



Navigational bronchoscopy: a guide through history, current use, and developing technology

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Abstract: The peripheral pulmonary nodule offers unique challenges to the clinician, especially in regards to diagnostic approach. Quite often the etiology of the nodule is spurious, though the specter of malignancy drives accurate classification of the nodule. Diagnostic approaches range in degrees of invasiveness, accuracy, and morbidity. Bronchoscopic access to these nodules had been plagued by low reported yields, especially in fluoroscopically invisible nodules. Navigational bronchoscopy, however, allowed more accurate access to peripheral nodules while maintaining a low morbidity, and thus reshaped the historic diagnostic algorithms. Though navigational bronchoscopy was initially associated with electromagnetic navigation, newer approaches to navigation and new technologies provide enthusiasm that yield can improve. In this article we will provide a historical approach to navigational bronchoscopy, from its origins to its current state, and we will discuss developing technology and its potential role in the evolving paradigm of the peripheral nodule biopsy.

Keywords: Bronchoscopy; navigational bronchoscopy; lung nodule; electromagnetic navigation

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Introduction

Navigational bronchoscopy is a type of technology that can be used to help access difficult to reach lesions within the pulmonary parenchyma. The term was initially synonymous with electromagnetic navigation bronchoscopy (ENB). In contemporary practice, it often encompasses peripheral bronchoscopy that is augmented by a computer-aided system (1). Navigational bronchoscopy has higher diagnostic yields when compared to conventional bronchoscopy; the American College of Chest Physicians recommends that ENB be used to obtain tissue from difficult to reach peripheral lung lesions (2). With the advent of lung cancer screening programs, the management of pulmonary nodules found during screening has come to the forefront of thoracic disease. Over 90% of the nodules found in

the National Lung Cancer Screening trial were benign in nature (3). To reduce morbidity, using a minimally invasive technique in an attempt to characterize these nodules is of paramount importance (4). Due to the increased use of cardiac CT scans (for coronary calcium scoring) and abdominal CT scans, the incidence of incidentally found lung nodules has also increased (5). Although found incidentally, these pulmonary nodules have significant clinical and economic ramifications (3).

A variety of navigational bronchoscopy platforms have been developed to address this unmet need. The primary goal of these systems is to assist with the procurement of diagnostic tissue in a minimally invasive and safe fashion. Since the early 2000s, there have been advancements in technology that have increased the accuracy of the navigation and improved user interfaces. This allows the

tools to be more adaptable across a variety of user skill levels and clinical settings. In this review, we summarize the history of navigational bronchoscopy and characterize the technology used in the past, active clinical use, ongoing clinical trials, and in the future.

History of navigational bronchoscopy

The first navigational systems were ENB platforms that relied upon the generation of an electromagnetic field around the patient's body. This allowed for the tracking of a sensor within this field. If the volume within the electromagnetic field could be mapped in a fashion which corresponded with a representative 3D reconstruction of the patient's anatomy (using CT imaging), then, in theory, the sensor could be "navigated" through this volume with its position being represented on a virtual 3D map of the lung (6). This contrasts with virtual bronchoscopy, which relies on the chest CT scan to generate a rendering of the airway but does not utilize a positioning function. In simplicity, ENB can be related to traveling with the assistance of a global positioning system, while virtual bronchoscopy can be related to traveling with the assistance of a roadmap.

The history of ENB traces back to the use of electromagnetic tracking devices in neurosurgery, urology, otorhinolaryngology, and cardiology (4,7). Early studies investigated the technology in swine models; Solomon *et al.* were the first to conduct these studies and publish their results (8,9). Dr. Solomon's work applied the Biosense Intrabody Navigation System (Biosense Webster Inc., Irvine, CA, USA); which, was already being used in cardiac electrophysiology and liver disease (transjugular intrahepatic portosystemic shunt procedures) (9). Independent of his work, an Israeli company (superDimension Ltd.) developed similar technology. Its application was in computer gaming; the location sensors were placed on handheld paddles. This technology was subsequently miniaturized so that it could be applied within healthcare. Initially used within cardiac electrophysiology, the technology migrated to intrapulmonary applications and bronchoscopic navigation. This formed the foundation for modern ENB platforms (8). Commercialization of the superDimension™ system (Medtronic, Minneapolis, MN, U.S.A.) led to the wide adoption of ENB. The field of navigational bronchoscopy accelerated from this critical junction.

The first human trial using ENB was published in 2006 (10). Since then, dozens of studies have been published utilizing

ENB, most of which using a superDimension™ platform. During this time period, many technological advances to registration algorithms, user interfaces, and tools have been implemented. These advances were applied both within the superDimension™ platform and with other ENB-based systems, such as the SPiN Thoracic Navigation System™ by Veran Medical Technologies™ (St. Louis, MO, USA). Electromagnetic navigation is not limited solely to pure ENB systems; some models of contemporary robotic-assisted bronchoscopy platforms also utilize electromagnetic guidance within their workflows (6). Additionally, a variety of non-ENB guidance platforms have also been developed: such as LUNGVISION™ (Body Vision Medical Ltd., Ramat Ha Sharon, Israel) and Archimedes™ by Broncus Medical® (San Jose, CA, USA). LUNGVISION™ uses augmented fluoroscopic and C-arm based tomography to achieve navigation to and localization of peripheral lung nodules, respectively. The Archimedes™ platform uses fluoroscopic guidance as part of its bronchoscopic transparenchymal nodule access procedure.

Over the past two decades, there have been tremendous technological innovations in navigational bronchoscopy. This has led to the availability of a variety of approaches and platforms for navigating to and successfully sampling pulmonary lesions.

Technology in current clinical practice

Interpretation of each technology's performance in the medical literature is challenging, and often confounded by bias. Given the many iterations of technological advancements and improvements in user interface, it is difficult to generalize the results of prior studies that used earlier-generation software and catheters. Importantly, there are no head-to-head human trials that have assessed competing navigational platforms or technologies. Anecdotally, there appear to be performance differences among the platforms that depend on a variety of characteristics: lesion size, lesion location, patient's body habitus, etc., though this has yet to be proven in a well-designed clinical trial. Given the capital expense of these technologies, it is unlikely that a head-to-head comparison would have a significant impact on clinical practice. However, understanding the performance advantages and limitations of each individual technology is of paramount importance, with meaningful clinical consequences.

Platform-independent factors that can affect yield do appear to exist. For instance, it has been shown that

diagnostic yields are lower when navigational systems used in isolation. The use of adjunctive imaging modalities such as fluoroscopy or radial probe endobronchial ultrasound (RP-EBUS) has been proven to increase diagnostic yield (11). Factors such as lesion location, lesion size, presence of a bronchus sign, anesthesia strategy, and registration error also have significant implications (12). It is likely that other non-technological factors such as user experience and expertise, as well as experience with patient selection, contribute to performance as well (12).

As detailed in the following section, there are a variety of platforms to choose from. Knowledge of their fundamental principles and available data is essential to successful use.

Traditional navigation platforms

superDimension

The *superDimension*TM system is a well-known ENB system. It was initially released in 2004 and has undergone several series of hardware and software upgrades since. At present, it is the most widely used ENB system. Over 90% of all ENB procedures are performed using this platform (13). Like most other electromagnetic navigation systems, a recent chest CT scan is needed for the planning. *superDimension*TM recommends a specific CT scan acquisition protocol, highlighted by a slice thickness between 1.0–1.25 mm and a slice interval range between 0.8–1.0 mm (14).

Early studies were primarily single-center case series and varied significantly in their design and outcomes. Since its inception, there have been numerous published studies describing the diagnostic yield using the *superDimension*TM system. They are summarized in *Table 1* (15).

The *superDimension*TM platform was recently evaluated in a large, prospective, multicenter study (NAVIGATE). The primary focus of the NAVIGATE study was to evaluate the safety profile of navigational bronchoscopy for peripheral lung lesions (16). Many other outcomes were reported, including diagnostic yield. This prospective, multicenter observational cohort study included over 1,000 patients from 29 centers in the United States. These centers were a mix of both academic and community-based healthcare facilities. Recruitment at each site was capped to 75 subjects to preserve heterogeneity and limit bias. The main inclusion criteria were patients with peripheral lung lesions who were undergoing ENB. Almost half of all lesions (49.1%) were less than 20mm in size. Fifty-eight percent of lesions were

in the upper lobe; the median distance between a lesion and pleura was 9.0 mm. Successful navigation and tissue acquisition rate was 94.4%, the 12-month diagnostic yield was 72.9%, and the 12-month sensitivity for malignancy was 68.8%. In this study, complications rates were low: pneumothorax rate of 4.3%, serious bleeding rate of 1.5%, and respiratory failure rate of 0.4%. Limitations of the study included its single-arm non-randomized design, the potential of patient selection bias, and the potential inability to generalize the results to operators who perform less than five ENB cases per month (16). To date, it is the largest published ENB study (16).

*SPiN Thoracic Navigation System*TM

The *SPiN Thoracic Navigation System*TM is the ENB platform offered by Veran Medical TechnologiesTM. It has a variety of fundamental differences from the *superDimension*TM. A proposed advantage of the VeranTM system is that the complementary tools (Always-On Tip Tracked[®] Instruments) house electromagnetic sensors that allow tracking of the instrument position and the target lesion throughout the procedure. This could possibly eliminate the need for fluoroscopy (17). The key differentiating features between the two systems are summarized in *Table 2*.

Complementary to the ENB component, the Veran Medical TechnologiesTM *SPiN Perc*TM system also allows a pulmonologist to access nodules percutaneously. The combination of the ENB and *SPiN Perc*TM components allows for a seamless transition from an endobronchial to a transthoracic needle aspiration during a single procedural setting. A multicenter clinical trial regarding the diagnostic yield of a staged procedure [endobronchial ultrasound transbronchial needle aspiration (EBUS-TBNA), ENB, and electromagnetic navigation-transthoracic needle aspiration (ENM-TTNA)] for the diagnosis of pulmonary nodules is being conducted (18).

There is no head-to-head published data that compares the VeranTM and MedtronicTM ENB systems. In the largest published prospective study of the VeranTM system, a combination of EBUS-TBNA, ENB, and ENM-TTNA were used to assess solitary pulmonary nodules. Overall, the ENB component was diagnostic in 33% of cases; rates rose to 73% when an air bronchus sign was present (19). The combination of ENB and ENM-TTNA yielded a diagnostic rate of 87%. The mean lesion size in this study was 20.3 mm,

Table 1 Summary of diagnostic yields from electromagnetic navigational bronchoscopy platform studies

Lead author	Year published	Diagnostic yield (%)	Electromagnetic navigation bronchoscopy platform
Becker	2005	69	superDimension™
Gildea	2005	74.1	superDimension™
Schwarz	2006	69.2	superDimension™
Eberhardt (a)*	2007	59	superDimension™
Eberhardt (b)*	2007	87.5	superDimension™
Eberhardt (c)*	2007	67.4	superDimension™
Markis	2007	62.5	superDimension™
Wilson	2007	59.9	superDimension™
Bertoletti	2009	77.4	superDimension™
Lamprecht	2009	76.9	superDimension™
Eberhardt	2010	75.5	superDimension™
Seijo	2010	66.7	superDimension™
Mahajan	2011	77.1	superDimension™
Brownback	2012	74.5	superDimension™
Jensen	2012	65.2	superDimension™
Lamprecht	2012	83.9	superDimension™
Pearlstein	2012	85.1	superDimension™
Balbo	2012	70.7	superDimension™
Karnak	2013	91.4	superDimension™
Khan	2013	75.0	superDimension™
Mohanasundaram	2013	89.4	superDimension™
Loo	2014	94.0	superDimension™
Odronic	2014	85.7	superDimension™
Bowling	2015	73.6	superDimension™
Ost (a)*	2016	38.5	superDimension™
Ost (b)*	2016	47.1	superDimension™
Garwood	2016	77.9	superDimension™
Ozgul (a)*	2016	71.4	superDimension™
Ozgul (b)*	2016	73.1	superDimension™
Al-Jaghbeer	2016	60.0	superDimension™
Copeland	2017	75.8	superDimension™
Mukherjee	2017	96.8	superDimension™

Table 1 (continued)

Table 1 (continued)

Lead author	Year published	Diagnostic yield (%)	Electromagnetic navigation bronchoscopy platform
Saenghirunvattana	2017	78.8	superDimension™
Sun	2017	82.5	superDimension™
Gu	2017	92.9	superDimension™
Patrucco	2018	69.0	superDimension™
Folch	2019	73.0	superDimension™
Anderson	2020	68.0	superDimension™
Yarmus	2016	33.0	Veran™
Flenaugh	2016	90.2	Veran™
Raval	2016	83.3	Veran™
Belanger	2019	74.0	Veran™

*, multiple studies published by an author during the same calendar year.

and the mean distance from the pleura was 12.6 mm. In a retrospective, multicenter study that included 129 ENM-TTNA, a diagnostic rate of 73.7% was achieved with the transthoracic component alone. When combined with ENB, the rate increased to 81.1% (20). The pneumothorax rate was noted to be 17.8%, over half of which needed the placement of a chest tube. In another retrospective study, the diagnostic yield of the ENB component (n=92) was 74% (21). Although these studies were conducted at large academic medical centers, there is data that evaluates the system in other settings. In a community-based practice, the diagnostic rate with the Veran™ ENB system was 78.3% (without a bronchus sign) and 88% (with a bronchus sign) (22).

Archimedes™

Archimedes™ by Broncus Medical® (San Jose, CA, USA) is a virtual bronchoscopic planning and navigational platform. It uses the LungPoint® Virtual Bronchoscopic Navigation System; it is the only virtual bronchoscopic navigation platform currently on the market. The console is designed in a way that a virtual endoscopic map is displayed adjacent to the live endoscopic image. It does not have an electromagnetic navigation component. The system reconstructs the airways and major vessels from the CT

Table 2 Key differences between superDimension™ and Veran™ electromagnetic navigation bronchoscopy systems

Differences	superDimension™	Veran™
Prerequisite CT imaging	Inspiratory scan within 30 days of procedure is recommended	Same day expiratory and inspiratory imaging recommended
Electromagnetic field generator	Location board needs to be placed under the patient	Mobile field generator that can be placed in a variety of locations
Field mapping	Mapping of procedure bed and room recommended	Not required
Tracking	No live tracking via tools	Continuous monitoring and tracking via electromagnetic sensor embedded tools
Registration	Via locatable guide that is passed through the working channel	Automatic registration
Percutaneous biopsy	Not available	Possible via SPiN Perc™
Integrated fluoroscopic navigational technology	Available with superDimension™ Navigation System with fluoroscopic navigation technology	Not available

scan; it calculates a centerline for each airway. The target lesion is superimposed on the virtual bronchoscopic view. Based on internal testing, the manufacturer states that the user is guided to within 3mm of the target (23). The unique feature of Archimedes™ is that it allows the creation of a tunnel through the lung parenchyma, around blood vessels (bronchoscopic transparenchymal nodule access) (24). In the first-in-human study (n=12), the overall diagnostic yield was 83% (25). Only ten patients were able to have a tunneled path created; biopsy yield was 100% in this group. In order to assess safety and efficacy, all patients who underwent a bronchoscopic biopsy via the creation of a tunneled pathway proceeded to surgical resection immediately after the biopsy. No adverse events were noted during the bronchoscopic procedures. As a follow-up, a prospective feasibility and safety study showed a diagnostic rate of 100% in five patients in which a tunnel was successfully created with the Archimedes™ system. Two patients developed a pneumothorax. In contrast to the previous study, this protocol did not include a surgical resection immediately after the bronchoscopic biopsy was obtained. In a multicenter retrospective analysis, the system was used to evaluate suspicious peripheral pulmonary nodules of 31 patients. The objective of the study was the assessment of procedural performance and safety across both academic and community hospitals. Overall, low procedural complication rates (three in total) and comparable average nodule access times were noted (26).

Novel navigational technology

Fluoroscopic navigation

One explanation for lower yields of bronchoscopic sampling of solitary pulmonary nodules is the divergence between the nodule location on the pre-procedural CT and its actual location during the procedure (27). The use of fluoroscopic navigation that incorporates digital tomosynthesis to re-register the target during the procedure is proposed to help mitigate divergence. The superDimension™ Navigation System with Fluoroscopic Navigation Technology is an example of a combined platform (13). In a study by Aboudara et al., the use of fluoroscopic guidance within ENB procedure resulted in higher yields than conventional ENB (79% vs. 54%, 177 nodules sampled in total) (27).

Similarly, the LUNGVISION™ (Body Vision Medical Ltd, Ramat Ha Sharon, Israel) platform utilizes fluoroscopic imaging in conjunction with artificial intelligence and machine-learning algorithms (28). Research is ongoing, but early clinical trial data shows localization success 85–96% and diagnostic yields of 75–92% (29,30).

Robotic-assisted bronchoscopy

Robotic bronchoscopy is the latest wave of navigational bronchoscopy. At present, there are two platforms that are currently available on the market. Both allow the operator to interact with a bronchoscope via a controller apparatus,

which allows precision control.

Auris monarch

The Monarch™ Platform by Auris Health® (Redwood City, CA, USA) is a robotic platform that was approved for use by the United States Food and Drug Administration in March 2018 (31). Rojas-Solano *et al.* used the system to sample 15 parenchymal lesions (32). In this cohort, a malignant diagnosis was found in nine of the patients; there were no significant adverse events noted. The system was also successfully used to obtain a diagnosis in 97% of nodules (n=77) among eight human cadaveric lungs (33). A retrospective study that assessed the platform across both academic and community medical centers in the United States revealed a diagnostic yield that ranged between 69.1–77%. A multicenter, prospective clinical trial that assesses the successful navigation of the system and the incidence of device or procedure-related adverse effects is currently underway (ClinicalTrials.gov Identifier: NCT03727425) (34).

Intuitive Ion

The Ion™ endoluminal robotic bronchoscopy platform by Intuitive Surgical® (Sunnyvale, CA, USA) is a robotic-assisted bronchoscopy platform that employs the use of fully articulating 3.5mm outer diameter catheter for accessing difficult to reach nodules (35). The working channel for this catheter is 2.0 mm in diameter. The system is designed to allow direct visualization during only a portion of the navigation process. After a specific depth is reached, the visualization probe must be removed. For real-time orientation and feedback, the rest of the navigation process dependent on the system's shape sensing technology. After reaching the nodule, the catheter is locked into place, and biopsies can be obtained. The catheter allows for 180-degree rotation in all directions. They have a custom-designed needle (Flexision™), which allows sampling around tight radius bends. Additionally, the console is designed in such a way that RP-EBUS, fluoroscopy, and live views of the lung can be presented on a single display. Small studies (29 patients) have shown high rates of reaching the target (96.6% success) and an overall diagnostic yield of 79.3% (88% for malignancy) (36). All the lesions in this study were ≤12.3 mm in size, and 41.4% did not have a bronchus sign present. Another study that evaluated successful navigation rates between ultrathin bronchoscopy with RP-EBUS, ENB, and the Ion™ platform showed that

the robotic system outperformed the other modalities with a successful navigation rate of 100% (37). Clinical trials are ongoing (ClinicalTrials.gov Identifier: NCT03893539) to assess the navigation success, biopsy success, and the sensitivity for malignancy from the obtained samples (38).

Cone beam computed tomography (CBCT)

CBCT is an imaging modality that is used frequently by interventional radiologists (39). These systems can reconstruct detailed, isotropic images of a specified anatomical area (40). Unlike traditional multidetector CT, CBCT relies on a high-resolution two-dimensional detector for image acquisition (41). The C-arm of the system needs to be rotated to acquire a 3D data set. Its use with peripheral bronchoscopy is relatively novel; one of the first reported series was published in 2014 (41). Currently, there are a variety of CBCT systems on the market from various manufacturers. It is challenging to classify CBCT under the umbrella of navigations systems; it is rather an adjunctive imaging tool that can help assist with more precise localization of lesions. In simplicity, it can be viewed as a refreshable, static map. As peripheral bronchoscopy is being performed, CBCT can assist with the adjustments to redirect to the lesion, as well as confirm “tool-in-lesion” prior to obtaining biopsy samples. Peripheral bronchoscopy with CBCT can be performed with or without the use of additional navigational bronchoscopy platforms. A study that paired CBCT with thin and ultrathin bronchoscopy showed a diagnostic yield of 70% (40). Although not assessed as a navigational tool, CBCT was used to evaluate the degree of sampling error between the peripheral bronchoscopic modalities in the PRECISION-1 study (37). As CBCT platforms become smaller and more affordable, their use may become more widespread within pulmonary medicine.

Future directions

Data that supports a reduction in lung cancer mortality with screening continues to mount (42). This, in combination with the overuse of chest CT scans, will likely lead to a higher incidence of lung nodule detection (43). For the management of these nodules, it is expected that current technology will continue to advance, and new technology will be developed. One such example of this is the Illumisite™ Platform by Medtronic. Published data is yet to be available; the single platform allows the combination

of a variety of guidance and localization techniques to help access a lesion (ENB, fluoroscopic navigation, continuous guidance, and transbronchial access) (44).

Conclusions

In summary, navigational bronchoscopy can be relied upon to reach pulmonary lesions that warrant sampling. There are numerous platforms using unique technology that are currently available on the market. The evidence behind the use of any of these systems, is at best of moderate quality. Most published literature is limited to case series or retrospective studies. When evaluating for high-quality evidence, there is a literature gap in this niche of pulmonary medicine and thoracic oncology. In addition to obtaining a diagnosis for parenchymal lung lesions, precise navigation and localization have other critical clinical applications. Dye marking for thoracic surgery and fiducial placement for stereotactic body radiation therapy both rely on precise navigation and localization (21,45). This precision may also have implications for therapeutic bronchoscopy. Bronchoscopic ablative techniques are currently being studied, accurate localization of lesions will be of paramount importance (46,47). The ceiling has yet to be reached this important and rapidly evolving clinical scenario of thoracic disease.

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