
Comprehensive Review of Mammotome® elite™

*Kimberly C. Hutcherson, MD/North Metropolitan Radiology Associates,
LLP/Gwinnett Breast Center/Gwinnett Medical Center Lawrenceville, GA 30046*

Introduction and Discussion

Minimally invasive breast biopsy (MIBB) is a well-established method of diagnosing most suspicious image-detected lesions and is now widely accepted as the standard of care. Open surgical biopsy, the alternative option, should be reserved for a select group of individuals, between 5% and 10%, whose lesions are not amenable to image-guided biopsy due to their location or patient limitations [1,2,3,4,5,6,7,9].

The major objective of MIBB is to derive sufficient histology to provide a confident radiologic-pathologic concordance while minimizing procedure time, cost and post-procedure morbidity [1,3,4,5]. For patients with malignant diagnoses, minimally invasive breast biopsy facilitates preoperative multidisciplinary treatment planning. The therapeutic team (surgeons, medical oncologists, and radiation oncologists) can accurately counsel patients with an efficient and definitive therapy plan that incorporates appropriate preoperative imaging staging, consultation with pertinent specialists, and surgical planning that includes sentinel lymph node dissection. Preoperative planning will increase the likelihood of adequate resection with clear margins at the initial surgery and minimize the need for re-excision [1,3,4,5].

Moreover, MIBB provides a major benefit for patients with benign lesions: radiologic-pathologic concordance of benign diagnoses eliminates the need for open surgical biopsy. Following MIBB, the patient has a small scar and minimal post biopsy changes as visualized on future mammograms [4,5].

Percutaneous needle tissue acquisition has transitioned from cytology (fine needle aspiration [FNA]) to histology (spring-load core biopsy [SLC] and vacuum-assisted biopsy [VAB]). This trend has been driven by the increased histological accuracy provided by larger tissue samples. These larger samples enable pathologists to provide definitive diagnoses and biological parameters to guide treatment planning [2,5].

MIBB Device Choices

There are many devices to choose from when performing an image guided minimally invasive breast biopsy. Image guidance options include ultrasound, stereotactic, MRI and MI guidance. A VAB system has been the standard of care device for stereotactic and MRI guided breast biopsies for the past decade. However, there are many options available for ultrasound-guided breast biopsies. The device that one chooses should be based upon ease of use, reliability of tissue acquisition, quality of the acquired tissue, and cost. Above all, after performing a radiologic-pathologic correlation, physicians must be confident that their biopsy device will provide tissue acquisition of sufficient quality to confirm a diagnosis (5,7).

Spring-loaded core biopsy

Most interventional breast physicians are well trained and comfortable using either 12 or 14-gauge spring-loaded breast biopsy devices. These devices are operator dependent and typically provide reliable diagnoses when used either freehand or under ultrasound guidance. They require minimal set-up, use minimal space and provide a low-cost option for quality care.

While there are real advantages, spring-loaded core biopsy devices do have distinct disadvantages. Primarily, the design of these devices necessitates a unique insertion and removal for every sample desired, causing procedural inefficiency. More passes are often needed to obtain adequate tissue samples, increasing the risk of discomfort or complications to the patient. Additionally, due to limitations in the capability of these devices, the samples obtained are often small and fragmented. The firing mechanism used to acquire tissue causes a popping noise that patients often find disconcerting. Furthermore, the requirement to fire devices creates the potential risk of complications with lesions that are located within sensitive areas (i.e., near a breast implant, near the patient's chest wall or in the axilla.)

Large tethered VAB

Large tethered VAB devices offer consistent quality tissue samples and subsequent reduced possibility of false-negatives as well as underestimation of the disease process. Another advantage is the ability to perform therapeutic removal of small, probably benign masses such as fibroadenomas. In these situations, the possibility of a sampling error has been virtually eliminated [2,8,9]. While large tethered VAB devices offer several advantages, there are limitations. One is their inability to biopsy all lesion types. Some lesions are less amenable to biopsy using large VAB devices due to their location (axilla, near implant, near chest wall, or near nipple) or the patient's history (lactating breast [10] or large painful mass). In addition, large tethered VAB devices require additional set-up time as well as more space in the biopsy room. Some facilities have space limitations and limited access to additional technologists to set up and monitor equipment; however they nonetheless desire to offer a high-quality VAB device for their patients.

Mammotome® elite™ Benefits

Mammotome® elite™ is the first single-insertion, tetherless, vacuum-assisted breast biopsy device with TruVac™ vacuum technology. This revolutionary device combines vacuum-assisted biopsy tissue quality (Figure 1) with the ease and speed of a core needle. The TruVac™ vacuum system both acquires and transports tissue from the biopsy site to the collection cup. This exciting new technology has greatly simplified the overall procedure by eliminating the need to remove the biopsy needle from breast tissue in order to retrieve a tissue sample. There is no need to re-visualize and relocate the mass to obtain additional tissue samples, greatly reducing the risk of sampling error. Additionally, there is no need to prepare (or “arm”) a needle with multiple hand maneuvers. Procedure time has been reduced significantly, with reliable tissue acquisition every 8 seconds. Compared with the 12-gauge multiple-insertion hand-held device used in my practice, the time to acquire tissue is extremely fast and accurate, with the ability to obtain 4 cores in 35 seconds.

The single-insertion, non-firing, bladed probe tip moves easily through tissue while maintaining control of the needle and minimizing the time required between tissue samples. The needle can easily be repositioned inside the mass to quickly obtain multi-level sampling as the needle aperture closes after acquisition of each tissue sample.

Set up of the Mammotome® elite™ is quite efficient. No additional staff is needed to monitor the biopsy equipment controls; the Mammotome® elite™ encompasses no additional floor space, as it only requires a small footprint of counter space for set-up and storage.

Ergonomically, the Mammotome® elite™ offers user flexibility that includes easily accessible one-touch sampling. The SelectGrip activation option allows selection of one of three preferred hand positions. Whether users grip overhand or underhand, one of three sample buttons are accessible. Additionally, the 360-degree needle rotation permits adjustment of the needle aperture orientation based upon position and desired approach to lesions.

Tissue markers are routinely placed following image-guided breast biopsies. Marking the biopsy cavity is beneficial for future follow-up, localizing biopsy sites for definitive surgery with malignant or atypical pathology and localizing the malignant site following neo-adjuvant chemotherapy [2]. With Mammotome® elite™, efficient and accurate placement of tissue markers is facilitated by the optional integrated coaxial cannula.

Tissue sample quality can be visualized through the clear sample cup and the tissue can be easily transported to pathology via the quick release design of the basket. The 13-gauge needle aperture collects more than three times the sample weight compared with a 14-gauge core needle (Mammotome® elite™, Devicor Medical Products, Inc. 2012.)

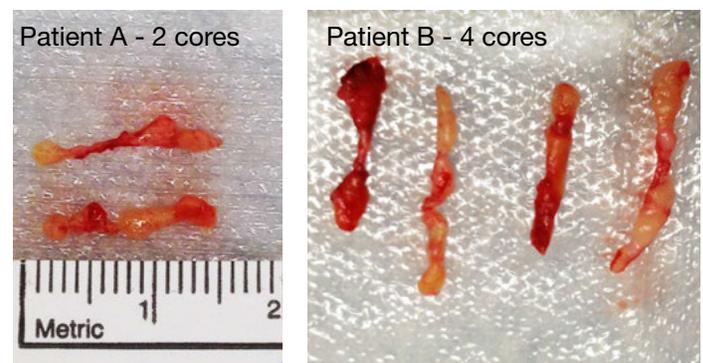


Figure 1: Mammotome® elite™ 13-gauge tissue samples

The ergonomic, reliable and efficient features of the Mammotome® elite™ will appeal to physicians who perform ultrasound-guided breast biopsies. Those using spring-loaded core devices or breast biopsy systems that require multiple insertions should re-evaluate their goals relative to their patient's needs and their practice efficiency.

Transition to Mammotome® elite™ in my practice

In my practice, I have transitioned from FNA to SLC to VAB devices in an effort to obtain diagnostic accuracy for suspicious breast lesions, thereby minimizing and/or eliminating insufficient or inconclusive diagnosis. My objective is to obtain quality tissue to provide a definitive diagnosis and biologic parameters to guide treatment planning; while minimizing procedure time, cost and post-procedure morbidity. When the Mammotome® elite™ was released, providing the option of single-insertion contiguous tissue samples with a 13-gauge aperture, I easily transitioned the device into my breast practice and eliminated those devices that required multiple-insertions. This addition to my practice has enabled me to safely biopsy all types of masses with a minimal learning curve for physicians and staff (ease-of-use and ease-of-setup); significantly shortened the time to acquire quality tissue samples (8 seconds); and enabled consistent visibility of suspicious lesions at all times during procedures, thus assuring confidence that the appropriate area of concern is biopsied.

Axillary lymph nodes

The sharp tip of the Mammotome® elite™ needle allows for easy placement through the cortex of a suspicious lymph node without node displacement (Figure 2.) This lightweight, tetherless device can easily be maneuvered in this sensitive area, minimizing the risk of complications. The 13-gauge Mammotome® elite™ aperture is highly visible during sampling and provides ample time to make slight adjustments if necessary. The ability to obtain contiguous samples through a single insertion is essential to maximizing the speed of this procedure. The TruVac™ vacuum system transports tissue from the biopsy site to the collection cup for easy transport to pathology.

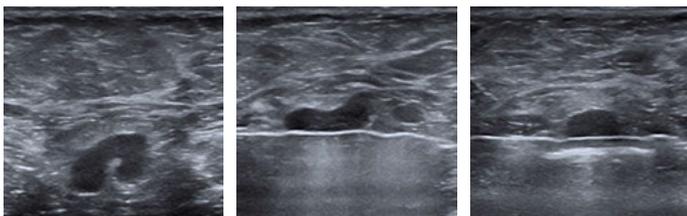


Figure 2: Metastatic Lymph Node

BI-RADS 5 or Large Benign Mass

Larger masses (malignant and benign) are also successfully

biopsied using the Mammotome® elite™. The non-firing bladed insertion tip moves easily through tissue, offering the ability to sample multiple levels of the mass quickly. The needle aperture remains closed after each sample, permitting quick and easy repositioning of the needle within the mass. The needle need not be removed from the breast to retrieve a tissue sample. The TruVac™ vacuum technology acquires large tissue samples and reliably transports tissue from the biopsy site to the collection cup.

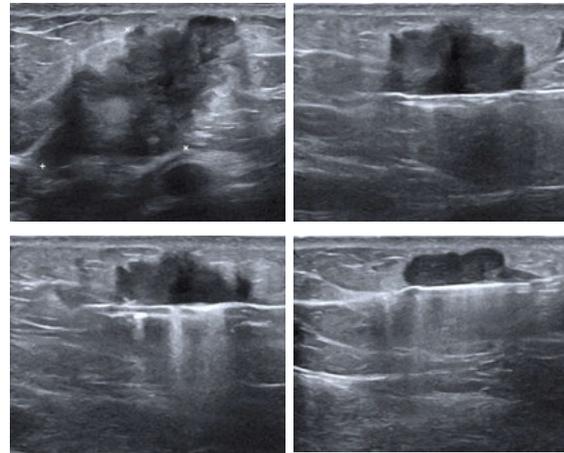


Figure 3: Large Cancer invading pectoralis muscle – Multiple levels of mass biopsied

Intraductal or Small Solid Mass

Intraductal masses or small solid (benign or malignant) masses are amenable to biopsy using the Mammotome® elite™. In figure 4, suspicious intraductal masses are identified in a pregnant/lactating female. Given the possibility of developing a milk fistula within this patient population, a small-gauge single-insertion device is ideal [10]. After the initial tissue sample is acquired, visibility of the mass will likely diminish. In this situation, the ability to maintain visibility of the biopsy site and obtain contiguous samples is essential to a successful biopsy.

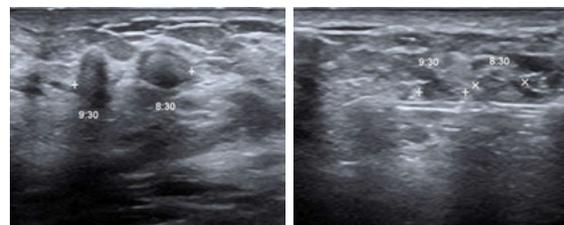


Figure 4: Intraductal Masses in Lactating Patient

Small (less than 1 cm) masses such as fibroadenomas are clearly seen in the 13-gauge aperture figure 5. The ability to place a needle beneath the mass and take multiple contiguous samples in one insertion offers the potential for complete therapeutic removal of the mass and significantly reduces sampling error.

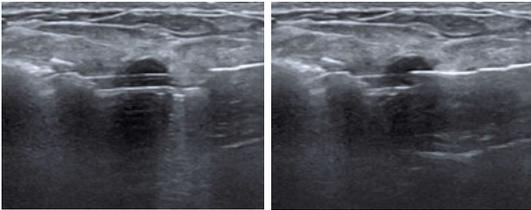


Figure 5: Small Solid Mass (Fibroadenoma)

Complex Cystic Mass

The Mammotome® elite™ offers several advantages to facilitate the biopsy of complex cystic masses. Simultaneously acquiring the solid and fluid components of the mass in the collection chamber virtually eliminates a sampling error ensuring an accurate pathologic diagnosis. The device's aperture is placed at the posterior surface of the mass. The TruVac™ vacuum technology acquires large tissue samples and reliably transports the tissue and fluid from the biopsy site to the collection cup. The quick release design of the collection basket enables touchless transfer of tissue and fluid to pathology.

If biopsy of a complex cystic mass is performed using a SLC device or other VAB system, the solid component of the mass is biopsied but the fluid component is not acquired unless aspirated initially. The possible limitation following aspiration of the fluid component is diminished visibility of the solid component of the mass. Mammotome® elite™ offers the ability to sample all components of the complex cystic mass for pathology. The integrated coaxial cannula subsequently enables efficient and accurate placement of the tissue marker following the biopsy (Figure 6.)

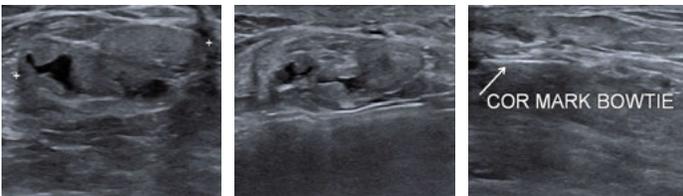


Figure 6: Complex Cystic Mass with Tissue Marker Placement

Conclusion

Mammotome® elite™ offers the best of both worlds—an easy-to-use and efficient device that acquires consistent quality tissue samples. With multiple interventional breast radiologists in my practice, the Mammotome® elite™ platform offers an added advantage of a quick learning curve that is easy to integrate. The inclusion of Mammotome® elite™ in my practice both complements and completes the tools at my disposal. I use larger gauge VAB devices to biopsy many lesions in the breast, particularly suspicious masses with calcifications (with specimen x-ray to confirm calcifications) and therapeutic biopsies of probably benign masses. Mammotome® elite™ offers a small gauge VAB device for sensitive masses that are less amenable to larger gauge needles (axilla, near implant, near the chest wall, near the nipple, lactating breast and large painful cancers). It combines the advantages of a single-insertion VAB device with the ease-of-use of a core needle. This makes the Mammotome® elite™ an ideal addition to my practice.

If your practice does not consistently use VAB devices, Mammotome® elite™ is an excellent starting point to transition from SLC to VAB devices. Mammotome® elite™ is engineered to bridge the gap between multiple insertion biopsy devices and single-insertion, ergonomically friendly VAB devices. The advantages over alternate systems are 1) a single insertion 13-gauge aperture; 2) multiple consistent contiguous samples; 3) ergonomic ease-of-use; and 4) closed TruVac™ vacuum system to transport tissue from the biopsy site to the collection cup for easy transport to pathology. The Mammotome® elite™ may be your only biopsy device or it may be used as a specialty device for avid larger gauge Mammotome biopsy users, when a smaller gauge VAB device for difficult-to-reach sensitive areas is required. Mammotome® elite™ is a revolutionary and novel device that should allow any center to seamlessly integrate the utilization of VAB technology into their practice.

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