



Clinical Highlights

Mammotome® Elite

Tetherless Vacuum-Assisted Biopsy System

13G Mammotome® Elite Biopsy Device vs. 14G Core Needle

Studies showed the 13 gauge Mammotome® Elite device successfully and accurately sampled lesions and reduced underestimation rate as compared to a 14 gauge core needle for non-mass breast lesions under ultrasound-guided breast biopsy¹⁻⁶

Original Article:	Ultrasound-guided cable-free 13-gauge vacuum-assisted biopsy of non-mass breast lesions
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Objective:

The objective of this study was to compare the outcomes of ultrasound-guided breast biopsy by the 13 gauge Mammotome® Elite device and conventional 14 gauge spring loaded core needle for patients with non-mass like lesions.

Methods:

Investigators conducted a prospective study of patients with ultrasound detected non-mass like lesions to identify patients meeting the following criteria:

- Non-mass like lesions classified as BI-RADS category 4 or 5
- Non-mass like lesions with and without suspicious microcalcifications on ultrasound, correlated previously using mammography or via breast MRI

216 patients met these criteria. The study included 125 patients with 145 lesions classified as BI-RADS category 4 or 5.

Clinical, radiologic and pathologic data was correlated and analyzed to determine the success rate between the two devices.

Device of choice for biopsy was determined based on patients consent to use the Mammotome® Elite device (wireless VAB) in place of a 14 gauge spring loaded core needle.

Discussion:

The 13 gauge Mammotome® Elite device was able to accurately target lesions and improve pathologic diagnosis when compared to 14 gauge core needle.

- The Mammotome® Elite device as a hand-held, cable-free VAB system was able to access lesions accurately.
- Significant reduction in DCIS underestimation was observed with the Mammotome® Elite device.
- No radiologic-pathologic discordance was observed with the Mammotome® Elite device during post-biopsy analysis of the samples.
- The Mammotome® Elite device provided larger tissue samples than the 14 gauge core needle.

No major complications were observed during and after biopsies with both the Mammotome® Elite device and 14 gauge core needle (n=145).

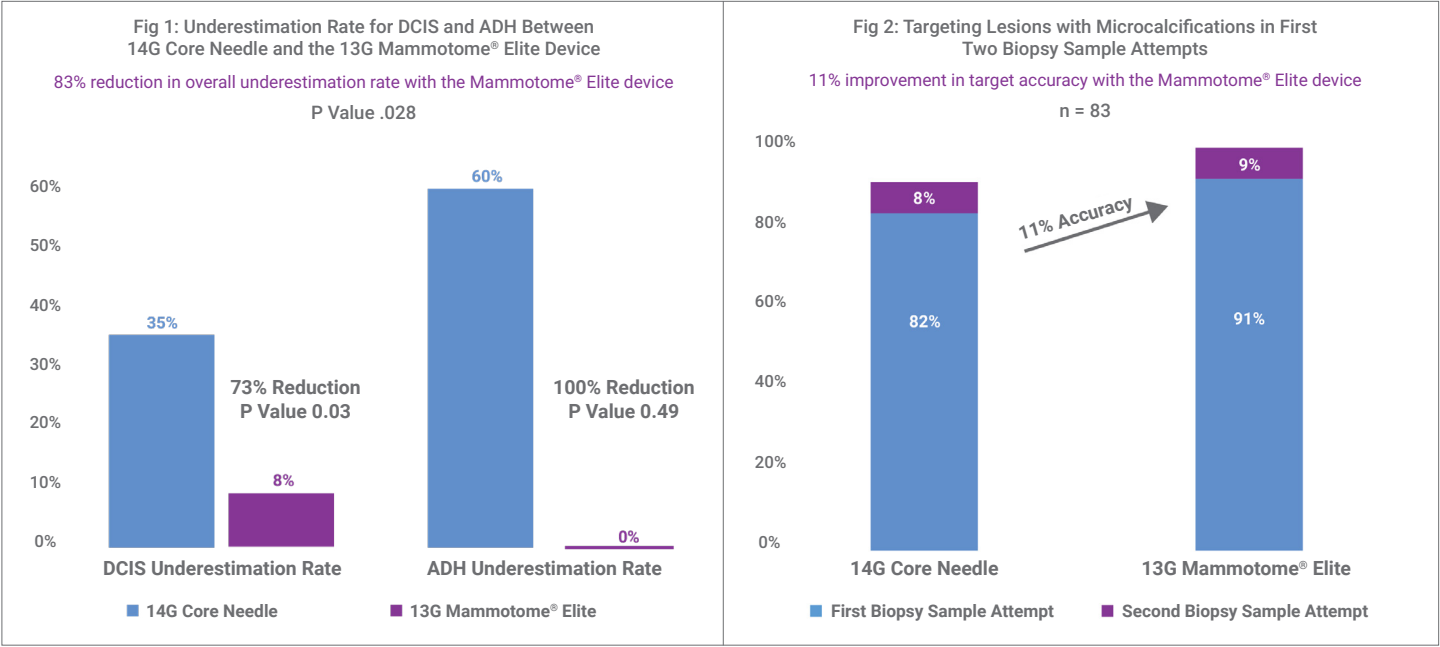
- Hematomas <3cm were observed on immediate post biopsy with both techniques.
- None of the patients developed hematomas or wound infections requiring treatment.
- Follow up of patients was limited to a week after biopsy and three months after biopsy.
- More tissue samples were easily obtained using the Mammotome® Elite device (avg. 9) in comparison to core needle (avg. 6) that helped in better histo-pathological correlation.

The ultrasound-guided 13 gauge Mammotome® Elite device was found to be superior in retrieval of microcalcifications visible under ultrasound for non-mass like lesions.

Results:

During the 16-month study period, which included 145 lesions and 125 patients, the results were:

- 100% accuracy in sampling of target lesions using the Mammotome® Elite device.
- 83% reduced underestimation of DCIS and ADH with the Mammotome® Elite device compared to 14 gauge core needle (Fig 1).
- 0% radiologic-pathologic discordance was observed with the Mammotome® Elite device.
- 100% accuracy in targeting lesions with calcifications using the Mammotome® Elite device.
- 11% increase in accuracy in targeting lesions with calcifications using the 13 gauge Mammotome® Elite device (Fig 2).



Key Points:

This landmark study demonstrates that the 13 gauge Mammotome® Elite device improves targeting accuracy, reduces pathological discordance, and decreases the appearance of mammographic alterations of a core needle.⁷

The finding of hypoechoic area in ultrasound with microcalcification showed statistical significance in occurrence of malignant lesions and positive prediction for DCIS.

- The Mammotome® Elite device provided accuracy in sampling these lesions efficiently. Multiple studies have identified non-mass like lesions with and without calcifications to be visible under ultrasound for biopsy.^{7,8}
- The frequency of malignancy tends to rise when calcifications associated with these lesions are visible under ultrasound.

This study examined the occurrence and visibility of non-mass like lesions under ultrasound and biopsy sample outcomes that prove the benefit of using the 13 gauge Mammotome® Elite device over a 14-gauge core needle.

Conclusion:

The Mammotome® Elite device is the leading single insertion, tetherless vacuum-assisted breast biopsy device for ultrasound-guided procedures. In addition to general ultrasound breast biopsy use on various lesion/mass types, the Mammotome® Elite device is also useful when suspicious nonpalpable, non-mass like lesions are visible under ultrasound with and without calcifications. Use of the Mammotome® Elite device improves accuracy and reduces false-negative biopsy results.

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*Clinicians noted were in practice at the institution at the time of the study.

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