

Navigating Breast Implants, Cancer, and Illness

Effective Date: February 2023



Background

With the recent increase in public awareness of breast implant associated concerns¹, it is important that primary care providers and specialists are aware of the evidence behind these concerns and of how best to handle them. Roughly 4% of Canadians have breast implants; extrapolating from American data, roughly three-quarters of implants were placed for aesthetic augmentation, and one-quarter for post-mastectomy reconstruction².

The purpose of this guideline is to assist primary care providers and specialists in managing patients with breast implants, specifically regarding breast implant integrity, breast cancer screening, and the recently recognized cancer known as Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL). In addition, we describe “Breast Implant Illness” (BII) which has gained notoriety as of late, particularly on social media. BII is a poorly understood cluster of generalized symptoms which may or may not be related to breast implants, to which we offer a pragmatic work-up strategy. Although not a malignancy, BII is included in this guideline to disentangle it from issues surrounding cancer care. Finally, for patients with implants and breast cancer who require radiotherapy, we describe potential sequelae and work up of associated symptoms.

Guideline Questions

1. How to recognize and manage patients with textured implants and concerns for breast implant-associated anaplastic large cell lymphoma (BIA-ALCL)?
2. How to recognize and manage patients with implants and concerns about Breast Implant Illness (BII)?
3. How do breast implants alter screening for breast cancer?
4. What are potential sequelae associated with radiating an implanted breast?

Search Strategy

The PubMed database was searched for relevant studies, guidelines and consensus documents published up to October 2022. The specific search strategy, search terms, and search results, are presented in Appendix A. Online resources from oncology-based health organizations and guideline developers were also systematically searched, and relevant guidelines from the American Society of Clinical Oncology (ASCO), and the National Comprehensive Cancer Network (NCCN) were also considered in the development of the recommendations.

Target Population

The following recommendations apply to adult patients with breast implants.

Summary of Recommendations

1. How to recognize and manage patients with textured implants and concerns for breast implant-associated anaplastic large cell lymphoma (BIA-ALCL)?

Be aware of the surface type of implants in your patients. Patients are usually given a card with the details of the implant. This information can also be obtained by contacting the plastic surgeon's office who placed the implant. Patients with macrot textured implants are at increased risk of BIA-ALCL. The most common presentation is unilateral breast swelling, typically presenting seven to ten years after implantation. Start with an ultrasound and aspiration of the fluid to check for particular markers. Refer to a plastic surgeon if results are positive for BIA-ALCL or equivocal. (*Level of Evidence: IV, Strength of Recommendation: A*).

2. How to recognize and manage patients with implants concerned with breast implant illness (BII)?

Patients with systemic symptoms may attribute their symptoms to their implants; however, BII is a diagnosis of exclusion. Appropriate workup should be exhausted before the patient is referred to a plastic surgeon for implant removal. (*Level of Evidence: IV, Strength of Recommendation: C*).

3. How do breast implants alter screening for breast cancer?

Breast screening for patients with breast implants done for cosmetic augmentation is similar to non-implanted patients, with the exception that Eklund views are used to displace the breast over the implant. Eklund views are ordered by the radiologist if the patient has known implants. However, patients who have had breast implants for reconstruction post-mastectomy do not need their new breast mound imaged unless they have a concern. Routine screening for implant rupture is not recommended; however, if the patient notes a change in shape or other abnormality, consider initial workup with an ultrasound. (*Level of Evidence: III, Strength of Recommendation: A*).

4. What are potential sequelae associated with radiating an implanted breast?

Radiotherapy can cause contraction of the capsule containing an implant, that was placed for augmentation or reconstruction. This may result in a tight-feeling, firm, and possibly distorted-appearing breast. If the patient is concerned, conduct routine breast imaging, and refer to the patient's plastic surgeon. (*Level of Evidence: III, Strength of Recommendation: C*).

Discussion

1. Breast Implant-Associated Anaplastic Large Cell Lymphoma

Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) is a rare peripheral T cell lymphoma. BIA-ALCL more frequently occurs in patients with textured surface breast implants or a history of textured surface breast implants or tissue expanders. Textured breast implants are used to decrease chances of capsular contracture and malposition³. Macrot textured (i.e., Allergan brand) implant surfaces have an irregular pattern of pores with a diameter of 600-800µm and depth of 150-

200µm, created by pressing uncured silicone into a bed of fine salt⁴. Microtextured (i.e., Mentor brand) implant surfaces have pores measuring 70-150µm in diameter and 150-200µm in depth, created by stamping the uncured silicone with negative-contact polyurethane foam⁴. The estimated risk of BIA-ALCL is considered rare in patients with macrotextured implants and very rare in patients with microtextured implants. The exact number of cases is not known due to limitations in world-wide reporting. As of April 2022, the U.S. Food and Drug Administration (FDA) was aware of 1,130 cases globally⁵. Of these cases, 71% were people with textured implants, 3% were people with smooth implants and 26% were in people with unknown implant texture⁵. Of the 37 cases with smooth implants, eight cases have a history of at least one textured implant, 18 cases have an unknown prior history, and 11 cases have a history of implants with unknown texture. In Canada, as of September 2021, there were 64 confirmed cases, 25 suspected cases, and three deaths⁶. Of the Canadian cases, 64 were in people with macrotextured implants, two were in people with microtextured implants, and 22 were in people with unknown implant texture⁷. There is currently one Canadian case of BIA-ALCL in a patient with smooth implants, but this patient has a history of textured implants or tissue expanders. Estimated risk values can be found on the [Health Canada website](#), which may be as high as one in 1,636, including unconfirmed cases, for macrotextured implants.

Diagnosis and Workup:

The most frequent presentation of BIA-ALCL is a large collection of periprosthetic fluid that appears at least one-year post-implantation (mean time seven to ten years)⁸⁻¹¹. Less commonly, patients present with a palpable mass, lymphadenopathy, skin rash, fevers, and capsular contracture.

The workup for suspected BIA-ALCL begins with an ultrasound exam to observe the effusion and aspirate it, to screen for any masses, and to evaluate the surrounding lymph nodes^{8, 12, 13}. If ultrasound results are inconclusive, magnetic resonance imaging (MRI) can be used¹⁰. Ultrasound guided fine needle aspiration of periprosthetic fluid is needed to confirm diagnosis. The minimum volume of fluid needed is 50 mL, but preferably as much fluid as possible should be aspirated^{8, 14, 15}. Any masses present should be biopsied¹⁰. The pathological workup must include cytology with cell block preparation, immunohistochemistry and/or flow cytometry for CD2, CD3, CD4, CD5, CD7, CD8, CD30, CD45 and ALK^{8, 10, 14}. BIA-ALCL cells are CD30 positive, ALK negative and have large anaplastic morphology on cytology^{10, 16}.

Once the diagnosis is confirmed, it is recommended to consult with a multidisciplinary team including medical, radiation, and surgical oncologists, pathologist, and a plastic surgeon^{8, 10, 14}. A preoperative workup and staging should follow, which includes: full history and physical with a breast, skin, and lymph node exam, complete blood count with differential and lactate dehydrogenase, comprehensive metabolic panel (glucose, calcium, sodium, potassium, carbon dioxide, chloride, albumin, total protein, alkaline phosphatase, alanine transaminase and aspartate aminotransferase, bilirubin, blood urea nitrogen and creatine), hepatitis B testing (if adjuvant chemotherapy is being considered), echocardiogram or multigated acquisition scan (if an anthracycline based regimen is indicated), pregnancy test (for patients of childbearing age), and a positron emission tomography/ computed tomography (PET/CT) scan^{8, 10}. A bone marrow biopsy is only needed for patients whom are suspected of having systemic ALCL⁸.

Staging for BIA-ALCL is done using the TNM solid tumour staging system (Table 1)^{8, 10, 17}.

Table 1: TNM stage classification of BIA-ALCL (based on a solid tumour TNM staging)⁸

TNM Classification		TMN Stage	
T: Tumour extent		IA	T1 N0 M0
T1	Confined to effusion or layer on luminal side of capsule	IB	T2 N0 M0
T2	Early capsule infiltration	IC	T3 N0 M0
T3	Cell aggregates or sheets infiltrating the capsule	IIA	T4 N0 M0
T4	Lymphoma infiltrates beyond the capsule	IIB	T1-3 N1 M0
N: Lymph nodes		III	T4 N1-2 M0
N0	No lymph node involvement	IV	T _{any} N _{any} M1
N1	One regional lymph node (+)		
N2	Multiple regional lymph nodes (+)		
M: Metastasis			
M0	No distant spread		
M1	Spread to other organs/distant sites		

Health Canada recommends that all histologically confirmed BIA-ALCL should be reported on a Consumer Medical Device Report Form ([Consumer Medical Device Report Form \(canada.ca\)](https://www.canada.ca/en/health-canada/services/medical-devices/consumer-medical-device-report-form.html))⁶.

Surgical Treatment:

Total *en-bloc* capsulectomy is the primary treatment for BIA-ALCL^{12, 17, 18}. This includes removing the implant with the capsule in its entirety, and excision of any masses with confirmation of negative margins^{8, 11}. Surgical specimens should be oriented and inked to aid in tumour site surveillance and cases of recurrence^{8, 12}. If the patient has bilateral implants, it is recommended to also remove the uninvolved implant and capsule, which reduces the risk of contralateral occurrence or second contralateral lymphoma¹¹. There is currently no evidence to suggest that radical mastectomy or sentinel lymph node biopsy is needed^{8, 12, 17} but any enlarged axillary lymph node should be excised during surgery^{11, 13}.

Adjuvant Treatments:

No adjuvant therapy is currently recommended for patients who have stage IA-IIA disease (Table 1)¹¹. Indications for adjuvant therapy are incomplete resections or patients with stage IIB-IV disease (unresectable chest wall invasion, regional lymph node involvement, distant disease)^{11, 17}.

Radiation Therapy.

Radiation therapy can be considered for patients with local residual disease following incomplete excision, positive surgical margins, or chest wall invasion^{10, 12, 14, 17}. The recommended dose is 24-36 Gy in conventional fraction sizes^{8, 10, 17, 19, 20}.

Systemic Therapy.

Systemic therapy can be considered for patients with incomplete excision or disseminated disease. First-line anthracycline-based regimens routinely used for systemic ALCL are recommended for BIA-ALCL. These chemotherapy regimens are CHOEP (cyclophosphamide, hydroxydaunorubicin,

vincristine, etoposide, and prednisone), or CHOP, or EPOCH (dose-adjusted etoposide, prednisone, vincristine, cyclophosphamide, and hydroxydaunorubicin)^{8, 10, 14, 15, 17}. Brentuximab vedotin, an anti-CD30 antibody drug conjugate, has shown to be favorable in case reports of BIA-ALCL^{14, 21, 22}. It's also been studied in combination with anthracycline-based chemotherapy for CD30 positive peripheral T-cell lymphoma patients and demonstrated an overall survival advantage over chemotherapy alone²³.

Surveillance:

Patients with no residual disease post-treatment should be followed up every 3-6 months for two years and then as clinically indicated^{8, 10}. This should include history and physical exam with or without contrast-enhanced chest/abdomen/pelvis CT or PET/CT. Imaging can be included every 6 months for the first 2 years and then as clinically indicated.

Other Breast Implant Associated Cancers:

As of September 2022, the FDA is aware of reports of other cancers in the capsule that forms around breast implants. These cancers include squamous cell carcinoma (SCC) and various lymphomas²⁴. These cancers are distinct from BIA-ALCL and are very rare. Currently the risk factors and incidence rates are unknown. A literature review for SCC associated with breast implants, revealed only a small amount of case studies or case series published between 1992-2022²⁵⁻³³.

Summary for Primary Care Providers:

Macrot textured Biocell Allergan (previously known as McGhan) implants and tissue expanders were recalled in Canada on April 4th, 2019, due to the increased risk of BIA-ALCL associated with them³⁴. If a patient has a textured implant, the implants do not automatically need to be removed. There is no clear indication for screening imaging, as the disease is rare, which reduces the efficacy of screening³⁵. Each patient can be managed individually with education, physical exam, and ultrasound can be considered if any swelling or masses are detected. Refer to the patient's plastic surgeon if there is concern.

2. Breast Implant Illness (BII)

Some patients with breast implants experience poorly defined systemic signs and symptoms, such as: fatigue, brain fog, joint pain, muscle pain, anxiety, memory loss, hair loss, depression, rash, autoimmune disease, weakness, inflammation and/or weight problems^{36, 37}. While not an official medical diagnosis, this condition is referred to as Breast Implant Illness (BII), which is thought to be related to inflammation induced by implants. However, BII lacks identifiable pathology, diagnostic criteria are unclear, and there are currently no evidence-based methods available to distinguish between BII and other conditions causing this symptom constellation³⁸. A propensity matched study in women in the military did not show any increase in report of systemic systems compared with nonimplanted controls³⁹. However, the literature is still murky, a large epidemiologic study suggested an association of BII symptoms with rheumatologic disorders⁴⁰.

There is some biologic plausibility in theories that link breast implants to inflammation, such as the presence of bacteria in the implant capsule⁴¹ and inflammatory cells in the capsule⁴². In 2011, a similar condition called Autoimmune Syndrome Induced by Adjuvants (ASIA) was described, wherein a genetically susceptible or predisposed individual develops autoimmune disease after being exposed to an environmental factor or adjuvant⁴³. Silicone is an adjuvant which, could be immune triggering in susceptible individuals. Currently, there is a lack of high-quality evidence linking silicone breast implants to a specific immunological disease⁴⁴.

There is an important communication disconnect between the medical literature and social media, particularly in advocating for *en bloc* capsulectomy for BII, which is an oncologic surgery with significant potential risks and is reserved for treating BIA-ALCL⁴⁵. Most data supporting BII come from single-surgeon practice experience with explanation in their cohort of patients. Many patients report having high satisfaction with implant removal⁴² and resolution of symptoms⁴⁶, although the complications with total capsulectomy are not trivial⁴⁷. It remains unclear why BII is reported at similar or more frequent rates with saline filled than silicone filled implants⁴⁷, albeit all implants have a silicone elastomer shell.

Summary for Primary Care Providers:

If patients are concerned about Breast Implant Illness, it is important to address their concerns. Other medical causes of the symptoms should be investigated and ruled out. This may also require including referrals to internal medicine or rheumatology, If workup fails to reveal any alternative pathology, patients should be referred to a breast plastic surgeon to discuss benefits and risks of removing their implants. A practical guide for surgeons (Figure 1) and primary care providers (Table 2) managing patients with concerns that their symptoms are implant-related is offered by McGuire⁴⁸, and summarized below.

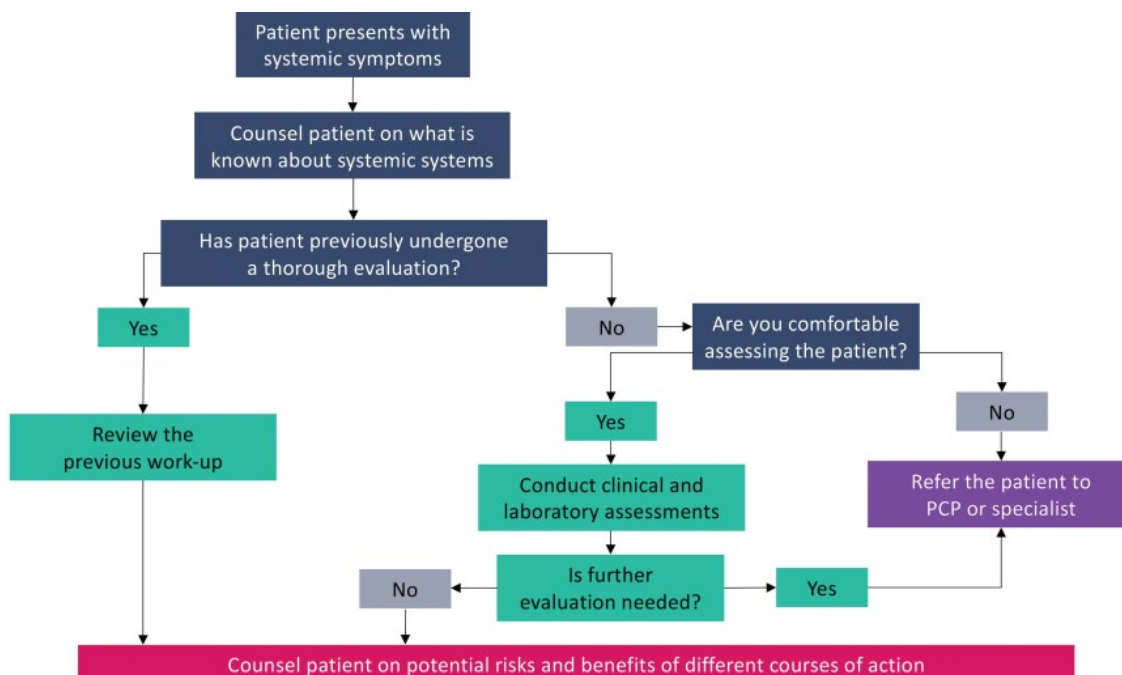


Figure 1: Algorithm for the management of systemic symptoms in patients with breast implants. PCP, primary care provider. (from McGuire et al. 2022)⁴⁸

Table 2: Lab and imaging assessment of, and referral for common systemic symptoms reported by patients with breast implants. (Modified from McGuire et al. 2022)⁴⁸

Symptom	Lab tests of overall health	Additional test to consider	Appropriate specialist(s) for referral
Fatigue	CBC, CRP, iron studies, vitamin B12, extended electrolytes, TSH	Cardiac imaging	Neurologist, psychiatrist, sleep disorders specialist, rheumatologist, internist
Brain Fog	CBC, CRP, iron studies, vitamin B12, extended electrolytes, TSH	Neurological imaging if indicated (eg, TIA/stroke, suspected cancer)	Neurologist, psychiatrist
Anxiety	CBC, TSH, ECG, extended electrolytes	None	Psychiatrist
Joint Pain	CBC, CRP, iron, ferritin, electrolytes, TSH, calcium	Radiography and autoantibodies (eg, ANA, RF, anti-CCP)	Orthopedist, rheumatologist
Hair Loss	Iron studies, thyroid tests	As per dermatologist	Dermatologist
Gastrointestinal Symptoms	CBC, CRP, fecal calprotectin, extended electrolytes, iron studies, TSH, H pylori testing	Colonoscopy as per gastroenterologist	Gastroenterologist

ANA, antinuclear antibody; CBC, complete blood count; CCP, anti-cyclic citrullinated peptide; CRP, C-reactive protein; ECG, electrocardiogram; ESR, erythrocyte sedimentation rate; LFTs, liver function tests; RF, rheumatoid factor; TIA, transient ischemic attack.

3. Breast Cancer Screening in Patients with Implants

Imaging the Augmented Breast:

Patients with augmented breasts still retain natural breast tissue. This tissue needs routine breast cancer screening- at the same intervals as patients without implants⁴⁹. Two additional mammography views (“Eklund” or displacement” views) are used on patients with breast implants⁵⁰, which help prevent the obstruction of small lesions by radio-opaque implants. In an Eklund view, the implant is pushed back toward the chest wall, while the breast tissue is pulled forward to allow more breast tissue to be imaged⁵⁰⁻⁵⁴. If the breast implant is immobile, the Canadian Association of Radiology recommends 90-degree lateral images in addition to the normal mammography views^{53, 54}. Digital breast tomosynthesis can also be used for implant displacement views⁵¹. It is therefore important to specify on a breast imaging requisition whether a patient has implants. Mammography results should be viewed by radiologists experienced in the evaluation of augmented patients.

Imaging the Reconstructed Breast:

There is currently no evidence for regular radiologic screening of asymptomatic post-mastectomy reconstructed breasts,^{55, 56} as there is no significant natural breast tissue left to image. More information can be found in Cancer Care Alberta’s guideline on [Breast Reconstruction Following Prophylactic or Therapeutic Mastectomy for Breast Cancer](#). Patients who have undergone a unilateral mastectomy with reconstruction still need imaging surveillance of the non-reconstructed breast. Cancer Care Alberta recommends a mammogram of the intact breast annually⁵⁷. If a patient is at a high risk for recurrent cancer, they may benefit from the addition of digital breast tomosynthesis to regular mammography screening⁵⁸. MRI is a good screening option for patients who have dense

breast tissue or are BRCA carriers because it is more sensitive in these populations compared to mammography⁵⁹. The American College of Radiology appropriateness criteria for imaging after mastectomy and breast reconstruction is listed in Table 3.

Most patients who undergo nipple- or skin- sparing mastectomy also do not need mammogram screening after reconstruction, as there is no current evidence to suggest that preserving skin or the nipple is less safe compared to total mastectomy^{58, 60-62}. As there is some retained breast tissue behind the nipple and areola, this area needs routine physical examination. Recurrences in retained nipples have been documented, -albeit at a similar rate of local recurrence in mastectomy skin, in non-nipple sparing procedures⁶³. If BRCA gene-positive patients choose to keep their nipples, MRI screening could be considered to image that area specifically, although there is a lack of evidence to support this practice⁶⁴.

Table 3: American College of Radiology appropriateness criteria for imaging after mastectomy and breast reconstruction⁶⁵.

Patient	Imaging Recommendation
Breast cancer screening: history of cancer, autologous reconstruction side(s)	DBT Screening: May be appropriate Mammography: May be appropriate
Breast cancer screening: history of cancer, implant-based reconstruction	Usually not appropriate
Breast cancer screening: high-risk, bilateral prophylactic mastectomy with implant-based reconstruction	Usually not appropriate
Mastectomy with reconstruction (implant based or autologous) and palpable lump or clinically significant pain.	Breast US: Usually appropriate DBT Diagnostic: May be appropriate Mammography Diagnostic: May be appropriate

DBT, digital breast tomosynthesis; US, ultrasound

Imaging for Implant Integrity:

Breast implants, whether silicone or saline filled, are encased in a silicone elastomer shell which may fail (rupture) at some point in its lifespan – generally starting at about six or seven years after implantation⁶⁶. Smooth round Mentor implants at six years showed a rupture rate of 1 to 4%⁶⁷. Allergan anatomic textured implants showed a rupture rate at ten years of 12-18%⁶⁸.

A saline-filled implant will generally go flat abruptly upon rupture. This releases harmless isotonic saline into the surroundings, but results in an obvious volume discrepancy to the contralateral side. A silicone-filled implant rupture often goes unnoticed, and may be intracapsular, with the silicone contained in the capsule, or extracapsular, where silicone extrudes beyond the capsule. Ruptured silicone may lead to shape change or capsular contracture. Symptomatic ruptures require surgery. Asymptomatic ruptures require a discussion of the pros and cons of replacement versus observation⁶⁶.

Currently there is insufficient evidence to show any benefits of screening for breast implant integrity in asymptomatic patients⁵⁷, as the risk and cost of screening outweighs any patient benefit⁶⁹. If the patient and physician detect an abnormality, Health Canada recommends a sensible imaging and referral program as described below⁷⁰:

- Step 1: Patient self-exam
- Step 2: Symptom or sign suspected
- Step 3: Physician physical exam
- Step 4: Ultrasound, mammogram, or both
- Step 5: MRI if ultrasound is negative or inconclusive
- Step 6: Consultation with surgeon for conversation about the risks and benefits of explantation of suspected implant rupture

Summary for Primary Care Providers:

Patients with breast augmentation need regular breast cancer screening, generally starting at age 45, every two years⁴⁹, depending on family history or BRCA gene positivity. Patients with reconstructed breasts do not need routine breast cancer screening unless they retain a natural breast. Screening can also be considered in gene-positive patients who opt for nipple-sparing mastectomies. Patient self-exam is the first line for screening for implant integrity.

4. Radiating Breast Implants

In Alberta, patients with pre-existing implants *in situ* or patients undergoing immediate reconstruction (implant based or autologous) who require radiotherapy based on tumour and nodal factors, receive 1.8-2.0 Gy per day, either as 50 Gy in 25 fractions or 50.4 Gy in 28 fractions⁷¹. The START-B trial using hypofractionated radiation therapy compared with conventional delivery demonstrated better cosmesis in patients with implants⁷². A radiation boost should still be considered for appropriate indications, like young age and close margins. The RT CHARM Phase III Randomized Trial of Hypofractionated Post Mastectomy Radiation with Breast Reconstruction has completed accrual with results pending. Information on this trial can be found here: (<https://clinicaltrials.gov/ct2/show/NCT03414970>).

Radiating the Augmented Breast:

There is little high-quality evidence on the adverse effects of radiation used to treat breast cancer in a patient with a prior augmentation. Primarily retrospective studies, using breast conserving therapy with whole breast radiotherapy on these patients, reveal new or worsening capsular contracture in 12-65% of patients⁷³⁻⁷⁷. While a few older studies^{75, 77} observed better cosmetic results in patients with older implants, a more recent study⁷³ observed no association on univariate analysis between time from implant placement to diagnosis and cosmetic result. This study also observed no association between radiation therapy type, boost, body mass index or tumour size and cosmetic result.

Radiating the Reconstructed Breast:

Post mastectomy radiation therapy (PMRT) may be given to cancer patients before or after tissue expander or implant placement. There have been many studies examining the effect of radiation in these patients. Patients who have PMRT after implantation have higher rates of reconstruction failure,

pain, infection, deformity, malposition, implant exposure and capsular contracture⁷⁸⁻⁸⁵. The historic concern of an immediate implant reconstruction blocking tissue from receiving the appropriate dose of radiation⁵⁷ has been overcome with modern techniques^{86, 87}. Despite capsular contracture, patient satisfaction can be quite high in patients undergoing mastectomy and reconstruction concomitantly, both for implant⁸⁸ and flap⁸⁹ reconstruction. Some advocate delaying breast reconstruction until after radiation therapy is complete, provided patients have autologous options in the future^{57, 85, 90}.

Summary for Primary Care Providers:

It is common for a reconstructed/implanted breast that has been radiated to change in appearance. If there is breast distortion or pain, screen for implant integrity with a diagnostic mammogram. If the work-up indicates implant rupture, or if the patient has an intact implant but is symptomatic, refer to the plastic surgeon for further discussion.

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Appendix A: Search Strategy

Database	Date	Search Strategy	Limits	Results
PubMed	Mar. 2, 2021	"Breast Implant-Associated Anaplastic Large Cell Lymphoma"[All Fields] AND ("manage"[All Fields] OR "managed"[All Fields] OR "management s"[All Fields] OR "managements"[All Fields] OR "manager"[All Fields] OR "manager s"[All Fields] OR "managers"[All Fields] OR "manages"[All Fields] OR "managing"[All Fields] OR "managment"[All Fields] OR "organization and administration"[MeSH Terms] OR ("organization"[All Fields] AND "administration"[All Fields]) OR "organization and administration"[All Fields] OR "management"[All Fields] OR "disease management"[MeSH Terms] OR ("disease"[All Fields] AND "management"[All Fields]) OR "disease management"[All Fields])	English language, full text, humans,	37
PubMed	May 17 2021	("breast implants"[MeSH Terms] OR ("breast"[All Fields] AND "implants"[All Fields]) OR "breast implants"[All Fields]) AND ("augment"[All Fields] OR "augmentation"[All Fields] OR "augmentations"[All Fields] OR "augmented"[All Fields] OR "augmenting"[All Fields] OR "augments"[All Fields]) AND ("radiate"[All Fields] OR "radiated"[All Fields] OR "radiates"[All Fields] OR "radiating"[All Fields] OR "radiation"[MeSH Terms] OR "radiation"[All Fields] OR "electromagnetic radiation"[MeSH Terms] OR ("electromagnetic"[All Fields] AND "radiation"[All Fields]) OR "electromagnetic radiation"[All Fields] OR "radiations"[All Fields] OR "radiation s"[All Fields] OR "radiator"[All Fields] OR "radiators"[All Fields])	English language, full text, humans	54
PubMed	Aug. 5 2021	("breast implant"[All Fields] AND ("radiate"[All Fields] OR "radiated"[All Fields] OR "radiates"[All Fields] OR "radiating"[All Fields] OR "radiation"[MeSH Terms] OR "radiation"[All Fields] OR "electromagnetic radiation"[MeSH Terms] OR ("electromagnetic"[All Fields] AND "radiation"[All Fields]) OR "electromagnetic radiation"[All Fields] OR "radiations"[All Fields] OR "radiation s"[All Fields] OR "radiator"[All Fields] OR "radiators"[All Fields]))	English language, full text, humans	86
PubMed	Oct. 12 2021	"Breast Implant"[All Fields] OR "Breast Reconstruction"[All Fields]) AND ("diagnosis"[MeSH Subheading] OR "diagnosis"[All Fields] OR "screening"[All Fields] OR "mass screening"[MeSH Terms] OR ("mass"[All Fields] AND "screening"[All Fields]) OR "mass screening"[All Fields] OR "early detection of cancer"[MeSH Terms] OR ("early"[All Fields] AND "detection"[All Fields] AND "cancer"[All Fields]) OR "early detection of cancer"[All Fields] OR "screen"[All Fields] OR "screenings"[All Fields] OR "screened"[All Fields] OR "screens"[All Fields]) AND "implant integrity"[All Fields]	English language, full text, humans	10
PubMed	Dec.15 2021	("breast implant illness"[All Fields])	English language, full text, humans	43
PubMed	Dec. 29 2021	("mammography"[MeSH Terms] OR "mammography"[All Fields] OR "mammographies"[All Fields] OR "mammography s"[All Fields] OR ("mammography"[MeSH Terms] OR "mammography"[All Fields] OR "mammogram"[All Fields] OR "mammograms"[All Fields])) AND ("view beijing"[Journal] OR "view"[All Fields]) AND ("embryo implantation"[MeSH Terms] OR ("embryo"[All Fields] AND "implantation"[All Fields]) OR "embryo implantation"[All Fields] OR "implantation"[All Fields] OR "implant"[All Fields] OR "implant s"[All Fields] OR "implantability"[All Fields] OR "implantable"[All Fields] OR "implantables"[All Fields] OR "implantate"[All Fields] OR "implantated"[All Fields] OR "implantates"[All Fields] OR "implantations"[All Fields] OR "implanted"[All Fields] OR "implanter"[All Fields] OR "implanters"[All Fields] OR "implanting"[All Fields] OR "implantion"[All Fields] OR "implantitis"[All Fields] OR "implants"[All Fields])	English language, full text, humans	12
PubMed	Oct. 04, 2022	((Breast Implants [Title/Abstract]) OR (Breast Implants [MeSH Terms])) AND ((Squamous Cell Carcinoma[Title/Abstract]) OR (Carcinoma, Squamous Cell[MeSH Terms]))	English language, full text, humans	8

Development and Revision History

This guideline was reviewed and endorsed by the Alberta Provincial Breast Tumour Team. Members include surgical oncologists, radiation oncologists, medical oncologists, and pathologists. Evidence was selected and reviewed by a working group comprised of members from the Alberta Provincial Breast Tumour Team, external participants identified by the Working Group Lead (including members of the Alberta Society of Plastic Surgeons, members of the hematology tumour team and primary care providers) and a methodologist from the Guideline Resource Unit. A detailed description of the methodology followed during the guideline development process can be found in the [Guideline Resource Unit Handbook](#).

This guideline was originally developed in 2023.

Levels of Evidence

I	Evidence from at least one large randomized, controlled trial of good methodological quality (low potential for bias) or meta-analyses of well-conducted randomized trials without heterogeneity
II	Small randomized trials or large randomized trials with a suspicion of bias (lower methodological quality) or meta-analyses of such trials or of trials with demonstrated heterogeneity
III	Prospective cohort studies
IV	Retrospective cohort studies or case-control studies
V	Studies without control group, case reports, expert opinion

Strength of Recommendations

A	Strong evidence for efficacy with a substantial clinical benefit; strongly recommended
B	Strong or moderate evidence for efficacy but with a limited clinical benefit; generally recommended
C	Insufficient evidence for efficacy or benefit does not outweigh the risk or the disadvantages (adverse events, costs, etc.); optional
D	Moderate evidence against efficacy or for adverse outcome; generally not recommended
E	Strong evidence against efficacy or for adverse outcome; never recommended

Maintenance

A formal review of the guideline will be conducted in 2026. If critical new evidence is brought forward before that time, however, the guideline working group members will revise and update the document accordingly.

Abbreviations

AHS, Alberta Health Services; ALK, anaplastic lymphoma kinase; ANA, antinuclear antibody; ASIA, Autoimmune Syndrome Induced by Adjuvants; AST, aspartate aminotransferase; BIA-ALCL, Breast Implant Associated Anaplastic Large Cell Lymphoma; BII, Breast Implant Illness; BRCA, breast cancer gene; CBC, complete blood count; CCA, Cancer Care Alberta; CCP, anti-cyclic citrullinated peptide; CHOEP, cyclophosphamide hydroxydaunorubicin vincristine

etoposide and prednisone; CRP, C-reactive protein; CT, computed tomography; DBT, digital breast tomosynthesis; EKG, electrocardiogram; EPOCH, dose-adjusted etoposide prednisone vincristine cyclophosphamide and hydroxydaunorubicin; ESR, erythrocyte sedimentation rate; FDA, U.S. food and drug administration; LFTs, liver function tests; MRI, magnetic resonance imaging; PET, positron emission tomography; PMRT, post mastectomy radiation therapy; RF, rheumatoid factor; SCC, squamous cell carcinoma; TIA, transient ischemic attack; TNM, tumour node metastasis; US, ultrasound.

Disclaimer

The recommendations contained in this guideline are a consensus of the Alberta Provincial Breast Tumour Team and are a synthesis of currently accepted approaches to management, derived from a review of relevant scientific literature. Clinicians applying these guidelines should, in consultation with the patient, use independent medical judgment in the context of individual clinical circumstances to direct care.

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Funding Source

Financial support for the development of Cancer Care Alberta's evidence-based clinical practice guidelines and supporting materials comes from the Cancer Care Alberta operating budget; no outside commercial funding was received to support the development of this document.

All cancer drugs described in the guidelines are funded in accordance with the Outpatient Cancer Drug Benefit Program, at no charge, to eligible residents of Alberta, unless otherwise explicitly stated. For a complete list of funded drugs, specific indications, and approved prescribers, please refer to the [Outpatient Cancer Drug Benefit Program Master List](#).

Conflict of Interest Statements

Dr. Bettina Lott reports payment for committee work for Alberta Health outside the submitted work.

Dr. Claire Temple-Oberle* has nothing to disclose.

Rachel Vanderploeg has nothing to disclose.

*guideline lead