Session #3649

Portable Video Intubation Stylet

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Students working toward the Baccalaureate degree in Mechanical Engineering Technology at the University of Cincinnati are required to complete a "Design, Build & Test" Capstone design project. Some of these projects are geared to meet the needs of the local community.

Intubation is a procedure by which an endotracheal tube is inserted into the trachea of a patient who requires assistance in breathing. It is a blind procedure that relies on imperfect, indirect methods for proper tube placement. This can be difficult and dangerous if the endotracheal tube is inserted in the esophagus. This procedure is typically performed by EMTs (Emergency Medical Technicians) while responding to emergency situations.

This paper describes a new intubation device, designed, developed and built as a capstone design project, which will improve the success rate of the intubation procedure.

Introduction

The need for intubation often arises from cardiac and/or pulmonary arrest. The intubation process is often difficult, and potentially dangerous to the patient. The success rate of intubation ranges from between 25% to 37% (1). In addition, accidental placement of the ET tube in the esophagus, called Esophageal Intubation, can lead to death, due to the lack of oxygen. K.Posner, R. Ward and F. Cheney (2), report Clinical Outcomes of Esophageal Intubations as follows:

- 81% died.
- 17% permanent brain damage.
- 1 % other permanent injury.
- 1 % Temporary injury.
- 0% No injury.

Properly negotiating the anatomy of the airway to place the endotracheal tube in the trachea requires that the intubator (EMTs) visualizes the endotracheal tube passing through the vocal cords of the patient during the procedure. Presently, the intubations performed by paramedics are accomplished with the help of a tool called a laryngoscope.

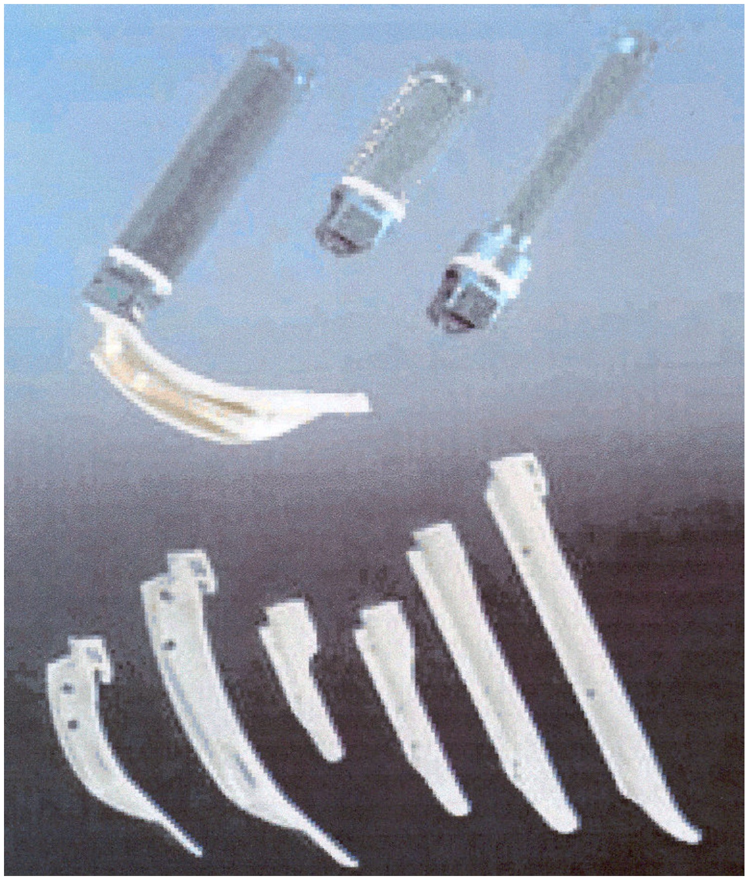

Figure 2
Laryngoscope

A laryngoscope is an instrument held with the left hand during intubation, and is used to divert the patient's tongue and epiglottis, thereby manipulating the oral cavity to expose the vocal cords. However, even when the laryngoscope is in an optimal position, the vocal cords may not be visualized for a number of reasons. Some of these include: small mouth opening, inability to flex the neck due to trauma, or the anterior position of the larynx. The proper placement of the endotracheal tube in the trachea is essential in every intubation. Fig 2 shows an EMT in bent position, performing an intubation on a mannequin, using a laryngoscope. Please note the awkward position of both the EMT and the patient.

The objective of this project was to develop a product to increase the success rate of the intubation procedure.

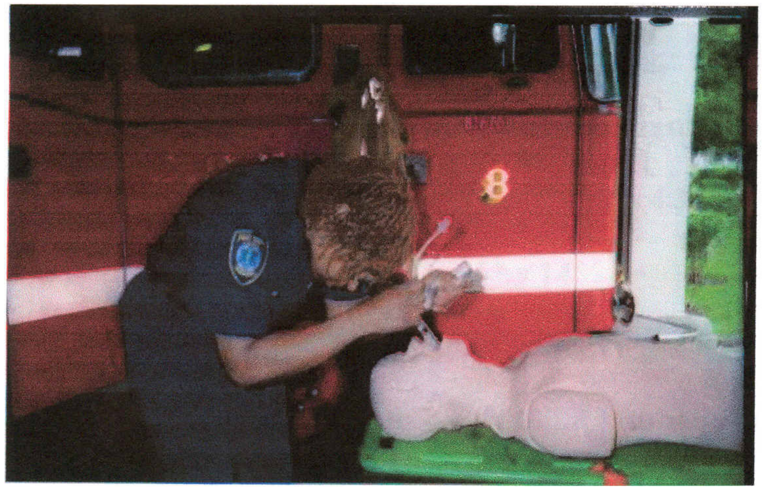

Fig 2
Paramedic Performing an Intubation using a Laryngoscope

Design

As with any project development, the first step was to survey customers to obtain their input to the design process. The survey was given to physicians, nurses and paramedics (EMTs). Some sample questions on the survey were:

- What is the most common complication of Endotracheal Intubation?
- How often do you attempt a Blind Intubation?
- How often are the vocal cords not visible?
- What is the common condition making the visualization of the vocal cords difficult?
- Would a device increasing the visibility of the vocal cords, when direct line of sight is not possible, improve the success rate of and time required for intubations?

The survey results and input obtained through personal interviews and the personal experience of Mr. Trimble, who works as an EMT, were used in developing product specifications. Additionally, existing products were researched.

Two of the current products on the market are Lighted Stylet and Combitube. The Lighted Stylet illuminates the patient's mouth, but the intubation is still blind. The Combitube can be inserted blindly and ventilation is achieved when the device has successfully entered the trachea. The disadvantage of this device is that the tracheal placement occurs only in 20% of the cases in the initial try. In the rest of the cases it enters the esophagus and must be retracted immediately.

Product Specifications:

- The device will accommodate Endotracheal tubes from 6.5 mm to 8.5 mm ID
- The device will weigh less than 5 lbs
- The device will facilitate vocal cord visibility during intubations
- He device will accommodate both nasal and oral intubations

Three conceptual designs were developed. The "best" one, Portable Video Intubation Stylet (PVIS), was identified using the Pugh Selection method.

Portable Video Intubation Stylet (PVIS)

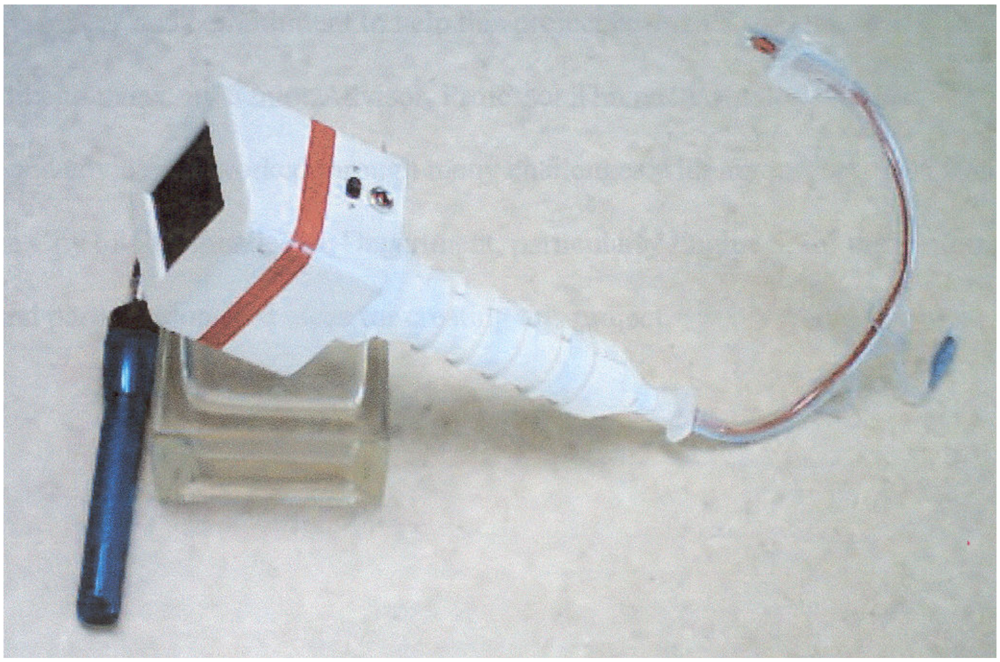

Fig. 3
Portable Video Intubation Stylet

The design of the Portable Video Intubation Stylet (PVIS, fig 3) was divided into 3 main sections. Those sections and their functions are listed below.

Handle

The handle is composed of a base and a top. The handle section of this device houses the power supply, the CCD (Charge-coupled device) camera, switch, and battery contacts. The handle was designed using Ergonomic/Human Factor Engineering standards (3). The production material of the handle will be medical grade HDPE. The handle will be produced using injection molding. However the prototype was produced by using a rapid prototyping process, using HDPE.

- **Power Supply** - The Power supply used is a 12v Ni-Ca battery. This is a military battery rated at 12v with max discharge 1330 mA continuous. This power unit provides power for both the CCD camera and the LCD display unit.

- **CCD Camera** – This High Quality color board Camera, requires a 12 volt power supply rated at 120 mA. It will operate at very low light availability (1 Lux). The selected CCD has a Composite Video output, which is compatible with the selected LCD. The CCD is mounted inside the handle base of the device.

Display Unit

The display is comprised of a LCD panel, and a face plate.

- **LCD Panel**- The LCD display unit is a miniature color video monitor, which accepts composite video input and produces a high resolution (234 H x 200 V) full color video on it's screen. The input/outputs of this device are compatible with the CCD and the power supply.

- **Face plate/Display unit** – It was designed using Ergonomic/ Human Factor Engineering standards. (3) The material used is the same as the handle material.

Fiber Optic Image Unit

The fiber optic image unit consists of a wound image bundle, and a lens set-up at the proximal end of the fiber optic bundle.

- **Wound Image Bundle** - Wound image bundles are produced by winding a multi fiber one layer at a time on a drum and assembling the desired number of layers in a separate laminating operation. The final flexible image bundle is comprised of individual multi-fibers bound only at the ends and separated in between, making it possible to transmit a high resolution image from end to end.

- **Lens -** The lens is be used to capture the image just distal of the image bundle. This lens is permanently fused to fiber optics prior to shipping. The lens is responsible for transmitting the image received from the proximal end of the fiber optics to the CCD.

Manufacturing & Assembly

The manufacturing phase of this prototype was divided into two parts: the outer shell housing, and the lens set-up housing. The outer shell housing consists of the handle and the LCD housing and supports. The material for the housing was Somos 10120 water clear plastic. The part was produced using SLA (Stereo lithography) at ANZA Rapid Prototype of Cincinnati. The lens set-up housing holds the lens needed to project an image from the proximal end of the fiber optics to the CCD camera. The material for the lens housing was ABS. It was milled in the College's shop using specifications obtained from Myriad Fiber Optics of Boston.

All assembly was performed manually in house. All parts were dry fitted, and primary tests were run to ensure proper operation prior to final assembly. For final assembly SLA parts were bonded using cyanoacrylate glue. Milled parts were assembled with thread and screw fasteners for easy assembly and disassembly. The electrical components were connected in accordance with the prepared electrical schematic shown in fig 4.

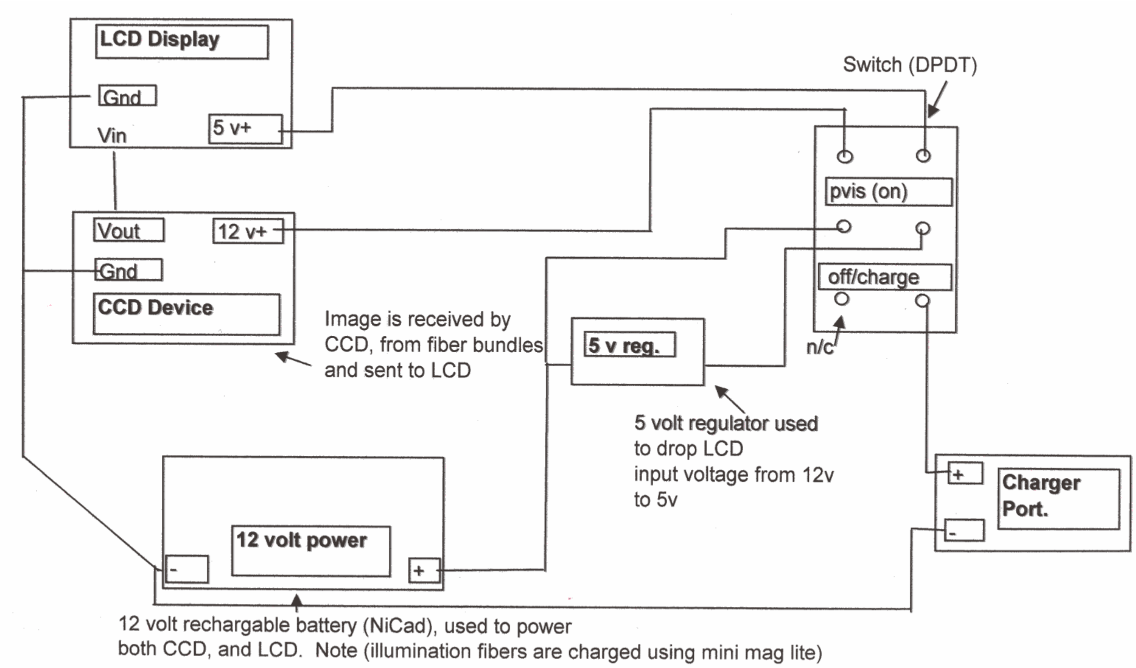

Fig 4

Testing

The PVIS accommodated endotracheal tubes from 4mm to 8.5 mm in diameter and it weighed 4.3 lbs. The device was tested by EMTs on a mannequin for intubation. The same EMTs performed intubation using the standard Laryngoscope. Both of these attempts were limited to twenty seconds. The intubation failure rate, using the standard Laryngoscope was forty percent, but was reduced to ten percent, using the PVIS. This improvement can be attributed to improved vocal cord visibility. As can be seen in figure 2, using the standard method, the EMTs have to bend over, whereas using the PVIS (fig 5) they can perform the intubation in a more comfortable position.

Fig 5
Paramedic Performing an Intubation using PVIS

Conclusions

References: PVIS is a definite improvement over the existing methods for the intubation process. It allows for better visibility of the vocal cords minimizing esophageal intubation. It also allows the EMTs and patients to be in a more comfortable posture during the procedure. Because of the liability issues the device was tested only on mannequins. It must be tested in the field before it can be adopted for wide spread use.

1 – JEMS (Journal of Emergency Medicine) 2003
2 – Adverse Respiratory Events in Anesthesia: A Closed Claim Analysis; Caplan R., Posner K., Ward R., Cheney F., Anesthesiology 1990
3 – Designing for Humans: The Human Factor in Engineering; John H. Burgess
4 – FDA, US Food and Drug Administration Center for Devices and Radiological Health
5 – Paramedic Emergency Care, Robert S. Porter, Brady, 2nd Edition

Thomas G. Boronkay, PhD, PE is a Professor in the Mechanical Engineering Technology department at the University of Cincinnati. He received his PhD from the University of Cincinnati. He has presented papers at ASEE Annual Conferences, ASME International Congress, and several international conferences and conducted CAD/CAM/CAE workshops nationally and internationally. He has also served in various capacities on the DEED, EDG and International Divisions' executive committees.

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Jamiel Trimble received his Bachelor of Science in Mechanical Engineering Technology from the University of Cincinnati in June 2003. He had been working as an EMT with the Cincinnati fire department throughout his college career. He continues to work there while finalizing his future plans.