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Original article

# Serial image changes in ultrasonography after the excision of benign breast lesions by mammotome<sup>®</sup> biopsy system



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#### ABSTRACT

Mammotome-an ultrasound guided vacuum-assisted breast biopsy (VABB) device, has proved beneficial to the treatment of benign breast lesions. The aim of this study is to analyze the characteristics of ultrasound images of residual cavity and the changes in ultrasound images at follow-up at different intervals after the excision of benign breast lesions by Mammotome<sup>®</sup> biopsy system. A series of 247 consecutive 8-gauge Mammotome<sup>®</sup> procedures were performed under ultrasound guidance and multivariate analysis was conducted. We found fibroadenoma and adenomatosis are appeared to be the most common pathological manifestations. Follow-up by ultrasonography at an interval of one month after excision of benign breast lesions by 8-gauge vacuum-assisted Mammotome<sup>®</sup> biopsy system, is not reliable due to the residual cavity formation. A follow-up schedule starting from at least 3 months after resection is highly recommended.

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#### 1. Introduction

Benign breast lesions (BBLs) distribute an elevated incidence for women worldwide (Lakoma et al., 2014). The benign process will happen in the majority of patients with a clinical breast lesion. The outcomes of proliferation of ductal or lobular tissue are manifested by the presence of palpable lumps or masses (Alcorn, 1973). Although BBL is not life threatening, it is worthy of attention due to its high incidence, its increasing size, and the potential to cause cancer (Jang et al., 2017). Therefore, it is essential to excise benign lesions. In order to avoid the observable incision of the breast and achieve a better cosmetic outcome, most patients prefer for the complete excision of the minimally invasive procedure. In recent years, such procedures are increasingly available due to the rapid technological progress in the development of minimally invasive diagnostic tools (Kong et al., 2016). The use of the

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Mammotome<sup>®</sup> biopsy system (Ethicon Endo Surgery, Inc., Cincinnati, OH, USA), an ultrasound guided vacuum assisted breast biopsy (VABB) system, was introduced in the late 1990s and has proven to be a valuable innovation in the treatment of breast lesions (Jiang et al., 2013; Pan et al., 2014). The benign breast lesions can be excised in a minimally invasive and more precise tissue harvesting manner using the ultrasound guided Mammotome biopsy system. Complete excision without residual tissue is possible in the most cases (Povoski, 2007; Povoski and Jimenez, 2007).

Till now, most of the researches have focused on hematomas, scars, perception of pain and recurrence, and follow ups between 3 and 60 months have reported after ultrasound-guided complete excision of benign breast lesions (Karanlik et al., 2015; Povoski, 2007; Debi et al., 2015; Meloni et al., 2001), however, very few studies reporting on follow-up by ultrasonography for close interval image change observation.

The aims of this study are to analyze the characteristics of ultrasound images of residual cavity and the changes in followup ultrasound images at different intervals after excision of benign breast lesions by Mammotome<sup>®</sup> biopsy system.

#### 2. Material and methods

This study protocol was approved by the Ethics Committee of Zibo Central Hospital (WSA03030). All the enrolled patients

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(age range from 19 to 50 years old) have signed the informed consent. It includes 247 patients for consecutive procedures performed from December 2011 to November 2012, under ultrasound guidance using the 8-gauge Mammotome<sup>®</sup> breast biopsy system.

Before the Mammotome procedure (Choi et al., 2015), patients were subjected to routine blood tests and blood coagulation examinations. All breast lesion excision procedures were performed by skilled professionals. A Terason t3000 ultrasound system (Teratech Corporation, Burlington, MA, USA) with high resolution linear array transducers (12L5A, 5-12 MHz) was used to provide real-time ultrasound guidance. Intracutaneous injection was performed by a local anesthetic consisting of 1-2 mL1% lidocaine with a 26gauge needle. After that an additional amount (5-7 mL) of a  $5 \,\mu g/ml$  epinephrine was administered just underneath the lesion in order to create a space for the mammotome hand-heldultrasound-guided device. A 3-5 mm skin incision was made and the 8-gauge Mammotome was positioned with the aperture of the needle just beneath the ultrasound-visualized lesion (Fig. 1). To ensure precise localization, the target lesion was rescanned with the probe. The vacuum biopsy resulted in excision of several specimens; the probe was then repositioned according to residual tissue as visualized by ultrasound images. In all patients, the biopsy was performed with a single insertion and a single placement of the device under the tumor. Depending on the size of the tumor, the location and consistency of the surrounding tissue, the duration of biopsy was 20-30 min.

The procedure was terminated when no remaining tumor could be identified, or the site of the lesion was obscured by air or blood (Fig. 2), which occurs during incision of a series of specimens. The patients herself compressed the breast for 5–10 min following the standard procedure. Then, the incision was covered with an elastic bandage and the patients were on bed rest for 6 h.

Histological examination was performed on all specimens. The excised specimens were dipped in 10% formalin and immediately submitted to the department of pathology, Zibo Central Hospital, for definite histopathologic diagnosis. If the patient had bilateral lesions; specimens from different breasts were separated. If not, the specimens were mixed even though multiple lesions were excised. The report was generally obtained within1 day. The follow-up was carried out with ultrasonography between 1 and





**Fig. 1.** An ultrasound image along thelongitudinal axis showing the 8-gauge Mammotome positioned with the aperture of the needle just beneath the ultrasound-visualized lesion.



**Fig. 2.** An ultrasound image along the longitudinal axis showing the area of 8-gauge Mammotome excision of the previously shown lesion.

48 months (1-, 3-, 6-, 12-, 24-, 48-months) in order to observe the ultrasonography image changing.

#### 3. Results

#### 3.1. Patient demographics and basic tumor characteristics

Patient demographics and characteristics of the original breast lesions as seen on the pre-Mammotome procedure ultrasound are shown in Table 1. In the cases of all 247 ultrasound-guided8gauge Mammotome biopsy procedures were performed, it was assumed that the ultrasound lesion had been completely excised during Mammotome core acquisition. Among 247 procedures, the majority of patients (81%) younger than 35 years appeared to have the breast lesion completely excised during the 8-gauge Mammotome core acquisition, and classification of the breast lesion showed a predilection towards BI-RADS category 3 (17%)



Patient demographics and characteristics of the original breast lesions seen on the pre-Mammotome<sup>®</sup> procedure ultrasound: all cases attempted to completely excise the breast lesion (n = 247).

( )	
Parameter	n (%)
Age (years)	
<35	199 (81)
≥35	48 (19)
Gender	
Female	245 (99)
Male	2(1)
Breast	
Unilateral	211 (85)
Bilateral	36 (15)
Palpable tumor	
Yes	120 (49)
No	127 (51)
Lesion location	
UOQ	136 (55)
UIQ	44 (18)
LOQ	35 (14)
LIQ	25 (10)
Subareolar	7 (3)
BI-RADS classification of ultrasound	
Category 3	42 (17)
Category 4	178 (72)
Category 5	27 (11)

UOQ, upper outer quadrant; LOQ, lower outer quadrant; UIQ, upper inner quadrant; LIQ, lower inner quadrant; BI-RADS, breast imaging reporting and data system. or 4 (72%). Most lesions occurred in the upper outer quadrant (55%) and unilateral breast (85%). A comparable number of palpable and non-palpable tumors were observed.

#### 3.2. Histopathological examination of specimens

The final histopathology of the material excised by ultrasoundguided 8-gauge Mammotome<sup>®</sup> biopsy rendered all the lesions benign, with fibroadenoma appearing as the most common pathological manifestation (Table 2). A variety of other benign breast diseases, such as adenomatosis, lipoma, papillomatosis and atypical ductal hyperplasia were also observed. No post-procedural infectious complications were observed.

#### Table 2

Histopathological characteristics for the ultrasound-guided 8-gauge Mammotome<sup>®</sup> biopsy technique: all cases attempted to completely excise the breast lesion (n = 247).

Fibroadenoma 219 (89)   Adenomatosis 15 (6)   Lipoma 5 (2)	Histopathological diagnosis	n (%)
Lipoma 5 (2)	Fibroadenoma	219 (89) 15 (6)
	Lipoma	5 (2)
Papillomatosis 6 (2) Atypical ductal hyperplasia 2 (1)	Papillomatosis Atypical ductal hyperplasia	6 (2) 2 (1)

#### 3.3. Interval change on ultrasound image follow-up

No single report has comprehensively detailed the ultrasound image on the close interval change conducted ultrasound-guided breast biopsies performed using the 8-gauge Mammotome® breast biopsy system. Except 8 patients who failed to return for follow-up examination, of the remaining 239 patients performed for the close interval follow-up examination (1, 3, 6, 12, 24, 48 months). In the case of fibroadenoma, as is shown in the Fig. 3, an ultrasound image taken on the last pre-operative day showed the site of the lesion as a region of low echogenicity (Fig. 3A). Interestingly, one month after resection, the earliest follow-up ultrasound image showed the excised site as a region of similar low echogenicity, i.e. an echogenic residual cavity (Fig. 3B). Another example of a comparable observation, this time in a case of a patient with adenomatosis, is presented in Fig. 4. A broader region, showing more of the surrounding tissue, is presented in Fig. 5, together with images of later follow-up time-points (Fig. 5A-D). Special attention is drawn to the lesion/excision site, indicated by a rectangular margin, as well as to the back of the residual cavity, indicated by a white arrow. From the analysis of all cases it was established that at the earliest follow-up, one-month after the resection, ultrasound images revealed a low echogenic residual cavity in 230 out of 239 patients, and accordingly, the echogenicity at the back of the cavity was slightly enhanced in comparison to normal tissues (Fig. 5B). At the 3-month follow-up, in 224 out of 239 lesions, the residual



Fig. 3. A 25 year-old female with fibroadenoma on ultrasound image. (A) A pre-operative ultrasound image taken on the day before excision. (B) A post-operative ultrasound image is taken one month after excision. The exact regions of the lesion or excision site are marked by a white rectangular margin.



Fig. 4. A 19 year-old female with adenomatosis on ultrasound image. (A) A pre-operative ultrasound image is taken on the day before excision. (B) A post-operative ultrasound image is taken one month after excision. The exact regions of the lesion or excision site are marked by a white rectangular margin.





Fig. 5. A 26 year-old female with fibroadenoma on ultrasound image. (A) A pre-operative ultrasound image taken on the day before excision. (B) A post-operative ultrasound image is taken one month after excision. (C) A post-operative ultrasound image is taken three months after excision. (D) A post-operative ultrasound image is taken six months after excision. The exact regions of the lesion or excision site are marked by a white rectangular margin. White arrows indicate the back of excision region.

cavity appeared to be resolved and the excision site was characterized by equal echogenicity. Echogenicity at the back of the cavity was slightly reduced compared to normal tissues, in contrast to the images from the one-month follow-up (Fig. 5C). Six months after the excision, in 199 out of 239 patients, the seroma of subcutaneous fat layer was obviously organized and equal echogenicity was observed. Echogenicity at the back was apparently attenuated in comparison to normal tissues (Fig. 5D).

#### 4. Discussion

The Mammotome<sup>®</sup> biopsy system is being increasingly applied not only for the diagnosis but also for the resection of benign breast lesions, and it has by now almost entirely replaced conventional open surgery for benign breast lesion resection (Iwuagwu and Drew, 2004). Its accuracy has been reported to range between 98 and 100%, which is comparable to that of open surgical biopsy (Baez, 2003; Chen et al., 2003). In addition it has the advantages of improved cosmetics, less pain, faster recovery and an enhanced quality of life (Choi et al., 2015).

The outcomes of percutaneous vacuum-assisted complete biopsies with the Mammotome in 1119 patients were reported by Luo et al. (2011). They concluded that breast tumors up to 30 mm can be safely and efficiently removed. This finding is in line with another study by Wang et al. (2013), who reported a complete removal associated with initial tumor size of 20 mm or less (Wang et al., 2013). In the current study, 239 patients with initial tumor size between 5 mm and 30 mm were used for interval follow-up examination at different intervals after excision, staring from one month.

Interestingly, in the 1-month ultrasonography follow-up, in 230 of 239 patients, we can see low echogenic residual cavity which does not have regular shape, clear boundary and envelop echo, there are no normal glandular characteristics such as "zebras" or "honeycomb", and in some cases, the gland structures are suddenly disrupted, which indicates that the residual cavity may be involved in non-glandular tissue. To some extent, this phenomenon confused the physician reading the ultrasound especially if they were not aware of about the patients'resection history by the mammotome device. They assumed they might be looking at "pseudo-rec urrence" or "tumor residue"?

To the best of our knowledge, it is not reliable to assess the due to the presence of hematoma, which is the most frequently occurring complication following breast resection by the mammotome device. In our experience, a hematoma presents as a region of low echogenicity in ultrasound images of early follow-up (one month after excision), at the site of the residual cavity. In 179 of 239 patients at the 3 months follow-up, in the residual cavity, equal echogenicity appeared instead of the low echogenicity, indicating hematoma was organized. The occurrence of hematoma was associated with the size and number of nodules, breast shape, and efficacy time of bandage. The application of pressure dressing during the initial 24 h was considered to be the most effective method of preventing bleeding from the resection site. It also prevented the growing hematoma inside the breast and the pain associated with bleeding.

Loo and Chow (2007) performed a recent systematic literature review according to which seroma formation was considered to be the commonest complication and the median rate of seroma formation incidence was 20% (Wings TY Loo). Seroma isthe accumulation of liquid (>50 mL) in the subcutaneous tissue (Amercian Cancer Society et al.) and is usually formed by plasma and/or lymph. It is widely accepted that seroma appears later than 3–6 months after resection (Amercian Cancer Society et al.; Saeb-Parsy et al., 2006). This is consistent with our current study, where six months after resection, in 40 out of 239 patients, we could see in the resection position clear residual cavity expressedas low echogenicity. A single subcutaneous drain, resulting in shorter total duration of drain placement, leads to lower incidence rates of seroma.

In our experience, there are several important factors for the healing rate of the residual cavity: First, the healing rate of residual cavity is dependent on the tumor location. Usually, tumors located in the shallow gland or lower quadrant gland resulted in high healing rate, whereas when tumors occurred deeper and required a whole gland resection, the healing rate was lower. Second, the amount of breast tissue excision is also related to healing rate: the higher amount is excised, the lower the healing rate. Third, tissue elasticity of the mammary glands and the appropriate tension of the compression bandage affect higher healing rate of the residual cavity.

However, limitations of the current study have to be acknowledged. First, the number of included patients was limited. Second, the sample size of benign lesions was relatively small. Recurrence incidence should be influenced by the sample size. Third, there is subjective difference in ultrasonic judgment, even though the ultrasound image follow-up was performed under standardized conditions by the same experienced radiologists. A precise analysis which includes the size and intensity of the residual cavity was not performed and should be undertaken in further work.

Although we recognize that our study is limited, we felt it was important to report our experience with ultrasound follow-up at different time intervals after resection of benign breast lesions by Mammotome. We report here the problems associated with early follow-up time-points, since such observations have not been reported to date, in the hope that our observations may help clinicians who attempt early post-operative ultrasound examinations, and relieve patients' anxiety in the early months of follow-up. It can be concluded from our experience that a follow-up schedule which starts from at least 3 months after resection, is adequate in order to avoid pseudo-recurrence induced by the residual cavity formation.

### 5. Conclusions

Our study shows, for the first time, an elaborate analyzing of the ultrasound image characteristics of residual cavity and the changes in ultrasound images at follow-up at different intervals after the excision of benign breast lesions by Mammotome<sup>®</sup> biopsy system.

Follow-up by ultrasonography at an interval of one month after excision of benign breast lesions by Mammotome<sup>®</sup> biopsy system, is not reliable due to the residual cavity formation. We highly recommend that a follow-up schedule start from at least 3 months after resection.

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