

The breast lesion excision system (BLES): a novel technique in the diagnostic and therapeutic management of small indeterminate breast lesions?

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Received: 19 May 2010 / Revised: 29 September 2010 / Accepted: 8 October 2010
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Abstract

Objective To investigate whether the breast lesion excision system (BLES) could render formal surgery unnecessary in patients with small indeterminate breast lesions.

Methods Following review board ethical permission and the consent of each patient, we aimed to perform a complete excision biopsy, with a margin, of small indeterminate breast lesions that measure less than 1 cm. 76 patients with small BIRADS type 3 breast lesions underwent a BLES biopsy. Mean radiological lesion size was 7.1 mm (range 2–10 mm).

Results 61 lesions had a final benign diagnosis, 6 of which underwent subsequent surgery although only 1 showing residual lesion. 15 lesions were malignant but with residual tumour at re-excision present in only 5 cases.

Conclusion The BLES biopsy is an efficacious technique at excising small indeterminate breast lesions with a complete margin without the need for follow-up diagnostic surgery in the majority.

Keywords Breast · Biopsy · Vacuum · Breast cancer · Ultrasound

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Introduction

Small solid breast lesions that are radiologically indeterminate sometimes yield an indeterminate histopathological assessment following a radiologically guided biopsy. Although some centres may wish to just follow these lesions up, increasingly these are being treated using radiological wire localisation followed by open surgery in the form of a wide local excision. However many of these are subsequently benign on final surgical pathology. More recently there have been alternative radiological management to excise biopsy proven benign lesions, usually fibroadenomas, in women wishing to have them removed [1]. This has been with vacuum assisted biopsy devices, such as the mammotome™ (Johnson and Johnson Ethicon Endo-Surgery Inc, Cincinnati, Ohio, USA) Encor™ (C.R. Bard, New York, USA) and Suros ATEC™ (Suros Surgical Systems Inc, Indianapolis, USA). The advantages of these more minimally invasive approaches to many women will undoubtedly make this technique increasingly popular [2–5]. They can be performed usually in less than 30 min, with only local anaesthetic and a minimal scar. Complication rates are very low, and the procedures are extremely well tolerated. These procedures are particularly suitable for young women where risk of the lesion being non benign is very low, and cosmesis is premium [2–5]. The obvious limitation of this technique however, is that as it is only able to remove lesions in a “piecemeal” fashion. Such excisions are unable to provide an assessment of margins of the excision, thus there is no way of determining completeness of excision and whether any residual lesion is left behind. While this may not be particularly relevant if the lesions excised are fibroadenomas, or other such similar benign lesions, it will however obviate the vacuum assisted excision from being utilised for many other more “border-

line” lesions where completeness of excision and a full margin status is desirable or essential.

Since 2001 the breast lesion excision system (BLES, Intact Medical, Framingham, USA), has been used as an alternative large biopsy device to other vacuum assisted biopsy devices in over 40,000 cases in the USA. It has been well validated as a safe and efficacious biopsy procedure [6, 7]. It however has the unique feature of using radio-frequency cautery to excise a small but whole sample in one piece with intact architecture and clear margins, as a swift local anaesthetic outpatient procedure. Our unit is the first in the UK where the BLES has been in operation since August 2007.

The purpose of our study is to evaluate the capability of the BLES to perform a complete excision biopsy (with a margin) of sub centimetre indeterminate small breast lesions, in the attempt to obviate the need for a surgical operation which a number of these would inevitably go on to require. As approved by the National Institute of Health and Clinical Excellence, this technique is thus in accordance with UK national guidelines for the management of such breast lesions [8]. We describe our findings in this technical report.

Methods

Full local hospital institutional board and medical device committee approval was obtained for this evaluation with the BLES. Patients with sub centimetre breast lesions that were considered radiologically indeterminate (BIRADs 3) at a formal radiological led multidisciplinary meeting and/or whom had a prior indeterminate core biopsy result (pathologically a B3 result) were considered potentially suitable to undergo a BLES excision biopsy rather than proceed to routine diagnostic surgical biopsy. They were then prospectively recruited and formally written consented for this procedure.

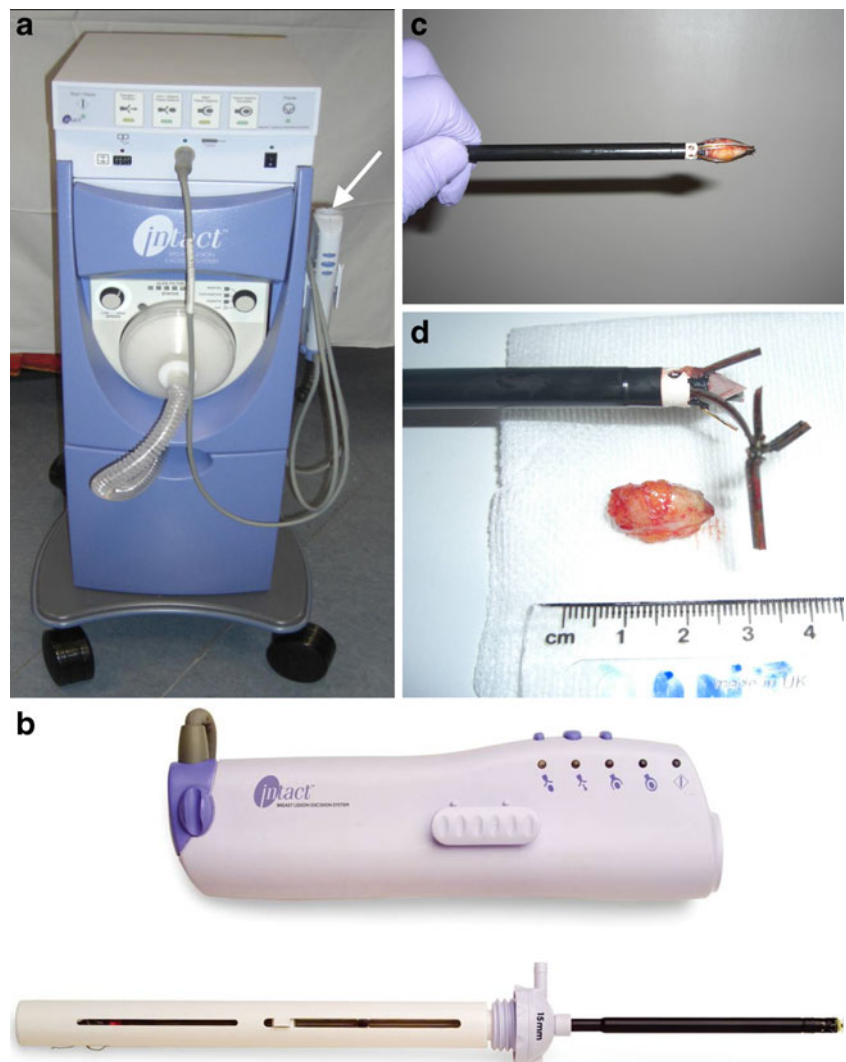
The BLES consists of a biopsy “wand”, measuring approximately 6 gauge, which is passed through a small skin incision to the edge of the anaesthetized target under ultrasound or stereotactic guidance. 5 metallic prongs (wand size depending) with their tips connected by an extensible cutting radiofrequency ring wire then pass from the wand and envelop an area of tissue ranging from 10 to 20 mm in diameter (depending on wand size) in only 8 s. The prongs pass RF waves into surrounding tissue in order to excise and allow haemostasis, but not to the extent of damaging the sample (Fig. 1). Wand sizes vary, with the smallest having a final capture diameter of 10 mm, the largest 20 mm. We utilised 15 mm and 20 mm wands. Wherever possible we utilised stereotaxis as the breast immobilisation was felt to allow a more accurate acquisition.

BLES can be used in most patients and in many breast lesions, but there are a number of clear contraindications. Patients fitted with a cardiac pacemaker or other radio-frequency devices are not suitable as the RF waves can potentially interfere with or damage these devices. It is not recommended for patients who are pregnant. As with other large biopsy devices caution has to be given to anti-coagulation and clotting disorders, but this procedure can be considered as equivalent to a vacuum assisted biopsy in its invasiveness and hence its protocol in this regard. Due to the RF wave emanating from the metallic prongs during the biopsy, and the risk of a thermal burn and possibly skin necrosis, careful attention has to be paid to the location of the lesion in relation to the skin surface and chest wall prior to performing a BLES procedure. A number of deep and superficial lesions as well as its use in the axilla are excluded. Tolerance to the procedure was assessed by a simple pain scoring questionnaire performed at least a week later in a proportion of the cohort.

Image guidance can be using mammography or ultrasound with visualisation of the BLES using ultrasound being straightforward, largely given its size (Fig. 2). What can be more difficult is keeping in view the target lesion, especially if it is more of a distortion than a mass, and especially when surrounded by 20 ccs of local anaesthetic. In addition the BLES, not being sharp ended, may push away a mobile lesion, and this can be difficult to get into an optimal position for an excision biopsy. Mammographic guidance using stereotaxis although not “real-time” allows immobilisation of breast and lesion and therefore possibly offers more control in excision accuracy. The BLES is activated at the touch of a button, the metallic prongs protrude under direct vision and encircle the target lesion. The whole wand with sample is then removed, and following a specimen radiograph, the samples placed in formalin and sent to histopathology. The specimens were then inked on the external surfaces and sections were taken perpendicular to the longest axis of the specimens. These sections were serially embedded and examined using standard pathological analysis as well as advanced pathological evaluation such as immunohistochemistry which was routinely performed.

Since August 2007, we have used this device in 92 patients with indeterminate (BIRADs 3) breast lesions. The first 10 cases were excluded from meaningful analysis as this was considered the minimal technical learning curve in obtaining a clear excision biopsy. 6 further patients were excluded from analysis as this was employed to obtain a diagnostic sample in larger lesions rather than an excision biopsy of a small lesion., 76 patients were included in the final study group, which consisted of lesions that were radiologically indeterminate (mammographically M3, or ultrasonically U3), 55 of these also having a pathological

Fig. 1 The breast lesion excision system (BLES) biopsy system and wand. **(a)** The equipment consists of an electronically operated base system with attached lightweight handheld piece where removable wands are inserted (arrow). **(b)** Handheld component and removable wand. **(c)** We have measured the wands to be 6-gauge in diameter and are passed through typically a 10 mm skin incision to the edge of the anaesthetized target under ultrasound or stereotactic guidance. 4 or 5 metallic prongs (wand size depending) with their tips connected by an extensible cutting radiofrequency ring wire then pass from the wand and envelop an area of tissue in only 8 s. The prongs pass radiofrequency waves into surrounding tissue in order to excise and allow haemostasis, but not to the extent of damaging the sample. **(d)** Wand sizes vary, with basket diameters ranging from 10 mm to 20 mm. Sample sizes accordingly fluctuate with the basket sizes. The sample is removed from the basket by cutting the prongs with sharp scissors



B3 biopsy result. 21 patients had no prior core biopsy performed but opted for a BLES procedure when given all the biopsy options following recall with an abnormal mammogram. All cases included in this technical study were performed by just one of the authors, S.A. The radiological and pathological size was recorded for these lesions as well as pathological diagnosis, follow-up surgical excision and imaging. All pathology was performed by one of two dedicated breast pathologists, both with more than 10 years of breast pathology experience.

Results

All procedures were well tolerated at the time of the procedure, with moderate to minor discomfort experienced in most patients for the 8 s of sample acquisition, but passing very shortly afterwards in all cases. This was formally evaluated with a simple pain scoring questionnaire

performed on follow up. Only one patient suffered more than moderate discomfort during the procedure, and no patients had more than mild discomfort in the time period immediately following the 8 s of the acquisition. Median pain score during the procedure was 3 (out of 10). Median satisfaction score 1 week following the procedure was 9.5 (out of 10). Median satisfaction score for the scar was 9 (out of 10) [9]. One patient had a delayed haematoma but this was managed conservatively. No post procedure wound infections have yet occurred.

45 procedures were conducted with 20 mm wands, 31 procedures were conducted with 15 mm wands. 20 procedures were performed under ultrasound guidance, 56 using stereotaxis on a prone table. Mean largest radiological lesion size was 7.1 mm (range 2–10 mm). Pathological specimens all yielded pathology appropriate to the target lesions, with minimal diathermy effects (<1 mm). Our pathologists found the specimens far faster and easier to analyse than equivalent sized vacuum assisted biopsy

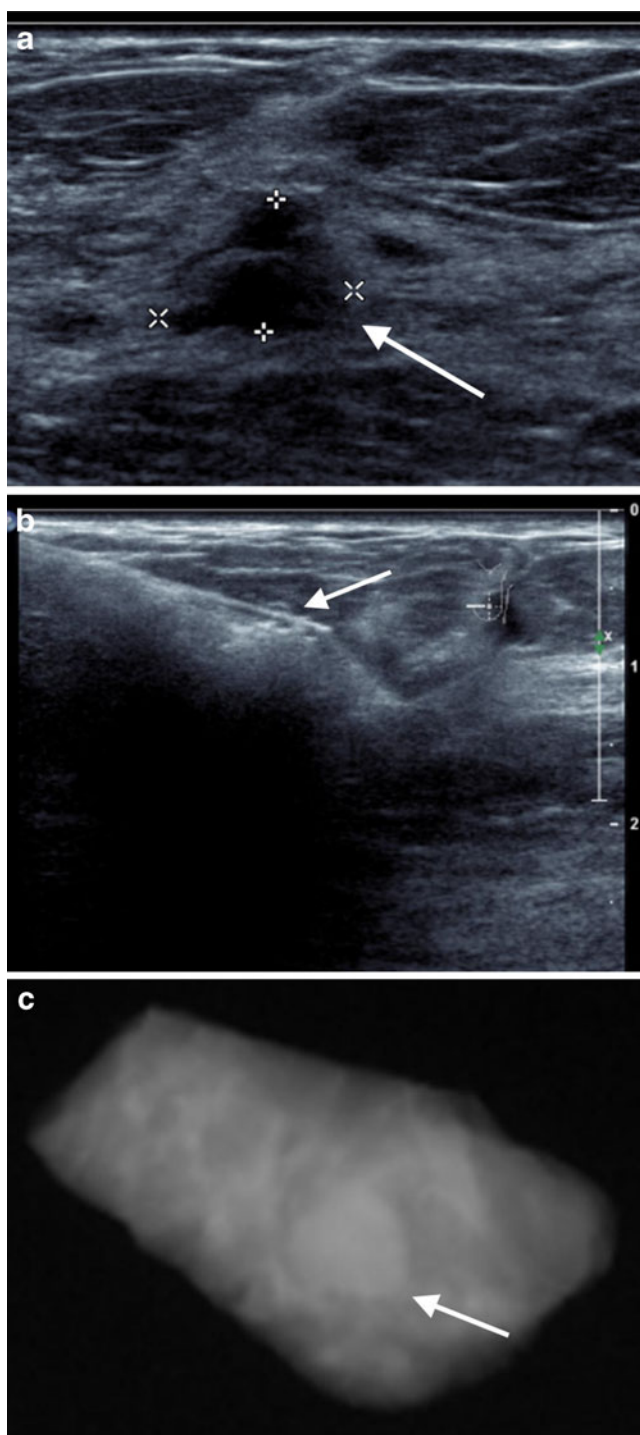


Fig. 2 Ultrasound guided BLES excision biopsy in a 51 year old woman. **(a)** An indeterminate lesion measuring only 6 mm is identified in the left breast. **(b)** A 15 mm diameter BLES is introduced under direct visualisation following the routine anaesthetic protocol. **(c)** Following excision, a specimen radiograph shows the lesion centrally placed in the sample and radiologically excised. This was confirmed as a benign papilloma, and also shown to be excised pathologically

specimens. This is in line with the USA experience [10]. Following fixation in formalin the samples measured approximately one gram and had a mammographic mean size of 21 mm (range 15–30 mm) × 10 mm (range 6–18 mm) × 9 mm (range 5–12 mm). They showed minimal diathermy artefact at the edge of the sections, which was invariably less than 1 mm in depth and very rarely interfered with the histological evaluation (Fig. 3). In these sections, apart from the diagnosis, the size of the lesion was measured accurately as well as the adequacy of the excision in all cases [11].

Final pathology is summarised in Table 1. 61/76 (80%) lesions had a final benign pathology. A total of 18 patients underwent subsequent surgical re excision. 6 of these were in benign/borderline lesions where margins were not complete or residual lesion was seen on the mammogram immediately following the procedure (5/11). Only one of these had residual lesion, with the BLES biopsy site identified in all cases. Tumour was seen at the biopsy margin in 8/15 malignant cases. On surgical re-excision of biopsy margins, residual disease was present in 5/12 patients (two having more extensive intermediate grade DCIS that was mammographically occult, another three with microscopic foci of DCIS at a distance from the excision). At histopathological analysis of the surgical resections, the BLES biopsy cavities were identified in all cases.

The 7 low grade DCIS cases with excision margins of >1 mm and no residual mammographic target were all discussed at the unit multidisciplinary meeting with regards proposed further management. Follow up surgery was offered in all but in these cases the volume and grade of disease was considered so low in risk that follow up only was offered as an alternative option. These cases were not considered of sufficient risk to

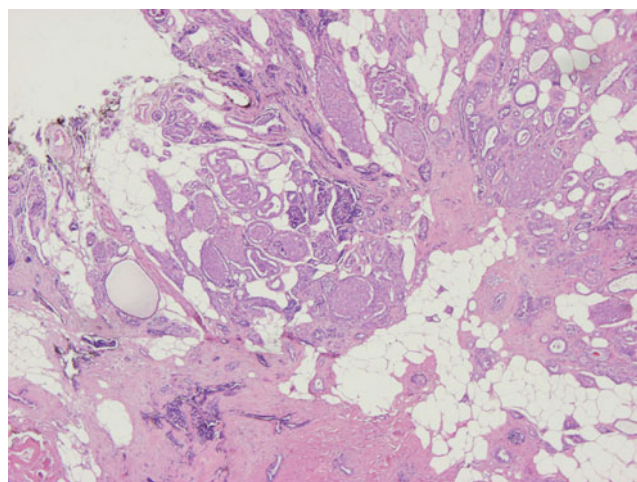


Fig. 3 A haematoxylin and eosin stained slide showing a radial scar within a BLES excision biopsy specimen that was completely excised pathologically. There were no atypical features

Table 1 Summary of final pathology

Lesion pathology	BLES excision margin of 1 mm or more	Residual lesion at follow up surgery
Atypical ductal hyperplasia	4/4	n/a
Columnar cell change with NO atypia	7/7	n/a
Columnar cell change with atypia	3/3	0/2
Fat necrosis	3/3	n/a
Fibroadenomatoid change	5/5	n/a
Fibrocystic change	7/7	n/a
Foreign body reaction	1/1	n/a
Papilloma, papillary change	13/15	1/2
Radial scar	7/12	0/2
Sclerosing adenosis	4/4	n/a
DCIS low grade	7/9	2/6
Other malignant lesions	2/6	3/6

warrant radiotherapy. 3 patients subsequently elected to decline a surgical margin excision when discussed at the outpatient clinic. These 3 cases now have had at least 18 months mammographic follow up on their radiologically excised DCIS, and all are negative to date. The four patients who did opt for margin excision surgery had no residual disease.

Discussion

We can validate the USA experience that the BLES biopsy is a well tolerated large biopsy procedure, with few complications. If used equivalently to a vacuum device just to sample rather than excise a breast lesion, then both advantages and disadvantages have to be considered. Although potentially slightly faster and in providing a single piece specimen for the pathologist, it is undoubtedly easier and more accurate to analyse in the laboratory, many lesions and the smaller breasts will not be suitable for this procedure. In addition the skin incision required to introduce the BLES is significantly larger than most vacuum needles. There is also the need to be extremely accurate with the needle positioning as essentially once the BLES is deployed, no further adjustments can be made to the acquisition. Indeed in our unit we have two other vacuum assisted biopsy machines which we also regularly use with great effect, with the different biopsy systems being complementary in our practice in differing radiological indications.

However in our study we have evaluated the capability of the BLES to perform excision biopsies which more measure

the procedure alongside diagnostic surgery, where there are potential morbidity and cost advantages. The results very much represent what can be achieved during the early stages of using this new technique specifically for radiological excision biopsies. Although having practised on phantoms prior to *in vivo* use, as with any new procedure, technical skill for both the stereotactic and ultrasound guided approaches will develop with experience. Allowing for this, the results are promising, with the procedure well tolerated in all cases. Aside from a single haematoma, there were no immediate or delayed complications and the specimens were excellent for pathological analysis. Although current wand sizes limit excision of many lesions, benign lesions of a suitable size and location were effectively managed in essentially a one-stop outpatient procedure. The BLES has been shown to be an efficacious tool at excising small benign breast lesions with a clear margin. In the majority of cases no residual radiological target has further confirmed this and in the cases requiring follow-up surgery, the majority have shown little in the way of residual lesion, even in malignant cases.

The NHS breast screening programme in the U.K. has been shown to save many lives every year, although it is not without its critics, particularly from the viewpoint that many women are over treated for non life threatening diagnoses. From this year it is extending, now to be routinely screening women from 47 to 73 and undoubtedly in order to detect cancers at an early stage a larger number of women have to be recalled from screening than will actually have the disease. This ultimately results in many benign core biopsies and sometimes diagnostic surgical biopsies. It is in the latter area that in our opinion breast screening particularly falls down currently and where the BLES may have a role in improving this. A benign surgical biopsy is failure of the non operative diagnosis of which the NHSBSP has a minimum and desired standard, and although the use of vacuum assisted biopsy has been used it is not optimal for all cases [12]. A piecemeal radiological excision for instance of a papilloma using a vacuum device, ignores the fact that in the few lesions of this pathology where ductal carcinoma *in situ* is associated, this is often present on the edge of the lesion. Without having a complete margin of excision in these lesions that are vacuum excised, there will undoubtedly be cases where this is not fully removed and the residual tissue may contain the ductal carcinoma *in situ* on the edge of the lesion. Indeed the literature with regards papilloma vacuum excision to date includes only several small series of cases and short term follow up data using this technique [13, 14]. While recurrence of a benign fibroadenoma following vacuum excision is problematic it is not potentially life threatening, but if even low grade malignancy is left behind following a vacuum excision of a papilloma or other borderline lesion then the conse-

quences may be serious. Therefore extending vacuum biopsies to indeterminate and potentially malignant lesions is certainly contentious, as the absence of a defined margin of excision will always be a criticism. The BLES clearly circumvents this problem and in a way provides a small but safe “surgical margin”.

Our sample size is small, and in particular the analysis of margins of malignant lesion excision, are not sufficiently statistically powered. Indeed this technique is not marketed or FDA approved for removal of malignant lesions, and it is only by coincidence that essentially a handful of patients with low grade non-invasive malignancy were managed purely in this fashion in our study. However, the results from this paper show that as wand technology improves, this may one day be possible. An upgraded system has recently been released, with FDA approval being considered for a more therapeutic remit. This will involve a larger and perhaps more efficient sample acquisition which may make margin negative excision of sub centimetre cancers a reality. This however will result in even larger skin excisions, which may not be cosmetically optimal, and naturally the accuracy of the BLES excision will be scrutinised much further. However, important future work may be to embark upon a prospective therapeutic study of this technique in its efficacy at achieving margin status in malignant disease.

Conclusion

This technical report shows that indeterminate small breast lesions can be managed successfully by using a BLES biopsy. Lesions shown to be benign following this diagnostic excision biopsy are in the majority completely excised and thus the pathologists can be confident in their diagnosis particularly in setting of many borderline lesions where small foci of malignancy can be subtle.

Acknowledgements No funding has been obtained in relation to this study and paper.

The authors state that there is no conflict of interest, financial or otherwise, involved in the preparation or the submission of this article.

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