Anesthesiology
81:1061–1067, 1994


# *Design and Development of Ultrathin-walled, Nonkinking Endotracheal Tubes of a New "No-pressure" Laryngeal Seal Design*

## *A Preliminary Report*

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***Background:*** **Endotracheal tubes (ETTs) of conventional design and manufacture greatly increase the air-flow resistance of the upper airways. This increase in upper-airway resistance can lead to a significant increase in the work of breathing and may necessitate the use of assisted mechanical ventilation. Current ETTs are relatively stiff and contribute greatly to patient discomfort. The inflatable cuffs now mounted onto the ETTs function well in short-term use but impart significant morbidity when used over longer periods. These issues were addressed by the designing of a low-resistance ETT.**

***Methods:*** **Using new techniques, we developed ultrathin-walled, wire reinforced ETTs of conventional configuration and ETTs the oropharyngeal-section diameter of which was a few millimeters larger than the diameter of the tracheal section. The wall thickness was a constant 0.20 mm. The wire reinforcement was stainless steel flat wire or superelastic nickel–titanium alloy. The superelastic nickel–titanium alloy reinforcement made those ETTs crush-proof; after forceful manual compression, recovery was complete. To obtain a seal with the upper airways, we first shaped a short section of the oropharyngeal section of the ETT from round to oval (or egg-shaped) to conform better to the larynx. We then attached to this segment numerous soft, pliable, 0.025–0.075-mm-thick rings of polyurethane to occlude voids for potential air leaks from within the larynx.**

***Results:*** ***In vitro*** **pressure–flow studies showed a decrease by as much as four- or fivefold in air-flow resistance in the adult ETT range, effectively increasing the internal diameter by 2.3–3.7 mm, compared with conventional ETTs of the same outside diameter.** ***In vivo*** **studies for 24 h in sheep showed no air leaks at airway pressures to 30 $cmH_2O$ and minimal leak at greater pressures. The gross appearance of the trachea was normal.**

***Conclusions:*** **Although the new tubes appear to offer advantages to those currently used, testing in humans is required to assess the clinical utility of the tube-cuff design. (Key words: Equipment: cuffs; endotracheal tubes.)**

CRITICAL components of the endotracheal tube (ETT), as we know it today, were introduced by Trendelenburg as early as 1871 with the development of an inflatable cuff at the end of a rigid ETT[1]; and by Magill with the introduction of rubber tubes at the end of World War I, in 1917.[2] By 1964, the polyvinyl chloride ETT with an integral inflatable cuff became commercially available; it now predominates in all adult clinical applications, with little variation among manufacturers.[3]

Patient treatment during mechanical ventilation may be confounded by many factors. Some modes of ventilatory support, such as continuous positive airway pressure, intermittent mandatory ventilation, and other forms of assisted ventilation, all aim to increase reliance on the patient's spontaneous efforts. Previous studies have clearly shown that the added burden imposed by breathing circuits, and in particular the burden imposed by the ETTs, results in a net increase in resistive load and hence an increased work of breathing.[4] Often this results in a delay or an inability to separate the patient from mechanical ventilator. By the same token, the original decision to institute controlled or assisted ventilation may have been prompted by the increased resistive load following tracheal intubation; whereas such decision could have been avoided or delayed if an ETT of greatly reduced airway resistance had been available.

Using a new technology, we have produced an ultrathin-walled (UT), wire-reinforced ETT having a resistance to gas flow nearly equal to that of the upper airway of a normal subject. By using a special superelastic nickel–titanium shape-memory alloy (Nitinol, Fort

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Received from the Laboratory of Cell Biology, National Heart, Lung, and Blood Institute, National Institutes of Health, Bethesda, Maryland. Accepted for publication June 23, 1994.

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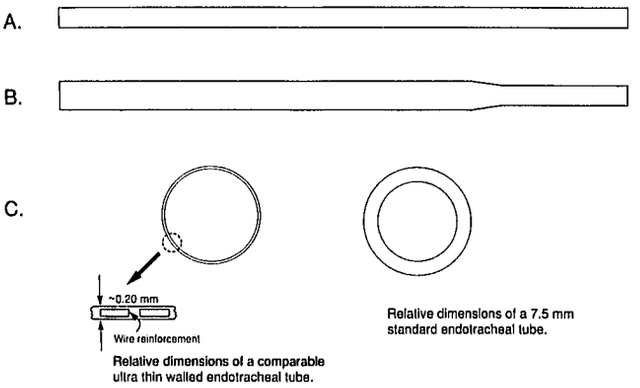


**Fig. 1. (*A*) The mandrel used to fabricate the ultrathin-walled endotracheal tube (UT ETT) is a straight rod coated with a release agent. (*B*) The mandrel used to fabricate the ultrathin-walled two-stage endotracheal tube (UTTS ETT) has a short, smaller (tracheal) section and a longer, larger oropharyngeal section. (*C*) Relative cross-sectional views of a 7.5-mm standard endotracheal tube (right) and UT ETT of the same outside diameter. The internal diameter of the UT ETT is increased by 2 mm by a great decrease in wall thickness.**

Wayne Metals, Fort Wayne, IN), the ETTs were made truly kink-proof, and crush resistant: after forceful squeezing of such ETT, and release of force, recovery of its original cross-sectional shape was invariably complete. This tube, to which was added a newly configured "cuff," was tested *in vitro* and *in vivo* to assess potential clinical usefulness.

## Materials and Methods

We fabricated UT, nonkinking ETTs by first machining a steel mandrel to the exact internal dimensions of the desired ETT. Some mandrels were of the same dimension throughout as in conventional ETT (UT ETT), and others included a short section of smaller diameter (to rest within the trachea) and gradually widened at 2° to a larger diameter for the oropharyngeal section (UT two-staged [UTTS] ETT) (fig. 1). The mandrel was placed in a rotating lathe and a solution of 15% polyurethane (Lycra) in dimethylacetamide was metered onto the rotating mandrel. After air drying, this yielded a layer of approximately 0.05 mm. We wound onto the mandrel a flat 0.1 × 0.5 mm, or 0.17 × 0.5-mm-wide ribbon of work-hardened stainless steel #304 spring wire at a pitch of 10 per centimeter. At times, more than one layer of polyurethane was deposited to attain enhanced stiffness of the finished ETT. In some tubes, we replaced the flat stainless steel wire with superelastic shape-memory alloy wire displaying pseudoelasticity at ambient temperatures (Nitinol, Fort Wayne Metals). The properties of the superelastic memory alloy allowed us to fabricate ETTs that were crush-proof: after forceful manual occlusion, recovery was complete. Next, we metered another layer of polymer solution, air dried, and then placed the mandrel in a circulating hot-air oven at 80°C for final cure. The total wall thickness, including wire reinforcement, was to be approximately 0.20 mm throughout the whole range of sizes of adult ETTs.

Following final cure the body of the ETT was removed from the mandrel. ETTs reinforced with stainless steel wire were then placed in a press, which shaped a 4–5-cm section of the second stage of the UTTS ETT (which was to rest within the larynx) in such manner that it became oval (or egg-shaped) in cross-sectional view (fig. 2); in this process, the lesser axis was reduced in width to the approximate outside diameter of the first stage of the UTTS ETT, while the greater axis was proportionately increased (figs. 2 and 3). It was the purpose of this design to shape the ETT to better conform to the approximate anatomical dimensions of the airway at the level of the vocal processes and the larynx rather than to adhere to the traditional round ETT design, that is, to shape the ETT so that it would better match the longer anteroposterior dimension of the glottic opening and be narrower in the transverse width. Following trimming and finishing operations, the ETTs were to be heat set to a desired curved configuration.

From 0.025- or 0.075-mm-thick soft, pliable polyurethane sheets a variable number (8–20) of ring-

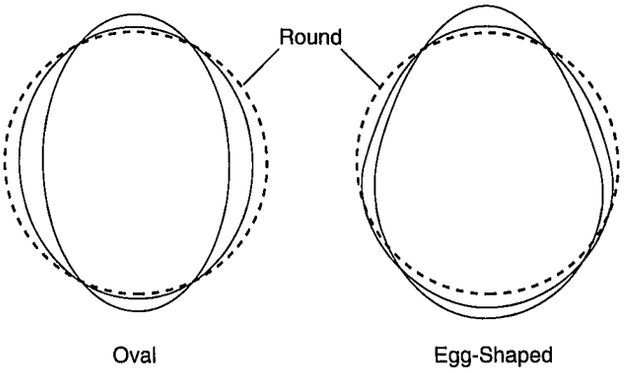


**Fig. 2. (*Left*) Conventional round standard endotracheal tube (dotted lines). By applying lateral force, the horizontal axis shortens while the vertical axis increases, generating an oval outline. (*Right*) The circle (dotted lines) is deformed to yield an egg-shaped outline.**

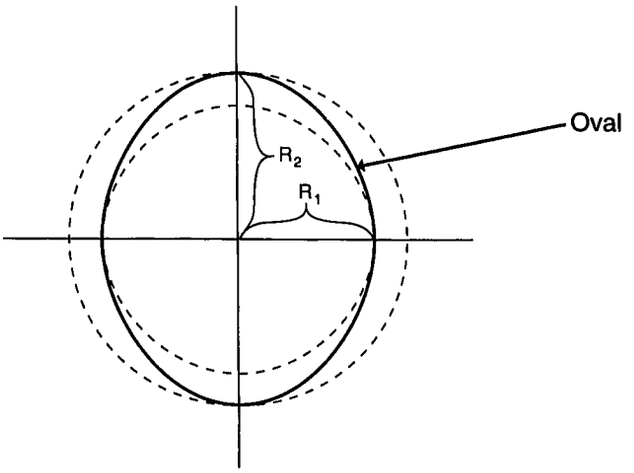


**Fig. 3. The oval outline (solid line) is confined within two circles (dotted lines) with a radius of $R_1$ (horizontal axis) and a radius $R_2$ (vertical axis).**

shaped discs ("gills"), were solvent cemented onto the oval (or egg-shaped) portion of the ETT. The external diameter of those gills was 50–100% larger than the outside diameter of the ETT. It was the purpose of those gills to provide in effect a "no-pressure" seal at the level of the glottic opening, to help reduce or eliminate possible air leaks from around the ETT (fig. 4). There were no gills or cuffs placed on the tracheal portion of the ETT.

*In vitro* pressure–flow studies were performed on ETTs of current design of various sizes; pressure–flow studies were also performed on standard, commercially available ETTs from various manufacturers (Sheridan, Mallinkrodt) (fig. 5). From pressure–flow curves it became possible to compute static air-flow resistance for all ETTs, at given air flow. Because the pressure–flow curves of commercially available ETTs did not differ much from manufacturer to manufacturer, they were listed as "standard ETTs." Because of great difference in wall thickness between standard ETTs and the new line of ETTs, it was pointless to equate the new line of ETTs by the internal diameters. Rather, we chose to equate our present line of ETTs with the same, or a hypothetical standard ETT (the "equivalent standard ETT") that had the same pressure–flow characteristics.

All animal studies had been approved by the Animal Care and Use Committee of the National Heart, Lung, and Blood Institute, National Institutes of Health, Bethesda, MD. After induction of anesthesia with pentobarbital, we intubated the trachea of six 26–28 kg

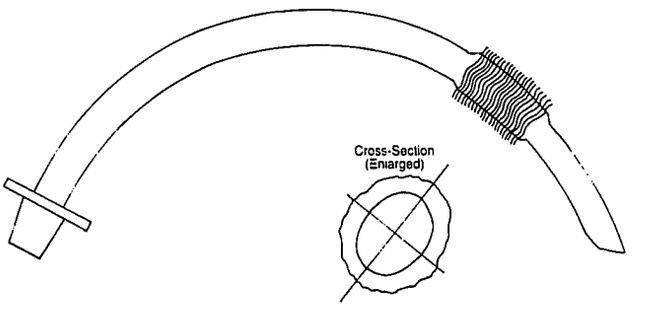


**Fig. 4. An ultrathin-walled two-stage endotracheal tube (UTTS ETT) with oval laryngeal section and "gills" attached. Cross section at the level of the gills.**

sheep with a commonly available hollow introducer, over which the UTTS ETT of above design readily glided into place. We carefully verified location and position of the oval (or egg-shaped) portion of the ETT by direct vision, and by roentgenographic films. The ETT was then secured to a bite block. The sheep were maintained under general anesthesia and paralysis using pentobarbital at 4 $mg \cdot kg^{-1} \cdot h^{-1}$ and pancuronium bromide at 0.06 $mg \cdot kg^{-1} \cdot h^{-1}$. The ETTs were connected to a Siemens 900 C Servo Ventilator, and the lungs were ventilated at a respiratory rate of 15/min, and an initial tidal volume (VT) of 8–10 ml/kg in the volume controlled mode. To achieve a greater peak inspiratory pressure (PIP), we increased VT so as to increase PIP in increments of 5 $cmH_2O$, up to a PIP of 50 $cmH_2O$. We then increased positive end-expiratory pressure to 5 and 10 $cmH_2O$, and repeated the studies. Air leak was computed from difference in inspiratory and expiratory tidal volumes, as read from the Servo Ventilator. Similar studies were also performed with a standard ETT of approximately same outside diameter,

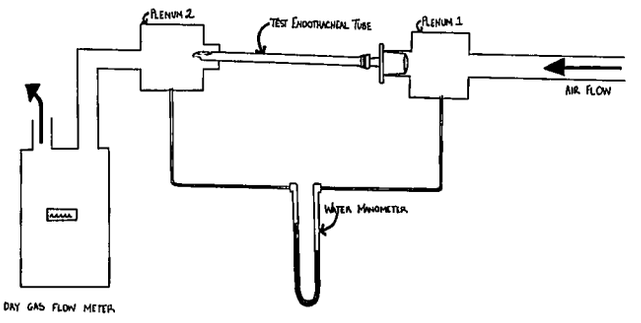


**Fig. 5. Experimental setup for pressure–flow studies. Plenum 1 and plenum 2 are chambers approximately 400 ml in volume.**

from which the cuff had been excised, or not inflated. The purpose of those studies was to assess air leak around a standard ETT of approximately same outside diameter at the level of the larynx, that is, at the narrowest portion of the upper airways, and without relying on the inflated cuff of the standard ETT for an airway seal.

In two separate studies, we maintained controlled ventilation for 24 h in healthy anesthetized sheep in whom the trachea had been intubated with UTTS ETT of appropriate dimensions for the size of the sheep. Following this, the sheep were killed with intravenous and potassium chloride. The trachea was carefully dissected, and the trachea and larynx were visually inspected.

## Results

The ETTs were highly flexible, could be acutely bent 180° (around a pencil for example) without kinking, and transmitted little torque on manual twisting; in other words, the ETTs were not rigid. The ETTs of this new design weighed approximately one third the weight of conventional polyvinyl chloride ETTs. On pressurization, there was some distension in the longitudinal direction but not radially: while the tube lengthened, its diameter did not change. This lengthening was a function of wall thickness, and ranged from 0.05 mm/cm$H_2O$ for a 30-cm ETT with a wall thickness of 0.2 mm to substantially less in ETTs with thicker walls.

While ETTs produced with stainless steel wire required moderate care to avoid damage, the ETTs reinforced with Nitinol wire were uniquely different, as they could be occluded by forceful finger pressure, for example, with full and complete recovery on release of pressure (fig. 6). In routine use, the ETTs were secured to a bite block.

The increase in internal diameter in the new line of UT and UTTS ETT was achieved solely on the basis of decrease in wall thickness (table 1). By virtue of a smaller wall thickness, we increased the internal diameter of a 7.5-mm conventional size ETT to 9.5 mm in the UT ETT tube, the outside diameter being the same (10.0 mm) (table 1). At a gas flows of 0.5–1 l/s, this amounted to a two- or threefold decrease in air-flow resistance (fig. 7). In the UTTS ETT, with the outside diameter of the tracheal portion of the UTTS ETT same as that of a standard 7.5-mm ETT, the pressure–flow curve was equal to an imputed 10.8-mm standard ETT (table 1 and fig. 7); at a gas flow of 0.5–1 l/s, this amounted to a four- or fivefold decrease in air-flow resistance.

When the UTTS ETT with and oval cross section (lesser-axis, outside diameter equivalent to that of a 8.7-mm conventional ETT and greater-axis, outside diameter equivalent to that of a 10.5-mm conventional ETT) (fig. 3), and attached gills at the level of the larynx was placed into the larynx of the sheep, there was no air leak at pressures to 30 cm$H_2O$, at positive end-expiratory pressure to 10 cm$H_2O$, in a 28-kg sheep; there was a minimum air leak starting at pressures 30–35 cm$H_2O$ (table 2). In comparison, there was a prohibitive air leak over 80% at any level of positive end-expiratory pressure when using a comparable conventional 9.0-mm ETT (outside diameter 12.0-mm), with the cuff removed or not inflated. Following 24 h of mechanical pulmonary ventilation with same UTTS ETT, there was no significant change in air leak from start of the studies.

The gross appearance of the excised trachea, glottis, and the vocal cords was normal. The UTTS ETT was well positioned and could be readily advanced or withdrawn with little force.

## Discussion

While the use of presently available commercial ETTs is unlikely to have major adverse effects in short-term

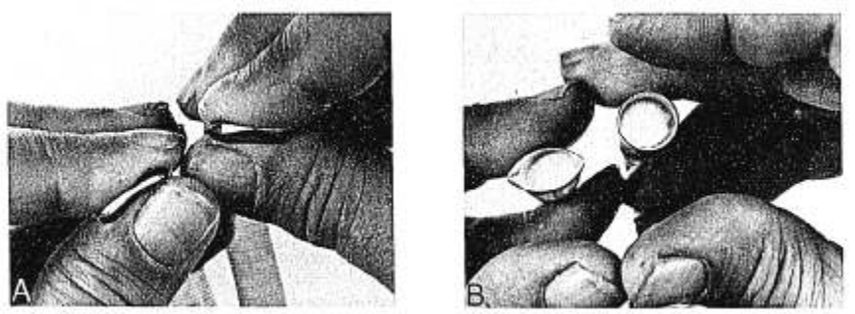


**Fig. 6. (*A*) Two ultrathin-walled endotracheal tubes of identical dimensions are forcefully pinched shut. Stainless steel wire–reinforced endotracheal tube (left); superelastic Nitinol wire–reinforced endotracheal tube (right). (*B*) After release of forceful finger pressure, there is significant bending of the stainless steel reinforcing wire (left); recovery of the superelastic Nitinol reinforced endotracheal tube is complete (right).**

**Table 1. Cross-sectional Dimensions of Standard, Ultrathin, and Ultrathin Two-stage Endotracheal Tubes of Same Length**

| Standard Endotracheal Tube | | Ultrathin Endotracheal Tube | | Ultrathin Two-stage Endotracheal Tube | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | 1st Stage | | 2nd Stage | | |
| ID (mm) | OD (mm) | ID (mm) | OD (mm) | ID (mm) | OD (mm) | ID (mm) | OD (mm) | Equivalent to standard ETT (mm) ID |
| 5.7* | 7.6 | 7.2 | 7.6 | 7.2 | 7.6 | 9.2 | 9.7 | 8.0 |
| 6.2* | 8.3 | 7.9 | 8.3 | 7.9 | 8.3 | 9.5 | 10.0 | 9.0 |
| 7.5 | 10.0 | 9.5 | 10.0 | 9.5 | 10.0 | 11.0 | 11.4 | 10.8 |
| 8.0 | 10.7 | 10.3 | 10.7 | 10.3 | 10.7 | 12.5 | 12.9 | 11.7 |

In the ultrathin two-stage endotracheal tube (UTTS ETT), the first stage was limited to 6 cm, with the remainder made up of the larger second stage. Equivalent standard endotracheal tube (equivalent standard ETT).

* Dimension of inputed standard endotracheal tube, with standard wall thickness. In these two sizes the mandrels were machined from fractional drill rod (in inches), with no exact match in the metric system.

applications, problems encountered in long-term orotracheal or nasotracheal intubation have been serious, and have defied solution.[5] This report deals with preliminary laboratory and animal studies aimed at designing adult-sized endotracheal or orotracheal tubes.

Conventional ETTs traditionally are made from sections of extruded polyvinyl chloride tubing, or else are produced by the dipping method.[6] It is well known that conventional ETTs impart a significant increase in upper-airway resistance, particularly so if for technical or other considerations one chooses a smaller ETT than otherwise might have been indicated. Our production technology allowed us to produce ETTs with a greatly reduced airway resistance through two means. First, by keeping the wall thickness approximately 0.2 mm, we greatly increased the internal diameter of the ETTs. Second, by fabricating a UTTS ETT, we could further reduce the airway resistance. For example, instead of a 7.5-mm standard ETT, a UTTS ETT with the same outside dimensions at its distal end converts into what

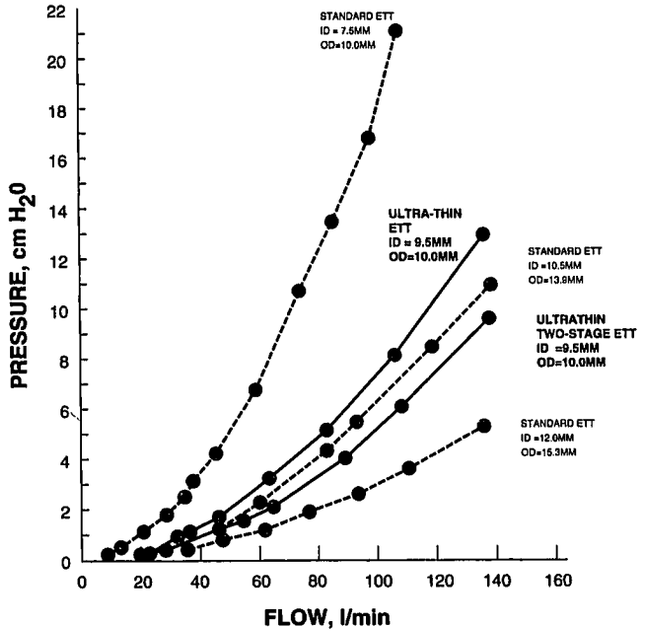


**Fig. 7. *In vitro* steady-state pressure–flow studies of selected standard endotracheal tubes, ultrathin endotracheal tubes (UT ETT), and ultrathin-walled two-stage endotracheal tubes (UTTS ETT). The UT ETT and UTTS ETT were of same length as the closest standard endotracheal tube with same pressure–flow characteristics. Dashed lines = pressure–flow curves of 7.5-, 9.5-, and 12.0-mm standard-length endotracheal tubes (ETT); solid lines = pressure–flow curves of one UTS ETT and one UTTS ETT of same distal outside diameter as that of a standard 7.5 mm ETT, of same lengths.**

**Table 2. Tracheal Leak as a Percent of Tidal Volume**

| Peak Airway Pressure ($cmH_2O$) | PEEP* ($cmH_2O$) | | | PEEP† ($cmH_2O$) | | |
|---|---|---|---|---|---|---|
| | 0 | 5 | 10 | 0 | 5 | 10 |
| 15 | 0 | 0 | 0 | 80% | >90% | 100% |
| 20 | 0 | 0 | 0 | 82% | >90% | 100% |
| 25 | 0 | 0 | 0 | 82% | >90% | 100% |
| 30 | 0 | 6% | 0 | | | |
| 35 | 5% | 6% | 4 | | | |
| 40 | 10% | 12% | 8% | | | |
| 45 | 19% | 11% | 8% | | | |

ID = internal diameter; OD = outside diameter.

* Horizontal axis: ID = 11.4 mm; OD = 11.9 mm. Vertical axis: ID = 14.2 mm; OD = 14.7 mm.

† Standard round endotracheal tube without cuff: ID = 9.0 mm; OD = 12.0 mm.

amounts to a 10.8-mm conventional ETT based on pressure–flow characteristics (fig. 7); the air-flow resistance for the latter UTTS ETT is virtually identical to the air-flow resistance of the major upper airways in an adult male whose trachea is not intubated.[7] The four sizes UTTS ETTs listed in table 1 cover the entire expected range of the adult ETTs.

The new ETTs were but one third the weight of a standard ETT, incomparably more flexible, nonkinking, could not be crushed (with Nitinol reinforcement) (fig. 6), and did not impart a significant torque on the distal end when the proximal end was manually twisted.

We diverged from traditional means of attaining a seal with the upper airways because of several reasons. Technically, it became a simple matter to shape the laryngeal portion of the ETT into an oval (or egg shape) to approximate more accurately the internal laryngeal structures, rather than to retain the traditional round design. This, we thought, would lead to a decrease in point pressure on the vocal processes and other structures of the larynx, and reduce pressure necrosis, an important goal in itself; and by virtue of the much greater flexibility of the ETT, to also reduce possible torque, and eliminate motion of the ETT within the larynx. By a better fit of the ETT, it became feasible to fill voids around the ETT within the larynx with rings (toroidal shapes) of thin, soft plastic film (a fraction of the thickness of tissue paper), which readily deformed to fill small voids. Invariably, the presence of entrained tracheal mucous greatly enhanced this purpose, resulting in what amounted to self-fitting, "no-pressure" seal at the level of the larynx. We have performed preliminary studies lasting as long as 24 h to determine whether dye placed in the oropharynx may reach the trachea; any discoloration noted on the gills did not extend beyond the level of the vocal cords. Finally, by removing the inflatable cuff from the ETT, we opened the prospect for greatly decreased tracheal injury following tracheal intubation. The egg-shaped section of the glottic portion of the ETT has advantages over an oval section, as it more closely matches the anatomic shape of the glottic opening. On the other hand, an oval section cannot be accidentally malpositioned because of its inherent symmetry. These, and other issues remain still to be explored.

When we compared conventional ETTs (with cuff removed, or deflated) with the new design ETTs of same outside diameter and with the attached gills, there was consistently no air leak with the latter, at least to pressures of 30 $cmH_2O$, while there was a prohibitive leak in the former. This suggested that it was possible to eliminate the conventional inflatable cuff, which is the cause of tracheal lesions, and to move the site of the airway seal to the more rigid structures of the larynx in the form of an accommodating, no-pressure seal system. Our studies had as an important goal to decrease the contact pressure on the laryngeal structures to reduce or eliminate pressure necrosis, by distributing any load over a much larger area of contact, and to cushion such contact by interposing the gills (made slippery by ever-present mucus). Our animal experiments have been limited to relatively short, 24-h studies and must be explored further over a much longer period with whatever design is finally chosen.

We have incorporated into some ETTs a new material, Nitinol wire. Unique among alloys, Nitinol exhibits remarkable kink resistance, it renders the wire reinforced ETT truly crush proof, a feature of great importance when dealing with ETTs of a wall thickness of 0.2 mm. Realistically, some protection to the UT ETT and UTTS ETTs is necessary to protect it from damage or bite at the level of the mouth through reinforcement or through a bite block.

Optimally, a proper fit of the UTTS ETT is important. It is difficult to state how much allowance there may be for undersized or oversized ETTs of this design, an aspect that is still to be determined; the size and the number of gills and the thickness of those gills are other variables that need to be further explored.

The UT ETT, of one diameter throughout, can in principle be used both orotracheally, or nasotracheally. At the same outside diameter, the internal diameter of the UT ETT is 1.5–2.3 mm larger than the internal diameter of a standard ETT; this translates into a two- or threefold decrease in air-flow resistance. The UT ETT might be particularly suited to nasotracheal applications: There is no reason why an inflatable cuff could not be attached to this line of ETTs for special use, or routinely for short-term applications; or to inflate the cuff only when absolutely needed. As the goal of this study was to totally redesign the ETT, we gave it little priority.

The concept of modifying the shape of a standard ETT in its laryngeal portion was suggested by Hengerer *et al.* in 1975 for the purpose of reducing grooving in the vocal cords.[8] They proposed changing the shape of a 2-cm section of an ETT into a triangle for use in newborns. Miller and Sethi suggested attaching silicone rubber rings onto the most distal portion of the ETT for the purpose of attaining an airway seal within the trachea (but not with the larynx).[9] These and other efforts have been hindered by enormous difficulties in a very complex problem.

Bishop *et al.*, reviewing laryngotracheal injury following prolonged tracheal intubation, suggested that the ideal shape of the ETT at the level of the larynx ought to be pentagonal in cross section[10]; the technology then available made such solution not possible. In this report, we have tried to address some of those concerns, and have laid the ground work for future progress.

This preliminary report introduced a new technique for the manufacture of ETTs, rather than to present a collective experience in a large number of animals using one ETT design alone. The latter approach would be appropriate once commercial manufacture has commenced. We have now convincingly shown that UT ETTs of exceptionally low air-flow resistance can be fabricated; that those ETTs can be fabricated with crush-proof wire reinforcement; and that UT ETTs can be fabricated to graded internal dimensions, rather than of constant internal diameter throughout. Most importantly, this technology allows us to shape the laryngeal portion of the ETT to closely match the shape of the (egg-shaped) glottic opening; and that a seal with the upper airways can be effected through compliant gills mounted on the oval (or egg-shaped) section of the ETT, effecting a seal at the level of the glottis. This line of low-resistance ETTs may find earliest clinical application where success depends on reduced work of breathing, on patient effort and cooperation, such as in continuous positive airway pressure.

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