The Laryngoscope

Development of an Improved LASER-Resistant Endotracheal Tube

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Objectives: Surgical fires, particularly within Otolaryngology, remain a surprisingly frequent and devastating complication of laser-related surgery in the oropharynx and airway; Current estimates suggest anywhere from 200 to 600 surgical fires per year in the United States, with 20%–30% of these occurring as a complication of laser surgery and 90%–95% of these occurring in the head and neck region. Unfortunately, the complications of laser surgery in the airway may include respiratory failure, airway burns with stenosis, and may result in mortality.

The most commonly utilized endotracheal tube for protection against inadvertent laser strikes, the Laser-Shield II tube (Medtronic), was removed from the commercial marketplace in 2016 after cases of airway fires were reported as a result of feature deficiencies in the product (FDA MAUDE Database review). Since the demise of the Laser-Shield II tube, alternatives such as the Mallinckrodt laser tube and handmade reinforced tubes have been utilized, although shortcomings in design and features have made these options less appealing to practicing Otolaryngologists. Creating a laser-safe endotracheal tube is critical for safe upper airway surgery. This paper evaluates new technologies, materials, and technical innovations in endotracheal tubes that may advance patient safety in laser-assisted Otolaryngology procedures.

Study Type: This paper evaluates new technologies, materials, and technical innovations in endotracheal tubes that may advance patient safety in laser-assisted Otolaryngology procedures.

Methods: First, this article reviews the background of laser surgery in Otolaryngology and the consequent risk of surgical fire with resultant development of laser-resistant endotracheal tubes and commercial availability. Next, a review of claims and national database review of product failures related to previous laser-resistant endotracheal tubes is performed through the FDA MAUDE database. This includes an evaluation of cases: review of techniques in laser airway surgery including spontaneous ventilation, decreased O_2 concentration, currently available endotracheal tubes including "handmade" fixes for perceived safety risks, and determination of failure points for previous laser-resistant endotracheal tubes. Third, the paper reviews the requested features of an "ideal" laser-resistant endotracheal tube. Finally, the paper reviews failure testing from an initial, unsuccessful attempt at material development and the consequent development of alternative technologies that address failure points from previous endotracheal tubes and addresses requested features with a detailed analysis of FDA-approval required testing. Extensive lab testing of the new tube predicts a significant reduction of risk in vivo with inability to perforate the shaft or cuff of the tubes under standard working conditions.

Results: While no iteration of a laser-resistant endotracheal tube is entirely laser safe, advances in technology can improve the safety profile of these devices. The new tube contains a double cuff, a soft and flexible shaft to minimize laryngeal insertion trauma, a smooth external surface, a tight-to-shaft balloon, and methylene blue dye in the cuff to alert the user to inadvertent penetration. These characteristics were the most requested by laryngologists in the development of a new laser-resistant tube. The newest endotracheal tube brings the features most requested by Otolaryngologists in a laser-resistant tube, and improves the safety profile over previous tubes.

Conclusion: Development of a new endotracheal tube represents an advancement in safety for the Otolaryngologist in laser airway surgery. Understanding the previous history and the science behind surgical fire formation is essential in advancing safety for patients in the future.

Key Words: laser, otolaryngology, safety, surgical fire.

Level of Evidence: N/A

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INTRODUCTION

This paper aims to evaluate the history and background of laser-resistant endotracheal tube development, and describe our attempts to create a new laser-resistant tube that improves upon previously existing technologies.

BACKGROUND

Laser-assisted surgery remains one of the mainstays of laryngeal, airway, and head and neck surgery in Otolaryngology.[1] Unfortunately, with the utilization of lasers in the airway comes an increased risk of complications including scarring, stenosis, and the risk of surgical fires. In the United States, surgical fires occur with an estimated 600 incidents per year,[2] although this number may be an exaggeration of the actual rate of occurrence and the incidence is likely decreasing in response to

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increasing awareness and education around the issue.[3] More recent estimates from the Emergency Care Research Institute (ECRI) suggest that 90–100 surgical fires occur annually in the US, with 20 to 30 of these cases resulting in severe injury and 1 to 2 mortality events per year.[4] More than 90% of surgical fire cases occur in the head, neck, and upper chest area, leaving Otolaryngologists disproportionately at risk for this surgical complication.

For a fire to occur during surgery, three elements must be present in close proximity—an oxidizer, an ignition source, and a flammable fuel substrate to propagate the fire, commonly referred to as the "fire triangle" or "fire triad".[5] In laser surgery of the head and neck, one of the common fuels remains the endotracheal tube. With the inadvertent laser strike as the ignition source, the tube as the fuel, and the stream of oxygen as the oxidizer, the entire fire triad is at play.

Lasers remain a potent ignition source in Otolaryngology procedures. Previous literature found the highest incidence of surgical fires occurring during endoscopic airway surgery. In that paper, 27% of surgical fires occurred during endoscopic airway surgery; 96.3% of the endoscopic airway surgery fires had a laser as the ignition source, and endoscopic airway surgery was the most common surgery performed resulting in surgical fire.[6]

Frequently, an inadvertent laser strike against an endotracheal tube is a common source of fire, as it places all three elements of the fire triad in close proximity. Non-reinforced, "regular" endotracheal tubes made of polyvinyl chloride (PVC) provide little resistance against penetration by a CO_2 or KTP laser, allowing for easy ignition of a column of oxygen contained within the tube. One test of the non-reinforced PVC endotracheal tubes confirmed the ability to ignite a fire using a CO_2 laser at a setting of 5 W in as little as 1 s in the presence of 53% oxygen; even under 30% oxygen an ignition occurred with a non-sustained flame.[7] To mitigate this risk, traditionally Otolaryngologists and anesthesiologists have relied on marketed "laser safe" reinforced endotracheal tubes to reduce the risk of fire formation in laser-assisted surgery. Tests of the most popular metal-reinforced endotracheal tubes confirm the inability to ignite the tube at any power of a CO_2 laser or in any oxygen concentration, with the caveat that the distal tip of many commercially produced "laser safe" tubes are not reinforced; therefore, still at risk of ignition of an inadvertent laser strike at the distal tip of the endotracheal tube.

Shortly after the introduction of the CO_2 laser into the Otolaryngologist's arsenal in the early 1970s,[8] multiple laser-resistant endotracheal tubes were brought to market to reduce the risk of fire ignition secondary to inadvertent laser penetration of the tube. The Mallinckrodt Laser-Flex tube (Fig. 1) was introduced in 1987,[9] and the Medtronic Laser-Shield II (Fig. 2) was brought to market in 1990.[10] The Laser-Shield II (Fig. 2)

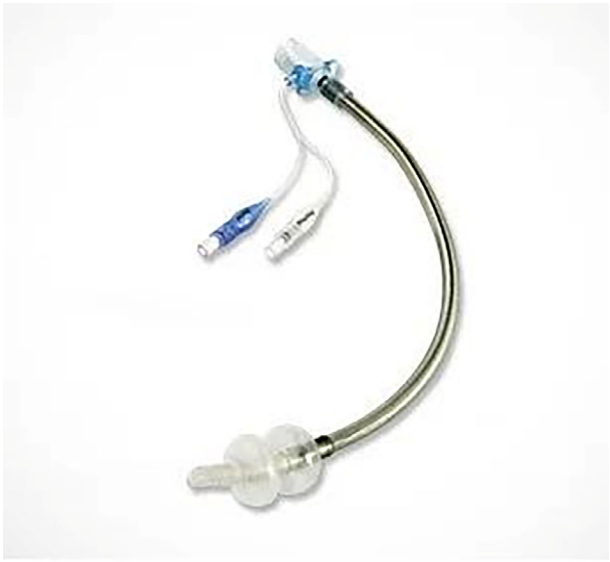

Fig. 1. Mallinckrodt LaserFlex endotracheal tube [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]

Fig. 2. Medtronic Laser shield II [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]

Fig. 3. Rusch lasertubus [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]

TABLE I.
Laser-Shield II Incidents Reported in MAUDE.

Complication	Fire Reported
Nasal synechiae	No
Cuff struck by laser with perforation	No
Cuff leak, cause unsure	No
Leak at inflation line	No
Cuff burst, dye causing laryngospasm	No
Laser strike to distal end of tube	Yes
Cuff struck by laser with perforation	Yes
Cuff struck by laser with perforation	No
Cuff leak, cause unsure	No
Tube combustion, likely laser strike	Yes
Laser strike to distal end of tube	Yes
Laser strike to distal end of tube	Yes

quickly became the market leader and the most utilized tube because of its ease of insertion without resultant tissue trauma, while the Laser-Flex tube (Fig. 1) was often criticized for its rough exterior texture and the resulting risk of laryngeal or airway trauma during tube placement. In 1995, the Rusch Lasertubus (Fig. 3) received FDA approval for use as a laser-resistant endotracheal tube[11] (see Table I). The Norton Laser endotracheal tube was considered to be entirely "laser proof' because it was manufactured from a spiral-wound, interlocking stainless steel and could be autoclaved. However, it lacked a cuff and is no longer manufactured.

The first iteration of the Medtronic Laser-Shield tube in early analyses suggested no significant increase in safety over the traditional PVC tubes against CO_2 laser ignition, and recommended hand-wrapping the tube with metallic foil as an alternative.[12] Studies of later iterations of the Laser-Shield II (Fig. 2) tube confirmed excellent resistance to penetration by the CO_2 laser along the tube above the cuff; however, multiple studies also confirmed vulnerability to penetration of the tube at the distal, non-reinforced tip of the tube, along with inadvertent penetration of the cuff balloon.[13] For undisclosed reasons, the Laser-Shield II tube (Fig. 2) was removed from the commercial market in 2016, shortly after a negligence lawsuit was filed, during which they were not found negligent or held liable for damages. (In the case of Anderson vs. Paugh, Schatz, Medtronic, and Central Washington Health Services, Medtronic was determined by the jury to be not negligent and was not held liable for damages.[14]) Currently, while multiple options for reinforced endotracheal tubes exist on the market, discomfort around the materials, ease of insertion, and potential for local tissue trauma to the larynx have become pitfalls of the available options.

When surgical fires occur, the resultant complications can be devastating. Multiple mortalities have been reported, typically as a result of airway fires during laser airway surgery or tracheostomy. Operating room fires represented a third of legal claims during monitored anesthesia care (MAC) cases.[15] In one review from the early 2000s, malpractice claim payments to plaintiffs after a surgical fire averaged $71,345 with the maximum payment noted to be $321,323.[16] However, more recent liability verdicts in 2013 have resulted in payments of over $30,000,000 for airway fires resulting in massive facial burns or death, suggesting that malpractice

TABLE II.
Laser-Flex Incidents Reported in MAUDE.

Complication	Fire Reported
Cuff failed to deflate	No
Cuff failed to inflate	No
Cuff failed to inflate or deflate	No
Tracheal injury from cuff inflation	No
Laryngeal injury from textured exterior of tube	No
Laryngeal injury from textured exterior of tube	No
Tube connector not removable	No
Laryngeal injury from textured exterior of tube	No
Tube could not be placed because of stiffness	No
Tube could not be removed	No
Tracheal injury from textured exterior of tube	No
Tube could not be placed because of stiffness	No
Cuff failed to deflate	No
Device noted to have air leak	No
Laryngeal injury from textured exterior of tube	No
Tube could not be placed because of stiffness	No
Tube could not be placed because of stiffness	No
Tube could not be placed because of stiffness	No
Cuff failed to inflate	No
Cuff failed to deflate	No
Cuff burst during procedure	No
Laryngeal injury from textured exterior of tube	No
Cuff failed to inflate	No
Device noted to have air leak	No
Cuff leak	No
Cuff burst during procedure	Yes
Laryngeal injury from textured exterior of tube	No
Tube could not be removed	No
Device noted to have air leak	No
Tube could not be removed	No
Airway fire, exact cause not described	Yes
Cuff burst during procedure	No
Cuff failed to inflate or deflate	No
Cuff noted to be broken before use	No
Cuff failed to deflate	No
Cuff burst during procedure	No
Cuff failed to inflate	No
Cuff failed to inflate	No
Cuff burst during procedure	No
Tube failed, unable to ventilate	No
Cuff burst during procedure	No
Device noted to have air leak	No
Tube could not be placed because of stiffness	No
Cuff burst during procedure	Yes

verdicts associated with this type of complication are increasing with time. With laser-assisted endoscopic airway surgery being reported as one of the highest risks of surgical fire formation for Otolaryngology patients, enhancing safety for laser airway surgery by improving the available laser-resistant endotracheal tubes is paramount to improve patient safety.

MAUDE ANALYSIS

An analysis of the FDA Manufacturer And User Device Experience (MAUDE) database was performed to evaluate surgical fires that occurred with laser-resistant endotracheal tubes. The MAUDE database is a self-reported repository of device failures, and it is likely not a comprehensive analysis of previous incidents involving laser-resistant endotracheal tubes. Incidents may be filed by anyone who was involved in a device failure or witness to an incident; the database is narrative. The likely cause of each incident and outcome was logged by analyzing each individual report of failure by device. Unfortunately, as this is a self-initiated database report, the author cannot identify for each case who filed the report.

1. MAUDE incidents involving the Laser-Shield II (Fig. 2; Search terms "laser shield, Laser-Shield and Laser-Shield"). A total of 12 reports were located in MAUDE; 5 of these described a surgical fire occurring during laser procedures (Table I)
2. MAUDE incidents involving the Mallinckrodt Laser-Flex (Fig. 1; search terms: "Laser Flex", "Laser-Flex", "Laser-Flex". "Mallinckrodt" term searched but filtered to only include those indicating specific use of the laser tube, and "regular" non-reinforced Mallinckrodt tubes were removed from the list): seven injuries related to trauma from the textured exterior of tube. A total of three surgical fires were reported in the database. At least eight incidents noted of difficulty inserting or removing the tube secondary to stiffness of the tube. (Table II)
3. Rusch Lasertubus (search terms "Lasertubus", Rusch Laser"): 76 reports of issues with laser tube kinking, twisting, or laser coating coming off of ETT surface, along with 26 reports of problems with cuff inflation or deflation. One incident of tube balloon causing injury to trachea with tracheal rupture was reported. No cases of surgical fire were reported.

USE OF THE LASER IN OTOLARYNGOLOGY

Ever since Otolaryngologists added it to their surgical arsenal in the early 1970s,[17] the laser remains most popular within laryngeal microsurgery,[18] and remains a staple for transoral microsurgery for head and neck cancer,[19] airway surgery in both adults and children,[20,21] and has expanded to include ear surgery, sinus surgery, and facial plastic and reconstructive surgery. Laser surgery has significant advantages in precision of dissection, hemostasis, and controllable parameters of depth of penetration, and time of energy delivery and mode. The adaptation of new laser wavelengths has allowed even more specific applications for different types of lesions and tissues. However, laser heat poses risks to soft tissues, and potentially to patients. Laser heat produces scarring and damage to adjacent soft tissues other than the area of dissection,[22,23] but more concerning is the possibility of the laser causing burns to unwanted areas, or worse, serving as the ignition source for a surgical fire.

Initial reports of laser-ignited surgical fires begin almost as early as the advent of lasers in Otolaryngology surgery.[24,25] Unfortunately, even as the judicious use of laser technology has advanced, isolated case reports of laser-ignited fires persist in our field and many others.[26,27] While numerous case reports continue to appear in the literature, surgical fires are not always brought to light in the medical literature for reasons of malpractice protection. As many surgical fire malpractice cases are settled out of court with strict non-disclosure agreements, many of these legal cases also do not appear in searches of legal databases as a legal ruling was not brought through the court system. However, some of the largest malpractice settlements around surgical fire remain from laser-related cases in Otolaryngology. The author of this article has reviewed litigation surrounding laser-ignited fires in Otolaryngology, and some of the largest lawsuits in Otolaryngology have been related to severe morbidity and mortality from these incidents.

PREVENTION OF LASER-RELATED FIRES IN OTOLARYNGOLOGY

Much has been written about the prevention of surgical fires. As all three elements of the "fire triad" are required to ignite a surgical fire, removal of one arm of the triad significantly reduces the risk of fire. While it is described that removal of the ignition source can entirely eliminate the risk of surgical fire, they have been reported even in minimally oxygen-enriched environments. Both intrinsic and extrinsic fuels exist during any surgical procedure, making it impossible to eliminate this arm of the triad.

Prior to starting any surgical case, it is recommended that a "fire time-out" be performed as a part of any preoperative checklist. A standardized system such as the Silverstein Fire Risk Assessment Tool, as utilized in the Christiana Health System, is often useful to identify high-risk procedures to all team members before initiation of surgery[28] (Fig. 4). Attention to removal of one or more arms of the fire triad will significantly reduce the risk of fire. As this relates to laser fires in Otolaryngology, decreased FiO_2 likely reduces the risk of fire formation in mechanical models,[29] as this is reducing the oxidizer arm of the fire triangle. The Joint Commission, ECRI, and the Anesthesia Patient Safety Foundation have all agreed that reduction of FiO_2 to levels of 30% or less is preferable, and that any procedure requiring 30% FiO_2 or higher should utilize a closed oxygen delivery system (endotracheal intubation or an LMA), instead of an open system (nasal cannula or face mask) which is reserved for FiO_2 30% or lower. Minimizing oxygen concentration seems to provide a margin of improvement in safety to reduce the risk of fire formation,

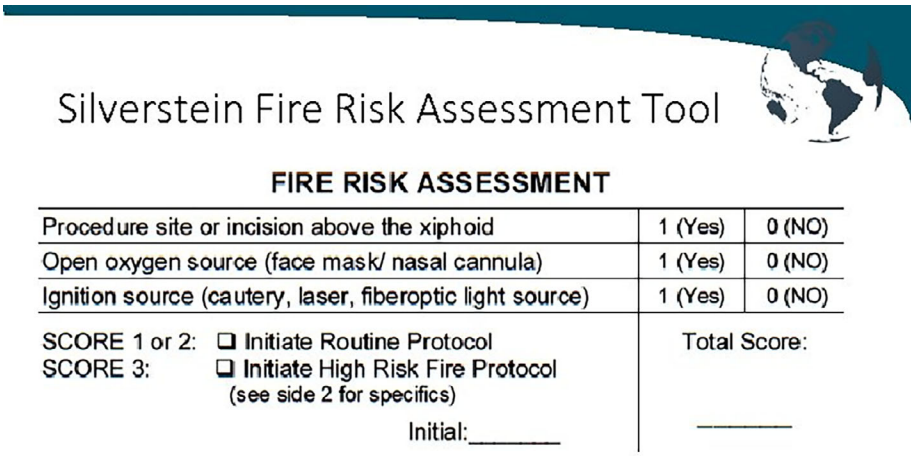

Fig. 4. Silverstein Fire Risk Assessment Tool, as utilised by Christiana Care Health System [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]

and surgical cases involving an ignition source should always be performed at the minimum O_2 necessary to keep the patient safe and oxygenated. Because elimination of supplemental oxygenation entirely in Otolaryngologic surgery is impractical, attention to minimizing risk becomes paramount.

Similarly, elimination of potential ignition sources dramatically decreases the risk of fire in otolaryngology surgery. Typically, the two most common ignition sources reported include electrosurgical devices and lasers. In one review, lasers represented the ignition source in 97% of airway and endoscopic laryngeal surgical fires.[6] Elimination of ignition sources and use of non-igniting instrumentation only (cold steel instruments) likely reduces or eliminates the risk of surgical fires associated with endoscopic airway surgery.

Finally, modification of the "fuel" arm of the fire triad can have a significant impact on the development of fire formation. Multiple fuel sources exist in laryngeal and airway surgery; potential fuel sources can be both intrinsic (e.g., fat, muscle, soft tissue) and extrinsic (e.g., oxygen tubing, towels, drapes, and pledgets). However, the most common fuel source in laser airway surgery remains the endotracheal tube, as it both contains the oxidizer (oxygen flowing through the tube) and is directly exposed to an inadvertent strike from the laser-based ignition source. While utilization of laser-resistant endotracheal tubes may reduce the risk of laser ignition, all previous laser-resistant tubes were vulnerable to cuff explosion or ignition of the distal tip of the tube when inadvertently struck by a laser. With pure oxygen flowing out the distal end of the endotracheal tube, ignition in this location creates a column of fire colloquially referred to as a "blowtorch effect".

Numerous cases of fire ignition have been reported from cuff explosion due to inadvertent laser strikes; for this reason, double-cuffed tubes are often utilized to provide a second layer of protection so that if the proximal cuff is damaged by laser ignition, the distal cuff remains intact and separates the distal airway and the vulnerable tip of the endotracheal tube from the proximal laser strike. Cuff disruption is certainly thought to be associated with the ignition of fire in endoscopic laser surgery.[30] Cuff integrity represents an important aspect of prevention of surgical fires by minimizing oxygen concentrations in the hypopharynx; however, surgical fires have even been reported in cases where the cuff was thought to remain intact.[31] Utilization of wet pledgets on the cuff, while once thought to provide an additional layer of protection to the ETT cuff, can dry out and easily become another potential flammable fuel as the pledgets are made of cotton and thus combustible.[32] Eliminating the use of an endotracheal tube through the use of spontaneous ventilation, jet ventilation, or apneic anesthetic techniques during suspension laryngoscopy may reduce the risk of fire formation, but comes with the difficulties associated with spontaneous ventilation and Total IntraVenous Anesthetic (TIVA) technique.

Finally, handmade "one-off" solutions have been adapted to try to compensate for perceived failings of previously available laser safe endotracheal tubes. However, hand-wrapped tubes, initially utilized in the 1980s, have been abandoned in favor of commercially available tubes which have more consistency in production and quality. Hand-wrapped tubes and use of rubber tubes are not recommended by the FDA in laser cases, since their ability to consistently prevent fire ignition is largely unknown.

FEATURES OF THE IDEAL LASER-RESISTANT TUBE

Due to the relatively recent removal of the single-cuff, metal-reinforced Laser-Shield II tube (Fig. 2) from the market, the Otolaryngology community has found itself in a difficult situation where the most desirable features in an endotracheal tube, which makes it ideal for mitigation of fire risk in laser airway cases, are not available. In 2016, Friedman and colleagues delivered an online questionnaire to members of the American Broncho-Esophagological Association and American Head and Neck Society.[8] From this study, numerous desirable characteristics of laser-resistant endotracheal tubes were quantified; respondents favored endotracheal tubes that were soft and flexible, had a smooth external surface, and had a deflated balloon that remained tight to the shaft. All three of these characteristics were present in the Laser-Shield II (Fig. 2), likely explaining its popularity as the most commonly used laser-resistant tube. After the removal of the Laser-Shield II tube from the market, the Mallinckrodt Laser-Flex tube (Fig. 1) became the most popular remaining option; however, the Laser-Flex tube had only one of the less-requested desired characteristics in that it had a double-cuffed design, so that a distal cuff serves as a second layer of protection in the case of an inadvertent proximal cuff penetration.

From this, Friedman described that the ideal laser-resistant endotracheal tube would have the following characteristics: (1) soft and flexible tube to minimize trauma to the larynx during insertion, (2) smooth surface to prevent laryngeal trauma and ease in positioning of the laryngoscope, (3) contain a tight-to-shaft balloon, (4) maintain a double cuff design, and (5) have a preloaded, color dye in the cuff. To date, no laser-resistant tube has provided all five of these elements. Review of the MAUDE database, as noted above, contains multiple reports of laryngeal injury from tube placement and characteristics of the tube, along with numerous cases of balloon malfunction coupled with inadvertent fire formation from cuff explosion in a single-cuff design.

Current and previously available laser-resistant tubes all have some advantages and some significant disadvantages.[33] Some of these are listed in Table III.

DEVELOPMENT OF A NEW LASER-RESISTANT ENDOTRACHEAL TUBE

Phase I (Development): Testing of a New, Compound Material

With the goal in mind of reaching as many desirable characteristics in a new laser-resistant endotracheal tube as possible, the author and manufacturing team approached the design of a new endotracheal tube. The first attempt centered around the development of an endotracheal tube from new, previously untested composite materials. Traditional endotracheal tubes and previous laser-resistant tubes have relied on Polyvinylchloride (PVC) tubing as a base, while the Laser-Shield II tube (Fig. 2) used a silicon base wrapped with aluminum. The CO_2 laser easily penetrates PVC tubing and has been shown to penetrate the non-reinforced distal tip of a Laser-Shield II tube within 5 s.[7,12] PVC is a plastic material, while silicone is a rubber material. Non-reinforced PVC material is highly combustible when in the presence of an oxidizer, but it may occasionally be used safely under stringent conditions to prevent ignition.[34,35] However, because of its high combustibility, PVC is not recommended for use in the presence of any oxidizer and laser ignition source.

In contrast, silicone is a rubber material, which is softer and more pliable than PVC, although PVC may soften when placed in the airway after the material warms. Silicone tubes may be easier for laryngeal placement because of their pliability,[36] however, this same pliability may also increase the risk of occlusion of the lumen of the endotracheal tube if the tube becomes kinked or bent.[37] Silicone rubber has an ignition temperature over 315°C while PVC is known to ignite at less than 149°C. However, while silicone may be more resistant to laser penetration, it still remains penetrable under standard testing conditions. Metal reinforcement by wrapped

TABLE III.
Advantages and Disadvantages of Previously Available Laser-Resistant Endotracheal Tubes.

Tube	Advantages	Disadvantages	Fire Reduction Strategy
Laser-Flex	Metal external wrap nonflammable; resistant to kinking or occlusion	May cause external tissue trauma from corrugated metal on external surface; distal tip is exposed PVC which could result in ignition	Metal wrap around tube
Laser-Shield II	Tape wrapping over metal smoother for placement and decreased external tissue trauma	Single cuff design; laser strike of the Teflon tape results in exposed metal which may reflect laser beam; distal tip is susceptible to ignition	Tape layer over metal tubing
Lasertubus	Rubber is partially resistant to laser penetration; metal wrapping and double cuff design	Rubber still penetrable with laser; absorbent sponge covering may be ignited if dried out	Rubber layer over metal to add two layers of protection
Laser-shielding tube	Thicker cuff to increase resistance to laser puncture	Non-reinforced silicone rubber, can be penetrated by CO_2 laser	Rubber is impregnated with ceramic to decrease risk of penetration
Norton laser endotracheal tube	Considered to be only true "laser proof" tube; spiral metal contains no combustible materials; reusable	Cuffless design could allow for ignition of column of oxygen; tube is no longer produced in any manner	Spiral metal with no ignitable materials

aluminum as traditionally found in laser-resistant tubes protects the underlying silicone material from laser penetration, but inadvertent reflection of the laser beam off metal may cause surrounding tissue damage from laser reflection.

Rather than reinforcing a traditional PVC with aluminum metal wrapping as in a traditional laser-resistant tube, we developed a compound material that contained both aluminum and silicone. Ideally, this would provide the maximal benefit to patients in providing laser resistance (aluminum) with minimal reflectivity (matted material), while simultaneously avoiding the unprotected rough external metal wrapping of the Laser-Flex tube (Fig. 1), often described as a "laryngeal cheese grater" causing localized tissue trauma, due to the corrugated surface of the tube created by the wrapping tape.

To create the compounded material, raw silicone was obtained in powdered form, which is maintained in a canister. To utilize silicone in its commonly accepted forms, the powder is mixed with an acetone-like solution, which creates a dough-like consistency of pure silicone material when dried. (This is the type of silicone traditionally seen in silicone caulking material, which can be spread and molded). The dough-like material is mixed with aluminum powder and then formed into a sheet, which can then be molded into a tube or any other shape of compounded material. The composition was created by weight (50/50 or 25/75 silicone/aluminum ratio). Interestingly, at concentrations of 85% aluminum by weight, the outer layer of the material would peel when shaped into tube-like form; therefore, 75% was determined to be the maximum aluminum weight that could be reasonably utilized.

Initial trials began with three compounded materials; a standard 100% silicone material as a baseline, a composite of 50% silicone by weight and 50% aluminum by weight, and a composite of 25% silicone and 75% aluminum by weight, using the same emulsifiers. The CO_2 laser (OmniGuide) with attached Helium-Neon beam was activated directly into a sheet of the composite material initially at settings of 5, 10, 20, and 25 W for time intervals of 15, 30, and 60 s. The diffuser remained at a constant focus throughout testing, distance from the tip of the laser to the material was standardized to 3 cm, and the laser was activated in continuous mode to emulate worst-case circumstances, as ultrapulse or interval firing of CO_2 lasers may decrease surrounding thermal damage. Paper underneath the composite material served as a marker to determine if complete laser penetration of the compound material occurred. If a positive test occurred (complete penetrance through the compound material) the test was completed. A validated thermal scanner (Fluke 279 FC True-rms, Fluke Biomedical Corporation) was calibrated and used to scan the temperature of the material at the location of the laser strike.

Initial testing began with a noncompounded 100% silicone material. Findings are noted in Table IV. As expected, higher laser wattages resulted in complete penetrance of the material in as little as 10 s. Of note, the 5-watt laser setting resulted in no penetrance of silicone material even after 60 s, further confirming that a silicone-based material is likely preferable to a PVC material alone in laser resistibility as determined from previous generation silicone-based tubes like the LaserShield. However, complete penetration occurred in as little as 10 s at higher laser settings of 25 W.

Next, the composite material of 50% silicone, 50% aluminum by weight was tested under the same circumstances. Findings are noted in Table V. With this composite material, again no penetration was noted at lower laser settings. Penetration of the material still occurred at higher CO_2 settings, although the presence of the aluminum compound seems to add some additional protection, requiring longer times to completely penetrate the material.

Finally, the composite material of 25% silicone and 75% aluminum by weight was tested using the same methodology. Findings are noted in Table VI. With this composite, penetrance still occurred at higher laser wattages. Notably, penetrance occurred slightly quicker than at a 50/50 mix, but still at longer times than in 100%

TABLE IV.
100% Silicone Material Mix Tested Against CO_2 Laser.

100% Silicone	Time	Penetrance	Max Temp	Notes
5 W				
	30 s	No	93	
	60 s	No	139	
10 W				
	30 s	No	94	
	60 s	No	110	
20 W				
	30 s	Yes	89	Penetrance at 15 s
	60 s	Deferred	—	
25 W				
	30 s	Yes	158	Penetrance at 10 s
	60 s	Deferred	—	

TABLE V.
50%/50% Silicone/Aluminum Material Mix Tested Against CO_2 Laser.

50/50 Silicone/ Aluminum	Time	Penetrance	Max Temp	Notes
5 W				
	30 s	No	96	
	60 s	No	148	
10 W				
	30 s	No	114	
	60 s	No	161	
20 W				
	30 s	Yes	138	Penetrance at 22 s
	60 s	Deferred	—	
25 W				
	30 s	Yes	117	Penetrance at 18 s
	60 s	Deferred	—	

TABLE VI.
25%/75% Silicone/Aluminum Material Mix Tested Against CO_2 Laser.

25/75 Silicone/ Aluminum	Time	Penetrance	Max Temp	Notes
5 W				
	30 s	Deferred		
	60 s	Deferred		
10 W				
	30 s	Deferred		
	60 s	Deferred		
20 W				
	30 s	Yes	188	Penetrance at 20 s
	60 s	Deferred	—	
25 W				
	30 s	Yes	432	Penetrance at 15 s
	60 s	Deferred	—	

silicone material. Additionally, the temperature readings were markedly higher with this composite than other compound ratios, likely related to the increased heat associated with laser striking aluminum and heating the predominant metal component. The heat generation may also explain the quicker times to complete penetration of this composite.

As with the initial Laser-Shield tube made of silicone impregnated with aluminum powder (which predated the Laser-Shield II and was eventually removed from the market),[38] the composite material would cause charring and became very hot when a CO_2 laser was applied for extended lengths beyond 30 seconds. Furthermore, the material could be penetrated with a CO_2 laser set at 25 W within 30 s. While 30 s of direct laser application is unlikely in any real-world surgical application, the risk of unpredicted laser penetration with subsequent ignition was too great for the use of the compounded silicone/aluminum materials to have any practical applicability (see Fig. 5).

Additionally, with the composition of increased aluminum, sparking was noted from laser contact which served as a visible warning that the material was being struck by the laser. This type of visible spark could, in theory, provide an additional mechanism of protection by creating "visual feedback" to alert the surgeon that the laser was striking the tube instead of the desired tissue. While this might have some practical utility, the presence of visible sparking combined with the ability to penetrate the tube at higher laser settings provided enough concern that the decision was made to abandon the idea of fashioning the compounded silicone/aluminum material in favor of a differing design. Additionally, to extrude silicone/aluminum compound into the shape of a tube requires an emulsifier. When the emulsifier was added to higher concentrations of aluminum, it was noted that there were gaps between the aluminum particles that were filled with the emulsifier. When heated, this caused the aluminum particles to separate, allowing the laser beam to easily pass through the tube material through obvious 'cracks' in the tubing. This leaves open the possibility of tube failure, which would be entirely unacceptable from a patient safety standpoint.

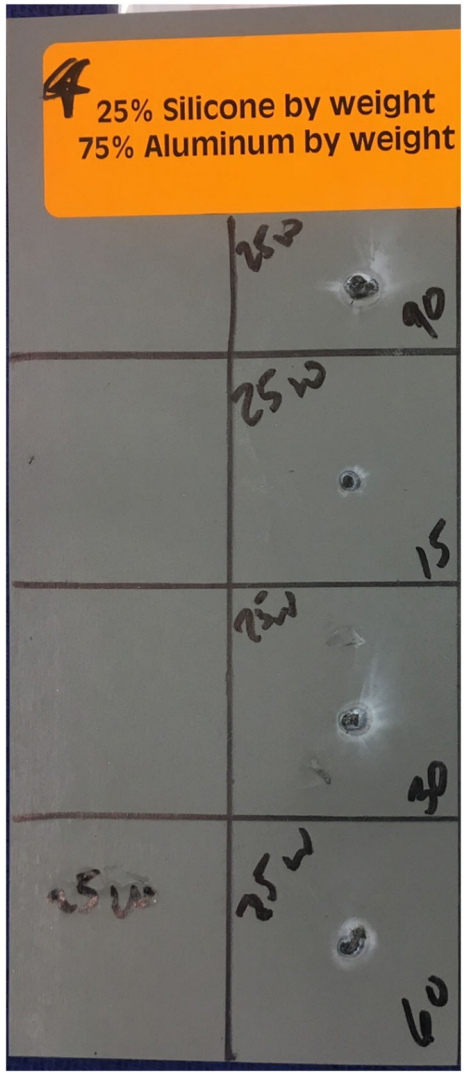

Fig. 5. Penetration of 25/75 silicone aluminum mix by CO_2 laser [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]

Phase II (Development): Feature Improvements Over Previous Endotracheal Tubes

The decision was made to try to incorporate suggestions of qualities of the ideal laser-safe endotracheal tubes identified by the survey of the ABEA and AHNS on existing or previously existing tube models. Specifically, multiple points about previous tubes were addressed:

1. The decision was made to utilize a silicone tube rather than PVC. Previous testing of PVC tubes confirmed easy penetration of PVC tubing within 1 s, while penetration of silicon material at the distal tip of the previous Laser-Shield II (Fig. 2) took at least 5 s in other tests.[32] Furthermore, testing of our 100% silicone material in Phase I of these trials suggested that pure

silicone material as a base could provide longer delays before the tube was penetrated when compared to previous testing of PVC materials. The expectation was that using silicone instead of PVC might provide an additional margin of safety by extending the length of time of an inadvertent laser strike before tube penetration occurred. Additionally, because PVC is a stiffer material, and previous literature suggests increased difficulty with tube insertion (intubation) using stiffer materials, silicone may allow for less traumatic tube insertion.

2. Metal wrapping reinforcement: Because pure silicone tubes are still highly penetrable to laser strikes, the decision was made to provide reinforced metal wrapping. Two advancements were considered for aluminum metal wrapping of the silicon tube over previous iterations of tubes.
   a. This iteration of the tube was completely wrapped the entire length of the tube, *including* the distal tip of the tube (distal to the inflatable balloons). This eliminates the risk of ignition of the distal tip of the endotracheal tube from an inadvertent laser strike if the cuff is deflated as noted in the Laser-Shield II (Fig. 2).
   b. The metal wrap overlaps itself on each pass around the tube, which prevents any gap through which a laser could penetrate the tube regardless of any angle, bending or twisting of the tube. The thickness of the aluminum metal wrap is 0.001 cm.
3. Double cuff design: meeting the desired characteristics noted by Friedman et al, the tube has a double cuff design, allowing for a second distal protective cuff to remain in place and inflated if the proximal cuff is inadvertently violated, reducing the risk of ignition of a distal column of oxygen in the trachea below the tip of the endotracheal tube.
4. Methylene blue dye is placed in both cuffs, to alert the surgeon if one or both cuffs are violated.
5. Silicone covering over the metal wrap to protect the aluminum tape and maintain a smooth outer surface of the endotracheal tube.
6. Cuff made of silicone to decrease the likelihood of ignition from an inadvertent hit from the laser.

Phase III (Testing): Safety Testing of the New Endotracheal Tube

Laser safety testing. The newly designed endotracheal tube (Fig. 6) with the characteristics described above was tested under rigorous conditions in line with FDA requirements for a 510 k application. For an initial positive control test, a non-reinforced "regular" PVC endotracheal tube known to be non-resistant to laser energy was struck directly with a CO_2 laser and a KTP laser held 1 cm from the tube at settings of 20 and 10 W respectively, while 100% oxygen was piped through the tubes. Both of these tests resulted in ignition with sustained flame formation in under 2 s. A negative control was tested by using the Laser-Shield II tube (Fig. 2); using both the CO_2 laser at 60 W and the KTP at 15 W on the shaft of the tube containing 100% oxygen resulted in no ignition after 5 min of laser firing. The distal tip was not tested, as this has resulted in positive ignition by multiple other authors. In both of these trials, no ignition was noted after 5 min of continuous direct laser irradiation.

Next, the newly designed tube was tested under standardized conditions, utilizing both the CO_2 laser and KTP lasers held at standardized distances from the shaft of the tube. In addition, the distal tip and cuff balloons were tested with the balloons inflated with saline as in standard use. With the CO_2 laser, no ignition could be created even with the laser set to a maximum of 60 W at neither the shaft nor distal tip in the presence of 100% oxygen at high flow levels. With the KTP laser no ignition occurred at the maximum 15 W tested at both locations. (Tables VII and VIII).

However, the cuff balloons were susceptible to perforation with both CO_2 and KTP lasers. It has long been known that filling a cuff with an aqueous solution instead of air reduces the combustibility of involved materials because water serves as a "heat sink" which can rapidly absorb and conduct localized heat away from the area of a laser impact. This prevents the cuff wall from reaching an ignition temperature, thus allowing additional time

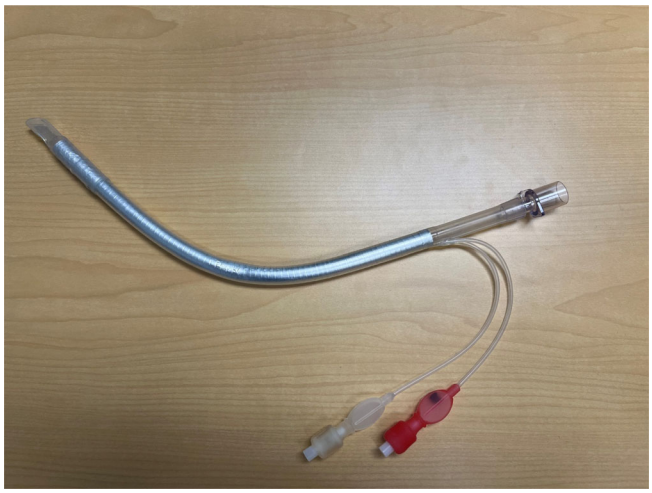

Fig. 6. New endotracheal tube after production [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]

TABLE VII.
CO_2 Laser Tested Against New Tube Design.

CO_2 Laser	Wattage 5 W	10 W	20 W	60 W
1 s	Negative	Negative	Negative	Negative
5 s	Negative	Negative	Negative	Negative
10 s	Negative	Negative	Negative	Negative
1 min	Negative	Negative	Negative	Negative
5 min	Negative	Negative	Negative	Negative

TABLE VIII.
KTP Laser Tested Against New Tube Design.

KTP Laser	Wattage 5 W	10 W	15 W
1 s	Negative	Negative	Negative
5 s	Negative	Negative	Negative
10 s	Negative	Negative	Negative
1 min	Negative	Negative	Negative
5 min	Negative	Negative	Negative

before a cuff is perforated if it is inadvertently struck with a laser. If a saline-filled cuff is inadvertently perforated, it releases a stream of solution that can both cool and extinguish potential combustion.[39] In our trials, the CO_2 laser fired at the balloon in a saline-filled area provided significant slowdown of perforation, but an air bubble in the saline which rises to the top of the balloon (anteriorly, when the tube is placed in anatomic position) could be burst with the laser quickly if the beam is pointed directly at the air bubble. It is recommended that the cuff contain as little air as possible, as saline in the cuff appears to be protective against cuff penetration from the laser.

Electrosurgical device testing. Because modern transoral surgical procedures often involve the use of electrosurgical devices in close proximity with endotracheal tubes (e.g., tonsillectomy, transoral cancer resection), fire risk remains whenever electrocautery can penetrate an endotracheal tube in the presence of supplemental oxygen. To test this, a standard non-reinforced PVC endotracheal tube was anchored to a chicken breast which was grounded to a ForceFX electrosurgical generator (ValleyLab, Boulder CO). At a setting of 15 W in Monopolar Coagulate mode, the tube was penetrated within 5 s and fire could be produced when 100% oxygen was flowing through the endotracheal tube at 5 L/min. Contact with organic tissue (chicken) facilitates penetration of the endotracheal tube. Similarly, the balloon of the non-reinforced endotracheal tube penetrated easily with electrocautery.

With the newly designed, reinforced endotracheal tube in the same conditions, no penetration could be made into the lumen of the tube in neither Coagulate nor Cut modes for both "fulgurate" and "spray" modes for coagulation (medium and high), and no fire could be created. Similarly, no penetration of the balloon was possible on the silicone tube, suggesting that silicone provides an additional element of protection against electrosurgical contact resulting in inadvertent surgical fires.

Heat dissipation testing. Heat production tests were utilized using a standard thermal probe (Fluke 279 FC) to test the temperature of the device and reflect the degrees of possible tissue damage that may occur from heating of the tube with the laser. The experimental tube exhibited a temperature increase to 51.0°C after direct, continuous CO_2 laser strike for up to 60 s at 60 W, with an average of 47.7°C maximum temperature after

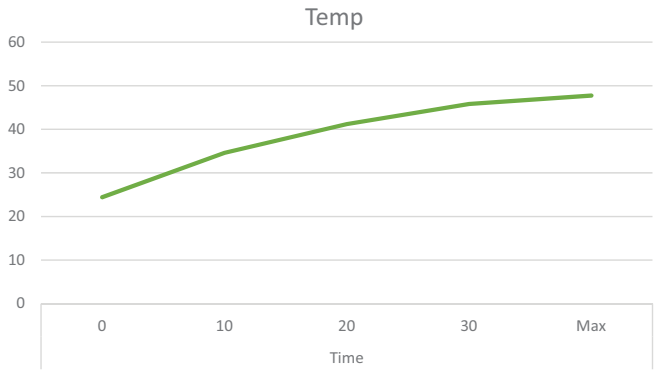

Fig. 7. CO_2 Laser at 60 W, temperature of experimental tube over time of exposure [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]

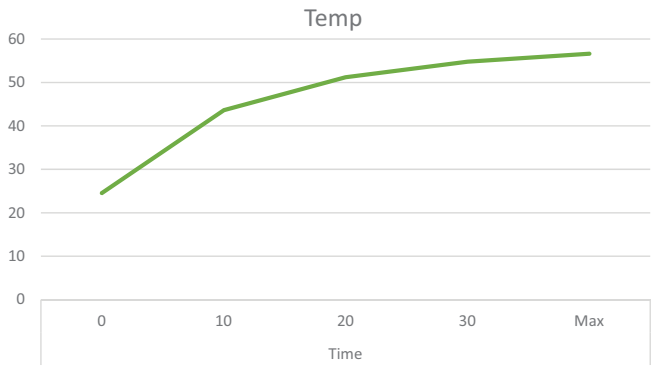

Fig. 8. KTP Laser at 15 W, temperature of experimental tube over time of exposure [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]

5 trials (Fig. 7). This was compared to the same testing performed in the Laser-Shield II instructions for use (IFU) where the temperature increase on the surface is 43.2°C. Similarly, the KTP laser showed an average observed temperature increase of 56.6°C (maximum 59.9), comparable to the Laser-Shield II (Fig. 8).

Finally, both lasers were fired directly at both the experimental tube and the Laser-Shield II tube to assess temperature over time, with temperature assessed at 30-s intervals up to 5 min. Notably, the experimental tube ran on average 20°C warmer than the Laser-Shield II tube with CO_2 (Fig. 9), but about the same as the KTP (Fig. 10), suggesting that the CO_2 absorption into silicone may result in warmer temperatures. None of the testing circumstances resulted in ignition, however, and both lasers resulted in tube temperatures below the 80°C temperature often thought to result in direct tissue damage.

This testing of the experimental tube allows for some limited conclusions. First, the new tube is able to withstand high-wattage laser strikes (that are likely unrealistic in any pertinent clinical scenario) without ignition, even in the presence of high oxygen. This maintains the standard of the previously available Laser-Shield II tube (Fig. 2), suggesting that the new tube would be able to withstand a similar laser strike without increased risk of ignition. Additionally, the temperatures of the tube, even

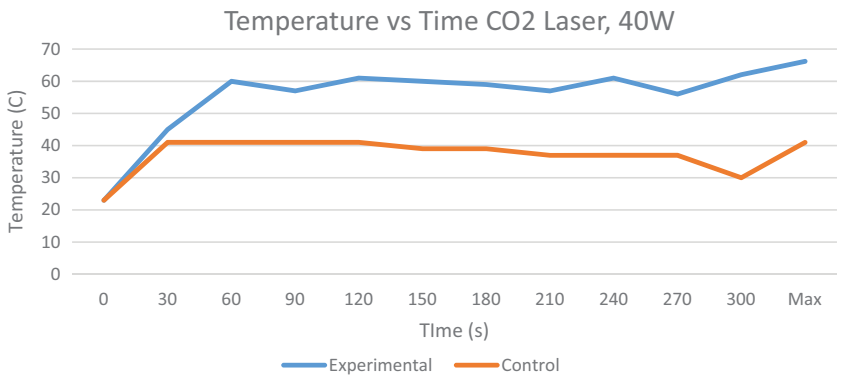

Fig. 9. CO_2 laser at 40 W against new tube (experimental) versus control tube (Laser-Shield II) [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]

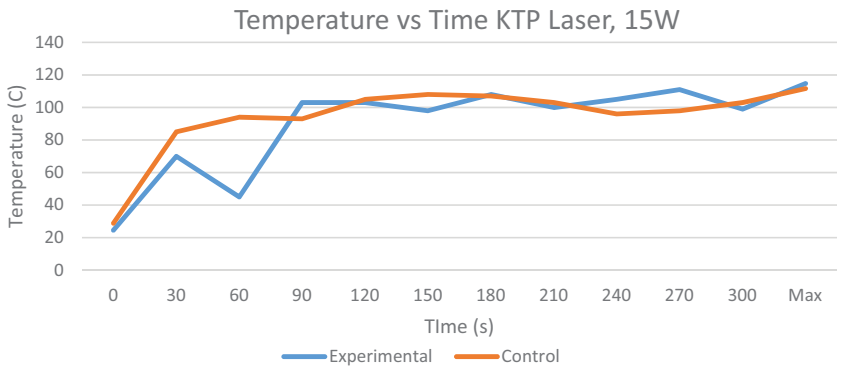

Fig. 10. KTP laser at 15 W against new tube (experimental) versus control tube (Laser-Shield II) [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]

at high-wattage and long-duration laser strikes, remain similar to the Laser-Shield II. Finally, while saline inflation of the cuff does significantly reduce the risk of laser strike perforation, it is not entirely protective, as an air bubble in the inflated cuff will still perforate easily if struck by a laser. However, with a double cuff design and dual balloons inflated with methylene blue dye, the surgeon will have an additional layer of safety before distal oxygen is released to the proximal airway secondary to a single cuff perforation.

The new endotracheal tube is available through the manufacturer at a cost that is slightly lower than the market cost of the LaserShield II when it was commercially available. The tube described here provides advantages over previous laser-resistant tubes including a double cuff design, silicone material that is more pliable, easier to insert, and more resistant to laser penetration than PVC, and fully reinforced to prevent inadvertent ignition at the tip of the tube. The author believes that this tube represents an advancement over other commercially available tubes, in particular by removing the "cheese grater" design of the Mallinckrodt laser tube and a higher margin of safety over other available tubes, as described above.

As noted, however, there is no singular tube that can completely eliminate the risk of operating room fire during laser surgery. Like all other tubes, the new endotracheal tube has limitations and drawbacks. While the double-cuff design reduces the risk of ignition by adding a second layer of protection, the same laser strike that deflates the proximal balloon could deflate the distal balloon, resulting in ignition. While the cost of the endotracheal tube at market is similar or slightly lower than the cost of the LaserShield II, it is more expensive than a non-laser-resistant endotracheal tube. Finally, no mechanical device can remove human factors including incorrect usage of the tube in violation of the instructions for use or use of exceptionally high FiO_2 concentrations during surgery. These drawbacks should be considered whenever choosing a tube or technique for laser airway surgery.

CONCLUSION

Surgical fires remain a vexing problem that occurs disproportionately in Otolaryngology, as Otolaryngology procedures around the head, face, oral cavity, airway, neck, and upper chest bring all three elements of the "fire triangle" into close proximity——an oxidizer, a flammable fuel substrate, and an ignition source. Laser surgery of the airway, oral cavity, and oropharynx remains one of the highest risks for surgical fire formation, as the laser is a potent ignition source. Removal or reduction of one arm of the fire triangle may reduce the risk of fire formation. Although a decrease in oxygen concentration decreases the

oxidizer in the field and the removal of an ignition source will reduce arms of the fire triad, endotracheal tubes have remained a dangerous flammable fuel when inadvertently struck by a laser. Additionally, while numerous previous endotracheal tubes have been available in the marketplace for reduction of laser fires, an entirely "laser-safe" tube does not currently exist. Instead, laser-resistant tubes have provided a risk reduction for laser fires by utilizing a metal composition or metal wrapping, and the use of double-cuffed tubes. These changes are an improvement over the discontinued Laser Shield II in two specific ways: (1) accounting for human error through the use of the double cuff, and (2) wrapping the distal tip with the metal wrapping to eliminate the common occurrence of the distal tip catching fire. Using previously published data on the most desired characteristics for a laser-resistant tube, we describe both a failed attempt at a new composite material around which to build a new tube, and a successful tube construction that integrates the desired characteristics and shows significant technological advances in patient safety against inadvertent laser-ignited surgical fires.

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