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In Vivo Demonstration of a Bevel Tip Steerable Needle with an Integrated Fluid Channel

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INTRODUCTION

Bevel tip steerable needles have been the subject of intense study in surgical robotics over the past 20 years [1], [2]. This led to recent demonstration of autonomous needle steering in the lung in vivo in animals [3]. The pervasive paradigm in all of this past work has been that the needle acts in a manner analogous to a catheter's guidewire. That is to say, the needle steers to the target, a plastic catheter-like sheath is slid over it, and then the needle is removed. The sheath provides a passage to the target for subsequent liquid injection or for tool insertion for biopsy or other therapy delivery (e.g. thermal ablation probes).

While the sheath paradigm can work well, there remain scenarios where one may not wish to withdraw the needle. For example, one may wish to leave the sensor(s) embedded at the needle tip (e.g. magnetic tracking coils, thermal sensors, etc.) in place to monitor therapy delivery. Or one may wish to reposition the needle to several nearby targets to increase treatment volume or adjust the shape of the treatment volume. In such cases, multiple complete needle/tool withdrawal and insertion steps would be cumbersome and might also reduce accuracy.

With this in mind, we propose a bevel tip steerable needle with an embedded fluid channel for liquid drug delivery (see Fig. 1). By using the helical laser patterning proposed in [4], we can create a steerable needle large enough to house both a magnetic tracking coil and a fluid delivery lumen, but that is still flexible enough to steer in lung tissue. This is the first steerable needle through which injections can directly take place, and this would not be possible without the recent idea of laser patterning the needle's shaft.

MATERIALS AND METHODS

Our steerable needle has a hinged bevel tip with a helical dovetail pattern laser cut into the distal shaft (Medical Device Imagineering, Inc., Somerset, NJ) using a fiber laser (Rofin Inc.). We use the helical dovetail parameters as described by [4]. Within this 1.8 mm outer diameter (OD) needle, we insert a 30-gauge nitinol fluid channel (0.36 mm OD), and a 6 degree of freedom (DOF) magnetic tracking coil (0.9 mm OD), which are both fixed at the tip using a cyanoacrylate adhesive. The tip of the fluid channel is flush with the needle bevel as shown in Figure 1. Our group has previously developed imaging, planning, and control approaches for delivery of such needles into the lung bronchoscopically [3].

We experimentally demonstrated the efficacy of this new needle design in ex vivo and in vivo experiments, as shown in Figure 2. The veterinary team anesthetized the pig and administered a paralytic. They then performed a tracheotomy to bypass the porcine upper respiratory structures, which geometrically differ from human anatomy and would make direct bronchoscope insertion challenging.

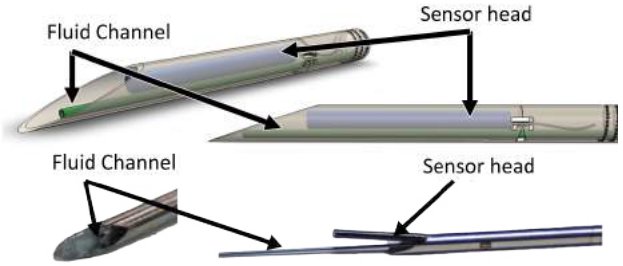

Fig. 1 Fluid channel needle design.

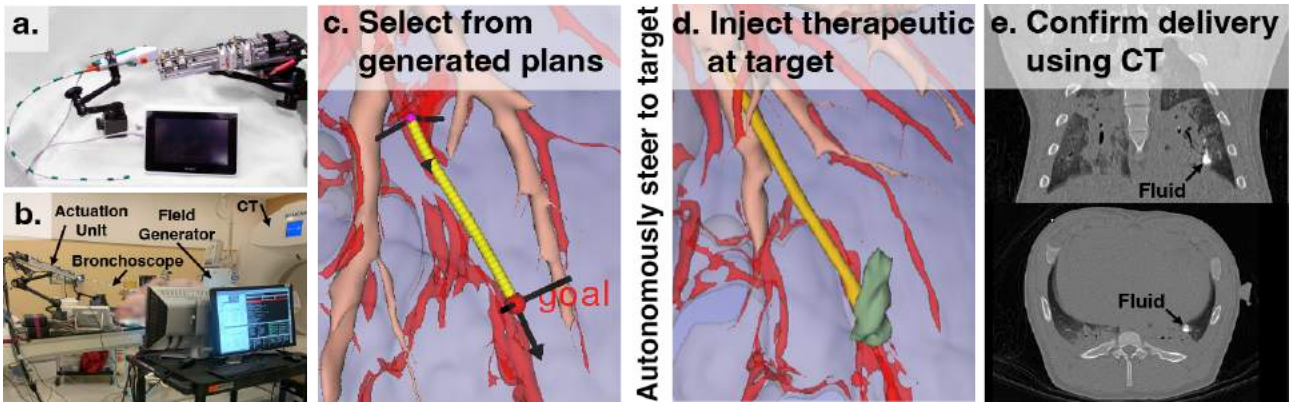

Fig. 2 Clinical workflow and fluid delivery: a. robotic actuation system, b. in vivo experimental setup, c. segmented representation of insertion plan, d. segmented rendering of the deployment and delivered fluid, e. post-operative CT scan including coronal (top) and transverse (bottom) views of the radiopaque fluid injection.

We collected a preoperative CT during a breath hold and segmented and registered it to the animal, as described in [3]. We used the method in [5] to generate a sampling-based motion plan for the robotic system, planning needle motion from the airways to the target. To reduce the effects of respiratory motion, we performed the needle insertions during a breath hold. After delivering the needle along the planned path to the desired target in the lung, we injected 0.5 mL of radiopaque fluid (1:1 ratio of Omnipaque (TM) and saline), through the needle's internal fluid channel, into the lung paranchemya. After the experiments, the veterinary team identified no complications and confirmed that the animal remained hemodynamically stable.

RESULTS

We confirmed the steerability of the fluid channel needle ex vivo, using the process described in Rox et al. [4], in which needle curvature was characterized based on fitting a circular arc to magnetic tracking data collected during open loop insertion. The fluid channel needle's 96 mm radius of curvature was comparable to the 100 mm radius of curvature in Rox et al. This is noteworthy since the fluid channel needle's diameter is larger, which underscores the point made in Rox et al. that helical dovetail patterning decouples steerability from shaft diameter. This decoupling provides greater flexibility in interventional tool integration into steerable needles.

We steered the fluid channel needle in an in vivo porcine model with a final targeting error of 1.59 mm in magnetic tracker space and successfully injected contrast agent through it. CT scans of the coronal and transverse views after fluid deployment can be seen in Figure 2. The location of the fluid is labeled in each.

DISCUSSION

We note that the fluid channel we used in this work was small in diameter. Thus, while it is suitable for some fluids, it is too small for most existing biopsy devices or interventional tools to pass through it. In the future, the size of the fluid channel could be increased by increasing the needle's overall diameter or by replacing the 6DOF magnetic tracking coil with a smaller 5DOF coil. Note that observers and controllers exist, enabling the 5DOF coil to be used for this purpose [1], [3].

Note also that we do not propose the idea of an integrated fluid channel as a replacement for the traditional catheter-like sheath. Rather we believe that it will be complementary and useful for a subset of all needle steering applications, where direct therapy monitoring or needle tip repositioning mid-therapy is desired. The successful in vivo experiments included in this paper demonstrate the feasibility of the approach.

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