DESIGN AND DEVELOPMENT OF A LOW-COST PEDIATRIC VIDEOLARYNGOSCOPE

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ABSTRACT

Endotracheal intubation is performed to provide ventilatory support to a patient of any age. Every medical procedure that requires general anesthesia requires intubation, and for this reason, it is a life-saving procedure. This maneuver is a challenge in pediatric patients between 0 months and 12 years of age, since their anatomy and oxygen consumption differ compared to an adult.

In patients with difficult airways, where there is no good visibility of the structures, a videolaryngoscope is used. It has higher success rates compared to a conventional laryngoscope. Its use has become widespread since the COVID-19 pandemic, as it reduces exposure to respiratory secretions.

This article presents the design, manufacture and testing of a low-cost pediatric videolaryngoscope, for patients between 6 and 12 months, and which are intended to respond to the low availability of this type of equipment in Colombian health care centers. The BioDesign Innovation Process methodology was adapted for its creation. The prototypes were manufactured using 3D printing. Validation was performed by 28 experts using simulators and the results were promising, obtaining a success rate of 98.8% for the designed device.

Keywords: Pediatric videolaryngoscope, Pediatric intubation, Biomedical design, Design process, 3D printing

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1 INTRODUCTION

An endotracheal intubation maneuver is performed to provide ventilatory support to a patient of any age, who for whatever reason is unable to maintain proper oxygenation. For this reason, it is a life-saving procedure. Endotracheal intubation is one of the most frequent surgical techniques in medicine and is performed daily in operating rooms, intensive care units, special care units, and emergency rooms within clinics and hospitals. Also, in pre-hospital care of patients in public places, especially in cases of trauma or cardiac arrest. In addition, any medical procedure requiring general anesthesia needs adequate intubation (Myatra *et al.*, 2022; Ramón and Juan Pablo, 2011). Poor intubation technique can result in death, loss of teeth, or cause injury to structures such as the vocal cords, arytenoid cartilages, pharynx, and larynx. This situation may become more critical in pediatric patients.

Intubation or airway management in children is challenging (Gupta *et al.*, 2021). Compared to adults, the structures that make up the airway are smaller in diameter and length; in addition, the tongue occupies more space relative to the oral cavity and the oral opening is more limited; the larynx is more anterior and superior, the epiglottis is larger, narrower, and omega-shaped (Miller *et al.*, 2019). Additionally, children present a softer rib cage, with less bone support making inspiratory efforts less efficient. Furthermore, their oxygen consumption according to weight, triples relative to adults, making them more susceptible to hypoxemia. Therefore, the processes to ensure adequate oxygen delivery to tissues by intervening the airway through endotracheal intubation and subsequent mechanical ventilation must be more efficient to avoid grave consequences (Sun *et al.*, 2014). Some of the main causes of cardiac arrest and permanent neurological damage in children are due to oxygenation difficulties. Because of this, airway management is a critical skill, not only in the surgical context but in any situation where ventilatory support is required in patients whose condition does not allow them to maintain appropriate oxygenation to meet physiological (Fiadjoe *et al.*, 2016).

The technique to perform intubation requires a device known as a laryngoscope, in use since 1940 (Swaika *et al.*, 2019). The procedure consists of inserting the laryngoscope through the right side of the oral cavity up to the glossoepiglottic groove, moving the tongue to the left, pulling the device upwards until the vocal cords are visualized, and inserting the endotracheal tube, always visualizing its successful passage through the cords (Ramón and Juan Pablo, 2011). The laryngoscope consists of a grip handle and a blade, which has a light at the tip; once inside the oral cavity, it allows the visualization of the vocal cords and epiglottis, to introduce a tube through the airway and provide ventilatory support by using a ventilatory support machine or a self-inflating bag (Komatsu *et al.*, 2010; Konrad *et al.*, 1998; Rujirojindakul *et al.*, 2014).

The use of conventional laryngoscopes requires a long learning curve (more than 40 procedures). In addition, constant training is indispensable to maintain an acceptable success rate. Because of this, other types of devices have been developed. In 2001, Dr. John Pacey introduced the first video laryngoscope for adult use (Myatra *et al.*, 2022) and in 2005, the company Verathon launched the first Glidescope video laryngoscope for pediatric use (Wallace and Engelhardt, 2015). A video laryngoscope is a laryngoscope that has been enhanced with an external viewing system by attaching a video camera near the distal end of the blade (Myatra *et al.*, 2022). Its creation and use have generated an important technological advance in human airway management, especially in difficult airways, in which a conventionally trained anesthesiologist has difficulties in face mask ventilation, endotracheal intubation, or both (Gupta *et al.*, 2021; Ramón and Juan Pablo, 2011).

The video laryngoscope has allowed better visualization of the anatomical structures of the airway, reduction of force on the tissues of the oral cavity, generation of less tissue distraction, and reduced stress and risk of unsuccessful attempts in performing intubations (Gupta *et al.*, 2021). Consequently, a lower complication rate for patients and a shorter learning curve for the staff being trained are observed. In addition, due to the pandemic generated by COVID 19, the World Federation of Societies of Anesthesiologists (WFSA) recommended the use of video laryngoscopes as a mechanism to avoid contagion, by minimizing exposure to respiratory secretions due to the increased distance between the patient and the person performing the maneuver, this situation has also increased its use in the world (de Jong *et al.*, 2020; Thampi *et al.*, 2020).

Before the pandemic, the priority was the patient's well-being; now it is just as important to maintain the physical integrity of the health personnel, for this reason, the surgical techniques of many procedures have undergone changes, and there is an urgent need for these personnel to be trained

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quickly and safely. Additionally, its use has been extended as a practical tool for teaching using simulators, since it allows real-time feedback and better communication among medical personnel (Myatra *et al.*, 2022).

A variety of video laryngoscopes are commercially available worldwide, the most representative in the pediatric area are C-MAC (Karl Storz), Glidescope, TruView, Airtraq, McGrath, and KingVision Ablade. These devices differ from each other by some variables such as cost, different shells, anti-fogging system, and useful life of the device (reusable or disposable), among others (Gupta *et al.*, 2021; Wallace and Engelhardt, 2015). In Table 1, a description of the most important characteristics of each device is mentioned.

Regarding the situation in Colombia in the use of pediatric video laryngoscopes, a search was performed in different scientific databases such as Science Direct, Scopus, Pubmed, and Scielo, with the search terms: video laryngoscope (including video laryngoscope) AND pediatric (including pediatric, infant and children) and no reports of their use in the country were found. In addition, after consulting with some specialists from various institutions in Medellin, a city of 2,427,129 inhabitants with 21 health centers of medium and high complexity, it was found that, of 8 organizations (where access was obtained to collect data), 4 do not have video laryngoscopes to perform intubations in pediatric patients. Table 2 shows the institutions and the devices available in each one.

The objective of this study is the design, manufacture, and testing of a low-cost pediatric videolaryngoscope in collaboration with Pablo Tobón Uribe hospital, CES university and EAFIT university, that responds to the needs of patients between 6 and 12 months of age, that adapts and optimizes the visualization of anatomical structures, increasing success rates and user comfort while adapting to the particular conditions of our health care system. Existing devices, either due to cost, consumables, or low availability of technical support, although necessary and supported by a large amount of literature, are not available in health care centers.

The device was designed based on the analysis of the airways of pediatric patients. The prototypes were fabricated using 3D printing. For the video capture system, a commercially available camera that can be connected to different visualization systems such as computers, tablets or smartphones was used. The video laryngoscope was tested and validated by 28 experts with various levels of expertise in airway management, executing the maneuvers in intubation simulators. Each specialist performed 3 intubations using the implemented videolaryngoscope and 3 intubations using a conventional straight-blade laryngoscope. Promising results were obtained, since in 98.8% of the intubation attempts with the videolaryngoscope, the maneuver was successfully performed. A high learning curve was obtained with this device and the average intubation time was shorter than with the conventional laryngoscope. The tests were carried out in the simulation center of the Pablo Tobón Uribe Hospital.

Table 1. Most popular video laryngoscopes available worldwide

Device	Description	Advantages	Disadvantages	Price
C- MAC	External screen to the device, no channel for guiding the tube.	Good resolution, can be used as a teaching tool	High cost, and handle is very large and makes it difficult to use on pediatric patients.	Starting at $2,500 USD
Glidescope Video Laryngoscope	No channel for guiding the tube and display external to the device.	Reusable blade, anti-fogging mechanism.	An acute angle of the blade is needed to facilitate intubation.	Starting at $1,150 USD
TruView Video laryngoscope	No channel for guiding the tube. Pediatric blades sizes 0, 1, 2 and 3.	Built-in oxygen stream for apneic oxygenation and anti-fogging mechanism.	Much longer intubation times have been reported and high cost	Starting at $5,000 USD
Airtraq Video laryngoscope	Optical laryngoscope with channel. Pediatric blades sizes 0 and 1.	Shorter intubation times and higher success rate for difficult pediatric airways have been reported.	For conventional intubations, longer intubation times have been reported.	$150 USD disposable

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McGrath Video laryngoscope	The device allows the exchange of disposable shells. The display for image visualization is integrated into the handle of the device.	Integrated display, disposable shells, reusable device, and hydrophilic optical surface coating to reduce light source fogging.	There might be difficulty in directing the tube through the vocal cords and may require external manipulation or the use of an intubation guide.	Starting at $2,500 USD
KingVision® a Blade Videolaryngoscope	Single-component, wireless, lightweight, portable, curved reusable device with non-channeled or channeled high-angle disposable blade.	Portable, disposable shells, reusable device. It has a USB port to project the video on another monitor or record it on a memory stick.	The tip of the cannulated blade may increase the time required for intubation.	Starting at $1,993 USD

Table 2. Medellín institutions and available pediatric video laryngoscopes

Institution	Degree of complexity	Pediatric Videolaryngoscope	Description
Pablo Tobón Uribe Hospital	High complexity	C-MAC, Karl Storz	Pediatric blade sizes 0 and 1
University Hospital San Vicente de Paul	High complexity	HugeMed, China	Angled pediatric blade, without channel. Non-neonatal
Hospital General Medellín	High complexity	HugeMed, China	Straight blade and angled blade without channel
Las Américas Clinic	High complexity	Not available	-
CES Clinic	Mid complexity	C-MAC, Karl Storz	Blade 0 (neonates up to 1 year) and blade 1 (between 1 and 2 years)
Leon XIII Clinic	Mid complexity	Not available	-
EMSA Clinic	Mid complexity	Not available	-
SOMA Clinic	Mid complexity	Not available	-

2 MATERIALS AND METHODS

The methodology used for this development was adapted based on the BioDesign Innovation Process methodology, see Figure 1. BioDesign Innovation Process is a multidisciplinary and systematic approach methodology, in which medical innovation can be reproduced, taught, and learned through an iterative cycle focused on observation. The needs of the users are fundamental as the basis for the development of the concept, in addition to cycles of creation and testing to guarantee improvements in the initial ideas and learning by the development team (Yock et al., 2015).

2.1 Explore

An intensive immersion was carried out at the Hospital Pablo Tobón Uribe, where the following activities were performed: interviews with anesthesiologists on the use of devices for the management of the airway in children, observation of patients in the operating room while they were being intubated, practice of pediatric intubation in simulators, observation, and analysis of a commercial videolaryngoscope used in the institution for pediatric intubation. The gathering of information was carried out to understand the importance of the procedure, the proper surgical technique and the basic requirements to perform a successful maneuver. In addition, a literature review was performed in scientific databases on the use of medical devices for pediatric intubation. Based on the problems/opportunities found, design specifications for pediatric video laryngoscopes were defined and compiled in terms of attributes, criteria, metrics, ideal value, and validation tool.

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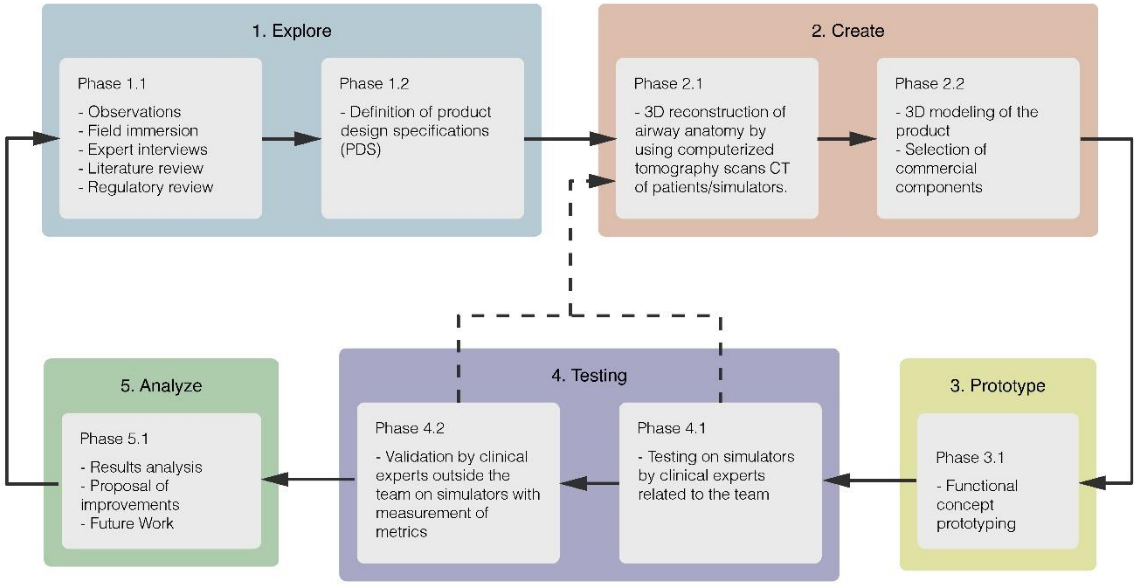

Figure 1. Phases of the implemented methodology

2.2 Create

An analysis of the anatomy of the pediatric airway and how it changes as the child grows from 6 to 12 months of age was performed. Some airways from physical intubation simulators and other digital ones, which were obtained from the processing of medical images (CT) and a further 3D reconstruction, were analyzed. The last process was performed in the Simpleware ScanIP software. Next, 3D modeling of some ideas was done using a reverse engineering software, Geomagic Desing X. The objective of this phase was to adapt the curvature of the device to the shape of the different anatomies obtained from medical images.

2.3 Prototype

The different prototypes were created using additive manufacturing on a Prusa I3 MK3 3D printer, which works under FDM technology, and varied materials such as PLA, ABS and TPU were explored. Also, some parts of the prototypes were manufactured on a Formlab Form 3 printer, which works under SLA technology.

2.4 Testing

For prototype testing, iterative cycles of creation and trials were conducted by an anesthesiologist expert in intubation with 15 years of experience. Every time a prototype was manufactured, it was evaluated on a commercial pediatric intubation simulator, its performance was analyzed, improvements were established, they were implemented on the 3D modeling, the updated version was manufactured and then tested again on the simulator. In this first stage of testing, the device had to achieve successful intubation, a correct visualization of the internal structures, a reduction of the oral opening and, in general, a reduction in the size of the device.
After obtaining a refined functional concept, a validation was conducted with several specialists available during a working day on the simulation center of the Pablo Tobón Uribe Hospital. The following protocol was established:

- Tests were performed to validate the device for patients between 6 and 12 months.
- A commercial pediatric simulator of Laerdal company of 6 months of age was used, which was available at the simulation center of the Pablo Tobón Uribe Hospital.
- The designed videolaryngoscope was compared in the tests with a conventional pediatric straight-valved laryngoscope as recommended by the project's clinical advisor.

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- The test begins with data collection from the specialist, a presentation of the simulator and a brief description of the intubation techniques used for pediatric videolaryngoscopes and laryngoscopes.
- Each specialist was asked to perform a total of 6 attempts, 3 with each of the devices in an interleaved manner. Intubation test with laryngoscope and then with videolaryngoscope; always starting with the laryngoscope.
- During each attempt, the time, the success, or failure of the maneuver, in case of failure, the cause of failure and observations of the device designed by the specialist were taken.
  - Time was defined as the duration in seconds required from the first contact with the oral cavity up to the verification of intubation with a self-inflating bag. This parameter was measured with a stopwatch.
  - Success or failure was determined by the increase in lung size at the time of verification with the self-inflating bag. The test personnel visually checked this parameter.
  - Causes of failure were defined as esophageal intubation, no visualization of the vocal cords, or difficulty passing the tube. The test personnel visually verified this parameter.

Figure 2 shows a flow chart with the protocol for the above-mentioned validation tests with experts.

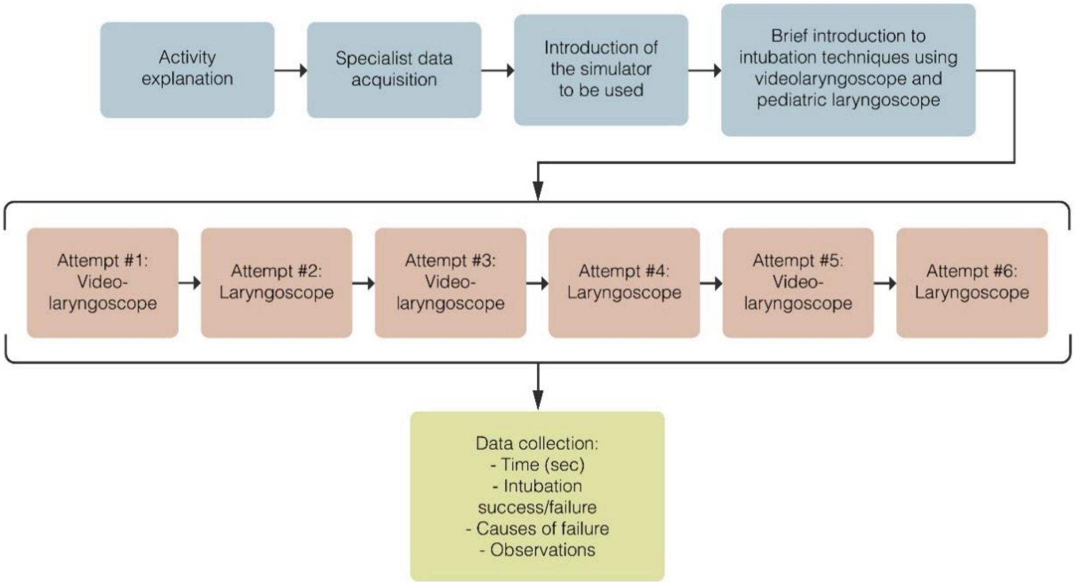

Figure 2. Protocol flowchart

2.5 Analyze

The results of the expert tests were analyzed using tabulation and graphs in Microsoft Excel software. The success rates for each of the devices and the learning curve for the video laryngoscope were studied. The learning curve was developed with the average of the intubation times of all the specialists for each of the attempts with the video laryngoscope. Finally, the observations of the medical staff related to the surgical technique when using the device in the simulators were considered.

3 RESULTS

3.1 Explore

During the field immersion and meeting with specialists, critical points of pediatric endotracheal intubation were obtained to consider in the design of the new device:

- Dental pieces can be damaged if excessive force is performed.
- There are diverse types of blades, with different curvatures to be used according to the age and pathologies of the patients.
- Channels to guide the tube facilitate the process by directing it more effectively into the trachea.

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- In many cases it is a procedure that requires agility and speed in order to avoid the risk of death of the patient due to lack of oxygenation.

Based on these findings, a list of the main product design specifications PDS was developed, see Table 3.

Table 3. Product Design Specifications PDS

Attribute	Criteria	Metrics	Ideal value	Validation tool
Design for assembly	Ease of assembly	Assembly time [Sec]	60	Stopwatch
		Number of parts [#]	<5	Expert validation
		Tools required in assembly [#]	0	Expert validation
Design for manufacturing	Geometry allows injection molding	Yes/No	Yes	Expert validation
Maintenance	Allows sterilization of all parts	Yes/No	Yes	Sterilization tests
	Allows replacement of all parts	Yes/No	Yes	Expert validation
Curvature	Curvature adapted to anatomy	Yes/No	Yes	Expert validation
Image alignment	Allows to keep the camera in a fixed orientation	Yes/No	Yes	Expert validation
Camera price	Commercial value of the selected camera	$ USD	<10	Commercial value

3.2 Create

During this phase, a 3D reconstruction of the airway of a 6-month-old child was obtained, which served as a reference for the 3D modelling of the device, especially the curvature of the blade. Figure 3 shows how the device adapts to the patient's anatomy.

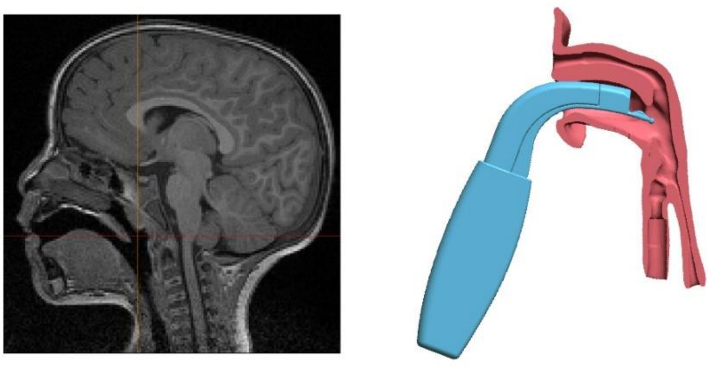

Figure 3. Phases of product creation and design

A device consisting of 4 parts was obtained: blade, channel, handle, and positioner, and 1 commercial camera. The blade and the channel were manufactured in PLA and assembled by mechanical interference. The blade was designed with the anatomical curvature of the airway, which helped to achieve a better visualization of the structures of interest and to adequately direct an endotracheal tube into the trachea. It also served to contain, protect, and guarantee the position of the video camera. The channel's main function was to contain and route the camera cable and was designed to slide endotracheal tubes between 3.0 and 3.5 mm in diameter.

The handle was manufactured in 3D printing using a flexible filament and was designed to fulfill the following functions: to serve as a gripping surface for the person performing the maneuver, to allow

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the exit of the camera cable to be connected to a visualization device and to keep the whole device assembled by exerting pressure on the other rigid parts achieving the assembly without using tools.
The positioner was manufactured in Grey Formlabs resin and was assembled to the video camera using glue, its purpose was to keep the camera orientation always in the same position in which the maneuver should be executed. To ensure proper adhesion of the positioner to the camera, it was necessary to design and manufacture an alignment system that ensures that the positioner is always located in the correct position with respect to the camera and therefore the entire device. The smallest commercial video camera available on the market was 3 mm in diameter and 30 mm in length. These dimensions allowed us to obtain an oral aperture of 13 mm. Figure 4 shows the parts that make up the device created.

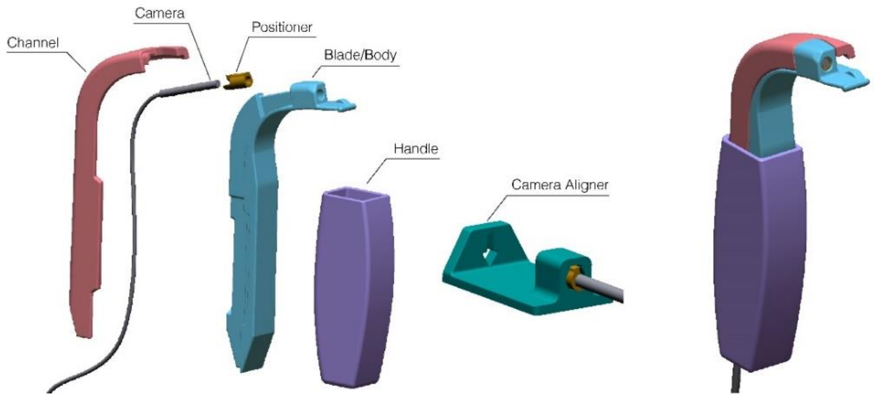

Figure 4. On the left the parts of the device and on the right the assembled device.

3.3 Prototype

Prototypes of the different versions were obtained with their respective improvements and in the end a design was achieved with all the functional assemblies and with a channel that allowed the tube to slide correctly to perform the maneuver. In addition, the handle fulfilled the expected assembly function of integrating all the parts of the device. Figure 5 shows the prototype of the final functional design.
The approximate manufacturing cost of the final prototype, including the camera and without considering the display system and a profit margin, was $130 USD.

Figure 5. Final functional design prototype connected to a smartphone.

3.4 Test and analyze

During the validation of the device by experts at the surgery session at the Pablo Tobón Uribe Hospital, 28 specialists with 5 different specialties were randomly selected: anesthesiologists (residents and specialists), urologists, plastic surgeons, nurses, and medicine students with an average of 7.21 years of experience between them.
On the study session, a success rate of 92.9% was obtained for the conventional laryngoscope tests and a success rate of 98.8% for the video laryngoscope tests. For the attempts with the videolaryngoscope, average times of 32.14 sec, 20.17 sec and 21.32 sec were obtained for attempts 1, 2 and 3 respectively; and, during the tests with the laryngoscope, average times of 37.10 sec, 22.32 sec and 19.17 sec were obtained for attempts 1, 2 and 3, respectively. Overall, the average intubation time with laryngoscope was 26.2 sec and with video laryngoscope was 24.5 sec. Furthermore, as evidenced in Figure 6, a high learning curve was obtained for the videolaryngoscope with maximum negative slope of 6.68. The

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blue data corresponds to the curve and the straight trend line including all the data in the calculated averages and the orange data corresponds to the curve and the straight trend line eliminating failed intubation times in the averages. The test session is shown in Figure 7.

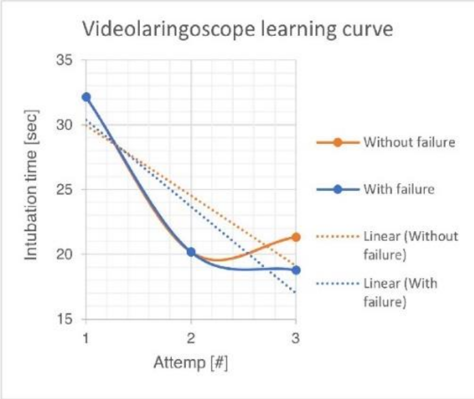

Figure 6. Learning curve graph for videolaryngoscope

In the observations made by the specialists, it was found that the channel complicates the detachment of the tube when removing the device from the oral cavity. Apart from this, all the feedback obtained about the design and performance was positive.

Figure 7. Validation tests with medical personnel (In the pictures: Dr. Rojas Cortes and Maria Jose Londono). On the left laryngoscope attempt and on the right videolaryngoscope attempt.

4 DISCUSSION

A video laryngoscope for children between 6 and 12 months of age was designed and manufactured based on the BioDesign Innovation Process methodology that met the design specifications. The prototype of the device manufactured by additive manufacturing had an approximate cost of $130 USD, it is expected that a mass production using an injection molding process could generate a considerable decrease in the final cost of the product.

It is expected that this development, in its later phases, can become a solution for the needs of the Colombian and Latin American healthcare system, as well as the challenges posed by situations such as those experienced since 2020 due to COVID-19, where it has become increasingly important to provide healthcare personnel with medical devices that are easy and safe to use.

During the development of the methodology, immersion in the clinical field and having the possibility of establishing specifications and designing under the guidance of clinical experts was essential for obtaining positive results. 3D printing technology allowed multiple iterative cycles of creation, prototyping and testing to be carried out very quickly; around 20 versions could be created using this technology. The use of simulators was essential to conduct the testing phase of the different prototypes created, since it allowed us to evaluate functional aspects of the design and aspects related to the surgical technique to be implemented for a successful intubation. In the testing phase with experts, it was possible to identify a reduction in the intubation time with the designed device in comparison with the conventional laryngoscope. It was also found that the use of the videolaryngoscope provides a more comfortable position for the person performing the maneuver, reducing fatigue. In addition, it was evident that the distance between the patient and the specialist was increased, avoiding the exposure to respiratory secretions.

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The approach used for this work could potentially be used by other teams for the design and development of medical devices and simulators.

As future work, we propose to improve the adjustment between the device channel and the endotracheal tube, so that it can slide and be removed from the device with less force; this aspect is important, since it prevents extubating, meaning that the tube slips out of the airway and therefore it is necessary to repeat the maneuver. Finally, the device is expected to undergo preclinical and clinical trials on real patients, in order to obtain the necessary requirements to comply with the regulations and bring the product to the market.

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