Reducing Tracheal Complications in Endotracheal Intubation Patients Using Automated Cuff Pressure Modulation

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Endotracheal tube intubation is the third most frequent procedure, performed approximately 13-20 million times yearly in the United States (Mosier et al., 2020). Despite the regularity of the procedure, intubation-related complications such as tracheal injuries, laryngeal injuries, and ventilator-associated pneumonia are ubiquitous due to improper cuff pressure management methods (Ganti et al., 2018). Current techniques, such as the pilot balloon and minimal leak technique, have proven ineffective and inconsistent in managing pressure. As a result, over 71.6% of intubation patients have abnormally high cuff pressures (Ramírez, 2014). Therefore, the purpose of this research was to design an endotracheal tube with automated cuff pressure modulation synced with the respiratory cycle. Increasing and decreasing cuff pressures as patients inspire and expire should theoretically relieve pressure placed on the trachea during intubation and reduce many of the complications associated with endotracheal tubes. The device was designed using two pressure sensors to evaluate the instantaneous pressure and cuff pressure, two DC motors to inflate and deflate the cuff, and an Arduino microcontroller to control the units. To test the device for its functionality, intubation was simulated by blowing into the tube. The results found that the endotracheal tube successfully automatically modulated the cuff pressure to pressures of 25 cmH₂O and 14-15 cmH₂O with the respiratory cycle. Therefore, the presented proof-of-concept design to modulate the cuff pressure of endotracheal tubes is a viable solution to reduce intubation-related injuries.

Introduction

Tracheal intubation is a common, yet critical procedure performed during respiratory failure or shock. This procedure is the third most frequently performed procedure in United States hospitals, performed on approximately 13-20 million patients each year in the U.S. alone (Mosier et al., 2020; Sultan et al., 2011). Intubation involves inserting an endotracheal tube (ETT) through the patient's nose or mouth into the trachea to open the airway during airway obstruction, cardiac arrest, apnea, and/or loss of consciousness (Cleveland Clinic, 2021). The tube is then connected to a ventilator or other supply of air. Most commonly, intubation is performed before surgery or for anesthesia. However, despite its regularity, intubation can be very dangerous as it is a complex process that depends on the success of preparation, positioning and placement of the tube, cuff pressure, and postintubation management (Ganti et al., 2018).

Because of the numerous steps required for proper intubation, intubation-related injuries are common. Two regular injuries from endotracheal tubes are postoperative sore throat and hoarseness, which occur for 72% and 40-59% of patients, respectively (Christiansen et al., 2021). Ventilator-associated pneumonia from improper cuff inflation occurs in 9-27% of intubation patients (Efrati et al., 2012). In addition, leakages around an endotracheal tube, which can cause improper ventilation, hypoxemia, and pollution from anesthetic mixtures, are a very common problem that occurs up to 11% of the time in the ICU (Gupta, 2015). Depth placement of endotracheal tubes is an additional issue that affects 1.2% of intubation patients, which, due to the large number of patients each year, still affects a large number of people. (Ganti et al., 2018). Furthermore, oral pressure injuries are another common issue occurring in 22.6% of intubation patients. Finally, the most common and dangerous issues are tracheal and laryngeal injuries, with laryngeal injuries occurring in 57% of intubation patients (Hyzy, 2022). The primary cause for many of these injuries is the management of endotracheal tubes.

As mentioned earlier, endotracheal tubes are used for intubation to open the airway and provide a direct supply of air. Standard endotracheal tubes range from 6.00 mm - 8.00 mm in diameter and are made of polyvinyl chloride (Haas et al., 2014). They have a slight curve, a beveled tip, and depth markings. One of the most important parts of an endotracheal tube is the cuff. The cuff is a balloon attached near the end of the tube that can be inflated via the outlet port near the opening of the ETT (Haas et al., 2014). The primary function of the endotracheal tube cuff is to provide a seal in the trachea to prevent the leakage of gas. An often overlooked function is to keep the tube centered in the trachea and protect the tracheal mucosa. An improperly inflated cuff can lead to mucosal damage, tracheal edema, tracheal blood flow, lesions, tracheomalacia, bleeding, tracheal rupture, stenosis, nerve palsy, ischemic necrosis, mucosal damage, and tracheoesophageal fistula (Al-metwalli et al., 2021). However, cuff pressures below 20 cmH₂O create an incomplete seal which can lead to inadequate ventilation, oral secretions, and ventilator-associated pneumonia (Chenelle et al., 2014).

The lack of cuff pressure management is a widespread issue throughout healthcare. Nwosu and his team (2015) describe the lack of knowledge on cuff pressure maintenance. The results from a survey they conducted in Nigeria found that only 31.1% of care providers knew the optimal cuff pressure. Additionally, only 3.1% had ever used an accurate manometer to check the pressure. Other studies in Pakistan and the United States found that 72% of healthcare workers lacked knowledge on the hazards of improper cuff pressure, and only 35% of care providers knew the optimal pressure range (Nwosu, 2015). Another study conducted by Ramirez (2014) concluded that only 28.4% of endotracheal tube patients have cuff pressure in a safe range. Sultan et al. (2011) reported that 58% of patients intubated by ambulance personnel had cuff pressures greater than 40 cmH₂O. The mean pressure set by paramedics was 108 cmH₂O, and 91% of all intubated patients in the ICU had unsafe cuff pressures.

Despite all of the knowledge and research on the frequency of unsafe cuff pressures, issues still remain due to the lack of proper techniques and common practices in healthcare to check cuff pressure. Chenelle et al. (2014) demonstrated that simple changes in patient positioning could lead to significant and often dangerous changes in cuff pressure. The current methods used to assess cuff pressure are the finger pressure technique which measures the size and pressure of the pilot balloon, and the minimal leak technique which determines if the trachea is fully occluded using a stethoscope over the sternal notch. However, the inadequacy of these methods can lead to unnecessarily high and low cuff pressures which can result in laryngotracheal complications (Al-metwalli et al., 2021). A study conducted by Ramirez et al. (2014) evaluated the effectiveness of the two techniques. The mean pressure using the finger technique was 36.9 cmH₂O and 25.3 cmH₂O using the minimal leak technique. However, despite the safe average cuff pressure, 41.7% of the minimal leak group had cuff pressures less than 20 cmH₂O and 23% had cuff pressures higher than 30 cmH₂O (Ramirez, 2014). Overall, manual cuff pressure methods have lacked the accuracy to reduce injury. A study by Jain & Tripathi (2011) found that irrespective of an anesthesia provider’s experience, manual methods resulted in 27% of patients with cuff pressures greater than 40 cmH₂O, showing that there is still a lack of proper cuff management.
Currently, there is still no ideal method or device to manage the cuff pressure of endotracheal tubes, which is vital to the safety of intubation patients. The proposed solution in this research project was to design an endotracheal tube that could effectively modulate the cuff pressure with a patient's respiratory cycle. The Human Anatomy Lab textbook shows that the trachea is formed of cartilage pieces connected by the fibroelastic membrane, which is formed by the tracheal muscles and connective tissues (LibreTexts, 2021). The fibroelastic membrane mainly allows the trachea to expand during exhalation or inhalation (LibreTexts, 2021). Reviewed by Dr. Tobin from the Department of Anesthesia and Perioperative Medicine at MUSC, modulating cuff pressure to be higher during inspiration when the trachea is expanded and lower during expiration when the trachea is contracted could be a possible solution to allow for a lower average cuff pressure while maintaining a complete seal of the trachea. This adaptation of endotracheal tubes by modulating cuff pressure with the ventilatory cycle should provide a solution to cuff pressure management issues and ultimately reduce tracheal injuries and other intubation-related injuries.

Literature Review

There have been numerous approaches to improving the safety of intubation by reducing endotracheal tube injuries.

Over the years, there have been many changes and variations in the structure of the tube, such as the RAE ET prebent shape for easier placement and extension of the tube, different materials to allow for laser surgery like copper and aluminum wraps, and sensors to monitor nerve integrity (Haas et al., 2014). Other variations include the Parker Flex-Tip, which uses a soft curved tip to prevent tissue trauma, armored tubes for reinforced flexibility, the Hunsaker Mon-Jet Tube for subglottic ventilation, and the LITA tube with a separate channel for anesthesia (Haas et al., 2014). However, the majority of these developments have not been widely distributed in health care due to their inefficiency and reliability.

There have also been many developments in the design of the cuff for endotracheal tubes. These include tapered cuffs, foam cuffs, self-inflating cuffs, and cuffs from different materials such as polyurethane or PVC, all with the goal of better fitting the cuff to a patient and preventing injury (Haas et al., 2014). Despite the benefits that these different variations provided, they all sacrificed at least one aspect of the standard endotracheal tube such as reliability or cuff strength. Another type of cuff researched was ultrathin cuffs, which significantly reduced pressure-related injuries, but was not successful due to its permeability (Efrati et al., 2009). One of the primary developments in cuffs has been low-pressure high-volume cuffs. Original cuffs were high-pressure low-volume cuffs, meaning they had smaller diameters and increased pressure to seal the trachea (Altıntaş et al., 2021). However, ever since these cuffs were identified as problems due to the pressure they place on the trachea, the convention has been high-volume low-pressure cuffs that provide the same seal without causing injuries (Al-metwalli et al., 2021).

Aside from the construction of endotracheal tubes, there have been few developments in managing pressure. As mentioned earlier, the conventional methods used by healthcare providers (the pilot balloon technique and minimal leak technique) have proved to be ineffective in managing safe cuff pressure. One of the most accurate methods to measure pressure is by using a manometer, a pressure gauge that attaches to the pilot balloon, however, there has been a lack of availability and experience in using them (Nwosu et al., 2022). A study in Nigeria found that only 3.1% of healthcare providers had ever used a manometer, and another study in Pakistan found that only 27% of healthcare providers had used a manometer (Nwosu et al., 2022). Most importantly, manometers are not the most effective solutions because they have been shown to require frequent calibration, cause air leaks during detachment, cause slight aspiration, and lead to possible cross-contamination through patient use (Al-metwalli et al., 2021).

Another development in cuff pressure management is automated cuff pressure monitors. These systems continuously adjust cuff pressure to a set range. A comparison of manual and automatic methods found that the manual group had an initially high pressure that continued to modulate above 25 cmH₂O. The automatic group maintained a steady pressure of around 25 cmH₂O. However, these automated cuff pressure systems have not seen widespread implementation in the healthcare system (Chenelle et al., 2014). This is because, despite their exorbitant costs, automated systems have not shown superiority in reducing injury. Jain & Tripathi (2011) found that although they can manage cuff pressure in a safe range, they do not reduce the chance of tracheal mucosal injuries in comparison to manual cuff management issues.

It can be seen that there is still a gap in research as to effective ways to manage safe cuff pressures. The proposed approach in this project was inspired by current Bi-PAP (bilevel positive airway pressure) systems used to treat sleep apnea, which deliver a lower expiratory positive airway pressure and higher inspiratory positive airway pressure (Altıntaş et al., 2014). These improve adherence to PAP systems and reduce complications (Altıntaş et al., 2014). Bi-PAPs use pressure transducers to measure the instantaneous flow of air and modulate pressure (Estes & Cattano, 2004). Chadha et al. (2011) applied similar principles to an endotracheal tube and tested its effectiveness on intubated pigs, finding that it could be an effective solution to reducing pressure injuries.

Methods

To investigate the method of modulating cuff pressure in endotracheal tubes to reduce tracheal injury, a device was designed, constructed, and then prototyped.

Endotracheal Tube Device

The goal of the design is to modulate cuff pressure with the respiratory cycle. When a patient is intubated, the instantaneous pressure, which is the pressure flowing through the endotracheal tube at the exact moment, increases during inhalation and decreases during exhalation. Measuring instantaneous pressure can determine when a patient inhales or exhales. The identification of when a patient inhales or exhales was derived from the design of current BIPAP, sleep apnea treatment systems that generate varying air pressures down a patient's trachea based on the respiratory cycle (Estes & Cattano, 2004). These systems use a pressure sensor/transducer to compare the instantaneous flow of air with the average pressure to effectively determine inspiration and expiration (Estes & Cattano, 2004). As mentioned earlier, the standard endotracheal tube features a 15 mm opening and a valve with a pilot balloon that inflates the cuff. To construct the instantaneous pressure measuring system, 15 mm tubing was securely attached to the opening of the endotracheal tube. A perpendicular hole was made in the tube, and a 4 mm barbed connector was inserted into the hole. 4 mm tubing was then connected from the barbed connector to a pressure sensor.

The second component of the design was controlling cuff pressure. The first goal was to continuously monitor cuff pressure to prevent overinflation or underinflation. This is similar to the design of current automated cuff pressure controllers, which constantly monitor cuff pressure and use an air pump to adjust the pressure to the level set by the operator (Jain & Tripathi, 2011). To accomplish this, the inflation valve of the endotracheal tube cuff was connected to the male Luer lock port of a three-way stopcock. The perpendicular end of the stopcock was connected to 8 mm tubing, which was then connected to 4 mm tubing. The 4 mm tubing was then connected to a second pressure transducer. The next step was to control the...
Figure 1. *Instantaneous Pressure Measuring System.* The model above is a 3D diagram of the instantaneous pressure measuring system. This system measures the pressure of the air that enters the endotracheal tube to identify when a patient inhales or exhales. This is done by connecting the 4 mm tubing to the 15 mm tubing from the endotracheal tube and attaching the 4 mm tubing to a pressure sensor.

Figure 2. *Cuff Pressure Modulating System.* The model is a 3D rendering of the endotracheal tube device. A three-way stopcock connected to the pilot balloon measured and controlled cuff pressure. The toggle switches are not accurate representations of the solenoids and are symbolic of a valve.

Figure 3. *Full Endotracheal Tube Device.* The model above is the complete design of the device that compares instantaneous pressure with cuff pressure to constantly modulate pressures and alleviate injuries.
cuff pressure using motors. The direct opposite end of the stopcock was similarly connected to 8 mm tubing, which was then connected to the 4 mm tubing. The 4 mm tubing was then connected to a 4 mm brass three-way coupling on the perpendicular end, and two separated strands of 4 mm tubing were connected to the parallel ends of the coupling. Each end of the tubing was then connected to the barbed port of the three-way solenoid valve. The two 5V DC Mini Air Pumps were connected to the other plastic port of the solenoid valve and the final metal port was blocked off with electrical tape. Solenoid valves were used to prevent air from leaking from the cuff through the motor. The valves were only opened when the DC pumps were turned on to keep the system airtight. DC air pumps feature two ports; one port vacuums air and the other port blows out the air. The left side of the three-way coupling tubing was connected to the vacuum port of the DC motor and the right side was connected to the air pump port of the second DC motor. This allowed for one motor to increase the cuff pressure and the other to decrease the pressure.

Circuit

The cuff pressure modulating system was mainly controlled by an Arduino UNO Rev3 microcontroller. The Arduino was paired to a breadboard by connecting the 5V port on the Arduino to the positive side of the breadboard using 22 AWG wire. The ground port was then connected to the negative side of the breadboard. The instantaneous pressure transducer was paired to both the Arduino and the breadboard by connecting the SCK and OUT ports on the transducer to the 12 and 11 ports of the Arduino and connecting the remaining ports to the positive and negative ports on the breadboard. The same was repeated for the cuff pressure sensor, with the SCK and OUT ports on the transducer connected to the 9 and 8 ports on the Arduino.

The second part of the circuit focused on the motors that inflated and deflated the cuff. Relays were used for the solenoids and motors since they needed their own 6V power sources that the Arduino could not supply. The six volts were provided from four battery packs that held four double AA batteries each. The relays were all connected to the Arduino and breadboard as labeled on the relay. The common port on the relay was wired to the positive side of the DC motor and the Normally Open port on the relay was wired to the positive side of the four double-A Battery pack holders. In between the common port and DC motor was a chain of resistors totaling 39.4 Ω. The chain consisted of two 8.2 Ω resistors, two 6.8 Ω resistors, and two 4.7 Ω resistors. The resistor chain was needed to decrease the speed of the motor so that the cuff pressure would increase at a slower and steady rate which could be read by the pressure sensors and prevent overinflation of the cuff. The negative wire of the battery pack was then connected to the negative end of the DC motor. The same connection to the relay was followed for the solenoid valves except for the resistor chain which was unneeded for the solenoids. The motor and solenoid valve for inflation was connected to ports 4 and 7 respectively and the components for deflation were connected to ports 5 and 6.

![Figure 4. Circuit Drawing for Endotracheal Tube Device.](image)

The image above is a circuit diagram of all electrical components used for the system. The pressure sensors, solenoid valves, relays, and motors were all connected to a breadboard and an Arduino microcontroller in order to be operated.

Code

The primary function of the code was to measure the instantaneous air pressure flowing through the endotracheal tube to increase and decrease cuff pressure with the respiratory cycle. The Q2-HX711-Arduino-Library made by Russell (2015) was adapted to read two pressure sensors and display them on the serial monitor. The instantaneous pressure was measured by reading pins 11 and 12 and was labeled avg_val_2. Avg_val_2 had a constant normal reading of approximately 8540000. The cuff pressure sensors were measured through pins 8 and 9, were labeled avg_val, and had a normal reading of around 9370000. To make the data easier to read, all values from the pressure sensor were scaled down by dividing by 100000. Therefore, the instantaneous pressure sensor had a normal reading of 85.40 and the cuff pressure sensor had a normal reading of 93.70.
Since details of the Arduino library used to receive values from the pressure sensor were not described, the pressure values received needed to be calibrated in cmH\textsubscript{2}O. According to Ramirez et al. (2014), the safe cuff pressure range is between 20 and 30 cmH\textsubscript{2}O. Since the trachea expands during inspiration and contracts during expiration, it was decided to modulate the cuff pressure to 28 cmH\textsubscript{2}O when a patient inhales, due to a higher risk at pressures of 30 cmH\textsubscript{2}O, and 20 cmH\textsubscript{2}O when a patient exhales. The cuff pressures were reviewed and approved by Dr. Catherine Tobin from MUSC. To calibrate the pressure sensor values to the cuff pressure values, a cuff pressure manometer was used. The brass coupling and motors were disconnected from one end of the stopcock, and 8 mm tubing was instead attached. The tubing was then connected to the cuff pressure manometer and the code was run. The cuff was manually inflated to pressures of 20 and 28 cmH\textsubscript{2}O, and the pressure sensor values were approximately 10400000 and 11900000 respectively, scaled down to 104 and 119. According to Jain & Tripathi (2011), the ideal current average pressure is 25 cmH\textsubscript{2}O, which corresponds to pressure sensor values around a little under 112.

The code consisted of a series of ‘if’ statements. If the instantaneous pressure (avg\_val \_2) was greater than 8600000, indicating inspiration with a slight buffer range over the normal value, and the cuff pressure (avg\_val) was less than 11800000, ports 4 and 7 were turned on. This meant the solenoid valve and air pump motor were turned on. However, if the cuff pressure was already 11800000, both ports remained low. If the instantaneous pressure was less than 8450000, indicating expiration, ports 5 and 6 were turned to high, meaning the vacuum motor turned on. If the cuff pressure was below 10400000, both ports were turned low. The series of ‘if’ statements were repeated continuously. The full code is shown in Figure 5.

Data Collection

Data collection was split into two different parts: experimentation for the endotracheal tube device with automatic cuff pressure modulation and experimentation for the standard endotracheal tube as a control. Since it is not feasible or possible to test the effectiveness of the device in reducing injuries due to limitations as a high school student, data collection revolved around proving the functionality of the device. For the first part, the researcher used their mouth to blow into the endotracheal tube to simulate changes in instantaneous cuff pressure that would come from normal inspiration. Since the changes in instantaneous cuff pressure are designed to follow the inhalation and exhalation of patients, they do not need to be monitored or kept constant. As such, inconsistencies associated with using the mouth were irrelevant as long as proper breathing patterns were followed. In intubation patients, inhaling would mean air flowing down the tube while exhaling would be air counteracting the downflow of air through the tube. Therefore, for the experiment, air was blown into the tube to represent inhaling, and was sucked out of the tube to represent exhaling. One trial included a twice repeated cycle of 3 seconds of inspiration, 3 seconds of rest, and 3 seconds of expiration, a twice repeated cycle of 2 seconds of inspiration, 2 seconds of rest, and 2 seconds of expiration all repeated twice, and a twice repeated cycle of 1 second of inspiration, 1 second of rest, and 1 second of expiration. Cuff pressure data were collected in the serial monitor throughout the trial from the computer linked to the Arduino. Five trials were performed.

The control for the experiment monitored the cuff pressure in normal intubation without the modulating system. To test the endotracheal tube for the control, the brass coupling was disconnected from the stopcock and the open port on the stopcock was connected to the cuff pressure manometer. As mentioned earlier, the average safe cuff pressure is 25 cmH\textsubscript{2}O. Therefore, the manometer was used to manually inflate the cuff to 25 cmH\textsubscript{2}O, and one trial was conducted by measuring the cuff pressure and instantaneous pressure using the sensors.

Results

As mentioned earlier in the methods, both pressure sensors used in the experiment read in unknown values in the millions. To calibrate the pressure sensor for cuff pressure, a cuff pressure manometer and pressure sensor were used together, and the values were compared. A cuff pressure of 28 cmH\textsubscript{2}O, the set inhalation cuff pressure, translated to approximately 119 for the pressure sensor value. A cuff pressure of 20 cmH\textsubscript{2}O, the set exhalation pressure, was approximately 104 with the pressure sensor. The control of 25 cmH\textsubscript{2}O was approximately a little under 112. Since the exact instantaneous pressures were irrelevant, the pressure sensor values for those parts were not calibrated.

Table 1 is a condensed data table that displays the average cuff pressure and instantaneous pressure value each second for each 36 second trial. The full data table is linked in the Appendix 1. Every nine values were averaged to form Table 1 with one average pressure value each second. The instantaneous pressure values modulated in increasingly smaller intervals, and for all five trials, the cuff pressure values also changed. However, the cuff pressure values for the control standard endotracheal tube remained constant.

Figure 6 is a graph of the cuff pressure values in comparison with the instantaneous pressure values over the 36 second trials. The black lines show the control, with the bottom line showing instantaneous pressure, and the top line showing cuff pressure. With the modulating instantaneous pressures, the cuff pressure in the control endotracheal tube remained constant throughout the trial. The red lines show the instantaneous pressure across five trials and the blue lines show the cuff pressures across all five trials. The instantaneous pressure lines modulated in increasingly smaller increments, and in response, the cuff pressure lines modulated to a constant minimum and maximum pressure value.

Table 2 shows the average pressure values for each interval. The instantaneous pressures were composed by averaging the pressure values for each second of inhalation, exhalation, or rest. The cuff pressure averages were calculated differently to avoid including the cuff pressures while the motors were still either inflating or deflating the cuffs. The cuff pressures reported in the table are averages of the final cuff pressure changes. However, the designed endotracheal tube had a mean cuff pressure of 119.29 (SD = 111.40), and rest (M = 111.45). However, the designed endotracheal tube had a mean cuff pressure of 119.29 (SD = 111.23) during inhalation, which was shown by the instantaneous pressure of 89.52 (M = 89.52), and had a mean pressure of 97.41 (M = 97.41) during exhalation, which was shown by the instantaneous pressure of 81.13 (M = 81.13). During the period of rest after inhalation, the mean cuff pressure was 97.41 (M = 95.71), meaning it remained fairly constant. The standard deviation of cuff pressure with the modulating endotracheal tube was 1.44 (SD = 1.44) during inhale, 1.84 (SD = 1.84) during exhalation, and 0.56 (SD = 0.56) during rest.

Figure 7 compares pictures of both the cuff and the pilot balloon during inhalation (on the left) and exhalation (on the right). As expected, the cuff on the right is inflated less than that on the right, as signaled by the wrinkles in the cuff. However, the pilot balloon looks similar in both pictures.

No inferential statistical tests were conducted for the data since there were too few trials. Furthermore, the research was engineering-based and data collection was carried out solely to test if the designed endotracheal tube functioned properly by modulating cuff pressure. No significance values or change in pressure values needed to be evaluated to confirm proof-of-concept.
/*
Pressure Measurements with the
MPS20N0040D Breakout Board
with the HX710B/HX711 ADC
5V Supply Voltage
*/

#include <Q2HX711.h>

const byte MPS_OUT_pin = 8; // OUT data pin
const byte MPS_SCK_pin = 9; // clock data pin
const byte MPS_OUT_pin_2 = 11; // OUT data pin
const byte MPS_SCK_pin_2 = 12; // clock data pin
int avg_size = 1; // #pts to average over

Q2HX711 MPS20N0040D(MPS_OUT_pin, MPS_SCK_pin); // start comm with the HX710B
Q2HX711 MPS20N0040D_2(MPS_OUT_pin_2, MPS_SCK_pin_2); // start comm with the HX710B

void setup() {
  Serial.begin(9600); // start the serial port
  pinMode(5, OUTPUT);
  pinMode(7, OUTPUT);
  pinMode(4, OUTPUT);
  pinMode(6, OUTPUT);
}

void loop() {
  float avg_val = 0.0; // variable for averaging
  for (int ii=0; ii<avg_size; ii++) {
    avg_val += MPS20N0040D.read(); // add multiple ADC readings
    delay(50); // delay between readings
  }
  avg_val /= avg_size;
  Serial.print("avg_val="); // print out the average
  Serial.print((avg_val/100000));
  Serial.print(" ");

  float avg_val_2 = 0.0; // variable for averaging
  for (int ii=0; ii<avg_size; ii++) {
    avg_val_2 += MPS20N0040D_2.read(); // add multiple ADC readings
    delay(50); // delay between readings
  }
  avg_val_2 /= avg_size;
  Serial.print("avg_val_2="); // print out the average
  Serial.println((avg_val_2/100000));

  if (avg_val_2 > 8600000 & avg_val < 11800000) {
    digitalWrite(5, LOW);
    digitalWrite(6, LOW);
  }
  if (avg_val < 12600000 & avg_val > 11800000) {
    digitalWrite(4, LOW);
    digitalWrite(7, LOW);
  }
  if (avg_val_2 < 8450000) {
    digitalWrite(4, LOW);
    digitalWrite(7, LOW);
    digitalWrite(6, HIGH);
  }
  if (avg_val < 10400000) {
    digitalWrite(5, LOW);
    digitalWrite(6, LOW);
  }
  delay(5); // Delay a little bit to improve simulation performance
}

Figure 5. Code to Modulate Cuff Pressure With Respiratory Cycle. The code above both displays all pressure values in the serial monitor and controls the motors to inflate and deflate the cuff. The code was written using the Q2-HX711-Arduino-Library to read the pressure values and TinkerCad to assist with writing the rest of the code. The values printed to the serial monitor were scaled down, however, they remained the same in the rest of the code.
Table 1. This data table compares the cuff pressure and instantaneous pressures between all five trials and the control. It was formed by averaging every 9 pressure values from the original data table in the Appendix 1, providing one pressure sensor value each second.

<table>
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<th>Time</th>
<th>Control Pressure</th>
<th>Trial 1 Pressure</th>
<th>Trial 2 Pressure</th>
<th>Trial 3 Pressure</th>
<th>Trial 4 Pressure</th>
<th>Trial 5 Pressure</th>
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Figure 6: Comparison of Instantaneous Pressure and Cuff Pressure During Modulation Period

Table 2. Instantaneous and Cuff Pressure Average Data Tables for Endotracheal Tube Device. This table is composed of the average pressure values when inhale, exhale, and rest were simulated. The instantaneous pressures are averages of all pressure values during either inhale, exhale, or rest. The cuff pressure values are the averages of values at the end of each period of inhale, exhale, or rest.

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Figure 7: Comparison of the Cuff and Pilot Balloon of the Endotracheal Tube During Inhale and Exhale. These images compare the cuff pressure and pilot balloon of the endotracheal tube. The picture on the left is an image of the tube during inhale when the cuff pressure decreases, and the picture on the right is the cuff and pilot balloon during exhale when the cuff pressure decreases.
Discussion

The purpose of this research project was to modify the current design of endotracheal tubes to reduce the chance of tracheal injuries in intubation patients while maintaining the same functionality as the standard endotracheal tube. Therefore, the engineering goal was to create a detachable and reusable device that could be connected to the endotracheal tube to constantly and automatically modulate the cuff pressure with the respiratory cycle. This meant increasing cuff pressure during inhale when the trachea expands, and decreasing cuff pressure during exhale when the trachea contracts. To accomplish this, a device was constructed with two motors, pressure sensors to measure the cuff pressure and instantaneous pressure, and a microcontroller to constantly compare the pressures and either inflate or deflate the cuff.

To test the device, the instantaneous pressure was purposefully modulated to stimulate intubation, and the cuff pressure was recorded. As seen in Figure 6, the blue line for cuff pressure and the red line for instantaneous pressure line up and match. Each time the instantaneous pressure was increased, decreased, and kept constant, the cuff pressure immediately followed suit. Also, the cuff pressure was modulated to a constant minimum and maximum pressure. This meant that the device effectively monitored the instantaneous pressure and responded to modulate cuff pressure.

Table 2 shows that the control pressure was around 111 ($M = 111.23$, 111.40, 111.45). As mentioned in the calibration section of the methods, a pressure of approximately 112 correlates to a cuff pressure of 25 cmH$_2$O. The pressures match, meaning the control was valid. Table 2 also shows that the average maximum and minimum correlates to a cuff pressure of 28 cmH$_2$O. As mentioned in the calibration section, a cuff pressure of 28 cmH$_2$O corresponds to a value of 119 with variation and a pressure of 20 cmH$_2$O corresponds to approximately 104 from the pressure sensor. These were the aimed modulation pressures. The maximum pressure value of 119.29 matches 28 cmH$_2$O, meaning the device was successful in inflating the cuff during inhale. However, the minimum exhale cuff pressure of 97.41 during the modulation was lower than the aimed value of 104. Using the same calibration technique mentioned in the methods, a pressure of 97.41 correlates to a pressure of 14-15 cmH$_2$O, which is lower than the goal of 20 cmH$_2$O. Despite being a lower pressure, as seen in Figure 7, the cuff still remained well inflated during the deflation cycle and the pilot balloon remained inflated. Additionally, a pressure of 14-15 cmH$_2$O is still completely safe since it fully seals that trachea during exhale. Chadha et al. (2011) found that even a cuff pressure of 7 cmH$_2$O was safe during expiration. Importantly, the standard deviations for the cuff pressure remained low ($SD = 1.44$ for inhale, $SD = 1.84$ for exhale, & $SD = 0.56$ for rest). The variation in pressures during each cycle of either inhale, exhale, or rest was low, meaning the cuff inflated to the same pressure each time. This indicates that the device is reliable.

The constructed device was also reusable and did not impede the function of the endotracheal tube. As seen in Figure 3, the device only attached to the endotracheal tube in two locations. The first point was the valve used to inflate the cuff, and the second was the tubing that connects to the opening of the endotracheal tube. The tubing can easily be removed and maintains the same size for possible attachments to the endotracheal tube.

Overall, the engineering goal was mostly met. The designed device was reliable, simple, could be reused, functioned to modulate cuff pressure, and held proof of concept to reduce the chance of tracheal injuries and other complications during intubation. However, despite modulating the cuff correctly in time, the device deflated the cuff to a safe but lower than aimed pressure of 14-15 cmH$_2$O.

The device, therefore, is proof of concept that reduces the chance of tracheal complications during intubation. According to LibreTexts (2021), the trachea features fibroelastic membranes which allow the trachea to expand during inhalation. The cuff of an endotracheal tube needs to be high enough to fully seal that trachea when it expands, placing pressure on it when it contracts. A modulating system allows the cuff to fully seal the trachea at all times while reducing pressure and stress on the trachea. Another attempt at a device that decreased cuff pressure for the ventilatory cycle tested the endotracheal tube on pigs. Although Chadha et al. (2011) included no details on the design of the device, they found that decreasing pressures significantly reduced the chance and severity of laryngeal, subglottic, and tracheal injuries. Since the proposed design in this project automatically modulates and adjusts to the respiratory cycle, it is more accurate and is a proof of concept design to significantly reduce any pressure-related complications associated with intubation.

The primary cause of the increased deflation of the cuff is the 5V DC air pumps used. Since the motors used were of lower quality, they did not supply a gradual and smooth supply of air. As explained in the code section, each time a pressure value was read, it was evaluated to either turn on or off the motors. Once the decision was made, the next pressure value was found. Each time the vacuum motor was signaled to turn on, it removed too much air too quickly before the next pressure value was found. This meant that the pressure value dropped and by the time the next pressure value was evaluated to turn off the motor, it was too late. Resistors were used to decrease the speed of the motors to the absolute minimum, however, due to the lower quality of the motor, it vacuumed air in somewhat shorter bursts rather than a gradual and smooth vacuum of air. The solution to the issue is a simple fix: use higher quality motors that require more voltage combined with more resistors to allow for a more gradual and steady decrease in cuff pressure. This would allow the system to detect the low pressure and turn off the motor before the cuff decreases to too low of a pressure.

There are a few procedural improvements that could be made to refine the device, reduce the complexity, and reduce the costs. The primary issue is the deflation of the cuff. Using higher-quality motors and a higher-quality potentiometer would prevent the motor from pulling out too much air too quickly, which would allow the code to detect the lower pressure sooner and stop the vacuum motor in time. This would allow the cuff to deflate around 106 instead of going down to 97.41. Another much-needed improvement would be changing the pressure sensor. Using more expensive, high quality pressure sensors would allow for the measuring of pressure in cmH$_2$O, which would improve accuracy and results. To reduce device complexity, the circuit could be adjusted to run everything on a single battery supply, instead of four independent supplies, since no two energy-using components are run simultaneously. Finally, to reduce the costs, one resistor could be used instead of a chain of six resistors. During the construction of the device, resistors were simply added one by one to reduce the output of the motor as much as possible. Replacing it with one larger resistor depending on the air pumps used could reduce costs.

The proposed device in this project is already life-size and fully functional. The future steps would be to modify the device with filters and other components to make it sterile for patients and then test its functionality in animals. Studies, such as one by Ullah et al. (2020), created an optical monitoring system for endotracheal tubes and tested the tubes in pigs. The modulating endotracheal tube could be used to intubate pigs, and the injuries could be monitored to test the effectiveness of the device over a normal endotracheal tube. If the device proves to reduce tracheal injuries, the final steps would be to test in humans to confirm the device’s ability to reduce tracheal injuries in intubation patients.

Overall, the proof-of-concept device presented in this research paper is a viable solution to reducing tracheal injuries in millions of intubation patients each year. The device is also economically viable since tracheal injuries have shown to increase patient stay time in hospitals, which increases costs for patients and the healthcare system. Finally, the device is fully automated and reduces the workload for anesthesiologists or nurses to practice intubation.
Notes and References


Appendix 1. Full Data Table For The Comparison of Instantaneous Pressure Values and Cuff Pressure Values Over 36 Second Trials of Simulated Intubation can be found at: https://docs.google.com/spreadsheets/d/1i2Vln8zZe91FznZqpTDH6x85vUHkEEEqozK1MWYbo/edit?gid=1951086786&range=G11