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PERSPECTIVE

Evolution in Image-guided Preoperative Breast Lesion Localisation

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ABSTRACT

Successful surgical excision of nonpalpable breast lesions requires precise image-guided localisation. Wire localisation is the most well-established technique, but it has many disadvantages related to its external part. Intraoperative ultrasound may obviate the need for additional localisation device placement, but that requires sonography training of surgeons. Radioguided occult lesion localisation has been available for two decades, yet it is not available in every centre due to the lack of support from the nuclear medicine unit. Like wire localisation, the procedure must be performed shortly before the surgery, which poses scheduling challenges to imaging and surgery departments. Non-radioguided wireless devices have been developed to overcome these drawbacks. Their most prominent advantages are the feasibility of being placed before the day of surgery, which provides logistic flexibility, and their lack of an external component resulting in no restriction on surgical approach. Evidence of the success of this technique is growing. This article provides an overview of the commonly used image-guided breast lesion localisation techniques in Hong Kong, highlighting the merits and limitations of each technique. Future research directions for the novel wireless devices are also discussed.

Key Words: *Breast neoplasms; Radiography; Surgery*

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中文摘要

影像導引術前乳腺病灶定位進展

黃婷、鄔潔欣、馮惠鈺、周智敏、馬嘉輝

成功手術切除不可觸及的乳腺病灶需要精確的影像導引定位。導線定位是最成熟的技術，但它有許多與其外部部件相關的缺點。術中超音波不一定需要放置額外定位裝置，但需要外科醫生接受超音波檢查訓練。放射引導隱匿性病灶定位已有二十年歷史，但由於需依賴核醫學科支持，並非每個中心都可以使用。而且，與導線定位一樣，該程序必須在手術前不久進行，這為影像和手術部門的日程安排帶來挑戰。已開發的非放射引導的無線設備可克服這些缺點。它們最大的優勢是可以在手術前任何一天放置，提供了靈活性，而且它們沒有限制手術方法的外部組件。越來越多證據表明這項技術取得了成功。本文概述了香港常用的影像引導乳腺病變定位技術，強調了每種技術的優缺點，同時討論新型無線設備的未來研究方向。

INTRODUCTION

Advances in breast imaging and increasing breast cancer awareness have led to a rise in the detection of small breast lesions.[1] Together with effective neoadjuvant chemotherapy that allows good tumour shrinkage, there is an increasing need for image-guided localisation of nonpalpable breast masses.[2] Accurate localisation is of paramount importance for successful surgical excision.

Wire localisation is a conventional breast localisation method. However, as part of the wire is external, it can cause patient discomfort, wire dislodgement, and may have an impact on the surgical approach.[1-8] Intraoperative ultrasound may omit the need for preoperative localisation, requiring surgeons to be competent with sonography skills. It is limited to sonographically visible targets (either the lesion itself or a sonographically visible marker). Radioguided occult lesion localisation (ROLL) requires support from nuclear medicine for the preparation of tracer and scintigraphy. Despite the absence of a protruding component, it must be performed on the same day or a day before the operation with the accompanying lack of scheduling flexibility, similar to wire placement.[3]

Non-radioactive wireless localisation devices, such as magnetic seeds, radar reflectors, and radiofrequency identification (RFID) tags, have emerged recently to address these limitations.[1-8] Since they are approved for long-term implantation, the scheduling of their placement and the operation can be decoupled. Such flexibility can be particularly useful during the pandemic era, as appointments can be rearranged easily for infection control reasons.

This article provides an overview of the common techniques used for image-guided breast localisation in Hong Kong, with a review of the local experience in utilising wireless localisation and a brief discussion of future research directions.

WIRE LOCALISATION

Wire localisation is a well-established technique, which was first described in 1966.[1] It is considered the gold standard and the reference standard for research in other localisation techniques.[2] The procedure is performed on the same day, or uncommonly a day before surgery.[1,3]

A 3-to-15–cm wire is deployed via a 16-to-20–gauge needle delivery system, with the external part taped to the skin to secure its position.[1,4,5] It can be placed under mammographic, sonographic, or magnetic resonance imaging (MRI) guidance.[1] Different configurations of the distal anchoring wire end are available, commonly in hook, barb or pigtail shape.[4] Some wires have a thicker portion to give surgeons a better tactile sensation when approaching the target.[1] It is low in cost, with reported technical success rates of 65% to 100% and specimen margin clearance rate of 58% to 84%.[6] Multiple wires can be placed with minimal distance restriction between wires (Figure 1).[4]

Wire localisation has a number of drawbacks. The protruding part of the wire can cause patient discomfort,

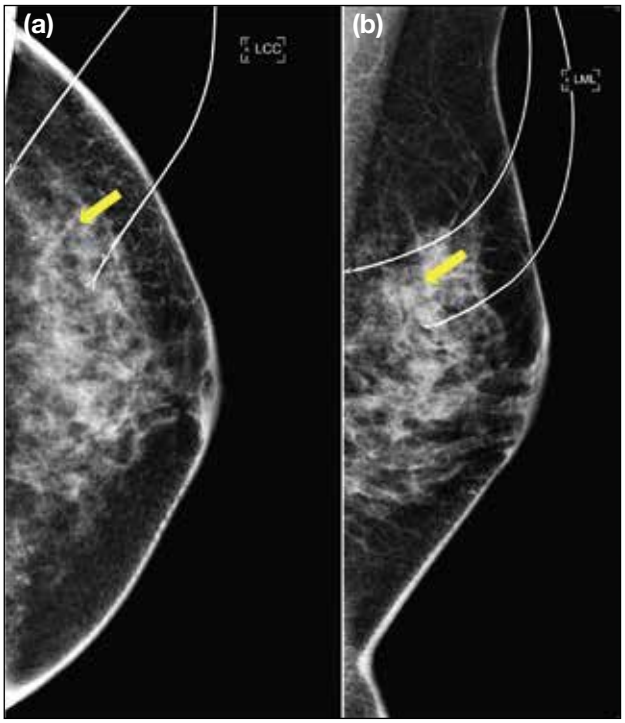

Figure 1. (a) Craniocaudal and (b) mediolateral mammographic views of a 48-year-old woman with a group of amorphous microcalcifications of 3-cm span in the left breast (arrows), which was previously biopsy-proven to be atypical ductal hyperplasia. Bracketing of the microcalcifications was successfully performed with wires placed at the superolateral and inferomedial edges of the group of microcalcifications, respectively.

dislodgement, migration, kinking, transection, or fragmentation.[1,4,6] The surgical incision site is constrained by the wire entry site and healthy tissue along the wire course is inevitably excised during wire retrieval, potentially causing poorer cosmesis.[1,4] Wire placement on the day of surgery prolongs presurgical fasting and increases the risk of vasovagal syncope.[1,4] The bundling of the wire placement and operation schedules also can impair workflow efficiency.[4]

INTRAOPERATIVE ULTRASOUND

Intraoperative ultrasound was first described in the literature in 1988.[2,3] It is performed using a multi-frequency sonographic probe (7-18 MHz) inside a sterile probe cover, which is introduced into the breast incision site.[3] The target can be the lesion itself or a sonographically visible clip marker, which is either of a special shape (Figure 2) or associated with bioabsorbable material (Figure 3), to make it easily visible with ultrasound.

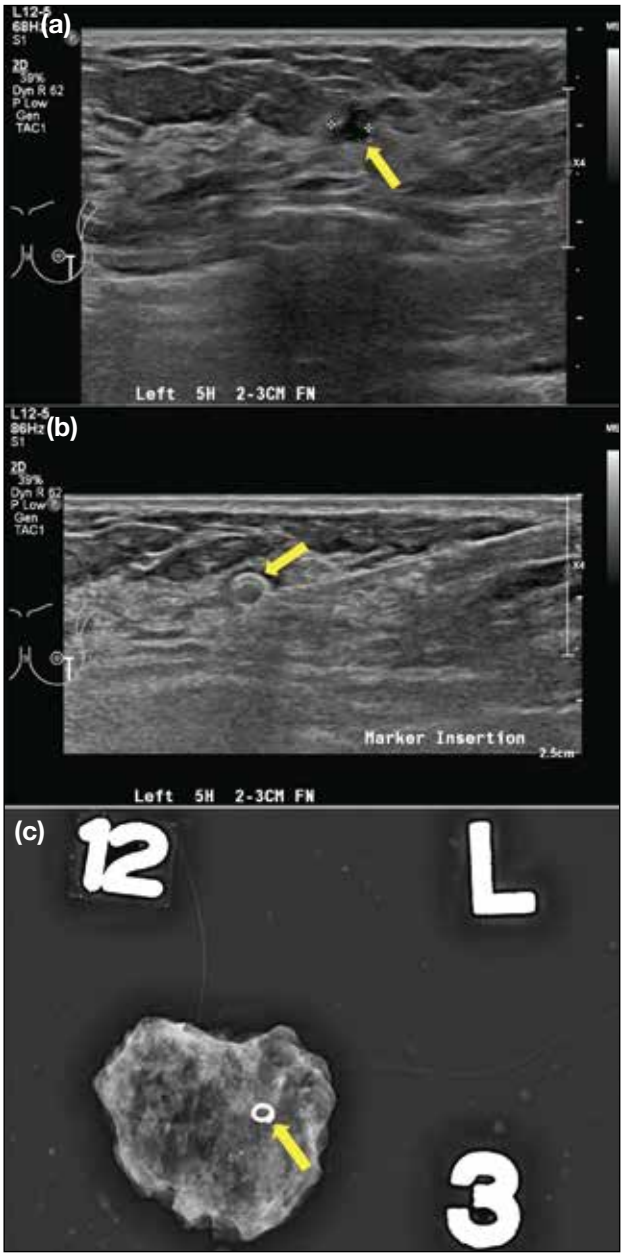

Figure 2. A 61-year-old woman with known diffuse punctate microcalcifications (mammograms not included) was referred for biopsy of a sonographically-detected lesion in the left breast at 5 o'clock position at 2 to 3 cm from the nipple. (a) Ultrasound showing a subtle indistinct hypoechoic lesion (arrow). (b) After the biopsy, a ring-shaped marker was inserted into the area and was easily visible (arrow). The biopsy yielded a mucocele-like lesion with atypical ductal hyperplasia that was subsequently excised under intraoperative ultrasonic guidance. (c) The specimen radiograph confirmed the presence of the marker (arrow), with the final pathology showing the mucocele-like lesion with low-grade ductal carcinoma in situ and clear margins.
Abbreviations: 3 = 3 o'clock position; 12 = 12 o'clock position; L = left.

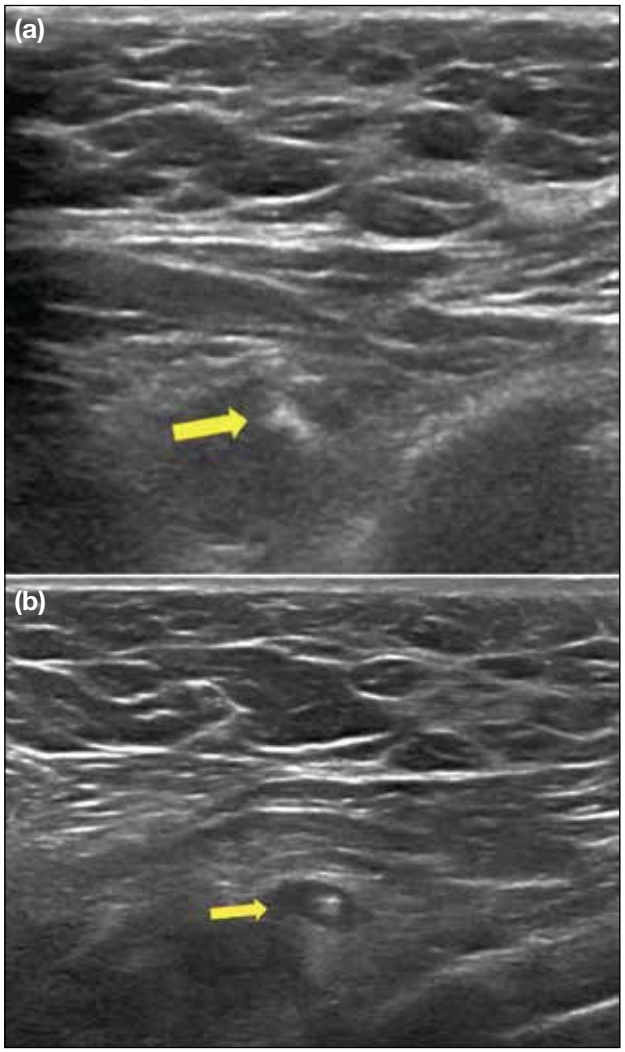

Figure 3. A 44-year-old woman had biopsy-confirmed left axillary nodal metastasis from an ipsilateral intraductal carcinoma (not shown). (a) A hydrogel-based marker was placed in the node and was seen as a small echogenic structure on ultrasound at the time of deployment (arrow). (b) Ultrasound 1 week later demonstrated the marker being more clearly visualised as a nearly anechoic oval structure of the hydrated hydrogel embedding the echogenic marker (arrow).

The major advantage of this technique is the feasibility of continuous intraoperative assessment of the margin, thereby allowing the resection of less surrounding healthy breast tissue with possible better cosmesis.[3] It is reported to have better negative margin rates when compared with wire localisation, thus reducing the chance of re-excision due to close or involved margins.[3] If the target itself is visible on ultrasound, no additional image-guided device placement is necessary. This can reduce patient anxiety and relieve the workload burden of the radiology department.

This method requires surgeons to be well-trained in breast ultrasound and requires an ultrasound machine in the operating theatre.[2,3] Multiple lesions in the vicinity may cause confusion with the actual target. A sonographically visible clip marker or a skin marker can be placed under sonographic guidance in the radiology department before the operation to aid the surgeons identifying the target. Sonographically visible clip markers can also be inserted under mammographic or MRI guidance to localise lesions which are initially sonographically occult. However, the reported risk of clip marker migration >1 cm from target is 2% to 28%.[6]

OTHER WIRELESS TECHNIQUES

The other commonly available intraoperative wireless techniques in Hong Kong include ROLL and non-radioguided devices such as radar reflectors (Savi Scout; Merit Medical, Aliso Viejo [CA], US), magnetic seeds (Magseed; Endomag, Cambridge, United Kingdom), and RFID tags (LOCalizer; Hologic, Santa Clara [CA], US). Their mechanism is based on the transmission of electromagnetic waves set at a specific wavelength.[4,5] Each system is composed of a probe that detects the signal from the radioactive tracer or the wireless marker and a console that emits real-time audio and visual information to guide the surgeon.[4,5] They have no impact on the surgical incision site and provide a point signal source that allows continuous reorientation to locate the target, enabling less non-targeted tissue to be excised and potentially better comesis.[1,4,6]

All of these techniques require a high startup cost for purchasing the console and the probe, and more expensive recurrent expenses for purchasing the tracer or the single-use marker.[4] They cannot be performed under MRI guidance as part of the equipment is MRI incompatiable.[1,3,7]

Radioguided Occult Lesion Localisation

ROLL was first introduced in Europe in 1999.[3] An occult lesion can be located with a gamma probe after injecting ^{99m}technetium-labelled radioisotope into it under mammographic or sonographic guidance.[3]

ROLL shows technical success (93%-100%) and margin clearance (60%-100%) comparable with wire localisation.[6] It can map the sentinel lymph node simultaneously (sentinel node and occult lesion localisation [SNOLL]) [Figure 4].[3] Due to tracer decay, the surgery must be performed within a time limit after tracer injection.[3] There is a risk of accidental

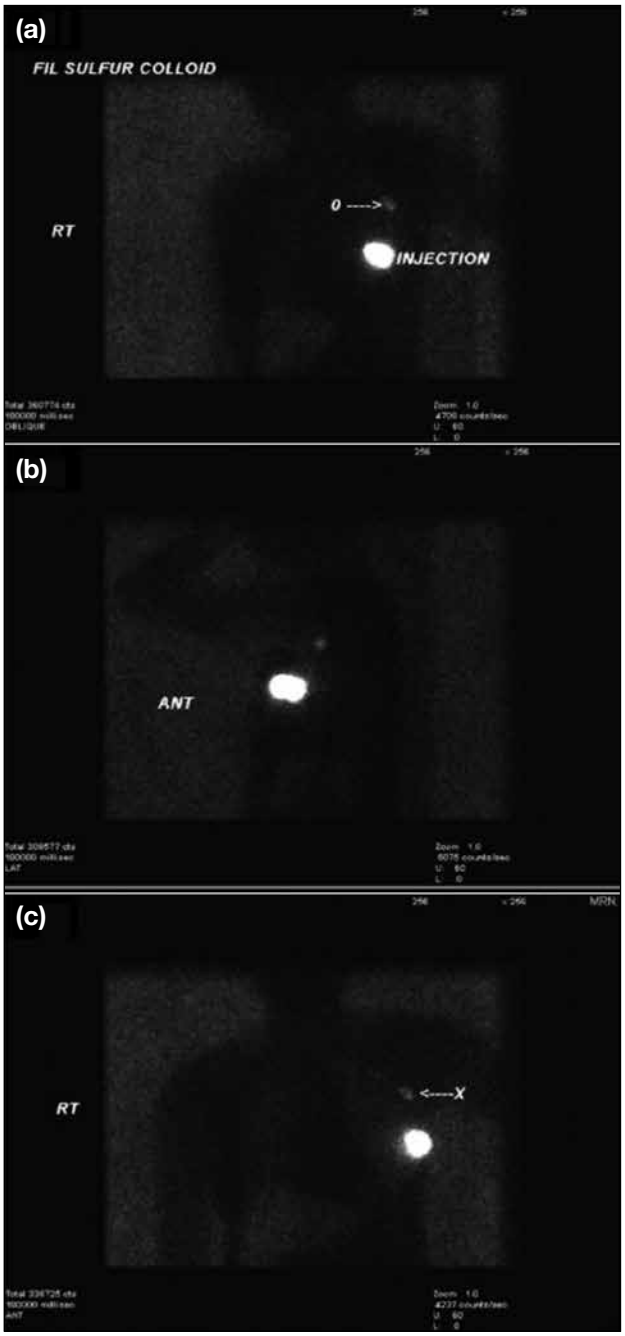

Figure 4. Scintigraphic images of (a) left anterior-oblique, (b) left lateral, and (c) anterior views of a 52-year-old woman who underwent sentinel node and occult lesion localisation for high-grade ductal carcinoma in situ. Filtered ^{99m}technetium-labelled sulphur colloid tracer was injected into the tumour at 1-to-2 o'clock position 6 cm from the nipple under sonographic guidance (not shown). A sentinel lymph node was seen cranial to the injected activity in the left axilla, which is marked as 'O' in (a) and 'X' in (c), respectively.

intraductal injection that leads to conversion to wire localisation, especially when targeting the more duct-abundant subareolar region.[9] The use of a radionuclide requires support from the nuclear medicine department and involves radiation safety precautions. Another disadvantage is the radiation exposure to patients and staff, although the dose is very low.[10,11] A single-centre study found it to be feasible in localising two targets in the ipsilateral breast in eight patients (double-ROLL technique),[10] but the technique is not commonly described in the literature.

Non-radioguided Localisation

These new techniques involve markers that are approved for long-term implantation.[7] This allows decoupling of the day of marker placement and the day of surgery, leading to more flexibility for the involved departments and the patients.[1-5,7,8] Without the need for same-day localisation in the radiology department, the patient can undergo operation as the first case of the schedule. These localisation systems do not involve any radioactivity. Some of them are licensed to localise lymph nodes for targeted axillary dissection as well.[4]

Although multiple markers can be used in the same breast, they should be at least 2 cm apart in order to be detected separately.[4] Placing two devices in the same location of the breast with one in anterior depth and one in posterior depth is not recommended as the signal from the superimposed devices may be mistaken as one single source in the supine patient intraoperatively.[4,5] The marker cannot be repositioned once deployed and has a depth limit for its detection.[1,2,4,5,8]

Radar Reflectors

Radar localisation was the first US Food and Drug Administration (FDA)–approved (2014) non-radioguided wireless system.[8] It uses a radar reflector 12 mm in length, including a body with an infrared receptor and two nitinol antennae on either side, deployed with a 16-gauge delivery needle.[1-4] A new mini 8-mm–long design became available recently.[12] The console sends micro-impulse radar signals to the handpiece probe, which emits infrared light to activate the reflector.[4,8] The reflector reflects the radar signal back to the handpiece, which is interpreted and presented by the console as audible and numerical information about the reflector proximity, with an accuracy of ± 1 mm.[4,8] This method can localise lesions up to 6 cm deep.[1,4]

The marker is placed under sonographic or mammographic guidance and can be used to localise lesions in the breast, lymph nodes, or soft tissue.[3] It achieves 85% to 93% surgical margin clearance.[4] Its

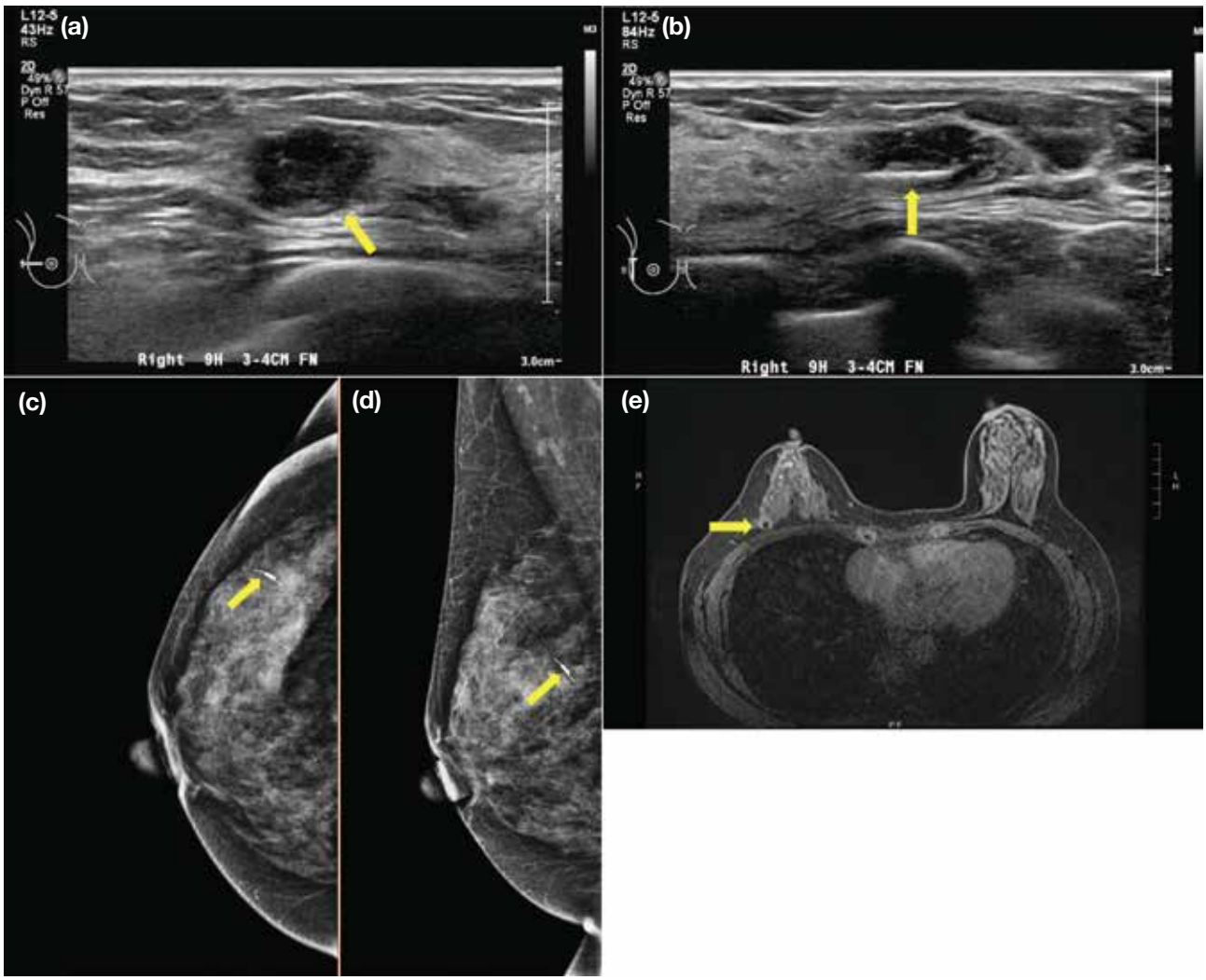

Figure 5. (a) A 52-year-old woman was diagnosed with invasive ductal carcinoma in her right breast at the 9 o'clock position 3 to 4 cm from the nipple (arrow). (b) A radar reflector was inserted into the tumour under sonographic guidance, with the reflector placed in the centre of the tumour (arrow). (c) Post-procedure craniocaudal and (d) mediolateral oblique mammographic views were obtained to establish the baseline position of the reflector (arrows). There were incidental findings of multiple oval low-density lesions which were confirmed cysts on previous ultrasound (not shown). (e) T1 post-gadolinium with fat saturation sequence of patient's restaging magnetic resonance imaging after neoadjuvant chemotherapy showing a tiny signal void within the residual enhancing tumour (arrow), signifying the presence of the radar reflector with minimal susceptibility artefact that did not impact the interpretation.

distinctive feature of minimal susceptibility artefact may be useful in patients that require MRI to monitor response to neoadjuvant chemotherapy (Figure 5).[2]

Since the antennae are made of nitinol, there is risk of nickel allergy.[1,4] Dampened signal can occur when dense objects such as haematomas, wires, or calcified masses are located between the reflector and the probe.[4] Halogen lights in the operating theatre must be shielded or directed away from the surgical site.[4] Marker deactivation may occur through direct contact with electrocautery or antenna transection during dissection.[3,8] The micro-impulse radar signal may interfere with cardiac implants, hence caution is warranted in patients with such devices.[13]

Magnetic Seeds

Approved by the FDA in 2016,[1] the magnetic seed system uses a 5 × 1 mm^2 stainless steel seed, which is retained in an 18-gauge sterile introducer needle with a terminal plug.[1,4] The probe transiently magnetises the seed and detects its magnetic field for real-time localisation.[1,4] The seed has a depth detection range up to 3 to 4 cm from the skin.[1,4,5]

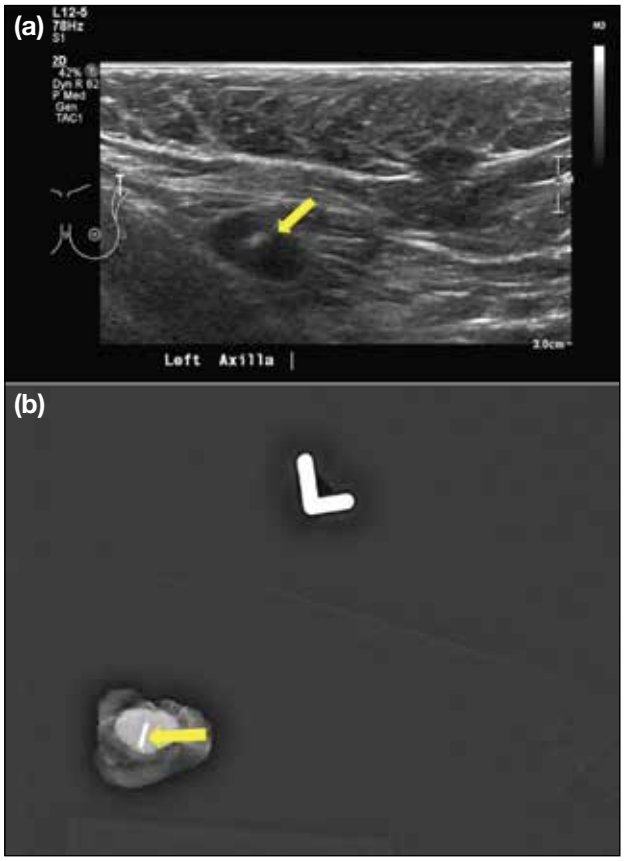

Figure 6. A 55-year-old woman with prior history of left mastectomy for invasive carcinoma was found to have nodal recurrence in the left axilla. (a) Sonographic guided magnetic seed placement into the left axillary lymph node was performed, with the magnetic seed located at the centre of the lymph node (arrow). (b) Subsequent surgical specimen radiograph confirmed the presence of the magnetic seed within the lymph node (arrow).
Abbreviation: L = left.

The seeds are approved to be deployed into the breast and axilla under sonographic or mammographic guidance (Figure 6).[3] The reported margin clearance rate is 78.1% to 83%.[4] The same console and probe can be used for sentinel lymph node mapping using a superparamagnetic iron oxide tracer, resulting in an entirely magnetic technique.[4] The magnetic seeds are made of low-nickel stainless steel, reducing concern for nickel allergy.[1]

These seeds are contraindicated in patients with pacemakers or implanted chest wall devices.[4] The minimally absorbable terminal plug is made of beeswax, which may cause allergic or foreign body reaction.[4] Non-ferromagnetic surgical instruments need to be used to avoid interference, incurring an additional cost.[4,5] The magnetic seed casts a 4-to-6–cm susceptibility artefact on MRI, thus is not preferred in patients who require subsequent breast MRI.[1,2,4,5]

Radiofrequency Identification Tags

This device received FDA approval in 2017.[3,4] The tag consists of a ferrite rod wrapped in copper and a microprocessor, which are enclosed within an antimigratory polypropylene cap.[4] It involves the use of radio waves for signal transmission.[4] The reusable portable loop reader can be used directly on the skin to detect tags up to 6 cm deep.[1,4] The 8-mm single-used pencil-sized probe can detect tags up to 3 cm deep.[4]

The tag can be inserted under sonographic or mammographic guidance (Figure 7). Limited high-quality published data are available for RFID tags given its shorter history.[3] One study reported 97% margin clearance.[4] Each tag has a unique identification number displayed on the reader, allowing easy intraoperative differentiation of multiple tags in the same breast.[1,2,4] The pencil-sized probe allows a smaller incision without obscuring the surgeon's visualisation.[4]

As the tag is sizable (11 × 2 mm^2) and is deployed via a 12-gauge applicator, it may be more prone to migration during intraoperative manipulation due to a wider deployment tract.[3] Its size may also pose a challenge during deployment in hard masses or through dense breasts.[3] The associated 2-cm MRI artefact may limit subsequent MRI breast evaluation.[1] Its use in axillary lymph nodes is off-label currently, and caution should be taken in patients with defibrillators or pacemakers due to potential interference by the radiofrequency signal.[3,4]

The above common techniques for image-guided breast localisation in Hong Kong are summarised in the online supplementary Table.

LOCAL EXPERIENCE WITH WIRE-FREE LOCALISATION AND FUTURE RESEARCH DIRECTIONS

ROLL was introduced in Hong Kong in the early 2000s, but is not available in some centres due to the absence of a nuclear medicine department. Compared to wire localisation, it has a shorter procedure time and similar specimen margin clearance and re-excision rates.[11] Poorer stereotactic-guided localisation is associated with targeting invasive carcinomas, possibly related to their fibrotic and hard texture.[14] Small breasts are also more susceptible to suboptimal stereotactic-guided ROLL as a minor discrepancy in z-axis (depth) can lead to a significant difference after release of breast compression.[11] This limitation may be more concerning in the Chinese population due to their tendency to have thin breasts.[15]

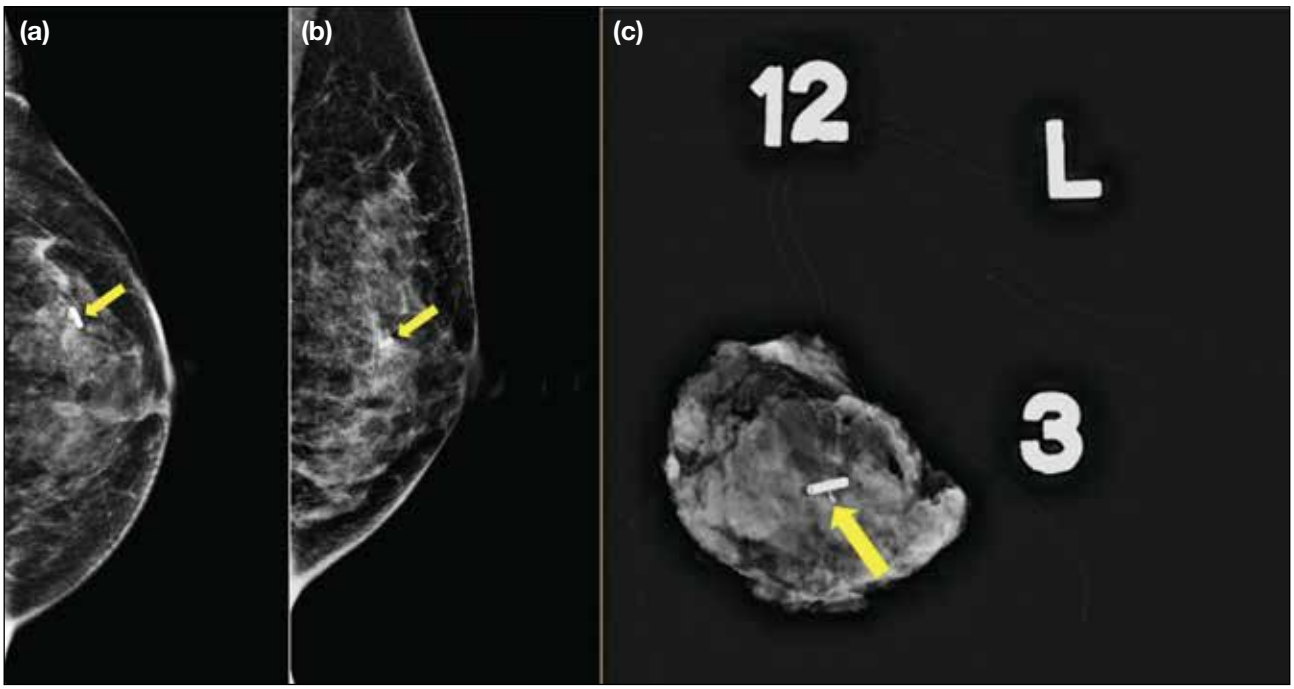

Figure 7. A 45-year-old woman had vacuum-assisted biopsy performed for a tightly clustered group of microcalcifications in the upper outer quadrant of the left breast, which was confirmed to be intermediate-grade ductal carcinoma in situ (biopsy images not shown). The omega-shaped marker at the biopsy site was localised by radiofrequency identification (RFID) tag under stereotactic guidance. Post-procedure left (a) craniocaudal and (b) mediolateral mammograms showing the RFID tag (arrows) locating immediately anterior to the marker. (c) Subsequent surgical specimen radiograph confirmed the presence of the marker and the RFID tag (arrow).
Abbreviations: 3 = 3 o'clock position; 12 = 12 o'clock position; L = left.

The first available non-radioguided wireless device in Hong Kong was the magnetic seed, which was introduced in 2019.[16] Its feasibility for schedule decoupling, and its safety and efficacy in terms of technical success, complications, margin clearance, and need for re-excision have been demonstrated.[16] It has been found non-inferior to ROLL and wire localisation.[17,18] Its successful use in papillary lesions and in targeting multiple lesions are illustrated.[16,17,19] Related to the shorter history, there is only one published article about the initial experience with radar reflectors in Hong Kong,[13] while there is none for RFID tags. Radar reflectors are found feasible to be placed before the day of surgery, and to be safe, with a high technical success rate.[13] More research is needed to establish local long-term data.

Although these devices have a depth limitation for detection, it may not be a significant concern in Chinese women who tend to have thinner breasts.[13,15,16] The migration risk should theoretically be lower in Asian women given their higher frequency of dense breasts, but accordion-effect–related migration of magnetic seeds and radar reflectors is still observed.[13,16,18] Moreover, the large size of a RFID tag may make its placement in a dense breast technically more difficult.[3] Prospective studies with larger sample size are needed to validate these postulations in our population.

The non-radioactive wireless markers are approved for long-term implantation, therefore assuming a potential role in replacing ordinary clip markers in highly suspicious masses at the time of biopsy. Although the cost is high, this may eliminate the need for another localisation procedure, which reduces the operational cost. A full cost analysis is required. Future local research should also evaluate specimen weight, surgical cosmesis, and patient's and operator's satisfaction.

CONCLUSION

A number of presurgical breast lesion localisation techniques are currently available in Hong Kong, each having its own advantages and disadvantages. The novel devices eliminate some drawbacks of the traditional methods, but large-scale studies are needed to provide more evidence in our population given their epidemiologically different breast characteristics. The

decision to choose the best suitable localisation method should be a joint consensus by radiologists and surgeons after thorough consideration of each individual patient's condition and the features of the target lesion(s).

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