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The Critical Role Portable Ultrasound Plays in the Management of Breast Cancer Patients

Dennis R. Holmes, M.D., F.A.C.S | Breast Cancer Surgeon and Researcher
Barry Rosen M.D, F.A.C.S | Breast Cancer Surgeon

Introduction

This white paper will review the critical role that portable ultrasound can play in the management of breast cancer patients, from the office to the operating room. Technology improvements, portability, user experience, training of breast surgeons and workflow will be discussed.

Recent decades have seen increasing utilization of surgeon-performed ultrasound assessment and management of patients with breast diseases. Nonetheless, a survey of fellowship-trained breast surgeons published in 2012 noted that only 39% of respondents considered themselves well-trained in breast ultrasound, and only 28% were well-trained in ultrasound-guided biopsy.[1]

To address this area of need and growing surgeon interest, multiple surgical societies and surgical training programs have established hands-on ultrasound courses and certification programs to ensure surgeon competency in ultrasound interpretation and ultrasound-guided procedures.[2-3]

In addition to increasing surgeon competency, a major factor facilitating the growth of surgeon-performed ultrasound has been advancements in ultrasound design and technology that have expanded the realm of ultrasound beyond the radiology department to include the surgical practice. Ultrasound may now be integrated into every phase of patient care, serving as a supplement to physical examination, to image-guidance of office-based and intraoperative surgical procedures, to postoperative surveillance and follow-up. Although surgeon-performed ultrasound does not diminish the importance of radiology-performed ultrasound, compact, simplified ultrasound designs have increased the portability, operability, and affordability of ultrasound units, while also improving imaging quality and patient satisfaction.

The effort to increase surgeon utilization of ultrasound has been advanced one step further by the development of miniaturized, wireless, hand-held, and increasingly more affordable pocket-sized ultrasound devices that bring ultrasound capability to each and every point of patient care.[4,5] The portability of these units effectively turns every physician examination room into an ultrasound room and ensures that the image seen in the office will be reproducible in the operating room.

A critical role of the breast surgeon is to alleviate patients' concerns regarding the possibility of a cancer diagnosis. It is well established that the greatest anxiety exists in the time between the identification of a breast abnormality and the establishment of a diagnosis.[6] Office-based ultrasound facilitates an efficient problem-solving work-up and is a real-time decision tool that can expedite the diagnosis and avoid many unnecessary steps in a patient's care. This may also facilitate more efficient workflow in a breast center by triaging less complex patients who would otherwise not require a formal radiologic evaluation.

Handheld Ultrasound System

The most recent advancement in ultrasound portability is the introduction of the Viera™ portable ultrasound system (Hologic, Inc., Marlborough, Massachusetts, USA). The Viera portable ultrasound system is a hand-held, wireless ultrasound device consisting of a 14-4 MHz linear array transducer that can be paired via Wi-Fi or Bluetooth to an iOS or Android smart device for image viewing, imaging annotation, and image capture. As the unit is cordless, there is one less device to drape off the operating room table, eliminating cumbersome wires of tethered ultrasound systems. Despite its miniature size and weight [16.7 cm (h) X 9.9 cm (w), X 4.3 cm (d), 540 grams], the Viera system is capable of capturing high-resolution images comparable in quality to larger mid-tier cart-based ultrasound systems. Each unit consists of 192 piezoelectric elements arranged in linear array, utilizing four software beamformers to achieve resolution down to 7 cm, augmented by spatial compounding to reduce imaging noise and speckle. B-mode, M-mode, color flow Doppler, power Doppler, and needle enhancement modes permit a range of uses for breast, vascular, and small parts (thyroid, etc.) diagnostic and interventional procedures.

For the breast surgeon, the Viera system is equipped with breast optimized modes that eliminate dozens of buttons and controls found on typical ultrasound units. Automated time, gain compensation and pre-optimized focal zones permit automated depth-based imaging, minimizing the need for imaging adjustment. Pre-set workflow is simplified to diagnostic and interventional breast modes with controls for dynamic range and dense breasts. The dense breast control optimizes the speed of sound for dense tissue. A customizable annotation package enables efficient documentation, and a breast reporting package allows quick documentation for accurate billing and audit. Secure SSL encryption and HIPAA-compliant protocols allow cloud-based image storage, which can also be integrated with existing PACS or DICOM Services.

The Viera portable ultrasound device is housed in a magnesium shell that buffers the system from damage if dropped from a normal working height (3ft.). The absence of external moving parts further reduces the risk of damage. Water-tight housing, which is IPX7 rated, permits submersion in liquids for up to 30 minutes. The device may also be cleaned with approved germicidal wipes and high-level disinfectants like Cidex OPA. Sterile covers are also available for intraoperative and other sterile procedures.

Clinical Applications

Surgeon-performed breast ultrasound not only increases the sensitivity and specificity of physical examination, it also forms the foundation of a growing number of diagnostic and interventional procedures that have become integral to the management of benign and malignant breast conditions. Furthermore, with the shift toward value-based reimbursement and increased focus on patient outcomes, access to point-of-care ultrasound-guided procedures significantly expand the breast surgeon's sphere of service. The following section lists a sample of clinical applications that are well-suited for surgeon-performed examinations in the office or in the surgical suite.

Office-based use of handheld portable ultrasound:

- **Adjunct to physical examination.** Surgeons with office-based access to ultrasound commonly utilize breast ultrasound as an extension of their physical examination.[7] Depending on the surgeon's experience, office-based ultrasound allows the surgeon to quickly assess and resolve breast pain and lump complaints and triage symptoms that require further workup; identify indeterminate or suspicious findings that warrant a formal radiologic breast imaging workup; and provide convenient follow-up of benign lesions that have been previously worked up. Together, these efforts reduce patient and surgeon anxiety by eliminating or minimizing delays in the diagnostic evaluation of breast symptoms.

- **Minimally invasive biopsy and clip placement.** Ultrasound-guided minimally invasive breast biopsy (MIBB) and clip placement are some of the most widely performed office-based procedures done by surgeons.[8] Ultrasound may be employed to guide MIBB of nonpalpable masses, improve the targeting and accuracy of MIBB of palpable breast masses, and guide core biopsy or FNA of axillary nodes. Ultrasound may also be utilized to guide placement of biopsy site markers to document the location of the biopsied lesion at the time of minimally invasive biopsy.

- **Marker placement prior to neoadjuvant systemic therapy.** In patients selected for neoadjuvant chemotherapy, ultrasound-guided placement of a biopsy site marker within a breast mass and/or biopsy-positive lymph node facilitates targeted excision of the breast lesion or abnormal node if the lesion becomes clinically unapparent following neoadjuvant chemotherapy or endocrine therapy.[9]

- **Percutaneous excision of benign breast masses.** Ultrasound-guided percutaneous excision using large bore (e.g., 8-9 gauge) vacuum-assisted breast biopsy devices is a minimally invasive and cost-effective alternative to open surgical resection of small fibroadenomas and benign intraductal papillomas.[10]

- **Documentation and/or aspiration of breast cysts.** Ultrasound image documentation of asymptomatic breast cysts and/or ultrasound-guided aspiration of symptomatic breast cysts permit quick resolution of a common source of patient concern and identify solid masses that warrant additional workup.[11]

- **Aspiration of post-operative seromas.** Seroma formation is a common sequela of breast and axillary surgery and is sometimes symptomatic. Ultrasound-guided aspiration of a lumpectomy, mastectomy, or axillary seroma greatly increases the safety of the procedure and facilitates complete seroma aspiration.

- **Aspiration of breast abscesses.** Oral antibiotics combined with ultrasound-guided aspiration of small (<3 cm) breast abscesses or indwelling catheter drainage of larger (>3 cm) breast abscesses is the optimal management of uncomplicated simple breast abscesses.[12,13] Surgical incision and drainage should be reserved for patients with complicated breast abscesses (e.g., elevated white blood count, febrile, immunocompromised, diabetic) or multiloculated abscesses that fail percutaneous drainage.

- **Cryoablation.** Percutaneous ultrasound-guided cryoablation of fibroadenomas is another minimally invasive alternative to open surgical resection for fibroadenomas measuring up to 4.0 cm. Percutaneous ultrasound-guided cryoablation of small invasive breast cancers is currently the subject of ongoing clinical trials, but will likely become a standard treatment option available for surgeons with access to office-based ultrasound.[14,15,16]

- **Brachytherapy catheter placement.** Ultrasound-guided placement of intracavitary brachytherapy catheters for accelerated partial breast irradiation has become a well-established alternative to whole breast irradiation following breast conserving surgery. In addition to guiding accurate catheter insertion into the lumpectomy cavity, ultrasound permits precise assessment of tissue conformity and skin distance to ensure effective and safe delivery of radiotherapy.[17]

- **Drainage catheter placement.** Ultrasound may be used to guide precise placement of a pigtail or seroma catheter for management of a recurrent breast or axillary seroma.

- **Sentinel node biopsy.** Preoperative ultrasound improves axillary staging and can identify patients who are candidates for sentinel node biopsy.[18] It is particularly useful for evaluating the clinical response to neoadjuvant systemic therapy for both the index tumor and axillary lymph nodes.[19]

Intraoperative use of handheld portable ultrasound:

- **Ultrasound-assisted lumpectomy.** It is estimated that 20%-30% of all lumpectomies for the treatment of breast cancer require re-excision to obtain adequate margins.[20] The incorporation of intraoperative ultrasound has been shown to reduce re-excision rates and simultaneously reduce lumpectomy volumes for both nonpalpable breast cancers and palpable tumors.[21,22] The increasing adoption of oncoplastic techniques in breast-conserving surgery will only magnify the need for more precise localization techniques, making intraoperative ultrasound indispensable.

- **Localization of nonpalpable breast masses.** Surgeon-performed ultrasound-guided localization of ultrasound-visible nonpalpable breast masses has been shown to be an accurate and cost-effective alternative to wire-directed excision, eliminating common challenges associated with pre-operative wire placement. These include: surgical start time delays and scheduling restrictions; increase patient pain, anxiety and syncopal episodes; inaccurate or indirect wire placement; and wire dislodgement or wire transection. Ultrasound of the targeted lesion in the office prior to surgery will identify potential candidates for ultrasound-guided lesion localization.[23-24] Furthermore, using the same ultrasound ensures reproducibility of the image from the office to the operating room.

- **Hematoma-guided localization.** Patients without ultrasound-visible lesions such as calcifications may be candidates for surgeon-performed ultrasound-guided hematoma localization if the diagnostic MIBB left a small, but ultrasound-detectable, hematoma at the site of the biopsy. Ultrasound of the biopsy site in the office prior to surgery will identify potential candidates for hematoma-guided localization.[25,26] The portability of the Viera unit facilitates repeating the ultrasound in the holding area just prior to surgery to confirm that the hematoma has not resolved in the interim.

- **Lesion localization using ultrasound-visible markers**. Several ultrasound-visible biopsy site markers are currently available for placement at the time of initial MIBB or at a later time to facilitate ultrasound-guided localization.[27,28] Pre-operative review of radiology images should confirm that the marker remains at the site of the targeted lesion to ensure that there is minimal clip migration. Another requirement for hematoma or ultrasound-guided localization is the absence of suspicious microcalcifications extending beyond the immediate vicinity of the biopsy site marker.

- **Adjunct to wire localization.** Intraoperative ultrasound may be used to identify the trajectory and distal end of a localizing wire, allowing the surgery to more accurately determine the path of the wire, and lesion location, as well as eliminate the need for dissection of the wire from its skin entry point. Thus, the surgeon is able to place the incision in the best cosmetic location and use ultrasound to identify the terminus of the wire to target lesion resection.

- **Intraoperative wire placement.** Some surgeons find it useful to combine both wire localization and ultrasound localization of ultrasound visible lesions.[29] For such surgeons, ultrasound-guided placement of a localizing wire in the operating room after the patient has been anesthetized eliminates radiology scheduling and transport delays, patient discomfort, and wire misplacement/dislodgement issues that accompany pre-operative wire placement.

- **In vivo margin assessment.** Intraoperative ultrasound may be used to guide surgical resection of ultrasound-visible palpable and nonpalpable masses.[30,31] Ultrasound of the lesion during the course of dissection facilitates centering of the mass within the resection specimen, real-time planning and adjustment of surgical margins, as well as assessment of lesion proximity to the skin to guide skin flap dissection and/or skin resection.

- **Ex vivo specimen evaluation.** Intraoperative ultrasound may be used in a 'belt-and-suspenders' manner as an adjunct to specimen X-ray and other intraoperative margins assessment techniques to evaluate ex vivo gross margins following complete tumor resection.[32,33] Specimen X-ray commonly yields two orthogonal views of a rhomboid specimen and might misrepresent the width of a surgical margin if the anterior or posterior edge of the specimen projects beyond the margin closest to the mass.

- **Intraoperative radiotherapy (IORT).** Similar to catheter-based brachytherapy, intraoperative ultrasound at the time of IORT is generally used to confirm tissue conformity to the surface of the radiotherapy applicator and to document a safe minimal distance of the applicator to the overlying skin surface.

- **Axillary ultrasound after neoadjuvant systemic therapy.** Intraoperative ultrasound may be used as an adjunct to sentinel node mapping to localize clinically abnormal axillary nodes that remain following neoadjuvant systemic therapy.[34]

Imaging Documentation

The performance of office-based ultrasound necessitates having a system in place to store images and pertinent findings. Viera software includes a proprietary cloud-based storage system that will generate a formal breast ultrasound report using a touch-based template to record pertinent findings containing all elements necessary for a comprehensive ultrasound report. Images and reports can be exported and uploaded into one's existing EMR. In Exhibit 1, we provide a sample practice report template with the most common procedures, required terminology and common billing codes that are supported in the Viera software.

Alternatively, the Viera system supports direct integration with office- and hospital-based electronic medical records, provided there is a DICOM compliant file server. This enables convenient patient identification via Modality Worklist and direct upload of images to multiple DICOM servers.

Conclusion

Hand-held ultrasound offers many advantages over cart-based ultrasound units by providing ultrasound capabilities to each and every point of patient care. Hand-held ultrasound facilitates an efficient problem-solving workup and is a real-time decision tool that can expedite the diagnosis and avoid many unnecessary steps in a patient's care. This reduces patient anxiety and improves workflow in a breast center by improving room utilization. The portability of these units effectively turns every physician examination room into an ultrasound room and ensures that the image seen in the office will be reproducible in the operating room. Breast ultrasound is indeed ready for prime time and can be considered as a stethoscope for the surgeon. We propose that a hand-held ultrasound belongs, quite literally, in every surgeon's pocket.

ULTRASOUND PROCEDURE & REPORT FORM

Authorization #: _____

Date Requested: _____ Date Obtained: _____

Patient Name: _____

Date of Birth: _____

Date of Service: _____ ❑ TBD

❑ Aspiration of Post-operative Seroma (10160, -TC; 76942, -TC)
❑ Aspiration of Breast Abscess (10160, -TC; 76942, -TC)
❑ Ultrasound Guidance for Cryoablation (19105, -TC)
❑ USG Drainage Catheter Placement, soft tissue (10030, -TC)
❑ Global
❑ Other: _____
❑ Other: _____

INDICATION:

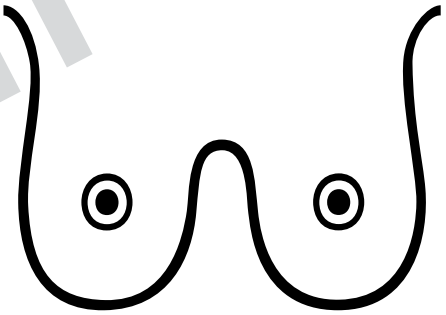
❑ RIGHT ❑ LEFT ❑ BILATERAL breast(s).

❑ Screening (Asymptomatic, Dense Breasts) (Z12.39)
❑ Other abnormal and inconclusive findings on diagnostic imaging of breast (R92.8)
❑ Breast Pain/Mastodynia (N64.4)
❑ Axillary Pain Right Upper Arm, Left Upper Arm (M79.621, M79.622)
❑ Nipple discharge (N64.52) (excludes abnormal findings in nipple discharge)
❑ Breast Lump/Mass (N63.10 - N63.20)
❑ Axillary Lump/Mass, right, left (N63.31-N63.20)
❑ Malignant neoplasms of breast (C50. _____)
❑ Ductal carcinoma in situ, right, left (D05.11, D05.12)
❑ Breast Cyst, right, left (N60.01, N60.02) (unspecified N60.09)
❑ Sebaceous Cyst (L72.3)
❑ Pilar and trichodermal cyst Inclusion Cyst (L72.0)
❑ Localized enlarged lymph nodes (R59.0)
❑ Clip placement For Neoadjuvant therapy (C50._____)
❑ Evaluate Response to Neoadjuvant therapy (C50._____)
❑ Other complications of procedures, not elsewhere classified, initial encounter (T81.89XA)
❑ Other complications of procedures, not elsewhere classified, subsequent encounter (T81.89XD)
❑ Mastitis without Abscess (Breast) (N61.0)
❑ Abscess of the Breast and Nipple (N61.1)
❑ Abscess (Breast, Post-part O91.12; Lactation O91.13)
❑ Mastitis (Post-part O91.22; Lactation O91.23)
❑ Other: _____

PROCEDURE:

❑ RIGHT ❑ LEFT ❑ BILATERAL breast(s).

❑ Ultrasound, breast, unilateral, real-time with image documentation, including axilla when performed; complete (76641, -TC)
❑ Ultrasound, breast, unilateral, real-time with, image documentation, including axilla when performed; limited (76642 -TC)
❑ Ultrasound, limited, joint or other nonvascular extremity structure(s) (eg, joint space, peri-articular tendon[s], muscle[s], nerve[s], other soft tissue structure[s], or soft tissue mass[es]), real-time with image documentation (76882, -TC)
❑ USG VABB/Core Biopsy & Marker Placement (19083, -TC)
❑ USG VABB/Core Biopsy & Marker Placement, each add'l (19804, -TC)
❑ USG Marker, Wire placement (19285, -TC)
❑ USG Marker, Wire placement, each additional (19286, -TC)
❑ USG Breast Cyst Aspiration (19000, -TC; 76942, -TC)
❑ USG Breast Cyst Aspiration, each additional (19001, -TC; 76942, -TC)



SITE#	1	2	3
Size (mmX mmX mm)	X X	X X	X X
Clock Position			
Distance From Nipple (cm)			
Margins	❑ Fuzzy ❑ Sharp ❑ Irregular ❑ Smooth	❑ Fuzzy ❑ Sharp ❑ Irregular ❑ Smooth	❑ Fuzzy ❑ Sharp ❑ Irregular ❑ Smooth
Echogenicity	❑ Anechoic ❑ Hypoechoic ❑ Isoechoic ❑ Hyperechoic	❑ Anechoic ❑ Hypoechoic ❑ Isoechoic ❑ Hyperechoic	❑ Anechoic ❑ Hypoechoic ❑ Isoechoic ❑ Hyperechoic
Internal Features	❑ Homogeneous ❑ Irregular ❑ Mixed	❑ Homogeneous ❑ Irregular ❑ Mixed	❑ Homogeneous ❑ Irregular ❑ Mixed
Posterior Features	❑ None ❑ Enhancement ❑ Shadowing	❑ None ❑ Enhancement ❑ Shadowing	❑ None ❑ Enhancement ❑ Shadowing
Edge Shadowing	❑ None ❑ Irregular ❑ Bilateral Symmetric	❑ None ❑ Irregular ❑ Bilateral Symmetric	❑ None ❑ Irregular ❑ Bilateral Symmetric
Height / Length	❑ Height > Length ❑ Height < Length	❑ Height > Length ❑ Height < Length	❑ Height > Length ❑ Height < Length
Axilla	❑ Benign ❑ Malignant ❑ Indeterminate	❑ Benign ❑ Malignant ❑ Indeterminate	❑ Benign ❑ Malignant ❑ Indeterminate
Impression	❑ Simple Cyst ❑ Complex Cyst ❑ Benign Solid ❑ 89 Fibroglandular Area ❑ Indeterminate ❑ Suspicious ❑ BIRADS 6 ❑ Other:	❑ Simple Cyst ❑ Complex Cyst ❑ Benign Solid ❑ 89 Fibroglandular Area ❑ Indeterminate ❑ Suspicious ❑ BIRADS 6 ❑ Other:	❑ Simple Cyst ❑ Complex Cyst ❑ Benign Solid ❑ 89 Fibroglandular Area ❑ Indeterminate ❑ Suspicious ❑ BIRADS 6 ❑ Other:
Plan	Observe Aspirate Biopsy Other:	Observe Aspirate Biopsy Other:	Observe Aspirate Biopsy Other:

Physician: _____ Signature: _____ Date: _____

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United States / Latin America
250 Campus Drive
Marlborough, MA 01752 USA
Tel: +1.877.371.4372
Sales: +1.781.999.7453
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www.hologic.com