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# Endotracheal Cuff System Performance Enhancement through Product Design and Development Methodologies

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**ABSTRACT**

Rapid prototyping (RP) is a popular method for product development and design in medical industries. Endotracheal tube (ETT) incubation is a common problem when using medical equipment. Among the difficulties that surgeons face during surgical procedures are the misinsertion of an endotracheal tube into the oesophagus and extubation due to the patient's limited mobility. The aim of this work is to design an innovative endotracheal tube holding model. The survey was carried out in order to identify the most common ETT problems. As a result, quality functional deployment and product design and development methodologies were utilised to select the design for all of the ideas, which were designed based on the demands indicated by the consumers. The concept score matrix was used to evaluate the designs. As a result, concept A is selected as the final design. The overall score for each concept was calculated to discover which concept has the highest rating. Based on the results of the concept scoring and concept screening, concept A is the most likely to be produced. The concept meets the most demanding needs of the users. The selected design was then created on the Fused Deposition Modelling (FDM) machine.

## 1. Introduction

An endotracheal tube is a breathing tube. As shown in Figure 1, the tube is bent. It is a typical medical device used to keep the airway open to ensure oxygen, medicine, or anesthetics can be delivered [1-3]. It is often used to assist those who have pneumonia, emphysema, heart failure, collapsed lungs, or serious injuries in breathing [4-8]. This tube will be inserted into the patient's nose or mouth and into his trachea. Most of the endotracheal tubes that are available today are made of polyvinyl chloride (PVC) [9-10]. There are also specialty tubes that are made of silicone rubber, latex rubber, or stainless steel. Most of the tubes have an inflatable cuff, but there are also tubes without the cuff. The inflatable cuff is used to seal the trachea and bronchial tree against air leakage and aspiration of gastric contents, blood, secretions, and other fluids. The uncuffed tubes use is limited to mostly pediatric patients [11-13]. According to the medical procedure, endotracheal intubation is

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the placement of a tube into the trachea (windpipe) in order to maintain an open airway in patients who are unconscious or unable to breathe on their own, as shown in Figure 2 [2,14,15].

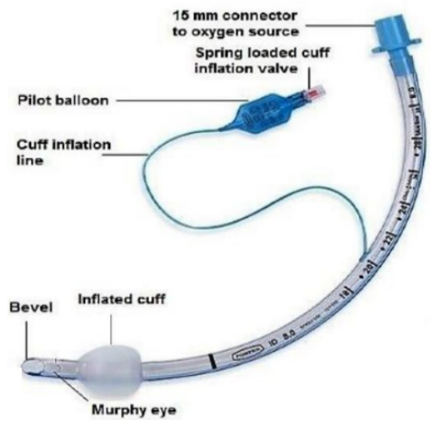



**Fig. 1.** Endotrachal cuff system [1]

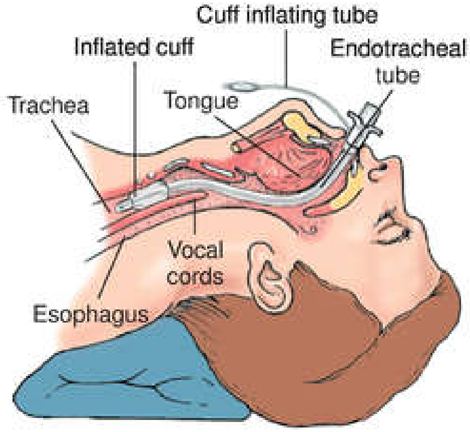



**Fig. 2.** Endotracheal tube placement [2]

There had been some previous research studies on the endotracheal tube and respiratory care, the role of the endotracheal tube cuff in microaspiration, and the management of a severed endotracheal tube [3, 4, 6, 8, 9, 11]. However, the problem with the current design is that it is dangerous. It occurs when a tube holder (ETT) performs endotracheal intubation, causing inappropriate fixation of an endotracheal tube, resulting in a difficult tracheostomy into the esophagus and an extubation that is not thoroughly investigated. This study describes the evolution of a contemporary endotracheal tube-holding device design by taking into account the designs of other manufacturers and researchers in order to simplify the process and make it easier to keep the endotracheal tube in the patient's trachea. The user's expectations are translated into the product design criteria for an endotracheal tube-holding device. Several design concepts are developed using CATIA software and then reviewed for selection by endotracheal tube-holding device users. The design concepts were chosen in two stages: concept screening and concept scoring. A prototype of an endotracheal tube was created employing fusion deposition modelling in order to select the design concept for further research and development (FDM). Prior to this study, a number of studies upon endotracheal intubation difficulties had been done, with a focus on mouth, lip, or nares pressure sore development, poor ventilation, or oxygenation due to tube obstruction. However, there is very little information available on research into endotracheal tube-holding device modifications to address the aforementioned issues. In order to make it simpler to maintain the endotracheal tube in the patient's trachea, this study proposes a development of the current endotracheal tube-holding device design. The user's requirements are turned into the product design specification for an endotracheal tube-holding device.

## 2. Methodology

Numerous studies have been conducted in order to identify the issues and problems associated with endotracheal tubes. The endotracheal tube self-extubated, which means it came out of the patient's mouth by itself. This was identified as a critical problem. For the literature review, all the information was gathered from various journals, articles, books, and websites. The literature review is divided into four sections: the product (endotracheal tube and endotracheal tube holder), rapid prototyping product development process, and quality function deployment. This survey had 130 respondents, all of whom were from the medical field (doctors, healthcare professionals, medical school students, etc.), with more than 80% of them having worked in the sector for more than three years. The results of the questionnaire were then analyzed. The results of the questionnaire were used as a guideline to design an endotracheal tube holder. Six design proposals were developed based on the responses provided in the survey findings. The software known as CATIA had been employed to create each of the six design concepts that had been designed. The designs were created in response to the user's specifications. Several factors that determined the design that satisfied the user's requirements have been identified when evaluating the design concepts. The concept screen developed when selecting requirements had been defined. The concept score was performed in order to restrict the number of concepts under consideration. Concept scoring had been established after concept screening. This round, the concept with the highest rating was selected. The additive manufacturing (3D printing) machine was subsequently employed to generate the final design concept.

## 3. Results

### *3.1 Quality Function Deployment (QFD)*

The QFD used to design the endotracheal tube holder was created with the customer's needs in mind. The completed QFD is displayed in Table 1. The researcher was able to list the client requirements based on the survey results and then assign a weight factor based on the responses provided by the respondents. Based on the technical aspect, design qualities are significant to the manufacture a product.

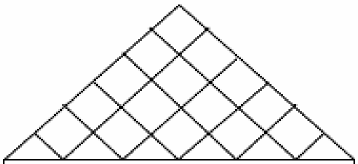
For the customer rating, five types of endotracheal tube holders from different companies were being compared. Product A is from Laerdal Medical Corp, product B is from Ambu Inc, product C is from Precision Medical, product D is from Hollister and product E is from Performance System. From the score, it can be concluded that the most preferred product is from Laerdal Medical Corp. However, in terms of the complexity of the design, product A scored the lowest mark. Thus, the researcher has decided to focus more on making the design of the endotracheal tube holder simpler. After the QFD was constructed, the researcher found out that the most important requirement that needs to be focused on is making the design simpler. This could be due to the complicated design of the current endotracheal tube holder on the market. A design that is complicated will be difficult to manufacture and thus will cause the manufacturing cost to be high.

The external dimensions of the tube holders are the subsequent most significant criterion. This could be because the holder needs to grip the tube tightly. If the holder's external dimension is not accurate, the holders will loosely retain the endotracheal tube, causing the endotracheal tube to be extubated on its own. The third critical criteria is the number of sizes. This could be due to the fact that the endotracheal tube comes in a variety of sizes. The sizes are determined by the age of the patients. The tube that goes through the lungs for adults is bigger than in youngsters. The material's robustness is the least significant factor.

### *3.2 Concept Generation*

Six design concepts were drawn out. The sketches for all of the proposals have been designed based on the needs determined by the users. The following is a description and explanation of each concept:

**Table 1**
Quality Function Deployment of the endotracheal tube holders



Strong positive
Medium positive
Medium negative
Strong negative

| | | Engineering Characteristics | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Improvement Direction | | ↓ | ↓ | ↑ | ↑ | ↑ | ↑ | | | | | |
| Units | | N | m | | n/a | n/a | n/a | Customer Rating | | | | |
| Customer Requirements | Importance Weight Factor | Force to open | External dimensions | Toughness of the material | No. of colors | No. of sizes | Simple design | 1 - Poor, 3 - OK, 5 - Excellent | | | | |
| | | | | | | | | A | B | C | D | E |
| Lightweight | 5 | | 9 | 3 | | | 9 | 3 | 3 | 3 | 3 | 3 |
| Compatible with 8.0mm endotracheal tube | 4 | | 9 | | | 3 | 9 | 3 | 3 | 3 | 3 | 3 |
| Easy to grip (locking device) | 4 | 9 | 3 | | | | 9 | 5 | 1 | | | 3 |
| Easy placement of endotracheal tube | 4 | | 9 | | | | 9 | 5 | 3 | 3 | 1 | 1 |
| Attractive | 3 | | | | 3 | | 3 | 5 | 3 | 3 | 1 | 3 |
| Simple design | 5 | | 3 | | 3 | | 9 | 1 | 3 | 3 | 1 | 1 |
| Low cost materials | 5 | | 3 | 3 | | | 9 | 1 | 1 | 3 | 3 | 1 |
| Low complexity of parts | 4 | | 3 | | | 9 | 9 | 1 | 3 | 3 | 3 | 1 |
| Low number of assembly step | 4 | 3 | | | | | 9 | 1 | 3 | 5 | 3 | 1 |
| Colour coded | 5 | | | | 9 | 9 | | 5 | 1 | 1 | 1 | 1 |
| Locking device | 4 | 9 | 9 | | | | 3 | 5 | 3 | | | 3 |
| Mouth cover | 5 | | 9 | | | | 9 | 5 | | 3 | | |
| Bite stick | 5 | 3 | 3 | | | | 3 | 5 | | 3 | | |
| Size/Dimensions | 4 | | 9 | | | 9 | | 5 | 3 | 5 | 1 | 1 |
| Geometric Shapes | 4 | | 9 | 3 | | 3 | 9 | 5 | | 5 | | |
| Importance Ranking | Absolute Importance | 99 | 222 | 57 | 69 | 141 | 432 | | | | | |
| | Relative Importance, % | 9.71 | 21.8 | 5.59 | 6.76 | 13.8 | 42.4 | Strong – 9 | | | | |
| | Rank Order of Ecs | 4 | 2 | 6 | 5 | 3 | 1 | | | | | |
| Technical Assessment ( 1 - low probability, 5 - high probability) | | 5 | 5 | 4 | 4 | 4 | 5 | Medium – 3 | | | | |
| Target Values (1 - low, 5 - high) | | 5 | 5 | 4 | 4 | 3 | 5 | Weak – 1 | | | | |

### *3.3 Design Concepts*

Figure 3 shows the endotracheal tube holder in Design Concept A is shaped like an ellipse. The bite stick is attached to the endotracheal tube holder in this design. This holder is likewise intended to completely conceal the patient's mouth. The endotracheal tube holder in this design concept B is square in shape, as shown in Figure 4. The holder is linked to the bite stick. This design will also completely cover the patient's mouth. The endotracheal tube holder is generated in the circular form for concept design C, as can be seen in Figure 5. This design does not protect the patient's mouth. The size is smaller than the previous patterns. The bite stick is linked to the holder. As demonstrated through the example shown in Figure 6, the endotracheal tube holder of design concept D is a structure made in the shape of a square. This design lacks a mouth cover and is solely meant to hold the endotracheal tube. Dimensions are also smaller than in previous iterations. The bite stick has a connection with the holder. Figure 7 represents design concept E that involves the endotracheal tube holder and is planned to be circular. The bite stick is not connected to the holder in this style. This holder is likewise built so that it does not cover the patient's mouth. Figure 8 represents the last design concept for concept F that involves the endotracheal tube holder being shaped like an ellipse. The design is identical to design concept A, except this design does not have a bite stick attached to it.

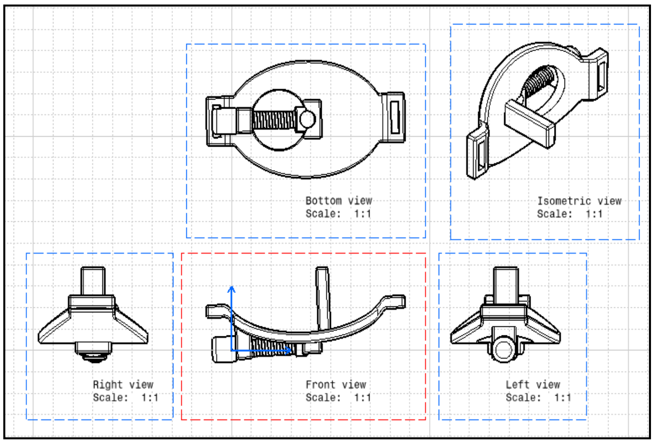



**Fig. 3.** Design concept A

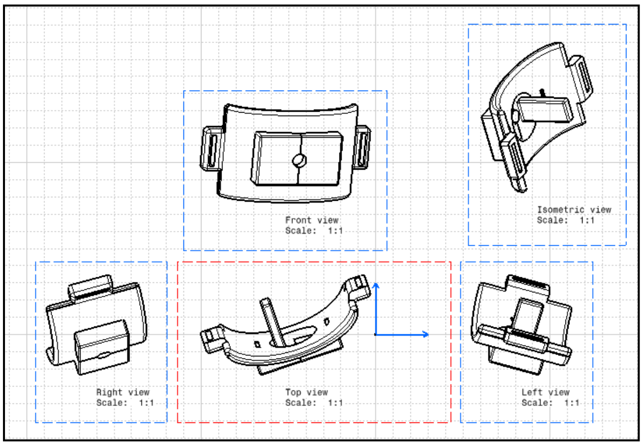



**Fig. 4.** Design concept B

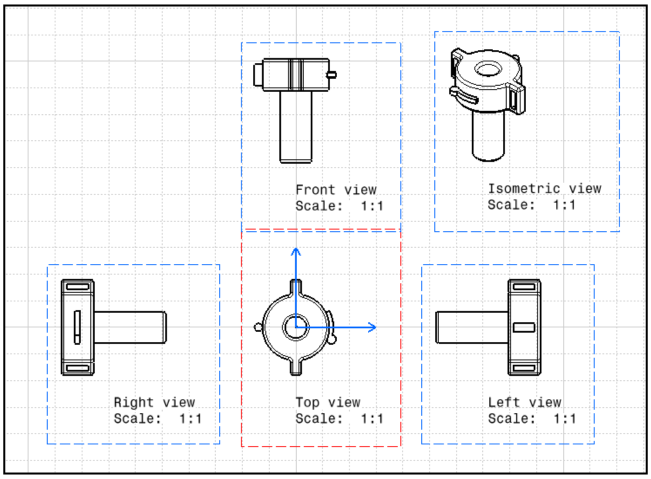



**Fig. 5.** Design concept C

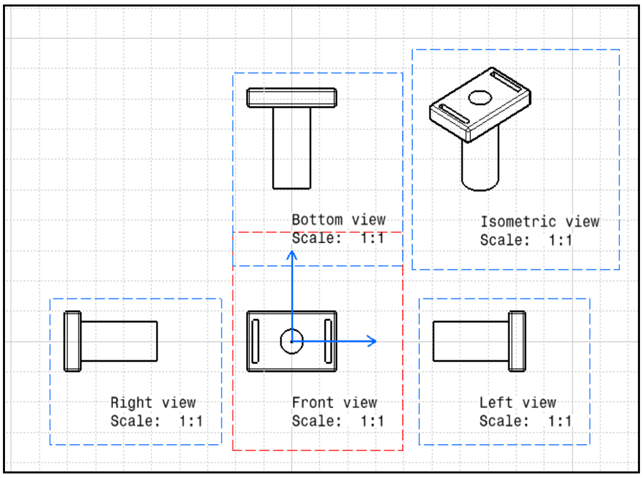



**Fig. 6.** Design concept D

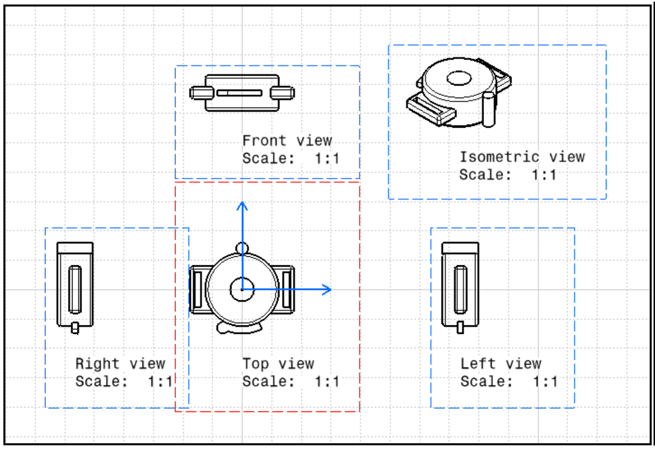



**Fig. 7.** Design concept E

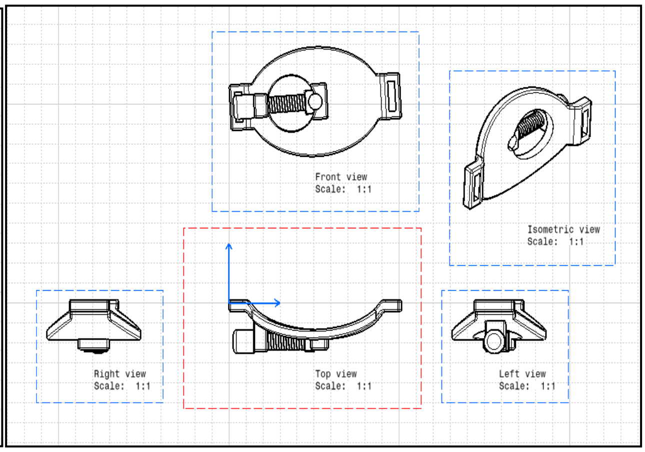



**Fig. 8.** Design concept F

### *3.4 Final Concept Selection and Fabrication of Prototype*

The goal of idea scoring is to determine which concept best meets the needs of the client. Concept A has the greatest rank, as stated in Table 2. As a result, concept A is chosen as the final design. The overall score for each concept was calculated to determine whose notion has the highest rank. Based on the findings of the concept scoring and concept screening, concept A is the most likely to be produced. The concept meets the users' most stringent requirements. The chosen design was then produced on the FDM machine. It is carried out once the desired final concept has been determined using the scoring matrix. Figure 9 displays the isomeric angle of the endotracheal tube holder. The FDM fast prototyping machine ~~is~~ takes 3 hours to produce the prototype.

**Table 2**
Scoring matrix

| SELECTION CRITERIA | Weight (%) | Design Concepts | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | A | | B | | C | | E | |
| | | Rating | Score | Rating | Score | Rating | Score | Rating | Score |
| **1.Functionability** | 35 | | | | | | | | |
| a. Easy to be connected | 10 | 5 | 50 | 4 | 40 | 4 | 40 | 4 | 40 |
| b. Easy to be detached | 10 | 4 | 40 | 4 | 40 | 3 | 30 | 4 | 40 |
| c. Oxygen flow | 5 | 3 | 15 | 3 | 15 | 3 | 15 | 3 | 15 |
| d. Leak proof | 5 | 3 | 15 | 3 | 15 | 3 | 15 | 3 | 15 |
| e. Compatibility | 5 | 4 | 20 | 4 | 20 | 4 | 20 | 4 | 20 |
| **2. Rigidity** | 20 | | | | | | | | |
| a. Easy to hold | 20 | 4 | 80 | 4 | 80 | 3 | 60 | 4 | 80 |
| **3.Surface texture** | 20 | | | | | | | | |
| a. Rough surface | 10 | 5 | 50 | 3 | 30 | 3 | 30 | 3 | 30 |
| b. Minimum sharp edges | 10 | 2 | 20 | 3 | 30 | 5 | 50 | 4 | 40 |
| **4.Material Consumption** | 15 | 4 | 60 | 3 | 45 | 3 | 45 | 3 | 45 |
| **5.Manufacturing Ease** | 10 | 2 | 20 | 4 | 40 | 4 | 40 | 4 | 40 |
| **Total Score ( Sj)** | | 370 | | 355 | | 345 | | 365 | |
| **Rank** | | 1 | | 3 | | 4 | | 2 | |

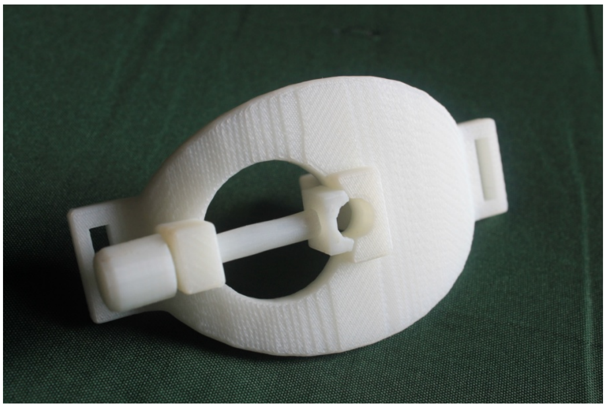


**Fig. 9.** isometric view section

## 4. Conclusions

This study looked at the fundamental design elements of an endotracheal tube holder. Product design and development technologies, particularly QFD, have been successful in creating important design criteria in measurable terms that are directly tied to customer qualities. They are as follows: lightweight Compatible, easy positioning of the endotracheal tube, low component complexity, and simple to use. Using the concept scoring matrix as a criteria-based decision a matrix, this research successfully managed to find the criteria scoring for determining which of numerous viable alternatives and solutions might be selected. This study was able to produce a prototype for a less complex and more intricate endotracheal tube holder configuration using rapid prototyping technologies.

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