

Microchipping the breast: an effective new technology for localizing non-palpable breast lesions for surgery.

Maggie L. DiNome, Amy M. Kusske, Deanna J. Attai, Cheryce P. Fischer, Anne C. Hoyt
 Breast Cancer Research and Treatment (2019) DOI: 10.1007/s10549-019-05143-w

A prospective, single-center pilot study evaluated the effectiveness of the FDA-cleared Radiofrequency Identification Localization System (RFLS).

Study Device Components

- Radiofrequency Identification (RFID) Tag: The RFID Tag is intended to be placed percutaneously anytime prior to the surgery. Each tag has a unique identifier. The tags themselves are passive with no energy source.
- RFID Tag Applicator: The applicator is preloaded with the RFID Tag.
- Localizer Reader: The portable, battery-operated reader broadcasts an unmodulated signal on a frequency of 134 kHz (this signal completes a circuit with the Tag, via which the Reader locates the Tag). The Reader transmits a sound that increases in pitch and volume as its proximity to the Tag grows. The Reader also continuously measures and displays its distance to the Tag.
- Surgical Probe: The pencil-sized probe is used with the Reader to locate the Tag and to guide surgical excision of the surrounding breast tissue. The probe's size allows it to be used for small incisions and doesn't hinder visualization.

Results

Fifty patients enrolled from Aug 2017 to Jan 2018 underwent successful surgical excision with the RFLS. Radiologists placed the Tag with mammogram or ultrasound guidance in 26 and 24 cases, respectively. On Likert questionnaires distributed to patients, surgeons, and radiologists, 94% of patients agreed/strongly agreed that the procedure went smoothly. Patients who underwent ultrasound localization and radiologists who placed under ultrasound guidance had significantly more positive views of the process; the surgeon scores were not significantly different between the modalities.

Primary endpoint (n = 50)	No. (%) or mean ± std. dev.	Exact CI or median (range)
Successful placement of RF Tag	50 (100)	92.9-100%
Successful retrieval of RF Tag	50 (100)	92.9-100%
Secondary endpoints – all patients (n = 50)		
Migration of RF Tag	0 (0)	0-7.1%
Days prior to surgery of insertion of Tag	1.4 ± 2.8	0.0 (0.0-14.0)
Closest depth measurement of Tag from skin (cm)	1.9 ± 1.1	1.8 (0.1-6.0)
Radial distance of Tag from incision (cm)	2.2 ± 2.1	2.0 (0.0-12.0)
Tissue weight (g)	13.4 ± 11.4	10.0 (1.6-60.0)
Tissue volume cm ³	30.7 ± 26.4	25.0 (3.8-159.3)
Secondary endpoints – patients with cancer (n = 33)		
Positive margins on final pathology	1 (3.0)	0.1-15.8%
Patients with cancer requiring re-excision	2 (6.1)	7.4-20.2%

Key Findings

- RFID tags were placed up to 14 days prior to surgery with no instances of migration observed.
- Survey responses indicated no real learning curve observed for radiologists and surgeons.
- The Localizer Reader's feature of continuous measurement of distance to the Tag and its ability to guide excision was found to be very helpful by surgeons which may have contributed to the low positive margin rate noted in the study. The significance of this observation will need to be validated in a larger study.
- There are now three non-radioactive wire-free alternatives for lesion localization. The authors recommend cost-sharing the adoption of a wire-free approach across surgical and imaging facilities, and further recommend the RFLS due to its small probe size and unique Reader features.

Conclusion

The RFLS is an effective, non-radioactive, wire-free approach to non-palpable breast lesion localization, and appears to have some user advantages over other methods.

MED-00374 Rev.001 (06/19) © 2017 Hologic, Inc. All rights reserved. Printed in USA. Specifications are subject to change without prior notice. Hologic is a registered trademark of Hologic and/or Hologic subsidiaries in the United States and/or other countries. All other trademarks and registered trademarks are the property of their respective owners. This information is intended for medical professionals in the U.S. and other markets and is not intended as a product solicitation or promotion where such activities are prohibited. Because Hologic materials are distributed through websites, eBroadcasts and tradeshows, it is not always possible to control where such materials appear. For specific information on what products are available for sale in a particular country, please contact your local Hologic representative or write to womenshealth@hologic.com. This information is presented for purposes of notification and is not intended as a substitute for the original publication. For full details, please obtain a copy of the complete publication referenced herein (DOI: 10.1007/s10549-019-05143-w).