Steps to Successs with ROLLIS: How to Commence Using Radioguided Occult Lesion Localisation with I-125 Seeds For Removal of Impalpable Breast Lesions

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Learning objectives

ROLLIS (Radioguided Occult Lesion Localisation with a low dose radioactive Iodine-125 seed) is a relatively new technique currently practised by only a few centres worldwide. Introducing ROLLIS in the hospital setting requires collaboration, education and training of Medical Physicists, Radiologists, Surgeons, Pathologists, Nuclear Medicine Physicians and Nursing Staff. We will show how this can be achieved in the multidisciplinary team setting.

Background

Mammographic screening programmes are increasing the detection of non-palpable breast lesions which require excision post core biopsy. A systematic review published last year concludes lower postive margin rates and fewer re-operations using radioactive Iodine-125 seeds for localisation compared with a hookwire. The authors state that results should be confirmed by multicentre randomized controlled trials. A pilot study is our first step towards this.

Audit shows our current hookwire localisation (HWL) has a relatively high re-excision rate (30.3 - 31%.) ROLLIS offers an opportunity to try to lower this and improve patient outcomes. This method of localisation can also be performed prior to the day of surgery making for easier scheduling.

Localisation without seed migration has been proven and the technique appears to be favoured by surgeons.

Other hypothesised advantages regarding improved patient acceptability and cosmesis require further evaluation. A pilot study is the first step in introducing this technique.

Imaging findings OR Procedure details

1. Development of a protocol to ensure safe handling and return of all seeds.

We utilised the existing literature in order to establish our safety procedures. Radiation dosimetry was performed to obtain approval from the local radiation regulatory authority. Approval was also obtained from institutional ethics committee and the Australian Regulatory Authority for therapeutic goods.
Our safety procedures included a protocol to limit and record operator exposures and prevent loss of I-125 seeds by tracking seed receipt, registering times at each location, including: deployment, at surgery, as well as retrieval and extraction at pathology, quality assurance and disposal. (See Fig 1)

Additionally, involved departments received work instructions regarding correct labelling of radioactive materials and specimens as well as advice on the use of ring badges and whole body dosimeter to assess for exposures.

2. Staff education regarding utility and safety of ROLLIS.

This was achieved both by lectures and practical teaching sessions. Didactic lectures included literature review, safety and how the technique would be implemented. Medical physicists, radiologists, surgeons, nuclear medicine, pathology, nursing and radiography staff were invited to attend and of course their feedback was crucial.

3. Practical Session

a) Radiologists Training:

Radiologists were given the opportunity to familiarise themselves firstly with the equipment used, including the delivery device. This is an 18G pre-loaded needle (SeedLock3™) with a 5mm seed (AnchorSeed™). The distal end of the needle is housed in a protective lead shield. The needle also has a blue plastic spacer (‘grip clip”) to prevent premature deployment of the seed. Both of these are removed immediately prior to use. (see Fig 2)

There then followed a demonstration of how the seed would be inserted under ultrasound and stereotatic guidance into a chicken breast. The former is outlined in the attached video footage. (See Fig 3)

Radiologists were then invited to practice the technique initially using non-radioactive seeds. Breast radiologists are already familiar with direct needle visualisation under ultrasound guidance and the deployed hyperechoic seed can also be clearly visualised as it leaves the needle. (See Fig 4)

b) Surgeons Training:

Following a live demonstration of I-125 seed detection in the chicken breast specimen with an intraoperative gamma probe ( also shown in the video footage) surgeons were invited to remove a "specimen" with a margin around the seed.
Surgeons are already familiar with the gamma probe for sentinel lymph node localisation but this allowed them the opportunity to familiarise themselves with the settings and sensitivities on the gamma probe (Neoprobe Neo2000 Model 2100) for I-125. A second chicken breast was prepared with I-125 seed and a small injection of Tc99m sulphur colloid. The probe allows for differentiation in detection of firstly the Tc-99m sulphur colloid and then the I-125 seed at the flick of a switch. (see Fig 5)

The final part of the demonstration illustrates how, via a specimen radiograph, we could localise the seed with two needles to facilitate seed removal by the pathologist. An annotated specimen radiograph shows the seed within the specimen (fig 6.) One vertical and one angled 21G needles were positioned in the super-oinferior plane to intersect at the seed and allow for accurate marking. This allows the pathologist to cut in the supero-inferior plane and locate the seed allowing for its safe removal prior to histopathological analysis.

The seed is then retrieved for quality assurance and contained in a lead pot stored for radioactive waste disposal. (see figures 6 and 7)

3. Implementation of ROLLIS in practice

We proceeded to a pilot study (to be described in a separate report) using 20 patients, across 2 hospitals. The participants underwent insertion of a 3 MBq I-125 seed as well as a hook-wire for localisation for excision of core biopsy proven malignant lesions. The hook-wire was placed to provide a back-up method of lesion localisation in case of difficulties with use of the seed. We devised standardised case report forms to collect information including the degree of difficulty experienced by the radiologists in placing the seed (compared with the hook-wire,) times taken for insertion, how easy the surgeon found removing the lesion using the seed and to what degree they depended on the seed vs the wire.

The location of the seed as it passed from one department to another was recorded in a sign in/sign out log book to track the seed and ensure all were returned for safe disposal.

Figure 8 is a mammographic example of preoperative localisation of a cancer with both I-125 seed and the hook-wire.

Figure 9 shows the appearances of both forms of localisation on a specimen radiograph, ready for the radiologist to mark location of the seed in-situ as described above.
The initial results have encouraged us to extend our pilot study in order that more staff, particularly surgical colleagues, familiarise themselves with this novel technique. Our ultimate aims will include decreasing our re-excision rate, proving the superiority of the ROLLIS technique by randomised controlled trial and investigate its’ other potential benefits.

Images for this section:
FLOW CHART – SEED LOCATIONS

MD Solutions → MTP
Ground floor G block Receipt/QA

MTP Ground floor G block Storage

Breast Centre 1st floor G block
I-125 seed localisation

Nuclear Medicine 1st floor G block
SLNB injection

Breast Centre 1st floor G block

DOSA 2nd floor G block
Awaiting surgery

Theatre 2nd floor G block
Surgical removal

Breast Centre 1st floor G block
Specimen radiograph

PathWest
Ground floor J block
I-125 seed recovery

MTP Ground floor G block Storage

Radioactive Waste Store
H-block
Waste disposal

DAY OF SURGERY

Seed is in situ

Seed is embedded in specimen
**Fig. 1:** Flow Chart depicting seed locations in the hospital prior to, during and after the day of surgery. MTP = Medical Technology and Physics DOSA = Department of Surgical Assessment

**Fig. 2:** Delivery Needle device (SeedLock3™) showing stages leading to deployment of I-125 seed (AnchorSeed™). Thanks to MD Solutions
Fig. 4: Example of the ultrasound appearances in a trial patient participant with the delivery needle and the I-125 seed seen separately.
Fig. 5: Gamma Detector, Neoprobe Neo2000 Model 2100, allowing for differentiation between Tc-99m sulfur colloid and I-125 seed radiotracer detection
**Fig. 6:** Chicken Fillet Specimen Radiograph with 2 x 21G needles in-situ to allow for seed location

**Fig. 7:** LEFT PICTURE: Chicken fillet specimen cut in the supero-inferior plane to allow for I-125 seed retrieval  RIGHT PICTURE: Transfer of I-125 seed using forceps into labelled lead pot for storage
Fig. 8: a) Solitary lesion (known invasive carcinoma) on the left breast MLO view of a study participant. b) I-125 seed and hook-wire in good position in situ on the left breast MLO and c) CC views
Fig. 9: I-125 seed and hook-wire in situ with the lesion well centred within the specimen.
Fig. 3: Video footage showing a) Insertion of I-125 seed in chicken breast under ultrasound guidance b) Detection of I-125 seed using the gamma probe detector; note maximum number of counts (or "beeps") when directly over the seed. c) Needle localisation of seed in specimen
Conclusion

ROLLIS offers many potential advantages over hookwire localisation. However the prospect of implementing this technique can seem daunting. The systematic approach presented above should allow a multidisciplinary team to start using this technique within a short space of time.

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References


