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The case for routine placement of breast biopsy markers

This paper will

- Introduce breast biopsy markers, their placement and imaging
- Discuss the clinical guidelines related to the use of biopsy markers
- Identify situations where the placement of biopsy markers helps clinicians and patients

Breast biopsy is routinely used for the investigation and management of suspicious breast lesions or abnormalities. Typically, a minimally invasive biopsy is performed using ultrasound, MRI, mammography or contrast-enhanced mammography for guidance. During this procedure, a biopsy marker – also known as a breast marker or clip – can be placed to mark the site for future imaging. The markers allow clinicians to identify areas which have been biopsied before, as well as distinguish between different sites with the use of different shaped markers. Biopsy marker use is generally widespread, and has become a routine standard of practice in many places, providing a useful tool for clinicians, and improving the patient experience for women undergoing breast cancer investigations.[1] However, the material used for markers, and their shapes, affects their stability and visibility to the different imaging modalities used during breast cancer investigations.[2] This paper discusses the benefits of placing biopsy markers, clinical guidelines relating to their use, and factors to consider in their selection.

Biopsy markers and their imaging

Improvements in the ability of imaging systems to detect non-palpable breast lesions have led to the development of image-guided localisation and biopsies. These minimally invasive core needle, fine-needle aspiration and vacuum-assisted biopsy techniques allow reliable sampling of suspicious lesions, and have almost entirely replaced surgical excision as a means of initial diagnosis. Given that over half of biopsies yield a benign result, this approach has significantly reduced the need for surgical interventions which might ultimately prove unnecessary, minimising the complications and costs associated with breast cancer diagnosis. However, the development of image-guided breast biopsy has created a need to identify and mark sites where biopsies have been taken. As a variety of imaging techniques are used during breast cancer investigation – such as ultrasound, mammography and MRI – markers that can be visualised with several of these methods allow comparison between images, even when the breast is viewed in different situations, for example, due to different positioning during interventions. In addition, different shaped markers can be used to identify different sites in the breast when multiple lesions are investigated. Use of these markers has become widespread in clinical practice around the world over the last decade, and clinical guidance from numerous national and international bodies now recommends their routine use during breast biopsy procedures to aid future patient management and improve outcomes.

Biopsy markers can be placed during different types of biopsy, and visualised using standard breast imaging techniques.

A.

B.

Figure 1: Breast biopsy markers can be placed during various biopsy procedures, including (A) MRI-guided biopsy and (B) stereotactic core biopsy.

Clinical guidance on breast marker placement

EU

Several European bodies have published guidance to support the use of breast biopsy markers. The European Society for Medical Oncology (ESMO) 2019 guidelines for early breast cancer diagnosis, treatment and follow-up recommend that a marker should be placed into the tumour at biopsy, to ensure resection of the correct site and enable pathological assessment of the surgical specimen.[3] In 2020, the European Society of Breast Imaging (EUSOBI) published recommendations for women and referring clinicians relating to image-guided localisation and breast biopsy.[4] The publication discusses the use of breast clips for marking a lesion post core needle or vacuum-assisted biopsy, as a tool to confirm a match between pathological results and imaging appearance, as well as for preoperative localisation. It highlights the importance of this approach for small lesions that will be completely removed by vacuum-assisted biopsy, for completely drained cystic lesions, and for candidates for neoadjuvant therapy – where successful treatment means the clip can be used to target and excise the tumour bed, even when the tumour is no longer visible. It states that a marker should always be placed after an MRI-guided biopsy, even if the lesion remains visible after biopsy. This confirms the correct sampling location and allows any subsequent intervention to be performed by means of the easier mammographic or ultrasound guidance.

The European Commission Initiative on Breast Cancer (ECIBC) has also made recommendations regarding the use of breast biopsy markers during breast cancer screening and diagnosis.[5] Its Guidelines Development Group (GDG) suggests using clip-marking after core needle or vacuum-assisted biopsy for surgical therapy planning in patients with breast cancer lesions. In addition, it notes that tumours may vanish completely in imaging under neoadjuvant chemotherapy (radiologic complete response), but residual tumour cells can remain, and have to be removed by surgery.

Clip-marking in these cases is important, in order to define the area of breast tissue which has to be removed. The clip is also useful for directing the pathologist to the tumour site, especially for huge tumour specimens or mastectomies, aiding thorough sampling of the tumour bed when the tumour may not be visible macroscopically. If the lesion or pathological area is widespread, more than one clip is sometimes used to define the extent of the disease, or to show which areas of an extended lesion biopsies have been taken from.

In addition to European recommendations, local guidance in some countries further supports the use of biopsy markers. For example, Belgian guidelines for laboratory handling and pathology reporting of breast carcinoma after neoadjuvant therapy state that 'placement of markers, such as clips or tattoos, at the time of initial biopsy or during therapy, is useful to ensure accurate localisation of the tumour bed at surgery'.[6] Furthermore, the German Guideline Program in Oncology (GGPO) provides consensus-based recommendations on the early detection, diagnosis, treatment and follow-up of breast cancer, and strongly recommends that 'the examiner shall take suitable measures to ensure that the localisation of the finding can be found again (e.g. by clip insertion)' during biopsy.[7]

UK

The UK's NHS Breast Screening Programme provides clinical guidelines for breast cancer screening assessment.[8] The fourth edition, published in November 2016, includes updated guidance on the use of breast markers, and advises the placement of markers 'to confirm the correct area has been sampled – for example, when changes are difficult to perceive – or if there is any doubt that the lesion seen on ultrasound corresponds to the mammographic changes'. Marker placement is considered particularly important to enable treatment planning/surgical localisation when there are multiple lesions, or when there is any risk that the area of concern could be removed or rendered difficult to see by the biopsy. The guidelines state that use of a marker, with mammographic documentation of its position, is the safest way to simplify communication within and between teams, ensuring the correct lesion is removed at surgery and aiding follow-up. They also highlight that marker placement can be helpful for better correlation between mammography and ultrasound imaging.

Around the world

The use of breast biopsy markers is also recommended in other countries around the world. This includes in the USA, where consensus guidelines from the American Society of Breast Surgeons (ASBrS), published in 2017, state that surgeons should 'place a clip or other marking device at the time of percutaneous biopsy of all suspicious lesions, to confirm appropriate sampling and improve the accuracy of future localisation if there is concern the lesion may be completely removed during MIBT, or if the patient is to undergo neoadjuvant therapy'.[9] Similarly, the American College of Radiology (ACR) recommends the use of markers in certain circumstances where they can help to identify the site of biopsy in the future.[10] In Canada, national guidelines by the Canadian National Neoadjuvant Breast Cancer Consortium (NABC) on the neoadjuvant treatment of invasive breast cancer recommend that, for invasive breast tumours that are eligible for breast-conserving surgery, a marker clip should be placed for preoperative localisation in the event of complete clinical and radiologic treatment response.[11] Both BreastScreen Australia and Breast Screen Aotearoa recommend the use of markers in several circumstances, including marking breast or axillary lesions that have been nearly or completely removed at the time of biopsy, confirming biopsy sites where multiple lesions are present, confirming ill-defined lesions, lesion mapping, and correlation across imaging modalities for diagnostic reasons.[12,13] In addition, the Australian federal health budget has recently agreed to fund breast markers for patients who need them.[14]

The placement of breast markers during biopsy is recommended by clinical guidelines around the world, including in the EU and the UK.

Region	Organisation	Recommendation
EU	ESMO[3]	'A marker should be placed into the tumour at biopsy, to ensure resection of the correct site and to enable pathological assessment of the surgical specimen.'
	EUSOBI[4]	'A marker…. can be placed in the biopsy site at the end of sampling with CNB or VAB to allow for subsequent checking of concordance between the pathological results and imaging appearance, as well as for preoperative localisation. This is especially important for small lesions that can be completely removed with VAB and are no longer visible after biopsy, and also for completely drained cystic lesions. Positioning a marker is also necessary to mark lesions in patients who are candidates for neoadjuvant therapy.' 'A marker is always placed after an MRI-guided biopsy, even if the lesion remains visible after biopsy. This confirms the correct location of the sampling but also allows performance of any subsequent intervention by means of the easier mammographic or US [ultrasound] guidance.'
	ECIBC[5]	'The ECIBC's Guidelines Development Group suggests using clip-marking after NCB/VANCB for surgical therapy planning in patients with breast cancer lesions.'
Germany	GGPO[7]	'The examiner shall take suitable measures to ensure that the localisation of the finding can be found again (e.g. by clip insertion).'
Belgium	Belgian Working Group for Breast Pathology[6]	'Placement of markers, such as clips or tattoos, at the time of initial biopsy or during therapy, is useful to ensure accurate localisation of the tumour bed at surgery.'
UK	NHS[8]	'The correlation between mammography and ultrasound is important to ensure any abnormalities seen relate to the same lesion on both modalities. Lesion size, shape and position should be considered and in cases where correlation is challenging, difficult or uncertain, then the placing of a marker (clip) under ultrasound and subsequently repeating the mammogram may be helpful.' 'Marker (clip) insertion is advised to confirm the correct area has been sampled, for example, when changes are difficult to perceive, or if there is any doubt that the lesion seen on ultrasound corresponds to the mammographic changes. Marker (clip) placing is particularly important to facilitate treatment planning/surgical localisation when there are multiple lesions or when there is any risk that the area of concern could be removed or rendered difficult to see by the biopsy.' 'A marker (clip), with mammographic documentation of its position, is the safest way to facilitate communication within and between teams and to ensure the correct lesion is removed at surgery or to facilitate follow-up.'

Table 1: Clinical recommendations on the use of breast biopsy markers in various regions. This is not an exhaustive list, and local guidelines should be consulted if not listed here.

Region	Organisation	Recommendation
USA	ASBrS[9]	'Place a clip or other marking device at the time of percutaneous biopsy of all suspicious lesions, to confirm appropriate sampling and improve the accuracy of future localization if there is concern the lesion may be completely removed during MIBT, or if the patient is to undergo neoadjuvant therapy.'
	ACR[10]	'A marker can be placed percutaneously at the biopsy site in order to mark the lesion location…. Potential indications for ultrasound-guided percutaneous placement of a marker include the following: **a.** To mark the location of a lesion no longer visible at the end of the biopsy procedure, usually because it has been completely or mostly removed. In such cases, care should be taken to ensure the marker is not inadvertently removed during biopsy. **b.** To correlate findings on different modalities or to correlate a specific lesion with its pathology on future imaging. This usage is especially important if there are multiple lesions or if the patient will be receiving treatment or future imaging at another center where complete record of her biopsy history may not be available. **c.** To mark the site of a cancer that may be treated with neoadjuvant systemic therapy and may consequently become less visible.'
Canada	NABC[11]	'For invasive breast tumours that are eligible for breast conserving surgery, a marker clip should be placed to be used for pre-operative localization in the event of complete clinical and radiologic treatment response.'
Australia	BreastScreen Australia[12]	'Marker placement should be used in the following circumstances: • marking the site of a lesion that has been totally or almost completely removed at needle biopsy or vacuum-assisted biopsy (e.g. calcifications and small masses) • confirmation of biopsy site if multiple lesions are present. When using vacuum-assisted biopsy, it is recommended that a different shaped marker is used for each biopsied lesion and appropriately documented • confirmation of the site of biopsy of an ill-defined lesion (e.g. mammographic architectural distortion) • if future surgery and/or preoperative localisation is considered to be potentially difficult due to lesion conspicuity OR if preoperative localisation is likely to be carried out using a modality different from the biopsy modality • local assessment team protocols, such as lesion mapping and for extensive areas • for correlation across modalities for diagnostic reasons.'

Table 1: Clinical recommendations on the use of breast biopsy markers in various regions. This is not an exhaustive list, and local guidelines should be consulted if not listed here.

Reasons to place biopsy markers

Surgical localisation

The placing of breast biopsy markers allows clinicians to identify and monitor tissues that have already been suspected and investigated for malignancy, and they effectively act as targets for the placement of surgical markers.[1,15,16] In the absence of markers, the suspected tissue is identified either by the presence of residual disease seen by mammogram or ultrasound, the localisation of bruises after biopsy, or by navigation using breast tissue landmarks.[17] However, these techniques are much less accurate at identifying target tissue compared to the use of breast markers. As a result, these techniques require a greater volume of sample tissue to be extracted to ensure the successful excision of the target tissue.[18] Minimally invasive breast biopsy procedures using breast markers have been proven to reduce positive margin rates compared to previous methods. For example, Nurko *et al.* demonstrated that, with the use of breast markers, clear margins were achieved in 90 % of patients, which is a significant improvement compared to approaches that did not use markers reported in the literature.[19]

Breast biopsy markers enhance surgical planning, allowing accurate localisation of the malignancy for placement of surgical markers.

Assess extent of disease

In some cases, multiple regions of the breast will be biopsied to investigate the severity and range of large disease areas. This provides valuable information about the extent of disease, and the volume of tissue that must be resected at surgery.[20] In these cases, placing markers at each biopsy site helps differentiate between benign and malignant tumours. This can assist clinicians in surgical planning and targeting of the correct regions, avoiding the risk of confusion or errors.[1] If more than one tumour is present in the same breast, markers at the different sites aid in surgical planning: the markers are easily seen with imaging modalities, and can be used to guide hook wire localisation before surgery, leading to bracketing of the irregularity.[21] As a result, the placement of biopsy markers has been shown to decrease positive margins and the need for reintervention after surgery.[22]

Using multiple breast biopsy markers can help monitor the extent of disease and differentiate individual lesions.

Enabling multi-modality correlation

Biopsy markers are a useful tool for correlating findings between imaging modalities.[23] It is common for abnormalities that are first detected by mammography or MRI to undergo further investigation by targeted ultrasound. In addition, ultrasound-guided biopsies are usually the preferred approach to sample the lesion. It is therefore important that the lesion being investigated corresponds between the different imaging modalities. Placing a clip during biopsy, followed by post-biopsy imaging using the original imaging method, can confirm that the correct lesion is being investigated. The need for correlating images was illustrated by Meissnitzer *et al.*, who used follow-up MRI imaging to look at 80 lesions originally detected by MRI, then biopsied under ultrasound guidance and found to be benign. Alarmingly, this study determined that 10 (12.5 %) of the ultrasound-located lesions did not correspond to the original MRI findings.[24]

Breast biopsy markers can help correlate between ultrasound, mammography and MRI images.

Applications in neoadjuvant chemotherapy

Neoadjuvant chemotherapy is used before surgery to shrink and debulk the tumour. However, in some instances, it has the effect of shrinking the tumour to the extent that it is no longer visible by imaging. In a study by Dash *et al.* of a cohort of 28 patients undergoing presurgical chemotherapy, near/complete cancer regression was seen in 57 % of patients.[25] In such cases, a clip placed during biopsy is the only reliable way to identify the site of the lesion on follow-up imaging and for surgical removal of the tumour bed. Furthermore, a review by Oh *et al.* of patients who had undergone neoadjuvant chemotherapy and breast-conservation therapy, found that the five-year rate of local control was 98.6 % in patients who had radiopaque clips placed, versus 91.7 % in patients who did not have tumour marker clips placed. The omission of tumour bed clips was associated with a hazard ratio of 3.69 for increased local recurrence compared with patients who did have radiopaque clip placement, showing that placing a marker during biopsy was associated with better local control, independent of stage and other clinicopathological findings.[26]

Breast biopsy markers are the only way to accurately identify lesion sites for tumour bed removal following a complete response to neoadjuvant chemotherapy.

Management of benign lesions

Placing breast biopsy markers simplifies follow-up, even if tumours are found to be benign, enabling future investigations to easily identify new lesions that have not previously been biopsied.[20] This means that, even if the patient moves between facilities, and in the absence of their medical records, unnecessary biopsies of lesions that have already been investigated will be prevented. Furthermore, when benign nodules – such as fibroadenomas – are removed with large-core, vacuum-assisted biopsy, the presence of a clip at the site assists follow-up, since the lesion would no longer be visible on imaging.

Breast biopsy markers allow monitoring of benign lesions, even in the absence of complete medical records, preventing unnecessary re-biopsy.

Targeting inaccessible lesions

MRI-guided core needle biopsy has been the standard method for sampling lesions that can only be visualised by contrast-enhanced breast MRI. However, the position of the lesion can change significantly after breast compression, resulting in poor accessibility by standard MRI-guided biopsy approaches. Wood *et al.* demonstrated a technique whereby a poorly accessible lesion was marked with a biopsy marker from a lateral approach during an MRI-guided core needle biopsy that could not yield a sample. The lesion was then identified by locating the marker by ultrasound, and a core needle biopsy was successfully performed.[27]

Breast biopsy markers support biopsy of inaccessible lesions.

What to look for when choosing a biopsy marker

The uses and benefits of biopsy markers are now well-established in clinical practice, as evidenced by the numerous guidelines recommending their routine use during the investigation and management of suspicious breast lesions or abnormalities. However, not all breast markers are created equal, and with a range of options on the market, there are some key considerations when selecting a marker that offers the most benefits during on-going treatment.

Long term visibility

When a breast biopsy marker is placed during the initial investigation of a lesion, this is often just the start of its use. If the result is benign, and the marker's usefulness is in marking the biopsy site during future breast screening, then it is preferable for the marker to show during imaging over a prolonged period of time. If the result is malignant, and the patient undergoes neoadjuvant chemotherapy, then the marker must last at least for the duration of the treatment, until removal of the tumour bed during surgery. Long term ultrasound visibility is particularly important in these cases, as this modality is often used for presurgical localisation to improve patient comfort and avoid ionising radiation.

The visibility of a marker using different modalities is dependent on its composition, and a number of surgical-grade materials are used for the manufacture of biopsy markers, including:

- **Stainless steel** – widely used due to its strength, durability and non-magnetic properties. It is biocompatible and generally well tolerated by the body.
- **Nitinol** – a shape memory alloy composed of nickel and titanium. It has the unique property of returning to a predetermined shape after deformation, which allows easier deployment and positioning during biopsy procedures.
- **Titanium** – lightweight with excellent corrosion resistance, making it suitable for long term placement.
- **Bioabsorbable polymers** – break down over time to be absorbed by the body. Often used for temporary marking, and may not require removal in certain cases, but are clearly unsuitable for long term imaging.

Migration

Migration of breast biopsy markers is a known complication of their use, which could hamper the achievement of clear margins after surgical removal, particularly when the marker is the only landmark of the lesion remaining after neoadjuvant chemotherapy.[28] However, improvements in design – in terms of both materials and geometries – have resulted in markers that anchor securely in place, reducing the possibility of migration. This is often achieved by the use of nitinol, and by incorporating a mesh design, which can expand into shape after deployment, with a more spherical or cave-like structure providing more stability in the surrounding tissue.[29,30]

Tumark® Vision

The Tumark family of biopsy markers – produced by Hologic – are made from biocompatible nitinol to provide long term visibility using a variety of imaging modalities, including X-ray, MRI and ultrasound. They can be placed at the site of biopsy using an 18 gauge, thin, sharp puncture cannula, enabling precise marking while ensuring minimally invasive treatment. The range includes a variety of different shaped markers – allowing different sites to be identified when multiple lesions are investigated – with each type consisting of a 3D spherical mesh structure that expands into shape after deployment and firmly anchors in the tissue, providing high echogenicity in ultrasound imaging, regardless of transducer positions.[29] Studies have shown that Tumark Vision markers offer good ultrasound visibility and easy detection in both horizontal and vertical axes. They also have a lower displacement rate compared to older clip styles, reducing the need for preoperative MRI or mammography to increase patient comfort.[30]

A. B.

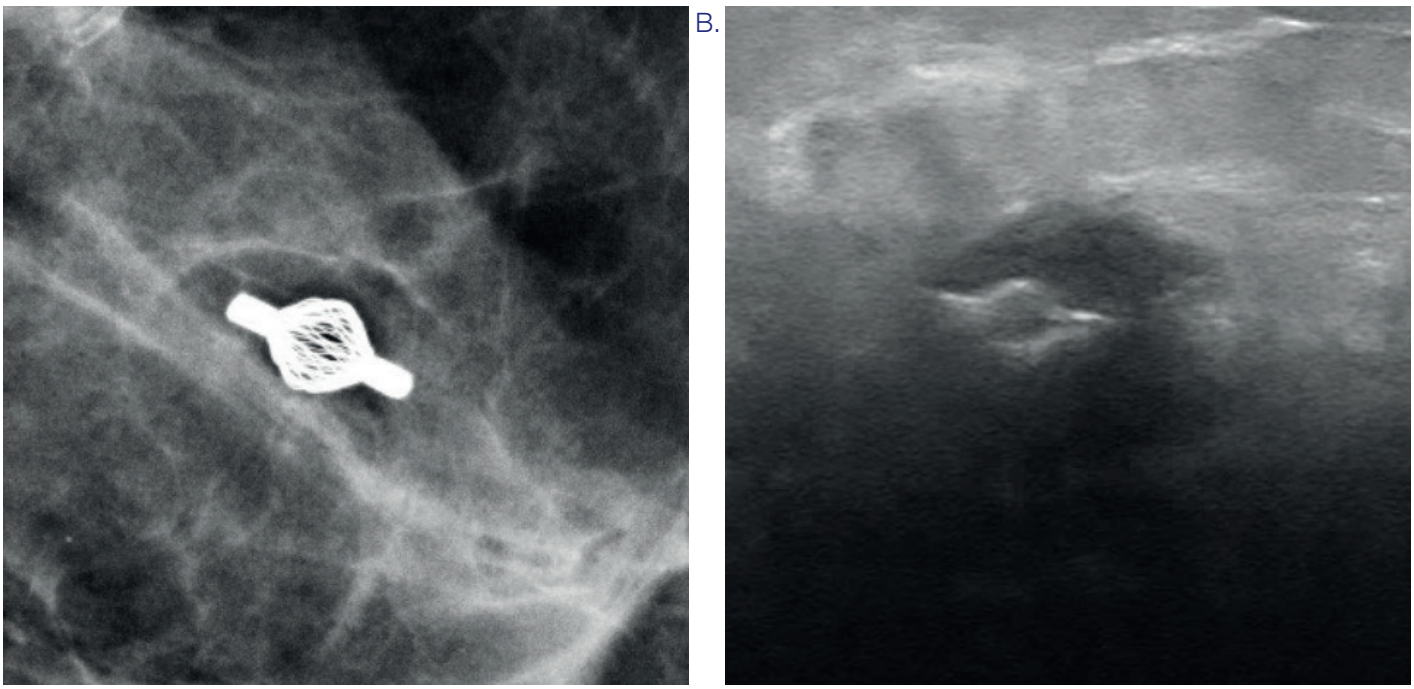

Figure 2: Tumark Vision under (A) mammography and (B) ultrasound. Images courtesy of Dr Stoeblen, Essen, Germany.

Conclusion and future developments

The use of breast biopsy markers is recommended to clinicians by guidelines across the EU, the UK, and around the world. Biopsy markers provide a valuable tool to identify sites that have already been biopsied. They facilitate accurate placement of surgical markers for excision of malignant lesions, or allow identification and follow-up monitoring of benign lesions, pinpointing previous investigations to screening radiologists in the future. They are particularly useful in women undergoing neoadjuvant chemotherapy, providing the only method to accurately pinpoint the lesion site when radiologic complete response occurs. The ability to visualise markers on different imaging modalities – including MRI, ultrasound and mammography – means that they can be reliably used to accurately follow lesions between identification, biopsy and surgery – even between facilities – as well as to target inaccessible lesions. By selecting markers with the best design and material properties for long term visibility on ultrasound, without migrating, clinicians can maximise the benefits for both themselves and their patients.

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