Variable-size Endotracheal Tube for Difficult Pediatric Intubation

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Problem Description

Intubation is a common procedure used to secure a patient's airway in emergent and non-emergent situations. During intubation, a laryngoscope is used to visualize the patient's vocal cords so that an endotracheal tube (ET) can be inserted through the cords into the trachea (Fig. 1A). The cuff, a small balloon at the end of the ET, is inflated before subsequent positive-pressure ventilation can occur. When a patient has what is known as a "difficult airway" due to various upper airway obstacles or pathologies, intubation can become significantly harder as the tube path becomes narrower (Fig. 1B). As pediatric airways are smaller in size and anatomically different from adult airways, the pediatric population carries more risks for intubation failure. Physicians may attempt to intubate with a smaller tube size, but this can excessively limit the ventilatory capacity required for a patient. In situations where intubation fails and the patient requires immediate ventilation, physicians proceed to tracheotomy. Compared to standard endotracheal intubation, tracheotomies are significantly riskier as they are a more invasive method of securing the airway through surgical access of the patient's trachea. There is a need for a way to reduce the difficulty of pediatric intubation associated with airway obstacles to prevent the need for tracheotomy for airway access.

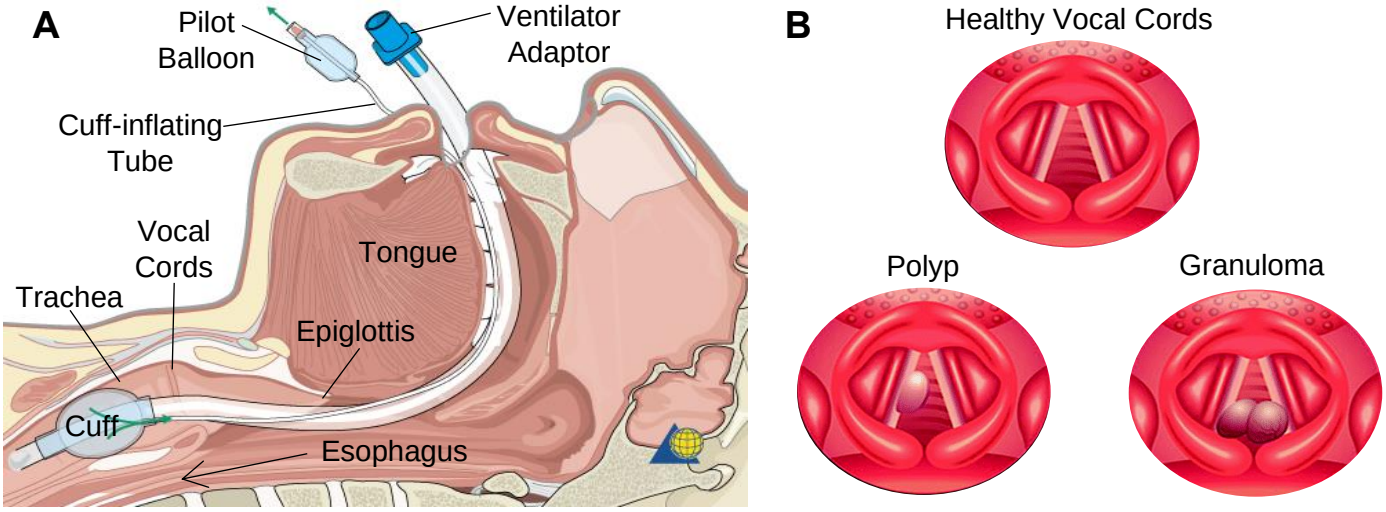

Figure 1. Intubation Background and Contexts. (A) Overview of intubation and endotracheal tube components [1]. (B) Visual of airway-narrowing obstacles at vocal cords [2].

Solution Concepts

The capability of the design to integrate with the current standard of care was given high priority early in the design process. Therefore, the design was predicated upon limiting practitioner training, being compatible with existing respiratory hardware (ventilator, laryngoscope, etc.), and achieving airway sealing for positive pressure ventilation. Consequently, proposed designs focused on making modifications to the standard ET design in order to improve ease of use in difficult intubation contexts. Mechanisms to change the size and/or maneuverability of ETs were investigated. Maintaining or reducing the amount of time it takes to intubate with the selected design was also prioritized. Considering these requirements, the selected design uses a novel mechanism to

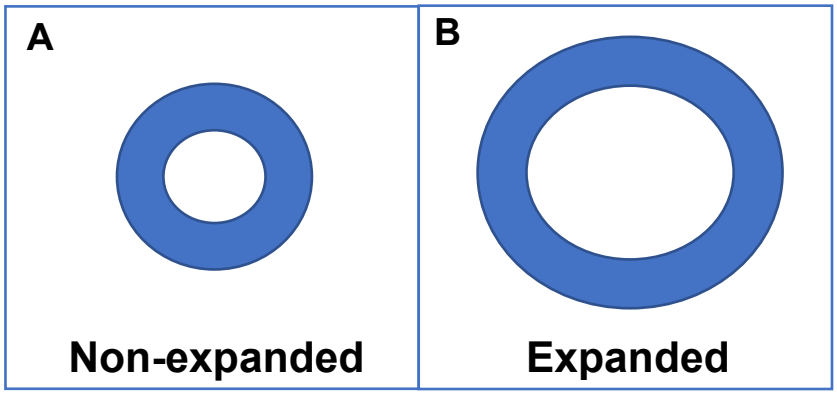

Figure 2. (A) Small diameter tube passes airway obstacle. **(B)** Physician activates novel mechanism to expand tube, sealing the airway for positive pressure ventilation and facilitating patient ventilation through larger tube diameter.

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change the size of the tube approximately 40%. The ET is inserted at 60% of its maximal size before the physician activates the mechanism to expand the tube anywhere within the 40% dynamic range (Fig. 2). The design incorporates components from standard endotracheal tubes for easy integration into the clinical setting; this is the key advantage of the selected design (Fig. 3). Given that there is no additional equipment needed for the intubation nor additional procedural steps in the intubation process, intubation time with this design is comparable to standard ET intubation time. Physicians would require little training to use a device with such high similarity to standard ETs.

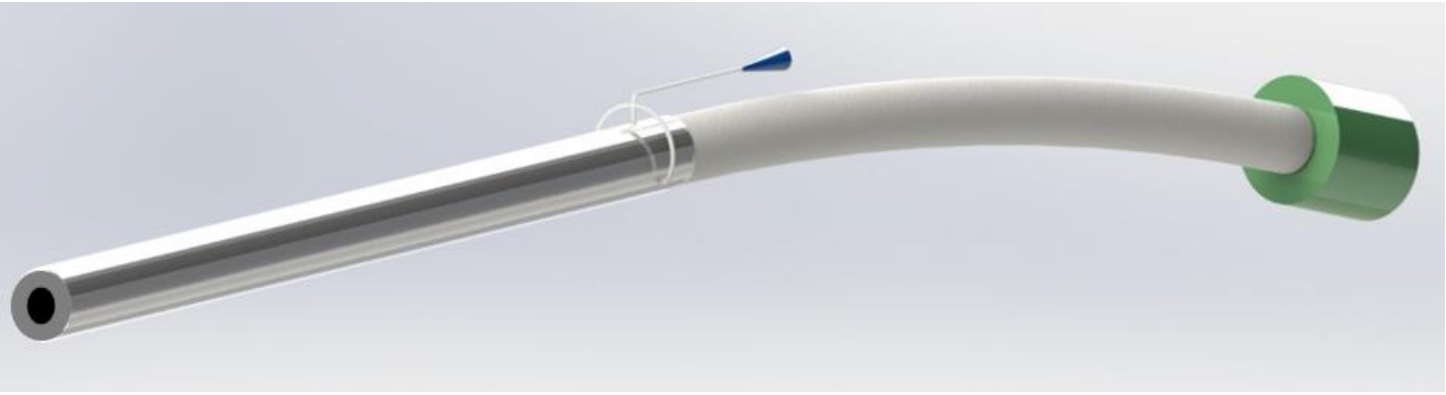

Figure 3. Render of final prototype with integrated ET components.

Reduction to Practice

The prototype was fabricated using methods in 3D printing and precision adhesive application. The team overcame numerous challenges in fabricating within the 1.3-millimeter thickness of the tube. In executing the design, key areas of understanding included theoretical versus real 3D printing resolution, the chemistry of adhesive bonding and inhibition, and mechanics of materials. Through an iterative process, the team developed repeatable and reproducible methods to fabricate the device.

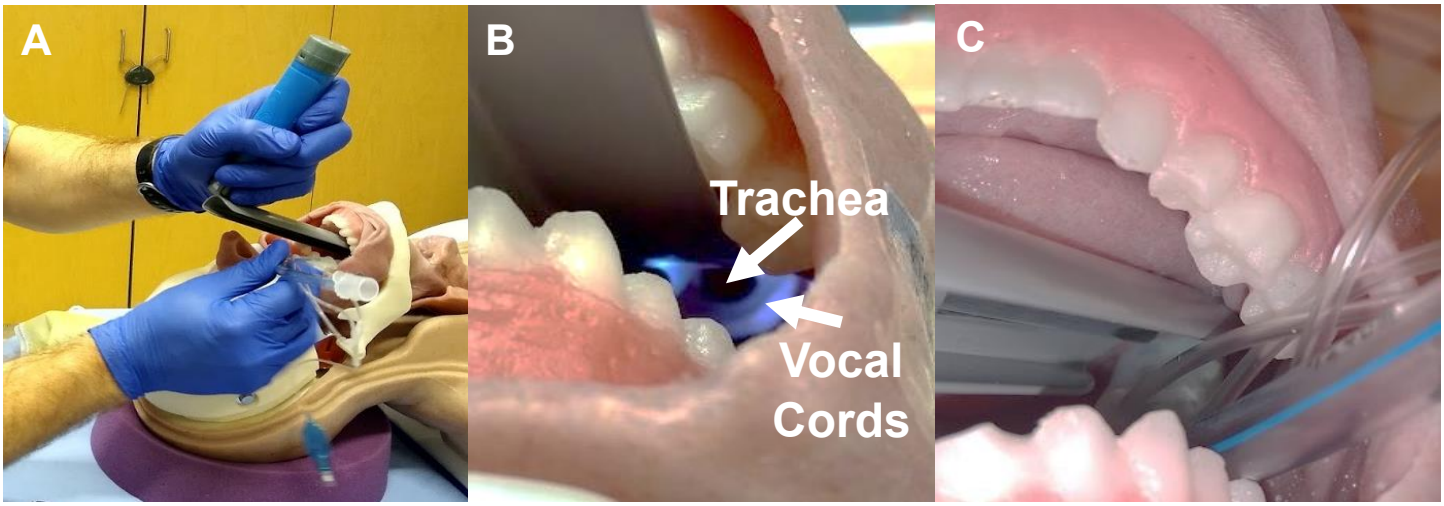

Figure 4. (A) Intubation simulation performed by trained physician. **(B)** Visual of vocal cords before intubation. **(C)** Visual of device insertion into vocal cords.

Design requirements indicated the inner diameter dynamic range of the tube should be 3.6 to 6.0 millimeters for an expansion capacity of 40%; this makes the expected patient population between 2 and 8 years old. In terms of clinical parameters, the dynamic range requirement covers 2.5 endotracheal tube sizes. The achieved inner diameter dynamic range was approximately 6.0 to 9.0 millimeters, or 3 standard endotracheal tube sizes; this makes the actual patient population between 8 to 18+ years old. Though the device did not meet size change requirements, it demonstrated success in clinical use during validation tests. A physician experienced with difficult intubation tested the device on an intubation simulation mannequin. During validation, the physician compared the device to standard ETs in terms of device-airway positioning, airway sealing capacity, and ventilatory capacity (Fig. 4). Following these tests, the physician gave the device an “Excellent” usability score

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of 90 on a Systems Usability Scale. The physician gave the team feedback requesting improvements in the curvature and robustness of the device. Given the excellent clinical performance of the device, the team has reevaluated the size change design requirements that the device did not meet during verification. Entering the younger pediatric range listed in the size change design requirements is more feasible in a manufacturing setting versus in this “made by hand” context.

Pathway to Implementation

The team has made an outline of how device manufacturing could be undertaken by manufacturers of standard ETs – the method involves structural and materials modifications to improve device curvature and robustness. Regarding intellectual property protection, the device is novel, useful, and non-obvious, making it patentable. While there are existing patents for variable size ETs, the device may have enough dissimilarity from these patents to attain freedom to operate. From a regulatory perspective, the device would ideally get approval as a class II device under the 510(k)-pathway using current ETs as a predicate. However, if the device does not demonstrate substantial equivalence to standard ETs using ASTM F2726:08, the device would get approval as a class III device under the PMA-pathway [3]. After approval, the device could be sold to hospitals and emergency medical agencies as an alternative to tracheostomy when intubating patients with difficult airways. The device has market potential outside of pediatrics for operation in a range of adult tube sizes. While the expected cost of device use is higher than standard intubation (CPT 31500), the device would represent a cost savings for patients and insurance companies in comparison to tracheostomy (CPT 31603-31605). Patients and insurance companies would also save money given the reduction in long-term disabling complications from tracheostomy.

References

[1] R. Banerjee, P. Brink, M. Cimerman, T. Pohlemann and M. Tomazevic, "Pelvic ring - Primary Survey: Airway," AO Foundation, 10 December 2015. [Online]. Available: https://www2.aofoundation.org/wps/portal/.
[2] M. Jicinsky and J. Mares, "Measurable Changes of Voice After Voice Disorder Treatment," *Proceedings of the Computational Methods in Systems and Software,* pp. 295-305, 2019.
[3] FDA, "Product Classification: Tube, Tracheal (W/wo Connector)," FDA: Medical Device Database, 4 May 2020. [Online]. Available: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=BTR.

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