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# Advances in Translaryngeal Tube Technology

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## ■ Introduction

Intubation of the trachea with a cuffed tube can be performed by the translaryngeal route (endotracheal tube) or through a tracheal stoma (tracheostomy tube). Tracheal intubation by one of these routes is the only way to simultaneously provide a secure airway, ventilatory support, and convenient access to the trachea. Unfortunately, the presence of an artificial airway bypasses many of the patient's natural defenses and so increases the chances of upper and lower airway colonization, aspiration, and infection [1]. Sedatives, analgesics or muscle relaxants may be required to improve tolerance of the airway; this risks cardiovascular, respiratory and neuromuscular complications. It is, therefore, desirable to avoid the use of artificial airways, for example, by using facemask oxygen or an external airway interface to achieve non-invasive ventilation (NIV). Indeed it has become clear that NIV as opposed to tracheal intubation can reduce morbidity and mortality in the critically ill. When an artificial airway is required it is the responsibility of both the medical devices industry and the clinician to minimize the complications consequent to its use.

The major complications directly related to the artificial airway in the critically ill are:

1. Airway colonization – risk of ventilator-associated pneumonia (VAP)
2. Airway injury – risk of laryngeal and tracheal pathology.
3. Tube occlusion – risk of hypoxemia, hypercapnea, and sudden death.

The design and quality of care of the artificial airway is critical in preventing these complications.

## ■ Endotracheal Tubes

### Physiological Impact of the Endotracheal Tube

The curvature of stiff polyvinyl chloride (PVC) endotracheal tubes causes pressure injuries at the contact points of the palate, posterior larynx, the cricoid cartilage, and the trachea at the level of the cuff and the tube tip [2]. Regurgitation of bile and gastric secretions may exacerbate these injuries and delay healing [3]. This mucosal injury predisposes to bacterial adhesion [1]. As well as providing a physical barrier to mucus clearance, endotracheal intubation can reduce tracheal mucus velocity [4] and prevents effective cough by preventing cord opposition and by increasing the need for sedation or muscle relaxation. The universal problem of aspiration past (high-volume low-pressure) cuffs [5–7] leads to rapid tracheal colonization [8].

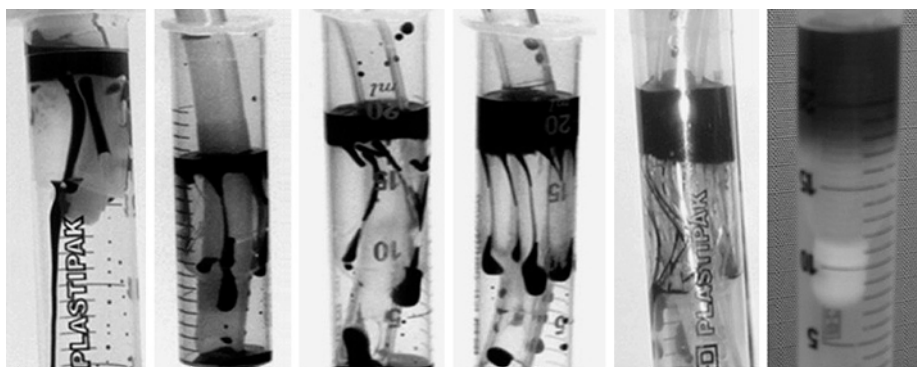
Pneumonia results if the nature of aspirated material and the pathogenicity of bacteria within it are sufficient to overcome lung defenses [1]. Feldman and co-workers investigated the sequence of colonization [9] beginning with the oropharynx after 1–2 days, followed by the stomach, then the lower respiratory tract (2–4 days), and thereafter the endotracheal tube. Bacteria within secretions attached to the tube lumen are protected from systemic antibiotics and are propelled into the lung by the shear forces of gas flow and by the passing of tracheal suction catheters [10]. Tube blockage with secretions is common [11] and may be delayed in larger bore tubes compared with smaller tubes. Larger internal diameter tubes produce a lower airway resistance but at the expense of more erosions of the laryngeal inlet and increased patient discomfort.

### Securing the Tube

A multicenter Spanish Study showed an 8% incidence of unplanned extubation, and accidental extubation carried a relative risk of 5.3 for the development of VAP [12]. Although endotracheal tubes are commonly secured using adhesive tape or cloth ties, commercial devices are available and provide more effective tube fixation [13, 14].

### Cuff Types

The large diameter high-volume low-pressure cuff has been the standard in intensive care for nearly 40 years. There is no tension within the wall of an inflated high-volume low-pressure cuff and so all the intra-cuff pressure is transmitted to the tracheal wall, enabling easy monitoring of the tracheal wall pressure by direct measurement. High-volume low-pressure cuffs reduce the incidence of associated tracheal injury compared with low-volume high-pressure cuffs [15]. Unfortunately there is an inherent design fault with these high-volume low-pressure cuffs in that they allow pulmonary aspiration to occur even when correctly inflated (Fig. 1) [5, 6, 16]. The rate of aspiration, however, is reduced with thinner cuff wall material and if unintentional falls in cuff pressure are prevented [6, 17].



**Fig. 1.** Left: Five high-volume low-pressure cuffs manufactured of material of decreasing thickness from left to right all inflated to 30 cmH<sub>2</sub>O. Note channels in folds within cuff walls increase in size with cuff material thickness. All high-volume low-pressure cuffs permit leakage. Far right: silicone LoTrach cuff prevents leakage because there are no folds.

## ■ Preventing Iatrogenic Injury From Endotracheal Tubes

### Preventing Aspiration

Aspiration past the inflated tracheal tube cuff is commonplace in the ICU by the mechanism described above. Most intubated critically ill tube-fed patients aspirate gastric contents; using tracheal pepsin as a marker, aspiration was identified in 89% of patients and those who aspirate frequently are 4 times more likely to have pneumonia develop than those who aspirate infrequently [18]. Preventing gastric overdistension, attention to patient position, avoiding patient transport, oral hygiene, and maintaining adequate cuff pressures have all been used in an attempt to limit regurgitation and aspiration [8]. Tube [19] and cuff [7, 20, 21] technologies have been developed to reduce aspiration.

### Preventing Mechanical Injury

Measures include control of tracheal wall pressure, using smaller external diameter tubes, appropriately supporting circuit connecting equipment, and maintaining good oral hygiene to reduce chemically damaging material [3]. Tracheal wall pressure should be routinely monitored and controlled at 20–30 cmH<sub>2</sub>O in all intubated patients in the intensive care unit (ICU). This reduces the late complication of tracheal stenosis related to high intracuff pressures and also reduces the quantity of tracheobronchial soiling related to low intracuff pressures. Tracheal tube design should ensure that the tube is flexible enough to fit the patient's anatomy with minimal pressure points at the level of the palate, arytenoids, cords, or trachea at the level of the tube tip.

### ■ Cuff Pressure Control

Surveys show that cuff pressure is not routinely monitored in many ICUs [22–24], leading to inappropriately high cuff pressures [25] and causing tracheal injury [26]. Too low a cuff pressure is also an important problem due to an increased rate of aspiration [6, 27] and an intracuff pressure persistently less than 20 cmH<sub>2</sub>O has been shown to be associated with the development of pneumonia within the first 8 days of mechanical ventilation (relative risk = 4) [17].

### Manual Inflators

The most common technique used for cuff pressure regulation is intermittent measurement and adjustment with a handheld cuff inflator/manometer. Temporary loss of cuff pressure can occur when measurement technique is poor. Manual cuff pressure inflators differ in bias and precision [28]. The compressible volume within the device will cause a fall in cuff pressure as soon as the pilot valve is connected. Manufacturers should keep the compressible volume to a minimum. Accidental depression of the deflation button on the inflator can also occur when inexpertly used.

### Lanz Balloon

The Lanz inflation balloon is an integral component of a brand of tracheal tube and has been available for nearly 30 years. This is an ingenious constant pressure balloon

combined with a pressure-regulating valve and protected in a PVC sleeve. The device maintains the cuff pressure in the desirable range preventing over- and under-inflation. It is surprising that this is not more widely used by clinicians as concerns regarding over- and under-inflation are eliminated.

### **Foam Cuffs**

A foam-filled high-volume low-pressure cuff [29] is also available. Air is aspirated prior to use, and after intubation of the trachea the pilot channel is opened allowing the cuff to inflate under the force of the expanding foam maintaining continuous inflation. Aspiration can still occur by the same mechanism as with conventional cuffs [6].

### **Electronic Cuff Pressure Controllers**

These are available to maintain cuff pressure in the desirable range but they are costly. The Tracoe cuff pressure controller ([www.tracoe.com](http://www.tracoe.com)) is a portable electrical device with a battery back-up designed to attach to the pilot valve of a tracheal tube and maintain the cuff pressure at a value set by the operator. An audible alarm detects unintentional disconnections and battery power failure. There are two potential disadvantages of this device. First, if the tube is unintentionally withdrawn into the larynx the device will further inflate the cuff preventing re-intubation (until the situation is recognized, the cuff deflated, and the tube re-positioned). Second, the inflator has a standard luer-locking connector. If this is accidentally misconnected to an intravenous line then a fatal air embolus will occur. A simple modification of the luer valve prevents attachment to an intravenous connector but allows connection to the tracheal tube connector.

## **■ Subglottic Secretion Drainage Tubes**

The Mallinckrodt HiLo Evac endotracheal tube has a dorsal port above the cuff designed to allow suctioning of secretions from the subglottic space to reduce the volume available for pulmonary aspiration. Studies show a reduction in pneumonia rates (particularly early onset VAP). A meta-analysis of five studies with a total of 896 patients showed subglottic secretion drainage reduced the incidence of VAP by a half [19]. There was a shortened duration of mechanical ventilation (2 days), length of ICU stay (3 days), and a delay in the onset of pneumonia (7 days). There are, however, some major disadvantages with this tube. The port of the HiLo EVAC tube is prone to blockage. This is most commonly due to the application of suctioning to a closed space allowing the tracheal mucosa to be drawn into the suction channel opening. Unfortunately, animal studies have shown that continuous suctioning causes tracheal injury even at lower negative pressures [30]. Therefore, only intermittent and not continuous suctioning can be recommended. This is likely to reduce pulmonary aspiration but will not eliminate it as aspiration past the cuff will be possible between episodes of subglottic secretion drainage. The incorporation of the subglottic port into the wall of the tube increases the rigidity of the tube. The death of a patient due to erosion of the stiff tip into the tracheal wall causing perforation and innominate artery fistula development has been reported [31] and tube displacement during ventilation has also been attributed to this stiffness [32].

## ■ New Technologies and Future Advances

The key initial steps in the pathogenesis of VAP that can be influenced by the design of the artificial airway are:

1. Colonization proximal to the cuff (the stomach, sinuses, dentition, oropharynx, larynx, and subglottis)
2. Aspiration of this microbial laden fluid past the tracheal tube cuff
3. Biofilm accumulation
4. Security of airway (avoidance of unintentional extubation)

Simple pragmatic measures such as hand washing, upper airway decontamination, and the reduction of aspiration by means of semi-recumbency and control of gastric volumes are currently the mainstay of defense against VAP. Recently researchers have turned their attention on improving the function of the simple tracheal tube by improvements in design.

### Antimicrobial Coating of Tracheal Tubes

Both antiseptic [33] and silver [34] coated endotracheal tubes have recently been evaluated in animal studies with regard to biofilm and pneumonia prevention. Berra and colleagues [33] investigated bacterial colonization of the ventilator circuit, the tube, and the lungs with a silver-sulfadiazine and chlorhexidine coated endotracheal tube in a sheep model. Coated endotracheal tubes had less biofilm and the ventilator circuits were protected from colonization. There was no difference in tracheal colonization. This is not surprising as coating of the tube lumen may reduce biofilm progression and re-inoculation of the tracheobronchial tree but will not prevent upper airway colonization and aspiration. Similarly Olson and co-workers reported the effect of using silver hydrogel coated endotracheal tubes on the lung bacterial burden of mechanically ventilated dogs challenged with buccal administration of *Pseudomonas aeruginosa* [34]. The silver coating delayed the appearance of bacteria on the inner surface of the endotracheal tube and the bacterial burden and inflammation in the lung was reduced. A recent prospective, randomized, single-blind, multiple-center study using a silver-coated endotracheal tube in 149 patients showed a reduced colonization rate and decreased bacterial burden but failed to demonstrate a reduction in the incidence of VAP [35]. These tubes can only impact on the incidence of VAP by reduction in bacterial burden but will not prevent aspiration of upper airway material past the cuff.

### Modification to the Hi-Lo Evac Tube

This tube has recently been modified to bring the dorsal opening closer to the cuff and to increase the luminal cross-section [36]. This is an attempt to address the common problem of the subglottic port becoming blocked by in-drawing of the tracheal mucosa.

### Tracheostomy Tubes with Subglottic Ports

Tracheostomy tubes are now also available with subglottic ports allowing intermittent suctioning. This is likely to offer advantages related to a reduction in aspiration. Logically one should perform subglottic aspiration prior to times when aspiration

past the cuff is likely, such as before tracheal suctioning, circuit disconnections, deflations of the cuff, or the loss of positive end-expiratory pressure (PEEP) [6].

### Mucus Shaver

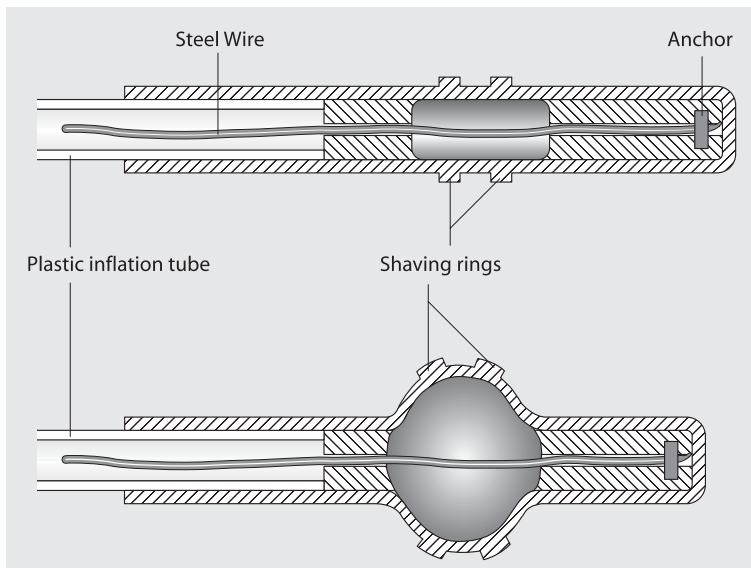
This is an experimental inflatable silicone rubber 'razor' designed to pass down an endotracheal tube and shave the endotracheal tube lumen free of mucus [37]. Regular use was associated with reduced accumulation of mucus/secretion and bacterial growth within the endotracheal tube during mechanical ventilation in a sheep model [38] (Fig. 2).

### Mucus Slurper

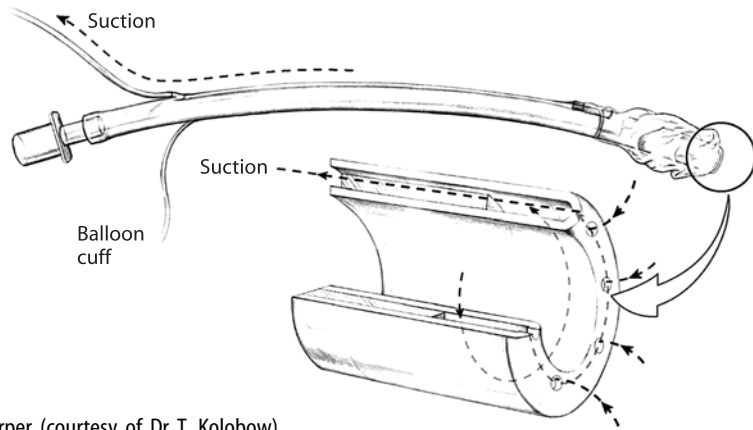
To reduce the build up of mucus within the endotracheal tube, Kolobow and co-workers have developed a prototype tracheal tube with an integral mucus aspirator ring at the distal tip [39], connected to a suction source. Preliminary studies in six mechanically ventilated sheep have shown that the mucus slurper reduced secretion accumulation within the endotracheal tube compared with a conventional tube and open suctioning. Human studies are awaited (Fig. 3).

### Thin-walled Cuffs

Cuffs made of thicker material have larger channels within the folds in the cuff wall, and, therefore, a more rapid rate of aspiration [6] (Fig.1). Innovative manufacturers are utilizing this effect in an attempt to reduce aspiration. (e.g., Seal Guard and Microcuff). These cuffs are made of very thin, yet robust material. Dullenkopf and co-workers have recently introduced the Microcuff endotracheal tube (Microcuff



**Fig. 2.** Mucus shaver. Above deflated, below inflated (courtesy of Dr T. Kolobow).



**Fig. 3.** Mucus slurper (courtesy of Dr T. Kolobow).

PET, Weinheim, Germany) [40], a thin polyurethane cuff that is likely to reduce the rate of subglottic to tracheal leakage. These appear particularly useful in pediatric practice where very low intracuff pressures are possible [40]. There are currently no clinical trials with outcomes of aspiration, lung injury, or infection.

### Kolobow Tube

Theodor Kolobow and colleagues have designed an ultrathin-walled, non-kinking, crush proof, wire reinforced tube with an oropharyngeal-section diameter larger than the diameter of the tracheal section, to reduce airway resistance. The tube has no cuff, but instead airway seal is achieved at the level of the glottis through a no-pressure seal made of 'gills'. The gills are made of numerous soft, pliable, rings of polyurethane to occlude voids for potential air leaks from within the larynx. This tube has been extensively tested in animal models and in this setting has been shown to provide an effective airway seal and to prevent aspiration of oropharyngeal indicator dye. These tubes are not currently commercially available (Fig. 4).

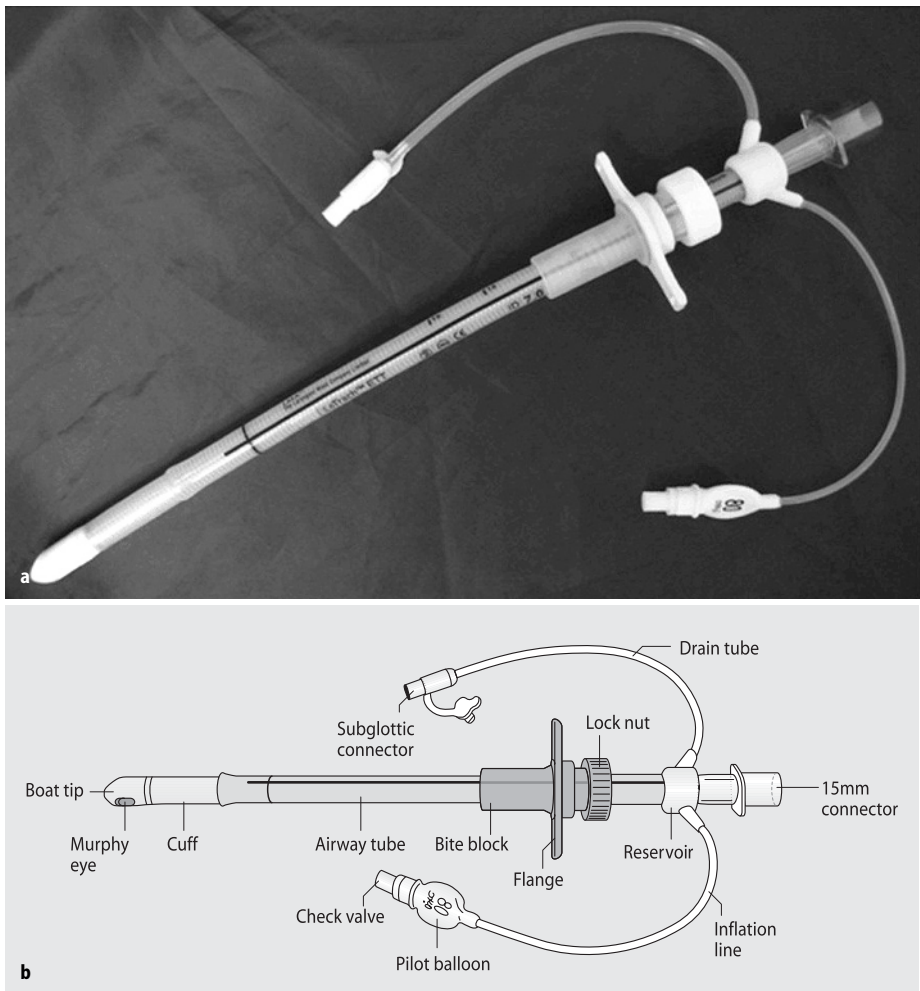
### LoTrach Tube

The LoTrach endotracheal and tracheostomy tube [7] ([www.LoTrach.com](http://www.LoTrach.com)) has been designed to reduce the risk factors associated with upper airway colonization, aspiration, and tracheal wall pressure control (Fig. 5).

**Low-volume low-pressure cuff:** The cuff is calibrated during the manufacturing process such that at a single working intracuff pressure the tracheal wall pressure is



**Fig. 4.** Kolobow's ultrathin walled 'gilled' tube (courtesy of Dr T. Kolobow).



**Fig. 5.** (a) LoTrach tube; (b) Diagram of LoTrach Tube

kept at a desirable level of 20–30 cmH<sub>2</sub>O [7]. There are no folds within the cuff wall to allow fluid to pass and leakage is prevented in a model trachea, in anesthetized patients, and in the critically ill mechanically ventilated patient [7]. To maintain inflation, the LoTrach can be used with either a constant pressure inflation device or with regular careful monitoring and correction of pressure using a manual manometer/inflator device.

**Subglottic ports:** The LoTrach tube has three integral fine bore subglottic ports which open distally in a position on three quadrants of the circumference of the tube immediately above the cuff. This provides maximum clearance of subglottic secretions independent of the geometry of the tube. The three ports join to one to allow intermittent suctioning with a standard syringe.



**Upper airway cleansing:** Despite best nursing care, it is impossible to provide adequate oral, pharyngeal, and laryngeal hygiene due to difficulty with access. This can lead to colonization. Because the low-volume low-pressure cuff completely prevents leakage, the subglottic ports can be used to irrigate the upper airway. Normal saline can be injected into the subglottis (taking care not to increase the subglottic pressure to over 30cmH<sub>2</sub>O). The fluid refluxes through the laryngeal inlet and into the oral and/or nasal cavity carrying secretions with it. A suction catheter at the anterior oral cavity and/or nares is used to remove the effluent. Between 50 ml and 500 ml is typically required to remove all the offensive material and irrigations are normally performed 1–3 times daily.

## ■ Conclusion

Aspiration is the pivotal step in the development of VAP [8, 41], the most common cause of nosocomial mortality in the ICU [42]. Conventional, low cost, high-volume low-pressure cuffed tubes do not stop the ubiquitous problem of aspiration in the critically ill [18]. New technologies should address aspiration and also the multiple other factors implicated in the pathogenesis of VAP. Critical care specialists and hospital administrators need to understand the impact of VAP in terms of mortality (doubled), length of stay (increased by 6 days), and cost [43]. A conventional tracheal tube costs less than a dollar to produce, whereas newer technologies cost considerably more. Price is, therefore, a barrier to the introduction of new devices into routine practice and this inhibits the development of this technology by the industry. However, in their recent editorial in *Critical Care Medicine*, Drs Shorr and Wunderink state “even marginally beneficial preventative interventions are likely to yield significant net savings” [44]. The justification for investment in prevention is easy, each episode of VAP costs \$10,000 [43], and so, if a preventative measure were estimated to reduce the VAP rate by just 2% (e.g., a fall in incidence from 20% to 18%), then it would be logical to invest \$200 per patient to gain clinical benefits whilst remaining cost neutral.

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