Detachable Bronchoscope With a Disposable Insertion Tube[1]

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1 Background

Many medical facilities can only afford to have a small number of bronchoscopes on hand due to their high cost. A typical bronchoscope costs between $15,000 and $30,000. To prevent cross-contamination between patients, bronchoscopes are completely immersed in a cleaning and disinfection solution during the reprocessing procedure [1]. This causes instrument downtime, limiting the amount of procedures that can be performed in a day. To completely sanitize a bronchoscope, a disinfectant and sterilant called Rapicide is used. A 4 gal jug of Rapicide, which costs between $150 and $175, is used in a heated machine that disinfects a bronchoscope for a half an hour. A typical bronchoscope cleaning machine costs approximately $50,000. Before and after cleaning, there is approximately 15 min of time spent preparing the scope. Once the bronchoscope is completely sanitized, it is ready for the next procedure.

A bronchoscope design with a disposable insertion tube end is proposed (see Fig. 1) that can be manufactured at a low cost, eliminating the time and cost associated with reprocessing. Another benefit of a disposable insertion tube is a reduction of the risk of cross-contamination between patients [2] since the portion of the instrument that goes into the body is disposed of. This differs from the previous attempts at a detachable bronchoscope, which still had the requirement of reprocessing and the risk of cross-contamination since these designs were not intended to be disposable [3].

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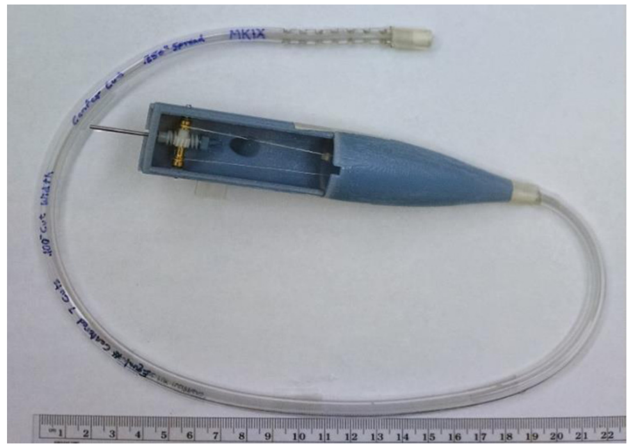


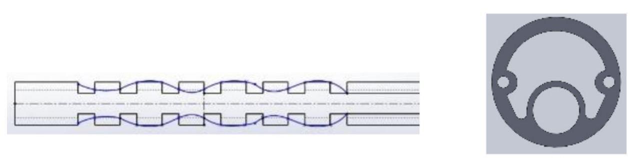
Fig. 1 Disposable end of detachable bronchoscope prototype

2 Methods

Figure 1 shows the prototype of the disposable insertion tube portion of the bronchoscope. The mechanism of operation for flexing the insertion tube is similar to a conventional bronchoscope where two angulation wires are used to flex the flexible portion of the insertion tube. However, since the design needs to be detachable, the angulation wires cannot be tied directly to the hand control as they are with a conventional bronchoscope. This allows the hand control to be on the reusable portion of the bronchoscope, which reduces the complexity and cost of the disposable portion. A worm gear drive system is used with two pulleys to lengthen and shorten the angulation wires (see Fig. 1). This worm gear drive approach allows the motor that drives the worm gear to be placed in the reusable handle portion of the bronchoscope.

In order to form the flexible portion of the insertion tube, cutouts are placed in a flexible plastic tube and the angulation wire is weaved through these cutouts (see Fig. 2(*a*)). Plasticized polyvinyl chloride tubing (6.35 mm OD and 4.32 mm ID) was used for the disposable insertion tube due to its affordability ($0.38/m), flexibility, and availability in dimensions that match those of current bronchoscope insertion tubes. A single-lumen tube is used, however, a multilumen tube would likely be used in a commercial model in order to contain the working channel (see Fig. 2(*b*)). Multiple design iterations were tested in order to determine the optimal geometry to allow for the tube to bend while keeping its structural integrity, preventing kinking of the working channel, and minimizing the force required to bend the tube so that it can be actuated by a handheld motor. There are four variables that impact the performance of the flexible portion: number of cuts on each side of the tube, cut alignment, width of cuts, and the center-to-center distance between each cut. In the final implementation, these cutouts would likely need to be sheathed in a flexible membrane material such as neoprene to isolate the interior of the bronchoscope during the procedure.

Based on the force and desired time it would take to complete a 180 deg bend in one direction, a geared motor with a 9.7:1 gear



(a) (b)

Fig. 2 (*a*) Bending section of insertion tube showing how the angulation wire is weaved through the cuts and (*b*) a proposed multilumen medical tubing cross section

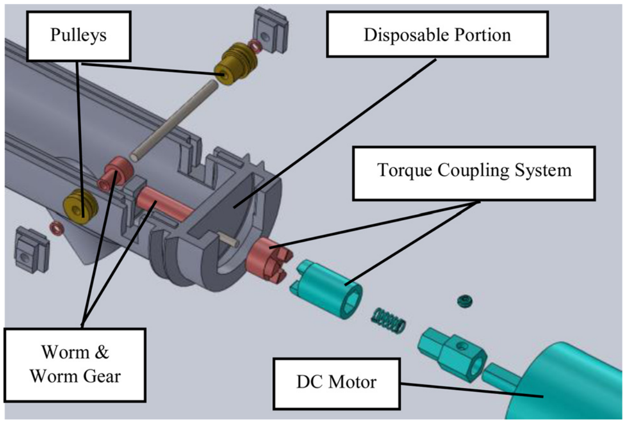


Fig. 3 Exploded view of the pulley drive mechanism

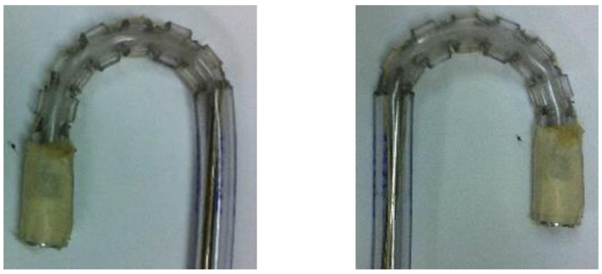


Fig. 4 Bendable end of insertion tube flexed to the left and right, respectively, using the optimal cutout geometry

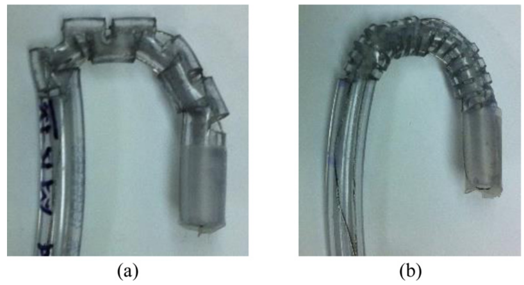


Fig. 5 (*a*) Kinking due to staggered cuts and (*b*) collapsing and twisting due to an increased number of staggered cuts and a reduced cut width

ratio is used in the reusable handheld portion. The gear motor allows for a relatively low 10:1 worm gear ratio in the disposable portion, which keeps the gearing dimensions small while also being able to supply enough torque to provide the force needed for angulation. The plastic worm and worm gear set cost $4.60 in low volumes. Both are attached to the shafts by a press fit.

The pulleys were designed so that they contain enough of the angulation wire to flex the insertion tube 180 deg in either direction and withstand 8.9 N of load. Due to the size and custom dimensions of the pulleys, they were made in house out of brass for its strength and ease of machining. Each pulley measures 6.35 mm in diameter and are pressed fit onto the shaft.

Since the bottom housing of the bronchoscope is intended to be disposable, a coupler was incorporated to allow the torque from the motor to be transferred to the gears. The spring loaded torque coupler system is shown in Fig. 3.

In order to control the motor, an Arduino Uno microcontroller with a motor driver shield was used. Currently, the implementation is open loop with a potentiometer lever in the handle controlling the current to the motor. For the final design, a closed loop controller will be implemented that will control the angle of the bronchoscope to be proportional to the potentiometer position utilizing the motor's rotary encoder as feedback.

3 Results

Through testing, it was determined that the optimal design includes seven nonstaggered cuts per side, a cut width of 2.5 mm, and with a center-to-center cut distance of 6.4 mm. Figure 4 shows this design fully flexed in both directions. Two designs that used staggered cuts, resulting in undesirable kinking and twisting of the insertion tube, are shown in Fig. 5.

Table 1 Measured angulation force

	Olympus BF P200	Steel wire	Kevlar thread
Force (N)	8.90	13.57	7.3

Since the diameter of the pulley, which the angulation wire wraps around, is only 4.8 mm, a small diameter wire is required. Originally, a 0.3 mm 304 stainless steel wire rope was used for angulation, which did not coil properly around the small diameter pulleys. The angulation wire was then switched to a braided Kevlar thread, which wraps around the pulleys well due to its low bending stiffness. Additionally, the Kevlar thread resulted in a lower required angulation force since it threaded more smoothly through the notches in the insertion tube. Kevlar thread is also half the price of the steel wire rope.

Measurements were taken to determine the required forces to angulate the insertion tube to an angle of 180 deg for both a conventional bronchoscope and the disposable prototype using both steel wire and Kevlar thread. The results can be seen in Table 1.

4 Interpretation

A prototype bronchoscope design with a disposable, and low cost, insertion tube has been demonstrated. The final design of this bronchoscope would utilize a CMOS camera chip and an integrated light-emitting diode (LED) light source, both of which have a low unit cost due to their use in mobile phones. A vendor for the CMOS camera has been identified that can provide a sufficiently small camera and lens assembly for less than $60. Multilumen medical tubing, as shown in Fig. 2(*b*), would be used for the insertion tube in order to accommodate the working channel, the Kevlar thread, and the electrical wires for the light source and CCD camera chip. This disposable and detachable bronchoscope design eliminates the cost and time associated with reprocessing and greatly reduces the risk of cross-contamination. Another potential advantage of having a disposable insertion tube is the ability to easily change insertion tubes for specifics tasks. A variety of insertion tube diameters and lengths could be kept on hand.

References

[1] Ernst, A., and Herth, F. J. F., 2013, *Principles and Practice of Interventional Pulmonology*, Springer, New York.

[2] Kovaleva, J., Peters, F. T. M., van der Mei, H. C., and Degener, J. E., 2013, "Transmission of Infection by Flexible Gastrointestinal Endoscopy and Bronchoscopy," Clin. Microbiol. Rev., **26**(2), pp. 231–254.

[3] Garcia, A. M., Kirk, K. D., III, Mulhauser, P. J., and Treacy, L. T., 2013, "Portable Endoscope for Diverse Medical Disciplines," U.S. Patent 8419623 B2.