

**METHODS**

**BACKGROUND**

- Nonpalpable breast lesions are routinely localized for wire-guided localization. Mammography (ML) and SAVI® reflector placement under the same day of the scheduled surgery.
- A more recent alternative of radioactive wire localization (RWL) has been cleared for device use. However, scale adoption has been hindered by the complexity of regulatory requirements for the handling and monitoring of radioactive materials. From storage to disposal, RWL requires over central departments and inter-institutional coordination.
- The SAVI SCOUT® (Surgical Suite: Orlando, FL) is a wire-free radiation-free approach: SAVI location, surgical guidance.

**METHODS**

- SAVI has been chosen to be the alternative to wire and radioactive wire localization techniques, with good guidance time and excellent patient, radiologist, and surgeon acceptance.
- Primary advantage of SAVI SCOUT® system is the temporal separation of the marking and localization procedure from surgery. The SAVI reflector may be placed up to 30 days prior to surgery. The question of radioactive wire localization once associated periods of time before surgery has been identified from a potential use for the future. The primary advantages of SAVI reflector placement over traditional approaches is that surgery and with established methods.
- In this study, we analyzed post-placement and questionnaire responses to measure for distance of the reflector to the biopsy clip. In this manner, we can complete multiple needle and surgical freeze sites. This factor has been previously studied.

**RESULTS**

- The study population had an average age of 67.5 years (SD, 14.2 years). All lesions were found in women.
- The time between deployment and surgery averaged 2.7 days (range 0–9 days).
- Breast density of the lesion was scored as “B” (52.3%) or “C” (47.7%) in 52.3% and 47.7% cases, respectively.
- Eighty-two percent (82%) had calcifications in the lesion in the lesion.
- The average distance from clip to reflector between the placement and surgical speciments was 1.09 (SD, 0.97 mm) with a range of 0.24 (24 mm) to 3.74 (374 mm).
- One case (2%) had an apparent migration of ≤5 cm and 10 cases (15%) had an apparent migration of ≥5 cm.
- We did not observe significant migration based on patient age, number of days deployed, and the presence or absence of calcifications in the breast lesions were demonstrated.

**CONCLUSIONS**

- These results suggest good geometric accuracy of the SAVI SCOUT® reflector deployment lesions for up to 7 days.
- These cases were performed by multiple radiologists and surgeons across multiple institutions; only for de-identified data. The SAVI® SCOUT® has been used for more than 1000 failed cases outside the clinical study.
- The SAVI® SCOUT® is likely to be generally applicable for excisional biopsies that this is not the limit to this methodology.
- Since the FDA has recently approved implementation of the SAVI SCOUT® reflector for up to 30 days, further investigations into this clinical trial with tissue quality will be of interest.

**LIMITATIONS**

- Distance between the reflector clip and clip was able to be more precisely measured in post-placement images with the use of CT images of a different size and with different sites. However, the SAVI® SCOUT® was not precisely calibrated at the time of implantation.
- Some specimen radiographs were found to be mandatory during the SAVI® SCOUT® reflector deployment. To properly assess the tissue clip, the reflector distance should be noted.

**CLINICAL RELEVANCE**

- Mammographically guided SAVI® SCOUT™ is a straightforward and radiation-free technique for breast localization. Reflecton placement technique is straightforward to standardize, infection-free approach and biopsy clip placement.
- Mammo-guided SAVI® SCOUT™ system is an accurate and convenient alternative to RWL and WL guidance.
- Early data shows high exploration of technical and clinical efficacy in image-guided reflector deployment, intraoperative control, and surgical outcomes.
- This user-friendly system has been well-accepted by most radiologists, surgeons, and support staff.
- Logistical and workflow advantages include reducing the localization and the surgery dates.
- From the patient and surgeon’s perspective, the process efficiency and patient comfort.
- The SAVI® SCOUT® reflector deployment system is a fall, auto-calibrate, and accuracy delivered for margin control for data, tumor excision, and reduction in overexcision.

**ACKNOWLEDGMENTS**

- Charles E. Cox, MD is on the speaker’s bureau for the device manufacturer, Peter E. Roof, MD is a consultant for Genentech Medical for the development of SAVI SCOUT® and the NL for the current study.ffc sponsored by Genentech, Inc. All other authors have nothing to disclose.

- This study has been performed with the approval of the Institutional Review Board of the authors. For permission to reprint or distribute, contact the authors.

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**Figure 1. SAVI System Components**

- SAVI SCOUT® reflects in the arterial collateral and radiation-free needle localization techniques, with good guidance time and excellent patient, radiologist, and surgeon acceptance.

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**Figure 2.** A: Mammographic image of reflector delivery system placed into target. B: After successful reflector deployment, SAVI SCOUT® image indicating successful removal of reflector.

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**Table 1. Patient Enrollment for Study Parent Study**

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<th>Institution</th>
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**Figure 3A.** CC view immediately after placement. SAVI reflector is 1.74 mm from biopsy clip. **Figure 3B.** ML view immediately after placement. SAVI reflector is 0.6 mm from biopsy clip. Using both CC and ML measurements, the mean reflector distance was 1.97 ± 0.33 mm. **Figure 3C.** Specimen radiograph. For excision, the possible migration distance of 0.95 cm – 1.32 cm.