Timely weaning and liberation from mechanical ventilation is not just sound clinical practice. It is a patient safety concept.

Ventilator support is set to offload disease-related work of breathing (WOB<sub>Disease</sub>). An additional ‘stealth’ WOB factor attributable mainly to ET tube narrowing (WOB<sub>imposed</sub>) may manifest only as weaning intolerance. Most weaning strategies lack consideration of WOB<sub>imposed</sub>. When patients unexpectedly detour from the planned course, a Rescue Loop™ can expedite their return to the path to success.
Partially obstructing ET tube secretions narrow the tube lumen and increase WOBImpeded, which can delay weaning from ventilatory support. Even small reductions in ET tube radius (r) result in significant increases in airflow resistance (R) due to the inversely exponential relationship between these. Resistance is further increased by turbulent airflow patterns due to bidirectional gas flow and irregular ET tube surface contours, especially when covered with secretions. Increase in resistance through the ET tube can be subtle and may become clinically manifest only during withdrawal of ventilatory support, when it can masquerade as weaning intolerance due to unresolved pulmonary disease. This typically leads to halting the weaning or pre-extubation trail.

**Poiseuille’s Equation**

\[
R \propto \frac{\eta \cdot L}{r^4}
\]

**Elevated ET Tube Resistance**

The graph above illustrates the WOB components experienced by mechanically ventilated patients. At the time of intubation, ventilatory support (blue) is instituted at a level sufficient to offset WOB\text{Disease} (the *reason* for intubation) and WOB\text{Imposed} (a *consequence* of intubation). Then, as the reason for intubation (respiratory failure) resolves and WOB\text{Disease} decreases, weaning from the ventilator begins. During this time, the true WOB\text{Imposed} (red) increases (due to ET tube narrowing from secretion accumulation) but may be erroneously assumed to remain constant throughout the intubation period (dashed red).

During weaning and/or during a pre-extubation trial, the level of ventilatory support (provided at a level to offset the WOB imposed by the ET tube at the time of intubation) is insufficient to offset the true WOB imposed by the ET tube that has become partially obstructed by secretions (bracket ‘A’). The insidiously elevated WOB\text{Imposed} can be misdiagnosed as high WOB\text{Disease} by the clinician (bracket ‘B’) and the patient’s weaning is halted or delayed. Bracket ‘C’ shows the difference between the presumed (dashed red) and the true (red) WOB imposed by the ET tube at the time of weaning. Lack of awareness or appreciation of this discrepancy may account for why roughly 20% of intubated patients may be at risk for being misdiagnosed as ‘weaning intolerant’ or ‘failure to wean’.

**Insidious Cause of “Weaning Failure”**

**Work Of Breathing (WOB) during Intubation and Mechanical Ventilation**

- **Disease onset**
- **Intubation & MV begins**
- **Wearing begins**
- **Pre-Extub trial**
- **Time**

- **Disease severity worsens**
- **ET tube narrowed by secretions**
- **Disease severity improves**

- **WOB (Physiologic + Disease)**
- **WOB (Imposed) due to ET tube (new)**
- **WOB (Imposed) due to ET tube narrowing**

[Graph showing WOB components and their changes over time]
LITERATURE REFERENCES

The negative physiologic impact of increasing ET tube resistance has been systematically quantified throughout decades of literature using a variety of methods that have looked at this issue from many different perspectives. All of these clinical and research pioneers, working independently from each other in different practice environments and in different eras of time, using different study methodologies on different patient populations, all reach the same conclusion.

"Inadvertent endotracheal tube obstruction was common in patients requiring mechanical ventilation and may be significant as early as at 24 h. Moderate obstruction in endotracheal tube lumens should be suspected in cases of difficulties in weaning, even in patients who were ventilated for less than 1 day."

"... endotracheal tube narrowing and intraluminal volume loss is common among patients with acute respiratory failure. This is a potentially important observation as it suggests that weaning from mechanical ventilation can be delayed as a result of such changes in the lumens of artificial airways. In addition, we demonstrated that both the duration of mechanical ventilation and the occurrence of ventilator associated pneumonia were associated with greater degrees of endotracheal tube intraluminal narrowing and volume loss."

"Organized secretions can significantly increase resistance as measured by the pressure drop of ETTs. The degree of change was highly variable, occurs in all sizes, and was unrelated to the duration of intubation. The performance of an ETT may be comparable to new tubes one to four sizes smaller. This may impact the tolerance of ventilator weaning."
Wilson AM, Gray DM, Thomas JG. Increases in Endotracheal Tube Resistance Are Unpredictable Relative to Duration of Intubation. CHEST 2009; 136:1006–1013

"Although there was considerable individual variation, values of ET tube resistance measured in vivo were generally higher than those derived from in vitro measurements at both peak flow rates tested, perhaps because of secretions, head or neck position, tube deformation, or increased turbulence. We conclude that ET tubes contribute significantly to total airflow resistance and that ET tube resistance is often significantly greater than indicated by in vitro studies. Estimates of work of breathing in critically ill patients must take into consideration the contribution of in vivo ET tube resistance on total pulmonary system resistance."

"If the physician had erroneously concluded that the cause of the weaning or preextubation trial failure was physiologic, the patient would have remained intubated, and ventilatory support might even have been increased. Prolonging ventilatory support unnecessarily has been called nosocomial respiratory failure or iatrogenic ventilatory dependency due to the perception of persistent parenchymal disease. In this study, we found that unexpected tachypnea observed during weaning and the preextubation trial in patients with otherwise acceptable pulmonary mechanics and blood gas exchange was related principally to the imposed work of the ETT..."
Under the old paradigm, about 20% of intubated patients may experience preventable delays in weaning and liberation from mechanical ventilation.

With the new weaning paradigm, a “Rescue Loop” is incorporated within an existing ventilator weaning protocol as a remedial pathway for patients who do not tolerate or fail a ventilator weaning trial. In a Rescue Loop™, a CAM Rescue Cath™ is used to safely, quickly and effectively clear secretions from the ET tube lumen of a patient with weaning “intolerance” or “failure”, as defined by criteria specified in the existing protocol. If indicated or desired, it may be used in conjunction with bronchoscopy, as illustrated below. If signs of weaning intolerance resolve in the Rescue Loop™, weaning is immediately resumed. Each day that a patient’s weaning is proactively expedited is one day less day of ventilator-associated risks and one day closer to liberation from mechanical ventilation.

**ILLUSTRATIVE CASES**

**Case 1**

*Failure?*

“The patient was weaned off mechanical ventilation uneventfully over the next 4 days, at the end of which he underwent a trial with continuous positive airway pressure (CPAP). The patient immediately decompensated with hypertension, tachycardia, marked agitation, desaturation, and “gasping” respiration. Return to pressure-controlled mechanical ventilation revealed reduced tidal volumes (from 800 to 400 mL). Minimal secretions were removed by suctioning of the tube…”

*Rescue*

“Fiber-optic bronchoscopy revealed significant luminal narrowing resulting from accumulation of biofilm; brown tenacious secretions in the distal lower lumen caused partial obstruction at various levels”


**Case 2**

*Failure?*

“The patient was getting weaning parameters and did well on the NIF, but became tachypneic and showed signs of increased WOB (use of accessory muscles, etc.) and was placed back on the vent overnight. The next morning… the patient's Resp rate was up (high 20's and Vt was decreased)”

*Rescue*

“The rescue cath. was used and a large mucus plug was removed. The patient's resp rate decreased to the mid-teens and Vt increased from 400 to 600cc and no signs of resp. distress and was successfully extubated [that day] and doing well.”

*Stone B, ahead of submission case series to Respiratory Care Journal 2010, (pub. pend., 2008)*
A well-planned extubation strategy includes a plan to “Rescue” patients who fail to wean due to elevated $WOB_{\text{Imposed}}$. Effective implementation of a good plan requires the right tool. The **CAM Rescue Cath™** is a weaning tool that can help “Rescue” patients not tolerating vent weaning or pre-extubation trials due to elevated $WOB_{\text{Imposed}}$.

The intuitive simplicity, tested and proven efficacy and impressive results of the **CAM Rescue Cath™** make it the ideal instrument for use even in the hands of clinicians with no advanced airway management skills.

**LOCKING CALIBRATOR**

The **CAM Rescue Cath™** is easily calibrated to the patient’s individual ET tube with a safety mechanism that directly locks the calibration disk against the handle rather than against the catheter, preventing accidental axial dislodgement and loss of calibration during clinical use. The **CAM Rescue Cath™**’s unique locking calibrator ensures cleaning of “the whole tube and nothing but the tube”.

**MaxFLO$^2_{\text{TM}}$ SECRETION REMOVAL**

The **CAM Rescue Cath™** suction port is narrower than that of other comparably sized suction catheters, but intentionally so in order to minimize its outer diameter for easier access to the distal tip of the ET tube. The patented **MaxFLO$^2_{\text{TM}}$** cleaning mechanism consists of a synthetic mesh that expands around a high grade, non-latex balloon. The balloon-based technology is the simplest and safest design available for its circumferential seal, which prevents secretions removed from the ET tube from falling through the mesh strands and into the airway (shown in the photograph on the left). Balloon-based expansion of the cleaning mechanism is also the safest based on the fact that there are no mechanical moving parts within the ET tube other than balloon inflation. Mechanical device malfunction within the airway (such as ‘jamming’ of mechanically-activated parts) can be catastrophic, but the balloon-based **CAM Rescue Cath™** cleaning assembly automatically defaults to a collapsed orientation for immediate removal from the airway if necessary. The balloon-tipped catheter concept is similar to the time-tested safety of vascular embolectomy catheters, but with the added efficacy of an enhanced secretion and blood-clot removal surface.

**SAFETY AND EFFICACY**

Whereas suctioning is very ineffective at removing secretions partially or completely obstructing the ET tube lumen, the **MaxFLO$^2_{\text{TM}}$** secretion removal mechanism on the **CAM Rescue Cath™** has been quantifiably proven to remove (in just seconds) all or nearly all secretions that accumulate within ET tubes of patients intubated for several days, weeks and even up to one month. For patients with thick or copious secretions and those failing to wean from mechanical ventilation, the **CAM Rescue Cath™** can safely remove obstructing ET tube secretions without the need for saline lavage.
In order to better understand and appreciate how the **CAM Rescue Cath™** outperforms standard ET tube suctioning techniques for secretion removal, patency throughout the entire length of clinically used ET tubes can be objectively quantified using acoustic reflectometry (AR). In these used ET tubes, the AR tracings indicate patency (on the $Y$ axis) at each point along the length of the ET tube (on the $X$ axis) at baseline (red), after suctioning with 14 Fr. catheter (yellow) and after a single **CAM Rescue Cath™** use (blue).
Baseline AR waveforms (red) confirm secretion accumulation occurs most severely in the distal third of ET tubes. Significant secretion-related obstructions may occur in short intubation periods, as shown in example ‘E’. Suctioning with a standard 14 Fr. suction catheter (yellow) has little or no effect on secretion removal. Examples ‘E’ and ‘G’ show similar degrees of obstruction before (red) and after suctioning (yellow) with only proximal shifting (not removal) of the secretions. Values in the gray circles indicate an approximate (~) equivalent ET tube size at the narrowest point (determines resistance and WOB). The **CAM Rescue Cath™** (blue) consistently removes secretions left behind by standard suction catheters. Clinicians experience and report impressive clinical results using the **CAM Rescue Cath™** in their ‘failure-to-wean’ patients. Now we know why. Wider ET tube lumen = decreased airflow resistance = decreased WOB_{imposed} = easier breathing.
Dear Clinical Colleagues,

Simply stated, more than anything else we want our patients to be safe. Airway patency and hygiene are absolute requisites for patient safety, yet during tracheal intubation, patients are unable to clear respiratory secretions that accumulate within their artificial airways. Clearance of secretions is normally performed by cilia movement and by cough and considered the “first line of defense” for the airway and lungs. However, tracheal intubation iatrogenically bypasses these natural defense mechanisms. As a result, secretions that accumulate within the ET tube focially narrow it, which increases airflow resistance and WOBimposed. This insidious but common occurrence can delay the weaning or liberation from mechanical ventilation of approximately 20% of patients, and sometimes can also lead to complete or near-complete ET tube obstruction.

Secretions typically consisting of respiratory mucus and bacterial biofilm accumulate within the ET tube, most concentrated in the distal third. Secretion accumulation occurs focally and along a spectrum of varying and unpredictable severity. This has been corroborated by numerous investigators using a wide variety of study methodologies. They report that under the watchful eyes of well-seasoned clinicians, ET tube secretions can stealthily progress to moderately severe levels obstruction. Even in ICUs that rarely experience severe ET tube obstructions, partial obstructions resulting from small quantities of mucus at the distal tip of the ET tube can result in physiologically significant increases in airway resistance. These seemingly insignificant partial ET tube obstructions can masquerade as weaning intolerance when the level of ventilatory support is reduced below the level necessary to offset the insidiously elevated WOBimposed. For example, a focal layering of secretions just one millimeter thin doubles WOBimposed.

Intubated patients want and deserve to be liberated from the ventilator without unnecessary delays or avoidable complications. Unnecessarily prolonged ventilatory support is more than ‘undesirable’ — it is inherently unsafe. This highly invasive supportive care leads to a significantly greater risk of pneumonia (VAP) and other serious complications, and adds considerable avoidable costs daily. Aggressive circuit humidification confers some protection from more severe ET tube ‘plugging’ due to inspissated secretions; however, significant ET tube narrowing has been reported as a “common” occurrence by leading intensivists in their own ICUs, despite practicing advanced humidification techniques. Unfortunately, many clinicians are under the misconception that their own patient population is somehow immune from this ubiquitous process leading to partial ET tube obstruction. Suctioning is a generally ineffective means of ET tube secretion removal, and using larger suction catheters or greater vacuum force leads to worsening iatrogenic deoxygenation. Irrigation of the ET tube in an effort to loosen secretions causes an iatrogenic aspiration of the contaminated secretions with each instance, with little known benefit for removal of secretions adherent to the ET tube lumen.

“Nosocomial” diseases or conditions and “iatrogenic” adverse outcomes are two highly unwelcomed realities of medical practice. As we treat patients for the diseases and conditions that they present with, we must also safeguard them from the risk of nosocomial diseases and iatrogenic events (“First do no harm”). Just as we institute antithrombotic therapy and decubitus precaution measures to prevent the iatrogenic consequences of keeping patients on “strict bedrest”, so too must we be vigilant for and prevent iatrogenic intubation-related events. Although usually instituted to offset WOBimposed that overwhelms patients’ respiratory physiologic reserve, ventilatory care is invasive and associated with a myriad of serious pulmonary and systemic complications, many of which are iatrogenic because they result from our interventions rather than as an extension of the original disease process. Intubation also deprives patients of the ability to communicate verbally, and it tethers and restricts them to an ICU bed, often requiring at least moderate sedation in order to tolerate the unpleasant experience. There’s a reason extubation is referred to as “liberation” from mechanical ventilation. If patients are receiving ventilatory support that is prolonged due to elevated WOBimposed, they are suffering from “nosocomial respiratory failure” or “iatrogenic ventilatory dependency” and may need to be “Rescued” from a vicious cycle of vent ‘weaning intolerance’ or ‘weaning failure’. With the Rescue Loop™ described in this document, we can offer ‘weaning intolerant’ patients an immediate second chance at weaning and possibly liberation from mechanical ventilation.

Omneotech® is a true pioneer and the leader in management of the artificial airway. Our Complete Airway Management (CAM) Catheters are so named because of the identified need to care for both the natural and artificial airways. Omneotech® is a unique company owned and operated by clinicians specialized in critical care medicine, anesthesiology, surgery and emergency medicine. We have worked ‘in the trenches’ on the wards, the ICUs, the ERs and the ORs of hospitals across the country, academic and community based, large and small. We have cared for intubated, ‘trached’ and mechanically ventilated patients our entire clinical careers and fully understand “First Do No Harm”, and how nothing affords us a better night’s sleep than knowing that our patients are safe. We understand how airway control and patency are top safety priorities. After more than a decade of research and development of our novel technology, including comprehensive non-clinical and clinical testing to ensure maximum safety and efficacy, we are proud to share with you our novel Rescue Loop™ and CAM Rescue Cath™. By incorporating a Rescue Loop™ into your ventilator weaning strategy, you can become an agent of change for this proactive and patient-centered paradigm shift.

Orlando Morejón, MD
President, Omneotech®

“It’s a no brainer”
— Clinicians evaluating CAM Rescue Cath™ at clinical conference

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