

Report: Medical & Business Potential of Bronchoscopy Robots



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Overview of Robotic Bronchoscopy

Bronchoscopy

Bronchoscopy is an endoscopic method of viewing a patient's airways in order to diagnose them. Doctors insert a bronchoscope, an instrument used for viewing the inside of a patient's airways and lungs, into the patient's airways through their nose, mouth, or a tracheostomy via an incision in the neck and trachea.¹ The purpose of a bronchoscopy is to look for abnormalities inside the lungs, with lung samples sometimes being collected during the procedure. Most bronchoscopies are typically done using metal tubes with lighting devices or with optical fiber equipment containing live video capabilities. In 1876, the first bronchoscopy procedure was performed using a rigid bronchoscope (shown in Figure 1) which was improved upon in the 1920's and commonly used until the flexible bronchoscope (shown in Figure 2) was invented in 1966.² Flexible bronchoscopy revolutionized the procedure, offering a more comfortable option for patients, an easier procedural method for doctors, and providing greater accuracy and precision.



Figure 1: Rigid bronchoscope ³



Figure 2: Flexible bronchoscope ⁴

Medical Robotics

As the field of robotics has rapidly advanced and expanded its applications, robot-assisted surgery has emerged as a way of utilizing the capabilities of robotic systems to perform surgical procedures. Benefits to medical robotics vs. open surgery include reduced pain and blood loss, enhanced incision accuracy, lower risk of infection, and better control and vision for doctors while operating. While robot-assisted surgical equipment is costly and requires surgical training to operate, the advantages provided by medical robotics for both doctors and patients alike are unparalleled. With robot-assisted surgery, surgeons can avoid fatigue by changing placements, hand tremors and other human errors are more easily identifiable by the robot, and the enhanced precision and accuracy for incisions leads to improved patient outcomes post-surgery.

¹ (Mount Sinai Health System, 2022)

² (Gerstein, 1907)

³ (Themes, 2016)

⁴ (El-Boghdadly, 2019)

Robotic Bronchoscopy

In 2018, the Monarch Platform by Auris Health became the first bronchoscopy robot to gain FDA approval and in 2019 the Ion Endoluminal System by Intuitive Surgical also gained FDA approval.⁵ The advancement of medical robotics in the form of robotic bronchoscopy has been viewed as a breakthrough for lung cancer screening. Bronchoscopy robots work by using a controller to move a flexible bronchoscope. This method allows doctors better access to different parts of the patient's air passages and produces a 3D map of the patient's lungs. Developing bronchoscopy robots was motivated in part by the need for improved methods to gather lung lesion samples and to detect lung cancer in earlier stages. Conventional bronchoscopy methods have been plagued by lower diagnostic yields due to the occurrence of navigational difficulties inside patient's airways and lack of direct visualization.⁶ The emergence of robotic bronchoscopy has offered better navigation and greater direct visualization of the airways, enabling doctors to overcome the limitations of guided bronchoscopy. Doctors typically use bronchoscopy robots on patients who need to find out if their lung mass or nodule is cancerous. As more companies invest time and resources into medical robotics, the medical and business potential of robotic bronchoscopy cannot be overlooked.



Figure 3: Bronchoscopy Robot from Intuitive Surgical⁷

Medical Potential of Robotic Bronchoscopy

Many lung cancer patients are not diagnosed until the cancer has already developed into the later stages. More efficient diagnostic methods are urgently important, in order to improve screening, diagnosing, and treating lung cancer patients. As previously mentioned, robot-assisted surgery has been proven to increase surgical accuracy, improve patient outcomes, and benefit both patients and doctors. Bronchoscopy robots are the future of preventative screening and lung cancer treatment. Robotic bronchoscopy is uniquely positioned to usher in a medical revolution for diagnosing and treating lung conditions.

⁵ (Agrawal, et al., 2020)

⁶ (Agrawal, et al., 2020)

⁷ (Intuitive Surgical, 2021)

Improved Access and Navigation

Robotic bronchoscopy affords doctors better views and angles of the patient's lungs and airways. Previously inaccessible and remote parts of the lungs are now directly visualized. The flexible bronchoscopes used in robotic bronchoscopy tend to be somewhat smaller and more flexible than existing bronchoscopes. The computer-assisted navigation provided by bronchoscopy robots creates 3D models of the patient's lungs, allowing doctors to view the inside of the air passages during the entirety of the procedure.⁸ For patients with a lung mass or nodule in a hard-to-reach place that needs to be diagnosed, robotic bronchoscopy offers improved access and navigation for doctors to locate, visualize, and diagnose the nodule.



Figure 4: 3D Visualization of the Branches of a Patient's Lung⁹

Collecting Lung Samples

Robotic bronchoscopy makes it easier for doctors to collect biopsy samples from patients. Doctors are able to safely and effectively sample peripheral lung lesions because the bronchoscopy robot can navigate through smaller passages in the airways while displaying a direct 3D visualization of the patient's lungs.¹⁰ This makes it easier for doctors to collect more accurate samples in target areas within the patient's lungs. Collecting lung samples is an integral component in screening for and diagnosing patients with various lung conditions, and robotic bronchoscopy makes it easier for doctors to collect necessary samples compared to standard bronchoscopy procedures.

Increased Surgical Accuracy

Doctors greatly benefit from the medical potential of bronchoscopy robots. Overall, human-machine systems often have greater precision and accuracy compared to humans. During procedures, doctors are prone to becoming tired and fatigued which can plague their performance. Robotic bronchoscopy solves this problem by allowing doctors to take shifts controlling the system, preventing doctors from continuing to operate suboptimally. Doctors can

⁸ (Fox Chase Cancer Center, 2020)

⁹ (Mayo Clinic, 2019)

¹⁰ (Mount Sinai Health System, 2022)

also be prone to hand tremors or other human errors during a bronchoscopy, while bronchoscopy robots are programmed to be steady and precise.

Better Patient Outcomes

Designed to be minimally invasive, robot-assisted surgery often requires no incisions or very small and precise incisions that heal quickly. Patients have a faster healing and recovery time from robotic bronchoscopy compared to standard bronchoscopy procedures, allowing them to have shorter hospital stays and a faster return to normal activities. Robotic bronchoscopy has also been shown to cause less risk of infection or blood loss in patients. The procedure is incredibly safe for patients, with very few cases of serious complications arising from robotic bronchoscopy.

Early Detection of Lung Conditions

Lung cancer is a leading cause of death for adults in the United States. Lung cancer can spread incredibly fast to various parts of the body, making preventative screening and early treatment of the utmost importance. Since so many lung conditions and lung cancer diagnoses go undetected, the benefits provided by robotic bronchoscopy have the medical potential to mark a shift in preventative screening. Bronchoscopy robots have ushered in a new era of efficiency for treating patients with lung conditions. For patients, the process of setting up screenings and multiple doctor's appointments can be inefficient, time-consuming, expensive, and lengthy. It can often take weeks or months for patients to even receive a diagnosis for their lung condition, before going through the process of surgical removal or starting alternative treatment methods. Since lung cancer can rapidly spread with few symptoms, valuable time is wasted with the widespread inefficiency of diagnosing and treating lung conditions. With robotic bronchoscopy, doctors are able to mark and precisely sample lung nodules then evaluate them on-site and make a diagnosis. If the lung nodule is found to be cancerous, doctors can remove the cancer during a second procedure on the same day. This saves patients tremendous time, effort, and anguish worrying about receiving a timely diagnosis and allows doctors to save time, resources and aid patients with efficient treatment and care. The medical potential of bronchoscopy robots to bolster preventative screening and lead to faster diagnosis and treatment is saving patient lives.

Leading Companies of Robotic Bronchoscopy

Monarch from Auris Health

As the first company to gain FDA approval for robotic bronchoscopy in 2018, Auris Health remains a leading company in this emerging market. After being acquired by Enticon in 2019, Auris Health has been under the Johnson&Johnson company umbrella. Prominent features of the Monarch system include an outer sheath, inner bronchoscope, four-way steering control, electromagnetic navigation guidance, and peripheral visualization.¹¹ The outer sheath is designed to provide support and stability to the system, while the inner bronchoscope is designed to

¹¹ (Johnson&Johnson MedTech, 2022)

navigate through smaller airway passages.¹² The Monarch system has a lightweight cart with attachments that can be replaced based on the speciality of the procedure, a flexible bronchoscope and a tower. Each component has wheels to be easily transportable between medical settings. In feasibility studies, researchers noted the Monarch system's enhanced ability to maneuver the end of the bronchoscope, greater precision to aim biopsy instruments, and several active articulation points.¹³ Prior to each procedure, a CT scan is done to aid the virtual 3D reconstruction in order to map potential pathways for the bronchoscopy robot. The Monarch system used electromagnetic navigation to navigate through pathways in the lungs.



Figure 5: Monarch System by Auris Health¹⁴

Ion from Intuitive Surgical

As the second company to gain FDA approval for robotic bronchoscopy, Intuitive Surgical is another key leader in the industry. Designed to tackle early lung cancer detection in patients, the Ion endoluminal system includes a bronchoscope that contains an ultra-thin scope and a vision probe. The ultra-thin scope enables the Ion system to reach remote and isolated locations and narrow airways within the peripheral lung. The vision probe contained inside of the bronchoscope is fed through the shape-sensing catheter. Rather than using electromagnetic navigation like the Monarch system, Ion uses shape-sensing catheter technology to locate lung masses and nodules. This allows doctors to control the bronchoscope by using a trackball controller to navigate through the patient's airways. Inside the catheter wall, the fiber optic shape sensor continuously measures the shape of the catheter to provide precise locational and navigational information. The integrated vision probe enables doctors to have live and direct visualization of the patient's lungs throughout the whole procedure. Once the intended lung

¹² (Lu, 2021)

¹³ (Agrawal, et al., 2020)

¹⁴ (Johnson&Johnson MedTech, 2022)

nodule is located, the Ion system is programmed with robotic control algorithms to keep the catheter in place.

Research studies show that the Ion system was able to achieve successful needle-in-nodule results from localization at a much higher rate than methods using electromagnetic navigation.¹⁵ Intuitive Surgical markets the Ion system as more precise and more flexible for more answers. The emphasis on precision can be seen from the fully articulating catheter, fiber optic shape sensor, and flexion needle that navigates around tight areas. The cloud biopsy approach of the Ion system allows doctors to input several biopsy attempts and provides visualization of alternative needle trajectories to collect the sample.



Figure 6: Ion Endoluminal System by Intuitive Surgical¹⁶

Galaxy System from Noah Medical

In March 2023, the Galaxy System by Noah Medical received clearance from the FDA. The Galaxy System offers unique medical potential because it is the only available system that integrates live tomosynthesis, a method for high-resolution limited-angle images, combined with a disposable bronchoscope.¹⁷ Features of the Galaxy System include live tomosynthesis, augmented fluoroscopy, an on-camera bronchoscope, direct visualization, and four-way bronchoscope articulation. The augmented fluoroscopy is intended to provide life navigation and lesion updates to doctors during the procedure.

Designed to improve efficiency and workflow in surgical settings and reduce the risk of cross-contamination during procedures, the disposable bronchoscope distinctly sets the Galaxy

¹⁵ (Lu, 2021)

¹⁶ (Intuitive Surgical, 2021)

¹⁷ (Azzano, 2023)

System apart from current market competitors. The Galaxy System features a transportable cart with an attached easy-to-use integrated interface to view the direct visualization of the lungs. Developed with the intention of meeting the user needs of bronchoscopists, the Galaxy System specifically focuses on peripheral lung navigation using integrated imaging. The proprietary technology developed by Noah Medical further highlights the unique offerings of the Galaxy System. Although the company has financial backing from prominent investors, the Galaxy System is the first commercial robotic system produced by Noah Medical and is competing with companies that have more extensive funding, resources, and experience in the medical technology space



Figure 7: Galaxy System by Noah Medical ¹⁸

Conclusion

In conclusion, the medical and business potential of robotic bronchoscopy is immense with great opportunity for advancement and expansion. Leading companies in the field of robotic bronchoscopy include Auris Health, Intuitive Surgical, and Noah Medical. While each of these robotic bronchoscopy systems are similar in nature, key differences exist in the product features, navigational technology, and procedural methods that distinguish each company. The business potential for robotic bronchoscopy is enormous, given the prevalence of lung cancer patients in the United States and the need for more preventative screening and earlier diagnoses. The development of this industry is relatively recent, with the first bronchoscopy robot receiving FDA approval around five years ago. Improved patient outcomes and greater precision and accuracy from current bronchoscopy robots has led to greater interest in entering this market, such as Noah Medical. Possible applications of robotic bronchoscopy include applying similar methods and technologies to the preventative screening and diagnosis of other conditions beyond lung cancer.

¹⁸ (Azzano, 2023)

References

- Agrawal, Abhinav, et al. "Robotic Bronchoscopy for Pulmonary Lesions: A Review of Existing Technologies and Clinical Data." *Journal of Thoracic Disease*, vol. 12, no. 6, June 2020, pp. 3279–86. <https://doi.org/10.21037/jtd.2020.03.35> Accessed 23 February, 2024.
- American Lung Association. *Robotic-Assisted Bronchoscopy*, 10 January 2022, www.lung.org/lung-health-diseases/lung-procedures-and-tests/rab Accessed 24 February, 2024.
- Azzano, Michael. "The Galaxy System™ by Noah Medical Receives FDA Clearance for Robotic Navigated Bronchoscopy." *Noah Medical*, 15 May 2023, www.noahmed.com/press-releases/the-galaxy-system-receives-fda-clearance-for-robotic-navigated-bronchoscopy Accessed 23 February, 2024.
- "Bronchoscopy." *Mount Sinai Health System*, 10 January 2022, www.mountsinai.org/health-library/tests/bronchoscopy#:~:text=A%20bronchoscope%20is%20a%20device%20used%20to%20see%20the%20inside,a%20rigid%20bronchoscope%20is%20used Accessed 24 February, 2024.
- El-Boghdadly, Kariem. "Flexible Bronchoscope." *ResearchGate*, August 2019, www.researchgate.net/figure/Flexible-bronchoscope_fig2_335358142 Accessed 23 February, 2024.
- Lu, Michael T., et al. "A Review of Robotic-Assisted Bronchoscopy Platforms in the Sampling of Peripheral Pulmonary Lesions." *Journal of Clinical Medicine*, vol. 10, no. 23, December 2021, p. 5678. <https://doi.org/10.3390/jcm10235678> Accessed 23 February, 2024.
- Mayo Clinic. "Robotic Bronchoscopy - Mayo Clinic." *YouTube*, 28 October 2019, www.youtube.com/watch?v=cEyZ9Txi8Zg Accessed 23 February, 2024.
- "Reshaping What's Next in Support of Early Lung Cancer Detection." *Intuitive*, 2021, www.intuitive.com/en-us/products-and-services/ion/reshaping-whats-next?gclid=EAIaIQobChMI0car3omU9gIV4o5bCh0PLAw4EAAYBCAAEgLVWvD_BwE. Accessed 23 February, 2024.
- "Robotic Bronchoscopy | Fox Chase Cancer Center - Philadelphia PA." *Fox Chase Cancer Center*, 25 November 2020, www.foxchase.org/clinical-care/conditions/lung-cancer/diagnosis/robotic-bronchoscopy Accessed 24 February, 2024.
- Themes, Ufo. "Rigid Bronchoscopy." *Radiology Key*, 25 March 2016, radiologykey.com/rigid-bronchoscopy Accessed 24 February, 2020.

“Tracheo-bronchoscopy, Esophagoscopy, and Gastroscopy : Jackson, Chevalier, 1865- : Free Download, Borrow, and Streaming : Internet Archive.” *Internet Archive*, 1907, archive.org/details/tracheobronchosc00jackuoft/page/n1/mode/2up Accessed 24 February, 2024.

“Uncovering Treatment Pathways With MONARCH Platform Robotic-assisted Procedures.” *Johnson&Johnson MedTech*, 2022, www.jnjmedtech.com/en-US/product-family/monarch. Accessed 24 February, 2024.

Appendix

Figure 1: Rigid bronchoscope



Figure 2: Flexible bronchoscope



Figure 3: Bronchoscopy Robot from Intuitive Surgical



Figure 4: 3D Visualization of the Branches of a Patient's Lung from the Mayo Clinic



Figure 5: Monarch System by Auris Health



Figure 6: Ion Endoluminal System by Intuitive Surgical



Figure 7: Galaxy System by Noah Medical

