



## In Vitro Evaluation of Endotracheal Tubes With Intrinsic Suction

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**Background:** Endotracheal tube (ETT) intubation impairs mucus clearance, which can lead to respiratory compromise. We compared three ETTs that have intrinsic capacity to aspirate secretions pooling above the cuff.

**Methods:** We evaluated the ability of three ETTs with suction, Hi-Lo Evac, Teleflex ISIS, and Portex Blue Line SACETT, to aspirate saliva and mucus simulants at continuous or intermittent vacuum pressures. We also evaluated the potential for a flexible tracheal membrane to obstruct the ETT suction port with applied vacuum. We measured the dimensions of the suction tubing at critical points to calculate differences in flow.

**Results:** In a rigid tracheal model, the ISIS aspirated saliva simulant more quickly with continuous low pressure suction than Evac ( $P = .0006$ ) and SACETT ( $P < .0001$ ) as well as with intermittent high pressure suction ( $P < .0001$ ). For mucus simulant, the ISIS aspirated stimulant better than the other ETTs at high intermittent suction ( $P < .0001$ ); the Evac was more effective than the SACETT ( $P = .0019$ ). For low and continuous suction, suction ports in all ETTs occluded with mucus, except for ISIS, at the highest continuous suction tested. In a trachea model with a flexible posterior membrane, this membrane either partially or completely occluded the suction port of all tubes at high continuous or intermittent suction. The ISIS was more prone to obstruction by the flexible membrane than the Evac. We found large differences in suction tubing cross-sectional area between the ISIS and the other tubes, and flow calculations using the Hagen-Poiseuille equation can explain the observed differences in volumes aspirated and tendency toward lumen obstruction.

**Conclusions:** The ISIS transmits suction pressure to the tube orifice more powerfully than the Evac and SACETT. This feature makes the ISIS less prone to obstruction by mucus but more likely to obstruct by tissue suction.

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**Abbreviations:** ETT = endotracheal tube; VAP = ventilator-associated pneumonia

Endotracheal tube (ETT) intubation impairs cough and mucociliary transport, and mucus stasis can lead to atelectasis, airway infection, and respiratory compromise. ETTs eliminate the normal protection against aspiration so that secretions from the oropharynx can pool above the ETT cuff and be aspirated

into the lungs, potentially leading to ventilator-associated pneumonia (VAP). One case of VAP can result in more than \$40,000 in additional hospital costs.<sup>1,2</sup>

The Hi-Lo Evac (Mallinckrodt Medical; St. Louis, MO) ETT can aspirate secretions above the ETT cuff through a separate lumen that supports continuous or intermittent aspiration of subglottic secretions. In a study of 140 intubated patients who had a conventional ETT and 140 treated with the Evac ETT, Cox regression analysis showed that the risk of VAP was

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more than three times greater for patients with the conventional ETT and suctioning than with the Evac tube ( $P = .001$ ).<sup>3</sup> A metaanalysis of published studies confirmed that the Evac can significantly decrease the rate of VAP in patients at greatest risk.<sup>4</sup>

Occlusion of this suction lumen can be caused by airway secretions or mucosal impaction from the applied suction, which can impair secretion clearance and potentially lead to airway damage. In a prospective study evaluating occlusion by these tubes, dysfunction of the suction lumen occurred in 19 of 40 (48%) patients. In 17 (43%) of these patients, the finding was attributed to blockage of the subglottic suction port by suctioned tracheal mucosa.<sup>5</sup> Additional published cases have confirmed these observations.<sup>6</sup>

Two other ETTs with suction capabilities have been developed. These differ in the subglottic suction port size, placement, and access. The ISIS ETT (Teleflex Medical; Research Triangle Park, NC) is a US Food and Drug Administration-approved pre-release with detachable suction line that allows the connection of suction to the tube for subglottic suctioning. The Portex Blue Line SACETT (Smiths Medical ASD Inc; Weston, MA) is a commercially available ETT with the capacity to aspirate secretions from above the cuff (Figs 1A, 1B).

This study investigated the effectiveness of 7.5-mm-sized ISIS, Evac, and the SACETT ETTs in aspirating mucus simulants with rheologic properties similar to human airway mucus. Evaluation occurred at selected continuous and intermittent vacuum pressures. We also developed a trachea model with a flexible posterior membrane similar to the posterior membranous trachea and used this to determine whether the posterior membrane prolapsed into the suction channel and occluded the ETT suction port during experimental use.

## MATERIALS AND METHODS

### Mucus Simulant

A mucus simulant was prepared daily using Polyox Water-Soluble Resin N-750 NF (Dow Chemicals; Woodbury, NJ), a polyethylene oxide with an approximate molecular weight of  $5 \times 10^6$ . This polymer simulant is homogenous and has viscoelastic properties similar to human airway mucus (Table 1).<sup>7</sup> We used this simulant in earlier studies of suction catheter design and performance.<sup>8</sup> Two concentrations of mucus simulant were used (0.5% and 1.5%) with rheologic properties similar to saliva and mucus, respectively.

### Suction Recommendations

In evaluating the suction effectiveness of the ETTs, we followed the suctioning recommendations by the manufacturers as closely as possible. All manufacturers recommend suctioning the

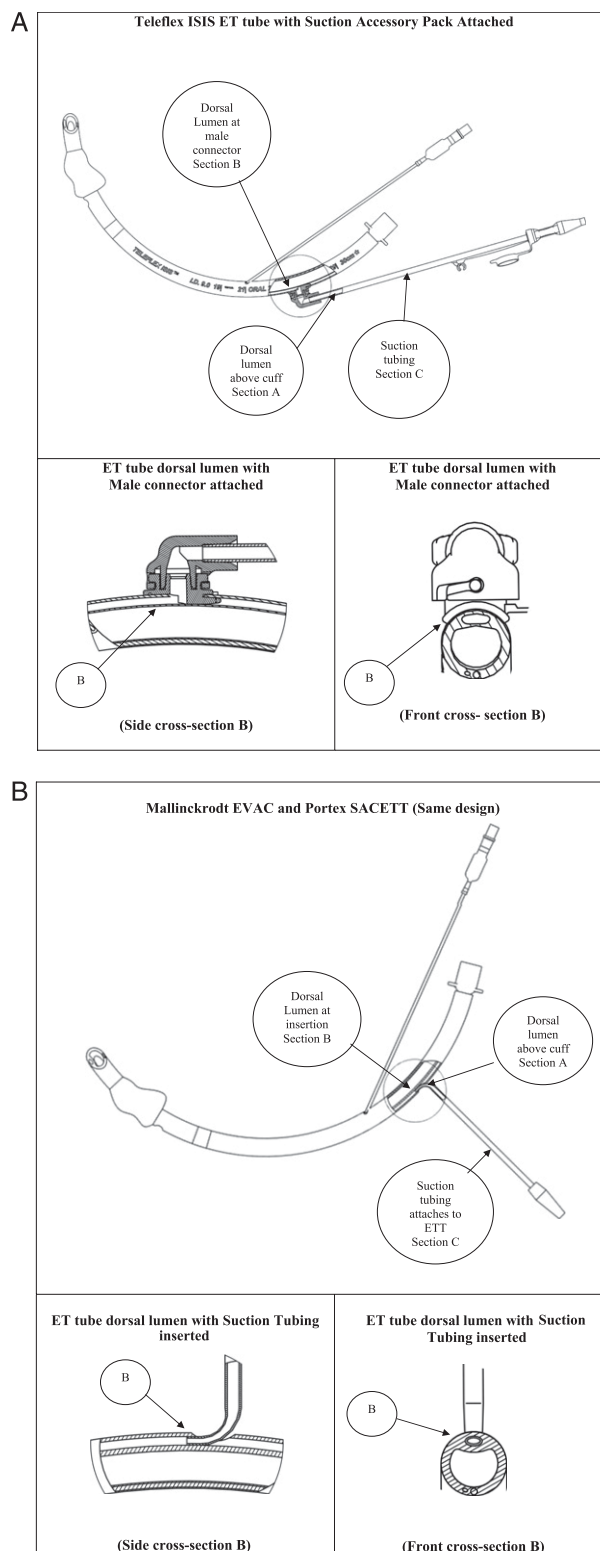


FIGURE 1. Diagrams of the endotracheal tubes studied. Diagram for the Teleflex ISIS (A). Diagram for the Hi-Lo EVAC and Portex Blue Line SACETT (same design) (B). Inset shows enlarged suction connector profile. ET = endotracheal.

secretions above the cuff using the minimum suction pressure required to effectively remove the secretions. Whereas Teleflex cautions that continuous suctioning above 20 mm Hg may cause

**Table 1—Characterization of Mucus Simulant**

Bulk Properties	0.50%	1.50%	ETT Mucus	CF Sputum
G' at 1 rad/s	43	414	328	1,003
G'' at 1 rad/s	45	277	206	1,188
G' at 100 rad/s	95	780	622	3,318
G'' at 100 rad/s	1,165	2,562	1,786	8,355

A mucus simulant was prepared daily using Polyox Water-Soluble Resin N-750 NF (Dow Chemicals; Woodbury, NJ). The viscoelastic measurements increase with mucus simulant concentration. The 0.5% simulant had G' (storage modulus or elasticity) and G'' (loss modulus or viscosity) that were close to that of saliva. The 1.5% simulant had G' and G'' that were close to that of normal airway mucus.<sup>7</sup> CF = cystic fibrosis; ETT = endotracheal tube.

trauma to the tracheal tissues in the area of the suction port, Mallinckrodt and Portex recommend using a continuous suction pressure of 20 mm Hg. All manufacturers state that intermittent suctioning using practices similar to standard tracheal suctioning also may be performed, typically using intermittent suctioning for 10 to 15 s with a suction pressure of –100 to –150 mm Hg.<sup>9–11</sup>

#### *Aspiration Effectiveness Using a Rigid Trachea Model*

The rigid trachea model consisted of a transparent acrylic cylinder with a 19 mm internal diameter secured at a 30° angle on a mounting rack. The ETT being studied was placed into the trachea model, and the cuff was inflated to  $25 \pm 2$  cm H<sub>2</sub>O and pressure confirmed with a manometer. The distal end of the ETT was open to the atmosphere. The proximal end of the ETT was connected to a Hudson RCI Comfort Flo Circuit and a Neptune Heated Humidifier (Teleflex Medical) set at 37° C with compressed airflow. The lumen suction line of the ETT was connected to a medical-grade suction trap attached to a regulated vacuum system (Boehringer Model 3720; Boehringer Laboratories Inc; Norristown, PA).

The relative effectiveness for mucus simulant aspiration of the Evac, SACETT, and the ISIS were compared. Effectiveness was determined by measuring the time to aspirate 0.5% and 1.5% mucus simulant under different test combinations, including three continuous suction pressures (10, 15, and 20 mm Hg), three intermittent vacuum pressures (100, 110, and 120 mm Hg) applied 10 s on and 5 s off, and two mucus simulant volumes (5 mL and 10 mL). These pressures cover the full range recommended by the manufacturers and in common use in hospital ICUs. The experimental conditions are shown in Table 2.

Between each assessment, the trachea model and ETT were cleaned with hot water followed by 1 minute of continuous vacuum suction (60 mm Hg) and then dried with pressured air. All procedures were repeated five times for each experimental condition. Mucus simulant aspiration was observed for a maximum of 60 min or until secretion aspiration was complete, whichever came first.

#### *Membrane Trachea Model and Occlusion Assessment*

The membrane trachea model was constructed with a transparent polyvinyl chloride tube with a 19.1 mm internal diameter and a 25.4 mm outer diameter. We removed a 14-mm portion of the tube wall for about two-thirds of the length of the tube. A Lifestyles Snugger Fit latex condom (Ansell Healthcare Products; Red Bank, NJ) was unrolled over the tube to produce a flexible posterior membrane. The ring portion of the condom was used to secure the membrane to the trachea tube. The distal

**Table 2—Experimental Conditions**

Suction Pressure, mm Hg	0.5% Simulant Volume, mL	1.5% Simulant Volume, mL
Continuous		
10	5 and 10	5
15	5 and 10	5
20	5 and 10	5
Intermittent		
100	10	10
110	10	10
120	10	10

The relative effectiveness for mucus simulant aspiration of the Hi-Lo Evac, Portex Blue Line SACETT, and Teleflex ISIS was determined by measuring the time to aspirate 0.5% and 1.5% mucus simulant under different test combinations, including three continuous suction pressures (10 mm Hg, 15 mm Hg, and 20 mm Hg), three intermittent vacuum pressures (100 mm Hg, 110 mm Hg, and 120 mm Hg) applied 10 s on and 5 s off, and two mucus simulant volumes (5 and 10 mL).

tip of the condom was cut to allow insertion of the ETT under investigation.

The exposed 14-mm portion of the simulated tracheal membrane allowed clear visualization of the membrane and ETT suction port, which enabled us to assess impaction of the latex condom into the subglottic suction port during mucus aspiration. The portion of the trachea model covered by the flexible membrane was somewhat greater than the area of the posterior membranous trachea in mammals, but this allowed for more accurate observation. For these studies, the Evac and ISIS ETTs were compared.

The ETT was placed into the membrane trachea model and the cuff was inflated to  $15 \pm 2$  cm H<sub>2</sub>O or  $25 \pm 2$  cm H<sub>2</sub>O and checked with a manometer. The lumen suction line of the ETT was connected to a suction trap attached to a regulated vacuum system. We evaluated three different continuous pressure conditions: 20 mm Hg, 120 mm Hg, and 200 mm Hg. All studies were performed using 5 mL of thin (0.5%) mucus simulant that was added to the trachea model with a syringe. The proximal trachea was sealed with Parafilm (Pechiney Plastic Packaging Company; Chicago, IL) to simulate proximal airway closure around the glottis. After each measurement, the ETT and trachea model were thoroughly cleaned, and a new membrane (condom) was applied.

We defined lack of membrane obstruction as uninterrupted aspiration of the mucus simulant and no visible prolapse of the membrane into the suction port. Partial obstruction was visible partial prolapse or intermittent obstruction with noticeable slowing of the rate of aspiration. Complete obstruction was defined as cessation of mucus aspiration after complete prolapse of the flexible membrane into the ETT suction port. All observations were made over 3 minutes.

#### *Cross-sectional Area of the Suction Tubing*

We measured the dimensions of the suction lumen and the suction tubing for each of the ETTs studied (Fig 2). Because these cross sections were not completely spherical, the cross-sectional area was measured with Digital RAM Optical Instrumentation (RAM Optical Instrumentation; Rochester, NY).

#### *Statistical Analysis*

Statistical analysis was performed using the StatView 5 statistical software package (SAS Institute; Cary, NC). Aspiration



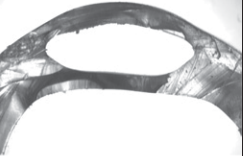
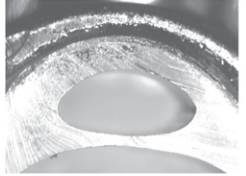
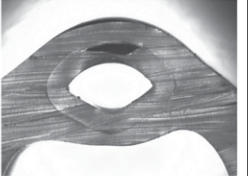
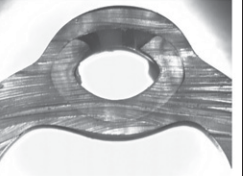

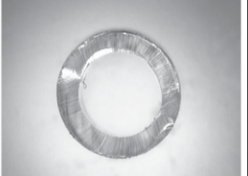
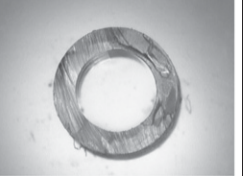
	Teleflex ISIS ET tube	Mallinckrodt EVAC ET tube	Portex SACETT ET tube
Suction lumen area (Cross-section)  Section A  See Figure 1 for cut location	  Area: 7.7 mm <sup>2</sup>	  Area: 5.4 mm <sup>2</sup>	  Area: 5.6 mm <sup>2</sup>
Dorsal Suction lumen area at the insertion point of the suction tubing (Cross-section)  Section B  See Figure 1 for cut location	  Area: 7.7 mm <sup>2</sup>	  Area: 2.8 mm <sup>2</sup>	  Area: 2.9 mm <sup>2</sup>
Suction tubing (Cross-section)  Section C  See Figure 1 for cut location	  Area: 8.5 mm <sup>2</sup>	  Area: 5.6 mm <sup>2</sup>	  Area: 5.4 mm <sup>2</sup>

FIGURE 2. Cross-sectional area of the suction tubing. Cross-sectional area of the suction lumen and the suction tubing measured at the three points are as shown in Figure 1. Because cross sections were not completely spherical, area was measured with digital RAM Optical Instrumentation. See Figure 1 legend for expansion of abbreviation.

effectiveness was analyzed by analysis of variance and Fisher exact test. By convention, differences were considered statistically significant at  $P < .05$ . All data are reported as mean  $\pm$  SD but graphically shown as means  $\pm$  SEM for clarity. Because the assessment of membrane occlusion was observational, no statistical test was applied.

## RESULTS

### Comparison of Suction Channel Effectiveness in a Rigid Trachea Model

**Continuous Suction Pressure and 0.5% Mucus Simulant:** The mean time it took to aspirate 5 mL or 10 mL of 0.5% mucus simulant from the ISIS, Evac, and SACETT ETTs at continuous pressure is shown in Figure 3 and Table 3. The time to aspirate mucus simulant was significantly different from ISIS vs Evac ( $P = .0006$ ) and ISIS vs SACETT ( $P < .0001$ ) but not Evac vs SACETT ( $P = .5$ ). As expected, effectiveness as measured by faster aspiration of secretions also was directly related to vacuum pressure ( $P = .0006$ ) (data not shown).

**Continuous Suction Pressure 1.5% Mucus Simulant:** The time to aspirate 5 mL of 1.5% mucus simulant

could not be measured accurately. These experiments were stopped at 60 minutes because low suction pressure led to occlusion of suction ports by mucus simulant and cessation of clearance in all ETTs at pressures of 10 mm Hg and 15 mm Hg and from the Evac and SACETT at 20 mm Hg. The ISIS was

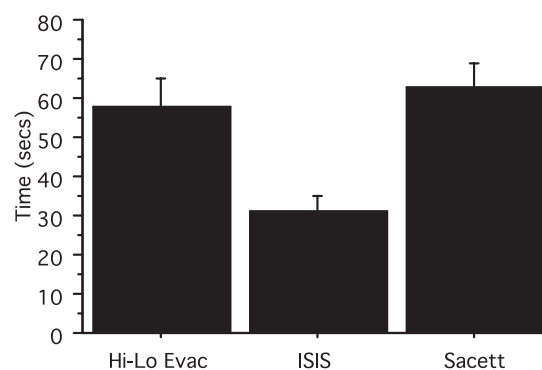


FIGURE 3. Thin simulant (0.5%) under continuous suction (volume, 10 mL). The Teleflex ISIS endotracheal tube (ETT) aspirated saliva-like mucus simulant significantly faster (31.2  $\pm$  14 s) than either the Hi-Lo Evac (57.5  $\pm$  28.9 s;  $P = .0006$ ) or the Portex Blue Line SACETT (62.9  $\pm$  23.8 s;  $P < .0001$ ) ETTs.



**Table 3—The Time To Aspirate Mucus Simulant Gels**

Experimental Condition	Time, s
0.5% (thin)	
Continuous	
Evac	39.64 ± 27.66
SACETT	48.52 ± 27.03
ISIS	23.72 ± 13.17
Intermittent	
Evac	10.83 ± 0.85
SACETT	11.23 ± 0.85
ISIS	8.52 ± 0.46
1.5% (thick)	
Intermittent	
Evac	231.27 ± 69.27
SACETT	315.27 ± 163.22
ISIS	105.53 ± 27.19

Data are presented as mean ± SD time to aspirate 5 mL or 10 mL of mucus simulant from the Teleflex ISIS, Hi-Lo Evac, and Portex Blue Line SACETT ETTs at continuous or intermittent suction pressure. See Table 1 for expansion of abbreviation.

cleared of 1.5% mucus simulant at 20 mm Hg, but this took a mean of 1,900 s (> 30 min).

**Intermittent Suction Pressure and 0.5% Mucus Simulant:** There were significant differences in the time to aspirate 10 mL of 0.5% mucus simulant from ISIS vs Evac ( $P < .0001$ ), ISIS vs SACETT ( $P < .0001$ ), and from Evac vs SACETT ( $P = .044$ ) (Fig 4, Table 3). Again, high vacuum pressure produced shorter aspiration times as anticipated.

**Intermittent Suction Pressure and 1.5% Mucus Simulant:** There were significant differences in the time it took to aspirate mucus simulant from ISIS vs Evac ( $P < .0001$ ), ISIS vs SACETT ( $P < .0001$ ), and Evac vs SACETT ( $P = .0019$ ). These findings are shown in Fig 5.

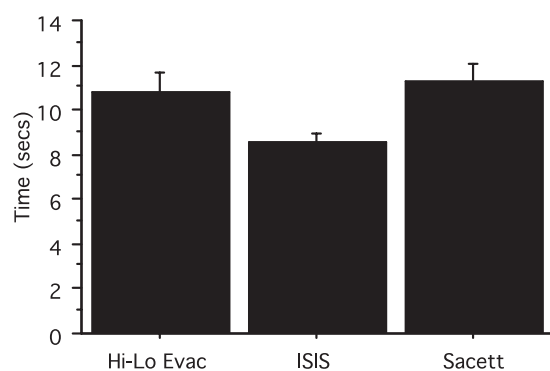


FIGURE 4. Thin simulant (0.5%) under intermittent suction (volume, 10 mL). There were significant differences in the time to aspirate 10 mL of thin saliva-like mucus simulant from Teleflex ISIS ( $8.5 \pm 0.5$  s) vs Hi-Lo Evac ( $10.8 \pm 0.9$  s) and Portex Blue Line SACETT ( $11.2 \pm 0.8$  s;  $P < .0001$ ) and ISIS vs SACETT ( $P < .0001$ ).

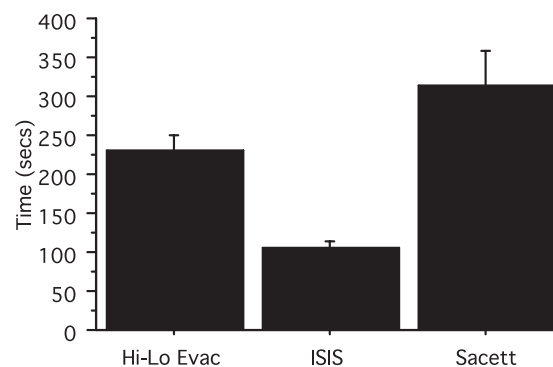


FIGURE 5. Thick simulant (1.5%) under intermittent suction (volume 10 mL; all pressures combined). There were significant differences in the time to aspirate mucus simulant from Teleflex ISIS ( $106 \pm 27$  s) vs Hi-Lo Evac ( $231 \pm 69$  s;  $P < .0001$ ), ISIS vs Portex Blue Line SACETT ( $315 \pm 163$  s;  $P < .0001$ ), and Evac vs SACETT ( $P = .0019$ ).

### Membrane Occlusion of Suction Port

Initially, we determined that when the proximal portion of the trachea model was open to air and there was no mucus simulant in the trachea, there was no membrane prolapse into the suction lumen at any vacuum pressure, including 200 mm Hg. However, in vivo the proximal ETT usually is partially sealed to the atmosphere by glottic closure. Furthermore, we wanted to simulate conditions of mucus aspiration, recognizing that as mucus was aspirated this would draw the membrane closer to the suction lumen and increase the likelihood of occlusion. We wished to study this condition at a range of continuous suction representing the full range of suction pressures reported in the literature (20–200 mm Hg). We also studied higher and lower cuff pressure because these could alter airflow along the ETT. These data are summarized in Table 4.

For the Evac tube, partial obstruction was observed when 5 mL of mucus simulant was continuously suctioned at 20 mm Hg or 120 mm Hg, and complete

**Table 4—Membrane Obstruction of the Suction Lumen With 5 mL of 0.5% Simulant**

Cuff Pressure and Continuous Suction	Evac	ISIS
15 cm H <sub>2</sub> O ± 2 cm H <sub>2</sub> O		
20 mm Hg	PO	PO
120 mm Hg	PO	CO
200 mm Hg	CO	CO
25 cm H <sub>2</sub> O ± 2 cm H <sub>2</sub> O		
20 mm Hg	PO	PO
120 mm Hg	PO	CO
200 mm Hg	CO	CO

Using 5 mL of saliva-like, thin mucus simulant, we assessed obstruction of the suction port by the flexible membrane at 20 mm Hg, 120 mm Hg, and 200 mm Hg and at sealing cuff pressures of 15 cm H<sub>2</sub>O and 25 cm H<sub>2</sub>O. CO = complete obstruction; PO = partial obstruction.

obstruction occurred at 200 mm Hg. For the ISIS tube, there was complete obstruction confirmed when 5 mL of mucus simulant was suctioned at 120 mm Hg and 200 mmHg, and partial obstruction was seen with a continuous pressure of 20 mm Hg. For both the ISIS and Evac tubes, complete obstruction occurred immediately after the suction pressure was applied and continued for the duration of the test. With partial obstruction, the prolapse of the membrane into the suction port only occurred after the mucus simulant was completely aspirated from the trachea model.

#### *Cross-sectional Area of the Suction Tubing*

The cross-sectional areas of the Evac and SACETT were nearly identical at the three critical measurement points, which was expected given their similar design (Fig 2). The suction tube cross-sectional area of the ISIS was about 40% greater than the Evac and SACETT tubes at the dorsal lumen and through the tube length. However, both the Evac and the SACETT are designed with a significant and similar narrowing of the lumen at the suction insertion point into the ETT (section B), whereas the ISIS does not change diameter. This design effectively decreases the cross-sectional area of the Evac and SACETT by 63% relative to the ISIS tube.

### DISCUSSION

This study evaluated the performance of the pre-release Teleflex ISIS ETT, comparing it with the Hi-Lo Evac and Portex Blue Line SACETT. There was no significant difference between the Evac and SACETT ETTs in the time to aspirate mucus simulant under continuous and intermittent suction pressure, but there was a highly significant difference comparing the effectiveness of the ISIS to the other tubes ( $P < .0001$ ), with the ISIS able to clear the mucus simulant much more quickly (Table 3). For all ETTs, it was difficult to aspirate thicker (1.5%) mucus simulant at low continuous suction pressure, leading to occlusion of the suction port by mucus. For higher pressure intermittent suction, again the ISIS performed significantly better than the other two tubes ( $P < .0001$ ). Up to a volume of 10 mL, the thin (0.5%) mucus simulant did not obstruct the lumen of any of the ETTs tested.

Using a trachea model with a flexible posterior membrane, there was intermittent or partial occlusion of the suction lumen once all mucus was aspirated at low pressure and complete occlusion of both the Evac and the ISIS suction lumen at the highest pressure (200 mm Hg). There was no occlusion when tested without a mucus load, and the proximal tra-

chea model was open to air. At intermediate suction pressure of 120 mm Hg, the Evac partially occluded, whereas the ISIS completely occluded. Due to increased efficiency (shorter time) to aspirate mucus, the ISIS suction channel became occluded more quickly than the Evac channel.

According to the Hagen-Poiseuille equation, fluid flow ( $F$ ) in a tube with a circular cross-section is determined by the length ( $L$ ) and diameter ( $d$ ) of the tube, the viscosity ( $G''$ ) of the fluid, and pressure ( $P$ ) in the tube as follows:

$$F = (P \times d^4) / (G'' \times L) \quad (\text{Equation 1})$$

and the area of the tube is:

$$A = \Pi \times (d/2)^2 \quad (\text{Equation 2})$$

The length of the suction tubing and attachment to the vacuum for each of these ETTs was approximately the same, and we tested mucus simulants at constant viscosities and pressures as shown in Tables 1-4. Because the cross-sectional area of these suction tubes and insertions were not spherical, we used digital RAM Optical Instrumentation to calculate the cross sectional area at three points along each suction tube as shown in Figure 2. If we then assume that these cross sections are circular and we hold  $L$ ,  $G''$ , and  $P$  constant, Equations 1 and 2 become:

$$F \propto (4A/\Pi)^2 \quad (\text{Equation 3})$$

This yields very similar flow through the Evac and SACETT, which is consistent both with our data and with the similar design of these tubes. However, flow through the ISIS is calculated to be two times greater at the dorsal suction lumen (section A), 2.4 times greater through the body of the tube (section C), and 7.3 times greater through the insertion point into the ETT (section B). This design change can explain the differences observed in this study. The ISIS transmits vacuum pressure to the suction orifice more powerfully than the Evac and SACETT, which makes the ISIS less prone to obstruction by mucus but more likely to obstruct by tissue suction.

These data suggest three possible ways to decrease the risk of tissue obstructing the suction lumen without decreasing the suction efficiency: (1) stopping suction when there is no mucus flow; (2) sensing when there is a sudden increase in suction at the proximal port, suggesting occlusion and briefly reversing flow; and (3) only using intermittent suction rather than continuous flow to clear mucus secretions. There also may be an opportunity to change the design of the suction port to retain effective suction while reducing the risk for membrane occlusion.

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**Author contributions:** Dr Mujica-Lopez: conducted most of the studies, wrote the first draft of the manuscript, and read and commented on the final manuscript.

Ms Pearce: prepared mucus simulants and measured their rheology, helped to edit progress reports and the first draft of the manuscript, and read and commented on the final manuscript.

Mr Narron: conducted the studies with the flexible membrane and read the final manuscript.

Mr Perez: provided test equipment, assisted in preparing the experimental setup, and read the final manuscript.

Dr Rubin: conceived the studies, wrote the proposal, conducted the statistical analysis, and edited the submitted manuscript and subsequent revision.

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