A New Sheath for Highly Curved Steerable Needles

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***Abstract*—Current steerable needles offer the potential to access hard-to-reach areas of the body, but typically do not directly deliver biopsy and therapy delivery, since the embedded sensor coils that enable accurate steering typically fill the inner lumen of the needle. Sliding a hollow sheath over the steerable needle and then removing the needle has previously been suggested as a way to provide a channel for biopsy and therapy delivery. However, for highly curved needles with long transmissions (e.g. those that go through endoscopes), standard sheaths are either too stiff (i.e. cannot be pushed over the needle without displacing its tip), or too soft (i.e. axially compress within the endoscope). To address this, we propose a new multi-material sheath design consisting of a catheter with good axial stiffness joined to a tip with low bending stiffness.**

I. Introduction

Steerable needles provide a minimally invasive approach to access hard-to-reach targets within the body. Initially, these needles were designed with percutaneous delivery in mind (see e.g. [1] among many others), and sheaths that slide over the needle (followed by needle removal) have been suggested as a way to create a channel for biopsy tools or therapy delivery [1], [2]. However, extending this concept to trans-endoscopic applications as suggested in [2] involves considerably longer needles and longer sheaths, as well as additional friction with the endoscope port. These factors introduce new constraints on the sheaths used. We have found that standard sheaths used in endoscopic procedures do not work well with high-curvature steerable needles. They either displace the needle tip in tissue because they are too stiff, or they bunch up axially inside the endoscope because they are too soft. To address this, we designed a new multi-material sheath that consists of a catheter with good axial stiffness that passes through the endoscope, attached to a tip with low bending stiffness that slides compliantly over the curved steerable needle in tissue.

II. Sheath Design Concept

The new sheath design is comprised of two sections: an initial 1 m long transmission section of extruded polyethylene (PET, Nordson Medical) that passes through the endoscope, and a 150 mm long distal tip section made from braid-reinforced thermoplastic elastomer (Pebax 40D, Duke Extrusion), as shown in Fig. 1. This enables the sheath to slide through a clinical endoscope (Ambu aScope with a 2.8 mm diameter port) and then over a highly curved steerable needle embedded in tissue at the endoscope's tip. The PET of the proximal transmission section slides through the endoscope with low friction and axial compression, while the thermoplastic tip slides easily over a curved needle. The two are bonded via a short length of ultra-thin heat shrink (Nordson Medical, wall thickness 0.01 mm). Note that in a future clinical version the two sheaths could be flowed together to eliminate the heat shrink, as is often done in catheter manufacture.

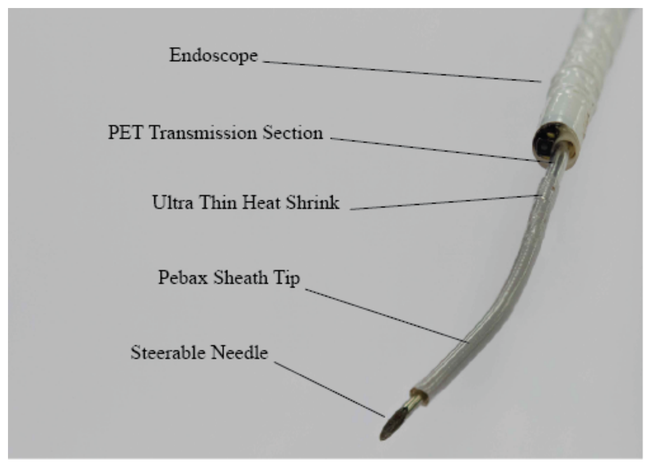

Fig. 1. Our new sheath deployed from an endoscope, carrying a bevel-tip steerable needle.

III. Conclusion

We have designed a sheath that addresses the unique constraints of high-curvature steerable needles deployed via endoscopes. Our solution is a multi-material sheath that provides simultaneous axial stiffness within the endoscope, while enabling the tip to be soft enough to pass over a highly curved needle, without displacing its tip in tissue.

References

[1] Majewicz, A., Marra, S. P., Van Vledder, M. G., Lin, M., Choti, M. A., Song, D. Y., and Okamura, A. M. (2012). Behavior of tip-steerable needles in ex vivo and in vivo tissue. IEEE Transactions on Biomedical Engineering, 59(10), 2705–2715.

[2] Swaney, P. J., Mahoney, A. W., Hartley, B. I., Remirez, A. A., Lamers, E., Feins, R. H., Webster III, R. J. (2017). Toward Transoral Peripheral Lung Access: Combining Continuum Robots and Steerable Needles. Journal of Medical Robotics Research, 02(01), 1750001.