

SAVI SCOUT as a Novel Localization and Surgical Navigation System for More Accurate Localization and Resection of Pulmonary Nodules

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Abstract

Background. Current techniques for localization and resection of lung nodules carry many intraoperative challenges for surgeons. This article proposes a new localization method for diagnosis and treatment of pulmonary nodules, which provides a navigational system for more accurate lung resection. **Methods.** We report the case of a 77-year-old female with a pulmonary nodule of the right lower lobe. A nonradioactive localization technology, known as SAVI SCOUT (Cianna Medical Inc, Aliso Viejo, CA), was placed by interventional radiology under computed tomography guidance preoperatively. Using the SCOUT Wire-Free Radar Localization System, the pulmonary nodule was robotically localized and resected. SCOUT removal was confirmed using the Trident Specimen Radiology System. The efficacy of this procedure was evaluated in terms of ease of use and procedure time by interventional radiology, surgical resection accuracy, diagnostic accuracy, simplicity, and ease to implement this technology in an existing hospital. **Results.** The SCOUT system allowed for the first reported case of successful SCOUT placement in lung tissue, targeted the pulmonary nodule intraoperatively, and facilitated accurate lung resection. **Conclusions.** The SCOUT system shows promising advancements in the ability to eliminate many challenges currently seen with lung nodule localization and resection.

Keywords

breast surgery, evidence-based medicine/surgery, image-guided surgery, robotic surgery

Introduction

Resection of lung nodules through minimally invasive thoracoscopic surgery currently presents many challenges in that they are thoracoscopically impalpable and invisible.^{1,2} Preoperative computed tomography (CT), bronchoscopy, or near-infrared imaging are utilized for localization of pulmonary nodules, and paired with various modalities including microcoils, hook wires, contrast media, dyes, and radiotracers to improve intraoperative localization and surgical excision success. Each of these modalities carries limitations with relation to intraoperative navigation, procedural placement time, same day placement and surgery scheduling, patient discomfort, dislodgement, and radiation exposure, which may ultimately result in unsuccessful resection. Dual imaging for localization has improved safety and accuracy of surgery but intraoperative navigation to lung nodules remains a challenge. This article presents the first case of implementing the SCOUT system for

pulmonary nodule localization and navigation for minimal lung resection.

The SCOUT system, originally developed for breast cancer lesion localization, includes an advanced nonradioactive radar reflector, console, and handpiece, which utilize radar to deliver the precise location of the reflector. SCOUT has been clinically proven in more than 50 000 cases for localization and resection of breast lesions at more than 400 medical centers in the United States (Cianna Medical, Aliso Viejo, CA). The reflector is Food and Drug Administration (FDA) cleared as a long-term implant with no restrictions on the length of time it can

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remain in tissue. Most important, the system provides both audible and visual feedback, including a real-time distance measurement, which allows for predictable specimen localization intraoperatively and confirmation of reflector removal immediately after resection. Currently, the SCOUT reflector claims to provide “60 mm depth detection range and 360° detection with 1 mm accuracy” (Cianna Medical). In August of 2018, the SCOUT reflector was FDA cleared for extended indication of its use in soft tissue.^{3,4} In this article, we present the first reported case of the SCOUT system being implemented for localization and resection of a lung nodule.

Patient and Materials and Methods

Patient Case

A 77-year-old female diagnosed with squamous cell cancer of the larynx was treated with radiation and chemotherapy. Post-therapy CT and PET/CT (positron emission tomography) showed an asymptomatic right lower lobe nodule, which was PET positive and demonstrated growth between the 2 imaging studies concerning for a metastatic lesion. She underwent a biopsy that was consistent with an adenocarcinoma of “possible/probable” intestinal origin with a negative TTF-1 and napsin A, and a positive CA-9, CDX2, and CK20. The surgical history is significant for colon resection for a cancerous polyp. She had tobacco exposure as a child but has never been a smoker and denies exposure to poisons or chemicals.

Pulmonary function tests showed a FVC (forced vital capacity) and FEV1 (forced expiratory volume in 1 second) of greater than 80% of predicted. The patient’s echocardiogram showed no acute changes on the stress portion of the examination. As previously mentioned, pathology showed adenocarcinoma in the nodule that was biopsied, and according to the immunohistochemical testing, it was consistent with possible intestinal origin as opposed to a lung primary.

Her complete gastrointestinal cancer workup was negative. We felt that this could be a primary lung lesion. The patient expressed that she wanted to remain active, and she requested that we resect the lesion. Standard protocol for resection was followed. She understood that if margins were not clear a lobectomy would be done. Her pulmonary function tests showed she could tolerate the procedure. We felt that a minimal surgery, segmentectomy as opposed to lobectomy would best serve this patient. We proposed to her a lung resection and excisional biopsy of the nodule in the right lobe performed robotically and/or video-assisted thoracoscopic surgery with preoperative localization using the SCOUT reflector.

Patient

Standardized preoperative workup was performed. Consent was obtained from the patient. SCOUT indication was confirmed by positive pulmonary nodule biopsy indicating an adenocarcinoma nodule. Based on the success and safety of SCOUT localization in other soft tissues, we felt our patient had potential for improved accuracy of resection and surgical outcome with the FDA cleared SCOUT Radar Localization System. Based on previous studies, we theorized the SCOUT system would benefit the patient in preserving healthy lung tissue, eliminating intraoperative radiation exposure, minimizing patient discomfort, and decreasing her intraoperative time. No financial support was provided by Cianna Medical for this study.

Surgical Technique

The patient was taken to interventional Radiology for standardized CT-guided localization techniques identical to the institutionalized percutaneous transthoracic needle biopsy technique used with other modalities.⁵ Confirmation of the SCOUT reflector was performed at the completion of the procedure. The total procedure time and ease of placement was the same as other modalities and there was no added procedural time overall. According to department protocol, a routine chest radiograph and observation was performed. The patient was then taken to the operating room (OR) for the resection.

The patient was taken to the OR and placed in supine position. Standardized one lung ventilator endobronchial tube placement and patient preparation for robotic resection and biopsy was followed. The usual 4 trocars were placed for the robot and an additional 15-mm assistant port was placed. Standard chest exploration was performed. The SCOUT handpiece was placed through the assistant port to define the angle, depth, and direction of the targeted specimen with audible and visual feedback (Figure 1). Standard technique was used to free up the area in question to be resected. The entire specimen was delivered through the chest wall in a 10-mm EndoCatch bag. The specimen was placed in the Trident Specimen Radiology System in the OR confirming the SCOUT reflector was within the center of the specimen. The specimen was then submitted to pathology. Pathology was able to use the handpiece to localize the nodule. Routine closure, drainage, and pain management protocols were utilized. The patient was extubated and breathing spontaneously, then transported from the OR to the post-anesthesia care unit.



Figure 1. Intraoperative photograph of the handpiece in the thoracic cavity guiding the surgeon directly to the lung nodule and SCOUT reflector for accurate lung resection. The handpiece was easily placed through the assistant port incision.

Results

The pulmonary nodule was successfully localized with CT imaging and guidance. The SCOUT reflector was easily placed into the lung nodule without complications. No new imaging modalities or other equipment was needed. The patient did not experience any discomfort post-procedure.

The SCOUT reflector that was placed in the lesion was easily identified visually and audibly with the handpiece, which confirmed the direction, orientation, and depth of the fiducial. The SCOUT reflector had standard appearance in the chest. No pulmonary changes occurred including pneumothorax, hemothorax, hemorrhage, or embolism. A segmentectomy of the superior segment of the lower lobe was performed with clear margins beyond the standard segmental resection. The Trident Specimen Radiology System confirmed presence of the SCOUT reflector in the specimen immediately in the OR (Figure 2). Pathology successfully located the nodule using the handpiece. On gross inspection by pathology, the margins were reported easily clear by 1.5 cm excluding the staple line.

A segmentectomy was performed successfully, which helped preserve the patient's lung function. The SCOUT system assisted in the ability to accurately locate the nodule and preserve healthy lung tissue. No unexpected events occurred. The SCOUT system decreased operative time in comparison to other modalities. The surgical procedure was completed without the use of C-arm fluoroscopy



Figure 2. The Trident Specimen Radiology System confirmed the SCOUT reflector was within the center of the specimen immediately in the operating room.

system and any ancillary equipment including shielding lead, bronchoscopy, CT, or personnel. There was no radiation exposure intraoperatively, the robotic equipment was able to stay docked since no C-arm was needed, and accurate resection was performed on first attempt.

Comment

The wire and radiation free SCOUT system is beneficial for its intraoperative navigational ability, which gives direction, orientation, and depth to a lung nodule facilitating more accurate resection. Current localization techniques are feasible and comparable in outcomes, and different patients may benefit from different methods. There is no gold standard approach for localization of pulmonary nodules due to disadvantages associated with all current localization techniques. Ultimately, the variables with current localization methods are to be improved with implementation of the SCOUT system including elimination of intraoperative radiation, elimination of same day placement and operation scheduling, no need for additional personnel or equipment, and decreased duration for intraoperative localization with the added navigation as demonstrated in our patient case.

Currently implemented across the nation for breast tissue⁶⁻⁹ and now proven effective in axillary nodes,¹⁰ the SCOUT system is taken one step further and for the first time successfully implemented in an open cavity soft tissue organ. The nonradioactive SCOUT system demonstrates efficacy and feasibility for lung nodule localization with limited patient complications, reduced intraoperative time, and more accurate lung resection.

Additionally, the SCOUT system can also be utilized to assist pathologists in localizing the lung nodule in question among multiple micronodules in a specimen.

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Declaration of Conflicting Interests

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References

1. Chen W, Chen L, Qiang G, Chen Z, Jing J, Xiong SD. Using an image-guided navigation system for localization of small pulmonary nodules before thoracoscopic surgery. *Surg Endosc*. 2007;21:1883-1886.
2. Lin MW, Chen JS. Image-guided techniques for localizing pulmonary nodules in thoracoscopic surgery. *J Thorac Dis*. 2016;8(suppl 9):S749-S755.
3. FDA expands indication for Savi Scout Reflector. *FDAnews*. <https://www.fdanews.com/articles/187914-fda-expands-indication-for-savi-scout-reflector>. Published August 8, 2018. Accessed April 5, 2019.
4. Cianna Medical Group. Indication for use of SAVI SCOUT® Wire-Free Radar Breast Localization System expands to include localization of soft tissue. *GlobeNewswire News Room*. <http://globenewswire.com/news-release/2018/08/06/1547351/0/en/Indication-for-Use-of-SAVI-SCOUT-Wire-Free-Radar-Breast-Localization-System-Expands-to-Include-Localization-of-Soft-Tissue.html>. Published August 6, 2018. Accessed April 5, 2019.
5. Wu CC, Maher MM, Shepard JA. CT-guided percutaneous needle biopsy of the chest: preprocedural evaluation and technique. *AJR Am J Roentgenol*. 2011;196:W511-W514.
6. Cox CE, Garcia-Henriquez N, Glancy MJ, et al. Pilot study of a new nonradioactive surgical guidance technology for locating nonpalpable breast lesions. *Ann Surg Oncol*. 2016;23:1824-1830.
7. Cox CE, Russell S, Prowler V, et al. A prospective, single arm, multi-site, clinical evaluation of a nonradioactive surgical guidance technology for the location of nonpalpable breast lesions during excision. *Ann Surg Oncol*. 2016;23:3168-3174.
8. Jadeja PH, Mango V, Patel S, et al. Utilization of multiple SAVI SCOUT surgical guidance system reflectors in the same breast: a single-institution feasibility study. *Breast J*. 2018;24:531-534.
9. Mango VL, Wynn RT, Feldman S, et al. Beyond wires and seeds: reflector-guided breast lesion localization and excision. *Radiology*. 2017;284:365-371.
10. Taback B, Jadeja P, Ha R. Enhanced axillary evaluation using reflector-guided sentinel lymph node biopsy: a prospective feasibility study and comparison with conventional lymphatic mapping techniques. *Clin Breast Cancer*. 2018;18:e869-e874.