



Guideline 17-10

A Quality Initiative of the  
Program in Evidence-Based Care (PEBC), Cancer Care Ontario (CCO)

**Breast cancer reconstruction surgery  
(immediate and delayed) across Ontario:  
Patient indications and appropriate surgical options**

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and the Breast Reconstruction Expert Panel*

Report Date: January 5, 2016

**WARNING**

Increased risk for Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) exists with the use of textured breast implants. See the Health Canada recalls and alerts webpage for more information

<https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2019/70045a-eng.php>

An assessment conducted in January 2021 indicated that Guideline 17-10 REQUIRES UPDATING. It is still appropriate for this document to be available while this updating process unfolds. The PEBC has a formal and standardized process to ensure the currency of each document ([PEBC Assessment & Review Protocol](#))

**Note added November 2021**

This document is in review and a new document will be forthcoming. Substantial changes will be made based on new literature and current clinical practice. In the interim, the following changes were made in consultation with the Surgical Oncology Program and the Breast Cancer Advisory Committee to reflect current practice and concerns:

**Recommendation 3:** In patients expected to require radiotherapy, the timing of breast reconstruction should be determined after multidisciplinary discussion including the general surgeon or surgical oncologist, medical oncologist, radiation oncologist, and plastic surgeon and with full consideration of the values and preferences of the patient.

**Recommendation 8:** Acellular dermal matrix (ADM) is currently widely used in breast reconstruction. The U.S. FDA<sup>1</sup> has issued a safety communication indicating that the complication rate (reoperation, explantation, and infections) may vary depending on the type of ADM, and this is being investigated.

Guideline 17-10 is comprised of 5 sections. You can access the summary and full report here:

<https://www.cancercareontario.ca/en/guidelines-advice/types-of-cancer/31721>

Section 1:	Guideline Recommendations
Section 2:	Recommendations and Key Evidence
Section 3:	Guideline Methods Overview
Section 4:	Systematic Review
Section 5:	Internal and External Review

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<sup>1</sup> United States Food and Drug Administration. Acellular Dermal Matrix (ADM) Products Used in Implant-Based Breast Reconstruction Differ in Complication Rates: FDA Safety Communication. Silver Spring (MD): US FDA; 2021 Mar 31 (cited 2021 Oct 8). Available from: <https://www.fda.gov/medical-devices/safety-communications/acellular-dermal-matrix-adm-products-used-implant-based-breast-reconstruction-differ-complication>.

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In Review

In Review

# Breast cancer reconstruction surgery (immediate and delayed) across Ontario: Patient indications and appropriate surgical options

## Section 1: Recommendations

*This section is a quick reference guide and provides the guideline recommendations only. For key evidence associated with each recommendation, the systematic review, and the guideline development process, see the Full Report.*

### GUIDELINE OBJECTIVES

- To provide clinical guidance with respect to suitability for breast reconstruction, timing of reconstruction, and optimal reconstruction techniques.
- To make recommendations that will inform decisions at the policy and administration level aimed at improving the quality of life of women with breast cancer in Ontario.

### TARGET POPULATION

- Women who have been diagnosed with breast cancer who have chosen or been recommended for therapeutic mastectomy.
- Women who are at high risk for breast cancer who have chosen or been recommended for prophylactic mastectomy.

### INTENDED USERS

General surgeons practicing breast cancer surgery, plastic surgeons, oncologists, administrators, other referring physicians, and oncology healthcare professionals (e.g., those involved in patient education or psychosocial programs).

### RECOMMENDATIONS

#### Recommendation 1: Patient education and preoperative evaluation

For women who have chosen or been recommended for therapeutic mastectomy:

- The discussion of immediate or delayed breast reconstruction should be initiated at the time that mastectomy is offered by the general surgeon.
- For women seeking immediate breast reconstruction for ductal carcinoma in situ (DCIS), preoperative evaluation with a general surgeon and a plastic surgeon should be performed.
- For women seeking immediate breast reconstruction for early stage breast cancer who will potentially require adjuvant chemotherapy or radiotherapy (RT), a medical oncologist and/or radiation oncologist should be included in preoperative evaluation, either through a formal consultation or by a multidisciplinary cancer conference.
- For women seeking immediate reconstruction, there should be adequate preoperative imaging of the breasts, aligning with existing guideline recommendations.

**Qualifying Statement**

- Please see Cancer Care Ontario guidelines regarding recommendations about the use of mastectomy versus breast-conserving therapy (BCT) in early stage breast cancer ([www.cancercare.on.ca](http://www.cancercare.on.ca)).

**Recommendation 2: Contraindications for immediate or delayed reconstruction**

- Relative medical (non-cancer-related) contraindications for breast reconstruction include:
  1. Morbid obesity (body mass index [BMI]  $\geq 40$  kg/m<sup>2</sup>);
  2. Current smoking status.
- Advance age is not a contraindication to breast reconstruction. There is no evidence that indicated a specific age cut-off as a contraindication; however, the number of people who received reconstruction after 70 years of age was limited.

**Qualifying Statements**

- If morbid obesity and smoking status have been resolved, then women may be appropriate candidates for breast reconstruction.
- None of the two characteristics listed above are absolute contraindications to reconstruction.
- There is insufficient evidence to indicate whether diabetes is a contraindication to reconstruction.
- Patients with increased (>BMI 30 kg/m<sup>2</sup>) are at higher risk for complications and are encouraged to lose weight if undergoing delayed reconstruction.

**Recommendation 3: Timing of immediate breast reconstruction**

- Immediate reconstruction is an appropriate option for women who are not expected to require postoperative RT. This includes women with:
  - Prophylactic mastectomy for prevention of breast cancer
  - In situ disease (ductal or lobular)
  - Tumour size to breast volume ratio that may preclude the use of BCT
  - RT not recommended (e.g., previous irradiation of breast or chest [Hodgkin disease], severe collagen vascular disease, or Tp53 mutation)
  - Small invasive cancers with extensive microcalcifications or atypia that would preclude BCT and there is a low likelihood of nodal disease.
  - Positive margins following breast-conserving surgery opting for completion mastectomy
  - Recurrent disease following failed initial BCT and not deemed to be at high risk for metastatic disease

- **Provisional Recommendation October 2021:** In patients expected to require radiotherapy, the timing of breast reconstruction should be determined after multidisciplinary discussion including the general surgeon or surgical oncologist, medical oncologist, radiation oncologist, and plastic surgeon and with full consideration of the values and preferences of the patient. [The 2016 recommendation indicated that the use of immediate breast reconstruction is not recommended for women expected to require postoperative RT]

**Qualifying Statement**

- **Provisional Qualifying Statement October 2021:** Women who will receive RT and are considering immediate breast reconstruction should be informed of the possibility of increased risk of complications, compromised esthetic outcome, and the potential for increased need for future revisional surgeries. The risk of these may vary depending on type and timing of RT, type of reconstruction, and patient characteristics.

**Recommendation 4: Skin-sparing, nipple-sparing, and areola-sparing mastectomy**

- Skin-sparing mastectomy (SSM), nipple-sparing mastectomy (NSM) and areola-sparing mastectomy (ASM) are incisions utilized simultaneously with immediate breast reconstruction
- SSM or NSM with immediate breast reconstruction can be offered to women at high risk for breast cancer (>25% lifetime risk) undergoing prophylactic mastectomy and women with known DCIS.
- SSM or NSM with immediate breast reconstruction is a reasonable option for women with early breast cancer who are believed to be likely lymph node negative.
- SSM, NSM, and ASM are **not** recommended for women intending to receive post-operative radiation with:
  - early breast cancer who are lymph node positive, inflammatory breast cancer or locally advanced breast cancer who will require postoperative RT.
  - any clinical skin or nipple-areolar complex (NAC) involvement by invasive tumour
- NSM and ASM are **not** recommended for women with Paget disease of the breast or women with a retroareolar tumour.
- NSM or ASM with immediate reconstruction is reserved for patients with minimal ptosis and do not require skin reducing incisions
- Women with multicentric DCIS or early invasive cancer within 2 cm of the NAC) who are contemplating NSM may consider a sampling taken from the base of the nipple for pathological assessment. Women found to have tumour involvement in the NAC either intraoperatively or postoperatively should have the nipple resected.

**Qualifying Statements**

- SSM, NSM, and ASM are oncologically safe when the tumour is resected with clear margins.
- Women considering NSM should be made aware that they will experience nipple anesthesia and that there is a risk of nipple necrosis.
- Likelihood of lymph node positivity should be determined by consultation with a breast surgeon with oncology expertise or by a multidisciplinary tumour board discussion. When required, for women with invasive breast cancer and clinically negative nodes, a standalone sentinel lymph node biopsy may evaluate lymph node status prior to definitive mastectomy.

**Recommendation 5: Delayed breast reconstruction**

- Delayed reconstruction should be offered as an option for any woman undergoing mastectomy who desires reconstruction, has completed any recommended adjuvant chemotherapy and/or RT, and does not have contraindications to breast reconstruction.

**Qualifying Statements**

- For women who have received RT, it is the opinion of the Expert Panel that reconstruction should not occur sooner than one year after mastectomy.
- For women with advanced disease (T4, or N2 or N3), it is the opinion of the Expert Panel that it may be optimal to wait two or three years before undergoing reconstruction when the risk of recurrence is lowered.

**Recommendation 6: Autologous tissue versus implant-based reconstruction**

- Women treated by mastectomy should be made aware that autologous tissue reconstruction and implant-based reconstruction are options for immediate or delayed reconstruction.
- Reconstruction methods should be selected based on patient and surgeon factors, because overall patient satisfaction and willingness to recommend reconstruction to others appear to be similar between autologous tissue and tissue-expander implant (TE/I)-based reconstructions. However, if women are candidates for either reconstruction, then they should be informed that TE/I reconstruction may be accompanied by a higher risk of reconstructive failure or soft tissue infection and that there is a trend toward decreased esthetic satisfaction with TE/I reconstruction over time. In patients who have received textured implants, they should be informed of the risk for a rare type of lymphoma called anaplastic large cell lymphoma (ALCL) that is associated with textured implants.
- Latissimus dorsi flap with or without implants is another option to TE/I or abdominal autologous tissue reconstruction.

*Radiation setting:*

- For women who have received prior RT to their breast as part of BCT, mastectomy with immediate autologous tissue reconstruction is the recommended option. Current evidence suggests that reconstruction using TE/I alone may be associated with an increased risk of complications.

**Qualifying Statement**

- Women desiring reconstruction in a previously radiated breast should be informed of the increased risk of complications compared with no radiation.

**Recommendation 7: Types of autologous tissue reconstruction**

- In patients who will undergo unilateral autologous tissue reconstruction, pedicled transverse rectus abdominis myocutaneous (TRAM), free TRAM, or deep inferior epigastric perforator (DIEP) flaps are all recommended options that are supported by positive patient-reported outcomes.
- In patients who will undergo bilateral autologous tissue reconstruction, DIEP flap is preferred over free or pedicled TRAM flap due to less functional disruption to the abdominal wall following surgery.
- Alternative autologous tissue donor types (e.g., gluteal flaps, thigh flaps) are suitable for selected patients in whom abdominal tissue is not available; however, the evidence on these types of reconstructions is very limited.
- All patients should be told of the risk of fat necrosis that can present as a nodule or mass after autologous tissue reconstruction, a benign condition that can mimic breast cancer recurrence. The risk of fat necrosis is likely to be greater following DIEP flaps compared with TRAM flaps.

**Recommendation 8: Acellular dermal matrix**

- Original 2016 recommendation: With the shortage of high-quality evidence on the use of acellular dermal matrix (ADM), no recommendation can be made for or against the use of ADM as an adjunct to implant-based breast reconstruction.
- **October 2021 note:** Evidence as to benefit of ADM has been accruing since the 2016 guideline, and ADM is now widely used in breast reconstruction. Several studies have suggested that ADM from different sources or preparation techniques may vary in utility and complications. The U.S. FDA<sup>2</sup> has issued a safety communication indicating that the complication rate (reoperation, explantation, and infections) may vary depending on the type of ADM, and this is being investigated.

**Qualifying Statements**

<sup>2</sup> United States Food and Drug Administration. Acellular Dermal Matrix (ADM) Products Used in Implant-Based Breast Reconstruction Differ in Complication Rates: FDA Safety Communication. Silver Spring (MD): US FDA; 2021 Mar 31 (cited 2021 Oct 8). Available from: <https://www.fda.gov/medical-devices/safety-communications/acellular-dermal-matrix-adm-products-used-implant-based-breast-reconstruction-differ-complication>.

- It is the opinion of the Expert Panel that direct-to-implant reconstruction in a *single stage* using ADM may be used as an adjunct to implant-based breast reconstruction to improve esthetic outcomes in selected women who have smaller and non-ptotic breasts.
- Patient selection and surgical technique are critical to good outcomes.
- Other than improved esthetic outcomes, ADM has not been shown to have any other benefit for *two-staged* TE/I reconstruction.
- Esthetic outcomes, especially the inframammary fold, are potentially improved with the use of ADM in implant reconstruction.

**Recommendation 9: Autologous fat grafting**

- With the shortage of high-quality studies on the use fat grafting, no recommendation can be made for or against the use of autologous fat grafting as an adjunct to improve esthetic outcomes in breast reconstruction.

**Qualifying Statement**

- Autologous fat grafting is a potential adjunct to improve esthetic outcomes in breast reconstruction following mastectomy; however, more high-quality evidence on the efficacy and safety of this procedure is necessary before its widespread implementation.

**Recommendation 10: Routine screening for breast cancer recurrence following postmastectomy breast reconstruction**

- There is insufficient evidence to support the use of postmastectomy surveillance mammography in the reconstructed breast.
- Women should be followed with clinical examination of the chest wall and reconstructed breast as per the regular breast cancer follow-up regimen.
- Diagnostic mammography, ultrasound, and magnetic resonance imaging may be helpful in the evaluation of symptomatic women with a reconstructed breast (e.g., lumps, skin changes).