

# A Bronchial Puncture Mechanism for Transoral Access to the Lung Parenchyma<sup>1</sup>

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## 1 Background

More people die from lung cancer each year than any other form of cancer. Over 150,000 lives are lost to the disease each year in the U.S. alone [1]. Early detection is critical in reducing the mortality rate, and despite advances in imaging, biopsy remains the only definitive diagnostic tool. The most common lung biopsy approaches are percutaneous and transoral. Percutaneous biopsy punctures the pleura (the membrane surrounding the lung) in order to reach the suspicious nodule and risks pneumothorax (lung collapse), which is a serious complication and can be deadly for patients with poor baseline lung function. Transoral lung biopsy is preferable due to the fact that the biopsy device never traverses the pleura.

However, current bronchoscopes cannot access the majority of the peripheral lung, due to their large diameter in relation to bronchi diameter. While smaller diameter endoscopes and endoscopy-like devices are under development, there will always remain locations where a path that exits the bronchi and travels through the parenchyma is desirable, either because it is shorter or because the nodule lies away from a usable bronchial access path. To facilitate the biopsy tool exiting the bronchi to reach such targets, we have developed the puncture mechanism described in this paper.

In addition to biopsy with a straight-line biopsy needle, our device may enable the use of steerable needles in the lung parenchyma. Recent advances in robotics such as concentric tube robots (CTRs) [2] and bevel-tip steerable needles [3] (among other new needle steering technologies) may be useful in reaching targets through controllable curved paths. But these technologies require the means of exiting the bronchi that we provide in this paper.

Inspired by the prior work showing that fast needle insertion can controllably transit tissue with minimal deformation [4–6], in this paper we develop a bronchoscope-deployed system that can drive the needle tip through the bronchial wall and surrounding

cartilage and connective tissue, providing a port for subsequent deployment of biopsy needles and/or steerable needles into the lung parenchyma.

## 2 Methods

Our concept is to deploy a stylet and CTR (both made from superelastic nitinol) through the tool port typically available in bronchoscopes (see Fig. 1). The CTR is curved, such that when it is deployed from the tip of the bronchoscope, it will naturally deflect toward the bronchial wall in a direction defined by the physician (set based on its axial rotation). The stylet is elastic, yet straight, and has a sharp tip.

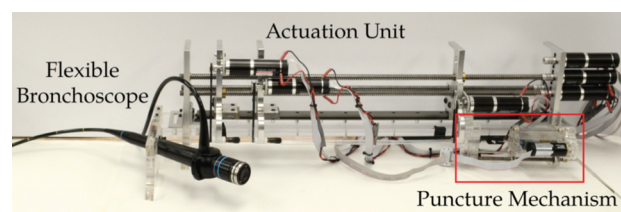
Based on this overall concept, our design challenge in creating a puncture mechanism was to construct a device capable of delivering adequate axial actuation to the back of the stylet, such that when it is placed against the bronchial wall by the CTR, it is capable of controllably puncturing the bronchial wall. The stylet can then be withdrawn through the CTR and removed, allowing the steerable needle to be deployed through the CTR into the lung parenchyma.

To make our device adjustable to a variety of surgeon-desired puncture dynamics and depths, we used a spring-based concept in which stylet dynamics can be adjusted by exchanging a replaceable spring and enabled user-specified puncture depth. We also sought a design that was compatible with a range of needle diameters, enabling the surgeon to create entry ports of different sizes in the bronchial wall, allowing a diverse set of steerable needles and other instruments to enter the parenchyma. Finally, it was determined that the device should be compact, lightweight, and detachable from the system after puncturing.

The mechanism's basic function is to compress a spring and then release it to propel the stylet rapidly forward, causing its tip to puncture the bronchial wall. The spring compression and shaft travel (setting puncture depth) are controlled with a motor. The mechanism is fired mechanically by pressing the trigger lever. The mechanism (shown in Fig. 2) uses a DC motor (1) to rotate a lead screw (2) via a gear train. This generates linear motion of the lead screw slide (3) that uses a captured nut to translate along a steel shaft (4).

The lead screw slide compresses the spring (5). The steel shaft and shaft collar (6) hold the spring as it is compressed by the lead screw slide, until the collar catches on the trigger lever (7). With the spring compressed and the collar secured, the lead screw slide position can be adjusted to control the puncture depth, as (3) constrains the travel of (6). A needle holder (8) is attached onto the steel shaft and the stylet (9) is secured into the holder. Once the stylet is secured and a puncture depth is selected, the trigger can be operated manually with the lever (10), located to the right of the pivot.

To allow for large linear adjustments with respect to the CTR actuation unit, the prototype was mounted onto a guide rail affixed to the actuation unit. A knob enables the surgeon to adjust the position of the puncture mechanism relative to the CTR actuation unit. The prototype weighs 225 g and is 130 × 65 × 70 mm. Screws are used to mount the puncture mechanism to the actuation unit.

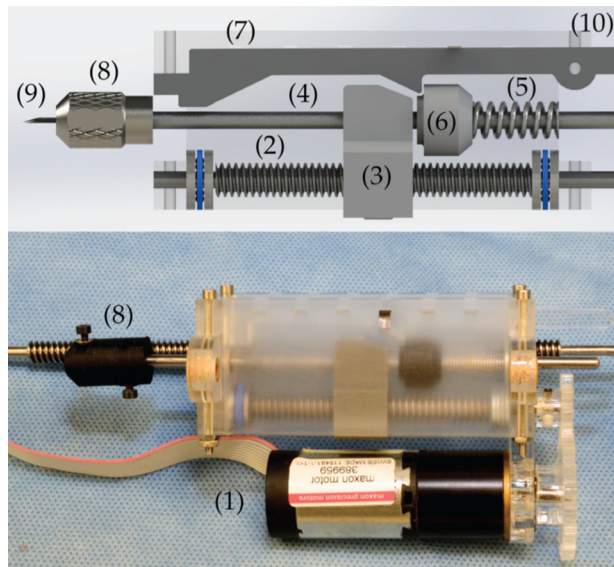


**Fig. 1 Puncture mechanism mounted on a concentric tube steerable needle [2] actuation unit, with both steerable needle and puncture stylet fed into a bronchoscope tool port**

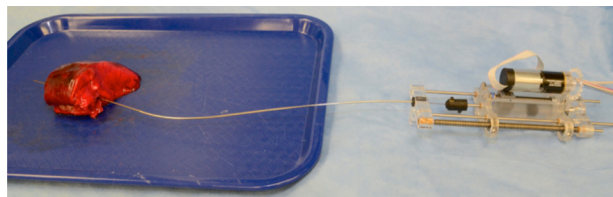
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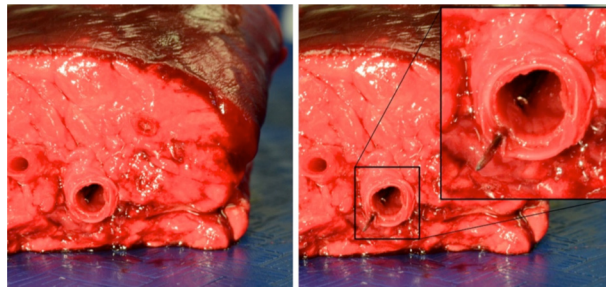
**Fig. 2** Side-view rendering of mechanism (top) and side-view of actual mechanism (bottom)



**Fig. 3** The experimental setup used to test the puncture mechanism. The stylet was passed through two curved concentric tubes and inserted into a porcine bronchial tube and the tip of the needle was placed against the bronchial wall before firing the puncture mechanism.

### 3 Results

The goal of this design and prototyping effort was to create a device that could successfully deploy the flexible stylet through the hollow lumen of the CTR and penetrate the bronchial wall. In order to test the design, we performed experiments with porcine lung samples. During testing, we inserted the stylet through a series of concentric precurved nitinol tubes to emulate the clinical scenario of deploying the stylet through the bronchoscope and through a long CTR (see Fig. 3). We then passed the nitinol tubes and stylet into a porcine bronchial tube and aligned the concentric nitinol tubes as they would be positioned during a biopsy. The stylet used in these puncture experiments had a diameter of 0.78 mm and a sharp tip. The angle of approach between the stylet and the bronchial wall was approximately 10 deg–20 deg. We triggered the puncture mechanism, forcing the stylet into the bronchial wall, and observed whether it successfully punctured the tissue. We repeated this test five times with different thicknesses of bronchi (between 1.15 and 2.5 mm wall thickness) and the stylet punctured



**Fig. 4** In the experimental validation, a series of curved concentric tubes are inserted into the bronchial tube (left), the mechanism is triggered, and the bronchial wall is punctured (right)

through the wall successfully each time, confirming that our mechanism is capable of puncturing through the bronchial wall from inside the bronchi, as intended. The result of one of our experimental trials is shown in Fig. 4.

### 4 Conclusion

We have presented a design for a bronchial puncture mechanism that can provide access to the lung parenchyma through a transoral approach with a bronchoscope and CTR. In initial tests in porcine lung samples, the device has proven effective at puncturing bronchial walls of varying thicknesses through a CTR inside the bronchi. Our design is compatible with a range of spring stiffnesses, puncture depths, and stylet diameters, so that these parameters may be adjusted in the future if necessary.

Given our successful experimental results in porcine specimens, future experiments will be performed on cadaveric human lungs. We intend to explore a range of parameters in these experiments including the effect of varying spring stiffness and puncture velocity on the deflection of the bronchial wall, and on the amount of damage sustained by neighboring lung tissue. The puncture mechanism shown in this work will enable physicians to safely traverse the bronchial wall into the parenchyma. We hope to thereby enable biopsy of many sites that today cannot be reached without risking pneumothorax.

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