DIGITAL LARYNGOSCOPE

A New Force Measuring Laryngoscope

António Silva[1], Pedro Amorim[2], Manuel Quintas[1], Luis Mourão[3] and Joaquim Gabriel[1]

[1] *Labiomep, IDMEC – Pólo FEUP, Faculdade de Engenharia da Universidade do Porto, Porto, Portugal*

[2] *Hospital Santo António, Centro Hospitalar do Porto, Porto, Portugal*

[3] *Department of Biomedical Engineering, Escola Superior de Engenharia e Gestão Industrial, Instituto Politécnico do Porto, Vila do Conde, Portugal*

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Abstract: A laryngoscope is a medical device commonly used in most hospitals worldwide and used to conduct an oral or endotracheal intubation which leads to changes in the patient parameters (heart rate, blood pressure, etc.) due to the force applied on the tongue and other soft-tissues. However, these parameters are being monitored continuously, and provide guidance for anaesthetists to control the drugs which may lead to an inadequate dosage. This work aims to develop a laryngoscope capable of measuring the force applied during a laryngoscopy. To measure the applied force, several solutions, based on different sensors, were analysed and tested. The traditional laryngoscope xenon lighting lamp was replaced by a high bright LED which result in a clear illumination and lower batteries consumption. A Bluetooth® communication module was also include to allow a real-time force acquisition and display.

1 INTRODUCTION

1.1 Context

A laryngoscopy, as analyzed in this work, is a medical procedure performed by anaesthetists in order to achieve a good intubation and mechanical ventilation, when the patients are subjected to general anesthesia (GA). The anesthesia has three goals: 1) disable the muscular activity to prevent inadequate movement of the patient, 2) created an unconsciousness (achieved by an hypnotic drug) state and 3) avoid the sense of pain (analgesia).

1.2 Main Goals

This research work intends to achieve the following objectives:

- Develop a new laryngoscope capable of measuring and record force in real-time;
- Create wireless communication ability via standard communication protocols;
- Real-time force warnings based on trigger values previously defined;
- Keep the common laryngoscopy procedure, weight and size;
- Analysis software to view the recorded data;
- Replace the usual Xenon light by the LED to improves visibility.

2 ENDOTRACHEAL INTUBATION

2.1 Laryngoscope

The laryngoscope is basically composed by two parts: the handle and the blade (Figure 1). The handle includes the lightbulb, the automatic switch (to turn on/off the light), the batteries and the axis to fit the blade. The blade possesses the correspondent socket to connect to the handle and a metal protected optical fiber to guide the light to the tip of the blade when the laryngoscope is in working position (B).

Laryngoscope failure is extremely rare, but over the years some have been registered, like (Desmeules H. 1998). However, when it occurs, it is in a very critical moment of the anaesthesia process, since the patient is in apnoea without autonomous breathing capability.

With the recent improvement in the overall technologies, new laryngoscopes started to appear

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Figure 1: Laryngoscope handle and Macintosh blade size 3 A) closed position, B) opened position.

Whether may be improvements on the materials, which may lead to disposable laryngoscopes, or improvements in electronics that includes the video-laryngoscopes (indirect laryngoscopies).

The disposable solution appears mostly because of the wars, since it those situations it would be difficult to have the sterilization equipment at a hand.

2.2 Other Works

One of the first works on this field was (Grogono, 1983). He used strain gauges to measure the forces in the patient mouth, Butt he did not explain how the data was processed to get the force.

Another notorious work was done by (Hastings, et al, 1996). He use springs and various sensors to measure the force and torque aplied to the laryngoscope. But, as previous work he did not tell which was the precision or sensitivity of the instrument.

On the other hand, there exist several studies related to laryngoscopy force and pressure measurements. But the target of this work was studying the diference between experienced *vs* novice users (Martin. J. L *et al*, 1994), nothing was said about the device it self.

In the last years, some new devices arrived to the market, called video laryngoscopes. These devices use a small video camera that transmits the image to a small screen outside of the patient mouth. Some studies like (Ray*, et al*, 2009) tried to compare the video-laryngoscopes with the standard laryngoscopes, but without a way to measure the damage or pressure applied to the patient, the importance or utility of these studies is greatly diminished.

2.3 Laryngoscopy

The laryngoscopy is a quick procedure which requires very precise movement and force control abilities, only achived by well trained professionals.

To perform a correct laryngoscopy the patient has to lay down on his back and put his neck in a hyperextension position, this causes the airway to be in the straightest position. With the Laryngoscope in the patients mouth, the endotracheal tube is positioned at the entrance of the mouth and the laryngoscope handle placed in a 45° (Figure 2 Y axis) with the patient torso. The endotracheal tube is then inserted between the vocal cords. This is when most damage occurs, whether due to an excessive force (F1) or by pulling the device in a wrong direction (wrong amount of F2 or/and M1). This leads to a larger force F that will hurt the patient or produce an incorrect positioning of the blade.

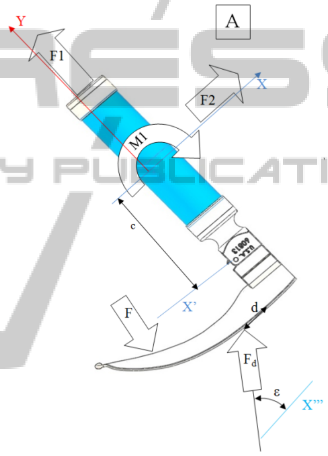

Figure 2: Forces during laryngoscopy.

By analysing the laryngoscope internal forces, it is easy to conclude that the force F and F_d generate a compression force in the contact point that occurs when the laryngoscope is in the open position.

Based on previous studies, the position of the force F along the blade can be estimated for normal situations (Silva 2010). Measuring it in real time may be possible but it requires the design of anew laryngoscope blade.

To set the trigger value for the maximum force, a wireless module was designed, in order to record real data from laryngoscopies (Gabriel 2010). With these results, a maximum force of 50 N in the tip of the laryngoscope blade Macintosh type, size 3 was set.

3 SENSOR POSSIBILITIES

The selection of the sensor that would lead to the most precise and sensitive situation, three solutions using the following sensors were evaluated:

1. Piezoresistive sensor
2. Hall effect sensor
3. Strain gauge sensor

In order to test these three sensors, it was build a testing handle that permit the evaluation of all three solutions, each one using a different sensor and a different pin.

3.1 Overall Comparison

Like in the most projects, the sensor should not be evaluated individually but together with the signal conditioning circuit and overall characteristics. That way, table 1 presents a general evaluation of the idealized solution for each sensor.

Table 1: Overall sensors evaluation.

Sensor	Piezo-resistive	Hall effect	Strain gauge
Electric noise	Medium	Low	Low
Space saving	Medium	Medium	High
Reliability	Low	Medium	High
Hysteresis	High	Low (near zero)	Low (near zero)
Equivalent noise (kgf)	0.2	0.36	0.02 – 0.03

It is notorious that the strain gauges present a far better solution than any other sensor for this particular application.

This is natural, since most of the commercial load cells use also strain gauges. The downfall is that due to the available size, a commercial load cell did not fit inside the laryngoscope handle.

Despite the other solutions, it was chosen to design a custom made load cell to fit in a new and redesigned laryngoscope handle.

4 FINAL PROTOTYPE

4.1 General Features

The device could be divided in to three different groups, mechanical parts, electronic circuits and data acquisition and analyse software.

4.2 Mechanical Parts

The mechanical parts were in a first-hand simulated using Solidworks®, this enabled the assembly simulation and mechanical tests using the FEA method.

The custom made load cell was also analysed using a FEA that enabled the optimization of the sensitivity *vs* mechanical strength to support the forces applied to it (using a safety factor of 2.2). The result was verified experimentally to prevent any future failure.

4.3 Software

The goal of the software was to receive the data from the digital laryngoscope interpret it and convert the raw data so it could be displayed as force and angles.

The final version could be installed in a computer whether use Microsoft windows, Mac OSX or Linux operating systems. This provides a big flexibility whether it may be install in an operation room or to analyse data in any other place.

The software is divided into four different tabs: Setup, Reader, DL Analyser and Quick Help.

5 RESULTS

One of the most notorious differences is the visibility increase provided by the illumination LED, Figure 3.

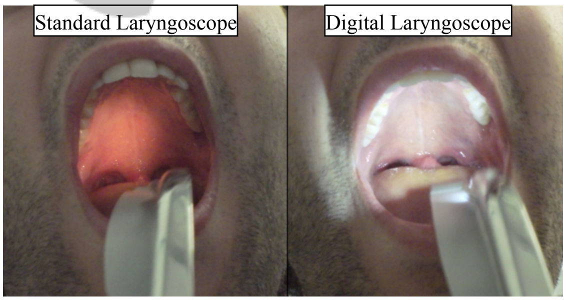

Figure 3: Light visibility comparison.

The appearance of the Digital Laryngoscope, Figure 4, is similar to the common one, being a little longer (12 mm) and thicker, the diameter was increased by 1.7 mm.

The device was tested in two different situations, with an intubation simulator and real life situations.

In the simulator, trained doctors reached a maximum force of 4.5 kgf (without warnings) and non-experienced user were able to complete the intubation with a maximum force around 2.7 kgf (with the Digital Laryngoscope warnings).

The real life tests (Figure 5) served to validate the device and the software. The global opinion was that the Digital Laryngoscope was very similar to

Figure 4: Standard Laryngoscope (left) and Digital Laryngoscope (right).

the other not requiring any special training or readjust of the global anaesthesia procedures.

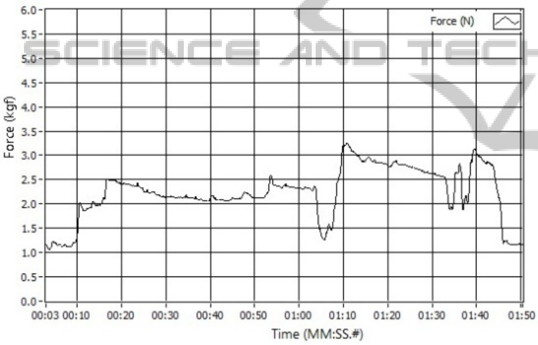

Figure 5: Force example.

6 CONCLUSIONS

The Digital Laryngoscope was accepted by the medical doctors with great enthusiasm. The overall opinion was that the visibility improvement was very good, greatly facilitating the intubation procedure. The force warnings were very easy to interpret and did not distract the doctor from the main goal (look at the vocal cords).

Another positive aspect is that the this device is completely compatible with the standards laryngoscope blades, meaning it is not necessary to buy a complete set of laryngoscope blades.

One other application for this device is in the training and teaching of the intubation procedure. The laryngoscope can be used at medical schools, to train future doctors and to help them to avoid possible damage in real patients. So, in relaxed and control environment, it is possible to train the intubation and have some numerical parameters that can give a helpful feedback to their training.

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