INTRODUCTION

Lung cancer is the deadliest form of cancer, killing more than 150,000 people each year in the United States alone [1]. It causes more deaths than breast, prostate, colon, and liver cancers combined [1]. To increase the survival rate of lung cancer, diagnosing the cancer early, while the tumor is still a small nodule, is key. Although suspicious nodules can be detected using medical imaging, definitive diagnosis typically requires biopsy. Unfortunately, the lung biopsy approaches currently in use have significant drawbacks, wherein they either cannot reach large portions of the lung, or carry significant safety risks. To bring safe and accurate biopsy to a larger class of patients, our research team recently developed a robotic transoral lung access system [2]. In this paper, we evaluate the system in inflated ex vivo porcine lung and visualize the results in a CT scanner (Fig. 1). We demonstrate the robot’s ability to reach nodules in the lung which are difficult for current approaches to reach safely. Currently, lung tumor biopsy is most commonly performed transtracheally, wherein a needle is hand-guided by a physician through the chest wall of the patient into the lung to the nodule. Unfortunately, this process has a diagnostic yield of less than 52% for nodules less than 1.5 cm in diameter [3]. In addition, transthoracic biopsy carries with it significant risk of pneumothorax (collapsed lung), a serious complication. An alternative approach that greatly reduces the risk of pneumothorax is transoral lung biopsy in which biopsy is performed via a bronchoscope. However, this approach is currently limited to nodules close to the bronchial tree or accessible through short straight paths from the airway [4].

Our transoral lung access system leverages the minimally invasive nature and lowered risks of the transoral biopsy approach, while having the potential to reach difficult-to-access lung nodules in the periphery of the lung with high accuracy [2]. The system consists of three stages deployed in sequence: a bronchoscope, a concentric tube channel, and a flexure-tip steerable needle (see Figs. 1 and 2). First, the physician guides the bronchoscope to a feasible location en route to the nodule. From the working channel of the bronchoscope, the concentric tube channel is deployed, bending toward the wall of the bronchial tree. Using a pneumatic puncture mechanism, the tube then pierces through and enters the parenchyma, orienting its tip toward the lung nodule. The flexure-tip steerable needle then deploys from the tip of the concentric tube and steers through the lung parenchyma, curving around sensitive structures such as large vasculature to reach the nodule. The needle’s controller uses an NDI Aurora 6-DOF magnetic tracking probe which is embedded in the tip of the flexure-tip steerable needle. The robot has previously been evaluated only in simulation [5] and in phantom gel [2].

In this paper, we report the first results for the deployment of the robotic lung access system inside an inflated ex vivo porcine lung in a CT scanner. We segmented the lung in the CT scan, including bronchial tubes and blood vessels. We steered the needle to avoid obstacles in the parenchyma (i.e., blood vessels and bronchial tubes) and achieved clinically-desirable accuracy in accessing targets near the lung periphery.

MATERIALS AND METHODS

We inflated the ex vivo porcine lung using a pressure regulator attached to an endotracheal (ET) tube inserted into the trachea. We connected a T-connector to the ET
tube, capped with a thin membrane to maintain lung inflation, through which we inserted the robot.

We estimated the needle’s maximum curvature by inserting the needle without rotation into inflated lung tissue, recording the tip’s path using magnetic tracking, and fitting a circle to the path. This curvature value was used in all future experiments.

To conduct the system experiments, we transported the system to the CT scanner, inflated the lung, and acquired a CT scan. We segmented the bronchial tubes and significant vessels in the CT scan using 3D Slicer.

The focus of our experiments was to evaluate the ability of the steerable needle to steer through lung parenchyma and accurately reach targets in the peripheral lung. We evaluated the steerable needle for 6 deployments. For each deployment, we started with the bronchoscope outside the lung and manually guided the bronchoscope into the airway. The concentric tube was then deployed from the bronchoscope’s tip to the bronchial tube wall where it pneumatically punctured into the lung parenchyma. Constrained to the reachable workspace of the needle, we chose a point on the surface of the lung as the target by projecting a straight line from the concentric tube and selecting a random offset. Although clinical peripheral targets would be just below the surface, we selected targets on the surface for ease of measurement. We then planned a needle path [5] that avoids the obstacles (i.e., the segmented blood vessels and bronchial tubes) and deployed the steerable needle using closed-loop control [6] to guide the tip of the needle along the planned path. We conducted 3 deployments with obstacle avoidance, and 3 deployments without obstacle avoidance in which we skipped motion planning and applied the automatic controller directly to the target.

RESULTS

We show CT scan slices in Fig. 3 for a deployment of the system. Table 1 shows the accuracy results for the 6 deployments (3 with obstacle avoidance and 3 without). The system used the experimentally determined maximum curvature of 0.498 m\(^{-1}\). The average tip error was 1.97 mm with obstacle avoidance and 1.07 mm without, with average needle insertion length 64.8 mm.

<table>
<thead>
<tr>
<th>Tip error (mm)</th>
<th>Run 1</th>
<th>Run 2</th>
<th>Run 3</th>
<th>Avg</th>
</tr>
</thead>
<tbody>
<tr>
<td>With obstacle avoidance</td>
<td>0.83</td>
<td>3.27</td>
<td>1.82</td>
<td>1.97</td>
</tr>
<tr>
<td>Without obstacle avoidance</td>
<td>0.19</td>
<td>2.47</td>
<td>0.55</td>
<td>1.07</td>
</tr>
</tbody>
</table>

Table 1. Tip error as measured by the magnetic tracker.

DISCUSSION

Our experimental results show that the device is on track to achieve accurate biopsy of clinically-relevant small suspicious nodules, which are defined by the American College of Radiology as being as small as 6 mm in diameter. The results also illustrate the trade-off of obstacle avoidance; the obstacles place constraints on the motion planner and controller that restrict the needle’s feasible workspace resulting in slightly larger tip error, but avoiding significant blood vessels is important to reduce the risk of internal bleeding.

The early diagnosis of suspicious lung nodules is integral to combatting lung cancer. To bring definitive diagnosis to a larger percentage of the population earlier in the course of the disease, a new class of medical devices will be required. Our transoral lung access system has the potential to be such a device. While integration into clinical workflows must still be investigated, in this work we showed the ability of the bronchoscope-deployed steerable needle to reach targets with high accuracy in inflated ex vivo porcine lungs.

ACKNOWLEDGEMENTS

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REFERENCES