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ACR PRACTICE PARAMETER FOR THE PERFORMANCE OF MAGNETIC RESONANCE IMAGING-GUIDED BREAST INTERVENTIONAL PROCEDURES

PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care¹. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the practitioner in light of all the circumstances presented. Thus, an approach that differs from the guidance in this document, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in this document when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to the guidance in this document will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of this document is to assist practitioners in achieving this objective.

¹ *Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing*, ___ N.W.2d ___ (Iowa 2013) Iowa Supreme Court refuses to find that the *ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures* (Revised 2008) sets a national standard for who may perform fluoroscopic procedures in light of the standard's stated purpose that ACR standards are educational tools and not intended to establish a legal standard of care. See also, *Stanley v. McCarver*, 63 P.3d 1076 (Ariz. App. 2003) where in a concurring opinion the Court stated that "published standards or guidelines of specialty medical organizations are useful in determining the duty owed or the standard of care applicable in a given situation" even though ACR standards themselves do not establish the standard of care.

I. INTRODUCTION

Image-guided core-needle biopsy (CNB) has become the procedure of choice for image-detected breast lesions requiring tissue diagnosis. Its advantages over surgical biopsy are well recognized, including less scarring, fewer complications, faster recovery, and less cost, while providing similar accuracy [1].

High-quality breast imaging evaluation is necessary to detect early or subtle breast lesions. Several imaging modalities are commonly available and in clinical use for image-guided breast interventions, including stereotactic, ultrasound (US), and magnetic resonance imaging (MRI). The choice of guidance technique will depend on lesion visualization, lesion access, availability of the imaging modality, efficiency, safety, patient comfort, and the experience of the physician performing the biopsy.

The use of breast MRI for diagnosis and especially for screening purposes has become increasingly common, with a marked rise in numbers of examinations noted over the first decade of the 21st century [2-4]. Consequently, the number of MRI-guided procedures has also increased. Therefore, the ability to offer MRI-guided biopsy is important for the facilities that perform breast MRI for diagnostic or screening purposes.

Unlike mammography or breast US, breast MRI protocols and magnetic strengths can vary considerably from one imaging facility to another. The American College of Radiology (ACR) published the Practice Parameters and Technical Standards to achieve and maintain Breast MRI Accreditation in an effort to standardize the guidelines for this examination. If a practice performs breast MRI but does not offer MRI-guided biopsy, the patient must be referred to another facility for the procedure. Occasionally, the original MRI examination may have to be repeated prior to the biopsy due to differences in the breast MRI protocols between the 2 facilities. This will result in additional time commitment, inconvenience, and expense to the patient. If MRI biopsy is not offered at the facility performing the breast MRI, a mutually agreed-upon arrangement should be established with another facility to accept biopsy cases without the need to repeat the examination. Essentially, this means that the 2 facilities have agreed on compatible breast MRI protocols and technical factors [2].

Additionally, the performance of MRI-guided biopsy allows the physician performing the biopsy to gain experience in imaging/histologic correlation and to appreciate when MRI-guided biopsy may or may not be possible, which may improve interpretive performance. Radiologists must be particularly attuned to the ways in which the technical parameters of MRI biopsy affect evaluation of radiologic-pathologic correlation. Radiologists who interpret breast MRI examinations without performing biopsies should make every attempt to follow up on their biopsy recommendations in order to audit their breast MRI program and gain insight into their interpretive performance [5].

II. GENERAL PRINCIPLES

MRI guidance enables percutaneous placement of a needle or probe within the breast to sample MRI-detected suspicious breast lesions. This technique, along with the other methods of image-guided biopsy, has changed the management of breast disease [6-12]. Percutaneous biopsy techniques have decreased the number of benign surgical biopsies generated from breast imaging programs and have decreased the number of surgical procedures needed to treat breast cancer [13,14].

Minimally invasive biopsy is preferable to open surgical biopsy for diagnosing image-detected breast lesions. Advantages of percutaneous biopsy procedures include:

- Reduced morbidity, with better cosmetic results and less scarring detectable on future breast imaging
- Improved cost effectiveness with less time lost from the patient's normal activities
- Accuracy comparable to that of open surgical biopsy

Successful use of MRI-guided breast interventional procedures relies on high-quality imaging, expertise in lesion recognition and patient selection, experience in MRI-guided techniques for accurate lesion localization and sampling, and effective methods of obtaining tissue for analysis [15-19]. The imaging assessment and the

histopathologic interpretations should be correlated for concordance by the physician performing the biopsy, and records should be kept to document results and patient management recommendations.

III. INDICATIONS/CONTRAINDICATIONS

A. Indications

MRI-guided breast intervention is suitable for many MRI-depicted suspicious abnormalities.

It is common practice to perform an MRI-directed US to evaluate for lesions identified on MRI, a practice supported by the advantages of US-guided biopsy in terms of cost, time, and patient comfort. However, certain lesion types may be less well identified on US than on MRI, and it may be appropriate to proceed directly to MR-guided biopsy when US investigation is thought unlikely to lead to identification of an imaging correlate. In particular, non-mass-enhancing lesions, nonmalignant masses, and smaller lesions are less likely to be seen on targeted US [20-24]. Lesions may also proceed to MR biopsy if there is concern about correlation between the lesion seen on US and the lesion detected on MRI.

Indications for MRI-guided breast biopsy intervention include, but are not limited to:

1. Lesions only seen with certainty on breast MRI or that do not have a definite correlate on mammography or US:
 - a. Lesions that are highly suggestive of malignancy (BI-RADS® Category 5 in the Breast Imaging Reporting and Data System)
 - b. Lesions that are assessed as suspicious abnormalities (BI-RADS® Category 4)
 - c. Lesions that are assessed as probably benign (BI-RADS® Category 3) only when there are valid clinical indications or when short-term-interval imaging follow-up would be difficult or unreasonable (eg, if the patient has a synchronous known breast cancer, is awaiting organ transplantation, plans to become pregnant in immediate future, etc) [25]
2. Repeat biopsy
Repeat MRI-guided percutaneous sampling is an alternative to surgical biopsy in cases when the initial biopsy results are nondiagnostic or are discordant with the imaging findings.
3. MRI-guided presurgical needle localization
 - a. To guide excision of malignant lesions seen only on MRI or with discordant or nondiagnostic findings on MRI-guided core biopsy
 - b. For lesions that are not technically amenable to MRI-guided core biopsy due to their location in the breast or the size of the breast
 - c. To allow complete excision of an MRI-demonstrated malignancy or high-risk lesion when its extent is larger than outlined on mammography or US or by previous tissue marker placement; bracketing localization with MRI guidance may be required

B. Contraindications

Inability to revisualize the target or breast lesion at time of biopsy following contrast injection is a contraindication to MRI-guided breast biopsy. In that scenario, it should be verified that 1) the patient received a successful bolus of contrast and 2) arterial inflow is not impeded by excessive breast compression. For lesions that are not seen at the time of attempted biopsy, follow-up diagnostic MRI should be obtained within 6 months to be certain that the lesion is indeed absent [26].

Prior to the procedure, the patient should be asked about allergies (particularly to gadolinium); use of medications such as aspirin, anticoagulants, or other agents known to impact bleeding times; and whether there is a history of bleeding diatheses. However, a recent report suggested that it is safe to proceed with biopsy when patients are

anticoagulated [27]. Decisions regarding postponement or cancellation of a procedure or cessation of anticoagulants can be made on a case-by-case basis at a programmatic level.

All general MRI safety precautions should be observed and gadolinium risk should be assessed [28-35]. For further information, see the [ACR Manual on Contrast Media](#) [36] and the [ACR Guidance Document on MR Safe Practices: 2013](#) [29].

The patient's size and ability to remain in the position required for the procedure should also be assessed in determining the appropriateness of the procedure for that patient.

IV. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Physician

MRI-guided breast biopsy procedures should be performed by qualified physicians. The physician should meet the qualifications outlined in the [ACR Practice Parameter for the Performance of Contrast-Enhanced Magnetic Resonance Imaging \(MRI\) of the Breast](#) [37]. He or she should thoroughly understand the indications for and limitations of breast MRI examinations and MRI-guided percutaneous breast interventional procedures. The physician performing the breast interventional procedure should have interpretative experience with breast MRI studies and be able to correlate the results of other breast imaging examinations and procedures, and the biopsy histopathology results with the MRI findings. The interpreting physician should thoroughly understand the basic physics of MRI techniques and MRI safety, including contrast safety issues.

Prior to the MRI procedure, the physician should be able to identify the significant lesion(s) on MRI so that biopsy or presurgical needle localization is performed on the correct breast lesion.

1. Initial qualifications

Training in breast MRI imaging interpretation, medical physics and specific hands-on training in the performance of MRI-guided biopsy are imperative to successful performance of this procedure.

The initial qualifications as outlined in the [ACR Practice Parameter for the Performance of Contrast-Enhanced Magnetic Resonance Imaging \(MRI\) of the Breast](#) provide this foundation [37].

2. Maintenance of competence

The physician should perform a sufficient number of procedures to maintain his/her skills. Continued competence should depend on participation in a quality control program as laid out under section VIII in this practice parameter.

3. Continuing medical education

The physician's continuing education should be in accordance with the [ACR Practice Parameter for Continuing Medical Education \(CME\)](#) [38].

4. Responsibilities for assessment of concordance

The physician who performs the MRI-guided biopsy or presurgical needle localization procedure (or a qualified physician-designee) is responsible for obtaining results of the histopathologic sampling to determine if the lesion has been adequately biopsied and is concordant or discordant with the imaging findings. These results should be communicated to the referring physician and/or to the patient, as appropriate, and documented in the final report.

B. Qualified Medical Physicist

See the [ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Magnetic Resonance Imaging \(MRI\) Equipment](#) [39].

C. Technologist

1. Initial qualifications

Technologists should meet the qualifications specified in the [ACR Practice Parameter for the Performance of Contrast-Enhanced Magnetic Resonance Imaging \(MRI\) of the Breast](#) [37].

2. Maintenance of competence

Technologists should participate in at least 6 MRI-guided breast interventions every 2 years.

3. Continuing medical education

Technologists should obtain 3 hours of continuing education in MRI-guided breast intervention every 3 years.

V. SPECIFICATIONS OF THE PROCEDURE

A. Prior to the Procedure

The written or electronic request for a MRI-guided breast intervention procedure should provide sufficient information to demonstrate the medical necessity of the examination and allow for its proper performance and interpretation.

Documentation that satisfies medical necessity includes 1) signs and symptoms and/or 2) relevant history (including known diagnoses). Additional information regarding the specific reason for the examination or a provisional diagnosis would be helpful and may at times be needed to allow for the proper performance and interpretation of the examination.

The request for the examination must be originated by a physician or other appropriately licensed health care provider. The accompanying clinical information should be provided by a physician or other appropriately licensed health care provider familiar with the patient’s clinical problem or question and consistent with the stated scope of practice requirements. (ACR Resolution 35, adopted in 2006)

The decision to recommend an MRI-guided breast interventional procedure should be made only after a complete imaging evaluation of the breast has been performed, including diagnostic mammography and breast US, if appropriate.

Benefits, limitations, and risks of the procedures as well as alternative procedures should be discussed with the patient. Informed consent should be obtained and documented.

Adherence to the Joint Commission’s Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™ is required for procedures in nonoperating room settings.

The organization should have processes and systems in place for reconciling differences in staff responses during the “time-out.”

B. Procedure Technique

The breast is stabilized with light to moderate compression between grid plates. A precontrast image may be obtained to confirm that the breast is adequately positioned so that the targeted lesion lies within the area of accessibility. If necessary, the patient can be repositioned (for example, if the lesion is posterior to the area of accessibility). A postcontrast MRI is then performed to target the specific location of the lesion. In cases where computer-aided detection (CAD) systems are used, the computer-generated coordinates are annotated and the skin entry site is prepared.

The breast, the field in which the procedure is to be performed, and the physician performing the procedure should be prepared in conformity with the principles of infection control. Local anesthetic should be administered. Documentation of appropriate needle/biopsy device positioning for sampling or localization should be obtained as part of the medical record.

Following performance of MRI-guided breast biopsy, a tissue marker should be placed at the biopsy site.

To minimize hematoma formation, the skin entry site and the region of needle sampling should be adequately compressed until hemostasis is achieved.

A postprocedure mammogram should be performed in 2 orthogonal views to document tissue marker position, and the report should state the position in relation to the biopsy site.

If a lesion for which biopsy was recommended is not seen at the time of biopsy, which can occur in up to 13% of cases, short-interval follow-up MRI should be obtained to be certain the lesion is indeed absent; (see below VI.C.4 and 5) [40].

VI. DOCUMENTATION

Permanent records of MRI-guided breast interventions should be documented in retrievable image storage format.

A. Image labeling should include permanent identification containing:

1. Patient's first and last names
2. A unique identifier (eg, medical record number and/or date of birth)
3. Examination date
4. Facility identification
5. Designation of the left or right breast
6. Annotation of sequence used
7. MRI technologist's identification number or initials

Physician identification may be included on the permanent image record.

B. The physician's report of MRI-guided breast intervention should include:

1. Procedure performed
2. Designation of the left or right breast
3. Description and location of the lesion
4. Approach used
5. Safety time-out having been performed
6. Type and amount of contrast material
7. Type of local anesthesia, if used
8. Skin incision, if made
9. Gauge of needle and type of device (spring-loaded, vacuum-assisted, etc)
10. Number of specimen cores or samples, if applicable

11. Tissue marker placement, if performed, with specification of name and shape of metallic marker
12. Complications and treatment, if any
13. Postprocedure mammogram, if obtained, documenting tissue marker placement and location of the marker with respect to the biopsied lesion.

C. Postprocedure patient follow-up should consist of the following:

1. Documentation of any delayed complications and treatment administered
2. A determination of concordance of pathology results with imaging findings should be documented in the final report. The technical constraints inherent to MRI biopsy may make the determination of radiologic-pathologic concordance challenging. Unlike US-guided biopsy, the biopsy needle cannot be visualized in real time. Unlike stereotactic-guided biopsy, in some MRI biopsy systems the introducer rather than the biopsy needle is imaged, serving as a proxy for needle location. Therefore, radiologic-pathologic correlation is key and imaging follow-up may be warranted. The radiologist performing the procedure (or a qualified physician-designee) is responsible for determining concordance and for taking appropriate steps to manage discordance. Pathology results must be checked and correlated with MRI lesion imaging appearance. If the lesion appearance is discordant with MRI biopsy histology, repeat MR-guided biopsy or surgical excision is recommended [41-43].
3. Management recommendations based on tissue sampling results, imaging information, and concordance analysis
 - a. Upgrade rates to malignancy and false negatives at biopsy may be slightly higher for MRI-guided biopsy than for stereotactic-guided biopsy and US-guided biopsy [44], which makes radiologic-pathologic review particularly essential [45,46].
 - b. Recommendations are based on tissue sampling results, imaging information, and concordance analysis. Surgical consultation is usually recommended for high-risk lesions known to be subject to upgrade, including atypical ductal hyperplasia, flat epithelial atypia, lobular neoplasia (atypical lobular hyperplasia and lobular carcinoma in situ), radial scar, complex sclerosing lesions, phyllodes tumor, and, to a lesser degree, papilloma [47-51]. However, controversies exist regarding high-risk lesions, and care should be individualized when appropriate [48,52]. For malignant results, patients are usually referred for consultation to a surgeon or oncologist.
 - c. If a lesion is both benign and concordant after MRI-guided biopsy, further intervention/excision will usually not be needed. However, because determination of concordance after MRI-guided biopsy may be challenging as described above, short-term follow-up may be recommended in order to identify any false-negative biopsy results. This may be particularly warranted for nonspecific benign pathology (eg, fibrocystic change) versus a more specific benign diagnosis [43,53].
4. Record of communication of positive biopsy results with the patient and/or referring physician
5. In the event that a lesion is not visualized at the time of biopsy, technical factors should be reviewed (eg, inadequate gadolinium contrast administration including intravenous contrast infiltration, excluding the lesion from the area covered by the breast coil, and excessive compression have all been noted to cause lack of lesion visualization on the day of biopsy). Background parenchymal enhancement may also mask a lesion. Because of the low but present risk of a missed malignancy, short-term follow-up is recommended for these cases.

D. Reporting should be in accordance with the [ACR Practice Parameter for Communication of Diagnostic Imaging Findings](#) [54].

E. Retention of the procedure images, including specimen images if obtained, should be consistent with the facility's policies for retention of mammograms and in compliance with federal and state regulations.

VII. EQUIPMENT SPECIFICATIONS

Several needle biopsy devices are available for MRI-guided procedures, including automated core needles and vacuum-assisted devices. The choice depends on the type of lesion as well as the operator's experience. However, vacuum-assisted devices have been shown to be most effective in performing MRI biopsy.

The MRI equipment specifications and performance must meet all state and federal requirements. The requirements include, but are not limited to, specifications of maximum static magnetic field strength, maximum rate of change of magnetic field strength (dB/dT), maximum radiofrequency power deposition (specific absorption rate), and maximum acoustic noise levels.

Technical Guidelines

1. Imaging protocol – The imaging protocol used for MRI-guided intervention is usually high resolution, and the images are obtained quickly as the suspicious lesion may not be visualized due to rapid contrast washout. Therefore, when selecting a protocol for intervention, there are competing demands between rapid acquisition and high resolution. Simultaneous bilateral imaging can be performed when lesions in each breast are being biopsied sequentially or at the same time.
2. Resolution – The slice thickness and the in-plane pixel resolution should be similar so that the lesion in question can be adequately visualized. Sequences using fat suppression are helpful to reduce fat signal so that subtraction imaging may not be necessary to identify the lesion. Sole reliance on subtraction imaging for assessing enhancement may result in misregistration due to patient motion and result in nonvisualization of the lesion, delaying the biopsy and allowing lesion washout. Some imaging protocols for MRI-guided interventional protocols may incorporate both fat suppression and subtraction, and motion-correction software may be helpful in reducing artifacts encountered with image subtraction.
3. Contrast – Gadolinium contrast enhancement is generally needed to identify the lesion that is to undergo biopsy. It should be administered as a bolus with a standard dose of 0.1 mmol/kg followed by a saline flush of at least 10 mL. There is no known benefit to reinjection of contrast following biopsy to verify lesion retrieval. Longer-acting contrast agents that remain within the lesion are under investigation.
4. Scan time – Scan time in relation to contrast injection is extremely important for lesion characterization. If a single postcontrast scan is acquired, the scan time should not extend beyond 4 minutes after bolus injection.
5. Examinations should be performed with a dedicated breast MRI coil equipped with a localization device.

VIII. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education appearing under the heading *Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education* on the ACR website (<http://www.acr.org/guidelines>).

Equipment monitoring should be in accordance with the [ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Magnetic Resonance Imaging \(MRI\) Equipment](#) [39].

Results of MRI-guided as well as other imaging-guided percutaneous breast interventional procedures should be monitored. The following records should be maintained for the facility, practice, and individual physicians:

Reason for Additional Biopsy	Data
Insufficient sample	<ul style="list-style-type: none"> • Number of insufficient cases • Number requiring additional biopsy/excision • Number upgraded after additional biopsy
Discordance with imaging	<ul style="list-style-type: none"> • Number of discordant cases • Number requiring additional repeat biopsy/excision • Number upgraded after additional biopsy
Atypical ductal hyperplasia (ADH)	<ul style="list-style-type: none"> • Number of ADH cases • Number requiring additional biopsy/excision • Number upgraded after additional biopsy
Lobular neoplasia (atypical lobular hyperplasia and lobular carcinoma in situ)	<ul style="list-style-type: none"> • Number of lobular neoplasia cases • Number requiring additional repeat biopsy/excision • Number upgraded after additional biopsy
Other high-risk lesions	<ul style="list-style-type: none"> • Number of high-risk lesion cases • Number requiring additional biopsy/excision • Number upgraded after additional biopsy

Complications requiring treatment categorized by type of biopsy (ie, CNB, FNA):

- Total number
- Number with hematoma (requiring intervention)
- Number with infections requiring treatment
- Number of other complications

Imaging findings and pathologic interpretation should be correlated by the physician who performs the biopsy or a qualified physician-designee. Postbiopsy patient follow-up medical audits should be performed to detect and record any false-negative and false-positive results. Because it is often impossible to document successful lesion sampling at the time of biopsy, follow-up MRI should be performed for nonspecific benign results that are felt to be concordant. This follow-up imaging can be performed in 6 to 12 months. If there is a question concerning the accuracy of sampling, follow-up MRI at a shorter interval may be indicated.

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