

Performance and Practice Guidelines for Excisional Breast Biopsy

Article I - Introduction

This American Society of Breast Surgeons (ASBrS) Performance and Practice Guideline summarizes the indications for and technique of excisional breast biopsy. The Guideline reflects the consensus of a panel comprising members of the Education Committee, the Board of Directors, and the Executive Committee, and is based on multiple sources from the peer-reviewed literature. This Guideline reflects what ASBrS considers to be optimal practice but may require modification based on the clinical circumstance, the physician's judgment, the patient's preference, and as scientific evidence continues to evolve.

Article II – Indications

Historically, surgical excision was the “gold standard” for the diagnosis of palpable breast masses and, early in the era of mammographic screening, for the diagnosis of suspicious nonpalpable lesions. In contemporary practice, core needle biopsy (guided by mammography, ultrasound, or MRI) has largely, but not completely, replaced surgical excision.

Current indications for excisional breast biopsy are as follows:

- a. Discordance between imaging characteristics (mammographic/sonographic/MRI) and core biopsy histology
- b. Nondiagnostic specimen from core biopsy (i.e., insufficient material, lack of calcifications, hemorrhage)
- c. Lesion anatomically unsuitable for core biopsy (lesion too far anterior, too far posterior, too close to breast implant)
- d. Patient anatomically unsuitable (breast tissue too thin, patient too large for biopsy table)
- e. Suspicious interval changes in a lesion previously diagnosed benign by core biopsy
- f. Atypical hyperplasia (duct or lobular) or LCIS on core biopsy
- g. Papillary and/or sclerosing lesion on core biopsy
- h. “Fibroepithelial lesion” (ie, fibroadenoma vs benign phyllodes tumor) on core biopsy
- i. Suspicious nipple discharge with normal breast imaging

Article III – Surgeon Qualifications

Surgeons must have successfully completed an American Board of Medical Specialties-approved surgical residency program and must have attained, or be admissible for, board certification by the American Board of Surgery (ABS) or its equivalent. Training in the technique of excisional breast biopsy is part of the surgical curriculum in all accredited training programs, and should encompass both palpable and nonpalpable lesions.

Article IV – Procedural Details and Prerequisites

A. Prerequisites

Excisional breast biopsy requires close collaboration between the radiologist, surgeon, and pathologist, and a different approach for palpable vs nonpalpable lesions. Whether palpable or nonpalpable, the first goal of excisional biopsy is *an intact specimen, not a piecemeal excision*. This will facilitate specimen radiography, pathologic processing, and (if cancer is found) reduce the rate and extent of re-excision.

For nonpalpable lesions, precise localization (by placement of a guidewire, a radioactive seed, or intraoperative ultrasound) is essential. The radiologist or surgeon should have the capability to localize lesions by the same methods used for the core needle biopsy: mammography, ultrasound, and (when available) MRI. When localization is performed by the radiologist, preoperative collaboration with the surgeon is essential to determine the number and extent of lesions, the method of localization (mammography, ultrasound, MRI, or a combination), and the number of wires (or seeds) required. Post-localization cc and lateral images are required to confirm appropriate localization, and should be present in the OR. *Annotation of the images by the radiologist to re-confirm orientation (superior, inferior, and medial, lateral) is particularly helpful.*

B. Technique

Excisional breast biopsy is typically done under local anesthesia with sedation. For palpable lesions consistent with fibroadenoma, a small incision, a very conservative excision (or enucleation), and placement of the specimen in formalin are sufficient. For indeterminate lesions, excision of the palpable abnormality, orientation of the specimen with sutures, and inking of margins by surgeon or pathologist are preferable. The incision should be placed to accommodate a reoperation should cancer be found, but since most indeterminate lesions will prove benign, the extent of resection should always be within the limits of a good cosmetic result and the cavity should be closed in layers as cosmetically as possible.

For nonpalpable lesions, the incision should be placed near the estimated site of the lesion, not the entry point of the localizing wire; for deep lesions it is particularly important to divide the breast tissue *along the course of the wire, not excising breast tissue until the distal (usually reinforced) portion of the wire is reached*. This will allow a symmetrical excision of the tissue surrounding the lesion, and avoid unnecessary removal of the normal breast tissue

superficial to it. For lesions which are *indeterminate* (ADH, ALH, LCIS, papilloma, duct excision), the specimen should be oriented with sutures, submitted for specimen xray or ultrasound to confirm removal of the lesion, with inking of the margins by surgeon or pathologist.

Article V – Documentation

Documentation prior to surgery should include an informed consent, encompassing all treatment options and a full discussion of risks and benefits. The operative report should include all appropriate patient identifiers, the name of the operation, the type of anesthesia, and a succinct description of the clinical setting, indication for surgery, and operative findings. The report should describe the extent of the resection (in particular, whether the excision was carried to the level of the skin and/or to the pectoral fascia), the number/type/orientation of specimens, and results of specimen x-ray or ultrasound. A copy of the operative report should go to all treating physicians and should be part of the permanent medical record. A plan for follow-up, including discussion of pathology results, wound care, and a plan for interval breast imaging should be part of the overall survivorship program.

Article VI – Equipment Specification and Quality Control

Routine general surgical instruments and operating room equipment are required. Intraoperative ultrasound, specimen radiography, and immediate consultation with the attending radiologist and pathologist should be available as needed.

Article VII – Quality Assessment/Improvement

- a. Core biopsy is sufficient for diagnosis of most benign breast lesions and >90% of breast cancers. Diagnostic excisional biopsy should be the exception, not the rule.
- b. Specimen x-ray or ultrasound to confirm removal of the target lesion is required for all excisional biopsies of non-palpable lesions.
- c. An institution-specific protocol should be in place for excisional breast biopsy, covering all aspects of the procedure and satisfactory to the surgeons, OR staff, radiologists, and pathologists involved.
- d. A policy for ongoing review of emerging evidence regarding the indications and outcomes of excisional breast biopsy should be in place.
- e. The medical record should document a plan for the post-surgical care and long-term follow-up of excisional breast biopsy, including the timing and type of breast imaging.

**Approved November 25, 2014
Board of Directors
The American Society of Breast Surgeons**

Acknowledgements

The guidelines were created by the Society's Education Committee