



New Technology Funding and Evaluation Program

Evaluation Report – Radio-guided Occult Lesion Localisation using Iodine-125 Seeds (ROLLIS) for breast cancer

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New Technology Funding and Evaluation Program – Evaluation Report

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Summary

Key lessons learnt from the initial implementation of the new technology:

- Plan for the time required to gain radiation licensing for the use of the I-125 seed
- Introduction of ROLLIS changes workflows in multiple departments and requires multidisciplinary support
- The learning curve for radiologists and surgeons is short (approximately 5 cases) as skills are transferable from hookwire technique. Pathologists must learn new skills and the learning curve is correspondingly longer
- ROLLIS is more comfortable and acceptable to patients than hookwire
- ROLLIS can be implemented at low cost because it uses existing equipment

Key learnings from ongoing use of the new technology including clinical effectiveness, safety and cost effectiveness:

- The ongoing costs are largely substituted (cost of ROLLIS instead of cost of hookwire) rather than additional
- ROLLIS in the pilot setting is safe and clinically effective. Larger scale data will be reported at the conclusion of the ROLLIS RCT
- There are significant efficiency and scheduling gains in radiology (ability to perform all procedures for the week in a single list) and surgery (ability to schedule from first on the list, no hookwire-associated delays, ease of coordination for patients requiring support for medical comorbidities or language interpretation)

Overall recommendation for future use, adoption and sustainability of this technology across the Queensland public hospital sector:

- ROLLIS should be considered for uptake in most centres as the preferred method of localisation. The gains are likely to be highest in high volume units, while ROLLIS may not be clinically or cost effective in smaller centres with difficult access to nuclear medicine facilities
- ROLLIS is appropriate to continue and is planned to become the preferred localisation method in the Gold Coast unit.
- ROLLIS is suitable for diffusion beyond the Gold Coast unit. The first training workshop hosted by the Gold Coast unit for national and international participants was held in October 2017.



Background

Health Technology

ROLLIS is a technique where a small seed containing a very low dose of radioactive tracer (Iodine-125) is placed into the breast lesion by the radiologist. The surgeon uses a hand held gamma probe in theatre to accurately localise the lesion, plan the most appropriate incision and then remove the lesion together with a margin of surrounding normal tissue (Bourke et al., 2015).

The medical device is a needle with wax plug containing a radioactive seed, which is placed into a heat-sealed pouch to maintain sterility (seed inside needle inside pouch).

The ROLLIS technique can be applied to all lesions, malignant or benign, which are impalpable and therefore require preoperative localization.

Following inclusion and exclusion criteria will be used:

Adult women 18 years and over who meet the following inclusion criteria:

- Histologically confirmed invasive or in-situ carcinoma that is impalpable or poorly palpable (requiring localisation)
- Candidate for breast conserving surgery, based on clinical and radiological evaluation.

Exclusion criteria and justification excluding participation in the study:

- Pregnancy: whilst the radiation dose involved in ROLLIS is very small, the ALARA principle (as low as reasonably achievable) mandates the exclusion.
- Lactation: Theoretical possibility of ductal migration of seed
- Multi-centric cancer
- Non-pleomorphic lobular carcinoma in-situ (LCIS): Management remains controversial

The technology will gradually be extended beyond these criteria as the service gains experience and gathers more data about its safety and efficiency. If successful, this implementation project will result in ROLLIS replacing hookwire as the usual method of localisation for both malignant and benign impalpable lesions.

Comparator

Hookwire localisation is the existing and approved method which is routinely used for the condition in Queensland. The hookwire is deployed into the breast by a radiologist using either ultrasound or mammographic (stereotactic) guidance. More than one hookwire may be inserted per patient, either to 'bracket' larger lesions or for multiple lesions. Localisation by hookwire occurs on the morning of surgery. The standard 2-view mammogram is obtained to confirm satisfactory positioning of the hookwire(s). If the position of a hookwire is not ideal, an additional hookwire may be added and the correctly placed hookwire clearly labelled for the surgeon.

The woman is then transported from the radiology department to the operating suite, where the breast lesion containing the hookwire(s) is excised under general anaesthetic.



Burden of Disease and Clinical Need

Breast cancer currently affects 1 in 8 Australian women. The Breast Service for Gold Coast Health receives approximately 300 referrals for new diagnoses of breast cancer annually. Of those, approximately 100 are impalpable and require preoperative localisation.

A range of benign breast conditions also require preoperative localisation for excision, accounting for approximately 100 additional localisation procedures annually. The total number of localisation procedures performed is therefore approximately 200 in total annually. The initial introduction of this technique applied to cancers only, and will now be gradually extended to benign lesions as well.

PICO parameters

PICO refers to the population, intervention, comparator and outcomes for the purposes of the evaluation.

Table 1. PICO parameters

Population	Women over the age of 18 years who are candidates for breast conserving surgery (BCS) with histologically confirmed invasive or in-situ carcinoma that is impalpable requiring localisation.
Intervention	ROLLIS
Comparator	Hookwire
Outcome	The incidence of inadequate margins (defined as in-situ or invasive tumour ≤ 5 mm from any radial margin) and the incidence of subsequent oncological surgery (defined as re-excision or mastectomy within 3 months) following breast conserving surgery.

Methodology

Firstly, the evaluation will establish whether planned implementation strategies have been met for a project. This is useful to understand the existing health care environment; and assessing the cause and effect relationship of a project's functions with its success (or failure).

Secondly, the evaluation will provide decision makers with the tools to assess whether a project has achieved its intended objectives and informs recommendations as to whether a project is likely to be sustainable.

Evaluation can involve both quantitative and qualitative evaluation indicators to measure outcomes, as well as stakeholder consultation in order to determine the full scope of the projects success.

Initial evaluation results will enable decision makers to determine whether a project should be continued, expanded, refined or discontinued at this initial stage.

Evaluation areas, questions and indicators

Evaluation questions address the key elements of program implementation and outcomes. Using the Health Technology Assessment (HTA) framework as a foundation the evaluation questions have been developed to align with each of the evaluation areas (refer to Appendix 1).

To address the evaluation questions, evaluation indicators have been developed by the HEAT team. In some cases multiple evaluation indicators were selected to provide a range of perspectives and data sources. Specific evaluation indicators to address safety and effectiveness of the new technology have been developed in consultation with the project team.



Evaluation findings

Alignment to project plan

To what extent was the new technology delivered in alignment with the project plan or full application?

Training of team members occurred as planned. There was a subsequent unexpectedly long delay of almost 12 months for ethics and SSA approval. The SSA was particularly complex, as governance of the project involved Research Ethics and the three departments of radiology, surgery and pathology. Each department required its own staffing, finance, and resource assessment, and the procedure seemed to differ in each department according to their organisational division. This difficult phase was successfully negotiated with considerable goodwill from each department and strong support from the Office for Research Governance and Development, Gold Coast Health.

This was followed by a further unexpected delay of 3 months in order to address radiation safety concerns, with new registration for the use of the ROLLIS seed, and licensing of involved radiologists and surgeons, required by the Radiation Council of Queensland.

Accounting for the delayed start, the procurement, commissioning and introduction to clinical practice of ROLLIS technology occurred according to the planned schedule. During the delay the project team completed multiple in-service meetings with the stakeholders - radiographers at both Gold Coast University Hospital and Robina hospital, Robina theatre staff, breast unit staff, and pathology staff. This built enthusiasm and knowledge within the stakeholders, which enabled the first patients to be recruited almost immediately after all the necessary approvals were completed. The technology was commissioned gradually, with careful initial patient selection. One or two procedures were performed weekly until workflows were established, followed by a progressive expansion.

Was the new technology project delivered within budget?

A standalone cost centre was created for the ROLLIS RCT, but costs specifically relating to ROLLIS proved difficult to capture as some costs were claimed by staff as part of their ongoing PDL allowance (e.g. travel and registration for the training workshop) and other costs were absorbed into the running costs of each department (e.g. application costs to add a new use for the I-125 seed to an existing permit) while other costs appear to have been small and claimed within petty cash arrangements (e.g. a serving tray bought from a local department store to catch stray seeds on the pathology bench).

Of the originally budgeted \$92 304 only \$44 289 was spent in the 12 months after clinical implementation. The bulk of this was for the cost of the seeds themselves and the labour costs for the trial coordinator. As implementation in other centres will likely occur outside of the ROLLIS RCT, the trial coordinator will not be required, leaving only the costs of the seeds themselves as the main cost. This makes ROLLIS a very attractive financial prospect because the cost of the seed compares favourably with the cost of the hookwire that it replaces (see sustainability section).



Reach (Stakeholder engagement)

To what extent were stakeholders exposed to the new technology?

Project Team:

40% of project team members surveyed reported being completely satisfied with the involvement of project team members in the implementation of ROLLIS while 20% were neutral in their response. 80% respondents were completely satisfied with the engagement by project support staff with 20% reporting being very satisfied. It was identified that the project was demanding in terms of time and change to existing work flows and the goodwill and hard work of the project team in this regard was appreciated.

Stakeholders:

Of the total stakeholders surveyed, 40% reported being very satisfied with the overall implementation of the technology while 60% reported being satisfied with the quality of information, education and training and the governance of the technology. One respondent was dissatisfied with the governance of the technology.

Governance

Were the governance structures appropriate and effective in supporting the implementation and ongoing use of the new technology?

20% respondents reported complete satisfaction with the governance of the technology while 40% respondents reported being very satisfied and 20% reported low satisfaction with the governance. The obstacles identified with low satisfaction primarily revolve around delays stemming from issues with ethics governance and radiation council governance. It was identified that parallel processes in Victoria and New South Wales were completed much more expeditiously.

From a scale of 'not at all satisfied' to 'completely satisfied', 60% respondents reported being very satisfied with the overall implementation of the technology while 40% reported being completely satisfied.

Clinical utilisation/experience

Were the appropriate number of staff trained to effectively deliver the new technology?

Staff training, competency and proficiency

There was a high level of enthusiasm for this project, and the project team formed quickly and remained stable for the duration of the implementation. The implementation of this complex project was aided considerably by pre-existing interprofessional collaborative working relationships between radiology, surgery, and pathology departments.

Key team members (one radiologist, two surgeons, and one pathologist) travelled to Perth, WA to train with the original ROLLIS technique development team. These key team members self-identified from the existing breast service. All had a breast subspecialty interest, and were not always the most senior representative of their specialty, as enthusiasm was seen as the key requirement.



Training from the WA team was achieved through a workshop that began with lectures to cover the theoretical aspects, followed by simulation exercises using chicken fillets, and finishing with a demonstration of competency by the Gold Coast team to achieve certification. The ROLLIS procedure proved to be intuitive and relatively easy to learn for surgeons and radiologists due to similarities with existing hookwire procedure, with approximately 5 simulations required for proficiency. The steepest learning curve was for the pathologist, as the ability to match the intraoperative specimen radiograph to the specimen, and then to successfully find the tiny seed without distorting the specimen too much, is an entirely new skillset. The training provided in Perth was of a high standard and does not require improvement.

An identical format was used for the first ROLLIS training workshop in QLD, co-convened between the WA and Gold Coast teams as part of the Australasian Society of Breast Disease annual scientific congress in October 2017. 26 registrants from breast centres in Australia, New Zealand and Thailand attended this workshop. Registration for the workshop closed just 3 weeks after it opened in order to keep numbers manageable, and a waiting list was created from which only one further registrant could be accommodated due to the lack of late withdrawals. This gives an indication of the level of national and international interest in the ROLLIS procedure. The ability to convene a training workshop of this scale only 15 months after the introduction of ROLLIS to the Gold Coast indicates the enthusiasm and capability built in a relatively short time within the project team. Further training workshops in other centres nationally and internationally are being planned.

The time required for training was accommodated within existing PDL allowances and did not require backfilling beyond than the usual arrangements for covering PDL, such as operating lists given to other surgeons, or radiology rostering adjusted. Service delivery was therefore not significantly impacted.

The original trained team have engaged in ongoing capacity building through peer mentorship, with mixed success. Twelve months after introduction to clinical practice, four additional pathologists have been trained in ROLLIS seed retrieval, one of the originally trained surgeons is still awaiting radiation licensing, and four radiologists have been trained in ROLLIS seed placement and will apply for radiation licensing shortly.

Were appropriate clinical guidelines and procedures developed for the implementation of the new technology?

As noted, strong and ongoing support from the team in WA allowed the Gold Coast team to simply 'borrow' existing guidelines and procedures. The majority were able to be utilised with only minimal changes to account for the local context, such as different phone numbers for the radiation safety officer and the use of locally available specimen grids.

Documentation was developed/adapted during the delay in ethics and radiation licensing, which allowed for multiple rounds of distribution, consultation and adjustment. The documentation at the time of clinical implementation was therefore already mature. It has effectively supported staff, and has not required any further adjustment except for a minor change to the seed tracking sheet to account for a change in requirements from the Radiation Council after clinical implementation.

In each department the procedures for ROLLIS have impacted on existing procedures, positively in surgery and radiology, and neutrally in pathology. These impacts are discussed in the following sections.



Was the early and ongoing clinical experience consistent with the project team's expectations?

The early and ongoing clinical experience has exceeded the project team's expectations. The WA team had reported on their experiences in the improvement of planning and treatment times, but as the developers of the technology, it was assumed that their gradual move to ROLLIS would have embedded a great deal of group learning and tacit knowledge. The ability to translate these benefits to a different state with a relatively inexperienced Gold Coast team was therefore unknown.

However, contrary to the Gold Coast expectation of a 'teething period', benefits were almost immediate. This speaks to the short learning curve and general applicability of ROLLIS, and is a promising sign for other units wishing to implement the technology. The improvement in planning and treatment times occurs mainly in the radiology and surgical phases. In radiology, while hookwire procedures can only be performed on the day of surgery, ROLLIS can be performed up to 10 days in advance and this allows all the procedures for the week to be performed in a single list, optimising the use of the radiology team's time. Similarly in surgery, while hookwire procedures can only be scheduled in the afternoon following insertion, ROLLIS can be performed from the first case onwards, or from mid-morning if the operating list is not on the same day as the radiology insertion list.

The improvements in planning and treatment time have continued to accrue since clinical implementation due to small and progressive refinements in the workflow, such as the inclusion of the lead radiographer in the operative booking process, allowing earlier planning of ROLLIS seed insertion date; and the development of a laminated 'theatre cheat sheet' with a step-by-step guide for theatre nursing staff, allowing novice nursing staff to be rostered in theatres with a planned ROLLIS procedure.

Briefly discuss the number of patients referred, assessed and treated using the new technology

The estimated total for the initial two surgeons was 100. The introduction of ROLLIS within a RCT mandated a 50:50 randomisation between hookwire and ROLLIS. The actual number recruited to the trial was 56 in the first 12 months from a single surgeon, as the second trained surgeon is still to gain radiation licensing. Accounting for these limitations there was an almost 100% recruitment of patients eligible for the ROLLIS RCT, as all patients who were eligible for the trial chose to take part, except for one.

Referral patterns have not changed, and the waiting time for surgery, which was already very efficient for category 1 bookings, 12 days on average, has also not changed. What has changed is the improved flow for both the interventional radiology suite and the operating theatre, with efficiencies gained from the ROLLIS technology allowing for a higher volume of other procedures in the same list with the same staffing.

Number of patients utilising the comparator

The new technology is expected to gradually become a replacement of the comparator. After 12 months, the RCT has almost completed recruitment and it is expected that ROLLIS numbers will then rise significantly as it becomes the preferred method of localisation in the Gold Coast unit.



Safety

Was the new technology as safe, or safer, than the comparator?

Number of adverse events (as defined by the project team) as a result of using the new technology

There was strong and ongoing support from the team in WA which allowed the Gold Coast team to take advantage of their prior learning, such as the sourcing of preloaded seed kits from a supplier in NSW, the use of well-developed protocols for seed tracking, the establishment of new workflows, and the use of logbook and auditing procedures for monitoring seed safety. This resulted in no significant adverse events in the 12 months after introduction of the technology into clinical practice on the Gold Coast.

A Safety Review Board is constituted as part of the national RCT governance. There have not been any sufficiently serious adverse events on the Gold Coast or other trial sites to require action by the Board.

Clinical effectiveness

Was the new technology as effective, or more effective, than the comparator?

Clinical effectiveness (as determined by the project team)

The ROLLIS procedure was easily understood by patients and the enthusiasm to take part in the ROLLIS RCT has been noted above. In this regard, similar to most breast cancer research, the project team benefited from the considerable 'pink ribbon' goodwill that exists in the community.

Interim analysis after the first 150 patients randomised nationally showed that superiority of patient-rated comfort and acceptability of ROLLIS over hookwire reached statistical significance (Ong et al., 2017). Other measures of clinical effectiveness (non-inferiority to hookwire for oncological safety and returns to theatre for close margins) will be reported as part of the ROLLIS RCT after completion of recruitment.

Costing/Economic analysis (if data available/collected)

Did the new technology provide the same or greater benefit, for the same or less cost than the comparator?

A formal economic analysis has not been performed. The cost of the ROLLIS kit (\$65 on trial, \$125 off trial) and hookwire kit (\$45) compare favourably. Staffing and equipment otherwise remain the same, as the gamma probe required for ROLLIS localisation is already in use for sentinel node biopsy procedures. The main additional costs are those of training (which, as noted, can now be carried out on the Gold Coast) and radiation licensing.

Theatre utilisation data from the 53 cases randomised to the RCT show 100 minutes of hookwire-associated delay versus 45 minutes of ROLLIS-associated delay. The hookwire-associated delay arose from the unpredictable time spent in radiology for hookwire insertion plus the transport time between the radiology department and the operating theatre. The ROLLIS-associated delay was related to a misunderstanding about trial paperwork i.e. this will be an avoidable delay when ROLLIS is performed outside of a trial setting.

Theatre utilisation data from the same time period also shows 120 minutes of hookwire-associated delay



for benign (non-RCT) cases. Therefore, over the course of this project, 220 minutes of theatre time for a single surgeon could have been saved if ROLLIS had been used instead of hookwire. This is a significant saving when multiplied across all the surgeons in a high volume unit.

Satisfaction

What was the level of satisfaction with the implementation and ongoing use of the new technology?

Seventy five percent of respondents in the Project Team identified areas of success with the implementation and adoption of the new technology. It was reported that despite delays from Radiation Health in approvals and licensing, their experience with the implementation of ROLLIS will enable them to process future licenses and approvals much faster. Patients tolerating ROLLIS seeds much better than a hookwire was also identified as an area of success with the implementation and adoption.

Eighty percent of respondents in the stakeholder group identified areas of success in the implementation of the technology. Increased efficiency as a result of no radiology involvement consequently avoiding delays in patient presentations was identified as an area of success. The ability to do a number of cases prior to surgery lead to better workflow and was identified as a success along with patients being happier with the technology. Majority of the respondents identified education provided by the clinical lead as a positive aspect while one respondent reported it as education overuse.

Context and Organisational feasibility

Were there any factors that facilitated, or barriers to, the implementation and ongoing use of the new technology?

Facilitators

Fifty percent of respondents surveyed from the Project Team reported there being facilitators to the implementation of the new technology. Support from research trial team in Perth and the benefit of their experience in anticipating and addressing logistical, training, and procedural barriers was reported as a facilitator to the implementation and adoption of ROLLIS. A medical physicist performed a series of in-services to staff that would come in contact with the new technology to ensure radiation hygiene and to address any staff concerns regarding exposure to ROLLIS seeds.

60% respondents from the stakeholder group identified the surgical team, along with radiographers and pathologists involved in the implementation of the technology, as facilitators in the implementation. One respondent commented on the lead surgeon's 'excellent education of all stakeholders' being a facilitator. No barriers were identified to the implementation of the technology.

Barriers

Fifty percent of respondents identified issues around delays in ethics governance and Radiation Health approvals and licenses as barriers to the implementation of ROLLIS.



What were the impacts (positive or negative) from the implementation and ongoing use of the new technology?

Seventy five percent of respondents reported no positive or negative unintended impacts of implementing ROLLIS while 25% identified there being unintended impacts. The benefit of predictable service time from theatre for pathology was identified as a positive unintended impact of implementing the new technology.

Half of the respondents surveyed reported that the implementation of the new technology could have been improved. The recurring themes in the suggestions made to improve the implementation were around streamlining the ethics governance process on the Gold Coast and improving the time required to gain the required approvals associated with the use of radioactive substances from Radiation Health. An opportunity to conduct faster and better engagement was identified as an area of improvement in implementation of the technology.

Is the continued use of the new technology sustainable?

ROLLIS technology is very sustainable because, apart from replacing the cost of the hookwire with the cost of the ROLLIS seed, the staffing and equipment remain the same. Ongoing training does not appear to be required to maintain proficiency in hookwire technique, and the same is expected to be true for the ROLLIS technique. Once a core team is trained, training of additional team members can be performed through peer mentorship. The only additional recurrent cost is therefore that of radiation licensing, currently \$277.50 for a 3 year licence.

It is expected that safety and efficiency will be confirmed with the RCT results. Gold Coast is a high volume breast centre and this is not likely to change in the foreseeable future, with patient numbers expected to gradually rise over time in keeping with population growth in the Gold Coast area.

Social and Ethical Considerations

Health equity is achieved by removing unfair and avoidable barriers that compromise health and wellbeing. The practice of health equity is focused on supporting fair access, fair chances and fair resource distribution to alleviate any disadvantage experienced by at-risk or vulnerable groups.

Did the new technology improve access and equity for patients compared to the comparator?

The improvement in patient comfort and acceptability as rated by the patients has been noted above. The availability of treatment and the average waiting time to breast surgery on the Gold Coast was already very good and has remained unchanged.

One of the main advantages of ROLLIS technology is in allowing patients to have surgery from the first case on the list onwards, and this has particular benefits for patients with medical problems such as diabetes, and those requiring coordination with other services such as pacemaker technicians or language interpreters. This compares to existing hookwire technology, where the late arrival of patients and the unpredictability of their arrival time have proven to be recurrent problems.



What was the patient experience for treatment with the new technology? (if relevant)

Fifty percent of respondents reported being completely satisfied with the patient experience while 40% reported neutral satisfaction and 20% skipped this question. The patients were reported as being the real winners with a more comfortable procedure, better theatre scheduling and fewer returns to theatre for unplanned operations.

The patient experience as rated by the patients themselves is a secondary outcome of the ROLLIS RCT, and the results of interim analysis of the first 150 patients recruited nationally has been noted above.



Appendices

Appendix 1 – Evaluation areas

Evaluation areas defined as part of the evaluation methodology and for the development of evaluation questions and indicators:

- Alignment to project plan: The extent to which the program has been delivered as intended or planned.
- Reach (Stakeholder engagement): The extent to which the program has been adopted by key stakeholders and the extent to which particular target groups have been adequately reached.
- Governance: The extent to which the governance structures in place effectively support implementation.
- Initial clinical utilisation/experience: clinical experience including: training, development of clinical documents, planning and treatment time; patient numbers, referral sources and demand.
- Safety: Frequency and severity of adverse events specific to the technology compared with alternative treatments(s).
- Clinical effectiveness: The effectiveness compared with the alternative treatment(s) measured in terms of length of stay, quality of life, morbidity, mortality or relative risk. Patient reported outcomes can be considered.
- Economic analysis: A measure of the net cost, efficiency or return on investment of the technology compared with alternative treatment(s).
- Satisfaction: Satisfaction by key stakeholders with the implementation of the program.
- Context and Organisational feasibility: A measure of 1) key environmental influences outside the scope of the project that may influence its success; 2) impacts that the new technology has had on the organisation.
- Social and ethical considerations: Identifies if the service is provides greater access and equity for patients and the overall patient experience.



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