

Breast implants

A guide for general practice

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Background

Silicone breast implants have been used for post-mastectomy breast reconstruction and cosmetic augmentation since the 1960s. Recent regulatory action has resulted in a few devices being suspended or cancelled from the Australian market.

Objective

The aim of this article is to summarise important clinical information on how best to assess women with breast implants, and recognise and manage adverse events related to these devices.

Discussion

It is hoped that this article will be a valuable aid to primary care practice in view of the increasing number of patients who will need ongoing surveillance and care.

BREAST IMPLANTS have been in use for reconstruction or augmentation since 1962. Initial breast implants were primarily silicone based with a smooth surface. In 1991, there was an increase in number of adverse events reported, including hardening, rupture and a possible link to autoimmune disease from silicone.^{1,2} Subsequently, in 1992 the US regulator, the Food and Drug Administration (FDA) imposed a 'voluntary moratorium' on silicone breast implants, restricting their use to breast reconstruction or for replacement following device failure.¹ This resulted in a large class action lawsuit.³ However, for the rest of the world, there are no restrictions for silicone breast implants. Since the early 1990s, newer technologies have been introduced, including the texturisation of the outer shell, cohesive gel fill and anatomic shapes (Figure 1).⁴

Subsequent to the Dow Corning crisis, there have been two further major regulatory actions related to breast implants. In 2010, a French-based implant manufacturer was found to be using non-approved industrial-grade silicone.⁵ This resulted in the recall of products and government-sponsored implant removal in the UK. The founder of the company was tried, convicted and jailed. In Australia, the Poly Implant Prothèse (PIP) crisis was the impetus for the establishment of the Australian Breast Device Registry (ABDR).⁶ The

second crisis related to implants occurred in 2019–20. During this time, there was an increase in the number of cases of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL), a T-cell non-Hodgkin lymphoma, which resulted in certain implant types being cancelled or suspended worldwide.^{7–9}

It is also important to consider that some patients undergo breast implant surgery overseas as part of a growing cosmetic tourism industry. Recent analysis has shown that cosmetic surgery performed overseas carries significantly higher risks of complications, notably infection.¹⁰

Types of breast implants

Breast implants can be classified based on their surface, fill and shape.

Implant surface

The outer shell of breast implants can vary significantly. Initially, breast implants were designed with a smooth outer shell. Texturisation was introduced in the late 1960s in an attempt to promote better tissue ingrowth and increase the implants' stability and longevity. There are number of different methods for imparting texture to the outer shell, including the use of imprinting, salt impregnation, gas vulcanisation and polyurethane coating. Jones et al proposed a numeric grading system ranging from grade 1 (smooth)

to grade 4 (polyurethane) based on the measurement of surface area/roughness.¹¹

Implant fill

Implants are typically filled with silicone gel or less commonly saline.

Implant shape

Implants are round (or spherical) or anatomic in shape. Anatomic implants require some surface texture to prevent rotation in the pocket.

Clinical use

Breast implants are used for four common indications:

- cosmetic breast augmentation
- post-mastectomy breast reconstruction
- congenital deformities of the chest/breast
- transgender surgery.

Breast augmentation remains the most popular elective cosmetic surgical procedure worldwide. Approximately 20,000 women undergo this procedure each year in Australia, with 75% for cosmetic augmentation and 25% for reconstruction.¹² Implants can be placed either above or partly below the pectoralis major muscle and can be inserted via a submammary (most common), peri-areolar or axillary incision. For women who have lost volume of the breast, either through weight loss or post-lactation, a breast lift (mastopexy) can be performed in combination with augmentation. This will leave a visible scar on the breast, usually in the shape of an inverted T, or less commonly around the areola. Implants are also used in transgender surgery (male to female) to create a breast mound,

usually in conjunction with oestrogen supplementation.

For post-mastectomy reconstruction, implants can be placed either immediately following mastectomy or after a period of tissue expansion. Expanders are used to stretch the skin/muscle pocket over a period of 3–6 months prior to conversion using a definitive gel implant. The use of mesh or dermal sheets to support the implant can also be used to control implant placement and/or reinforce the soft tissues.

Complications following breast implant insertion

Breast implants are not lifetime devices; they have an estimated lifespan of 10–15 years. The risk of adverse events begins to accumulate after the device is inserted (Figure 2). These can be

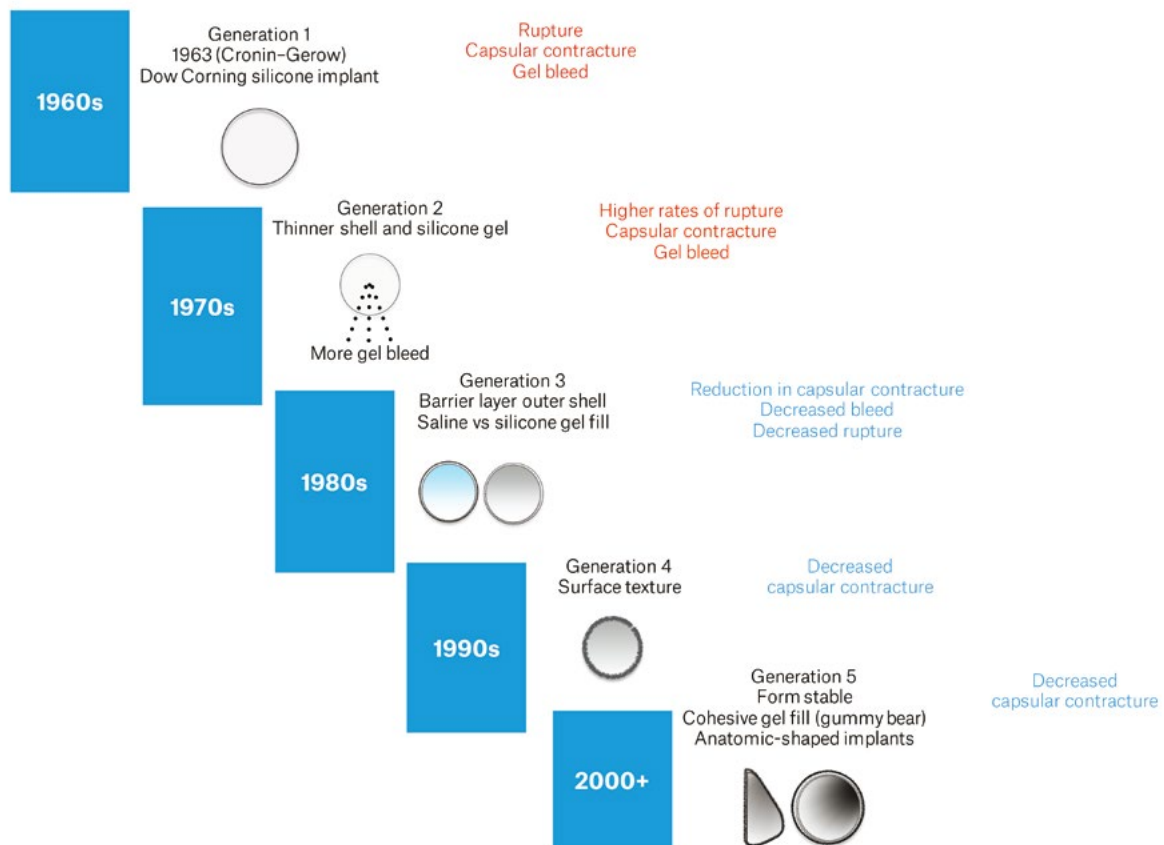


Figure 1. Generations of breast implants

classified into local (breast or implant related) versus systemic, and further subclassified into acute and medium/long term. Table 1 summarises the local complications following breast implant surgery.¹² In general, the risks associated with post-mastectomy reconstruction are higher than with cosmetic augmentation. Added to this are the risks of radiation and/or chemotherapy that can increase the risk of local implant complications. Patients with associated comorbidities, such as diabetes, obesity and smoking, also increase the risk of adverse events, especially infection.

Acute complications

Infection, haematoma, implant exposure and seroma are acute complications following breast implant surgery and

account for less than 5% of adverse events.¹² Pain, swelling, redness, discharge and wound breakdown 1-2 weeks following surgery require urgent referral to the treating doctor. Acute postoperative infection requires early intervention with antibiotics, surgical debridement and pocket irrigation to salvage the implant. If there is progression, however, the implant is usually removed. It would be reasonable to attempt replacement following a period of antibiotic therapy and tissue rest.

Capsular contracture

Capsular contracture is the most common reason for revision surgery (Figure 3).¹³ This presents as progressive hardening, distortion and deformity of the breast due to the development of a thick,

fibrous capsule around the implant. The principal cause of capsular contracture is the development and growth of a low-grade bacterial infection attached to the surface of the implant (biofilm), which stimulates inflammation and fibrosis over time.¹⁴ Other postulated causes include haematoma and/or foreign body reaction. Patients present approximately 3-5 years following initial surgery, and the rates vary from 5% to 9% over 5-10 years' post-implantation.¹⁵ The use of stringent bacterial mitigation (eg pocket irrigation with antibiotics/antiseptic and 'no touch' insertion) when implants are placed in surgery has been shown to significantly reduce the risk of capsular contracture.¹⁶⁻¹⁸ Severe capsular contracture can cause secondary implant rupture due to infolding, friction and weakening of the

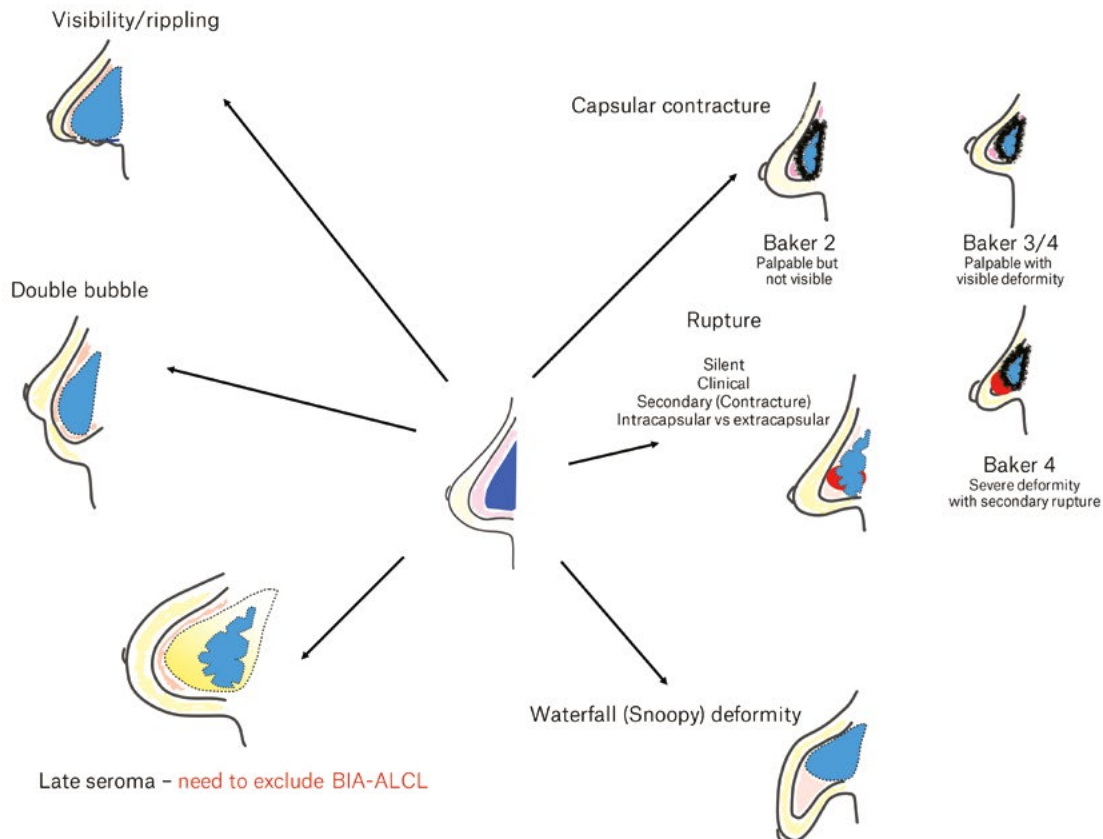


Figure 2. Adverse events resulting from breast implants
 BIA-ALCL, breast implant-associated anaplastic large cell lymphoma

outer shell. Capsular contracture is graded clinically using the Baker grade (Table 2).¹⁹

Implant rupture

Disruption of the implant shell and leakage of contents is termed 'implant rupture'. The contents can be held within the capsule (intracapsular) or leak into the surrounding breast tissue and/or lymph nodes (extracapsular). Extracapsular rupture may present as an acute foreign body reaction with swelling, redness and induration of the breast and surrounding chest wall. The patient may experience a sudden change in shape or projection of the breast, or in some cases may be completely unaware of the rupture (termed 'silent rupture'). This requires timely surgery for removal. Rupture is best detected by screening ultrasonography and can be confirmed by magnetic resonance imaging (MRI).

Implant mobility and visibility

The movement of the implant from its original pocket may cause visibility and/or palpability of the implant outer shell. This can manifest as a double bubble appearance, where the implant moves below the inframammary fold or into the axilla (Figure 4). In some patients with very thin parenchyma or weight loss following surgery, implant folding or rippling can also be seen and felt. For anatomic implants, rotation of the device can also cause distortion of the breast shape.

Waterfall (Snoopy) deformity

This deformity occurs when the breast and parenchyma drop below the position of the implant (Figure 5). It can occur after pregnancy/lactation and fluctuations in weight. Treatment usually involves implant exchange with a breast lift (mastopexy).

Breast pain

Pain in and around the breast implant is usually related to capsular contracture. Other causes of breast pain, including breast lumps, fibrocystic change and hormonally induced changes, can be timed with the menstrual cycle. Musculoskeletal strain and costochondritis also need to be considered. It is common after surgery to

have some neuralgia from the axillary and lateral thoracic nerve branches. Nipple sensitivity (either decreased sensation or hyperaesthesia) can also occur following breast implant placement.

Breast implant-associated anaplastic large cell lymphoma

Reports of a rare T-cell non-Hodgkin lymphoma occurring around breast implants have increased over the past decade.¹⁹ It is not classified as a breast cancer. BIA-ALCL has now been definitively linked to breast implants, and more specifically, textured surface devices.^{7,9,20-22} Clinically, this tumour manifests most commonly as a malignant effusion with fluid build-up in the space between the implant and capsule, causing

swelling and pain approximately 7-8 years following the initial procedure (Figure 6). In approximately 10-15% of women, BIA-ALCL presents as a peri-implant mass, usually detectable on ultrasound, which can subsequently spread to axillary and mediastinal nodes. Currently, there have been over 100 confirmed cases in Australia with four deaths.²³ The risk of BIA-ALCL is higher for implants with higher grades of texture.²⁴ The current accepted hypothesis for causation proposes that higher-grade texture provides a template for the growth of bacteria, ultimately transforming genetically susceptible T cells into lymphoma over time.²⁴ This theory is supported by clinical, laboratory and epidemiological evidence. All women considering breast

Table 1. Local adverse events in women with breast implants

Implant related	Breast related
<ul style="list-style-type: none"> • Capsular contracture • Rupture intracapsular/extracapsular/silent • Rotation • Displacement: double bubble, axillary migration • Visibility/rippling • Deflation (saline filled) • Folding • Breast implant-associated anaplastic large cell lymphoma 	<ul style="list-style-type: none"> • Parenchymal ptosis: waterfall (Snoopy) deformity • Breast pain • Benign breast lumps • Breast cancer

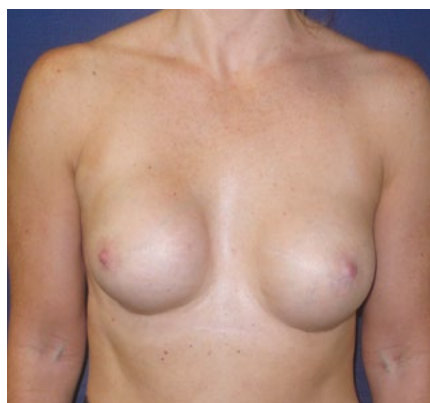


Figure 3. Right-sided grade 4 capsular contracture 10 years following primary breast augmentation



Figure 4. Left-sided double bubble

implant surgery should be informed of the relative risk of BIA-ALCL based on the type of implant recommended. Latest evidence has estimated the risk as one in 2000–3000 for devices with a grade 3 or 4 surface.²⁵ To date, there are no cases arising from exposure to smooth (grade 1) devices alone. The Australian regulator has now cancelled grades 3 and 4 devices in response to this risk.

A patient with suspected BIA-ALCL should proceed to breast ultrasonography and sampling of the peri-implant seroma. The presence of abnormal tumour cells that are CD30 positive and anaplastic lymphoma kinase negative confirms the diagnosis. For patients who present with a mass and no effusion, ultrasound-guided biopsy or open biopsy can confirm the diagnosis.

Once diagnosed, patients should be referred to a multidisciplinary team with expertise in breast cancer/reconstruction and be clinically staged using MRI/computed tomography–positron emission tomography. In approximately 88% of women in Australia, the tumour is detected in the earliest stages, when it is confined to the seroma and inner lining of the capsule. For these patients, surgical removal of the implant and capsule is curative. For more advanced disease, adjuvant chemotherapy, radiation therapy and immunotherapy are indicated.

Breast implant illness

Some women present with a range of systemic symptoms thought to be related to breast implants. These symptoms are diverse and include brain fog, memory

loss, myalgia, arthralgia, rashes, gastritis, hair loss, dyspnoea and loss of libido.²⁶ The term ‘breast implant illness’, which has coalesced as a term to describe this condition, remains poorly characterised. Studies investigating likely pathogenesis, natural history and outcomes following explantation are underway.²⁶ Patients are encouraged to register with one of these prospective trials.

Clinical approach to breast implant assessment

Figure 7 outlines a clinical, investigative and management flowsheet for the assessment of breast implants, and the diagnosis and management of non-acute complications.

History

All patients are now encouraged to keep details of their implant on a patient card. Some patients may also be now registered on the ABDR. A thorough history covering the following points should be taken:

- Implant history: indication for surgery, date(s) of procedure(s), type of implant (size, surface, brand, shape), placement of implant (above or below muscle), name of treating practitioner and location of surgery
- Symptoms related to implant and/or breast: pain, change in shape of breast, hardness/palpable lumps, deformity, change in sensation of nipple, nipple discharge and skin abnormalities
- Systemic symptoms: fatigue, joint pains and skin rashes
- Breast and reproductive history: pregnancy, lactation/breastfeeding, breast cancer/ovarian cancer history, menstrual history and hormonal status
- Other concurrent illness
- Family history of cancer (including lymphoma) and autoimmune disease
- Any recent imaging results.

Examination

Clinical examination should include a thorough examination of the breast, parenchyma and draining lymph nodes. Visual inspection, with arms by the side and raised above the head, of abnormal contour, visible lumps and skin changes should be noted. The degree of capsular

Table 2. Baker classification of capsular contracture¹⁸

Baker grade	Description
1	Breast implant is soft and is not palpable and/or visible (for women with breast implants for reconstruction). Grade 1B is where the implant is soft but visible, as the skin envelope is thinner
2	Implant is palpable, but no visible deformity
3	Implant is hard, palpable and with some minor visibility (eg puckering, rippling, change in shape). Ultrasound usually shows infolding
4	Implant is very hard and painful with significant deformity of breast and/or malposition. Ultrasound shows significant folding and/or rupture



Figure 5. Waterfall deformity bilaterally shown in three-quarter right view



Figure 6. Late right seroma. This patient had benign pathology. She also had bilateral waterfall (Snoopy) deformity.

contracture can be clinically assessed using the Baker grade (Table 2). The presence of any asymmetry or associated chest wall abnormalities should also be noted and documented. It is good practice to document the appearance on photographs with frontal, left and right three-quarter views (with the patient facing at a 45-degree angle) and right and left lateral views, if possible.

Investigations

If there is a clinical abnormality, a breast ultrasound is the gold standard

for detecting implant rupture, seroma or any peri-implant or capsular mass. A mammogram is also indicated if the patient has a high risk for breast cancer or where a patient has not been previously screened. Many women with breast implants wrongly assume that mammograms are not possible with implants in situ. A displacement technique can be used safely to protect the implant from damage.

At any stage in the work up, referral to the original surgeon who placed the implant should be considered. The need for

regular surveillance of women with breast implants is becoming both recognised and recommended. Many surgeons now conduct their own follow-up care for their patient cohort and have incorporated this into their standard of care.

Summary

With a significant proportion of the population accessing breast augmentation or reconstruction, it is useful for general practitioners to become familiar with how to assess patients with breast implants

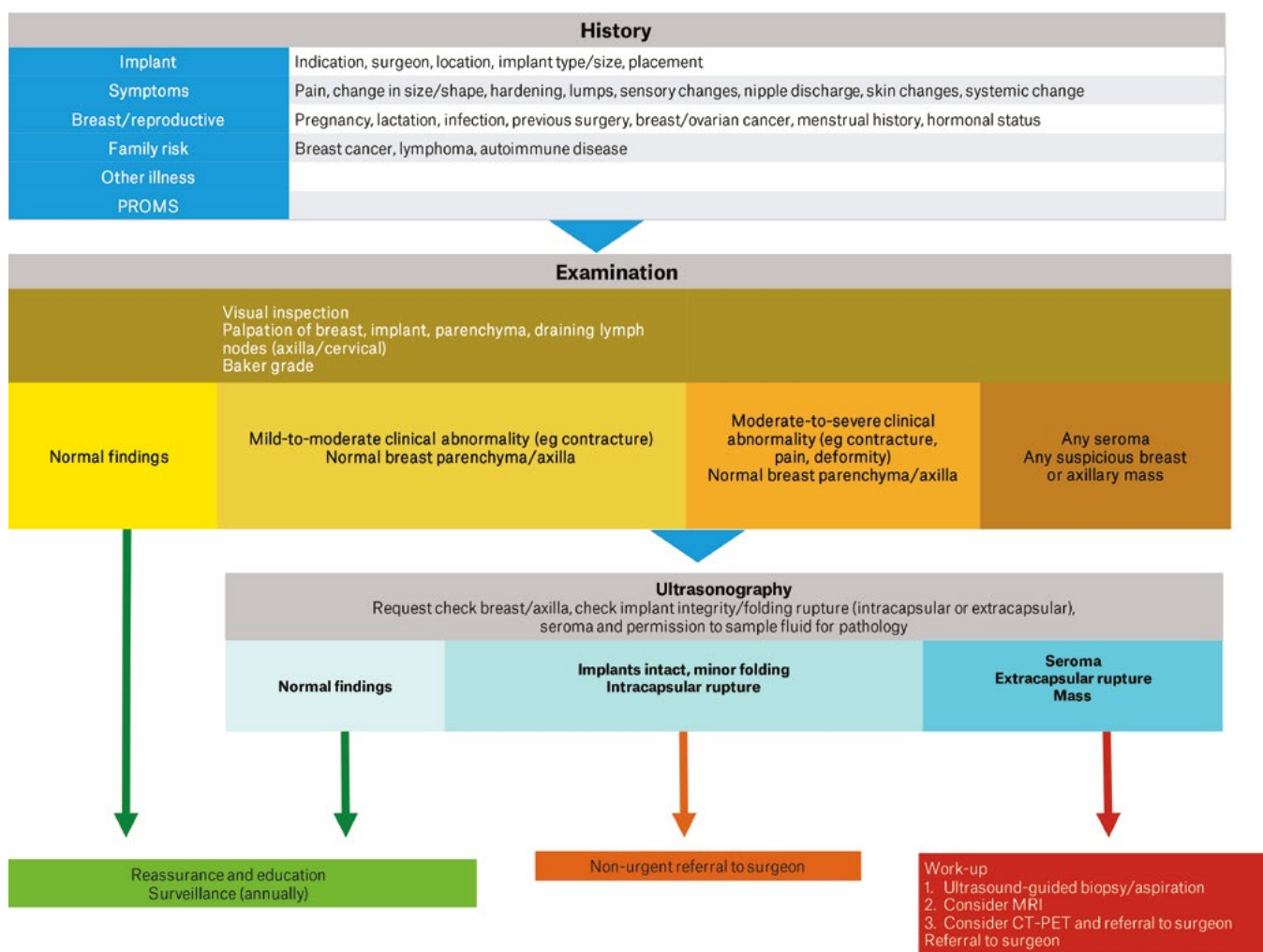


Figure 7. Clinical approach to the assessment of patients with breast implants, and the diagnosis and management of non-acute complications CT-PET, computed tomography-positron emission tomography; MRI, magnetic resonance imaging; PROMS, patient-reported outcome measures

and detect potential adverse events. In the aftermath of recent regulatory action, there are many understandably anxious patients who will require assessment and assurance, and in the event of a problem, timely diagnosis and treatment.

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References

- Deva AK, Cuss A, Magnusson M, Cooter R. The 'game of implants': A perspective on the crisis-prone history of breast implants. *Aesthet Surg J* 2019;39(Suppl 1):S55–65. doi: 10.1093/asj/sjy310.
- van Nunen SA, Gatenby PA, Basten A. Post-mammoplasty connective tissue disease. *Arthritis Rheum* 1982;25(6):694–97. doi: 10.1002/art.1780250613.
- Fisher JC. Silicone on trial: Breast implants and the politics of risk. La Jolla, CA: Sager Group LLC, 2015.
- Champaneria MC, Wong WW, Hill ME, Gupta SC. The evolution of breast reconstruction: A historical perspective. *World J Surg* 2012;36(4):730–42. doi: 10.1007/s00268-012-1450-2.
- Greco C. The poly implant prothèse breast prosthesis scandal: Embodied risk and social suffering. *Soc Sci Med* 2015;147:150–57. doi: 10.1016/j.socscimed.2015.10.068.
- Hopper I, Ahern S, Best RL, McNeil J, Cooter RD. Australian breast device registry: Breast device safety transformed. *ANZ J Surg* 2017;87(1–2):9–10. doi: 10.1111/ans.13819.
- Loch-Wilkinson A, Beath KJ, Knight RJW, et al. Breast implant-associated anaplastic large cell lymphoma in Australia and New Zealand: High-surface-area textured implants are associated with increased risk. *Plast Reconstr Surg* 2017;140(4):645–54. doi: 10.1097/PRS.0000000000003654.
- Collett DJ, Rakhorsh H, Lennox P, Magnusson M, Cooter R, Deva AK. Current risk estimate of breast implant-associated anaplastic large cell lymphoma in textured breast implants. *Plast Reconstr Surg* 2019;143(3S A Review of Breast Implant-Associated Anaplastic Large Cell Lymphoma):30S–40S. doi: 10.1097/PRS.0000000000005567.
- Magnusson M, Beath K, Cooter R, et al. The epidemiology of breast implant-associated anaplastic large cell lymphoma in Australia and New Zealand confirms the highest risk for grade 4 surface breast implants. *Plast Reconstr Surg* 2019;143(5):1285–92. doi: 10.1097/PRS.0000000000005500.
- Venditto C, Gallagher M, Hettinger P, et al. Complications of cosmetic surgery tourism: Case series and cost analysis. *Aesthet Surg J* 2020;sjaa092. doi: 10.1093/asj/sjaa092.
- Jones P, Mempin M, Hu H, et al. The functional influence of breast implant outer shell morphology on bacterial attachment and growth. *Plast Reconstr Surg* 2018;142(4):837–49. doi: 10.1097/PRS.0000000000004801.
- Hopper I, Parker E, Pellegrini B, et al. The Australian breast device registry 2016 report. Melbourne, Vic: Monash University, Department of Epidemiology and Preventive Medicine, 2018.
- Wong CH, Samuel M, Tan BK, Song C. Capsular contracture in subglandular breast augmentation with textured versus smooth breast implants: A systematic review. *Plast Reconstr Surg* 2006;118(5):1224–36. doi: 10.1097/01.prs.0000237013.50283.d2.
- Tamboto H, Vickery K, Deva AK. Subclinical (biofilm) infection causes capsular contracture in a porcine model following augmentation mammoplasty. *Plast Reconstr Surg* 2010;126(3):835–42. doi: 10.1097/PRS.0b013e3181e3b456.
- McGuire P, Reisman NR, Murphy DK. Risk factor analysis for capsular contracture, malposition, and late seroma in subjects receiving Natrelle 410 form-stable silicone breast implants. *Plast Reconstr Surg* 2017;139(1):1–9. doi: 10.1097/PRS.0000000000002837.
- Adams WP Jr, Conner WC, Barton FE Jr, Rohrich RJ. Optimizing breast pocket irrigation: An in vitro study and clinical implications. *Plast Reconstr Surg* 2000;105(1):334–38; discussion 339–43. doi: 10.1097/00006534-200001000-00051.
- Culbertson EJ, Felder-Scott C, Deva AK, Greenberg DE, Adams WP. Optimizing breast pocket irrigation: The breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) era. *Aesthet Surg J* 2020;40(6):619–25. doi: 10.1093/asj/sjz246.
- Deva AK, Adams WP Jr, Vickery K. The role of bacterial biofilms in device-associated infection. *Plast Reconstr Surg* 2013;132(5):1319–28. doi: 10.1097/PRS.0b013e3182a3c105.
- Spear SL, Baker JL Jr. Classification of capsular contracture after prosthetic breast reconstruction. *Plast Reconstr Surg* 1995;96(5):1119–23; discussion 1124.
- Miranda RN, Aladily TN, Prince HM, et al. Breast implant-associated anaplastic large-cell lymphoma: Long-term follow-up of 60 patients. *J Clin Oncol* 2014;32(2):114–20. doi: 10.1200/JCO.2013.52.7911.
- de Boer M, van der Sluis WB, de Boer JP, et al. Breast implant-associated anaplastic large-cell lymphoma in a transgender woman. *Aesthet Surg J* 2017;37(8):NP83–7. doi: 10.1093/asj/sjx098.
- Doren EL, Miranda RN, Selber JC, et al. U.S. Epidemiology of breast implant-associated anaplastic large cell lymphoma. *Plast Reconstr Surg* 2017;139(5):1042–50. doi: 10.1097/PRS.0000000000003282.
- Therapeutic Goods Administration. Breast implants and anaplastic large cell lymphoma Update – Suspended breast implant devices now cancelled. Symonston, ACT: TGA, 2020. Available at www.tga.gov.au/alert/breast-implants-and-anaplastic-large-cell-lymphoma [Accessed 26 February 2021].
- Rastogi P, Deva AK, Prince HM. Breast implant-associated anaplastic large cell lymphoma. *Curr Hematol Malig Rep* 2018;13(6):516–24. doi: 10.1007/s11899-018-0478-2.
- Loch-Wilkinson A, Beath KJ, Magnusson MR, et al. Breast implant-associated anaplastic large cell lymphoma in Australia: A longitudinal study of implant and other related risk factors. *Aesthet Surg J* 2020;40(8):838–46. doi: 10.1093/asj/sjz333.
- Magnusson MR, Cooter RD, Rakhorsh H, McGuire PA, Adams WP Jr, Deva AK. Breast implant illness: A way forward. *Plast Reconstr Surg* 2019;143(3S A review of breast implant-associated anaplastic large cell lymphoma):74S–81S. doi: 10.1097/PRS.0000000000005573.

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