16] In postmastectomy reconstruction, implants are inserted either at the time of mastectomy in the case of a direct-to-implant reconstruction or following the use of a tissue expander in a 2-stage approach; a breast tissue expander is an expandable temporary implant designed to stretch the tissues in preparation for permanent implantation.[2,17] Acellular dermal matrices (ADMs) are frequently used in breast reconstruction with tissue expanders or implants to provide adequate coverage and support for the implant without the need for additional muscle flaps; however, evidence on risks and benefits associated with use of ADMs in breast reconstruction is conflicting, particularly with respect to risk of seroma and infection.[18–20] Complication rates may also depend on whether the implant was placed underneath the pectoralis muscle in the chest (subpectoral placement), in front of it (prepectoral placement), or with its top portion under the muscle and lower portion over the muscle (dual-plane placement).[21–24] The following is an overview to inform the HCP of the potential complications that may be encountered in patients with breast implants during routine clinical practice, signs and symptoms, photographic examples, diagnostic procedures, and management strategies.

Complications With Breast Implants

Hematoma

Hematoma is considered a rare complication, occurring in less than 2% of reconstructive surgeries[25] or in up to 2.8% of all breast implant surgeries (Table 1).[3] Acute hematoma, which develops hours to days after the procedure, may result from blood vessel damage during surgery, whereas late hematoma, which is less common, may be caused by trauma to the breast.[25,26] A breast affected by hematoma will be bruised and enlarged with a painful lump.[25,27]

Table 1 Incidence of Breast Implant–Related Complications Documented in Previously Published Literature and Breast Implant Registries

Complication	Incidence in Literature	Proportion of Revision Procedures With Identified Complication in Registries
Hematoma	2% in reconstructive surgeries,[25] 2.8% in implant surgeries[3]	**Swedish**: 0.8%[28] **Australian**: 2.5% and 4.2% (combined hematoma/seroma) for cosmetic and reconstructive surgeries, respectively[29] **Dutch**: 1% and 3% (combined hematoma/seroma) for cosmetic and reconstructive surgeries, respectively[30]
Implant rupture	After 2 years: 2.5% with saline implants, 0.5% with silicone implants[8] After 10 years: 7.8% for primary augmentation, 5.2% for revision augmentation, and 9.8% for primary reconstruction surgery with silicone implants[31]	**Swedish**: 12.2%[28] **Australian**: 23.4% for cosmetic surgery; 17.7% for reconstructive surgery[29] **Dutch**: 21% for cosmetic surgery; 18% for reconstructive surgery[30]
Infection	Up to 9% of procedures,[3] with up to 4% within the first month[32]	**Swedish**: 1.8%[28] **Australian**: 0.6% for cosmetic surgery; 3.1% for reconstructive surgery[29] **Dutch**: 1% for cosmetic surgery; 4% for reconstructive surgery[30]

(*Continued*)

Table 1 (Continued).

Complication	Incidence in Literature	Proportion of Revision Procedures With Identified Complication in Registries
Seroma	Immediate postoperative period: 2.5% to 51%[33] All procedures: 6.5%[3] Late seroma: 0.8% to 1.8%[34]	**Swedish**: 2.6%[28] **Australian**: 2.5% and 4.2% (combined hematoma/seroma) for cosmetic and reconstructive surgeries, respectively[29] **Dutch**: 1% and 3% (combined hematoma/seroma) for cosmetic and reconstructive surgeries, respectively[30]
Capsular contracture	Up to 51.7%[3] Primary augmentation: 2.4% to 18.9%[35] Reconstructive: 10.1% to 26.8%[35] After 1 year: 6.1% for smooth implants, 2.7% for textured implants[36] After 2 years: 7.5% for smooth implants, 2.9% for textured implants[36]	**Swedish**: 25.0%[28] **Australian**: 36.6% for cosmetic surgery; 36.7% reconstructive surgery[29] **Dutch**: 30% for cosmetic surgery; 29% for reconstructive surgery[30]
Malposition	Shifting: 11.5%; asymmetry: 28%[3] Primary augmentation: 5%; secondary augmentation: 10%[37]	**Swedish**: 6.3%[28] **Australian**: 20.3% for cosmetic surgery; 27.6% for reconstructive surgery[29] **Dutch**: 3% for cosmetic surgery; 8% for reconstructive surgery[30]
Wrinkling/Rippling	Up to 20%[3] 19.4% for breast reconstruction; 19.5% for implant conversion[22,23]	
Animation deformity	75% in subpectoral/submuscular implants[38]	
BIA-ALCL	Unknown, but 1130 cases reported worldwide[3]	
Systemic symptoms	Unknown, but all patients have reported systemic symptoms (eg, brain fog, joint pain, anxiety, hair loss, depression, rash, fatigue) with all types of breast implants[39]	**Dutch**: 11% for cosmetic surgery; 4% for reconstructive surgery[30]
Squamous cell carcinoma in the capsule surrounding the implant	Unknown FDA reported 19 cases from published literature and 24 cases from medical device reports[40]	

Abbreviation: BIA-ALCA, breast implant–associated anaplastic large cell lymphoma.

Diagnosis of acute hematoma is straightforward, based on these clinical features, with imaging methods usually not required.[27] In cases for which imaging studies are obtained, hematoma density will decrease over time as the blood collected undergoes metabolic changes.[26,27,41] Imaging studies may be used for diagnosis in the absence of bruising.[27] The management of acute hematoma involves percutaneous drainage 7 to 14 days after the formation of hematoma to allow for liquefaction; surgical removal is indicated for late hematoma.[25,42] Therefore, a surgeon should be contacted for any type of hematoma. Formation of hematomas is unpredictable and therefore requires careful monitoring to prevent hemodynamic instability.[43] In cases where the skin is not hot to the touch (which would suggest a secondary infection), and the hematoma is small, the patient can be treated with antibiotic prophylaxis until able to visit a surgeon; advise patients that hematoma is a manageable complication and does not require emergency treatment, but does require consultation with a breast surgeon as soon as possible for resolution.[44] Urgent surgery may be warranted if the hematoma is expanding, painful, or swollen.[42,45]

Implant Rupture

Reported rates of breast implant rupture have varied depending on implant fill and surgical indication. Based on 10-year follow-up data from a large US Food and Drug Administration (FDA) postapproval study database on primary and revision augmentation and reconstruction surgeries in almost 100,000 patients using silicone and saline implants from two manufacturers, the rupture rate at 2 years postsurgery with saline implants was 2.5% versus 0.5% for silicone implants ($P<0.001$; based on 2007–2010 data from one manufacturer); the rupture rate at 3 years postsurgery was highest (1.0%) for revision augmentations ($P<0.001$; based on 2007–2009 data for the other manufacturer; Table 1).[8] The risk of rupture increases as the implant ages.[9] Ten years after primary augmentation, revision augmentation, or primary reconstruction surgery, the risk of implant rupture was 7.8%, 5.2%, or 9.8%, respectively, in a 10-year, open-label, prospective, multicenter clinical study of the safety and effectiveness of a single manufacturer's silicone gel breast implants in augmentation and reconstruction in 1788 patients (3506 implants).[31] Premarketing approval data from the FDA, meanwhile, indicate that rupture or leaking of either type of implant is reported in up to 31.2% of patients.[3] In several breast implant registries, implant rupture was the reported as the reason for 12.2% to 23.4% of revision procedures (Table 1).[28–30] Thus, the FDA recommends an ultrasound or magnetic resonance imaging (MRI) to assess silicone implant integrity/rupture 5–6 years postoperatively and every 2–3 years thereafter.[3] Screening recommendations from Health Canada and the Canadian Expert Advisory Panel include patient self-examination; physical examination from a physician if new signs and symptoms appear; further examination, if warranted, by ultrasound, mammogram, or both, of the implant and the breast; and, in cases of negative or inconclusive ultrasound, MRI read by a radiologist familiar with signs of implant rupture. Implant removal may be performed in consultation with the plastic surgeon if the MRI shows signs of rupture (Figure 1).[46] In addition to implant age, risk factors for implant rupture include underfilling of the implant, malfunctioning fill valves, manufacturing defects, or high-velocity direct blunt trauma to the breast.[9] Most implant ruptures are silent and present with no signs or symptoms. Patients who have symptoms may notice a change in breast shape, firmness, or size; capsular contracture; lumps; or breast pain and discomfort.[47] On physical examination, implant rupture is more easily detected with saline implants than highly cohesive silicone implants, because the saline implant will have deflated and the shape of the breast will have obviously changed, whereas rupture of the highly

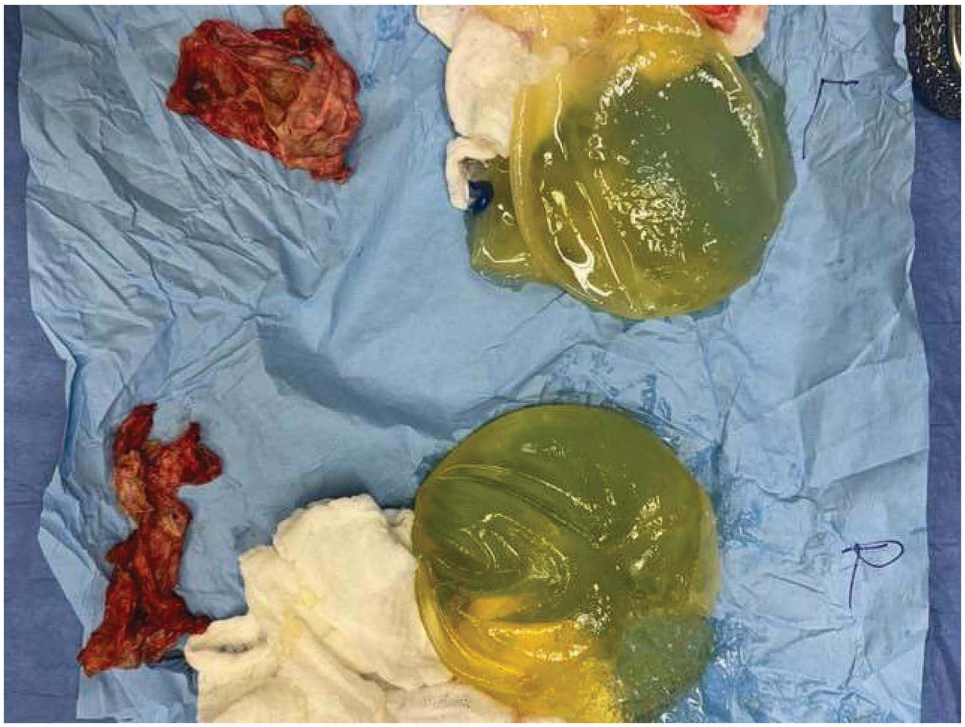

Figure 1 Implant rupture. Textured silicone gel breast implants that ruptured in several areas approximately 3 years after implantation. Although implant ruptures are typically asymptomatic, this rupture presented with pain and a misshapen breast. There was no history of trauma to the breast. An ultrasound was done to confirm the presence of the rupture. The implants were removed intact as much as possible and remaining free silicone was scraped from the cavity.

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cohesive silicone implant tends to remain intracapsular and the breast will continue to hold its shape despite compromise to the integrity of the implant.[9,44]

Detection of silicone implant ruptures may require imaging studies. An extracapsular silicone implant rupture occurs with extravasation of silicone beyond the fibrous scar tissue capsule into the surrounding tissues. This can result in a local tissue reaction and scar formation that may present as swelling, redness, change in breast shape, or a palpable mass. With this type of rupture, recommended imaging studies include MRI, and secondarily, mammography and ultrasound to assess the presence of silicone in surrounding tissues, but not computed tomography because silicone and surrounding tissues have similar radiodensity.[9,10,26,47] It is notable that unlike previous generations of silicone implants filled with noncohesive silicone, the contents of newer highly cohesive silicone implants will not spread to the surrounding tissue upon rupture and will remain intracapsular.[5] Intracapsular ruptures are most often asymptomatic and require imaging to detect.[47] FDA-recommended imaging studies include MRI and ultrasound.[3] Ultrasound has been shown to be almost as effective as MRI at detecting implant ruptures,[48] but is significantly more cost-effective in both women with and without symptoms.[49] In clinical practice, MRI is often used to confirm asymptomatic cases of intracapsular rupture diagnosed through ultrasound.[5] Given the density of the silicone, mammography is less sensitive for detecting this type of rupture.[9,10,26,47] In the case of confirmed saline or silicone implant rupture, the ruptured implant should be removed.[3,9] HCPs who treat women can advise those who are concerned about implant rupture that ruptured saline will be harmlessly reabsorbed[44] and that imaging will be used to confirm silicone rupture. In either case, the patient will be referred to a surgeon for removal of the implant, although not on an emergency basis.[44]

Infection

Up to 4% of patients will experience acute infection within the first month after breast implant surgery, whereas late-onset infections (at least 6 weeks after surgery) have a similar if slightly lower frequency, based on a review of breast reconstruction or aesthetic augmentation–related infection case reports and studies from 1987 through 2018 (Table 1).[32] Up to 9% of procedures involve infection, possibly requiring implant removal.[3] In several breast implant registries, infection was reported as a complication in 0.6% to 4% of revision procedures.[28–30] Gram-positive, biofilm-producing bacteria are predominantly associated with infection, and risk factors include the complexity of surgery, underlying conditions, and lifestyle/demographic factors such as smoking.[32] Diagnosis relies on clinical presentation, which may include the clinical sign of a "hot and red" breast[44] (Figure 2). Signs of early-onset infections (within 6 weeks after surgery) include swelling, flushing, breast pain,

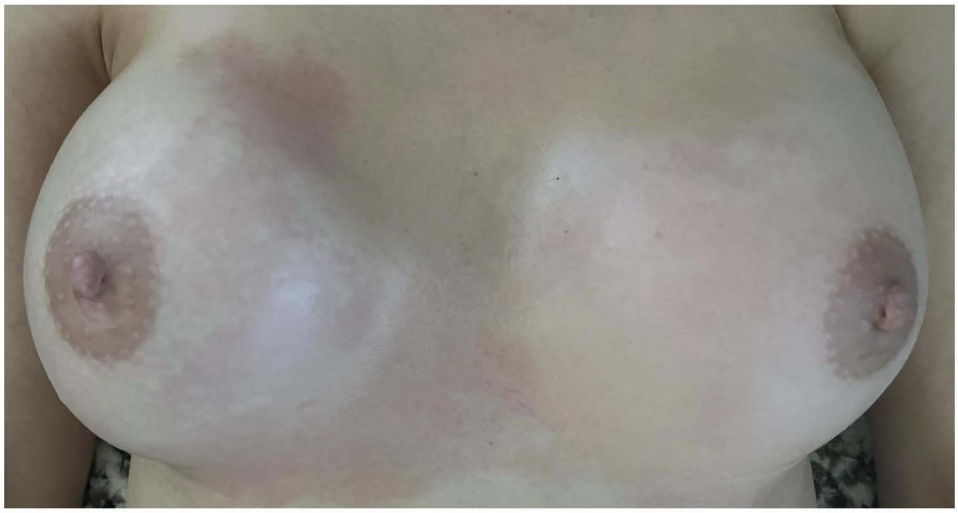

Figure 2 Infection. Six weeks after bilateral breast reconstruction with implants, the patient presented with pain, redness, and fever. The patient was treated with intravenous antibiotics and the infection resolved. When an infection presents, antibiotics are prescribed either by mouth or intravenously. If the infection does not respond to the antibiotics, surgical intervention is required, often requiring implant removal. If the infection is controlled by antibiotics alone, then it should be anticipated that a capsular contracture will develop relatively soon. This is demonstrated by implant malposition, with a shape change and firmness upon palpation. The photo depicts the altered appearance and asymmetry that occur, which will often require surgical correction, to include capsulectomy and implant replacement.

purulent discharge through surgical wounds, or systemic signs of infection, such as fever, increased heart rate, increased respiratory rate, or elevated white blood cell count.[32,44] Patients with late-onset infections typically present with a nonhealing surgical site, incisional drainage, dehiscence, or extrusion of the implant.[32]

To manage infection, the HCP may prescribe empirical antibiotic therapy, unless the infection poses risk of damage to skin or tissue, necessitating referral to a surgeon to determine whether surgical debridement, pocket irrigation, and/or implant removal is required.[10,32,44] If the breast is red and hot, antibiotic therapy should be started and the patient should be immediately referred to a plastic surgeon. In cases of acute postoperative infection, immediate action may be required to salvage the implant, avoid tissue damage, and prevent systemic infection.[10] Patients should be educated on wound care procedures, monitored for response to antibiotics, and, if needed, referred to a surgeon urgently.

Seroma

Seroma, which, in the context of this paper, is the accumulation of serous fluid in the area of implant placement, occurs with relative frequency in the breast during the immediate postoperative period (2.5% to 51% incidence; Table 1).[33] An overall seroma incidence of up to 6.5% of procedures has been reported.[3] The etiology for late seroma is not well understood, but early seroma may sometimes be caused by implant movement, an oversized pocket, or increased patient activity.[25,50] Patients should be counseled that early seroma, generally within the first year of surgery, is not uncommon, and the fluid will be reabsorbed, but if redness or heat is present or the patient generally feels unwell, infection may exist and immediate investigation and management by a surgeon is necessary.[33,44] Late seroma, occurring more than 1 year after surgery, has an incidence of 0.8% to 1.8%.[34] Seroma presents as swelling or increased volume in the operated breast, resulting in asymmetry and turgidity, which is often accompanied by pain, and can be assessed with ultrasound, CT, or MRI with periprosthetic fluid cytology.[25,44,50] Early seroma can be punctured percutaneously and drained; fluid cytology is useful if infection is suspected.[25] Late seroma should be assessed according to a patient's clinical situation and should include surgeon-directed fluid analysis and ultrasound or MRI, capsulectomy, implant removal, and possible replacement of the implant.[25] Although it is a rare presentation, BIA-ALCL can manifest as a late seroma, so fluid should undergo cytological examination to rule out cancer.

Breast Implant–Associated Anaplastic Large-Cell Lymphoma (BIA-ALCL)

Rarely, a malignancy may develop in the capsule surrounding the breast implant.[3] BIA-ALCL is a type of non-Hodgkin's lymphoma that, in rare instances, may also spread beyond the capsule.[3] The incidence rate of BIA-ALCL is unknown, but as of April 2022, the FDA reported 1130 cases worldwide (Table 1).[3] The etiology of BIA-ALCL is also unknown; however, BIA-ALCL has been associated with textured implants regardless of the fill type.[3,51]

The most common symptoms for BIA-ALCL are persistent swelling and a mass or pain in the area of the breast implant.[3] Symptoms may appear years after implant surgery.[3] Concurrent systemic symptoms, such as fatigue and joint pain, have been reported with BIA-ALCL.[3] This type of lymphoma may be suspected if the patient presents with delayed seroma (occurring 7 to 8 years after surgery), swelling, pain, or a mass in the capsule surrounding the implant; axillary lymphadenopathy may be present.[3,10,52–54]

Patients should be educated that BIA-ALCL is uncommon; however, if the malignancy is strongly suspected, diagnosis and prognosis are best handled by an oncologist in coordination with the breast surgeon who performed the implantation. Breast ultrasonography with fine-needle aspiration of the seroma is the recommended diagnostic testing for BIA-ALCL.[51,55] Both the FDA and Health Canada recommend collection of fresh seroma fluid and representative portions of the capsule to be sent for pathology tests to rule out BIA-ALCL.[56,57] Health Canada also recommends collection of any mass found within or around the implant. The presence of abnormal tumor cells that are CD30-positive and anaplastic lymphoma kinase (ALK)-negative in the seroma is indicative of the diagnosis, but for patients who present with a mass and no effusion, ultrasound-guided biopsy or open biopsy can confirm the diagnosis of BIA-ALCL.[10,51,53,55] Management of BIA-ALCL requires surgical intervention. Complete explantation/en bloc capsulectomy (ie, complete removal of the implant together with the surrounding intact capsule) is the standard treatment if BIA-ALCL diagnosis is confirmed, with some cases necessitating chemotherapy or radiation treatment.[3] First-line immunotherapy (brentuximab vedotin) is recommended for advanced/disseminated disease when surgery is not an option,[51] but brentuximab vedotin

may also be considered as an adjuvant treatment in advanced cases involving explant surgery.[58] According to the PROFILE Registry, a BIA-ALCL data registry arising from the collaborative efforts of the American Society of Plastic Surgeons/Plastic Surgery Foundation and the FDA, 31 deaths occurred worldwide as of September 2022,[59] so prompt referral in cases of suspected late seroma is advised.[3]

The FDA does not recommend the routine removal of textured or other types of breast implants in patients who have no symptoms.[56]

Capsular Contracture

Capsular contracture, a painful tightening of the fibrous capsule around the implant, may occur in up to 51.7% of patients (Table 1).[3] Rates of occurrence based on type and number of surgeries from a review of five clinical trials estimated that capsular contracture occurred in 2.4% to 18.9% of primary augmentation surgeries and 10.1% to 26.8% of reconstructive surgeries.[35] Capsular contraction was a reported complication in 25.0% to 36.7% of revision procedures noted in several breast implant registries.[28–30] Since the assessment of capsular contracture is a clinical assessment, thus subject to interpretation, its true incidence is difficult to ascertain. Capsular contracture, along with implant rupture, malposition, and change in size or shape of the breast, is one of the most common reasons for breast implant revision surgery.[35] Capsular contracture primarily arises from excessive peri-implant fibrosis, which may result from intraoperative factors (eg, bleeding, surgical trauma, hematoma, seroma, infection).[35] Late capsular contracture (6 months after surgery or later) is likely associated with biofilm formation that stimulates inflammation and fibrosis over time.[35] There is evidence that capsular contracture may occur more commonly with smooth implants.[60] Among 253 women who underwent primary breast augmentation between January 2017 and July 2019, the rate of capsular contracture was 6.1% for smooth implants and 2.7% for textured implants at 1 year, and 7.5% for smooth implants and 2.9% for textured implants at 2 years; these differences were not statistically significant.[36] Risk of contracture for smooth versus textured implants increased 4-fold with subfascial implant placement, whereas submuscular placement resulted in similar contracture rates for both types of implants.[36]

Capsular contracture is characterized by varying degrees of firmness and distortion of the breast, which are graded in severity (I to IV) according to the Baker scale[61] or Baker-Spear classification.[62] A class IV contracture is considered severe, requiring revision surgery,[62] typically a capsulectomy with or without a capsulotomy.[60] The underlying implant may or may not be replaced.[44] Although capsular contracture may be painful, it is not an emergency, but the patient should be referred to a surgeon.

Malposition

Implants can be displaced, become asymmetrical, or otherwise lose their initial and intended positioning when there are changes to the size of the pocket (ie, hematoma or seroma expands the pocket, leading to malposition), improper positioning of the implant during placement, trauma to the rib perichondrium, technical errors with dissection during surgery, postoperative massage, or excess activity.[37] Shifting of implants in up to 11.5% of patients and an overall incidence of asymmetry in up to 28% of all procedures have been reported,[3] and clinical trials suggested an average malposition incidence of 5% of primary augmentation surgeries and up to 10% of secondary (ie, revision) augmentation surgeries (Table 1).[37] In breast implant registries, malposition was a reason for 3% to 27.6% of revision procedures.[28–30] Patients with implant malposition present with asymmetry and/or an inferior, medial, superior, or lateral shift of the implant (Figure 3).[35,37] Malposition may occur more commonly with smooth implants because there is no texture to encourage friction/resistance between the implant and surrounding soft tissue.[37] In early malposition, nonsurgical external options may be used to adjust the implant pocket, including compression, taping, or specialized garments, but once malposition is firmly established, surgical correction may be needed.[35,37] Patients should be advised to visit the surgeon on a nonemergency basis, unless malposition is related to a more serious complication.

Wrinkling/Rippling

Visible rippling or wrinkling of the implant may affect up to 20% of patients (Table 1).[3] Similar incidences of rippling (19.4% and 19.5%, respectively) were reported in single-center studies of prepectoral breast reconstructions performed in

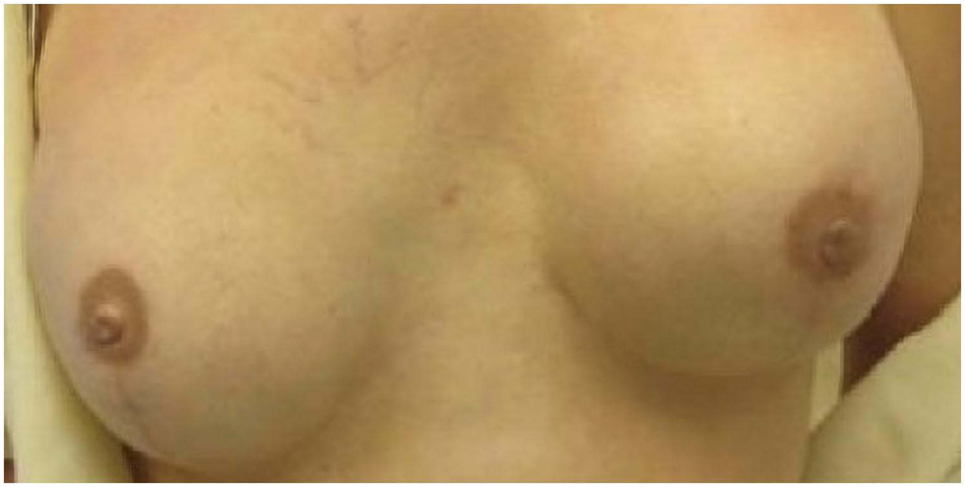

Figure 3 Malposition. Malposition of implant in left breast was caused by radiation and presented approximately 2 years after treatment for breast cancer and reconstruction with implantation. Key signs and symptoms included pain, malposition, and firmness to touch. Surgical correction was necessary and involved capsulotomy and implant replacement.

90 women between 2015 and 2018 and breast implant conversion surgeries from the subpectoral to prepectoral plane in 41 women between 2009 and 2019.[22,23] Rippling can be related to lack of overlying breast tissue support, thin-skin soft tissue mantles, and redistribution of glandular tissue, with breast reconstruction and revision surgeries being a risk factor.[23,25,63]

Clinical examination demonstrates visible rippling or wrinkling of the skin over the implant, with malposition/displacement or risk of capsular contracture.[23,35] Patients should be advised to visit a surgeon (though not urgently); management includes surgical revision and/or fat transfer to provide better tissue support.[23,35]

Animation Deformity

Characterized by an uncomfortable, spontaneous movement or twitching of the upper breast and implant triggered by certain movements of the arms or movements that engage the chest muscles,[24] animation deformity is caused by adherence of the patient's tissue to underlying pectoral muscle such that any activity that engages the pectoralis major muscles causes undesired movement of the breast mound and implant upward and outward.[38,64] A major contributing factor to the likelihood of developing animation deformity is insufficient breast tissue coverage, which can be associated with breast radiotherapy prior to breast reconstruction or subpectoral implant placement.[65–68] Animation deformity has a reported incidence of at least 75% with subpectoral/submuscular implantations (Table 1), which have historically been the preferred surgical approach for breast reconstructions for greater stability;[38] animation deformity is rarer with prepectoral implant placement.[69] Patient presentation typically includes pain and/or muscle spasm with muscle movement, often accompanied by nipple displacement.[24,38,64] As with rippling, management involves surgical revision (eg, surgical plane change to the prepectoral space), with or without fat transfer, and patients should be referred to a surgeon, with timing based on their level of discomfort.[23,35]

Breast Implant–Associated Anaplastic Large-Cell Lymphoma (BIA-ALCL)

Rarely, a malignancy may develop in the capsule surrounding the breast implant.[3] Breast implant–associated anaplastic large-cell lymphoma (BIA-ALCL) is a type of non-Hodgkin's lymphoma that, in rare instances, may also spread beyond the capsule.[3] The incidence rate of BIA-ALCL is unknown, but as of April 2022, the FDA reported 1130 cases worldwide.[3] The etiology of BIA-ALCL is also unknown; however, BIA-ALCL has been associated with textured implants regardless of the fill type.[3,51]

The most common symptoms for BIA-ALCL are persistent swelling and a mass or pain in the area of the breast implant.[3] Symptoms may appear years after implant surgery.[3] Concurrent systemic symptoms, such as fatigue and joint pain, have been reported with BIA-ALCL.[3] This type of lymphoma may be suspected if the patient presents with delayed

seroma (occurring 7 to 8 years after surgery), swelling, pain, or a mass in the capsule surrounding the implant; axillary lymphadenopathy may be present.[3,10,52–54]

Patients should be educated that BIA-ALCL is uncommon; however, if the malignancy is strongly suspected, diagnosis and prognosis are best handled by an oncologist in coordination with the breast surgeon who performed the implantation. Breast ultrasonography with fine-needle aspiration of the seroma is the recommended diagnostic testing for BIA-ALCL.[51,55] Both the FDA and Health Canada recommend collection of fresh seroma fluid and representative portions of the capsule, to be sent for pathology tests to rule out BIA-ALCL.[56,57] Health Canada also recommends collection of any mass found within or around the implant. The presence of abnormal tumor cells that are CD30-positive and anaplastic lymphoma kinase (ALK)-negative in the seroma is indicative of the diagnosis, but for patients who present with a mass and no effusion, ultrasound-guided biopsy or open biopsy can confirm the diagnosis of BIA-ALCL.[10,51,53,55] Management of BIA-ALCL requires surgical intervention. Complete explantation/en bloc capsulectomy (ie, complete removal of the implant together with the surrounding intact capsule) is the standard treatment if BIA-ALCL diagnosis is confirmed, with some cases necessitating chemotherapy or radiation treatment.[3] First-line immunotherapy (brentuximab vedotin) is recommended for advanced/disseminated disease when surgery is not an option,[51] but brentuximab vedotin may also be considered as an adjuvant treatment in advanced cases involving explant surgery.[58] According to the PROFILE Registry, a BIA-ALCL data registry arising from the collaborative efforts of the American Society of Plastic Surgeons/Plastic Surgery Foundation and the FDA, 31 deaths occurred worldwide as of September 2022,[59] so prompt referral in cases of suspected late seroma is advised.[3]

The FDA does not recommend the routine removal of textured or other types of breast implants in patients who have no symptoms.[56]

Systemic Symptoms Attributed to Breast Implants

Patients with breast implants may also report a variety of nonspecific systemic symptoms (ie, breast implant illness) that they associate with their breast implants, such as fatigue, brain fog, joint pain, anxiety, hair loss, depression, rash, autoimmune diseases, inflammation, or gastrointestinal symptoms, but there is currently not a formal medical diagnosis for systemic symptoms attributed to breast implants nor a formal diagnostic workup.[39,70] Systemic symptoms have been reported by patients with all types of breast implants regardless of fill, shape, surface characteristics, or time since surgery (Table 1).[39] Incidence rate, cause, and risk factors are unclear; research into systemic symptoms is ongoing.[39] In the Dutch Breast Implant Registry, breast implant illness was a reported reason for 4% and 11% of revision procedures following reconstructive and cosmetic surgeries, respectively.[30] Diagnostic tests can help determine the presence of an underlying and undiagnosed condition unrelated to the presence of breast implants and define next steps; accordingly, the HCP may prescribe tests to measure complete blood count, C-reactive protein, erythrocyte sedimentation rate, electrolytes, iron, creatinine, thyroid and liver function, serum IgG and IgM, vitamin D and calcium levels, and autoimmune disease markers.[70,71] Moreover, the HCP can assist the patient in the diagnostic process and facilitate the appropriate referral in relation to the findings.

An important first step in counseling the patient is validating the reality of the patient's experience, because the symptoms indeed need to be adequately and appropriately investigated.[70] Advise patients that testing by a specialist may be necessary to rule out any confounding etiology that might be the cause of the symptoms and treat the patient more effectively. Nonetheless, if the patient does seek explantation, en bloc capsulectomy is not indicated for relief of nonspecific systemic symptoms.[70] En bloc capsulectomy is a technique utilized for treating malignancy such as BIA-ALCL. Ongoing research sponsored by the Aesthetic Surgery Education and Research Foundation (ASERF) demonstrated that the type of capsulectomy has no impact on symptom improvement upon explantation.[72] Additionally, ASERF data demonstrated that few identifiable markers existed in blood, capsule tissue pathology, and microbes to explain self-reported systemic symptoms in women with breast implants who requested removal compared with 2 control groups.[73]

In the literature, conclusions on the association between nonspecific symptoms and breast implants have been inconsistent. Cohen Tervaert et al noted a causal association between silicone breast implants and breast implant illness,[74] and a retrospective cohort study reported increased odds of experiencing 3 or more health symptoms and multiple HCP visits after cosmetic surgery with silicone breast implants when compared to both preimplantation and women without implants.[75]

However, 2 cohort studies found no association between the prevalence of nonspecific symptoms among women with breast implants versus controls without implants.[76,77] Similarly, a meta-analysis found no evidence of an increased risk of connective-tissue disease, autoimmune disease, or rheumatic conditions due to breast implants.[78] Some experts have noted that there is not enough evidence to support breast implant illness as a disease entity and that large, prospective-based studies are needed to determine a causal association between silicone breast implants and nonspecific symptoms.[79]

Squamous Cell Carcinoma in the Capsule Around Breast Implants

Squamous cell carcinoma (SCC) in the capsule around breast implants is a very rare but potentially aggressive epithelial-based tumor that may develop in the capsule surrounding the breast implant.[40,55] It is not a cancer of the breast itself, and risk factors are unknown.[40,55] Incidence is also unknown, but the FDA reported 19 cases from the published literature and 24 cases from medical device reports (MDRs) as of January 2023 (the latter may include duplicate reporting of cases from the literature or other MDRs; Table 1).[40] SCC in the capsule around breast implants can occur with textured and smooth breast implants of either silicone or saline fill.[55] The most common symptoms are swelling, pain, lumps, or skin changes,[80] which may appear years after implant surgery.[80] Features include delayed seroma, unilateral swelling, pain, erythema, and, frequently, capsular contracture.[55,80]

If SCC in the capsule around breast implants is strongly suspected, diagnosis and treatment are best handled by an oncologist in coordination with the breast surgeon who performed the implantation. Breast ultrasonography of the seroma is the recommended diagnostic testing. The seroma specimen should be analyzed for immunohistochemistry, including CK 5/6, p63, and flow cytometry to look for squamous cells and keratin.[55] MRI with or without contrast may be used for differential diagnosis, ie, to rule out a mass, and positron emission tomography–CT is used for evaluating the extent of disease.[55] Typical pathologic findings are squamous cells in sheets with varying degrees of atypia and metaplasia and at least 1 focus of SCC.[55] Management of SCC in the capsule around breast implants requires oncological and surgical intervention with complete explantation/en bloc capsulectomy (ie, complete removal of the implant together with the surrounding capsule) if diagnosis is confirmed.[80] However, the FDA does not recommend breast implant removal in patients who do not have symptoms.[40]

Risk Factors for Reconstructive Breast Implant–Related Complications

Several patient-, provider-, and procedure-dependent factors have been reported to increase the risk of breast implant complications. In a retrospective cohort study of patients who underwent a mastectomy followed by reconstructive breast implant surgery, after adjustment for confounding factors, several risk factors for implant loss were noted, including a BMI >30 kg/m^2 (odds ratio [OR]=3.226, p=0.020), current active smoking status (OR=3.935, p=0.009), bra cup size larger than C (OR=3.132, p=0.015), a direct-to-implant reconstruction (OR=2.609, p=0.032), a nipple-preserving procedure (OR=4.182, p=0.004), and a surgeon with a lower surgical volume (OR=3.070, p=0.019 for 25–50 procedures over 4 years compared with >50 procedures; OR=4.086, p=0.010 for <25 procedures).[81] It has been hypothesized that obesity increases the risk of implant-related complications because women with obesity tend to have larger breasts requiring larger and longer mastectomy flaps with a decreased blood supply compared to shorter flaps, more postoperative dead space, and longer surgical times.[82] This hypothesis is in line with the noted increase in risk among women with a breast cup size larger than C. Smoking status has also been frequently identified as a risk factor for implant-related complications, likely a result of the vasoconstrictive properties of nicotine reducing blood flow to the tissue.[83] Other notable risk factors for complications in reconstructive breast implant procedures are older age and receipt of radiotherapy to the chest either prior to or following mastectomy. In a retrospective cohort study of patients who underwent 2-stage breast reconstruction, age >50 years was associated with an increased risk for complications possibly due to thinner skin, which may be more likely to experience extrusions, and more comorbidities than younger patients.[82] This study also found a 3.5 and 2.75 times higher risk of complications leading to explantation among women with a history of prereconstruction and postreconstruction radiation therapy, respectively. Autologous reconstruction may be a preferred treatment option for patients who have received radiation therapy.

Guiding Principles for Nonspecialist Physician Care of the Patient With Breast Implants

HCPs who provide care to women can play an instrumental role in the evaluation of breast implant patients. Based on the risk factors and variables involved in development of complications and symptoms as described above, HCPs should know the implant patient's surgical history (time of initial and subsequent breast surgeries, surgical indication, and surgical technique), breast care routines (eg, self-examinations, mammograms, MRI, and follow-ups with a plastic surgeon), placement of the implant, and the implant characteristics. Patients should be asked if they have noticed any changes to their implants or whether they have experienced trauma to the implants. Should a complication or symptom be identified, referral to the appropriate specialist or specialists is warranted, along with the specific strategies summarized in Table 2.

Regardless of whether complications or symptoms are extant, patients with breast implants should be encouraged to adhere to the routine imaging schedule recommended by the FDA and screening recommendations from Health Canada. In patients who have had a breast reconstruction, implant displacement views should be ordered to avoid delays in diagnosis.[84]

Table 2 Management of Suspected Complications in Patients With Breast Implants, Based on Common Signs or Symptoms

Sign or Symptom	Suspected Complication	Patient Counseling Points	Recommended Tests	Appropriate Specialists for Referral	Level of Urgency
Lump	Hematoma (if painful and bruised)	Condition is manageable, starting with antibiotics	MRI or CT in the absence of bruising	Surgeon	Low unless hot to the touch
	BIA-ALCL or SCC in the capsule around breast implants (if lump is mass accompanied by late seroma, swelling, pain, and other symptoms)	Lymphomas are rare and must be confirmed by oncologist	Breast ultrasonography, seroma specimen immunohistochemistry	Oncologist, surgeon	High
Hot, red breast	Infection	Treatment may involve uncomplicated wound care and aseptic measures, with implant removal reserved for special cases	Clinical presentation dictates diagnosis	Surgeon	Moderate depending on course of infection and response to treatment
	Implant rupture (if accompanied by breast deformation, pain, and discomfort)	Expelled saline will be harmlessly reabsorbed by the body, and silicone rupture must be confirmed with testing	MRI	Surgeon	Moderate
Swelling	Seroma	Occurrence early after surgery is common and not life-threatening; late seroma may be associated with more serious illness	Ultrasound, CT, or MRI with periprosthetic fluid cytology	Surgeon	Low if early; high if late
	BIA-ALCL or SCC in the capsule around breast implants (see above)				

(*Continued*)

Table 2 (Continued).

Sign or Symptom	Suspected Complication	Patient Counseling Points	Recommended Tests	Appropriate Specialists for Referral	Level of Urgency
Asymmetry	Seroma (see above)				
	Malposition	Malposition early after surgery may be corrected by noninvasive means (ie, compression) but later malposition requires surgical intervention	Clinical presentation dictates diagnosis	Surgeon	Low
	Implant rupture (see above)				
Deformity	Animation deformity	Patients should be advised to visit a surgeon (though not urgently)	Clinical presentation dictates diagnosis	Surgeon	Low
	Wrinkling/Rippling	Patients should be advised to visit a surgeon (though not urgently)	Clinical presentation dictates diagnosis	Surgeon	Low
	Capsular contracture	Surgical intervention is warranted if the hardening and distortion of the breast are severe; otherwise, it is not an emergency	Clinical presentation and Baker scale grading dictate diagnosis	Surgeon	Moderate depending on severity

Abbreviations: BIA-ALCL, breast implant–associated anaplastic large cell lymphoma; CT, computed tomography; MRI, magnetic resonance imaging; SCC, squamous cell carcinoma.

Conclusions

When a patient presents with concerns about their breast implants, the HCP is in a key position to reassure the patient, promptly identify potential complications or symptoms, provide timely referrals, and avoid unnecessary patient anxiety. Familiarity with breast implant complication diagnostic criteria, key signs and symptoms, risk factors, management strategies, and referral recommendations can help the HCP offer an appropriate level of care and manage the patient's concerns effectively. In this way, the HCP can play an instrumental role in the proper evaluation and care of patients with breast implants. It is our hope that the recommendations provided herein will further support HCPs who provide care to women in addressing the broad array of healthcare needs they encounter each day.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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