Novel Instrument Design for Electromagnetic Navigation Bronchoscopy*

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1 Purpose

The aim of this work is to enable a paradigm shift in the diagnosis and treatment of lung cancer through the development of a novel range of new steerable instruments which can demonstrate the dexterity and steerability of laparoscopic devices at the endoscopic scale (2-4 mm). Existing minimally invasive diagnosis modalities are overly reliant on radiation exposure and subsequent interventional imaging such as endobronchial ultrasound are difficult to deploy in the narrow outer airways where lung cancer is most likely to first occur. Novel approaches to interventional sensor placement enable accurate real-time tracking of instruments with full range of articulated tip motion, even to targets in the outer airways. This work features the first preclinical validation of a novel steerable endobronchial catheter for the biopsy of lung cancer in the outer airways.

2 Methods

An electromagnetic navigation bronchoscopy (ENB) system was developed by combining a novel steerable catheter design with existing open-source tracking hardware and visualisation software.

Bronchial catheter A novel steerable catheter design was developed by DEAM B.V. The design consists of a flexible 2.2 mm open lumen sheath through which an omnidirectional steerable 1.5 mm guide-wire is placed. The working length of the guidewire exceeds the length of the sheath such that the tip can steer both within and beyond the sheath's distal end. A 5 degree-of-freedom tracking sensor

* Supported by Science Foundation Ireland technical innovation and development award number 17/TIDA/4897, and by Eureka-Eurostars project number 11581; 'Mariana: Image-guided catheter navigation in the outer airways'.

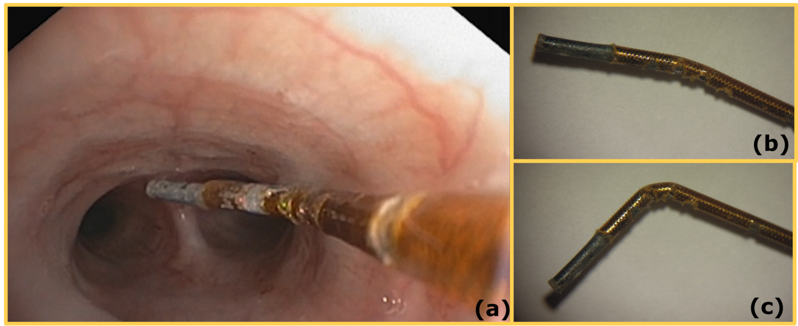

Fig. 1. (a) The tip of the omnidirectional steerable catheter in the trachea. (b) Catheter tip in neutral position and (c) deflected at 90° with respect to the shaft. The distal portion of the tip contains a 6 degree-of-freedom magnetic sensor.

is located distally on the sheath. A 6 degree-of-freedom sensor is located at the tip of the guidewire. The catheter design is compatible with standard 2.8 mm working channel bronchoscopes. A photograph of the steerable tip is shown in Fig. 1.

Electromagnetic tracking An open source electromagnetic tracking platform developed by University College Cork [3] was used to determine the position and orientation of the tracking sensors embedded within the catheter with respect to the tracking system field generator.

Visualisation CustusX is an open-source medical visualisation software tool for image guided surgery and was used in conjunction with the catheter and tracking system to provide a clinical interface for airway navigation [1]. The software's facilities for automatic airway segmentation [4] and registration [2] were used extensively in this study. A screenshot of the interface is shown in Figure 2.

Experimental procedure Preclinical validation of the catheter design was performed on a 34 kg porcine model. 8 radiopaque tumour markers were injected percutaneously under C-arm guidance (*Siemens Cios Alpha*) using an 11 Ga needle (*Cook Medical, Bloomington, IN, USA*). A total of four tumours were placed: left caudal (T4), right cranial (T1), right middle (T2) and right caudal (T3). All injected tumour models lay outside the main airway. A thoracic CT was performed thereafter to identify the final locations of the tumours within the airway. Automatic airway segmentation, centerline extraction and virtual tumour markup were then performed with CustusX.
Rigid patient-to-image registration was performed to align the coordinate systems of the electromagnetic tracking system with the CT image. An initial landmark registration was performed using 7 radiopaque fiducial markers on the chest of the pig. A final rigid point-cloud registration was completed with a survey of the trachea, left and right airways using the tracked catheter and bronchoscope.

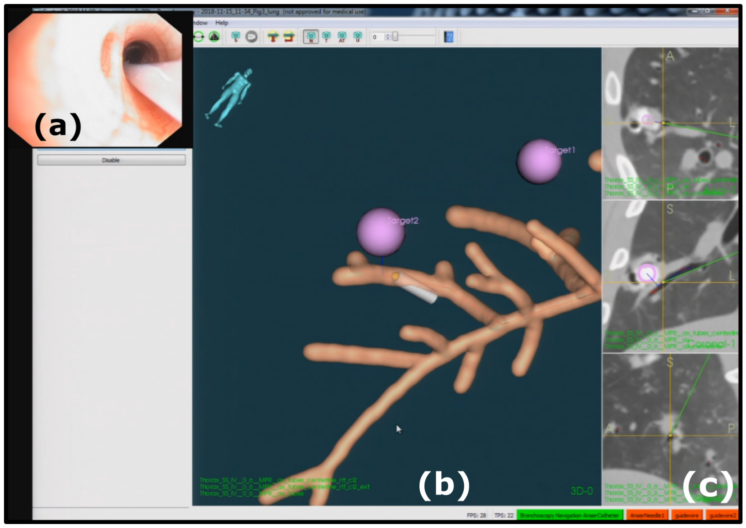

Fig. 2. Screenshot of the CustusX clinical interface showing (a) a live video feed from the bronchoscope camera, (b) 3D segmentation of the right lung airway with marked-up tumour targets (*pink*) and catheter tip location (*grey*) and (c) traditional sliced CT scan views showing location within airway.

Navigation to each of the tumour models (T1-T4) was attempted using the tracked catheter and 3D visualisation in CustusX. In each case, the live bronchoscope feed was used in conjunction with the 3D segmentation visualisation of the airway to identify the correct bronchi through which to navigate. Once the correct airway was identified, the catheter was advanced to the target using only the 3D visualisation. Successful catheter tip deflection and rotational mechanisms were demonstrated within the airway at bronchial bifurcations points. Upon reaching the closest attainable distance to the target, the steerable guidewire was removed from the catheter sheath and a marking fiducial ($3\,\text{mm} \times 0.5\,\text{mm}$ wire segment) was deployed in each case. A post-procedure CT scan was performed to verify whether successfully targeting had occurred by identifying the distance between the deployed wire fiducial and tumour model.

3 Results

The tumour targeting accuracy results are shown in Table 1. *Virtual distance* refers to the distance between the marked-up tumour and catheter tip position as reported by CustusX. *Real distance* is the distance measured between the wire fiducial and tumour model as read from the post operative CT scan. The post-operative CT scan indicated a significant pneumothorax had occurred to the upper right airways. The resulting deformation of the right lung made locating and confirming the targeting accuracy of tumour models T1 and T2 unattainable.

Table 1. Lung tumour targeting results.

Tumour ID	Tumour position	Size [cm]	Virtual distance [cm]	Real distance [cm]
T1	Right cranial	1.12×1.32	24.4	unconfirmed
T2	Right middle	1.21×1.02	25.7	unconfirmed
T3	Right caudal	0.78×0.98	8.7	18
T4	Left caudal	0.96×1.29	20.4	18.9

The major shortcoming of the experiment are the unattainable distance measurements for targets T1 and T2 due to the collapse of the right lung. Percutaneous access to the chest cavity carries a heavy risk of pneumothorax and, while initially undetected in the pre-operative CT scan, the pneumothorax may have developed slowly over the course of the procedure. This should be kept in mind when interpreting the distances of T3 and T4 in Table 1.

4 Conclusion

The preliminary results from this study represent the first preclinical validation of the Mariana project. A novel omnidirectional steerable guidewire and catheter was designed and successfully deployed within the airway of a porcine animal model. Tracking and navigation of the instrument was demonstrated within the airway confirming successful integration of electromagnetic tracking sensors within the instrument. Tumour models were targeted to an accuracy of 18-20 mm. Future work will see the refinement of the catheter steering and deflection mechanisms. Improvements in tumour placement will also be investigated in order to reduce the likelihood of pneumothorax in future experiments.

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