Assessing the accuracy of a multisection robotic bronchoscope prototype in localization and targeting of small pulmonary lesions

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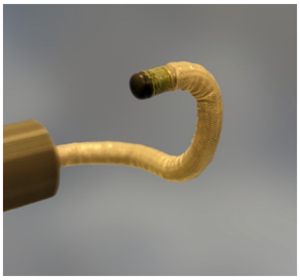
ABSTRACT

Objectives: Robotic bronchoscopy (RB) has emerged as a novel technique to address issues with the biopsy of small peripheral lung lesions. The objective of this study was to quantitatively assess the accuracy of a novel multisection robotic bronchoscope compared with current standards of care.

Methods: This is a prospective, single-blind, comparative study where the accuracy of a multisection RB was compared against the accuracy of standard electromagnetic navigational bronchoscopy (EM-NB) during lesion localization and targeting. Five blinded subjects of varying bronchoscopy experience were recruited to use both RB and EM-NB in a swine lung model. Accuracy of localization and targeting success was measured as the distance from the center of pulmonary targets at each anatomic location. Subjects used both RB and EM-NB to navigate to 4 pulmonary targets assigned using 1:1 block randomization. Differences in accuracy and time between navigation systems were assessed using Wilcoxon rank-sum test.

Results: Of the 40 total attempts per modality, successful targeting was achieved on 90% and 85% of attempts utilizing RB and EM-NB, respectively. Furthermore, RB demonstrated significantly lower median distance to the real-time EM target (1.1 mm; interquartile range [IQR], 0.6-2.0 mm) compared with EM-NB (2.6 mm; IQR, 1.6-3.8) ($P < .001$). Median target displacement resulting from lung and bronchus deformation during bronchoscopy was found to be significantly lower using RB (0.8 mm; IQR, 0.5-1.2 mm) compared with EM-NB (2.6 mm; IQR, 1.4-6.4 mm) ($P < .001$).

Conclusions: The results of this study demonstrate that the multi-section RB prototype allows for improved localization and targeting of small peripheral lung nodules compared with current nonrobot bronchoscopy modalities. (JTCVS Techniques 2024;26:112-20)



Prototype robotic bronchoscope catheter design.

CENTRAL MESSAGE

Our multisectional robotic bronchoscopy prototype allows for improved localization and targeting success rates of small peripheral lung nodules compared with current nonrobot bronchoscopy modalities.

PERSPECTIVE

Considering the newly adopted lung cancer screening guidelines, the ability to definitively diagnosis early-stage lung cancer within small pulmonary nodules is critical. Despite viable methods such as electromagnetic navigational bronchoscopy, there is still an unmet need for rapid, accurate, and minimally invasive biopsy techniques for patients with small peripheral lung lesions.

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Read at the 103rd Annual Meeting of The American Association for Thoracic Surgery, Los Angeles, California, May 6-9, 2023.

Received for publication May 2, 2023; revisions received April 30, 2024; accepted for publication May 10, 2024; available ahead of print May 24, 2024.

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2666-2507

https://doi.org/10.1016/j.xjtc.2024.05.011

Abbreviations and Acronyms

CT = computed tomography
EM-NB = electromagnetic navigational bronchoscopy
RB = robotic bronchoscopy

Lung cancer is the leading cause of cancer-related mortality in the United States, estimated to take 130,000 lives in 2023.[1] Lung cancer screening offers a 20% increase in survival by means of detecting, diagnosing, and treating lung cancers at the earliest stages[2] resulting in more than 36,000 avertable deaths per year.[3] Furthermore, new guidelines that expand screening eligibility are expected to result in 4 million Americans being diagnosed with a new pulmonary nodule on low-dose computed tomography (CT) scan every year[2-5] and 160,000 requiring surgery for definitive lung cancer diagnosis.[4,6] Although early screening readily allows for detection of suspicious lesions, definitive diagnosis of such lesions remains difficult.

Currently, there are several methods to biopsy a newly discovered pulmonary nodule. Surgical wedge resection is a well-established practice used for definitive diagnosis of palpable, superficial lesions. However, this approach is invasive, associated with morbidity, and poses appreciable difficulty when localizing small, ill-defined, and deep lesions within the lung parenchyma.[7] Alternatively, a percutaneous CT-guided core needle biopsy, although less invasive, is associated with significant rates of nondiagnostic sampling and complications such as pneumothorax.[8] Electromagnetic navigational bronchoscopy (EM-NB) with transbronchial biopsy has emerged as a viable alternative to both surgical and CT-guided core biopsy with higher rates of diagnostic biopsy success and less associated complications.[9] Still, EM-NB is not readily effective at targeting peripheral lung lesions due to the limited ability of these systems to make acute endobronchial turns and reach tertiary bronchi while preserving adequate visibility. Given the various limitations of surgical biopsy, CT-guided core biopsy, and EM-NB transbronchial biopsy, robotic bronchoscopy (RB) has emerged a novel technique to achieve a rapid, accurate, minimally invasive biopsy in patients with small peripheral lung lesions.

There are currently multiple robotic platforms that utilize either EM navigation guidance or shape-sensing technology to biopsy peripheral lung nodules. The innovation of these systems stem from their increased maneuverability into the outer lung periphery while preserving visualization and catheter stability.[10] A novel RB prototype has been developed that utilizes a multisectional catheter design and follow-the-leader technology to allow for precise catheter tip movement.[11-13] There are 3 independent bending sections of the catheter design, and the operator is able to directly control the most distal bending section. As the catheter advances, the follow-the-leader technology autonomously directs the remaining 2 sections to optimize bending, thus resulting in conformity of airway trajectory of the tip and a first-person view for navigation and direct aiming to the target. Preliminary results evaluating the accuracy and usability of the RB prototype, operated by expert and naïve users, compared with current nonrobotic standards of care, is presented.

METHODS

Device Development

The device is the result of a grant proposal to develop a prototype RB with the ultimate goal of creating a more precise, less expensive, more portable device and, ultimately, 1 with new functionality based on better understanding of the inherent technical needs and challenges. Canon USA supplied the engineering talent to build the prototype and address these technical challenges in unique ways surgeons would not typically have access to develop. The unique technical innovations are through Canon USA, but preclinical work and publications are the purview of the investigator without editing or restriction.

Study Design

In this prospective, single-blind, comparative study, differences between RB and EM-NB were assessed with regard to accuracy, navigation time, and anatomic deformation during lesion localization and targeting. No institutional review board number is provided because this study does not qualify as a human subject research study requiring institutional review board approval. No Institutional Animal Care and Use Committee was required for this study, given that no live animals were procured, housed, or utilized for the purposes of our study design.

Ex Vivo Lung Model

RB and EM-NB were operated in an ex vivo swine lung fixed on a pegboard with 6 doughnut-type fiducial markers (Multi-Modality Fiducial Markers MM3002; IZI Medical). The lung model was first imaged with a CT scanner in the deflated state and subsequently segmented using 3D Slicer (3D Slicer)[14] to generate a virtual airway map in the navigational software. Point-set registration was then performed by mapping the 6 fiducial markers surrounding the ex vivo lung to align the virtually segmented airway model in the EM-navigation software with the real time position of the lung.

Catheters

For EM-NB, a manual catheter (Edge 180° Firm Tip extended working channel; Medtronic) was equipped with the conventional manual bronchoscope (BF-XT160; Olympus). To eliminate the difference in navigation software, we used the navigation software we developed with 3D Slicer and the EM tracking system (Aurora; NDI) for both RB and EM-NB. The outer diameter of the robotic and manual EM-NB catheter was 3.8 and 2.7 mm, respectively.

Navigation

Five operators of varying bronchoscopy experience were recruited to navigate both RB and EM-NB to predetermined virtual targets in the swine lung model. The operators were blinded as to the location and order of the assigned targets at the start of the procedure. Each operator was allotted 10 minutes to become familiar with each bronchoscope system before beginning navigation attempts. To create the targets, an investigator inserted a needle-type EM sensor (Aurora 5DOF Needle 18G; NDI) in the outer one-third (~2 cm) of the lung before CT scanning, and the location of the EM needle was set on the reconstructed CT airway map as a 2-cm static virtual target with the tip of the needle at the center. Virtual static targets were placed bilaterally in each upper and lower lobe.

The operators were asked to navigate the RB and EM-NB systems and target each of the 4 static virtual radiographic targets, thus mimicking a bronchoscopic navigation procedure. A true biopsy attempt was not done during this study. Each attempt began at the carina and operators attempted navigation and targeting of each static target twice per bronchoscope system. The order of the targets was assigned using 1:1 block randomization. The operators were initially blinded to the position of the virtual targets until the first associated navigation attempt had begun.

During each navigation attempt, the position and orientation of the bronchoscope catheter tip was overlayed with the virtual static target and airway map and displayed to the operator. It should be noted that the virtual target is the predefined radiographic target "made" on the pre-procedure CT scan. It is set before bronchoscopic navigation and because a radiographic target, is both virtual and does not move with respiration; that is, static. However, the real-time position of the EM needle sensors was tracked to generate a virtual location mapped within the lung parenchyma, which accommodated movement and thus was dynamic and in real time. This also allowed for assessment of needle sensor displacement resulting from bronchoscopic navigation through the lung and airway, also known as CT-body divergence (Figure 1). The dynamic (real time) targets were not displayed to the operators during the experiment to assess true CT-body divergence of the bronchoscope without operator correction.

Operators were allotted 10 minutes per attempt to navigate the catheter as close as possible to the static 20-mm target center (Figure E1). If a navigation attempt lasted longer than 10 minutes or the operator was unable to navigate within at least 25 mm of the target center, the procedure was aborted and recorded as a failed attempt.

Data Collection

The primary end points of this study were targeting and localization success, accuracy, and navigation time required to localize and target each lesion. Localization success is defined as the ability to navigate the catheter within 25 mm of the target center, regardless of orientation. Targeting success is the ability to reorient the catheter in a perpendicular direction that is as close as possible to the center of the target with the threshold being within 20 mm of the target center. Anatomic deformation resulting from catheter insertion and navigation was also recorded because it increases CT-body divergence and decreases diagnostic yield. The success of each navigation attempt was assessed by the time of navigation and distance to the static virtual target as stated above. Accuracy was assessed in 2 different ways. Virtual accuracy was defined as the distance between the virtual CT static target and the normal vector of the catheter. Targeting accuracy was defined as the distance between the needle-type EM sensor (real-time target) and the normal vector of the catheter. Anatomic lung deformation was defined as the displacement of the dynamic real-time target defined by EM location versus the original static virtual target, chosen radiographically.

Study Validation

Before study implementation, a series of proof-of-concept and preclinical study validation experiments were executed using an ex vivo porcine model. Validation of the standard EM-NB system was necessary to ensure that the model was consistent with clinical standards. Additionally, EM room mapping was performed to minimize EM interference that could disrupt navigation. Accuracy of both systems was tested in the preclinical study and compared with published data to internally validate study procedures as well as the appropriate level of expertise for operators. Validation results showed comparable localization and targeting success to published data and no interference from the EM system was found.

Statistical Analysis

Navigation success was described using frequencies, whereas accuracy, time, and deformation were summarized using median and interquartile ranges (IQRs). Differences in accuracy, navigation time, and deformation were assessed using Wilcoxon rank-sum test. All statistical analysis was performed using Python version 3.7 (Python Software Foundation).

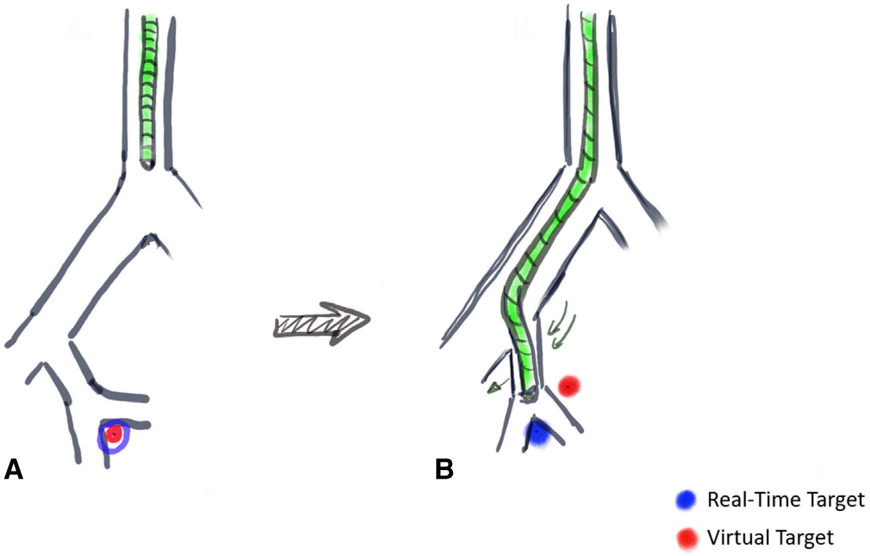


FIGURE 1. Depiction of computed tomography (*CT*)-body divergence. A, The bronchoscope is located at the carina of the lung bloc before navigation. Both the real-time electromagnetic (*EM*) target in the lung and virtual CT-defined target are at the exact same location. B, The bronchoscope has navigated to the assumed target location within the bronchial tree. The real-time EM target has shifted position compared with the virtual target because the bronchoscope navigation caused some displacement of lung tissue.

RESULTS

Five operators with various levels of medical training and bronchoscopy experience completed our study. Two operators were recent medical school graduates with no bronchoscopy experience. Two other operators were surgical residents in the middle of their training with roughly 20 bronchoscopy cases completed. The final operator was a surgical attending with more than 8 years of experience as a thoracic surgeon and roughly 50 bronchoscopy cases per year.

Navigational performance metrics of the RB and EM-NB platforms are detailed in Table 1. Both the RB and EM-NB platforms were driven to 4 independent targets twice for a total of 40 attempts each (8 per subject per platform). Of the 40 total targeting attempts per modality, 36 and 34 attempts were successful when utilizing RB and EM-NB, respectively (90% vs 85%). No significant differences were found between the 2 bronchoscopy modalities with regard to total navigation time (184 seconds for RB vs 140 seconds for EM-NB; $P = .43$).

Comparing accuracy between the 2 bronchoscopy modalities, as expected, there was no statistically significant difference in the ability of the RB (1.0 mm; IQR, 0.4-1.2 mm) or EM-NB (0.9 mm; IQR, 0.5-2.1 mm) to reach the virtual (CT) static targets (Figure 2). However, RB demonstrated significantly better accuracy toward the dynamic EM targets within the lung parenchyma compared with EM-NB ($P < .001$) with median distances to the dynamic targets of 1.1 mm (IQR, 0.6-2.0 mm) and 2.6 mm (IQR, 1.6-3.8 mm), respectively (Figure 2). Median target displacement resulting from lung deformation was found to be significantly lower ($P < .001$) when using RB (0.8 mm; IQR, 0.5-1.2 mm) compared with EM-NB (2.6 mm; IQR, 1.4-6.4 mm) (Figure 3).

TABLE 1. Navigational performance metrics of robotic bronchoscopy and electromagnetic (EM)-navigational bronchoscopy

Navigational performance metric	Robotic catheter (n = 40)	Manual catheter (n = 40)	*P* value
Successful attempts*	36 (90)	34 (85)	
Navigation time (sec)	184 (90-272)	140 (81-294.5)	.43
Accuracy (mm to center of target)			
Static CT target	1.0 (0.4-1.2)	0.9 (0.5-2.1)	.19
Dynamic EM target	1.1 (0.6-2.0)	2.6 (1.6-3.8)	<.001
Displacement (mm)	0.8 (0.5-1.2)	2.6 (1.4-6.4)	<.001

Values are presented as n (%) or median (interquartile range). *CT*, Computed tomography. *Successful attempt defined as navigating to the center of the target within 10 minutes or navigating within 25 mm of the center of the defined target.

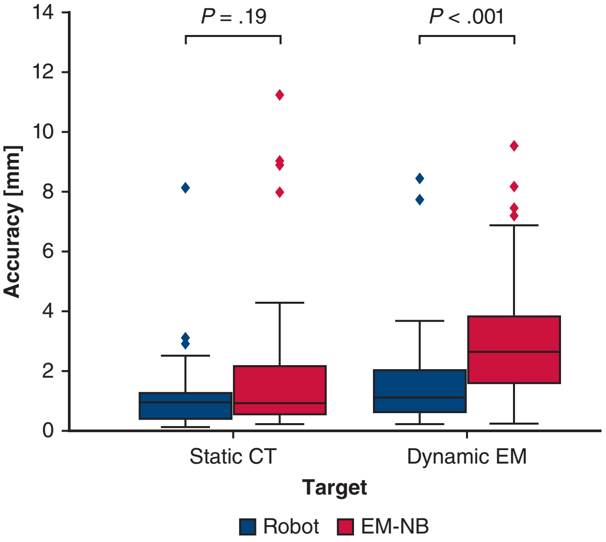


FIGURE 2. Accuracy stratified by bronchoscopic modality. On the *left* is the virtual accuracy of robotic bronchoscopy (*RB*) and electromagnetic navigational bronchoscopy (*EM-NB*). On the *right* is the targeting accuracy of RB and EM-NB. The *lower* and *upper borders* of each *box* represent the lower and upper quartiles (25th percentile, 75th percentile). The *middle horizontal line* represents the median. The lower and upper whiskers represent the minimum and maximum values of nonoutliers. Extra *dots* represent outliers. *CT*, Computed tomography.

Additional analyses of the navigational performance metrics were performed stratifying by operator bronchoscopy experience. With regard to accuracy toward the virtual (CT) static targets, the resident group navigated the RB system with significantly better accuracy compared with the EM-NB system ($P < .05$). No significant differences in accuracy to the static target were found between the 2 systems in the student or attending groups (Figure 4). Both the resident and student groups navigated with

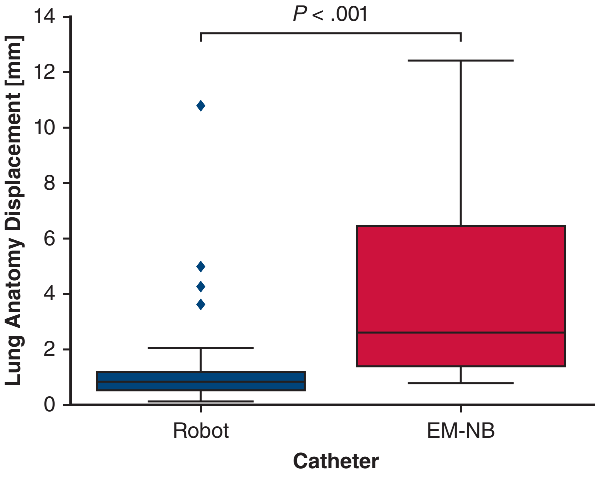


FIGURE 3. Anatomic lung displacement resulting from bronchoscopy. The *lower* and *upper borders* of each *box* represent the lower and upper quartiles (25th percentile, 75th percentile). The *middle horizontal line* represents the median. The lower and upper whiskers represent the minimum and maximum values of nonoutliers. Extra *dots* represent outliers. *EM-NB*, Electromagnetic navigational bronchoscopy.

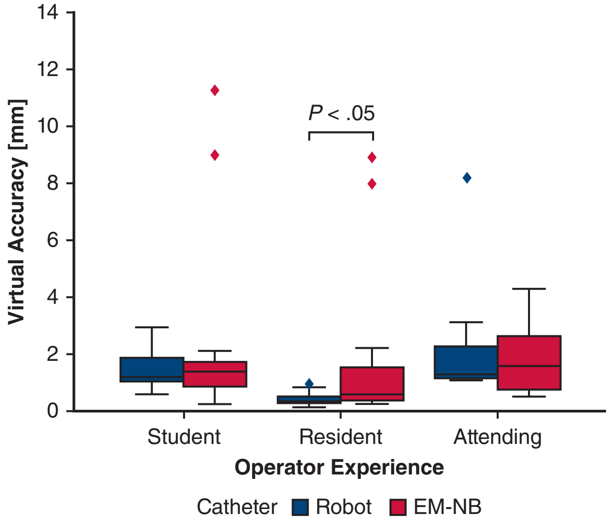


FIGURE 4. Accuracy to the static virtual computed tomography target stratified by operator experience. The *lower* and *upper borders* of each *box* represent the lower and upper quartiles (25th percentile, 75th percentile). The *middle horizontal line* represents the median. The lower and upper whiskers represent the minimum and maximum values of nonoutliers. Extra *dots* represent outliers. *EM-NB*, Electromagnetic navigational bronchoscopy.

significantly better accuracy toward the dynamic EM targets when using RB system compared with the EM-NB system (Figure 5). Among all 3 operator groups, RB was found to result in significantly less anatomic displacement compared with EM-NB (Figure 6).

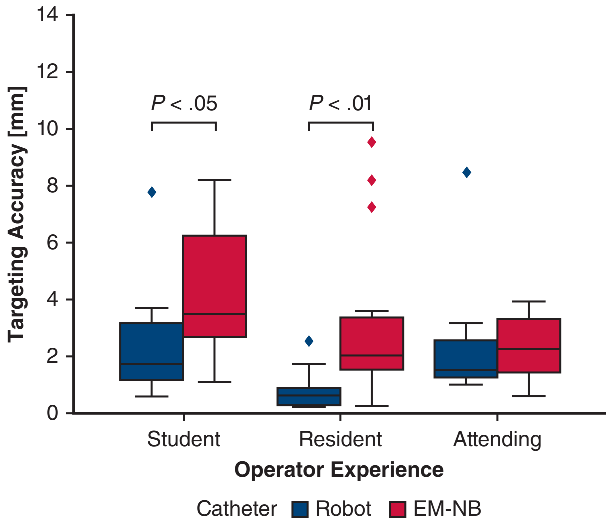


FIGURE 5. Accuracy to the dynamic electromagnetic target stratified by operator experience. The *lower* and *upper borders* of each *box* represent the lower and upper quartiles (25th percentile, 75th percentile). The *middle horizontal line* represents the median. The lower and upper whiskers represent the minimum and maximum values of nonoutliers. Extra *dots* represent outliers. *EM-NB*, Electromagnetic navigational bronchoscopy.

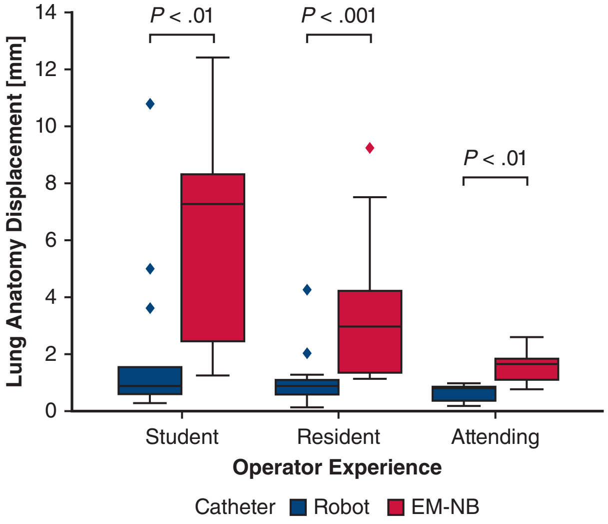
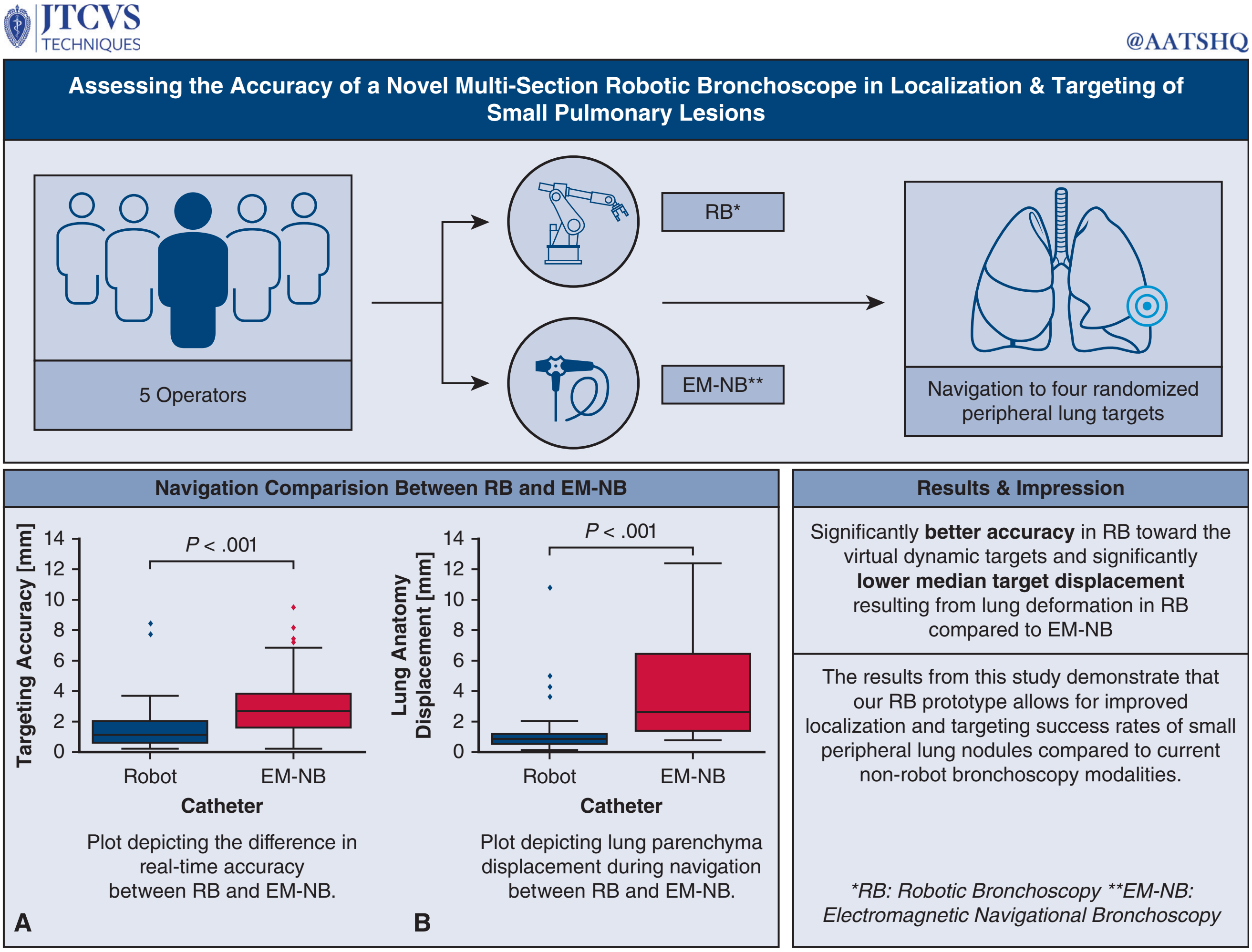


FIGURE 6. Lung displacement stratified by operator experience. The *lower* and *upper borders* of each *box* represent the lower and upper quartiles (25th percentile, 75th percentile). The *middle horizontal line* represents the median. The lower and upper whiskers represent the minimum and maximum values of nonoutliers. Extra *dots* represent outliers. *EM-NB*, Electromagnetic navigational bronchoscopy.

DISCUSSION

In this study, we set out to evaluate the accuracy and usability of our multisegment RB prototype compared with an EM-NB platform. We have chosen to compare the technical capabilities (ie, follow-the-leader technology) of this new multisectional prototypical RB versus the capabilities of a regular bronchoscope to characterize the technical limitations of nodule localization inherent in these technologies as a result of intrinsic issues such as lung deformation. Although subsequent design of the user interface, segmentation software, and the localization algorithm will need to take these technical challenges (unique to the lung) into consideration, we chose to not compare the current preliminary user interface in our current device versus commercially available RBs at this stage because any differences in performance would predominantly be due to differences between the user interfaces rather than differences in technical abilities, which may better address the intrinsic challenges of nodule localization that occur during the bronchoscopic procedure.

The results suggest that our prototype can navigate and locate peripheral lung targets with similar accuracy to that of current nonrobotic platforms (Figure 7). One comparative study assessing EM-NB to an RB platform reported a navigational success of 85% in the EM-NB group and 100% navigation in the robotic groups.[10] Others have reported navigational success of various robotic platforms ranging from 85% to 96.6%.[15] Our navigational results fall in line with these reported studies despite many of our operators having no prior bronchoscopic experience.



Assessing the Accuracy of a Novel Multi-Section Robotic Bronchoscope in Localization & Targeting of Small Pulmonary Lesions

5 Operators

RB*

EM-NB**

Navigation to four randomized peripheral lung targets

Navigation Comparision Between RB and EM-NB

Plot depicting the difference in real-time accuracy between RB and EM-NB.

Plot depicting lung parenchyma displacement during navigation between RB and EM-NB.

Results & Impression

Significantly **better accuracy** in RB toward the virtual dynamic targets and significantly **lower median target displacement** resulting from lung deformation in RB compared to EM-NB

The results from this study demonstrate that our RB prototype allows for improved localization and targeting success rates of small peripheral lung nodules compared to current non-robot bronchoscopy modalities.

**RB: Robotic Bronchoscopy **EM-NB: Electromagnetic Navigational Bronchoscopy*

FIGURE 7. Graphical abstract.

Although biopsies were not performed during this experiment, excellent proximity of targeting (within 1 mm of the target center) would be expected to yield very high results. Thiboutot and colleagues[16] were able to show that when a robotic catheter tip was within 10 mm of a nodule, there was a 68% central target hit rate during biopsy attempt. A multivariable analysis confirmed that the strongest predictor of a central target hit was robotic catheter distance to nodule (odds ratio, 0.89 per increase in 1 mm; $P < .001$), independent of the presence of a bronchus sign, divergence, or concentric radial endobronchial ultrasound view. We hope in future studies to showcase comparable biopsy rates given our promising preliminary navigation results.

Further investigation into our accuracy data yielded a significant difference between virtual CT and real-time EM navigation and target accuracy. Both RB and EM-NB navigations were within 1 mm of the center of the virtual CT target. However, when the real-time location was used instead of the static location at the end of navigation, there was a significant difference in accuracy (about 1.5 mm in favor of RB). When lung displacement was evaluated, there was a clear difference in the amount of lung parenchyma shifted by the manual bronchoscope compared with the RB. Investigators in other studies have shown that when a manual bronchoscope is placed in a wedge position, which is often the case during EM-NB for distal targets, there is large displacement of the lung parenchyma leading to missed targets.[17] It has been suggested that atelectasis of the distal lung tissue caused by the wedge position, as well as the introduction of various instruments in the airway, leads to large distortions of the airway beyond the bronchoscope.[18] This distortion of the lung tissue, which leads to changes in the EM target position but does no change the virtual target location marked on the CT, is a major contributor to CT-body divergence. Our results highlight the advantage of RB to overcome this lung distortion and help minimize CT-body divergence related to the bronchoscope.

Beyond the navigational advantage of RB, there is an undeniable ease of use compared with manual bronchoscopy. With manual bronchoscopy, a clear positive relationship exists between operator experience and successful localization and biopsy of pulmonary targets.[19] This is most evident in our experiment when the lung displacement is stratified by operator experience. Unsurprisingly, the medical students had the widest range in measured lung displacement compared with the attending when using the manual bronchoscope. The difference in experience leading to large tissue displacement was completely mitigated when using the RB platform, despite all operators being first time users with our prototype. A recent study showed that technical competency in EM-NB was achieved by a novice operator by the 47th operation, suggesting a prolonged learning curve.[20] In comparison to EM-NB, RB has been shown to have a more manageable cognitive load[21] and the current study demonstrates this well. This lowering of cognitive load was echoed by the current operators who mentioned less physical and mental fatigue using our RB platform.

Important limitations of this study are acknowledged. First, our participant pool was small and heterogeneous in terms of bronchoscopy experience. Despite the difficulty in creating generalizable results for specific operator groups, the heterogeneity of participants highlighted ease of use for an RB platform compared with an EM-NB platform. Secondly, our results are based on an ex vivo porcine lung model, which has subtle variations in lung anatomy compared with human anatomy. Also, because this was an ex vivo model, many extrinsic factors present during bronchoscopy of living patients were eliminated, most notably respiratory variation. Therefore, our results require consideration before being generalized to clinical settings. An additional limitation of our study is the lack of true comparison between robotic bronchoscopy platforms. As we develop a more refined interface and platform, we hope to provide a comparative study to support our preliminary results and will be better able to assess other technical challenges such as median target displacement resulting from needle deflection. Lastly, our results potentially overestimate the success rate of both navigation systems given that EM-needle targets provide highly resolute navigation and targeting directionality, whereas soft tissue and in vivo tumor that are not localized with a fluorescent dye or fiducial markers, do not provide such information to the bronchoscopist and is an attributable cause for clinically failed biopsies.

CONCLUSIONS

The results from this study demonstrate that the current RB prototype allows for improved localization and targeting success rates of small peripheral lung nodules compared with current non-RB hardware when assessed using the same EM software. Although these results are compelling, further in vivo large animal and clinical studies are needed to better examine the true diagnostic value of this novel platform with regard to biopsy and the subsequent application of a comparative clinical pilot trial of various robotic platforms.

Conflict of Interest Statement

This research was supported by the Canon USA Inc–Mass General Brigham Collaboration (“Preclinical Assessment of Robotic Snake for Lung Biopsy”). Canon USA Inc did not have editorial oversight as to the content of the manuscript with exception of confirming coverage of intellectual property. Mr Masaki is an employee of Canon Medical Research USA Inc. All other authors reported no conflicts of interest.

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Key Words: pulmonary nodules, interventional bronchoscopy, lung cancer, navigational bronchoscopy, robotic bronchoscopy

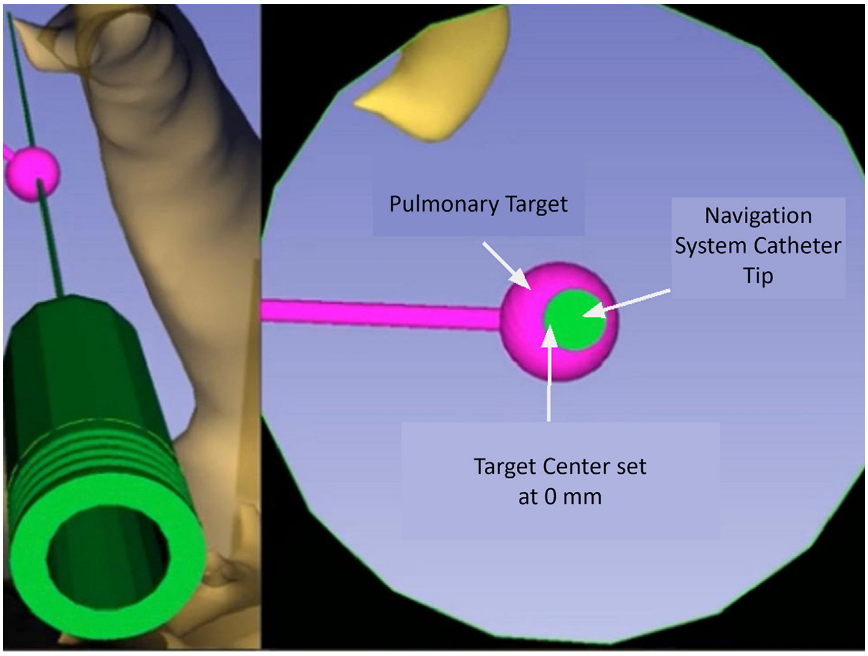

FIGURE E1. Targeting of a lesion that has been localized is shown. The target is represented in *pink* and the navigation system catheter in *green*. The catheter tip of the navigation system was aligned to the *center* of the electromagnetic needle target.