

ASPS Clinical Practice Guideline Summary on Breast Reconstruction with Expanders and Implants

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Summary: In March of 2013, the Executive Committee of the American Society of Plastic Surgeons approved an evidence-based guideline on breast reconstruction with expanders and implants, as developed by a guideline-specific work group commissioned by the American Society of Plastic Surgeons Health Policy Committee. The guideline addresses nine clinical questions including: patient education, immediate versus delayed reconstruction, risk factors, radiation therapy, chemotherapy, hormonal therapy, antibiotic prophylaxis, acellular dermal matrix (ADM), monitoring for cancer recurrence, and oncologic outcomes associated with implant-based reconstruction. The evidence indicates that patients undergoing mastectomy should be offered a preoperative referral to a plastic surgeon. Evidence is varied and conflicting regarding the association between postoperative complications and the timing of post-mastectomy expander/implant breast reconstruction and is often confounded by the use of radiation. There are several independent risk factors associated with post-surgical complications and reconstructive failure in patients undergoing post-mastectomy expander/implant breast reconstruction, such as smoking, obesity, preoperative breast cup size of C or greater, hormonal therapy (i.e., tamoxifen), and radiation treatment. Evidence is limited regarding the optimal timing of expand/implant reconstruction in the setting of radiation therapy but does suggest that radiation to the tissue expander or breast implant is associated with an increased risk of a postoperative complication. Evidence is also varied and conflicting regarding the association between acellular dermal matrix and surgical complications in the setting of post-mastectomy expander/implant breast reconstruction. There is no evidence to suggest that diabetes or chemotherapy are independent risk factors for surgical complications with expander/implant reconstructions. There is data to support the use of an appropriate preoperative antibiotic initiated 60 minutes or less from the time of incision, or within two hours for antibiotics with longer infusion times. Antibiotics should be discontinued within 24 hours of the completion of the procedure, unless a surgical drain is present. Furthermore, post-mastectomy expander/implant breast reconstruction does not adversely affect oncologic outcomes, and clinical examination is sufficient to detect a local cancer recurrence.

The American Cancer Society estimates that nearly 230,000 American women are diagnosed annually with invasive breast cancer.¹ Many women will undergo a mastectomy and, therefore, have the option of breast reconstruction. The cancer diagnosis and treatment decision-making process can be an overwhelming for patients. The American Society of Plastic Surgeons (ASPS) is committed to providing decision support, access to reconstruction, and quality care for all patients. Fortunately, through advocacy efforts, ASPS has reported a 3% increase in the use of breast reconstruction in just one year, with nearly 100,000 procedures performed in 2011, and the majority of these procedures involve a

tissue expander and implant.² The increased use of post-mastectomy breast reconstruction over the course of just one year highlights the significance of maintaining patient safety and optimizing surgical outcomes.

Breast reconstruction is a common consideration for breast cancer patients undergoing mastectomy. Breast reconstruction can be performed in an immediate or delayed setting, using a variety of techniques including an implant-based approach or an autologous tissue technique. A significant number of implant-based breast reconstruction procedures are a two-stage process, involving the insertion of a tissue expander. Once the expansion process is complete, the final implant can be placed, using either a saline or silicone gel-filled device.

DISCLAIMER

Evidence-based guidelines are strategies for patient management, developed to assist physicians in clinical decision making. This guideline was developed through a comprehensive review of the scientific literature and consideration of relevant clinical experience, and describes a range of generally acceptable approaches to diagnosis, management, or prevention of specific diseases or conditions. This guideline attempts to define principles of practice that should generally meet the needs of most patients in most circumstances.

However, this guideline should not be construed as a rule, nor should it be deemed inclusive of all proper methods of care or exclusive of other methods of care reasonably directed at obtaining the appropriate results. It is anticipated that it will be necessary to approach some patients' needs in different ways. The ultimate judgment regarding the care of a particular patient must be made by the physician in light of all the circumstances presented by the patient, the available diagnostic and treatment options, and available resources.

This guideline is not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all the facts or circumstances involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve. This guideline reflects the state of current knowledge at the time of publication. Given the inevitable changes in the state of scientific information and technology, this guideline will be reviewed, updated and revised periodically.

GUIDELINE DEVELOPMENT PROCESS

The American Society of Plastic Surgeons (ASPS) evidence-based clinical practice guidelines are developed using an objective, transparent approach, to minimize bias. A prospective systematic review of the current literature on breast reconstruction with expanders and implants was completed. A complete summary of the methods used to conduct the systematic review and complete the critical appraisal process for the guideline can be found at: <http://www.plasticsurgery.org/Documents/medical-professionals/health-policy/evidence-practice/breast-reconstruction-expanders-with-implants-guidelines.pdf>

Committee Composition

The guideline work group was chaired by Amy Alderman, M.D., M.P.H., as selected by the ASPS Health Policy Committee. The Health Policy Committee also selected additional work group members after a thorough review of applicants. The work group composition was a diverse representation of United States regions, practice type, and clinical, research, and evidence-based medicine experience and expertise. Three stakeholder organizations, including the American Society of Breast Surgeons,

American College of Radiology, and American Society of Clinical Oncology, were also invited to participate in the guideline development process, which was facilitated by ASPS staff. All workgroup members declared potential conflicts of interest and these were present in a minority of workgroup members, consistent with the Institute of Medicine’s recommendations for guideline development³.

LITERATURE SEARCH

A comprehensive search of PubMed, the Cumulative Index to Nursing and Allied Health Literature (CINAHL), and the Cochrane Library was performed by a guideline development methodologist using various combinations of the following search terms: “Mammoplasty AND reconstruction” OR “breast reconstruction,” and a wide range of MeSH indexing terms. The initial search identified a total of 2,749 articles that were subject to Level I screening, which were then narrowed to 62 studies, deemed relevant and of high to moderate quality (Table 1). These studies were evaluated via the ASPS critical appraisal process and were used to develop practice recommendations.

Recommendations were developed through a consensus process. After a thorough review of the evidence, Guideline Work Group Members jointly drafted statements for each recommendation during conference call meetings and online discussions. After each meeting, members had an opportunity to individually comment and revise the draft recommendations via an email discussion. Guideline Work Group Members participated in several rounds of revisions until unanimous consensus was achieved on each recommendation statement. Each recommendation in this guideline is accompanied by a grade indicating the strength of supporting evidence, taking into account the overall level of evidence and the judgment of the guideline developers.

Table 1. ASPS Scale for Grading Recommendations

Grade	Descriptor	Qualifying Evidence	Implications for Practice
A	Strong Recommendation	Level I evidence or consistent findings from multiple studies of levels II, III, or IV	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
B	Recommendation	Levels II, III, or IV evidence and findings are generally consistent	Generally, clinicians should follow a recommendation but should remain alert to new information and sensitive to patient preferences.
C	Option	Levels II, III, or IV evidence, but findings are inconsistent	Clinicians should be flexible in their decision-making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role.
D	Option	Level V: Little or no systematic empirical evidence	Clinicians should consider all options in their decision-making and be alert to new published evidence that clarifies the balance of benefit versus harm; patient preference should have a substantial influencing role.

CLINICAL QUESTIONS AND RECOMMENDATIONS

Clinical Question: Patient Education

In patients undergoing surgical treatment for breast cancer, what is the optimal time to discuss breast reconstruction options?

Recommendation

Patients undergoing mastectomy should be offered a preoperative referral to a plastic surgeon. The adoption of this approach by practicing surgeons would benefit breast cancer patients nationwide and would result in enhanced patient education of reconstructive options⁴⁻¹¹. **(Grade D)**.

Clinical Question: Immediate versus Delayed Reconstruction

- *In patients undergoing mastectomy for the treatment of breast cancer, what is the optimal time for implant-based reconstruction (i.e. immediate versus delayed) when radiation treatment is not required?*
- *In patients undergoing mastectomy for the treatment of breast cancer, what is optimal time for implant-based reconstruction (i.e. immediate versus delayed) when radiation treatment is required?*

Recommendation:

Evidence is varied and conflicting on the association between postoperative complications and the timing of post-mastectomy expander/implant breast reconstruction and is often confounded by the use of radiation. The inconsistent research findings and a lack of definitive evidence should alert physicians to evaluate each case individually¹²⁻¹⁷. **(Level II, III, IV Evidence: Grade C)**

Clinical Question: Risk Factors (Smoking, Obesity, Breast Size, Diabetes, Radiation Therapy [Overview, Previous Radiation, Radiation Therapy to Expander, Radiation Therapy to Implant, Optimal Timing of Radiation and Reconstruction, Overall], Chemotherapy, Hormonal Therapy)

In patients undergoing breast reconstruction following mastectomy, what are the risk factors when undergoing immediate implant-based reconstruction?

Smoking – Recommendation:

Smoking is associated with an increased risk of complications and an increased risk of reconstructive failure in patients undergoing post-mastectomy expander/implant breast reconstruction. Patients should be informed of the increased risks and advised on smoking cessation as means to prevent surgical complications. Additionally, it should be recognized that the necessity to proceed with surgery may preclude timely smoking cessation^{14, 16, 18-24}. **(Level II, III, IV Evidence: Grade A)**

Obesity – Recommendation:

A BMI of 25 or greater is associated with an increased risk of postoperative complications and reconstructive failure among patients undergoing post-mastectomy expander/implant breast reconstruction. These risks are even higher among patients with a BMI greater than 30. Obese patients should be informed of their increased surgical risks with expander/implant reconstructions and advised on practical weight loss solutions. Additionally, it should be recognized that the necessity to proceed with surgery may preclude timely weight management^{14, 20-22, 24-27}. **(Level III, IV Evidence: Grade A)**

Breast Size – Recommendation:

Preoperative breast size, specifically C or larger, may be associated with an increased risk of complication and an increased risk of reconstructive failure in patients undergoing expander/implant post-mastectomy breast reconstruction. However, much of the currently available evidence does not control for BMI, which is associated with both preoperative breast size and complication rates. Given the limited evidence and contradictory literature, physicians should be aware of this potential complicating factor^{14, 23, 27-28}. **(Level III, IV Evidence: Grade D)**

Diabetes – Recommendation:

There is no evidence to indicate that diabetes is a significant independent risk factor for the development of either postoperative complications or reconstructive failure in patients undergoing expander/implant post-mastectomy breast reconstruction. However, this information should not deter surgeons from continuing to practice glycemic control in the peri-operative period for breast cancer patients^{14, 16, 18, 21, 26}. **(Level II, III, IV Evidence: Grade B)**

Radiation Therapy, Overview – Recommendation:

Evidence indicates that patients undergoing post-mastectomy expander/implant breast reconstruction and receiving radiation therapy experience more postoperative complications than patients who do not require radiation therapy^{12, 17-18, 26, 29, 30-32}. **(Level III, IV Evidence: Grade B)**

Previous Radiation – Recommendation:

Evidence suggests that post-mastectomy expander/implant breast reconstruction patients are at an increased risk of experiencing postoperative complications if they receive radiation therapy prior to reconstruction. However, these results are inconsistent across the literature and better quality evidence is required^{14, 33-36}. **(Level III, IV Evidence: Grade C)**

Clinical Question: Radiation Therapy to Expander:

In patients undergoing mastectomy and radiation for the treatment of breast cancer, does radiation to the expander affect surgical outcomes?

Recommendation:

Evidence suggests that in patients undergoing post-mastectomy expander/implant breast reconstruction, radiation therapy to the expander leads to higher rates of postoperative complications³⁷⁻³⁹. **(Level III, IV Evidence: Grade B)**

Clinical Question: Radiation Therapy to Implant:

In patients undergoing mastectomy and radiation for the treatment of breast cancer, does radiation to the implant affect surgical outcomes?

Recommendation:

Evidence suggests that in patients undergoing post-mastectomy expander/implant breast reconstruction, radiation therapy to the implant leads to higher rates of postoperative complications^{16, 21, 33-34, 40-44}. **(Level II, III, IV Evidence: Grade B)**

Clinical Question: Optimal Timing of Radiation and Reconstruction

In patients requiring radiation therapy and undergoing immediate breast reconstruction after mastectomy when is the optimal time for radiation therapy?

Recommendation:

Evidence is limited to support optimal timing of radiation therapy for patients undergoing post-mastectomy implant/expander breast reconstruction. However, it is indicated that optimal time for radiation is within eight weeks of the mastectomy^{18, 42, 45-47}. **(Level II, III Evidence: Grade C)**

Radiation Therapy, Overall – Recommendation:

Evidence indicates that radiation therapy, regardless of when it is administered, is associated with an increased risk of complications and/or reconstructive failure in patients undergoing post-mastectomy expander/implant breast reconstruction. Patients should be counseled regarding associated complications. **(Level II, III, IV Evidence: Grade B)**

Chemotherapy – Recommendation:

Preoperative chemotherapy does not appear to be a significant risk factor for either postoperative complications or implant failure in patients undergoing post-mastectomy expander/implants breast reconstruction^{17, 21, 23, 36, 48-51}. **(Level II, III, IV Evidence: Grade C)**

Hormonal Therapy – Recommendation:

Hormonal therapy may increase the risk of postoperative complications and reconstruction failure in patients undergoing post-mastectomy expander/implant breast reconstruction. However, inconsistent research findings and a lack of definitive evidence should alert physicians to evaluate each case individually^{16, 23}. **(Level II, IV Evidence: Grade D)**

Clinical Question: Antibiotic Prophylaxis

In patients undergoing implant-based reconstruction after mastectomy, what is the optimal duration of antibiotic prophylaxis for prevention of postoperative infections:

Recommendation:

Patients undergoing post-mastectomy expander/implant breast reconstruction should receive a preoperative dose of an appropriate IV antibiotic initiated sixty minutes or less from the time of incision (within two hours for antibiotics with longer infusion times). Unless a drain is present, antibiotics should be discontinued within 24-hours of the completion of the procedure. If a drain is present, the role of antibiotics is less clear and should be left to physician preference. Of note, documenting a drain in proximity to the implant as a reason for continuation of IV antibiotics beyond the 24-hour postoperative period or switching to postoperative antibiotics within 24-hours of procedure completion is compliant with current SCIP guidelines. Presently, there is limited evidence on post-operative antibiotic prophylaxis. Overall, surgeons should adhere to their specific state and hospital guidelines on antibiotic administration⁵²⁻⁵⁵. **(Grade: D)**

Clinical Question: Acellular Dermal Matrix

In patients undergoing mastectomy and implant-based breast reconstruction, what are the outcomes associated with utilizing Acellular Dermal Matrix during reconstruction?

Recommendation:

Evidence on acellular dermal matrix (ADM) in post-mastectomy expander/implant breast reconstruction is varied and conflicting. Surgeons should evaluate each clinical case individually and objectively determine the use of ADM^{20, 25, 28, 33, 56-60}. **(Level III Evidence: Grade C)**

Clinical Question: Monitoring for Cancer Recurrence

In patients undergoing mastectomy and implant-based reconstruction, what are the screening recommendations to monitor for cancer recurrence?

Recommendation:

Clinical examination is sufficient to detect local cancer recurrence in patients undergoing expander/implant post-mastectomy breast reconstruction. Imaging studies are not required as part of routine surveillance. On the basis of clinical suspicion, imaging studies can be used for clinical indications on a case by case basis. Diagnostic imaging is indicated if there is any clinical evidence of recurrence⁶¹⁻⁶³. **(Grade D)**

Clinical Question: Effect of Implant-Based Reconstruction on Oncologic Outcomes

In patients undergoing breast reconstruction following mastectomy, what are the oncologic outcomes associated with undergoing immediate implant-based reconstruction?

Recommendation:

Post-mastectomy expander/implant breast reconstruction does not adversely affect oncologic outcomes. The need for post-mastectomy radiation therapy is often, but not always, apparent prior to surgery; accordingly, decisions regarding the sequencing of post-mastectomy breast reconstruction and radiation therapy are best made by a multidisciplinary team including the oncologic surgeon, plastic surgeon, medical oncologist and radiation oncologist⁶⁴⁻⁷⁰. **(Level III Evidence: Grade B)**

CONCLUSIONS

Currently in the US, expander/implant procedures are the most commonly performed technique for post-mastectomy breast reconstruction⁷¹. This guideline is designed to promote evidence-based clinical practice and to improve the quality of care for breast cancer patients. The recommendations address the risk factors, treatment, anticipated outcomes, and follow-up of patients undergoing breast reconstruction with expanders/implants for the treatment of mastectomy defects. The recommendations are linked to improvements in health outcomes in order to improve the quality of care delivered to the breast cancer population (Figure 1). The full guideline, including the development methodology, operative procedure, evidence summaries, and coding recommendations, can be accessed at <http://www.plasticsurgery.org/Documents/medical-professionals/health-policy/evidence-practice/breast-reconstruction-expanders-with-implants-guidelines.pdf>.

Figure 1. (Insert formatted diagram here)

APPENDIX A. ASPS EVIDENCE RATING AND GRADES OF RECOMMENDATION SCALES

Evidence Rating Scale for Therapeutic Studies

Level of Evidence	Qualifying Studies
I	High-quality, multi-centered or single-centered, randomized controlled trial with adequate power; or systematic review of these studies
II	Lesser-quality, randomized controlled trial; prospective cohort or comparative study; or systematic review of these studies
III	Retrospective cohort or comparative study; case-control study; or systematic review of these studies
IV	Case series with pre/post test; or only post test
V	Expert opinion developed via consensus process; case report or clinical example; or evidence based on physiology, bench research or “first principles”

Evidence Rating Scale for Diagnostic Studies

Level of Evidence	Qualifying Studies
I	High-quality, multi-centered or single-centered, cohort study validating a diagnostic test (with “gold” standard as reference) in a series of consecutive patients; or a systematic review of these studies
II	Exploratory cohort study developing diagnostic criteria (with “gold” standard as reference) in a series of consecutive patient; or a systematic review of these studies
III	Diagnostic study in nonconsecutive patients (without consistently applied “gold” standard as reference); or a systematic review of these studies
IV	Case-control study; or any of the above diagnostic studies in the absence of a universally accepted “gold” standard
V	Expert opinion developed via consensus process; case report or clinical example; or evidence based on physiology, bench research or “first principles”

Evidence Rating Scale for Prognostic/Risk Studies

Level of Evidence	Qualifying Studies
I	High-quality, multi-centered or single-centered, prospective cohort or comparative study with adequate power; or a systematic review of these studies
II	Lesser-quality prospective cohort or comparative study; retrospective cohort or comparative study; untreated controls from a randomized controlled trial; or a systematic review of these studies
III	Case-control study; or systematic review of these studies
IV	Case series with pre/post test; or only post test
V	Expert opinion developed via consensus process; case report or clinical example; or evidence based on physiology, bench research or “first principles”

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