

# Design of a Safer Tracheostomy Tube<sup>1</sup>

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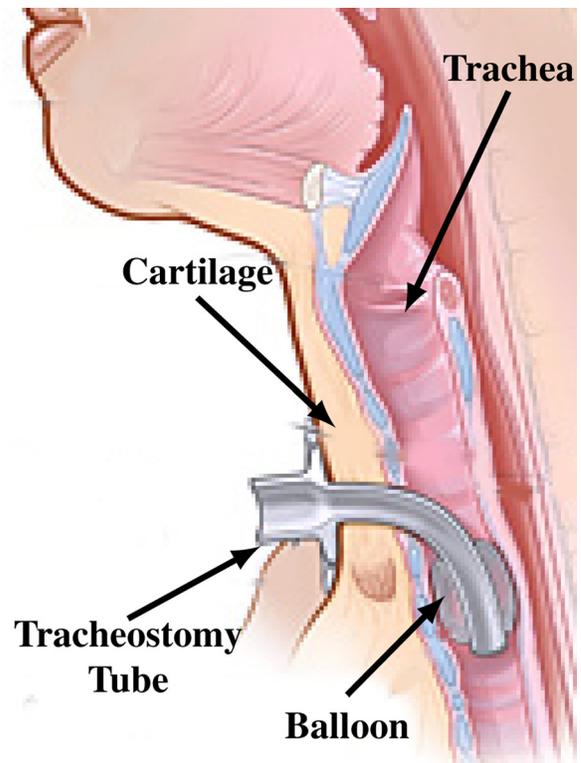
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## 1 Background

During a tracheotomy, the surgeon makes an incision through the front of the patient's neck (the incision is known as a tracheostomy) to access the trachea and inserts a tracheostomy tube (see Fig. 1), which serves as an alternative airway to the mouth or nose. After insertion, a balloon is inflated to the diameter of the trachea, which fixes the tracheostomy tube in place, allows for positive pressure ventilation, and creates a seal to the walls of the trachea.

Tracheotomies are a common procedure; approximately 120,000 procedures are performed each year in the U.S. [1]. There are several indications for a tracheotomy, but a review of 1130 cases spanning over a decade found that tracheotomies are done most often to assist in prolonged mechanical ventilation (~76%). They are also performed as an adjunct to head, neck, and chest surgery (~11%) and to relieve upper airway obstruction (~6%). The same study identified major complications, such as tracheal stenosis (i.e., narrowing) or hemorrhage, 4% of the time, and attributed eight deaths directly to the tracheotomy [2]. Other studies have found complication rates as high as 45% [3].

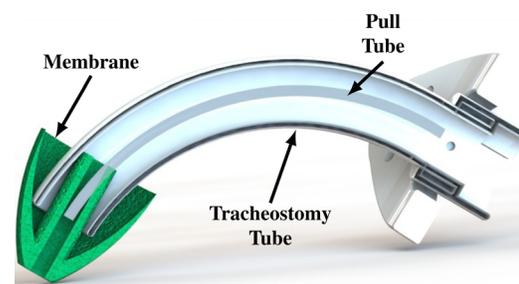
We hypothesize that a portion of these complications is attributable to a suboptimal tracheostomy tube design. Currently, during tube insertion, the folds of the deflated balloon or the tip of the tracheostomy tube itself (which has rough edges) often get caught on cartilage (see Fig. 1) within the incision, which can prevent further insertion. This is one of the main difficulties of inserting the tracheostomy tube. To proceed, surgeons have two options: They can push the tracheostomy tube harder to force the tube through the incision, or they can remove the tube, open the incision further, and reattempt to insert the tube. The first option can be dangerous since large insertion forces can lead to "backwalling" (i.e., puncturing through the back of the trachea) or the creation of a false lumen (i.e., a new passageway for air), which can cause the



**Fig. 1** A tracheostomy tube is inserted into the trachea through an incision on the neck. Once inserted, the balloon is inflated to secure the tube in the trachea and maintain the airway.

side of the neck to inflate and close the trachea. The second option of widening the incision is also not desirable because surgeons prefer to keep the incision as small as possible, and it increases the procedure time, which is often very time sensitive, especially in cases of upper airway obstruction.

In this paper, we propose a design addition to a conventional tracheostomy tube, where a thin, smooth membrane "umbrella" covers the distal end of the tube and the balloon. This membrane enables the device to be inserted through a predictable, repeatable incision size and prevents the tracheostomy tube tip and balloon features from catching on trachea cartilage, which facilitates easier insertion of the tracheostomy tube. After the tube has been inserted, this deformable membrane can quickly be pulled through the inside of the tracheostomy tube by deforming and inverting its umbrella-like shape. In what follows, we describe the design and manufacturing of this device.

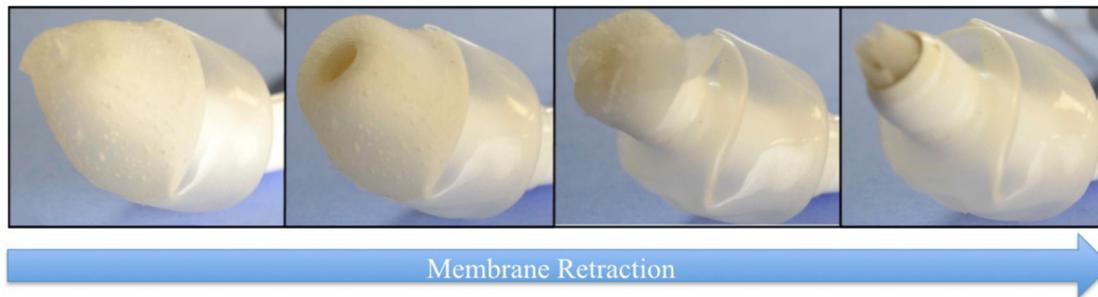


**Fig. 2** A cross-sectional depiction of the membrane design. The membrane covers the tube tip and the balloon (not pictured). A pull tube allows the surgeon to extract the membrane.

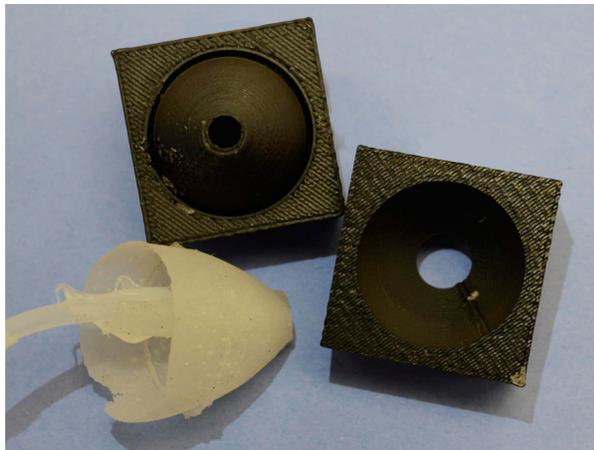
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**Fig. 3** The membrane is retracted through the tube, inverts its umbrella-like shape and is removed from the tracheostomy tube



**Fig. 4** The mold and the silicone membrane are shown. The mold was 3D-printed and filled with DragonSkin to produce the membrane.

## 2 Methods

We set out to create a membrane attachment (see Fig. 2) that would make the tracheostomy tube insertion process smoother and more repeatable. We determined three main design inputs: first, the membrane must be large enough to cover the outer layers of the deflated foam cuff as well as the tip of the tube itself. Second, the membrane must be capable of being removed without disturbing the tracheostomy tube or balloon. Finally, the membrane must be made of a biocompatible material.

These design inputs culminated in the concept of a highly deformable silicone umbrella membrane. The design intent was that this membrane could be placed inside the tracheostomy tube immediately prior to insertion, rather than becoming a permanent fixture to the tube. The umbrella-like membrane is attached to a pull tube that runs the length of the tracheostomy tube that the surgeon can grasp to deform the membrane, invert its umbrella shape, and remove it through the tracheostomy tube (see Fig. 3).

The device was fabricated by filling a 3D-printed mold assembly (see Fig. 4) with DragonSkin (a silicone compound, Smooth-On, Inc., Macungie, PA), placing it in a vacuum chamber to remove all bubbles, and allowing it to cure for several hours. While DragonSkin was the available material for our prototype, we intend for the final, biocompatible design to be made from polydimethylsiloxane, a known biocompatible silicone material. The pull tube was designed as a silicone tube inserted along the axis of the membrane and secured with a silicone epoxy (Smooth-On, Inc., Macungie, PA). According to the adhesive specifications for bonding silicone to silicone, the tensile strength of the bond is 750 psi, the tear strength is 100 pounds per inch (ppi) of bonding material, and the peel strength is 100 ppi.



**Fig. 5** The final prototype assembled to the tracheostomy tube

## 3 Results

One concern of this design is the potential for the pull tube to separate from the membrane during retraction, which could plug the tube or leave the membrane inside the trachea. To address this, we did three identical experiments characterizing the pull force required to remove the membrane. We tied the pull tube to a spring scale and gradually increased pull force until the membrane was extracted. The pull out force never exceeded 2 lb in the experiments. Since there is approximately 0.080 in. of membrane material at the bond and the peel/tear strength of the adhesive is 100 ppi, it would require 8 lb of force to peel or tear the membrane from the pull tube. Therefore, we estimate a factor of safety of over four for preventing failure of this bond.

The design of the membrane itself was challenging because smooth insertion requires a membrane that is not too thin, while easy retraction through the 7.8 mm tube argues for a membrane that is as thin as possible. The final membrane design smoothly thinned out from 0.045 in. at the tip to 0.006 in. at the most proximal edge. Figure 3 shows a step-by-step retraction of the membrane during testing. The membrane initially covers the tip of the tube and the balloon, begins to deform through the tube as it is pulled, inverts its shape, and then fits tightly within the inner diameter of the tracheostomy tube as it is pulled through. Although the current prototype can easily be pulled through the tracheostomy tube, a lubricant on the membrane would make the retraction process even easier for the surgeon. The membrane deformation does occlude the opening of the tracheostomy tube momentarily as it is pulled through, but this is considered to be acceptable for a short amount of time. The final assembled prototype is shown in Fig. 5. Ultimately, we envision the membrane as a prepackaged, sterile, disposable part. Alternatively, it could be prepackaged and pre-assembled with the tracheostomy tube.

## 4 Interpretation

We have presented a tracheostomy tube membrane design that creates a smooth, repeatable surface for insertion during a

tracheotomy. Because this design allows the tube to be inserted without getting caught, we believe that this tool will increase trachea tube insertion reliability and efficiency, while decreasing operating time. In future experiments, we intend to more quantitatively assess the forces required to use this device versus the current standard of care to prove the proposed benefits of the device.

## References

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