ENG40011 Stage 3 Report – Haptic Feedback Endotracheal Intubation using Vibration Motor

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***Abstract*—This project introduces a modified endotracheal tube (ETT) with a mini vibration motor for haptic feedback, aiding accurate intubation. Prototype testing on a manikin showed optimal performance at 3V, providing immediate feedback. At this stage, the prototype is intended for clinician training, as no biological or human clinical trials have been conducted. This application supports safe skill development, aligning with marketing and business planning strategies. Further development is needed to evaluate biological responses and refine the device for clinical use.**

Keywords *Vibration motor • Haptic feedback • Endotracheal intubation • ETT*

I. Introduction

A. Need Statement

Unintentional esophageal intubation remains one of the most serious complications in the intubation process today, potentially leading to morbidity or even death. Improving the safety and efficiency of endotracheal intubation, especially in emergency or critical care settings, is essential. Critically ill patients and children/infants are at most risk due to intubation, especially due to mispositioning.

B. Problem Background

A flexible tube is inserted through a patient's mouth or nose into their trachea (windpipe) to maintain an open airway, provide ventilation, or administer anesthesia. While it is a crucial technique in managing patient airways, intubation carries significant risks, particularly in emergency and critical care settings. According to a study on intubation-related mortality published in The Journal of the American Medical Association (JAMA), major adverse events were reported in 45.2% of patients undergoing tracheal intubation. Among these, cardiovascular instability occurred in 42.6% of cases, severe hypoxemia in 9.3%, and cardiac arrest in 3.1% [1]. Besides, studies report the percentage of unrecognized ETT displacement in the out-of-hospital setting being upward of 25% [2]. Another study found in emergency intubation (EI) of infants, out of 507 records reviewed, 477 met the inclusion criteria. Of these, 330 ETTs (69%) were improperly positioned, many not meeting depth guidelines. Fifty-six percent of the subjects were male, with a median age of 15.2 months (range: 3.4–59.4 months) [3]. Rates of unrecognized EI in emergency settings have been reported to be as high as 16 % [4-9]. The median intubation (ETI) failure rate to be nearly 10 % amongst pre-hospital providers [10]. These findings highlight the high-stakes nature of the procedure and underscore the need for advancements in intubation techniques that reduce the risk of complications, such as unintentional esophageal intubation and human error.

C. Decision Making

In this project, several potential ideas were considered and discussed to improve airway detection in endotracheal intubation. Concepts explored included a compact ultrasound probe, magnetic navigation with sensors, and a pressure-sensitive tube with sensors embedded at the distal end. Although promising, these ideas faced significant technical challenges, including integration difficulties at the ETT's distal end, limited product availability, and the need for extensive R&D. Further concerns about complexity, safety, and cost also factored into our decision-making process. Using Pugh matrices, a structured approach, we evaluated each option against criteria such as feasibility, reliability, cost-effectiveness, and ease of integration. This led us to select the vibration motor solution, which best met the project's requirements by providing a practical, real-time tactile feedback system using mini vibration motor (10mm wide) that is both simple and cost-effective, making it ideal for integration to the distal end of ETT.

D. Design Specifications

The design specifications for this haptic feedback-enabled endotracheal tube (ETT) focuses on providing real-time, tactile feedback to assist clinicians in differentiating the trachea from the esophagus during intubation, enhancing safety and efficiency. The device incorporates a compact, mini vibration motor (10mm*3mm max) at the distal of ETT that delivers safe and perceptible vibrations without altering standard ETT handling. With insulated circuitry, reliable power, the motor is controlled using Arduino IDE software to test the frequency (fixed) and voltage can be also controlled using potentiometer. Manikin testing can support understanding of the newly modified ETT to validate its functionality, with a target of reducing intubation errors getting haptic feedback. The design also prioritizes affordability, ease of prototyping/manufacturing, and adherence to medical device standards approval.

E. Strengths & Weaknesses of Design

The proposed solution of tactile haptic feedback using a mini vibration motor offers several strengths and weaknesses. Among its strengths, it provides real-time, intuitive feedback that enables clinicians to differentiate the trachea from the esophagus, reducing reliance on visual cues and supporting safer intubation. Its compact design integrates easily with the ETT and is cost-effective as a single-use device. However, there are some considerations for patient safety and device performance. The vibration motor may need careful calibration to prevent any risk of skin damage due to excessive vibration levels. Additionally,

considerations for patients with pacemakers are critical, as electrical components near the chest could pose interference risks. Furthermore, safety mechanisms must ensure that the motor does not produce excessive heat or malfunction electrically, which could compromise the patient's safety.

II. Freedom to Operate

A thorough review of patents from IP Australia, Google Patents, Espacenet, and WIPO revealed no existing patents directly covering the use of a mini vibration motor for tactile haptic feedback in endotracheal tube (ETT) placement. While related innovations exist, such as tactile sensing devices and intubation simulators, none directly overlap with the application of a vibration motor in a real-time clinical setting.

For instance, US20110030694 - System and method for imaging endotracheal tube placement and measuring airway occlusion cuff pressure, focuses on pressure sensing and imaging for verifying ETT placement [11]. Meanwhile, WO2015103567A1 - Intubation Simulator and Method describes a simulator for training purposes, utilizing haptic manipulators to simulate the intubation environment. Both of these examples emphasize training or diagnostic techniques but do not involve the use of vibration technology for real-time feedback during intubation [12]. System, Apparatus, and Method for Image-Guided Laryngoscope (US11839354B2) by W. H. Lee further highlights the use of simulators for training purposes, focusing on enhancing training efficacy with haptic feedback [13].

At present, this prototype is designed for clinician training, including for nurses, anesthetists, doctors, and paramedics, offering a real-life, real-time experience that surpasses traditional simulators. Although clinical trials on human subjects are yet to be conducted, making it beyond the current scope to evaluate its direct impact on emergency intubation, the device shows significant potential as a novel addition to clinical tools. By addressing unintentional esophageal intubation through innovative tactile haptic feedback, it fills a clear market gap. With further development, it could become a valuable asset in advancing safe, accurate, and efficient intubation practices. The prototype, in its current form, can serve as a valuable tool for clinician training, with further clinical applications possible once trials and safety data have been obtained.

I. Regulations and Standards

Our Arduino-based intubation device is designed to meet both Australian and international regulatory standards, ensuring patient safety, clinical effectiveness, and streamlined market entry.

1. ISO 13485: Quality Management for Medical Devices This international standard, recognized in Australia, requires strict quality management protocols across design, manufacturing, and post-market phases. Compliance with ISO 13485 demonstrates the device's adherence to high standards for quality and reliability, essential for clinical use globally and locally.

2. Therapeutic Goods Administration (TGA) Approval: For Australian market entry, TGA approval is required, validating the device's safety, performance, and quality. By meeting TGA standards and gaining inclusion in the Australian Register of Therapeutic Goods (ARTG), the device is certified for local use, with assessments aligned to international benchmarks like FDA and ISO standards.

3. FDA510(k) Premarket Approval: For access to the U.S. market, FDA 510(k) clearance is necessary to demonstrate safety and effectiveness. This regulatory pathway validates the device's substantial equivalence to approved devices, reinforcing its suitability for broader clinical applications and global distribution.

4. IEC60601 Medical Electrical Equipment Safety: As an electrical device, compliance with IEC 60601 is essential to ensure safety in clinical settings. This standard, recognized globally and by the TGA, certifies the device's electrical insulation, reliability, and compatibility with other medical equipment, providing vital safeguards against electrical risks.
5. ISO10993 Biocompatibility: The device's endotracheal tube component, which directly contacts patients, must comply with ISO 10993 to ensure biocompatibility. This standard confirms that materials used are safe and do not cause adverse reactions, making the device suitable for patient interaction worldwide.

Testing Outcomes and Standards Alignment

Prototype testing confirmed compliance with IEC 60601 for electrical safety and ISO 10993 for biocompatibility, ensuring safe clinical use. Additionally, the device's real-time feedback capability aligns with FDA 510(k) and TGA requirements for accuracy and procedural safety, reducing reattempt rates and supporting its ARTG inclusion for the Australian market and global deployment.

II. Economics of Solution

Our solution targets the $1.5 billion intubation and airway management market by providing a cost-effective alternative with real-time feedback capabilities. Below is a detailed breakdown of the costs, pricing strategy, and projected market entry approach.

Costing Breakdown:

Component Costs (Per Unit):

Arduino Uno: $25.00, **Vibration Motor**: $5.00, **Endotracheal Tube**: $10.00, **Sensors and Connectors**: $8.00, **Breadboard and Wires**: $3.00, **Battery Power Supply**: $2.00, **Miscellaneous Tools and Materials**: $5.00

Total Per Unit Component Cost: **$58.00**

Manufacturing and Assembly:

- **Assembly and Packaging Cost**: $23.00 per unit
- **Total Per Unit Cost (Component + Manufacturing)**: $81.00 with potential reductions to $50.00 in bulk production.

One-Time Regulatory and R&D Costs:

- **Regulatory Approvals**: $30,650 (FDA 510(k), ISO certifications)
- **R&D and Clinical Testing**: $15,000
- **Total Upfront Costs**: **$45,650**

Market Potential and Revenue Projections

With a unit price of $300, the device is positioned as an affordable yet effective alternative to high-cost video laryngoscopes and other complex intubation tools. The projected sales volume over five years—starting with 5,000 units in Year 1 and scaling to 35,000 units by Year 5—yields

a cumulative revenue of approximately $30 million, capturing just 2% of the $1.5 billion market.

Market Penetration Strategy

1. **Direct Sales** to hospitals and emergency care units that need reliable, cost-effective intubation tools.
2. **Distribution Partnerships** in emerging markets with high demand for affordable healthcare technology.
3. **Licensing and OEM Agreements** with established medical device manufacturers for broader production and distribution.
4. **Recurring Revenue** from consumables, maintenance, and support, estimated at $50 per unit annually.

Reimbursement Strategy

The device aligns with value-based healthcare models that prioritize cost savings and procedural accuracy. By reducing intubation reattempts, it supports **Medicare** and private insurance reimbursement, providing healthcare facilities with both clinical and financial benefits.

III. Materials and Methods

The materials required to develop the endotracheal tube vibration motor solution consisted of an Arduino Uno R3, 2x10mm 3 Volt vibration motors, Endotracheal tubes, Bread board, push button, hot glue kit, DC power kit and various connectors. The Arduino Uno was selected as the microcontroller due to its ease of use and cost-effectiveness. The 2x10 mm vibration motors were chosen for their affordability and accessibility, as well as for their suitability for prototyping purposes, performing effectively within the prototype model during initial testing.

The process to construct the endotracheal tube vibration motor involved a sequence of detailed steps, each requiring careful attention to the handling of small electronic components. Step 1: Connect the push button and connectors on the breadboard to complete a circuit with the Arduino's power pins. Step 2: Test this circuit with an LED to ensure functionality, using low voltage to confirm that pressing the button lights the LED. Step 3: Replace the LED with the vibration motor as the transducer, setting the Arduino's power range between 0 and 3 volts to vary vibration intensity. Step 4: Mark the cuff of the endotracheal tube to provide a precise guideline for cutting. Step 5: Cut along the marked line and roll back the cuff to allow placement of the vibration motors. Step 6: Attach the two vibration motors near the tube's tip, soldering additional wire lengths for secure connections, and ensure they are firmly adhered to the cuff area without obstructing airflow. Step 7: Roll the cuff back over the motors and reseal it with hot glue. Step 8: Inflate the cuff to evaluate its integrity and verify the seal's effectiveness. Step 9: Connect the motor wires to the breadboard and test various input voltages to assess vibration strength.

Following this, the prototype was ready for testing on a manikin to simulate real-life application.

Step 10: Insert the endotracheal tube with vibration motors into the manikin's throat, ensuring proper deflation of the cuff and careful handling of the electronics. Step 11: Position the tube in the trachea and initiate vibration testing at varying intensities. Step 12: Record the feedback from different input voltages, including assessments by group members and nurse, and refine the code accordingly.

IV. Results

Multiple tests on an intubation test manikin within Swinburne's nursing facilities yielded a range of results. The objective was to determine the optimal voltage level for detecting vibration at the manikin's collarbone to confirm the position of ETT in trachea. With both motors at voltages below 1.8 volts, the vibration was insufficient for group members and nursing staff to detect. This led to the conclusion that a minimum of 1.8 volts is necessary for effective haptic feedback. At 3 Volts, a strong and noticeable vibration was felt at the collarbone area, deemed adequate by all participants.

To simulate intubation, the endotracheal tube was inserted into the trachea using a laryngoscope, a critical tool in intubation procedures. This step required careful handing due to the prototype's fragility, contributing to an extended insertion time. A distinct difference in haptic feedback vibration was noted between placements in the trachea and esophagus. Vibration feedback from the tracheal position was primarily perceived around the collarbone and anterior throat, whereas esophageal vibrations were felt more diffusely towards the posterior and lateral regions of the neck.

V. Discussion

A. Discussion of Results

The haptic feedback from the vibration motors toward the manikin's collarbone provided preliminary but approximate results due to the structural limitations of the test manikin, resulting in averaged data rather than precise values. Detection of the endotracheal tube within the trachea was easily achieved at 3 volts for each motor, where the vibration strengths were both effective and posed no concerns regarding excessive intensity. Biological factors such as potential vocal cord spasms due to vibration, while not observed during testing, were highlighted as a consideration by a professional nurse assisting with the test. Feedback from nursing staff, representing the anticipated end users, was integral to evaluating the prototype's success, as their insights informed refinements and further testing criteria.

While the prototype's data lacks numerical precision, its efficacy was demonstrated by the significantly reduced detection time of the ETT's position within the trachea, achieved instantly upon button press. This contrasts with traditional methods that can take minutes, such as using stethoscope to listen to lung inflation sounds or measuring oxygen and carbon monoxide levels of the patient. These findings help address the problem of unintentional esophageal intubation, significantly enhancing both speed and safety of the procedure.

Refer to Figure 1, which displays the intubation test manikin with the endotracheal tube equipped with a vibration motor, inserted into the trachea for haptic feedback testing.

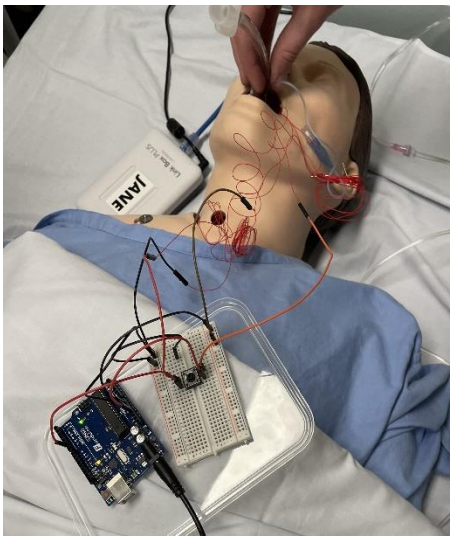

Figure 1. Intubation test manikin with ETT vibration motor prototype inserted into trachea for haptic feedback

B. Error Analysis

Although these experiments did produce valuable results regarding the viability of the basic principles of this device, the manikin used to achieve them was not a perfect stand-in for a real human body, bringing about some blind spots regarding how the proposed device would affect a live patient. When conducting the intubation experiments, it was first noticed that the manikin was considerably stiff, lacking the flexibility and general characteristics of human skin. Because of this, it was both difficult to properly place the tube into the trachea, and unsuitable for determining an ideal vibration intensity due to differences in how easily the vibrations would propagate. The manikin used also did not contain any material between the trachea and esophagus, only containing the basic anatomical structures. This also caused issues in analyzing the propagation of the motor vibrations.

Along with these structural problems, the manikin also did not allow for testing of many biological factors which would be important to consider in a real patient scenario. One significant factor to consider when using this on a live patient would be biological responses to both the vibrations and the vibration motors which stick out of the current design. These experiments, however, were not able to collect data on this, and so it is a potentially dangerous unknown to look out for in future trials. Additionally, these experiments could not collect data on patient comfort.

VI. Next Steps

A. Refined Design

Based on the results of the manikin testing and feedback from a medical professional, many areas of improvement can be seen regarding the design of the device prototype. It has been noted that the dual motors of the current design do not provide a uniform vibration intensity around the circumference of the tube which may cause issues in detecting the accurate position. These motors also protrude significantly from the tube which may provoke a negative biological reaction during insertion. To amend this, a custom vibrating ring could be developed and placed within the cuff (where the current motors are placed). While this would solve many of the design problems, the cost of developing and manufacturing these custom components would also be significant, so it may be best to continue using pre-made motors while further funding is secured.

The design would also benefit from a standardized manufacturing process, with the components being inserted into the endotracheal tube during the molding stage. This would allow for the easier insertion of the custom ring and would also allow for the wires to be more securely encapsulated within the tube, improving patient safety. Much like the design of the ring however, this custom process would also be costly. Achieving this would also most likely require research into existing endotracheal tube production methods and would benefit from consulting plastic working specialists to gain a greater understanding of the process.

An important aspect of the final design would also be the incorporation of a connected remote used to trigger the vibration motor. This remote would consist of a single button which, when pressed, would trigger the vibration motor for a short period of time (approximately 1-2 seconds). This remote would also store the battery for the device and could be disconnected when not in use, preventing the motor from being activated unintentionally.

B. Further Testing

As explained in the error analysis section of this report, there were many variables which the conducted experiments were not able to measure, and which would need to be analyzed further for development to continue. Primarily, the possible effects which this device could have on the human body (particularly those due to the vibrations) would need to be studied. This could be achieved through consulting with medical professionals, and eventually by testing the device on volunteer patients. Continued research would also need to be conducted to determine ideal vibration intensity and frequency.

C. Use as a Teaching Aid

While still in the development stage and prior to being approved for use in the hospital setting, this device could be marketed as a valuable tool for medical students, allowing them to more easily practice intubation on manikins. This would provide additional funding during the development period and could also be used to gain data and feedback to improve the device. Furthermore, this would allow medical students to gain experience with the device before it is introduced to the wider medical field.

VII. Conclusion

A significant problem with intubation is the accurate placement of the endotracheal tube. To improve this process, an endotracheal tube with attached vibration motors has been conceptualized, prototyped and tested, with the aim of the design being to assist medical professionals in quickly and easily identify the placement of the tube based on tactile feedback. Testing of the device has shown that while design problems are still present, the fundamental utility of the device is valid. Based on this, further development of this design is recommended.

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