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Endotracheal tube forces exerted on the larynx and a novel support device to reduce it

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Abstract

Objective: Endotracheal tubes (ETTs) are commonly associated with laryngeal injury that may be short lasting and temporary or more severe and life altering. Injury is believed to result from forces that these ETTs exert on the larynx. Here we quantify the forces of ETTs of various sizes on the laryngotracheal complex to gain a more quantitative understanding of these potential damaging forces. Here we also perform preclinical testing of a novel support device to offload these forces.

Methods: Endotracheal intubation was performed on a fresh human cadaver using various ETT sizes. A strain-sensitive graphene nanosheet sensor and a commercially available force sensing resistor were secured behind the larynx, anterior to the prevertebral fascia. The forces exerted on the larynx were measured for each of the commonly used ETTs. A novel support device, ETT clip (Endo Clip), was attached to the ETTs and changes in these forces were observed.

Results: Forces exerted on the laryngotracheal complex by various ETTs were observed to increase with increasing tube size. This pressure can be significantly reduced with a novel ETT clip.

Conclusion: Here we demonstrate the first quantitative measurement of forces that ETTs exert on the larynx. We demonstrate a novel device that can easily clip onto an ETT reducing pressure on the laryngotracheal complex. This preclinical test paves the way for a human clinical trial.

Level of evidence: 5.

KEYWORDS
airway stenosis—clinical, endotracheal tube, laryngeal injury, laryngeal trauma, laryngology, larynx, pressure injury

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1 | INTRODUCTION

Endotracheal intubation is performed over 15 million times in the United States annually.[1,2] Prolonged and short-term intubation can result in laryngeal injury; 7% of all anesthesia-related claims are airway injuries from endotracheal tubes (ETTs).[3] Laryngeal injury may include vocal fold paralysis, vocal cord granulomas, posterior glottic stenosis, and more.[4] Ninety-seven percent of patients intubated over 72 h will have some form of laryngeal injury.[5] Aside from long-term sequelae, the most common postoperative complaint is sore throat typically lasting 72–96 h.[6–10] A solution is needed to prevent laryngeal injury independent of intubation duration.

Many reports have looked at factors associated with postoperative sore throat and hoarseness.[6–8] The experience of the anesthesiologist performing intubations did not impact the postoperative outcome.[6] This suggests that postoperative laryngeal symptoms may not be the result of trauma during the intubation process, but rather from the physical presence of the ETT within the airway. Further supporting this hypothesis, these studies found that smaller ETTs could reduce, but not eliminate, postoperative symptoms. However, ETTs can only be downsized to a degree before ventilation becomes inadequate. Therefore, another solution must be sought.

High-volume low-pressure (HVLP) polyvinyl chloride (PVC) cuffed ETTs were introduced in the 1970s and remain the standard ETT in use today.[11,12] Over the last 50 years further widespread technological advancement of ETTs to prevent laryngeal injury has been lacking. Here we developed and test a device to reduce laryngeal injury by decreasing the force of the ETT on the posterior larynx, the most rigid and space-constrained region of the laryngeal inlet. It is this region that we believe is responsible for postoperative laryngeal symptoms both in the short and long-term. Figure 1 illustrates this problem with examples of resultant injuries. The sagittal computed tomography (CT) images (Figure 1A,B) show the near 90° bend the ETT must make around the tongue to enter the larynx. This creates pressure along the posterior larynx as the ETT tends toward its native less bent conformation (Figure 2B). The ETT support device (Endo Clip) we present is a low-profile clip that easily attaches to any ETT bending it anteriorly supporting its in situ conformation so that the larynx does not have to (Figure 2). The Endo Clip was developed from a deep understanding of upper airway anatomy, analysis of historical cross-sectional imaging, and rigorous iterative lab simulations. Here we provide a quantitative look at the forces of various ETTs on the larynx as well as the force reduction that is achievable with Endo Clip.

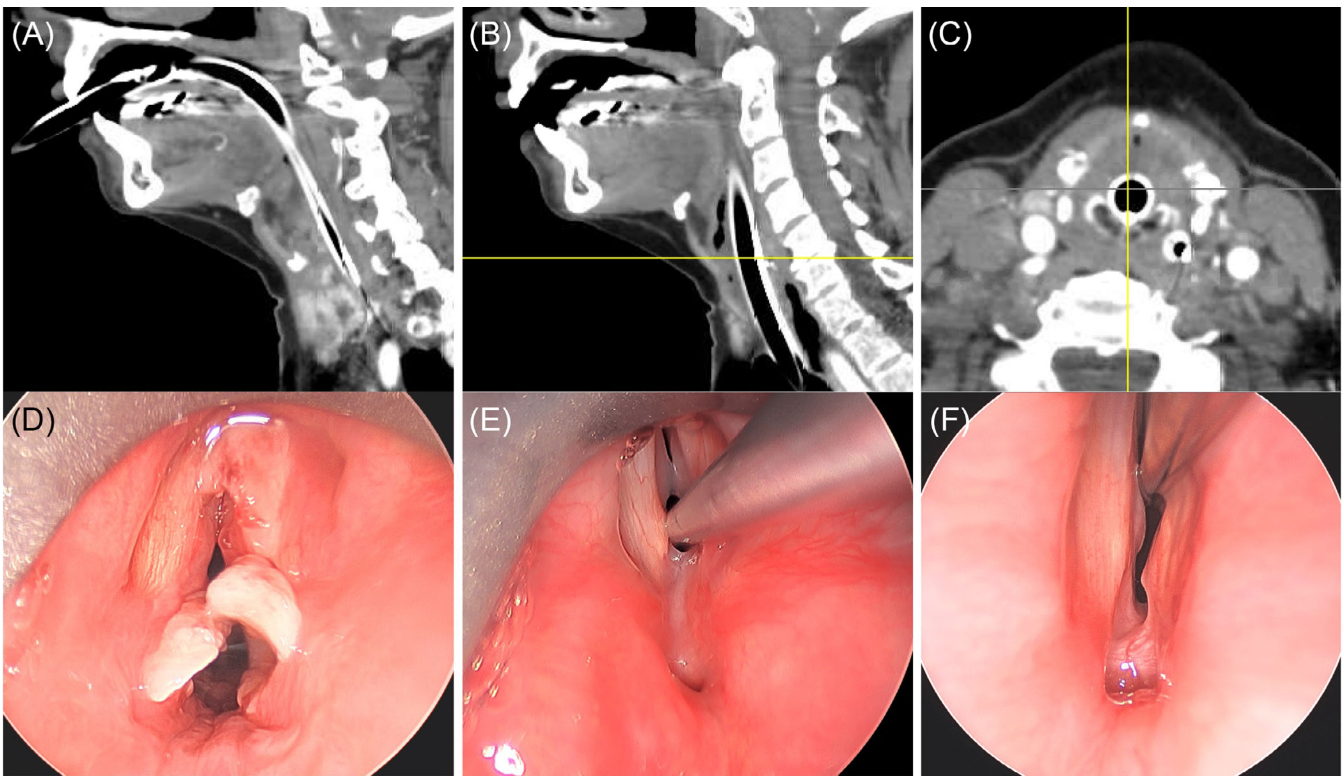

FIGURE 1 Laryngeal injury following intubation. (A) Sagittal CT soft tissue neck with contrast showing the endotracheal tube and the bend it must make in the oropharynx to get to the airway. (B) Localizing line showing close apposition of endotracheal tube and cricoid cartilage. (C) Axial CT soft tissue neck with contrast and localizing line showing close apposition of endotracheal tube with the posterior larynx. (D) Laryngeal exam following 3 days of intubation with a 7.0 mm ID tube in a 66-year-old female showing ulceration and granulation tissue. (E and F) Examples of posterior glottic/laryngeal stenosis resultant from endotracheal intubation. CT, computed tomography; ID, inner diameter.

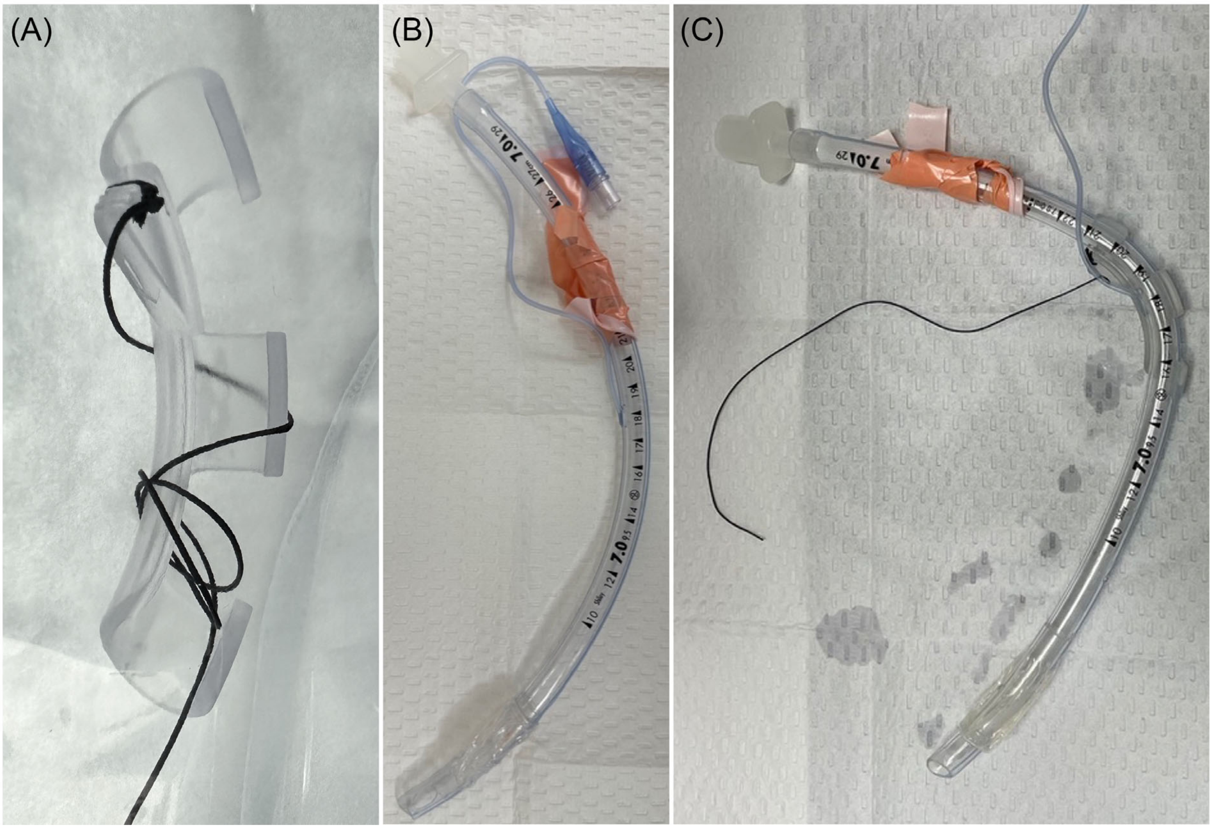

FIGURE 2 Endotracheal tube conformation and endotracheal tube clip. (A) Endotracheal tube support clip with attached suture. Suture is used in human applications for ease and safety of oral retrieval if needed. (B) 7.0 mm ID ETT showing its native curvature. (C) 7.0 mm ID ETT with the endotracheal tube clip attached showing the induced bend of the endotracheal tube. ETT, endotracheal tube; ID, inner diameter.

2 | METHODS

UC San Diego Institutional Review Board (IRB) deemed this study to be nonhuman subjects research and therefore exempt from IRB review. We first ran simulations using a high-fidelity airway mannequin (7-Sigma, Minneapolis, MN). We intubated the mannequin with the typical variety of ETT sizes and placed the Endo Clip on the tubes. We used a flexible fiberscope to obtain images of the ETT and its visual conformational changes (Figure 3).

Endotracheal intubation was performed on a fresh human cadaver using various ETT sizes ranging from 6.0 mm inner diameter (ID) to 8.0 mm ID (Shiley Hi-Lo Oral/Nasal Tracheal Tube Cuffed, Murphy eye; Covidien, Mansfield, MA). Dissection was performed behind the laryngopharynx to create a pocket anterior to the prevertebral fascia at the level of the cricoid cartilage (Figure 4). First, we used the strain-sensitive graphene nanosheet sensor (GNS) to detect the forces generated by the ETTs; strain is the sensor deformation resultant from an applied force. This sensor was made by embedding nanocomposite thin film in commercial Dragon Skin™ (Smooth-On, Inc, Macungie, PA). First, the bottom layer of the sensor was made by curing Dragon Skin™ in a short, cylindrical mold. Then, a layer of the nanocomposite ink was painted directly on the Dragon Skin™. A detailed fabrication process of the piezoresistive nanocomposite has been previously described.[13] Next, copper tape was attached at either side of the thin film, and silver paint was applied over the conjoined materials to minimize contact impedance. Upon drying of the silver paint, one more layer of Dragon Skin™ was poured over the top to form a protective layer. Lastly, thin multi-strand wires were soldered onto the two copper tape pieces to lengthen the leads and allow for easier connection with the data acquisition node. The data acquisition node utilized a CC1350 microcontroller (Texas Instruments, Inc, Dallas, TX) mounted on a custom printed circuit board (PCB). Voltage measurements were taken using the 12-bit analog to digital conversion (ADC) onboard the CC1350, at a rate of 70 Hz for approximately 10 s to ensure steady values were acquired. These measurements were then sent over Bluetooth Low Energy and received by another CC1350 board, where the data was exported for later processing. The pressures exerted on the larynx were measured for each of the commonly used ETTs. For each ETT, once baseline forces were measured, the Endo Clip was attached to the ETTs and changes in force were observed. We then repeated the testing with a commercially available force sensing resistor (FSR) (FlexiForce A201 Sensor, 4 N, 190.5 mm; Tekscan, Norwood, MA) for comparison and validation of our findings. Both sensors output a resistance value. This resistance value has a positive correlation with the force applied. Linearity of the FSR was confirmed using known weights. From this, a linear function provided a valid output in units of grams.

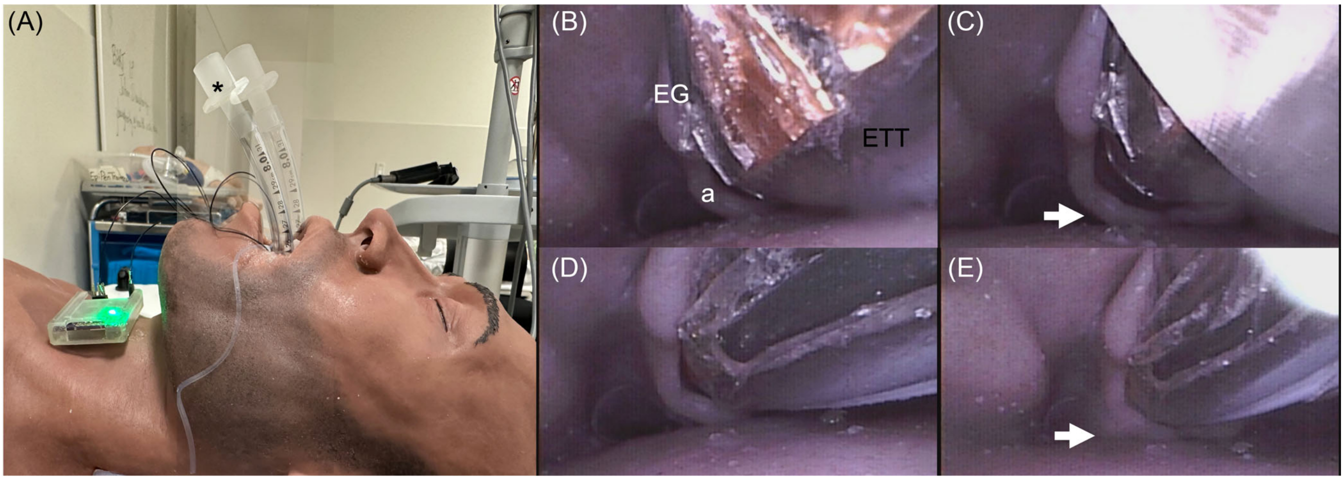

FIGURE 3 Mannequin simulations. (A) Mannequin intubated with an 8.0 mm ID ETT (photos are overlayed). The more transparent endotracheal tube is the tube without the support clip. The tube with the asterisk that is inferiorly displaced off the maxillary dentition is the tube with the support clip attached. (B) Laryngeal view with a 7.0 mm ETT without clip. (C) 7.0 mm ETT with clip, arrow showing improved space and visibility of arytenoids (a). (D) 8.0 mm ETT without clip. (E) 8.0 mm ETT with clip, arrow showing improved space and visibility of arytenoids. a, arytenoid; EG, epiglottis; ETT, endotracheal tube; ID, inner diameter.

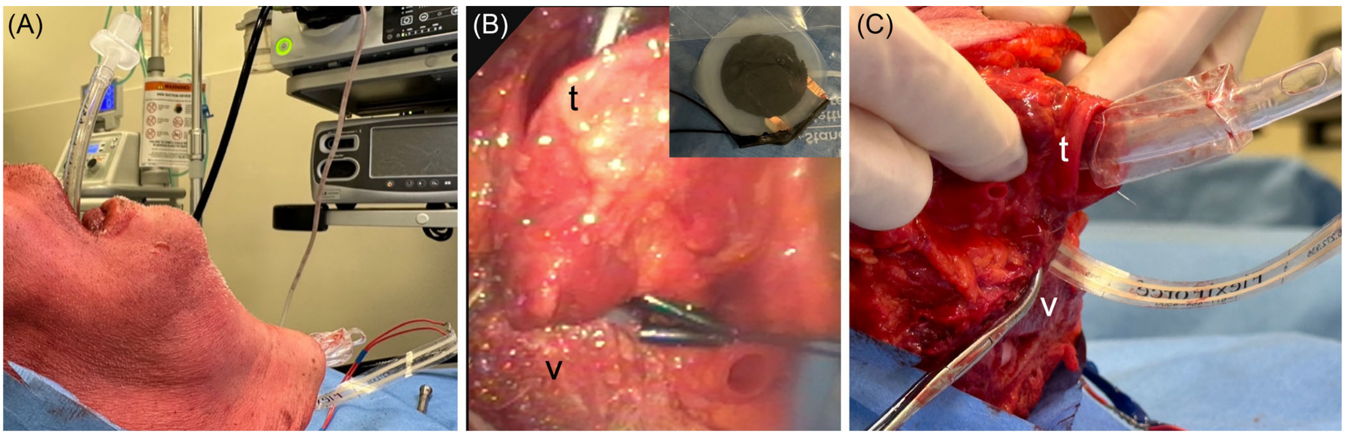

FIGURE 4 Cadaver testing. (A) Intubated cadaver showing oral and transcervical access. (B) Placement of the custom GNS sensor in a pocket behind the larynx and anterior to the prevertebral fascia. (B, inset image) Custom sensor. (C) Placement of the FSR in the retro-laryngeal pocket. FSR, force sensing resistor; GNS, graphene nanosheet sensor; t, trachea; v, vertebral body.

Student's paired *t*-test was used to compare the average resistance or grams resultant from an ETT with and without the Endo Clip applied. To test whether the Endo Clip significantly reduced measured pressures a one-tailed paired *t*-test was used. The level of significance was set at 0.05. Microsoft® Excel for Mac was used for this analysis (Version 16.71). This manuscript adheres to the statistical analysis and methods in the published literature (SAMPL) guidelines.

3 | RESULTS

Mannequin simulations provided great insight as to the conformational changes the ETT experienced with the clip applied. Figure 3 demonstrates the straightening of the distal tube and anterior deflection off the posterior larynx with clip application. Externally the tube can be seen to deflect slightly inferior reducing contact with the maxillary dentition.

Conformational changes were consistent when translated to the fresh cadaver application. The output of the GNS sensor was resistance measured in ohms. This value has a positive correlation with the force exerted on the sensor. As expected, the resistance measured, increased with increasing tube inner diameter, seeing the largest increase when transitioning from a 7.5 mm ID to an 8.0 mm ID (Figure 5).

The Endo Clip is easily applied to the ETT after orotracheal intubation. The clip is snapped onto the proximal end of the ETT and then advanced along the tube until the take-off of the pilot balloon tubing is encountered. The Endo Clip reduced the measured resistance in all conditions with greater resistance reduction seen for larger tube sizes.

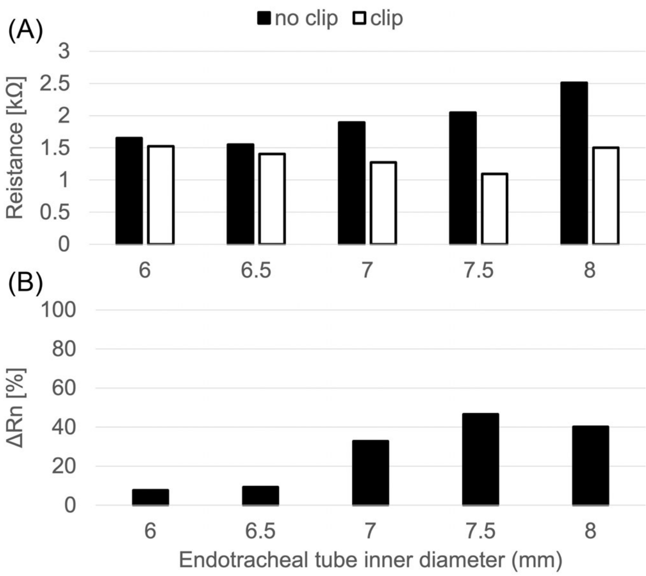

FIGURE 5 Measured resistance using the custom graphene nanosheet sensor. (A) Measured resistance for each ETT with and without the support clip. (B) Normalized % change in resistance for each ETT size with the application of the support clip; $[(R_{\text{no clip}} - R_{\text{clip}})/(R_{\text{no clip}})] \times 100$. ETT, endotracheal tube.

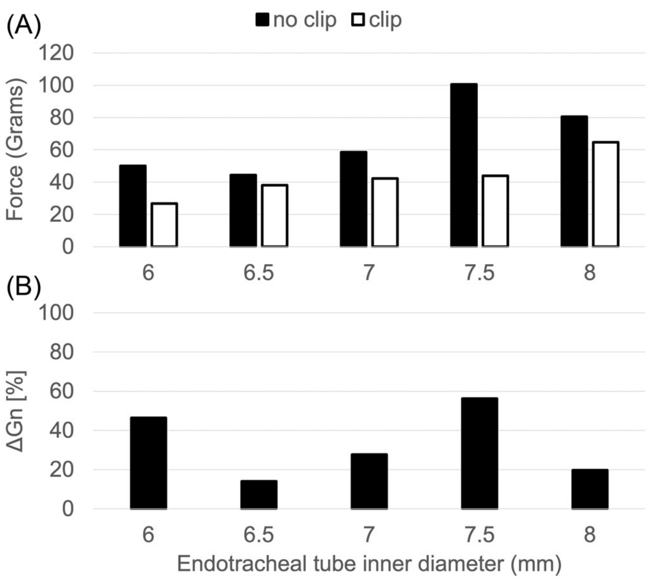

FIGURE 6 Measured force in grams using the force sensing resistor. (A) Measured force in grams for each ETT with and without the support clip. (B) Normalized % change in grams for each ETT size with the application of the support clip; $[(G_{\text{no clip}} - G_{\text{clip}})/(G_{\text{no clip}})] \times 100$. ETT, endotracheal tube.

The absolute resistance reduction was on average −570.3 ohms with 95% confidence interval [−198.2, −942.4]. This equates to an average reduction in resistance of 27.3%, ranging from 7.6% reduction for a 6 mm ID tube up to 46.6% reduction for a 7.5 mm ID tube (Figure 5). This reduction was statistically significant with *p*-value of .019.

The additional round of testing with the FSR provided validation of these findings (Figure 6). Here we see the measured force in grams increase most dramatically for tube sizes above 7.0 mm ID. Here the Endo Clip provided an average reduction in measured force of 32.9%, ranging from a 14.1% reduction for a 6.5 mm ID tube up to a 56.3% reduction for a 7.5 mm ID tube. The absolute force reduction was on average −23.7 g with 95% confidence interval [−6.7, −40.7]. This reduction was statistically significant with a *p*-value of .026.

4 | DISCUSSION

Laryngeal injury from endotracheal intubation is believed to result from the pressure exerted by the ETT on the larynx. The posterior larynx (posterior vocal folds and arytenoids) is most susceptible to injury because of the high pressures in this region. This can result in life altering posterior glottic stenosis which often requires multiple surgeries yet may fail to ever achieve premorbid function. Variables that logically would be expected to correlate with laryngeal injury, such as ETT size and duration of intubation have found mixed correlation in the literature.[14–16] Although many studies have looked at ETT size, no one has looked quantitatively at the laryngeal forces resultant from these tubes. Here we provide the first quantitative look at these laryngeal forces using a GNS sensor and FSR.

Here we find that resistance measured by the GNS sensor, which has a positive correlation to the experienced force and therefore pressure, increases with larger ETT size. A 6.0 and 6.5-mm ID ETT demonstrate similar resistance. The largest incremental increase is seen when increasing from a 7.5 to an 8.0 mm ID ETT. A 7.0 mm ID ETT is among the most common used in adults intubated for shorter periods of time such as for outpatient and inpatient surgery. However, 8.0 mm ID ETTs can often be seen in the intensive care unit as disease and ventilatory requirements may necessitate a larger caliber tube.[17,18] Smaller ETTs may result in inadequate ventilation, air leakage, higher risk of aspiration, and an inability to adequately suction or pass a fiberscope without interrupting ventilation.[19] However, our findings support that even a seemingly minor change from an 8.0 mm ID ETT to a 7.5 ETT may mean a large reduction in resultant laryngotracheal pressures and should be considered when feasible.

Further reduction in the laryngotracheal pressures have largely been limited by the design constraints of ETTs. Current ETTs must conform to the American Society for Testing and Materials (ASTM) standards. This dictates that ETTs must be circular in cross section and have a radius of curvature between 12 and 16 cm.[11,12,20] This leaves little room for innovation to reduce laryngotracheal pressures. The Endo Clip is designed to work with all existing ETTs (Figure 2). It is simple in design and execution. Here we show its implementation for the first time in a high-fidelity airway mannequin and fresh human cadaver.

The oropharynx and supraglottic airway through which an orotracheal tube must pass, before traversing the glottis, is a confined and often narrow space. In most cases when patients are intubated, this region is further constrained typically by muscle paralysis and supine positioning which allow the tongue and gravity to encourage collapse. The use of a high-fidelity mannequin helped elucidate the in situ conformational changes of the ETT created by the ETT clip (Figure 3). This provided visual confirmation that the ETT enters the larynx in a straighter geometry that permits greater visibility of the posterior larynx and arytenoids, suggesting that there is less pressure in this region. Without the ETT clip the ETT enters the larynx with greater curvature and appears to compress the larynx against the posterior pharynx and spine. The straightening of the distal ETT as it enters the glottic opening may provide additional advantages to the use of the Endo Clip. Namely, an improved position and lay of the ETT distal end within the trachea. High ETT cuff pressures and malposition of the ETT cuff and distal end are associated with tracheal injury and stenosis.[21] A straighter distal end may mean improved positioning of the ETT's distal beveled end and avoidance of contact to the tracheal side wall. This may result in less tracheal pressure injury and functionally may improve ventilation and tracheal suctioning. Notably, the assessment of this confirmational change in the mannequin model is visual and subjective. However, Figure 3 provides unedited images for interpretation. Overall, our visual findings are confirmed and supported by the cadaveric measures.

Fresh human cadaver testing with the strain-sensitive GNS and a FSR in this region is first of its kind. We used these sensors to better understand the incremental changes in laryngeal force with increasing ETT size as well as the potential benefit of the Endo Clip. With the sensors in the retro-laryngeal prevertebral pocket we were able to maintain a steady position and isolate the resultant force exerted on and transmitted through the larynx. Here we found that the Endo Clip was able to reduce the laryngeal force (resistance) with all ETTs ranging from 6.0 mm ID to 8.0 mm ID. For the 6.0 and 6.5 ETTs we saw a reduction of 7.6% and 9.3% respectively whereas for larger tube sizes the force reduction was much greater. For a 7.0, 7.5, and 8.0 ETT we saw a reduction of 32.7%, 46.6%, and 40.2%. This was confirmed using the commercially available FSR.

A limitation of this study is the use of a single fresh human cadaver for pressure analysis. Whereas a fresh cadaver is the closest model for a live human, the tissue properties will inherently be different. Additionally, different cadavers may have variable upper airway anatomy but the main anatomical constraints to orotracheal intubation are similar across individuals. As such, the use of multiple cadavers in this preclinical study was felt to be unnecessary. Additionally, we must recognize that the laryngeal inlet is inherently a confined orifice. In offloading the pressure that the ETT exerts on the posterior "cartilaginous" larynx, there must be increased pressure seen on the anterior "membranous" larynx as a result. We specifically designed the Endo Clip to provide the most ideal in situ ETT conformation, encouraging a conservative anterior bend of ETTs. Whereas we cannot be certain of the clinical relevance of this resultant anterior glottic pressure, we do know that the anterior "membranous" larynx is inherently more compliant, composed of well-vascularized muscle and the lamina propria in contrast to the rigid "cartilaginous" larynx including the arytenoid and cricoid cartilage. The literature on hospital-acquired pressure injuries consistently points to the most common anatomic locations being over bony prominences of the sacrum/coccyx, buttocks, and heel.[22] The posterior larynx, with the cricoid and arytenoid cartilages, is arguably most analogous to these regions of bony prominence and we know is more susceptible to injury.[4,5] As such, we anticipate the anterior pressure that occurs as a result of reduced posterior pressure will be a reasonable tradeoff and clinically worthwhile but future clinical testing will be required. We believe that the significant reduction in force on the posterior larynx that we observe here will result in less laryngotracheal complications following intubation. This preclinical work forms the basis for a forthcoming clinical trial using the Endo Clip in patients undergoing short duration orotracheal intubation for outpatient surgery.

5 | CONCLUSION

Intubation-related laryngeal injury has long been believed to result from high pressures on the posterior larynx. Here we demonstrate the first quantitative measurement of these laryngeal forces with the most marked increase seen for ETT sizes above 7.0 mm ID. We demonstrate a novel device that can easily clip onto an ETT creating an anterior bend in the tube that results in a reliable and significant reduction of force on the laryngotracheal complex.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

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