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Ontario Health (Cancer Care Ontario)**

**Postmastectomy Breast Reconstruction in Patients
with Non-Metastatic Breast Cancer**

*Toni Zhong, Glenn G Fletcher, Muriel Brackstone, Simon Frank, Renee Hanrahan,
Vivian Miragias, Christiaan Stevens, Danny Vesprini, Alyssa Vito, Frances C Wright
and the and the Breast Reconstruction Expert Panel*

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For information about this document, please contact Toni Zhong, the lead author, through the PEBC: Phone: 905-527-4322 ext. 42822; E-mail: ccopgi@mcmaster.ca

For information about the PEBC and the most current version of all reports, please visit the OH (CCO) website at <https://www.cancercareontario.ca/en/guidelines-advice> or contact the PEBC office at:
Phone: 905-527-4322 ext. 42822 E-mail: ccopgi@mcmaster.ca

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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

The objective of this work is to provide guidance on identifying which patients with breast cancer who are undergoing mastectomy are candidates for reconstruction, use of nipple-sparing mastectomy (NSM), the best timing of reconstruction (immediate or delayed), whether radiotherapy (RT) should influence timing, the choice between prepectoral versus subpectoral implants, and use of acellular dermal matrix (ADM) and autologous fat grafting as part of the reconstruction process.

For this document, “reconstruction” refers to immediate or delayed reconstruction of the breast mound, not including aesthetic flat closure.

TARGET POPULATION

Patients diagnosed with non-metastatic breast cancer who will undergo therapeutic mastectomy and are considering or decided on reconstructive surgery. For purposes of this document, reconstruction includes both immediate and delayed reconstruction with implants and/or autologous tissue but does not include aesthetic flat closure.

INTENDED USERS

1. Surgeons (general surgeons, surgical oncologists, plastic surgeons), radiation oncologists, and other clinicians involved in conducting mastectomies or in post-mastectomy reconstruction and adjuvant treatment.
2. Members of the Breast Cancer Advisory Committee, Ontario Health (Cancer Care Ontario), and others involved in the review and update of the Breast Cancer Pathway Map.

RECOMMENDATIONS

Recommendations on Type of Reconstruction (Implants or Various Autologous Flaps)

The authors deemed that the evidence and recommendations in Version 1 of this guideline are still relevant for this question and that an update was not required. As 17-10 Version 1 will no longer be available upon posting of Version 2, the relevant portions of the 2016 Recommendations and Systematic Review are included in [Appendix 6](#). Comparison of types of reconstruction or factors influencing their selection are not within scope of the current work.

Overall Recommendation for 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, breast surgeon, or surgical oncologist.

- For women seeking immediate breast reconstruction, preoperative evaluation should include a plastic surgeon.
- For women seeking immediate breast reconstruction 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.
- Decisions around the contralateral breast should be jointly made by the patient and medical team, considering the patient's family history and/or genetic profile if available and symmetry with the involved reconstructed breast, and include discussion of potential benefits and harms. Risk of new primary breast cancer may be a factor, and patients with risk factors for hereditary breast cancer should be referred for genetic assessment. The patient's preferences and values must be considered, and an informed discussion is recommended prior to mastectomy, along with a recommendation by the surgeon conducting the mastectomy (e.g., general surgeon, breast surgeon, or surgical oncologist) or reconstructive surgeon (or consensus of these) for or against contralateral prophylactic mastectomy.

Qualifying Statements

- Bilateral surgery is shown to increase complications risks.
 - In absence of genetic risk factors, contralateral mastectomy may decrease rates of new cancer but does not improve survival or recurrence.
 - Contralateral mastectomy with reconstruction may give better aesthetic results in some patients. When contralateral mastectomy is not indicated, balancing procedure to the contralateral breast can also produce aesthetic and symmetrical results.
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1. Effect of Patient and Oncologic Factors

Note 1: While an individual factor may not be sufficient to rule out reconstruction, risks of complications for different factors may be additive and must be considered together (e.g., diabetes plus smoking plus obesity). A validated risk tool may be useful in evaluating overall risks. Further, some risk factors may alter the risk-benefit analysis for some types of reconstruction more than for other types. Factors that affect flap perfusion/circulation may preclude skin- or nipple-sparing mastectomy. The degree of comorbidity (e.g., grade of obesity, controlled vs. uncontrolled diabetes, current vs. former smoking and amount smoked) need to also be considered.

Note 2: Published systematic reviews constitute the evidence base for Recommendations 1.2 through 1.6

The rationale for using higher level evidence was in part due to limited time and staffing resources, given the broad scope of this systematic review and is a usual trade-off. Furthermore, it is often the pragmatic choice to use higher level evidence synthesis publications for these kind of 'factor' questions, making use of work already done by others to avoid duplication. As no systematic review was found that covered age adequately, Recommendation 1.1 on age is based on a new systematic review of this topic (see Section 4).

Recommendation 1.1: Age

- Age on its own should not be used to determine whether to offer breast reconstruction to patients who are undergoing mastectomy as treatment for breast cancer. Competing risks of mortality and patient preferences should be part of the decision-making process; life expectancy and geriatric assessment may be considered.

Qualifying Statements for Recommendation 1.1

- Comorbidities including heart diseases and diabetes tend to increase with age and may affect suitability for operation or wound healing.
- While some older patients may place less importance on breast reconstruction, it should not be assumed for all, as individual preferences will vary.
- Some patients of any age may not want reconstruction and prefer mastectomy alone, and it should not be assumed that all younger patients will want reconstruction.

Recommendation 1.2: Body Mass Index, Smoking, Diabetes, Hypertension

- High body mass index (BMI), current and prior smoking status, diabetes, and hypertension are risk factors for complications and poorer outcomes but should not be used as absolute contraindications to reconstruction. It is recommended that uncontrolled diabetes be treated and that patients cease smoking at least several weeks prior to surgery and until incisions have healed.
- Reconstruction should be presented as an option, and patients informed that risks of specific complications such as skin or nipple necrosis and reconstructive failure are higher than in patients without risk factors.

Qualifying Statements for Recommendation 1.2

- Obesity is often defined as BMI >30 kg/m², although particularly in Asian countries a lower cut-off (25 kg/m²) is often used. Risks of complications increase with BMI above these thresholds on a continuum. Incisions and reconstruction techniques may need to be altered and include contralateral reduction if matching of the breasts is considered important to the patient. The amount of tissue removed, and repositioning of the nipple may result in ischemic complications and decreased sensation. In patients with multiple risk factors or comorbidities, the potential effect of all combined must be considered. A validated risk assessment tool may be used.

Recommendation 1.3: Breast Size

- Pre-mastectomy breast size and desired reconstructed breast size may influence type of reconstruction, complication rates, and cosmetic/aesthetic results; however, these factors should not determine whether to perform reconstruction. Patients and surgeons should discuss risks and benefits of various procedures.

Recommendation 1.4: Previous Surgery

- Abdominal scars, previous abdominal surgery, and previous breast augmentation are not contraindications to breast reconstruction but may influence the surgical and reconstructive planning and type of reconstruction performed.

Recommendation 1.5. Neoadjuvant Chemotherapy

- Patients who received neoadjuvant chemotherapy (NACT) should be assessed and considered for reconstruction in the same manner as for patients without NACT.

Recommendation 1.6: Radiotherapy

- Adjuvant radiotherapy (RT) should not be considered as a contraindication to either implant-based or autologous reconstruction. Patients should be informed that adjuvant RT is associated with increased reconstructive complications, and that these are greater in expander/implant reconstruction than with autologous reconstruction .

Qualifying Statements for Recommendation 1.6

- The type of complications varies between implant and autologous reconstruction. Autologous reconstruction may be preferred in patients at higher risk of implant-related complications.
- Timing of RT with respect to reconstruction may influence the degree or profile of complications and is not addressed here. The timing of reconstruction and use of RT is partially addressed in Recommendation 2.

2. Immediate versus Delayed Reconstruction

Recommendation 2

- For patients desiring breast reconstruction, both immediate and delayed reconstruction may be considered.
- When delayed reconstruction occurs after radiotherapy (RT), reconstruction should occur at least 6 months after completion of RT, or longer if the irradiated site is still acutely tight, inflamed, and prone to complications.

Qualifying Statements for Recommendation 2

- Preferred timing of reconstruction will depend on factors such as patient preferences, type of mastectomy, skin perfusion, comorbidities, pre-mastectomy breast size, and desired reconstructive breast size.
- Immediate reconstruction may provide greater psychological or QoL benefits for some patients.
- Access to and resources for delayed breast reconstruction can be very lengthy in parts of Ontario and immediate reconstruction would avoid being on a lengthy waitlist.

3. Nipple Sparing Mastectomy

Recommendation 3.1: Nipple-Sparing versus Skin-Sparing Mastectomy

- a) In patients who are candidates for skin-sparing mastectomy (SSM) and without clinical, radiological, and pathological indications of nipple-areolar complex (NAC) involvement,

nipple-sparing mastectomy (NSM) is recommended provided it is technically feasible and acceptable aesthetic results can be achieved.

- b) Patients should be informed that in the case of tumour involvement of subareolar tissues/margins based on pathologic analysis, or of NAC necrosis not responding to treatment, the nipple or NAC may need to be excised.
- c) The patient should be involved in the decision between NSM and SSM. The patient should be informed, along with reasons, if NSM is considered inappropriate and not being offered.

Qualifying Statements for Recommendation 3.1

- Comorbidities, larger breast size, and ptosis are risk factors for poor perfusion and subsequent skin flap and/or NAC necrosis. Reduction in breast size and repositioning of the nipple may require different incision locations. Blood supply to the skin flap/NAC may be improved with delayed reconstruction, staged mastectomy, or surgical delay when the oncologic treatment timeline allows.
 - Discussion of tattooing or nipple reconstruction with realistic restorative areola tattooing needs to be a discussion for psychological and physical well-being in patients for which NSM is not suitable.
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Recommendation 3.2: Patient Selection and Assessment of Nipple-Areolar Complex (NAC) Involvement

- a) Nipple-sparing mastectomy (NSM) can be considered in all patients with non-metastatic, non-inflammatory breast cancer without clinical signs of nipple involvement (bloody or pathologic nipple discharge, nipple retraction, Paget disease) and no nipple involvement by imaging and where it is surgically feasible and suitable aesthetic results can be obtained.
- b) An oriented subareolar sample must be obtained for pathologic evaluation. A sample of ducts from the nipple or complete nipple coring (total skin-sparing mastectomy [TSSM]) may be considered.
- c) In cases where specimens taken from the area immediately under or within the nipple are found involved by tumour, but the areola is not involved, nipple excision alone (i.e., areola-sparing mastectomy [ASM]) may be conducted provided clear margins are obtainable.
- d) Involvement of areolar skin not extending to the nipple may be treated as for other skin cancers and excised with clear margins.
- e) We recommend against intraoperative/frozen section pathologic analysis. Treatment decisions should be based on definitive/final pathology results.
- f) The patient should be informed that NAC or nipple excision is the standard treatment when the subareolar area is found to be involved with tumour on final pathologic analysis; the final decision should be made by the patient and surgical team. Planned RT may be a factor in the decision.
- g) Prior to a planned NSM, patients should be informed and consent to NAC or nipple removal if intraoperative surgical findings are indicative of cancer that cannot be resected without NAC or nipple excision.

Qualifying Statements for Recommendation 3.2

- SSM, ASM, and NSM aim to balance eliminating negative oncologic outcomes with maintaining a viable skin envelope. Differences in operative procedures and criteria may contribute to variations in oncomes between studies.
 - While intraoperative frozen section analysis was used in several of the published studies, it is less accurate and may result in false positives (and unnecessary NAC excision) or false negative (with involved NAC retained). When subareolar tissue is found involved by tumour on intraoperative/frozen section analysis, re-excision to obtain clear margins may be conducted as an alternative to immediate NAC excision.
 - Studies did not use a uniform definition of pathologies that would require NAC excision. Atypia and lobular carcinoma in situ (LCIS) in subareolar samples were not criteria to conduct NAC excision in several studies; frozen section analysis is not a reliable method of assessing epithelial cell atypia and is often misidentified in frozen section analysis.
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Recommendations 3.3 to 3.7: Surgical Factors in Nipple-Sparing Mastectomy

Evidence Note

Authors of studies included in the systematic review indicated that incision location, nerve preservation, skin tension, thermal damage in dissection, and operative planning are important surgical factors for outcomes of nipple viability/necrosis and sensation after NSM.

Several studies reported comparative data on incision location (see Recommendation 3.3) and a few on sensation (see Recommendation 3.4). For the other factors, the study authors presented these as generally accepted or based on their accumulated experience. These were not the topic of comparison/investigation. Recommendations 3.5 to 3.7 present these factors as important to be considered but do not provide specific recommendations or optimal approaches.

Recommendation 3.3: Incision Location

- a) Periareolar incisions (including hemi-periareolar) should be avoided unless there are oncologic or other specific reasons for their use. Periareolar incisions, if used, should encompass no more than one-third of the areolar circumference.
- b) To reduce nipple necrosis, inferolateral (lateral inframammary fold) or inframammary fold (IMF; central inframammary fold) incisions are preferred.
- c) In the case of previous breast surgery with scars, it may be preferable to reoperate using the same incision. This should be determined on a case-by-case basis.

Qualifying Statements for Recommendation 3.3

- Re-excision using the same incision location as for previous surgery is sometimes used to avoid multiple sets of scars that may have negative aesthetic impact. As the previous incision already disrupted blood supply in that area, reusing the same scars may also cause less additional complications.
- Inferolateral and IMF have least necrosis associated with them. Inferior radial (vertical inferior) or lateral radial (horizontal radial) incisions have been reported as resulting in intermediate levels of nipple necrosis.

- As indicated in Question 5 on acellular dermal matrix (ADM) use, inferolateral incisions may be preferred for subpectoral implants without ADM. Some have suggested that incisions in the IMF may not allow for enough support for implants unless ADM is used. There is not enough evidence in this regard to make a recommendation, but type and location of implant may influence the incision location.

Recommendation 3.4: Nerve Preservation

- Selection of incision sites should take into account both preservation of blood supply and minimizing nerve damage.

Qualifying Statements for Recommendation 3.4

- Priority should be to minimize nerve damage and optimize conditions for nerve regeneration. Partial sensation, while much lower than prior to mastectomy, may be maintained in some patients. Reconnecting nerves is sometimes attempted in autologous flap reconstruction.

Recommendation 3.5: Skin Tension

- When nipple-sparing mastectomy (NSM) is followed by immediate expanders or implants, excess tension should be avoided as it may interfere with blood flow and lead to necrosis.

Recommendation 3.6: Thermal Damage in Dissection

- Care should be taken to minimize thermal damage to the skin, blood vessels and nerves.

Recommendation 3.7: Operative planning

- Operative planning should be conducted jointly by the surgeon conducting the mastectomy and the plastic surgeon and include assessment of blood vessel location and skin perfusion. Perfusion of flaps should be monitored after operation.

4. Implant Plane/Location

Background

Early attempts at prepectoral breast reconstruction suffered from unacceptable rates of flap necrosis and capsular contracture (1), as well as lack of support and implant extrusion. Subpectoral implants were the standard of care for many years, but many patients experienced animation deformity, pain, restricted motion, as well as longer and more complex operations (2-4). The development and use of acellular dermal matrix (ADM), fat grafting, and tissue perfusion assessment technology to assess flap viability have reduced complications and led to more widespread use of prepectoral (and to lesser extent dual-plane) reconstruction (1, 5). In the studies included in the systematic review, ADM was usually used with prepectoral implants to provide support of the lower pole and/or to provide an additional layer between the skin envelope and the implant. In partial subpectoral (dual-plane) placement, ADM or other mesh was generally used to cover and support the lower half (lateral pole) of the expander or implant (the portion not under the pectoralis major muscle). Use of ADM is covered in Recommendation 5 and fat grafting in Recommendation 6.

Recommendation 4

- a) There is a role for both prepectoral and subpectoral implants; risks and benefits will vary, and decisions should be made during consultation between the patient and surgeons.
- b) In patients who are suitable candidates for implant reconstruction and have adequate mastectomy flap thickness and vascularity, prepectoral implants should be considered as they have some advantages over dual-plane or other subpectoral reconstructions.
- c) Patients should be informed of the possibility that subpectoral and submuscular implants may result in long-term animation deformity and related pain and sometimes implant malposition.

Qualifying Statements for Recommendation 4

- In patients with poor flap quality and vascularization, immediate prepectoral reconstruction was not generally offered; alternatives include subpectoral reconstruction, surgical delay prior to prepectoral reconstruction, or autologous flaps.
 - Type and location of implants or autologous tissue should be documented in patient records and available to clinicians conducting follow-up assessments and imaging.
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5. Use of Acellular Dermal Matrix (ADM) or Synthetic Absorbable Matrix

Background

ADM is usually used with prepectoral implants to provide support of the lower pole and/or to provide an additional layer between the skin envelope and the implant. The expander or implant could be wrapped entirely with ADM (most common), the pocket after SSM/NSM lined entirely with ADM, or ADM used only on the anterior surface and posterior lower pole. The use of ADM has led to being able to perform prepectoral reconstruction safely. In partial subpectoral (dual-plane) placement, ADM or other mesh was generally used to cover and support the lower half (lateral pole) of the expander or implant (the portion not under the pectoralis major muscle). ADM was sutured to the lower border of the pectoralis muscle and in the area of the IMF and often referred to as a sling providing support to the lower pole of the implant.

Recommendation 5

- a) Mastectomy flap perfusion should be assessed prior to reconstruction. ADM should not be used in case of poor mastectomy flap perfusion/ischemia that would otherwise be considered unsuitable for prepectoral reconstruction.
- b) Care should be taken in selection and handling of acellular dermal matrix (ADM) to minimize risks of infection and seroma.
- c) There is insufficient information to recommend a specific human ADM. Sterility level may be a factor in selection of a product.
- d) Undue tension on the mastectomy flaps should be avoided.
- e) Absorbable synthetic mesh may be an alternative to human ADM; however, comparative information is very limited, and no recommendation can be made.

Qualifying Statements for Recommendation 5

- Few studies with a direct comparison of reconstruction in the same plane with and without ADM were included in the systematic review. Most studies compare prepectoral reconstruction with ADM to subpectoral reconstruction (with or without ADM).
 - Limited data from small studies suggest that prepectoral reconstruction without ADM may be feasible in some patients and has similar complications with and without ADM (see [Table 4-12](#)).
 - Dual-plane reconstruction without ADM appears more common than prepectoral reconstruction without ADM. Alternatives to use of ADM in dual-plane reconstruction exist, including an inferolateral incision instead of IMF incision to provide more support, using fascia of serratus anterior muscle, or using the mastectomy skin alone. Repair of the IMF area may be required.
 - ADM use has been associated with increased risk of infection and seroma. Risks may vary with type and preparation of ADM; seroma rates are observed to be lower when ADM is perforated or meshed.
 - Fenestration generally refers to the process of creating slits (as done in meshing) but sometimes refers to perforations and this term is therefore ambiguous. In several studies, adding perforations or meshing was performed by the surgeon immediately prior to placement. These treatments are now available commercially as well but at added cost.
 - Bioabsorbable mesh has been used in several studies and may be beneficial, but information is insufficient to rank any compared with the commonly used human ADM or each other.
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6. Autologous Fat Grafting (Lipofilling)

Recommendation 6

- a) Fat grafting is recommended as a treatment for contour irregularities.
- b) Fat grafting is recommended as treatment for rippling following implant-based reconstruction.
- c) Fat grafting may be used to improve tissue quality of the mastectomy flap after radiotherapy (RT).
- d) Patients undergoing radiologic exams should indicate that they have undergone reconstruction including autologous fat transfer.
- e) Evidence on total fat grafting is more limited, and a recommendation cannot be made at this time.

Qualifying Statements for Recommendation 6

- Outcomes are highly dependent on method of fat harvesting and treatment, and on amount and location of injection. Excess pressure due to overfilling can cause fat necrosis and lower rates of fat survival.
- Palpable masses as a result of fat necrosis may occur in patients who have received fat transfer. These are generally benign on imaging and can be identified without biopsy in most cases.
- Enrichment/enhancement of stem cells is an area of active research but was not within the scope of this work.

- The optimal timing of fat grafting is unclear and may vary according to indication. The first session of fat grafting is usually at the time of expander-implant exchange or as a revisionary procedure several months after the final implant or autologous reconstruction, although there are sometimes reasons to use at the time of expander insertion or autologous flap placement. In patients with poor mastectomy skin flap quality, fat grafting prior to expander insertion (for delayed-immediate reconstruction) or expander-implant exchange (in case of radiation damage) may improve tissue quality and reduce complications. In patients requiring RT, fat grafting often occurs 2 to 6 months after the end of RT.

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