NICE advice

ATEC system for vacuum-assisted breast biopsy

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Summary

The ATEC breast biopsy system is a vacuum-assisted breast biopsy device. It can be used under ultrasound, stereotactic and MRI guidance. The evidence shows that the ATEC system works successfully with all 3 imaging modalities, with a trade-off between faster procedure times and sample quality, and the incidence of complications. The list price of the ATEC Sapphire console is £15,000 excluding VAT. The list price of the disposable components needed for each biopsy procedure varies between £239 and £459, depending on the type of image guidance used.

Product summary and likely place in therapy	Effectiveness and safety
• The ATEC system is a vacuum-assisted breast biopsy (VABB) device intended to collect breast tissue samples for diagnostic sampling of breast abnormalities. • The ATEC system would be used in place of standard biopsy techniques including core needle biopsy and open (surgical) biopsy.	• Seven studies were identified that reported outcomes for VABB with the ATEC system. One used ultrasound guidance, 4 used stereotactic guidance and 2 used MRI guidance. • In comparison with the Mammotome VABB system, 1 prospective study showed that the ATEC system had faster biopsy times, but decreased sample quality. A retrospective study showed the ATEC system was about 30 minutes faster than the Bard Vacora VABB system for a single biopsy site and 20 minutes faster for 2 biopsy sites. • Total excision was achieved in 64.7% of lesions for the ATEC 9 gauge and 60.0% of lesions for the ATEC 12 gauge, compared with 85.7% of lesions using the Mammotome 8 gauge and 88.9% of lesions with the Mammotome 11 gauge. • One prospective study showed that biopsies using the ATEC 12-gauge needle had statistically significantly more incidences of bleeding than those using the Mammotome 11-gauge needle. The same study showed that post-interventional haematomas were seen statistically significantly more often with the ATEC 12 gauge than with the Mammotome 11 gauge. Another retrospective study showed that pain was noted statistically significantly less frequently with the ATEC system than with the Vacora system. • One retrospective study showed no statistically significant difference between the ATEC 9 gauge and Mammotome 11 gauge for the frequency of atypical ductal hyperplasia, tumour upgrade rate or the mean number of biopsy samples taken. Another prospective study showed that the diagnoses made with ATEC-acquired samples agreed with surgical histology results.

Technical and patient factors	Cost and resource use
• The ATEC system consists of a console and a handpiece to collect the samples. It is available with different sized needles. • The system can deliver anaesthetic directly into the biopsy site during the procedure through a Y-valve at the rear of the handpiece. Saline lavage of the biopsy site can also be done using the system. • Tissue collection is controlled by the operator using a footswitch. Samples can be taken at a maximum rate of 1 every 4.5 seconds.	• The list price of the ATEC Sapphire console is £15,000. • The per procedure list prices of accessories needed for imaging modalities are £239 for ultrasound, £245.50 for stereotactic and £459 for MRI. Depending on the stereotactic device used, a reusable adapter may also be needed at an additional list price of £3500. • These prices do not include imaging costs or VAT.

• The ATEC system can be used under ultrasound or stereotactic guidance in an outpatient setting or can be used under 1.5T and 3T MRI guidance in a radiology department.	

Introduction

Breast cancer is the most common cancer in women in the UK with 49,939 diagnoses in 2011 (Cancer Research UK 2014a) and 11,643 deaths recorded in the UK in 2012 (Cancer Research UK 2014b). Men can also be affected by breast cancer, to a lesser extent, with about 350 cases diagnosed in the UK in 2011 (Cancer Research UK 2014a). The 2 main types of breast cancer are invasive and non-invasive. Invasive ductal breast cancer accounts for 75% of all breast cancers (Breast Cancer Care 2013). The most common non-invasive type is ductal carcinoma in situ (DCIS), which accounts for 20% of breast cancers (Breast Cancer Care 2012).

The prognosis for breast cancer is greatly improved if it is detected early (Jemal et al. 2004). Both men and women are actively encouraged to check their breasts regularly and to notify their GP if there are any changes. The NHS Breast Screening Programme is a screening programme for women aged 47–73 years. Screening is done every 3 years to try to detect breast cancer early. Breast screening is usually done using a mammogram. Ultrasound is sometimes used to locate a suspicious lesion in dense breast tissue or provide more information, such as whether the lump is solid or contains liquid.

Suspicious lesions have 3 assessments (clinical, radiological and histopathological assessment) before curative surgery. After clinical and radiological assessment, suspicious lesions are always biopsied for histological assessment. Core needle biopsy is the current approach used in the NHS, where 1 sample is taken at a time, using 1 needle insertion per sample. Vacuum-assisted breast biopsy (VABB; also known as vacuum-assisted core

biopsy or VACB) combines needle biopsy with vacuum suction to collect multiple biopsy samples. VABB can be coupled with ultrasound, stereotactic or magnetic resonance imaging techniques to guide the biopsy needle to the correct location. Tissue collected using VABB is then sent for histopathological analysis. The ability of VABB to collect multiple samples with a single needle has the potential to reduce procedure times for patients and may reduce discomfort during breast biopsy in a minimally invasive manner. In addition, it ensures that tissue samples are taken from all parts of the lesion.

Technology overview

This briefing describes the regulated use of the technology for the indication specified, in the setting described, and with any other specific equipment referred to. It is the responsibility of healthcare professionals to check the regulatory status of any intended use of the technology in other indications and settings.

About the technology

CE marking

Hologic was awarded a Class IIa CE mark for the ATEC breast biopsy system in January 2009. The CE mark covers the console (ATEC Sapphire) and disposable handpiece. Other components needed for the ATEC system, such as the dedicated ATEC canister, adapter, remote tissue filter adapter, tissue adapter and needle guide, are Class I components.

Description

The automated tissue excision and collection (ATEC) system is a vacuum-assisted breast biopsy device. The system can be coupled with ultrasound, stereotactic or MRI techniques to help locate the suspicious lesion during breast biopsy.

The ATEC system consists of the ATEC Sapphire console unit, a disposable handpiece, which already contains a needle, and a tissue filter. The handpiece weighs 204 g, and is 4.2 cm in diameter and 26.8 cm long (excluding the needle). Needles are available in combinations of sizes (9 or 12 gauge, 9, 12 or 14 cm lengths and 12 or 20 mm apertures). Tissue collection is controlled by the operator through a footswitch. The time interval between each sample collection is dictated by the operator, however the ATEC system has

a maximum sampling rate of 1 sample every 4.5 seconds. The vacuum, generated by the ATEC Sapphire console, draws the tissue into the ATEC tissue filter at the rear of the needle for collection. The tissue filter is then removed and the tissue can be transferred to a tube or container in preparation for histological assessment. Body fluids such as blood, and saline used during the biopsy, are collected in the canister. The operator rotates the needle within the lesion to ensure that biopsy cores are taken from all parts of the lesion.

Once tissue collection is complete, the biopsy site can be washed with saline using the handpiece. This is claimed to reduce the risk and size of haematoma (a collection of blood). Anaesthetic can also be delivered locally into the biopsy site either automatically or manually through a Y-valve at the back of the device to control pain without interrupting the biopsy procedure. Anaesthetic is delivered in a radial pattern with each biopsy cycle, ensuring the local area is anesthetised. After the biopsy procedure, a radiopaque biopsy marker can be introduced and positioned using the handpiece needle by a side deployment delivery system.

The same handpiece can be used for both stereotactic- and ultrasound-guided procedures. For stereotactic-guided procedures, a specific needle guide and adapter are also needed depending on the stereotactic imaging system used. An MRI-guided procedure needs a dedicated handpiece and an introducer localisation set. Also, because all the handpieces are completely disposable there is no need for cleaning after use. The ATEC Sapphire console can also be used with Hologic Eviva handpieces.

Setting and intended use

The ATEC breast biopsy system is intended to be used to collect breast tissue samples for diagnostic sampling of breast abnormalities. The healthcare setting in which it is used depends on the imaging technique (MRI, ultrasound or stereotactic). Both stereotactic- and ultrasound-image-guided biopsies can be done in an outpatient setting by a radiologist or advanced practitioner. MRI-guided biopsies will be done in a radiology department by a radiologist or advanced practitioner. Biopsies done under the 3 imaging modalities are all minimally invasive.

Current NHS options

Methods for breast biopsy include open, image-guided core biopsy and vacuum-assisted breast biopsy (VABB). Open biopsies are more invasive and are often done under general anaesthesia; image-guided core biopsy and VABB are minimally invasive and are done

under local anaesthesia.

Image-guided core biopsies remove a single core of tissue from a lesion using a hollow needle. Several cores of tissue are often needed for accurate diagnosis, requiring multiple needle insertions into the breast.

The NHS Breast Screening Programme's clinical guideline on breast cancer screening assessment states that, where available, VACB (also known as VABB) may be considered the sampling method of choice for:

- microcalcifications
- after a B1/B3/B4 result at 14-gauge core biopsy
- diagnostic excision of papillary lesions and radial scars or complex sclerosing lesions without atypia that have been diagnosed at core biopsy.

NICE is aware of the following CE-marked devices that appear to fulfil a similar function to the ATEC breast biopsy system:

- Original Mammotome (Devicor Medical Products)
- EnCor (C. R. Bard).

Costs and use of the technology

List prices for the ATEC breast biopsy system and the components needed, excluding VAT, are tabulated in the appendix.

All 3 imaging modalities need an ATEC Sapphire console, which costs £15,000. One console may be used for all modalities. Per procedure prices for each imaging modality (including necessary components and excluding the ATEC Sapphire console price) are:

- £239 for ultrasound image-guided biopsies, which includes a disposable handpiece and a 9- or 12-gauge needle, and an ATEC canister.

- £245.50 for stereotactic image-guided biopsies, which includes a disposable handpiece and a 9- or 12-gauge needle, an ATEC canister and a 9- or 12-gauge needle guide compatible with the imaging system. A reusable ATEC adapter at an additional one-off cost of £3500 is also needed. Adapters are specific to the stereotactic imaging device used.
- £459 for MRI-guided biopsies, which includes a disposable MRI-compatible handpiece and a 9-gauge needle, an ATEC canister and an introducer localisation set.

An annual service contract is also available for the ATEC Sapphire console at a maximum annual cost of £1500.

Likely place in therapy

The ATEC system would be used where VABB is indicated as an alternative to core needle biopsy or open biopsy.

Specialist commentator comments

According to specialist commentators, VABB is used to biopsy both B2 (pathologically benign) and B3 (atypical) lesions. VABB is also used to remove fibroadenomas and papillomas that have already been diagnosed through core biopsy. In addition, VABB is used to sample areas where more tissue is needed for diagnosis, for example, if microcalcification is detected during routine screening.

Three specialist commentators noted that VABB is unlikely to completely replace core biopsy, 1 of whom stated that, in their experience, core biopsy is the gold standard. However, another commentator stated that it is likely to be used in place of some open and core biopsies.

One specialist commentator stated that they would prefer a longer procedure with good quality samples and less bleeding instead of a fast procedure; quality of samples being important for histological assessment. This commentator felt that the evidence suggested the quality of samples obtained with the ATEC system may not be as good as those taken with other VABB systems. One specialist commentator stated that sample quality does not seem to have a bearing on the pathological accuracy, and therefore the ATEC system would not compromise outcomes. Another specialist commentator noted that VABB, regardless of the system used, produces larger quantities of tissue and the time taken for

the pathologist to review them will be longer. The same specialist commentator noted that pathology services are already under pressure.

One specialist commentator added that the flexibility of the device, allowing it to be used with different imaging systems, is a significant advantage for hospital-based services.

Two specialist commentators noted that the price of the ATEC system is comparable to competitor VABB systems. Another specialist commentator stated that an annual service contract is an attractive proposal.

Haematoma has been recorded as a complication in the included studies. Two specialist commentators noted that haematomas can occur with any VABB device and with core biopsies.

One specialist commentator stated that the evidence supports using this device in the clinical workplace. They noted that the time needed to take a biopsy sample would be of low importance but that the ATEC system appears to be faster than other VABB devices. However; they pointed out that the faster biopsy time has not reduced the number of complications observed.

One specialist commentator stated that the ATEC system would have a role in the practice of VABB and that it generally compares favourably with other devices on the market. Another specialist commentator noted that the device has a place in breast diagnostics and particularly in managing B3 lesions, but should not be considered as a replacement for first-line core biopsy, considering the risk of haematoma.

Equality considerations

NICE is committed to promoting equality and eliminating unlawful discrimination. In producing guidance and advice, NICE aims to comply fully with all legal obligations to:

- promote race and disability equality and equality of opportunity between men and women
- eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

Although men and women can develop breast cancer, it is far more common in women. Additionally, the risk of developing breast cancer increases with age. Sex and age are protected characteristics under the Equality Act 2010. People diagnosed with cancer are considered to be disabled under the Act and are therefore protected from the point of diagnosis.

Evidence review

Clinical and technical evidence

Regulatory bodies

A search of the Medicines and Healthcare Products Regulatory Agency website revealed no manufacturer Field Safety Notices or Medical Device Alerts for this device. Twenty two reports of adverse events related to the ATEC device were identified from a search of the US Food and Drug Administration (FDA) database: Manufacturer and User Device Facility Experience (MAUDE). Table 1 lists the events and outcomes that were noted.

Table 1 Summary of adverse events and outcomes relating to the ATEC device on the FDA MAUDE database

Event	n=22	Outcome	n=22
Lesion pushed away	1	Hologic enhanced quality checks	1
Biopsy too small	1	Repeat procedure	1
Component missing	5	Procedure repeated	1
		Component replaced	1
		Not stated	3
Device continued taking biopsies	2	Patient unharmed	2
Device stopped during biopsy	1	Not stated	1
Difficulty removing device from the breast	1	Not stated	1

Device failed pre-procedure quality assurance checks	1	Not stated	1
Haematoma	1	Patient hospitalised	1
Inner/outer cannula broke off	2	Cannula still in patient	1
		Patient unharmed	1
Operator needle stick injury	1	Not stated	1
Suresight tip disengaged	1	Patient unharmed	1
Needle tip broke off/bent/lodged	5	Needle tip still in patient	2
		Occurred before procedure	1
		Patient unharmed	2

Clinical evidence

Thirty-three potentially relevant studies were identified, from which the following were excluded: 2 German-language publications, 2 reports that did not separate ATEC results from other vacuum-assisted breast biopsy devices, 1 abstract with no results, 2 posters with limited information, and 1 poster of a study also available as a full paper. The remaining 26 studies used the ATEC system with either ultrasound-, stereotactic- or MRI-guided imaging. Studies were selected for further assessment and prioritised according to design (from highest to lowest) as follows: prospective comparative, prospective non-comparative, retrospective comparative and retrospective non-comparative. No randomised controlled trials were identified. This resulted in 7 studies: 1 for ultrasound-guided, 2 for MRI-guided and 4 for stereotactic-guided. A detailed summary of included studies is in the appendix; key outcomes are summarised in table 2.

Table 2 Key study outcomes

Study	Comparator(s) and imaging technique	Outcomes and safety	Summary of findings

Hahn et al. 2010 62 biopsies from 59 patients, prospective comparative study Single centre (Germany)	Mammotome ATEC 9 gauge versus Mammotome 8 gauge ATEC 12 gauge versus Mammotome 11 gauge. Ultrasound, iU 22 12 MHz, Philips Healthcare	Operating time: ATEC 9 gauge 9.6 minutes, Mammotome 8 gauge 9.7 minutes (p=0.931). ATEC 12 gauge 6.9 minutes, Mammotome 11 gauge 6.2 minutes (p=0.640). Total excision of lesions: ATEC 9 gauge 64.7%, Mammotome 8 gauge 85.7%. ATEC 12 gauge 60.0%, Mammotome 11 gauge 88.9%. Two ATEC 9-gauge procedures stopped because of needle clogging due to the canister not being secure. One needle deviation with Mammotome 8 gauge that needed a second needle.	Study results favour the Mammotome for total excision only.

Schaefer et al. 2012 178 patients, prospective comparative study Single centre (Germany)	Mammotome ATEC 9 gauge versus Mammotome 8 gauge ATEC 12 gauge versus Mammotome 11 gauge Stereotactic, prone table, Fischer Imaging	Fewer incidences of bleeding with Mammotome 11 gauge versus ATEC 12 gauge (p=0.015). No significant differences in bleeding with ATEC 9 gauge versus Mammotome 8 gauge. Fewer post-interventional haematomas with Mammotome 11 gauge versus ATEC 12 gauge (p=0.001). There were no significant differences in scar formation at any needle size. No correlation between scar formation and bleeding or haematoma (p=0.8).	Study results favour the Mammotome 11 gauge for fewer incidences of bleeding and post-interventional bleeding.
Eller et al. 2014 189 patients, comparative study with patient questionnaire Single centre (Germany)	Mammotome ATEC 9 gauge versus Mammotome 11 gauge Stereotactic, Mammotest Plus/S, Fischer Imaging	Patient questionnaire: no significant difference for patient condition during procedure (p=0.25) or 1 week after biopsy (p=0.2). Haematomas (n=179) identified using mammography, in 62/145 (43%) of ATEC 9 gauge procedures and 12/34 (35%) of Mammotome 11 gauge procedures. Questionnaire reporting complications: ATEC 9 gauge 62/150 (41%), Mammotome 11 gauge 7/39 (18%) (p=0.005).	The study results favour the Mammotome for fewer incidences of haematoma.

Order et al. 2013 146 patients, randomised comparative study Single centre (Germany)	Mammotome ATEC 9 gauge versus Mammotome 8 gauge ATEC 12 gauge versus Mammotome 11 gauge Stereotactic, prone table, Fischer Imaging	Sampling time: ATEC 9 gauge was 244.84 s faster than the Mammotome 8 gauge, and the ATEC 12 gauge was 267.58 s faster than the Mammotome 11 gauge (p<0.001). Sample quality (judged by a blinded pathologist): both Mammotome needle sizes produced significantly higher-quality samples than both ATEC needle sizes (p<0.001). Underestimation of micro-invasive cancer was seen in both the Mammotome and ATEC sizes.	The study results favour the ATEC system for shorter biopsy time and the Mammotome system (both needle sizes) for higher sample quality.
Eby et al. 2009 991 patients, retrospective comparative study Single centre (USA)	Mammotome ATEC 9 gauge versus Mammotome 11 gauge Stereotactic, Lorad prone table, Hologic	No significant difference between the rate of tumour upgrade (from benign to malignant) between ATEC 9 gauge and Mammotome 11 gauge (21.6% and 20.4% respectively, p=0.87). The number of samples taken by each system was not statistically significantly different, with the ATEC 9 gauge taking an average of 9.9 samples and the Mammotome 11 gauge taking an average of 10.5 samples (p=0.4).	The study results did not favour either system for upgrade frequency or the mean number of samples taken.

Liberman et al. 2003 20 patients, prospective comparative study Single centre (Germany)	ATEC versus surgical histology MRI, 1.5T Signa, General Electric Medical Systems	The procedure was a technical success in 95% of the patients. Complications: In mammograms taken after VABB (26 lesions), haematoma and air were seen in 54% of lesions whereas air without haematoma was seen in 28% of lesions. Clinical haematoma that was resolved was seen in 1/19 patients. Disagreements between comparators: ATEC diagnosis agreed with surgical histology in 89% of cases. ATEC falsely diagnosed benign lesions in 10% of patients (these were positive under surgical histology. 1/5 lesions diagnosed as invasive cancers using ATEC was diagnosed as benign by surgical histology.	The study results did not favour either procedure. However, the study showed that there was a high level of agreement between the ATEC system and surgical histology.

Schrading et al. 2010 349 patients, 475 lesions, retrospective comparative study Single centre (Germany)	Vacora ATEC 9 gauge versus Vacora 10 gauge MRI, 1.5T Gyroscan ACS II, Philips Healthcare	More needle localisations for open biopsy needed with Vacora 10 gauge (115 patients, 121 lesions) compared with ATEC 9 gauge (34 patients, 38 lesions). More biopsies were possible with ATEC 9 gauge (158 patients, 267 lesions) versus Vacora 10 gauge (42 patients, 49 lesions). ATEC produced more biopsy samples (mean=12) than the Vacora system (mean=8). ATEC was statistically significantly faster (mean 36 minutes) versus Vacora (mean 69 minutes) for a single biopsy site (p=<0.005) and for 2 lesions (ATEC mean=70 minutes, Vacora=90 minutes, p<0.005). The ATEC system had a higher positive predictive value for malignant lesions than the Vacora system (43% and 29% respectively). Pain was noted statistically significantly less frequently with the ATEC system (6%) than with the Vacora system (38%; p<0.012). Prolonged bleeding after ATEC biopsy was seen in 1 patient, needing compression for 150 minutes. A 3 cm haematoma was seen in 1 patient after Vacora biopsy.	The study results favour the ATEC system for being able to do more procedures with the device over needle localisations for open biopsy, more biopsy samples, faster procedure time, higher positive predictive value for malignant lesions, and less pain during the procedure.

Abbreviations: VABB, vacuum-assisted breast biopsy.

Recent and ongoing studies

No ongoing or in-development trials on the ATEC vacuum-assisted system for breast biopsy were identified.

Costs and resource consequences

In 2013–2014, there were 3170 finished consultant episodes of breast biopsies in England; 3118 of these were in women. Of these, 1625 were done using vacuum-assisted breast biopsy (VABB) or needle core biopsy, 977 were open (surgical) biopsies, 434 were wire-guided open (surgical) biopsies, 95 were breast biopsies specified as 'other' and 39 were unspecified breast biopsies (Health and Social Care Information Centre 2015).

The payment by results tariffs (Department of Health 2013) for outpatient attendance, leading to consultant-led breast surgery (service code 103), are as follows:

- first attendance, single-professional and multi-professional: £150 (WF01B and WF02B respectively)
- follow-up attendance, single professional and multi-professional: £86 (WF01A) and £99 (WF02A) respectively.

The NHS costs for combined day case or ordinary elective spells for breast excision (Payment by results tariff, Department of Health 2013) are:

- unilateral major breast procedures category 2 with intermediate complications and co-morbidities (CC): £2163 (HRG code, JA07E)
- unilateral major breast procedures category 2 without CC: £2020 (HRG code, JA07F)
- unilateral intermediate breast procedures without CC: £1128 (HRG code, JA09G).

VABB is widely used in the NHS and, according to the manufacturer, the ATEC system is currently in use in 22 NHS hospitals across the UK. The system uses 1 console coupled to different accessories for use under ultrasound, stereotactic and MRI guidance, so there is no need for a dedicated biopsy system for each imaging modality. For MRI guidance, the ATEC system works successfully with both 1.5T and 3T MRI systems (Dogan et al. 2012).

Strengths and limitations of the evidence

Hahn et al. (2010) prospectively evaluated 2 VABB systems in a randomised study with statistical analyses included. The authors described the inclusion and exclusion criteria. The number of patients assigned to either ATEC or Mammotome was relatively even, as was the distribution of patients with BI-RADS III, IV and V. In table 4 of the paper, the operating times of the Mammotome and ATEC systems are presented in mm; these are presented in minutes elsewhere in the paper.

Schaefer et al. (2012) compared biopsies taken with ATEC and Mammotome, using a range of needle-gauge sizes. The study is quite large, with 178 patients, but is based upon retrospective data. The outcomes are important complication factors including bleeding, haematoma and scar formation, but the study did not assess histological sample quality produced by either system. The evaluation of scar formation was subjective. In addition, haematoma is a common complication with VABB regardless of the device used.

Eller et al. (2014) was mainly a questionnaire-based patient-reported study. This is the only study that deals with patient experience during the biopsy procedure, and compares ATEC with Mammotome. It was a well-sized study, surveying 189 patients. However, the 2 treatment groups were highly unbalanced with 145 patients in the ATEC group and 34 patients in the Mammotome group. This study does not contain comparative data on the clinical effectiveness of the ATEC device, or histological sample quality produced by the device. The study compares 11-gauge with 9-gauge needles, which are very different in size; the 11-gauge needle is smaller than the 9-gauge needle. A better comparison would have been 11 gauge with 12 gauge or 8 gauge with 9 gauge. In the study, question 5 asked whether participants preferred VABB over open surgical biopsy. However, the authors did not state whether the participants had previously had open surgical biopsy and so may have had no experience to compare with VABB. Although the authors present the incidence of haematoma, this is a common complication with VABB regardless of the device used.

Order et al. (2013) compared biopsies taken using ATEC and Mammotome, with a range of needle-gauge sizes. The outcomes were important comparative factors, such as biopsy time and histological sample quality. This study was also prospective, which reduces bias. Histological quality was a multi-factorial judgement made by a blinded pathologist, which reduces the bias in the study. Pathologists are highly likely to regard histological sample quality as more important than biopsy time.

Eby et al. (2009) compared the ATEC and Mammotome systems in a retrospective study in which patients had stereotactic-guided VABB and were consecutively allocated to the 2 study groups. Inclusion and exclusion criteria were noted by the authors, and the study had a large sample size of 991 patients. Statistical analysis methods have been described and applied. However, there is a large discrepancy in the size of the 2 groups, with 391 patients in the Mammotome arm and 600 patients in the ATEC arm. VABB can underestimate the incidence of atypical ductal hyperplasia and ductal carcinoma in situ as can core needle biopsy because of sampling error. VABB allows more samples to be collected, or even complete excision in some instances, and so reduces sampling error in an effort to decrease histological underestimation. However, it must be noted that the ATEC device is not intended to be used for complete excision of the suspicious lesion. This study shows that both the ATEC and Mammotome systems have similar atypical ductal hyperplasia diagnosis and upgrade frequencies.

Liberman et al. (2003) evaluated the ATEC system under MRI-guidance and compared the diagnosis made using the ATEC biopsied lesions with the diagnosis made after surgical biopsy, to validate the method. The authors have stated inclusion criteria but not exclusion criteria, and it is not clear if the people in the study were enrolled consecutively. The patient numbers were low (n=20) and this was reduced to 19 people after a technical failure. The authors of the study did not carry out any inferential statistical analysis of the data; this is probably because of the low patient numbers. The authors present data on haematoma incidence, but this is a common complication with VABB regardless of the device used.

Schrading et al. (2010) did a comparative study of the ATEC and Vacora systems. This study had a large number of patients (n=349) and compared outcomes from the 2 systems. However, no inclusion or exclusion criteria were stated and it is unclear whether the study participants were consecutively enrolled. The authors concluded that operator confidence with the ATEC system led to a change in patient care compared with needle localisation. However, the devices were not compared simultaneously, with the ATEC phase (July 2006 to December 2007) following 18 months of using the Vacora VABB device (January 2005 and June 2006).

Relevance to NICE guidance programmes

NICE has issued the following guidance:

- Early and locally advanced breast cancer: diagnosis and treatment (2009) NICE guideline CG80.
- Image-guided vacuum-assisted excision biopsy of benign breast lesions (2006) NICE interventional procedure guidance 156.

References

Breast Cancer Care (2012) Ductal carcinoma in situ (DCIS). [online, accessed 20 August 2015]

Breast Cancer Care (2013) Invasive ductal breast cancer. [online, accessed 20 August 2015]

Cancer Research UK (2014a) Breast cancer incidence statistics. [online, accessed 20 August 2015]

Cancer Research UK (2014b) Breast cancer mortality statistics. [online, accessed 20 August 2015]

Department of Health (2013) Payment by results 2013–14, payments by result (PbR) in the NHS. [online, accessed 04 August 2015]

Dogan BE, Le-Petross C, Stafford JR et al. (2012) MRI-guided vacuum-assisted breast biopsy performed at 3 T with a 9-gauge needle: preliminary experience. American Journal of Roentgenology 199: W651–W3

Eby PR, Ochsner JE, DeMartini WB et al. (2009) Frequency and upgrade rates of atypical ductal hyperplasia diagnosed at stereotactic vacuum-assisted breast biopsy: 9-versus 11-gauge. American Journal of Roentgenology 192: 229–34

Eller AJ, Janka R, Lux M et al. (2014) Stereotactic vacuum-assisted breast biopsy (VABB) – A patients' survey. Anticancer Research 34: 3831–7

Hahn M, Kagan KO, Siegmann KC et al. (2010) Mammotome versus ATEC: a comparison of two breast vacuum biopsy techniques under sonographic guidance. Archives of Gynecology and Obstetrics 281: 287-92

Health and Social Care Information Centre (2015) Hospital Episode Statistics, Admitted Patient Care, England - 2013–14: procedures and interventions. [online, accessed 4 August 2015]

Jemal A, Clegg LX, Ward E et al. (2004) Annual report to the nation on the status of cancer, 1975–2001, with a special feature regarding survival. Cancer 101: 3–27

Liberman L, Morris EA, Dershaw DD et al. (2003) Fast MRI-guided vacuum-assisted breast biopsy: initial experience. American Journal of Roentgenology 181: 1283–93

Order BM, Schaefer PJ, Peters G et al. (2013) Evaluation of two different vacuum-assisted breast biopsy systems: Mammotome system 11G/8G vs. ATEC system 12G/9G. Acta Radiologica 54: 137–43

Public Health England (2010) Clinical guidelines for breast cancer screening assessment (Clinical Guideline No. 49). [online, accessed 23 October 2015]

Schaefer FK, Order BM, Eckmann-Scholz C et al. (2012) Interventional bleeding, hematoma and scar-formation after vacuum-biopsy under stereotactic guidance: Mammotome-system 11g/8g vs. ATEC-system 12g/9g. European Journal of Radiology 81: e739–45

Schrading S, Simon B, Braun M et al. (2010) MRI-guided breast biopsy: influence of choice of vacuum biopsy system on the mode of biopsy of MRI-only suspicious breast lesions. American Journal of Roentgenology 194: 1650–7

Search strategy and evidence selection

Search strategy

The following search strategy was used to search Ovid MEDLINE (R) 1946 to July Week 2 2015:

1 exp breast/ or mammary glands, human/

2 Image-Guided Biopsy/ or Biopsy/ or Biopsy, Needle/

3 vacuum/

4 1 and 2 and 3

5 ATEC.ti,ab.

6 4 or 5

7 (vacuum adj10 breast biopsy).ti,ab.

8 6 or 7

Similar search strategies were adapted for Medline in Process, Embase, Cochrane Library (all components), Pubmed, Scopus and Web of Science. The searches returned a total of 498 references after duplicate removal.

Evidence selection

Retrieved results were independently sifted by 2 researchers using the selection criteria below, and disagreements discussed and resolved.

- Population/setting: people who need breast biopsies for suspected cancerous and benign lesions.
- Intervention: vacuum-assisted breast biopsy.
- Comparator: other vacuum-assisted breast biopsy devices (for example, Mammotome, Bard Encor), core needle biopsy, breast biopsy surgery.

- Outcomes:
  - pain/discomfort
  - biopsy duration
  - number of total excisions
  - technical success rate
  - bleeding during intervention
  - haematoma post-procedure
  - scarring
  - cancer detection
  - ductile carcinoma in situ.

After the first sift, 465 records were removed due to the following criteria:

- non-English language studies
- not relevant to selection criteria
- review articles and protocols.

Thirty-three references remained and full text articles were retrieved for these. Further studies were excluded due to the following criteria:

- results for ATEC not separated from other results
- no results presented
- poster presentation.

Twenty-six studies remained after exclusion based on the above criteria. The literature was split into the 3 different imaging techniques (ultrasound, stereotactic and MRI) used to guide the biopsy procedure. Studies were selected with the following priority from highest to lowest: prospective comparative, prospective non-comparative, retrospective comparative and retrospective non-comparative. Finally, 7 studies were included in this briefing: 1 for ultrasound-guided, 2 for MRI-guided and 4 for stereotactic-guided.

Appendix

Contents

Data tables

ATEC system price lists

Table 3 Overview of the Hahn et al. (2010) study

Study component	Description

Objectives/ hypotheses	The aim of this study was to evaluate the diagnostic reliability, biopsy duration and medical and technical complications of 2 VB systems.
Study design	Prospective, randomised comparative study.
Setting	Single-centre (Germany). Patients were enrolled during April 2006 to July 2007. There was no follow-up.
Inclusion/ exclusion criteria	Inclusion criteria: • diagnostic indication for VB of suspect breast lesions or diagnostic–therapeutic indication for VB of benign symptomatic lesions • age 18–80 years • written consent. Exclusion criteria: • previous VB at the same site • allergy to local anaesthetic • pregnancy.
Primary outcomes	BI-RADS distribution according to the biopsy method, histological results, mean lesion size, mean operating time and total excision.
Statistical methods	Mann–Whitney U tests were carried out where appropriate. Uni- and multivariate logistical regression were used to predict the effect of different parameters on complete lesion excision; uni- and multivariate linear regression were used to predict the effect of parameters on biopsy duration.
Patients included	59 patients were enrolled in the study and 62 biopsies were done. Mammotome 8-gauge and 11-gauge biopsies: n=30. ATEC 9-gauge and 12-gauge biopsies: n=32.

Results	**BI-RADS grading** BI-RADS III, IV and V grading was seen in 18, 13 and 1 instance(s) respectively for the ATEC system, and 19, 10 and 1 instance(s) for the Mammotome system. **Histological results** A range of benign and malignant states was seen in the 62 biopsies: ADH (3.2%), DCIS (3.2%), invasive ductal carcinoma (1.6%), papilloma (6.5%), fibroadenoma (45.2%), scar (8.1%), LCIS (1.6%) and other benign lesions (30.6%). **Total excisions** Total excision was achieved in 64.7% and 60.0% of biopsies using the ATEC system with 9-gauge and 12-gauge needles respectively. Total excision was achieved in 85.7% and 88.9% of biopsies using the Mammotome with 8-gauge and 11-gauge needles respectively. **Multivariate logistic regression for sonographic complete resection** The statistically significant influencing variables were BI-RADS IV lesions (OR 0.10; 0.02 to 0.45; p=0.003) and the mean lesion size (OR 0.81; 0.71 to 0.93; p=0.002). **Multivariate logistic regression for biopsy duration** The statistically significant influencing variables were BI-RADS IV lesions (OR −2.29; −4.83 to 0.25; p=0.077) and the maximum lesion size (OR 0.25; 0.06 to 0.44; p=0.01).
Conclusions	Both systems are suitable for clinical applications involving diagnostic tissue removal from focal lesions in the breast. Imaging-guided complete resections can be achieved more often with the Mammotome.
Abbreviations: ADH, atypical ductal hyperplasia; BI-RADS, breast imaging-reporting and data system; DCIS, ductal carcinoma in situ; LCIS, lobular carcinoma in situ; OR, odds ratio; SD, standard deviation; VB, vacuum-biopsy.	

Table 4 Summary of the results from the Hahn et al. (2010) study

	n	Mean (mm)	SD (mm)	
Mean lesion size				
Mammotome 8 gauge	21	14.2	4.6	ns, p=0.685
ATEC 9 gauge	17	14.9	6.4	
Mammotome 11 gauge	9	8	3.9	ns, p=0.088
ATEC 12 gauge	15	10.5	3.7	
Mean operating time				
Mammotome 8 gauge	21	9.7	5.6	ns, p=0.931
ATEC 9 gauge	17	9.6	5.9	
Mammotome 11 gauge	9	6.2	3.9	ns, p=0.640
ATEC 12 gauge	15	6.9	3.7	
Abbreviations: ns, not significant; n, number.				

Table 5 Overview of the Schaefer et al. (2012) study

Study component	Description
Objectives/ hypotheses	To prospectively evaluate the correlation of scar-formations after vacuum-assisted breast biopsy with different systems, needle-sizes and interventional bleeding or post-interventional haematoma.
Study design	Consecutive, prospective, comparative study.
Setting	Mammary Diagnostic, Gynaecology and Radiology Departments, Kiel, Germany.
Inclusion/ exclusion criteria	Inclusion criteria: Patients presenting with suspicious microcalcifications seen on mammography. Exclusion criteria not stated.

Primary outcomes	Bleeding during intervention, post–interventional haematoma and scar tissue formation. Each metric was scored as small, moderate or severe. Bleeding or haematoma definitions: small bleeding or haematoma – a maximum of 20 ml blood aspirated or discrete density area of a maximum extension of 1.5×1.5×1.5 cm in projection of the target area in post-interventional mammography; moderate bleeding or haematoma – a maximum of 20–40 ml blood aspirated or density area of a maximum of 3.0×3.0x3.0 cm; severe bleeding or haematoma – more than 40 ml blood aspirated or density area of more than 3.0×3.0×3.0 cm. Scar formation definitions: minimal – a very vague density seen only along the z-axis of the biopsy probe; moderate – a density area or an architectural distortion on one or both projection planes in the target area of the biopsy site; severe – a lesion causing diagnostic problems regardless of the knowledge of previous biopsies and so needing additional mammography, ultrasound, re-biopsy or MRI imaging.
Statistical methods	The Chi-square trend test was used for inter- and intra-group analysis of differences between the groups. A p-value of <0.05 was considered to be significant.
Patients included	479 consecutive patients had VAB under stereotactic guidance, using the Mammotome system with 11-gauge or 8-gauge needles or the ATEC system with 12-gauge or 9-gauge needles. Out of 479 patients the results for only 178 patients are presented. These patients did not have open surgical biopsy, and had at least a 2-plane follow-up mammogram after 6 months post VAB. Needle size was determined by the size of the lesion: for small lesions (>15 mm diameter) ATEC 9 gauge or Mammotome 8 gauge were used; for larger lesions (<15 mm diameter) ATEC 12 gauge or Mammotome 11 gauge was used. Mammotome 11-gauge and 8-gauge needles were used in 84 and 31 patients, respectively. ATEC 12-gauge and 9-gauge needles were used in 37 and 26 patients, respectively.

Results	The mean number of biopsy samples taken was 22.71 for the Mammotome 8-gauge needle (range, 6–24; standard deviation [SD], 4.173), 24.48 for the Mammotome 11-gauge needle (range, 7–48; SD, 3.695), 24.46 for the ATEC 9-gauge needle (range, 24-36; SD, 2.353), and 24.65 for the ATEC 12-gauge (range, 12–35; SD, 3.946). **Bleeding** There was no significant difference in the bleeding rates of the Mammotome 8 gauge compared with the ATEC 9 gauge (p=0.135). There were significantly fewer incidences of bleeding with Mammotome 11 gauge than the ATEC 12 gauge (p=0.015). **Haematoma** No significant differences between the different ATEC needle sizes (p=0.596). No significant differences between Mammotome 8 gauge and ATEC 9 gauge (p=0.352). Haematomas occurred significantly more often with the Mammotome 8 gauge than Mammotome 11 gauge (p=0.029). Significantly fewer haematomas with Mammotome 11 gauge compared with the ATEC 12 gauge (p=0.001). **Scar formation** No significant differences between Mammotome 8 gauge and 11 gauge or ATEC 9 gauge and 12 gauge for scar formation. No significant differences in scar formation between Mammotome 8 gauge and ATEC 9 gauge (p=0.823) or Mammotome 11 gauge compared with the ATEC 12 gauge (p=0.609). There was no correlation between the risk of scar formation and the occurrence of bleeding or haematoma (p=0.800).
Conclusions	The larger needle sizes of Mammotome (8 gauge) and ATEC (9 gauge) did not result in statistically significantly different rates of bleeding or haematoma formation. However, the Mammotome 11 gauge showed statistically significantly fewer bleeding events and haematoma formation than the ATEC 12 gauge. There was no statistically significant difference in scar formation between Mammotome and ATEC systems regardless of needle gauge.

Abbreviations: SD, standard deviation; VAB, vacuum-assisted biopsy.

Table 6 Overview of the Eller et al. (2014) study

Study component	Description
Objectives/ hypotheses	To analyse how patients experience stereotactic-guided vacuum-assisted breast biopsy (VABB) both physically and mentally.
Study design	Prospective, comparative study with a patient questionnaire element.
Setting	Radiology and Gynaecology & Obstetrics Departments, Erlangen, Germany.
Inclusion/ exclusion criteria	Inclusion criteria: patients with breast microcalcifications classified as BI-RADS 4 or 5 (all were sent questionnaires). Exclusion criteria not stated.
Primary outcomes	Percentage of benign or malignant lesions identified by histological result. Results from a questionnaire on the patients' experience of the biopsy; Q1 and Q2 were rated excellent, very good, good, fair or poor): Q1: Your condition during biopsy. Q2: Your condition the week after the biopsy. Q3: Complications (yes or no). Q4: Evaluate your cosmetic result after biopsy. (satisfactory or non-satisfactory). Q5: Retrospectively, would you prefer a vacuum-assisted biopsy to an open surgical biopsy? (yes or no).
Statistical methods	Pearson's Chi-square-test.

Patients included	211 patients; 189 responded to questionnaire or phone call. Median age 61 years (range 32–87). VABB was done in 150 patients with ATEC (9 gauge), 39 with Mammotome (11 gauge). Post-interventional mammograms were available for 179/189 (95%) patients (Mammotome 34/39, 87%; ATEC. 145/150, 97%). For the remainder, the images were given to the patients and so were not available for analysis.
Results	The 2 different devices did not show significant differences for biopsy accuracy. Complications (n=69): • haematoma 51/69 (74%) • severe pain 23/69 (33%) • combined haematoma and severe pain 7/69 (10%) • palpable scar tissue (3/69, 4%). 15 patients did not regard haematoma or pain as a complication. Post-operative mammograms were done in 179/189 people. Haematomas were seen in 74/179 mammograms: 62/145 (43%) patients with ATEC; 12/34 (35%) patients with Mammotome. However, 58/189 (31%) patients biopsied thought they had a haematoma. There was no significant difference between the 2 devices for patient condition while having the biopsy or 1 week after the biopsy (Q1, p=0.25; Q2, p=0.2). In Q3, the ATEC system was significantly more frequently associated with complications (ATEC: 62/150; Mammotome: 7/39; p=0.005). The authors note that the smaller diameter of the ATEC needle (9 gauge) may have higher traumatic potential than the 11 gauge Mammotome needle.

Conclusions	Most patients preferred VABB to surgical biopsy. ATEC was not statistically significantly different to Mammotome for biopsy accuracy, but was statistically significantly worse for complication rates including haematomas. Younger patients more readily reported complications than older patients, and were more sensitive to the cosmetic results post-biopsy.
Abbreviations: BI-RADS, breast imaging-reporting and data system; Q, question; VABB, vacuum-assisted breast biopsy.	

Table 7 Overview of the Order et al. (2013) study

Study component	Description
Objectives/ hypotheses	To compare 2 stereotactically-guided vacuum-assisted biopsy systems, measuring time effectiveness and harvested sample quality.
Study design	Randomised, part-blinded, comparative study
Setting	Mammary Diagnostic, Gynaecology and Radiology Departments, Kiel, Germany.
Inclusion/ exclusion criteria	Inclusion criteria: patients presenting with suspicious microcalcifications seen on mammography. Exclusion criteria not stated.

Primary outcomes	Time taken to collect histological samples. Four time slots: system set-up; the biopsy itself starting with the first skin incision and ending with the last sample gathered; preparation of tissue samples to be sent to pathologist; cleaning the site for the next patient. Quality of samples for histology was judged by a blinded pathologist. Tissue fragmentation was judged as: 0 (having no tissue); 1 (multiple fragments, none >5 mm in length); 2 (multiple fragment, at least one ≥5 mm); 3 (at least 1 fragment, ≥10 mm). Crush artefacts were graded as: 0 (no tissue); 1 (severe crush, destroying most of the sample); 2 (some crush, does not impair interpretation of biopsy), 3 (limited or no crush artefacts). Adequacy of tissue for diagnosis was graded: 0 (no tissue); 1 (tissue, but provides non-diagnostic samples); 2 (allows sufficient diagnosis); 3 (specimen with textbook quality).
Statistical methods	Means and standard deviations reported for sample collection time, evaluated biopsy quality compared using Mann–Whitney U test and Chi-squared. P value set at <0.05 for significance.
Patients included	146 people presenting with suspicious microcalcifications seen on mammography. Calcifications were classified as BI-RADS 4 or 5. Mammography was used to further subdivide the patients into those with small lesions (<15 mm, small-gauge biopsy needles were used – ATEC 12 gauge or Mammotome 11 gauge), or large lesions (>15 mm, ATEC 9 gauge or Mammotome 8 gauge). Large lesions: 34 people biopsied with Mammotome 8 gauge and 37 people with ATEC 9 gauge Small lesions: 37 people biopsied with Mammotome 11 gauge and 38 people with ATEC 12-gauge needles.

Results	Sampling time The ATEC 9 gauge was 244.84 seconds faster than the Mammotome 8 gauge ($p<0.001$). The ATEC 12 gauge was 267.58 seconds faster than the Mammotome 11 gauge ($p<0.001$). Significant time differences were only seen in the biopsy performance stage itself, not for the system setup, sending to the pathologist or clean-up for the next patient. **Sample quality** Highest-quality samples: • the ATEC 9 gauge – 20 (13.7%) patients • the Mammotome 8 gauge – 15 (44.1%) patients • the Mammotome 11 gauge – 10 (27%) patients. Medium-quality samples: • the ATEC 9 gauge – 20 (13.7%) patients • the Mammotome 8 gauge – 17 (11.6%) patients • the ATEC 12 gauge – 21 (13.4%) patients • the Mammotome 11 gauge – 20 (13.7%) patients. Lowest-quality samples: • the ATEC 9 gauge – 14 (37.8%) patients • the Mammotome 8 gauge – 2 (5.9%) patients • the ATEC 12 gauge – 17 (44.7%) patients • the Mammotome 11 gauge – 7 (18.9%) patients. Mammotome (of both sizes) provided significantly better sample quality than the ATEC system (of both sizes) ($p<0.001$). In 3/68 (4.4%) of patients with malignant lesions, a histological underestimation was found with vacuum-assisted biopsies, when a DCIS was diagnosed, but the histology of the surgical specimen had shown

	micro-invasive cancer. One of these was collected with the 8 gauge Mammotome, and the other 2 with ATEC 12 gauge and 9 gauge respectively. The small number of these patients means that statistical analysis cannot be performed for significance.
Conclusions	The ATEC system provides statistically significantly faster sample collection, and Mammotome system provides statistically significantly higher-quality histological samples for analysis.
Abbreviation: BI-RADS. breast imaging-reporting and data system.	

Table 8 Overview of the Eby et al. (2009) study

Study component	**Description**
Objectives/ hypotheses	To determine the frequency and upgrade rate for atypical ductal hyperplasia diagnosed with stereotactic 9 gauge vacuum-assisted breast biopsy and to compare the frequencies and upgrade rates of atypical ductal hyperplasia between 9 gauge and 11 gauge vacuum-assisted breast biopsy.
Study design	Retrospective, consecutive, comparative data study.
Setting	Radiology Department, University of Washington Medical Centre, USA.

Inclusion/ exclusion criteria	Inclusion criteria – specimens were included if: • the VABB pathology report indicated ADH without concomitant in situ or invasive cancer • ADH was accompanied by other high-risk histology, such as ALH or radial scar. Exclusion criteria – specimens were excluded from the upgrade analysis if: • the biopsied lesion was not surgically excised, for example if the patient did not report for follow-up at the same hospital site, or opted for mastectomy • diagnosed as columnar cell change with atypia, flat epithelial atypia, or ALH if ADH was not also present.
Primary outcomes	Frequency of ADH, rates of upgrade (from benign to malignant), and the number of VABB samples between 9- and 11-gauge procedures.
Statistical methods	Chi-square, Fischer's Exact and Student's t tests used. $p<0.05$ was considered significant.
Patients included	Retrospective database analysis: Patients with BI-RADS category 4 or 5 who had stereotactic VABB procedures. 991 patients: 391 consecutive Mammotome 11-gauge biopsies, 600 consecutive ATEC 9-gauge biopsies.
Results	Mammotome 11 gauge versus ATEC 9 gauge: The frequency of ADH was similar for ATEC 9 gauge (13.8%) and Mammotome 11 gauge (14.8%) VABB (p=0.66). The difference in upgrade rate between ATEC 9 gauge (21.6%) and Mammotome 11 gauge (20.4%) was not significant (p=0.87). The difference between the mean number of samples taken with ATEC 9 gauge (9.9) and Mammotome 11 gauge (10.5) was not significant (p=0.4).
Conclusions	No statistically significant differences between ATEC 9-gauge and Mammotome 11-gauge sizes were found for the frequency of ADH identified, the number of biopsy samples taken, or the upgrade rate.

Abbreviations: ADH, atypical ductal hyperplasia; ALH, atypical lobular hyperplasia; BI-RADS, breast imaging-reporting and data system; VABB, vacuum-assisted breast biopsy.

Table 9 Overview of the Liberman et al. (2003) study

Study component	Description
Objectives/ hypotheses	The purpose of this study was to evaluate a new method of doing MRI-guided vacuum-assisted breast biopsy in a study of lesions that had subsequent surgical excision.
Study design	Prospective, consecutive, comparative study.
Setting	Single-centre (Germany).
Inclusion/ exclusion criteria	Inclusion criteria: Patients scheduled for MRI-guided needle localisation of a non-palpable mammographically occult lesion. The patients must have had an MRI at the study-site institution as part of screening of patients at high risk for breast cancer or for assessing the extent of disease, if logistics allowed the biopsy to be done on the day of her surgery, and if her surgeon approved her participation. Exclusion criteria: not stated.
Primary outcomes	Technical success, lesion characteristics, lesion biopsy procedure, number of biopsy specimens collected, clip deployment and positioning, time to do the biopsy, review of mammograms taken after biopsy, final histology and correlation of histology from VABB specimens with surgical samples.
Statistical methods	Summary statistics have been presented.
Patients included	20 patients, median age 51 years (range 19–64 years). 27 lesions from 19 patients were biopsied in total.

Results	**Technical success** The biopsy was technically successful in 19 (95%) of 20 patients. In 1 woman, the biopsy device could not be inserted and the lesion needed surgical excision. **Lesion characteristics** 27 lesions were biopsied in 19 patients. There were single lesions in 11 of the patients and 2 lesions in 8 of the patients who had a biopsy. The median size of these 27 lesions was 1.0 cm (range, 0.4–6.4 cm). A separate skin incision was made for each lesion that was biopsied. **Number of biopsy specimens collected** The median number of specimens obtained per lesion was 8 (range 6–14). In 23 lesions, only a single round of tissue collection was needed. Four required repeat acquisition. **MRI clip deployment and positioning** Clip placement was successful in 25/26 (96%) lesions. The first attempt at clip placement was successful in 20/26 (77%) lesions, and a second attempt was successful in 5/26 (19%) lesions. One placement failed despite 2 attempts. **Median time to do the biopsy** (From the original axial localising images to the final images obtained after clip deployment). Single lesion: 35 min (mean, 35 min; range, 24–48 min) 2 lesions: 65 min (mean, 69 min; range, 62– 86 min). Tissue collection time: 38 sec (mean, 41 sec; range, 29–87 sec). **Mammograms** Haematoma with air in 14/26 lesions (54%), Air without haematoma in 10/26 lesions (38%). No changes (biopsy site was not visible on the mammogram) in 2 (8%) lesions. Complication in 1/27 (4%) lesions (1/19 patients, 5%): a clinical

	haematoma, which resolved with compression and did not delay subsequent surgery. **Correlation of VABB with surgical histology** 24/27 agreement of VABB samples with surgical histology. 2/20 VABB benign lesions were diagnosed malignant by surgical histology. 1/5 VABB invasive cancers was diagnosed benign by surgical histology.
Conclusions	MRI-guided VABB is an alternative to surgery and to existing MRI-guided needle biopsy methods in clinical use for the histologic diagnosis of MRI-detected lesions. Further work with more patients is needed, including optimisation of equipment and techniques for biopsy and clip placement, potential use of long-acting contrast agents, imaging–histologic correlation, and long-term follow-up.
Abbreviations: ADH, atypical ductal hyperplasia; DCIS, ductal carcinoma in situ; MRI, magnetic resonance imaging; VABB, vacuum-assisted breast biopsy.	

Table 10 Summary of the results from the Liberman et al. (2003) study

VABB histology	Surgical histology			
	Benign	ADH	DCIS	Invasive cancer
Benign	18 (67%)	1 (4%)	1 (4%)	0 (0)
ADH	0 (0)	0 (0)	1 (4%)	0 (0)
DCIS	0 (0)	0 (0)	1 (4%)	0 (0)
Invasive cancer	1 (4%)	0 (0)	0 (0)	4 (15%)
Abbreviations: ADH, atypical ductal carcinoma; DCIS, ductal carcinoma in situ; VABB, vacuum-assisted breast biopsy.				

Table 11 Overview of the Schrading et al. (2010) study

Study component	Description
Objectives/ hypotheses	The purpose of this study was to evaluate 2 systems of MRI-guided vacuum-assisted breast biopsy and to investigate the influence of the choice of system in the care of patients with lesions found only at MRI.
Study design	Retrospective, comparative study.
Setting	Single-centre (German), patients were recruited between January 2005 and December 2007.
Inclusion/ exclusion criteria	No inclusion or exclusion criteria were stated.
Primary outcomes	Number of patients and lesions having handheld (Vacora), console (ATEC) or needle localisation; lesion characteristics; procedure time; histological results.
Statistical methods	The Student's t-test and Wilcoxon's signed rank test were used to compare the biopsied lesion size and biopsy time. A value of p=0.05 was accepted as indicating statistical significance.
Patients included	349 patients (mean age, 52.5 years; range, 28–76 years) had MRI-guided intervention (needle localisation or VABB). 475 lesions were seen on MRI. 149 patients (159 lesions) had needle localisation, and 200 patients (316 lesions) had VABB. Two study periods with different devices were compared: • First – 18 months (January 2005–June 2006): MRI-guided VABB with Vacora with 10-gauge needle (Bard). • Second – 18 months (July 2006–December 2007): VABB with console ATEC 9 gauge (Hologic).

Results	**Patient demographics, clinical indications** There was no statistically significant difference between the number of patients or lesions that had vacuum biopsy or needle localisation using the Vacora or ATEC devices (p>0.05) for mean age and distribution of clinical indications for breast MRI. **Number of patients and lesions having handheld (Vacora), console (ATEC) or needle localisation** Total: 349 patients, 475 lesions. Vacora 10-gauge localisation: 115 patients, 121 lesions. Vacora 10-gauge VABB: 42 patients, 49 lesions. ATEC 9-gauge localisation: 34 patients, 38 lesions. ATEC 9-gauge VABB: 158 patients, 267 lesions.
	Mean time to do single- and multiple-site vacuum biopsy Mean number of biopsy specimens: Vacora 8 (range, 4–16); ATEC 12 (range, 6–25). Mean single-site biopsy time: Vacora 69 minutes (range, 35–95); ATEC 36 minutes (range, 23–64); p<0.005. Mean biopsy time for 2 lesions: Vacora 90 minutes (range, 62–134); ATEC 70 minutes (range, 40–112); p< 0.005. **Pain tolerance and procedural complications** 16/42 patients (38%) biopsied with the Vacora had notable pain during stylet placement and during biopsy. 16/267 (6%) biopsied with ATEC had notable pain during needle placement, none during actual tissue sampling. This difference was statistically significant (p<0.012). No major complications or infections were seen during or after vacuum biopsy. 1 ATEC-biopsied patient had continuous venous bleeding after manual compression lasting >90 minutes. 60 minutes of further manual compression stopped the bleeding. 1 Vacora patient had a 3 cm haematoma at the biopsy site.

Conclusions	Smaller lesions were biopsied in less time and with higher operator confidence with ATEC because of the procedural advantages of using the console-based system. As a result, there was a major shift in the care of patients with lesions identified by MRI alone, away from lesion localisation to increased use of MRI-guided VABB.
Abbreviations: SD, standard deviation; VABB, vacuum-assisted breast biopsy.	

Table 12 Summary of the results from the Schrading et al. (2010) study

	Vacora		
Procedure	**Non-malignant (n)**	**Malignant (n)**	**Positive predictive value (%)**
Needle localisation	55	66	55 (66/121)
Vacuum biopsy	35	14	29 (14/49)
Total	90	80	47 (80/170)
	ATEC		
Procedure	**Non-malignant (n)**	**Malignant (n)**	**Positive predictive value (%)**
Needle localisation	18	20	53 (20/38)
Vacuum biopsy	151	116	43 (116/267)
Total	169	136	45 (136/305)
Abbreviation: n, number.			

ATEC system price lists

Table 13 Prices of standard ATEC components (excluding VAT)

Component	**Quantity supplied**	**Price**

ATEC Sapphire console	1 (can be used for all 3 imaging modalities)	£15,000
9-gauge (3.7 mm) needle, 9/12 cm length with 12/20 mm aperture size for ultrasound and stereotactic imaging	5	£1170
9-gauge (3.7 mm) needle, 14 cm length with 20 mm aperture size for ultrasound and stereotactic imaging	5	£1170
12-gauge (2.7 mm) needle, 9/12 cm length with 20 mm aperture size for ultrasound and stereotactic imaging	5	£1170
9-gauge (3.7 mm) needle, 14 cm length with 12/20 mm aperture size and MRI compatibility	5	£1550
Range of 9-gauge and 12-gauge needle guides for compatibility with Fischer, GE, Siemens, Instrumentarium and Lorad prone/upright stereotactic systems	5	£32
ATEC 400 cc canister with lid	10	£50
Stereotactic adapters for use with upright systems or prone table	1 (reusable)	£3500
9-gauge introducer localisation set for MRI	5	£720

Table 14 Prices of optional ATEC components (excluding VAT)

Component	Quantity	Price
ATEC tissue filter	5	£30
ATEC remote tissue filter adapter	5	£45
SecurMark biopsy site marker	10	£734
TriMark biopsy site marker	10	£678
Note: Markers are available in different configurations to match the needle length and gauge used during the procedure.		

Changes after publication

December 2015: One comment deleted from the Specialist commentator comments section.

About this briefing

Medtech innovation briefings summarise the published evidence and information available for individual medical technologies. The briefings provide information to aid local decision-making by clinicians, managers and procurement professionals.

Medtech innovation briefings aim to present information and critically review the strengths and weaknesses of the relevant evidence, but contain no recommendations and **are not formal NICE guidance**.

Development of this briefing

This briefing was developed for NICE by Cedar. The interim process & methods statement sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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Declarations of interest

No conflicts of interest were declared.

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