

# Effectiveness of the diagnostic pathway of BLES: could it be safely used as a therapeutic method in selected benign lesions?

Tuğba İlkem Kurtoğlu Özçağlayan 

Sibel Özkan Gürdal 

Meltem Öznur 

Ömer Özçağlayan 

Mücahit Doğru 

Biröl Topçu 

## PURPOSE

In this study, we aimed to investigate the breast lesion excision system (BLES) as a tool and a practical alternative technique to surgical biopsy and other percutaneous biopsy methods for suspicious lesions. We also wanted to share our initial experience with BLES and compare it with standard percutaneous biopsy methods.

## METHODS

From July 2015 to December 2016, a total of 50 patients who had high-risk lesions which were diagnosed with core needle biopsy (CNB) or had lesions with radiology pathology discordance, or had high-risk factors, high-grade anxiety, or suspicious follow-up lesions were enrolled in the study. These lesions were classified as Breast Imaging Reporting and Data System (BI-RADS) 3 or 4, which are under 2 cm. Pathologic diagnoses before and after BLES were evaluated comparatively. The diagnostic and therapeutic success and the complications of CNB and BLES were analyzed.

## RESULTS

After BLES, two cases were diagnosed as atypical lobular hyperplasia and atypical ductal hyperplasia. Since the surgical margin was negative, re-excision was not required. Two cases were diagnosed as malignant, and no residual tissue was detected in the operation region. Total excision rates were reported as 56%. Minor hematoma was observed in only 1 out of 50 cases (2%), and spontaneous remission was observed. Two patients (4%) complained of pain during the procedure. Radiofrequency-related thermal damage to the specimen showed: Grade 0 (<0.5 mm) damage in 88%, Grade 1 (0.5–1.5 mm) in 10%, Grade 2 (>1.5 mm or thermal damage in diffuse areas) in 2%, and Grade 3 (diffuse thermal damage or inability to diagnose) in 0%. We found a significant positive correlation between classification of thermal damage and lesion fat cell content ( $r = 0.345$ ,  $P = 0.015$ ).

## CONCLUSION

BLES is a safe technique that can be effectively used with low complication rates in the excision of benign and high-risk breast lesions in selected cases. It may also provide high diagnostic success and even serve as a therapeutic method in high-risk lesions, such as radial scar, papilloma, and atypical lobular hyperplasia with high complete excision rates without fragmentation of lesions.

From the Departments of Radiology (T.İ.K.Ö. ✉ [dr tugba ilkem@yahoo.com](mailto:dr tugba ilkem@yahoo.com), Ö.Ö., M.D.), General Surgery (S.Ö.G.), Pathology (M.Ö.), Biostatistics (B.T.), Namık Kemal University School of Medicine, Tekirdağ, Turkey.

Received 21 September 2018; revision requested 11 November 2018; last revision received 03 February 2019; accepted 18 February 2019.

Published online 28 August 2019.

DOI 10.5152/dir.2019.18427

With the increased effectiveness of screening programs, the incidence of non-palpable breast lesions is also increasing. This situation leads to an increase in the rate of diagnostic biopsies for suspicious lesions (1–3). All preferred percutaneous biopsy methods have both advantages and disadvantages. The ideal biopsy method should obtain pathologic specimens in larger sizes to increase diagnostic accuracy and minimize the necessity of recurrent biopsy in suspicious results. It should prevent the loss of time and energy and allow the evaluation of surgical margins in possible malignant lesions. The lesion should be examined by the appropriate imaging methods and the most effective biopsy method should be chosen. The selected biopsy method should be minimally invasive, yet be able to give the most definitive result, while not affecting the next possible surgical procedure. The goal is to avoid unnecessary surgical procedures for benign lesions, while avoiding recurrent biopsies by obtaining sufficient tissue from high-risk and malignant lesions to plan a treatment course.

You may cite this article as: Kurtoğlu Özçağlayan Tİ, Özkan Gürdal S, Öznur M, Özçağlayan Ö, Doğru M, Topçu B. Effectiveness of the diagnostic pathway of BLES: could it be safely used as a therapeutic method in selected benign lesions? *Diagn Interv Radiol* 2019; 25:428–434.





**Figure 2.** The 20 mm wand from the breast lesion excision system.

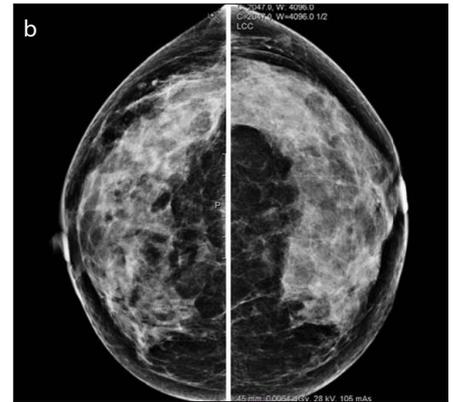
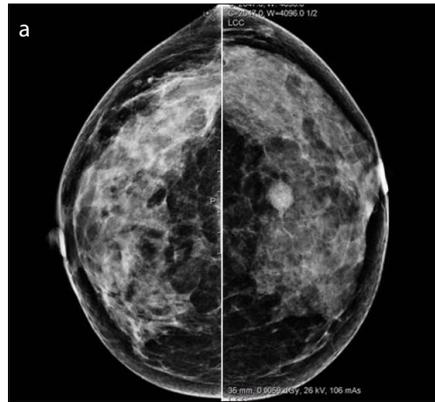


**Figure 3.** Sample of breast lesion excised with the Intact BLES.



**Figure 4.** After the BLES biopsy, a suture is visible on the skin.

the distance between the tissues was increased by applying local anesthesia to the area between the lesion and the skin or between the lesion and the pectoral muscle. A cut of about 6–8 mm was made on the skin.



**Figure 5. a, b.** Mammography image (a) shows an indeterminate lesion in the left breast. Image (b) taken one year after the BLES biopsy, in the routine follow-up of the area of the lesion, shows no residue.

In the imaging guidance, the wand was positioned to border the target lesion. After the RF was run, the lesion was surrounded by five metallic prongs emerging from the tip of the wand for 10 s, and the lesion was separated from the adjacent tissue by burning. Gases and liquids produced due to tissue heating during RF application were aspirated by a vacuum connected to the wand. The target tissue was removed using the wand, and the procedure was terminated (Fig. 2). An unfragmented specimen was obtained (Fig. 3). At the end of the procedure, a clip mark was left in the biopsy region for lesions with previous suspicious pathologic diagnosis. The incision was closed with a single suture (Fig. 4). To prevent burns, the skin was cooled with ice cold water after the procedure in two cases (<2 mm) where the lesion was located very close to the skin. Biopsy specimens and previous CNB results were evaluated by the same single pathologist. Collected data included the histopathologic diagnosis, surgical margin, thermal damage around the specimen, and specimen-fat ratio.

Postprocedural complications were recorded as early complications if they occurred during and immediately after the procedure (up to 60 min) and recorded as late complications (after the departure of the patient from the breast unit) if they occurred in follow-up. After the procedure, patients were followed up by the surgeon at postoperative day 3 for care and incision control; at one and six months, patients were followed up on US by the radiologist. The presence of remaining residual lesions and postop changes were recorded. Further US follow-up was performed in the first and second year according to routine follow-up protocol. The routine mammography was performed at time for scanning (Fig. 5).

Early complications were hemorrhage, skin burn, allergic reaction to local anesthesia, patient fainting during the procedure, and pain during the procedure; late complications were organizing hematomas, large skin burns, and infection at the area of the biopsy. During the procedure, the patients were asked to describe their pain from the treatment and to assign the degree of pain from 1 to 10 according to numeric pain intensity scale.

The specimen thermal damage associated with the RF was classified according to the diameter in 4 categories: Grade 0 (<0.5 mm), Grade 1 (0.5–1.5 mm), Grade 2 (>1.5 mm or thermal damage in diffuse areas), and Grade 3 (diffuse thermal damage or inability to diagnose).

### Statistical analysis

In the analysis of the data, PASW Statistics 18 for Windows statistical package program was used. Variables were expressed as mean, standard deviation, frequency and percent. Relations between the variables were tested by Pearson correlation analysis. Chi-square test was used to compare categorical variables. Statistical significance was accepted as  $P < 0.05$ .

### Results

A BLES biopsy was performed on 50 lesions under US or stereotactic guidance. Characteristics of the patients and procedure details are shown in Table 1. The mean age of the patients was  $43.16 \pm 11.5$  years. The lesions were classified as BI-RADS 3 in 26 patients (52%) and BI-RADS 4 in 24 patients (48%). The mean target size was  $14.9 \pm 4.15$  mm. The size of the probe used was 15 mm for 24 patients (48%) and 20 mm for 26 pa-

**Table 1.** Baseline characteristics of patients using the BLES procedure

n=50	
Age (years), mean±SD (range)	43.16±11.5 (20–77)
Guidance	
Stereotactic	1 (2)
Sonographic	49 (98)
Probe size	
15 mm	24 (48)
20 mm	26 (52)
BI-RADS	
3	26 (52)
4	24 (48)
Type of radiologic abnormality	
Microcalcifications	1 (2)
Mass	49 (98)

Data are presented as n (%) unless otherwise noted.  
BLES, breast lesion excision system; SD, standard deviation; BI-RADS, breast imaging reporting and data system.

**Table 2.** The relationship between lesion diameter and removal of lesions

Size of radiologic abnormality	Complete removal (n)	Incomplete removal (n)	Total	P
≤10 mm	14	0	14	0.001
>10 mm	14	22	36	
Total	28	22	50	

**Table 3.** Concordant and discordant pathologies

Concordant lesions	CNB (n)	BLES (n)
Fibroadenoma	15	15
Papilloma	5	5
High-risk lesion	14	14
Benign	2	2
Total	36	36
Discordant lesions	CNB (n)	BLES (n)
Fibroadenoma	3	1 (High-risk lesion) 2 (Benign)
Papilloma	1	1 (High-risk lesion)
High-risk lesion	5	5 (Fibroadenoma)
Benign	4	2 (High-risk lesion) 1 (Papilloma) 1 (Malignant)
Total	13	13

CNB, core needle biopsy; BLES, breast lesion excision system.

tients (52%). In one patient, a second probe was used because the lesion was bilobular, extending in different planes. In another case, a second basket was used because the first basket was empty. One symptomatic hematoma developed (2%) but did not require surgical intervention. Two patients (4%) complained of pain during the procedure, and their definition of pain according to numeric pain intensity scale was defined as 4 and 5, respectively. Evaluation of pain showed that the procedure was acceptable, causing minimum pain. In the early period, skin burn, allergic reaction due to local anesthesia, and fainting during the procedure were not seen in any of the patients; also, no large skin burn, no delayed wound healing, and no infection were seen in the late period. All patients had good cosmetic outcomes. On US follow-up, fat necrosis was observed in the lesion area of one patient. In 45 cases, postoperative distortion was observed at one month, and postoperative distortion was observed in 10 patients at six months. In 28 cases (56%), no macroscopic and histopathologic lesions were detected in the surgical area. Radiologic target lesions with a diameter of <10 mm were completely removed histopathologically. In our case series, the mean size of histologically completely removed lesions was 11.3±2.9 mm, while that of lesions with partial resection was 17.9±2.5 mm. The relationship between the number of completely removed lesions and lesion diameter is shown in Table 2.

Prior CNB results were available in all cases except one. Post-CNB and post-BLES pathology results were classified in five groups as fibroadenoma, high-risk lesion, intraductal papilloma, benign lesions, and malignant lesions. Fibroadenoma and complex fibroadenomas were evaluated in the fibroadenoma group, nonproliferative lesions and lesions diagnosed as breast tissue were evaluated in the benign group, and proliferative lesions and atypical proliferative lesions were evaluated in the high-risk group. Since previous CNB was not available in one case, it was not included in the comparative evaluation. In 36 cases (73%), the CNB results and the BLES results were consistent with pathologic diagnosis. The results of 13 cases were discordant (Table 3); five cases classified in the high-risk group after CNB were diagnosed as fibroadenoma after BLES. A case diagnosed as fibroadenoma, a case diagnosed as papilloma, as well as two cases classified in the benign group according

**Table 4.** The histopathologic upgrade and downgrade ratios of discordant pathologies

Upgrade (n=5, 10.2%)		Downgrade (n=5, 10.2%)	
CNB	BLES	CNB	BLES
Fibroadenoma (n=1)	High-risk lesion (n=1)	High-risk lesion (n=5)	Fibroadenoma (n=5)
Papilloma (n=1)	High-risk lesion (n=1)		
Benign (n=2)	High-risk lesion (n=2)		
Benign (n=1)	Malignant (n=1)		
Total (n=5)	Total (n=5)		

CNB, core needle biopsy; BLES, breast lesion excision system.

to CNB, were placed in the high-risk group after BLES. After comparative evaluation of histopathologic results between CNB and BLES, upgrade ratio was determined as 10.2% (5/49) and downgrade ratio as 10.2% (5/49), respectively (Table 4).

There was a family history of breast cancer in seven patients and a history of breast carcinoma surgery in one patient. There was only one patient who had a breast-conserving surgery history and had undergone a stereotactic procedure for the fine linear microcalcification area in the surgery area. This case was classified as BI-RADS 4. Pathologic diagnosis after BLES was invasive breast carcinoma. After the procedure, the patient had mastectomy without axillary dissection. There was no residue invasive focus on post-surgical mastectomy specimens. In another malignant case, the lesion showed enlargement in the follow-up by ultrasonography. The diagnosis was benign lobular proliferation, and surgical excision was recommended after CNB. Pathologic diagnosis after BLES was mucinous carcinoma. Invasive tumor cells were not detected when cavitation excision and sentinel lymph node biopsy were performed. The sentinel lymph node biopsy result was negative.

RF-associated thermal damage of specimens was observed in patients as follows: Grade 0, 88%; Grade 1, 10%; and Grade 2, 2%. There was no thermal damage to prevent pathologic diagnosis (Grade 3) in any specimen.

The relationship between fat cell content ratio in the specimen and RF-associated thermal damage diameter was assessed by the Pearson correlation test. We found a significant positive correlation between the diameter of thermal damage and lesion fat cell content ( $r=0.345$ ,  $P=0.015$ ).

## Discussion

In the solid lesions of a typical sampling of breast lesions, CNBs and VACNBs are frequently the preferred standard methods. Excisional biopsy methods include wire marking, roll marking, excision in the presence of intraoperative US, and the BLES method, which has recently become popular.

BLES is a biopsy technique that uses RF energy to enter a small incision made in the skin under local anesthesia and remove the suspected lesion in a single-piece percutaneously. In addition to its diagnostic use in recent years, BLES is an alternative method that can be used as a therapeutic modality using excision, especially in selected benign cases. It is also a useful method for sampling suspect microcalcifications. A number of case series have shown that this method can be used in lesions detected by US (1, 14). In recent studies, it is emphasized that suspect microcalcification areas that cannot be seen by US should be sampled and excised with mammography guidance (15, 16).

It is possible to demonstrate that the lesion is surrounded in real time when BLES is applied with US guidance and to determine whether the lesion can be completely removed at the macroscopic level. As in our case, it can be predicted that residual lesions may remain in the lobular contoured lesions extending in different planes even though the target lesion dimensions are less than 2 cm. In such cases, a new probe to remove the residual lesion in the same application can be inserted into the same access route, and the procedure can be repeated using the probe at different angles. In order to predict such a condition, it is suggested to measure the lesion dimensions in two separate planes absolutely per-

pendicular to each other in the US examination prior to the procedure. BLES allows for the removal of lesions less than 20 mm in diameter, unlike other biopsy methods with imaging guidance. This feature has enabled BLES to become an important alternative to surgical biopsy in selected cases (1). Short hospital stays, outpatient setting, minimal incision, and good cosmetic results are the advantages of BLES over surgical biopsies. In surgical (open) biopsies, a wider incision and deep tissue removal are required, especially for deeply located lesions. Furthermore, with BLES, it is not necessary to remove the tract like the surgical biopsies made by marking with wire. This method only allows removal of the target mass, but theoretically reduces the risk of implanting the biopsy tract along the axes during the removal of malignant lesions as it burns the lesion boundaries with RF energy.

The ability to be applied in outpatient clinics without requiring general anesthesia makes BLES a good option, especially for elderly patients. In our case series, we had a 77-year-old patient with gastric carcinoma who had a smooth oval contour breast lesion (17×6 mm) with a significant increase in size compared with the size recorded in the previous examinations of the lesion. The CNB result indicated benign lobular proliferation. However, after BLES, the lesion was diagnosed as mucinous carcinoma. Also, no residual tumor was found in the operation area after surgery.

BLES has several defined complications, all of which can be well tolerated by patients. The complications of the procedure are grouped as early and late complications in the literature (17). In our study, as an early complication, one case (2%) developed hematoma that could be controlled by external compression, and two cases (4%) developed pain during the operation. No late complication developed. Al-Harethee et al. (17) reported early complications in 11 cases (8.2%), including minor hemorrhage controlled by external compression in six cases, hemorrhage requiring deep skin sutures in three cases, and skin burn in two cases. In addition, wound infection in 17 cases (12.6%), delayed wound healing in five cases, minor hematoma in five cases, and antibiotherapy in four cases were reported. Hematoma, infections, and other complications were not reported in a study of 1600 cases by Killebrew et al. (13). In our study, only minor morbidity (1/50; 2%) was

determined; this was compatible with other studies reporting hematoma rates of 0.6% (12) and 16% (18).

Although BLES is a safe and effective method with minor complication rates as reported in many publications in the literature (17), it is a system that cuts and separates tissues with RF energy, leading to thermal damage to the specimen. For this reason, it has been thought that there may be diagnostic failure in pathologic specimens due to thermal damage, and many studies have been done on this subject. In a study by Allen et al. (1), it was reported that most specimens suffered thermal damage in the surrounding tissue less than 0.5 mm from the lesions, which did not cause diagnostic failure (1). In another study of 166 cases by Seror et al. (19), authors reported a 4% rate of thermal damage that leads to pathologic diagnostic failure. In our study, similar to the those in the literature, the thermal damage rates were found in 88% of cases less than 0.5 mm and no specific damage was detected which could lead to diagnostic failure. Additionally, a study by Wasim et al. (20) found that the rate of thermal damage was correlated with the increase in the fat content of the specimen. Similarly, in our study, an increase in the diameter of the burn was observed as the fat content in the specimen increased.

Superiority of the BLES method over VACNB is that the lesion can be removed without being fragmented into small parts, that is, as a single entity, and the surgical margin can be assessed (17). This is important because the inability to accurately sample suspicious lesions histologically will lead to an inadequate histologic diagnosis. For example, in cases with biopsy-resultant ADH, it is possible to detect DCIS after surgery or detect an invasive focus after surgery in a case with biopsy-resultant DCIS. The most important factor that shows the diagnostic reliability of a biopsy method is the low rate of underestimation. In a study of 1600 cases comparing BLES and VACNB methods performed by Killebrew et al. (13) there was a statistically highly significant difference in the underestimation rates in atypical benign lesions, but a much less significant statistical difference in the underestimation rates (3.2%) in DCIS. In the complete excision of DCIS, they found a statistically significant difference between BLES and VACNB. In another study by Sie et al. (12),

underestimation rates in atypical lesions were reported as 9.4%, and underestimation rates in DCIS were reported as 5.2%. In our study, atypical lesions were detected in two cases after BLES, but a sufficient number of patients could not be reached for statistical analysis. Because the surgical margin was determined to be negative after BLES, clinical and radiologic follow-up was performed in these two cases.

Our patients did not have surgical biopsy except for two patients in our series who were diagnosed as malignant. No residual tumor was detected in these two patients after surgery. In our study, 28 cases (56%) were detected with complete resection upon radiologic imaging. But in the pathologic evaluation of 11 of these 28 complete removed lesions, surgical border was reported as <1 mm. In the literature, total excision rates were reported as 30%–76.3% (13–24) in malignant lesions; this is similar to the findings in our series. In a systematic review by Sanderink et al. (21) the diagnostic or therapeutic accuracy and safety of BLES was evaluated based on 14 articles and 4272 BLES biopsies. The main lesion size on imaging ranged from 5.7 to 10 mm. Overall complete excision rates ranged from 30%–76.3%. Scaperrotta et al. (15) used BLES for small clusters of suspicious microcalcification in 105 patients and, based on their total excision rates, suggested that BLES may potentially have a therapeutic role in selected patients. However, Milos et al. (16) reported that BLES is a diagnostic tool and cannot be considered as a therapeutic tool because total excision was seen in only 44.1% (15/34) of the lesions. Also, for complete removal target lesion size is important. Medjhouli et al. (14) and Seror et al. (19) compared complete resection rates and target lesion dimensions and reported that target lesions of 10 mm or smaller could be removed with a safe surgical margin. In our case series, 14 out of 28 lesions smaller than 10 mm were completely removed.

In two cases with ADH and atypical lobular hyperplasia (ALH) after BLES, surgical resection was not performed because the surgical margin was negative. In the case of a total excision of the intraductal papilloma diagnosed with a nipple discharge, the nipple discharge discontinued after the procedure. Niinikoski et al. (22) studied feasibility of BLES for the management of small benign and high-risk lesions such as

intraductal papilloma and reported 46.6% complete excision rate.

The small number of patients is the major limitation of our study. The inadequacy of our DCIS and ADH numbers to determine underestimation rates is another. However, we have not had enough experience to evaluate the success of BLES in stereotactic guidance. In order to perform the operation with this method, the probe and probe of the prone table must be compatible with each other. The process has to be supported by manual adjustments, and it is possible to make additional shots in case of incompatibility. In this situation, the experience of the radiologist becomes even more critical. Because of these disadvantages, we could only apply a stereotactic method in one selected case. This was a case of breast-conserving surgery with a diagnosis of breast cancer and a newly developing cluster microcalcification field in the operation region. This case was diagnosed as invasive ductal carcinoma after BLES. The case was accepted as a local recurrence, and mastectomy without axillary dissection was performed.

In conclusion, based on the cases reported in the literature and our own experience in selected cases, BLES is a reliable method with low underestimation rates, especially in ADH and DCIS. As an added advantage, when used in experienced hands, it can provide high diagnostic success and even serve as a therapeutic method in high-risk lesions, such as radial scar, papilloma, and ALH. In the future, we hope that BLES will be able to give promising results in malignant lesions less than 1 cm and lesions with complete response after neoadjuvant chemotherapy. However, it will be necessary to produce a solution for the sentinel lymph node for this method to be practically applied in malignant lesions.

#### Conflict of interest disclosure

The authors declared no conflicts of interest.

#### References

1. Allen SD, Nerurkar A, Della Rovere, GU. The breast lesion excision system (BLES): a novel technique in the diagnostic and therapeutic management of small indeterminate breast lesions? *Eur Radiol* 2011; 21:919–924. [CrossRef]
2. Hoffmann O, Stamatis GA, Bittner AK, et al. B3-lesions of the breast and cancer risk analysis of mammography screening patients. *Mol Clin Oncol* 2016; 4: 705–708. [CrossRef]

3. Blanks R, Wallis M, Jenkins J, Alison R, Wilson RG. An analysis of 11.3 million screening tests examining the association between recall, biopsy and cancer detection rates in the English NHS breast cancer screening programme. *Clin Radiol* 2019; 74:384–389. [\[CrossRef\]](#)
4. Parker SH, Lovin JD, Jobe WE, Burke BJ, Hopper KD, Yakes WF. Nonpalpable breast lesions: stereotactic automated large-core biopsies. *Radiology* 1991; 180:403–407. [\[CrossRef\]](#)
5. Elvecrog EL, Lechner MC, Nelson MT. Nonpalpable breast lesions: correlation of stereotactic large-core needle biopsy and surgical biopsy results. *Radiology* 1993; 188:453–455. [\[CrossRef\]](#)
6. Liberman L. Centennial dissertation: percutaneous imaging-guided core breast biopsy-state of the art at the millennium. *AJR Am J Roentgenol* 2000; 174:1191–1199. [\[CrossRef\]](#)
7. Gorsuch H, Wilburn-Bailey SJ. Ultrasound-guided, vacuum-assisted, percutaneous excision of breast lesions: an accurate technique in the diagnosis of atypical ductal hyperplasia. *J Am Coll Surg* 2005; 201:14–17. [\[CrossRef\]](#)
8. Burbank F, Parker SH, Fogarty TJ. Stereotactic breast biopsy: improved tissue harvesting with Mammotome. *Am Surg* 1996; 62:738–744.
9. Liberman L, Cohen MA, Dershaw DD, Abramson AF, Hann LE, Rossen PP. Atypical ductal hyperplasia diagnosed at stereotactic core biopsy of breast lesions: an indication for surgical biopsy. *AJR Am J Roentgenol* 1995; 164:1111–1113. [\[CrossRef\]](#)
10. Liberman L, Kaplan JB, Morris EA, Abramson AF, Menell JH, Dershaw DD. To excise or to sample the mammographic target: what is the goal of stereotactic 11-gauge vacuum assisted breast biopsy? *AJR Am J Roentgenol* 1996; 179:679–683. [\[CrossRef\]](#)
11. Citgez B, Atay M, Yetkin GR, Kartal A, Mihmanli M, Uludag M. The breast lesion excision system (BLES) a preliminary experience. *Ann Ital Chir* 2016; 87:583–588.
12. Sie A, Bryan DC, Gaines V, et al. Multicenter evaluation of the breast lesion excision system, a percutaneous, vacuum-assisted, intact-specimen breast biopsy device. *Cancer* 2006; 107:945–949. [\[CrossRef\]](#)
13. Killebrew LK, Oneson RH. Comparison of the diagnostic accuracy of a vacuum-assisted percutaneous intact specimen sampling device to a vacuum-assisted core needle sampling device for breast biopsy: initial experience. *Breast J* 2006; 12:302–308. [\[CrossRef\]](#)
14. Medjhouli A, Canale S, Mathieu MC, Uzan C, Garbay JR, Dromain C, Balleyguier C. Breast lesion excision sample (BLES biopsy) combining stereotactic biopsy and radiofrequency: is it a safe and accurate procedure in case of BIRADS 4 and 5 breast lesions? *Breast J* 2013; 19:590–594. [\[CrossRef\]](#)
15. Scaperrotta G, Ferranti C, Capalbo E, et al. Performance and role of the breast lesion excision system (BLES) in small clusters of suspicious microcalcifications. *Eur J Radiol* 2016; 85:143–149. [\[CrossRef\]](#)
16. Milos RI, Bernathova M, Baltzer PA, et al. The breast lesion excision system (BLES) under stereotactic guidance cannot be used as atherapeutic tool in the excision of small areas of microcalcifications in the breast. *Eur J Radiol* 2017; 93:252–257. [\[CrossRef\]](#)
17. Al-Harethee WA, Theodoropoulos G, Filippakis GM, et al. Complications of percutaneous stereotactic vacuum assisted breast biopsy system utilizing radio frequency. *Eur J Radiol* 2013; 82:623–626. [\[CrossRef\]](#)
18. Diepstraten SC, Verkooijen HM, van Diest PJ, et al. Radiofrequency-assisted intact specimen biopsy of breast tumors: critical evaluation according to the IDEAL recommendations. *Cancer Imaging* 2011; 11:247–252.
19. Seror J-Y, Leesieur B, Scheuer-Niro B, Zerat L, Rouzier R, Uzan S. Predictive factors for complete excision and under estimation of one-pass en bloc excision of non-palpable breast lesions with the Intact® breast lesion excision system. *Eur J Radiol* 2012; 81:719–724. [\[CrossRef\]](#)
20. Al-Harethee WA, Kalles V, Papanagioutou I, et al. Thermal damage of the specimen during breast biopsy with the use of the Breast Lesion Excision System: does it affect diagnosis? *Breast Cancer* 2015; 22:84–89. [\[CrossRef\]](#)
21. Sanderink W, Laarhuis B, Strobbe L, Bult P, Karssemeijer N, Mann R. A systematic review on the use of the Breast Lesion Excision System in breast disease. *Eur J Cancer* 2018; 92(Suppl 3):S153–S154. [\[CrossRef\]](#)
22. Niinikoski L, Hukkinen K, Leidenius MHK, Ståhls A, Meretoja TJ. Breast Lesion Excision System in the diagnosis and treatment of intraductal papillomas - A feasibility study. *Eur J Surg Oncol* 2018; 44:59–66. [\[CrossRef\]](#)
23. Allen SD, Osin P, Nerurkar A. The radiological excision of high risk and malignant lesions using the INTACT breast lesion excision system. A case series with an imaging follow up of at least 5 years. *Eur J Surg Oncol* 2014; 40:824–829. [\[CrossRef\]](#)
24. Sklair-Levy M, Rayman S, Yosepovich A, Zbar A, Goitein D, Zippel D. The Intact® breast lesion excision system as a therapeutic device for selected benign breast lesions. *Breast J* 2018; 24:304–308. [\[CrossRef\]](#)