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Tool for Transbronchial Biopsies of Peripheral Lung Nodules

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ABSTRACT

Lung cancer is the leading cause of cancer deaths worldwide. In order to determine if lung nodules are cancerous, a biopsy needs to be taken. There is a need to be able to perform more of these biopsies through a transbronchial approach in order to reduce the risk of pneumothorax that is associated with transthoracic biopsies. This is particularly the case at the periphery of the lung where the bronchioles become too small for a traditional bronchoscope. The proposed biopsy tool incorporates a compact coaxial camera and illumination configuration to make it more compact than a traditional bronchoscope. It also includes a new flexible needle design that allows a biopsy to be taken adjacent to a radial ultrasound transducer. The navigation and tissue biopsy capabilities of the proposed device are demonstrated through benchtop and animal testing.

Keywords: Lung cancer, biopsy needle, bronchoscopy, ultrasound, EBUS, flexible needle.

BACKGROUND

Lung cancer is the leading cause of cancer deaths worldwide [1] and is commonly diagnosed through a biopsy of lung nodules that have been identified by a computed tomography (CT) scan of the chest [2]. If the nodules are centrally located in the lung, they can be easily biopsied using a bronchoscope. The challenge comes in biopsying nodules located at the periphery of the lung where a standard bronchoscope is too large to reach the smaller bronchioles. To biopsy these peripheral nodules, a transthoracic needle biopsy can be performed under CT guidance. The drawbacks of transthoracic needle biopsies are a significant risk of pneumothorax [3] and radiation exposure to the patient. Therefore, it is desirable to perform these biopsies through a transbronchial approach, if possible. Electromagnetic navigation bronchoscopy (ENB) systems provide a means to navigate to the periphery on the lung by using an electromagnetic position sensor to superimpose the position of the probe onto a CT scan of the lung. The drawbacks to existing ENB systems are the significant cost of these systems, both in capital equipment and disposables, the additional radiation exposure to the patient to obtain the required ENB protocol CT image used for the navigation [4], and the lack of video and ultrasound feedback for these systems. Another navigation approach is to correlate the optical feedback from a bronchoscope to a CT scan for localization. One such system is the LungPoint system [5]. Like the ENB systems, the LungPoint system suffers from the lack of ultrasound imaging to verify that the bronchoscope is adjacent to the tumor. There is a need for a biopsy tool that can navigate to the periphery of the lung and also provide ultrasound imaging to verify the location of the lung nodule relative to the tool.

The proposed biopsy tool (see Figures 1 and 2) incorporates radial endobronchial ultrasound (EBUS) capability, video feedback, and steerability into a device that is small enough to navigate to the periphery of the lung without the need for the expense of an ENB system. Additionally, it allows the biopsy needle to be deployed without removing the tool so that the biopsy can be performed in real-time while the nodule can be seen in the ultrasound image. This ability to take a biopsy without removing the EBUS probe is a critical feature of the device since it allows the physician using the device to ensure that the biopsy needle is entering the nodule. Currently, physicians need to remove the EBUS probe before inserting the biopsy needle, which makes it difficult to know if the needle is reaching the nodule.

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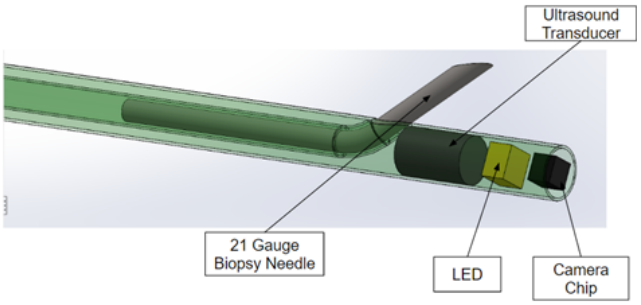

Figure 1: Proposed lung biopsy tool device with integrated camera, ultrasound transducer, and flexible needle.

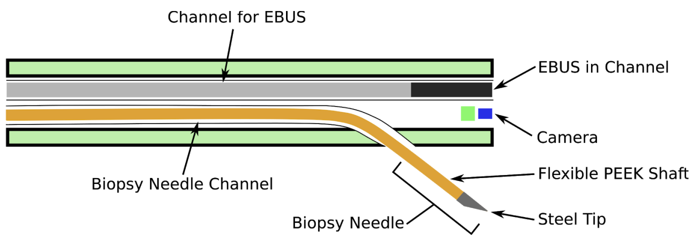

Figure 2: Cross section of proposed lung biopsy tool device with integrated camera, EBUS channel, and flexible needle.

It is desirable to make the device disposable in order to eliminate the need to sterilize the device between procedures, which is challenging due to the small diameter channel for the biopsy needle. In order to do this, the device is designed to work with existing radial EBUS probes through a channel in the device (see Figure 2). This allows the cost of the device to be kept low and allows facilities to make use of the radial EBUS probes that they likely already have.

In order to reduce the diameter of the proposed device, the camera and LED illumination are located in a coaxial arrangement (see Figure 1). The camera and illumination are located side-by-side in a typical bronchoscope. Also, in order to take the biopsy adjacent to the radial EBUS probe, it is necessary to have the needle bend as it exits the biopsy tool. In order to achieve the required flexibility of the needle, a new biopsy needle concept was prototyped that has a polymer shaft and a steel tip. This needle design will have improved flexibility over existing Nitinol needles [6].

The goals of this study were to demonstrate the navigation capability of the proposed biopsy tool using the coaxial camera-LED arrangement and to demonstrate the biopsy capabilities of the flexible biopsy needle. Both of these characteristics are new with this device. The testing consists of both benchtop and animal testing. A swine model was used for the animal testing since this is the same animal model that was used to test the original ENB systems [7].

METHODS

In order to keep the cost of the device low, a flexible silicone tube (4.65mm OD and 3.35 mm ID) was used to form the main body of the device and the angulation portion was formed by notching the tube (see Figure 3). Polyolefin heat shrink tubing was used to increase the rigidity of the tubing in order to facilitate better control of the tool as it is inserted into the airway. Angulation is achieved by the use of two Nitinol wires attached to a pulley-lever system incorporated into the handle. For simplicity, the two angulation wires are shown connected together in Figure 3 at the distal end of the device. This pulley-lever system provides a control method that lengthens and shortens the angulation wires. This method is similar to a traditional bronchoscope. The geometry of the notches for the threading of the Nitinol angulation wires is shown in Figure 3. The two center notches have a lens shape to facilitate bending of the tube by removing material in the direction of bending. The end holes are small holes that have a diameter that is just larger than the Nitinol wire. Making the end holes smaller helps to constrain the direction of bending and prevents the tubing from twisting when it is being angulated.

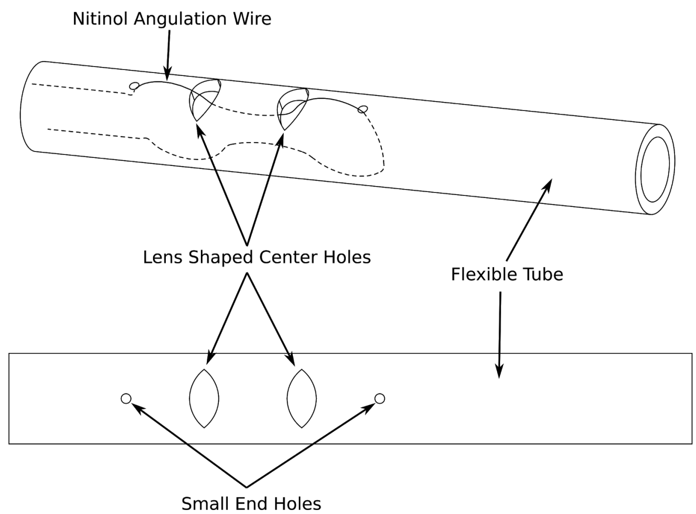

Figure 3: Notch geometry for angulation portion of biopsy tool.

In order to prevent kinking, and to facilitate the tube returning to the straight position after being angulated, a coil spring was inserted into the interior of the angulation section (see Figure 4). In addition, the Nitinol wires are terminated at the distal end of the coil spring. Terminating the Nitinol wire on the spring rather than the tube eliminates the problem of the Nitinol wire pulling through the tubing.

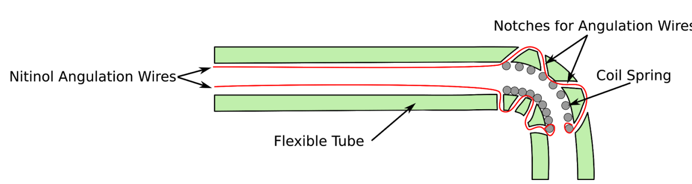

Figure 4: Angulation portion of biopsy tool with notched flexible tube, Nitinol angulation wires and coil spring.

One of the challenges that needed to be solved for the design was to develop a flexible needle that can be deployed adjacent to the EBUS transducer so that the area adjacent to the EBUS field of view can be biopsied. In order to achieve this goal, the shaft of the prototype needle is made from high strength polyether ether ketone (PEEK) tubing and the tip is constructed from stainless steel (see Figure 2). The stainless steel is required in order to make the needle sharp enough to penetrate tissue. The stainless steel tip was affixed to the polymer shaft by epoxy bonding.

The imaging system was implemented using the AWAIBA NanEye 1 x 1 mm CMOS camera and the Samsung LM101A 1.18 x 1.18 mm LED chip. The NanEye camera is designed to be low cost at volume and will enable the prototype tool to be disposable. Due to the small size of the biopsy tool, the camera and LED were arranged in a novel coaxial configuration (see Figure 1). The LED was powered by a pair of size AA 1.5V batteries and a simple potentiometer circuit in the handle was used to adjust the brightness of the LED light.

RESULTS

After several design iterations, benchtop testing and an animal study were performed with the final working prototype. The final outer diameter of the device was 5.16 mm. Although this is smaller than conventional bronchoscopes (the Ambu aScope disposable bronchoscope has an OD of 6.25mm), the test prototype was larger in diameter than the originally proposed design. Thinner walled custom sized tubing will allow the biopsy tool to have an OD closer to 2 mm in order to allow it to be navigated all the way to the periphery of the lungs.

Figure 5: Top left and top right: working mechanical prototype. Bottom left and bottom right: open prototype handle.

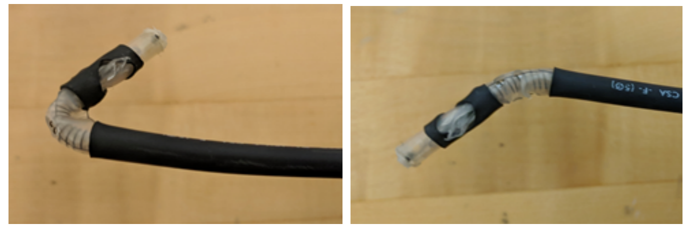

Figure 6: Tip of prototype biopsy tool in angulated positions.

Figures 5 and 6 show various views of the working mechanical prototype. The handle portion was 3D printed from ABS plastic and included the pulley and lever system to angulate the tool. The handle also housed the battery and circuitry for the LED illumination.

Benchtop testing was performed on a 2D model of a section of the lungs to test the navigation capability of the device and the ability to deploy the flexible needle and to perform a biopsy. A gelatin phantom tissue model was used during benchtop testing to mimic tumor tissue and to test the ability of the flexible needle to collect a tissue sample (See Figure 7). To obtain a tissue sample, a syringe was used to create a suction on the biopsy needle similar to what is currently done to obtain tissue biopsies.

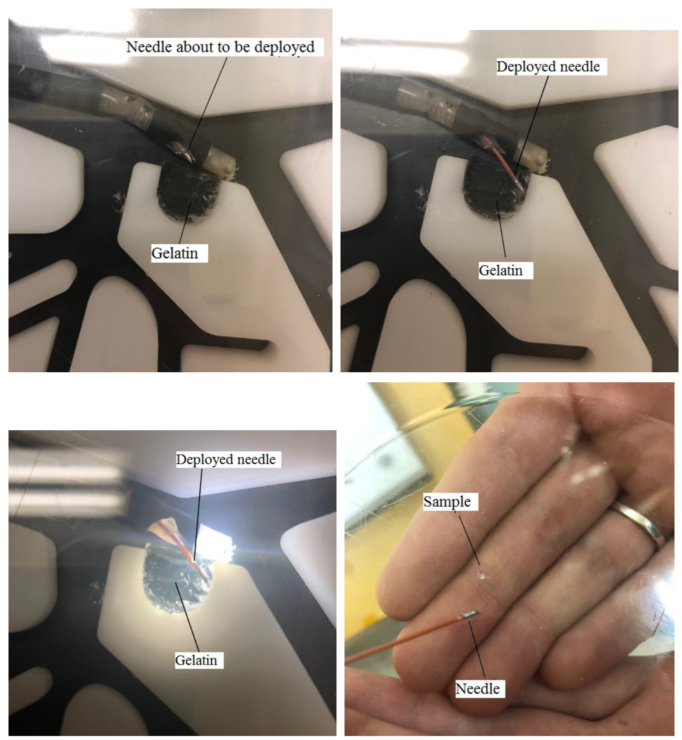

Figure 7: Benchtop testing. Top left: tip of the scope before needle deployment. Top right: needle deployed. Bottom left: needle deployed with lighting. Bottom right: recovered sample (Gelatin) in petri dish.

A swine model was used for the animal testing. One question we sought to answer was whether sufficient illumination could be achieved with the novel coaxial configuration of the camera and LED proposed in the tool design. Figure 8 shows a view from the camera in the biopsy tool prototype during the animal study. The study confirmed that sufficient illumination can be achieved with the coaxial configuration of of the camera and the LED. The tool could also be successfully navigated to various portions of the lungs, including the upper lobes, which requires a sharp turn of the tool. Fluoroscopy imaging was used to verify the deployment of the biopsy needle as shown in Figure 9.

A second goal of the animal study was to show that the flexible needle could be successfully deployed to obtain a tissue samples. It was possible to deploy the flexible needle with the lung biopsy tool in position (see the left half of Figure 9). However, a tissue sample was not obtained. It was determined that this was due to the way the needle was sharpened, which did not lead to coring of the tissue. An improved needle sharpening procedure was used to obtain the tissue sample in the benchtop testing results shown in Figure 7. The results highlight the importance of needle tip geometry in obtaining a tissue sample.

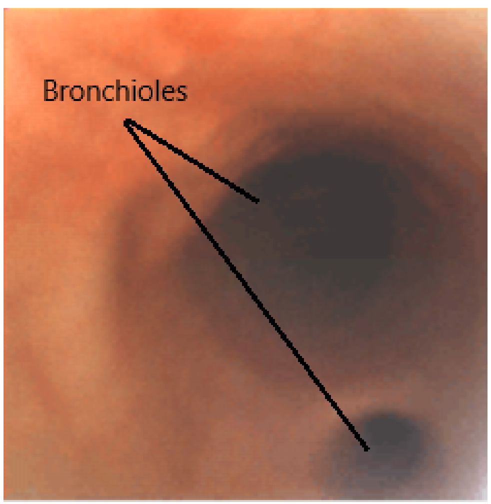

Figure 8: Video image from lung biopsy tool during animal study showing sufficient illumination from coaxial arrangement of camera and LED.

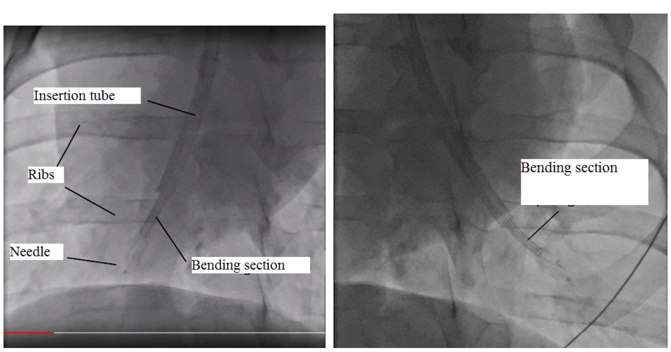

Figure 9: Video images of the fluoroscopy taken during the animal study. The needle is shown deployed on the left image.

DISCUSSION

This study demonstrates the navigation capability of the proposed biopsy tool using the novel coaxial camera-LED arrangement. This arrangement allows the tool to be smaller than current bronchoscopes thus permitting the biopsy of nodules located more distally in the lungs. The study also demonstrates the biopsy capabilities of the flexible biopsy needle during benchtop testing. Both of these characteristics are new with this device.

The tool can be made even smaller if the camera module and EBUS model are made interchangeable as shown in Figure 10. The tool would first be navigated visually to the correct portion of the lung with the camera module in place (Figure 10b). The camera module would then be removed and the EBUS model would be inserted (Figure 10a). This would allow the tool to be smaller since space would not be required to have the EBUS channel adjacent to the permanent camera module as required in the design shown in Figure 1.

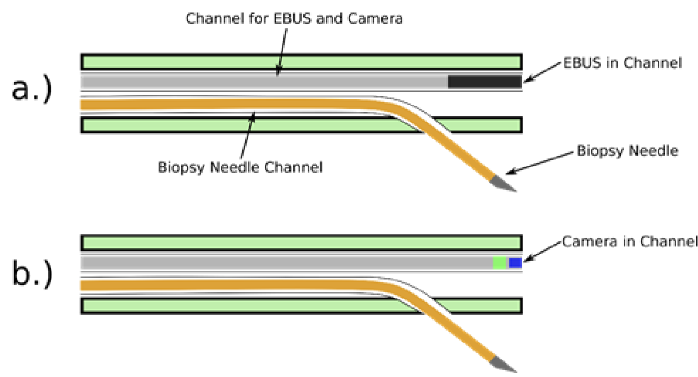

Figure 10: Biopsy tool with interchangeable EBUS model and Camera module

In conclusion, this proposed solution provides a real-time biopsy and tumor visualization platform, which is not possible with existing biopsy systems. The ability to visualize the tumor while performing the biopsy will have the potential to dramatically increase diagnostic yield, reducing procedure time and reducing the need for transthoracic needle biopsies. The next step for this project is to demonstrate tissue biopsy capabilities of this device with the radial EBUS probe incorporated.

ACKNOWLEDGMENTS

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