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Design and performance of a flow sensor CoroQuant used with emergency lung ventilator CoroVent during COVID-19 pandemic

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Abstract

At the time of COVID-19 pandemic onset in spring 2020 a project CoroVent was initiated with the aim to design and produce emergency lung ventilators and distribute them to hospitals. No flow and tidal volume sensors were available for the project. The lack of tidal volume sensors was a consequence of the rapidly increased demand for mechanical lung ventilators and their consumables. The aim of the study was to develop a special flow sensor CoroQuant for the CoroVent ventilators. The sensor based on pneumotachographic principle, manufactured by the plastic injection moulding of polypropylene, meets the requirements for precision of tidal volume measurement defined by international standard ISO 80601-2-12 for mechanical lung ventilators. CoroVent ventilators with CoroQuant sensors were distributed to 27 hospitals in the Czech Republic for free upon the requests from the medical facilities and started to be clinically used, thus preventing lack of lung ventilators in hospitals in the Czech Republic.

1. Introduction

The onset of the COVID-19 pandemic in Europe was accompanied by an insufficient number of devices for mechanical lung ventilation in Italy at the beginning of March 2020 [1]. Subsequently, other countries reported a shortage of lung ventilators [2]. After analysis of the availability and capacity of lung ventilators in the Czech Republic, the CoroVent project was proposed and the team of experts for its implementation was established on March 15, 2020.

The aim of the CoroVent project was to design and manufacture lung ventilators suitable for patients with respiratory failure due to COVID-19 pandemic. In contrast to a number of activities leading to the production of emergency lung ventilators based on simple solutions using breathing resuscitation bags, raft pumps and other improvised solutions [3], the CoroVent project aimed to develop a lung ventilator that meets the requirements for ventilators used in intensive care units and that enables so-called protective lung ventilation in accordance with the latest recommendations supported by evidence based medicine [4]. In addition to the precise setting of ventilation parameters, reliability and compliance with safety requirements in accordance with international technical standards, it was necessary to design a method and implementation of accurate measurement of ventilatory parameters. At the time of COVID-19 pandemic onset and at the time of CoroVent project implementation, there were no flow rate and tidal volume sensors for clinical use available that could be used with the newly designed CoroVent ventilator. The lack of tidal volume sensors was a consequence of the rapidly increased demand for mechanical lung ventilators and their consumables worldwide. Therefore, it was not rational to rely on products already designed and used clinically, because they were not available and without a possibility to order them. Therefore, designing a special sensor for CoroVent ventilator was the only solution.

In practice, lung ventilators for intensive care units use two basic principles for measuring flow and tidal volumes [5]. The first principle of the flow sensor is based on a heated wire. The wire is powered by a constant electric current source. The gas flowing around the heated wire cools it and thus changes its electrical resistance, which is reflected in a change in voltage measured on the heated wire ends. The second principle of flow and volume measurement uses a resistive element. The pressure difference developed on this element depends on the flow rate. The pressure drop is registered by a pressure transducer and then recalculated to the actual flow rate using the pressure-flow characteristics of the flow sensor. This sensor is referred to as a pneumotachograph.

A pneumotachograph flow sensor principle with an inserted resistive element was finally chosen for the measuring system of the CoroVent lung ventilator. The reasons for choosing the pneumotachograph type of
sensor are its simple construction, shorter development time and suitability for mass production. As a consequence, this solution allows cheaper and faster manufacturing and easy sterilization of the sensors [6].

The aim of this study was to design and optimize a CoroQuant flow sensor for measuring gas flow and tidal volumes with a CoroVent lung ventilator and to describe its pressure-flow characteristics, precision and other properties essential for its use in patients requiring mechanical lung ventilation.

2. Methods

2.1. Requirements for the CoroQuant sensor

In order to be suitable for the monitoring of patients during mechanical ventilation, the requirements for accuracy, the flow rate span and other features were defined. The flow sensor should be able to measure bidirectional flow of the ventilation mixture in the range of flows from 0 to 80 L/min. The accuracy of the designed sensor is defined by the requirements in the international technical standard ISO 80601-2-12, which requires the accuracy of measuring volumes up to 4 mL ±15% of real delivered value [7]. The sensor should respond rapidly and inexpensively. The sensor connectors should allow connecting to common components of the patient’s ventilation circuit. A biocompatible material should be used for the sensor manufacturing.

2.2. Design of the CoroQuant sensor

The designed sensor is a 12 cm long tube, which is on both sides terminated by 2 cm long conical connectors (according to EN ISO 5356-1 on conical plugs and sockets) [8]. The technical drawings of the sensor are presented in Figs. 1–3. A four-armed resistance element (Fig. 4) is placed in the inner space of the sensor. This resistance creates a pressure drop when the ventilation mixture flows through the element. Two channels for measuring the pressure difference are built into the resistance element and they end by two hollow mandrels, which are used for connection of hoses to transfer the pressure difference to the pressure transducer located inside the CoroVent ventilator. The complete 3D model of the CoroQuant sensor is presented in the STL format in the Supplementary material S1 available online at https://ventilation.fbmi.cvut.cz/data/.

2.3. Measurement of the pressure-flow characteristics

Flow characteristics of the manufactured CoroQuant sensor were measured in order to allow recalculation of the recorded pressure difference to the actual flow rate. A Fluke VT900A (Fluke Biomedical, Cleveland, OH, USA) gas analyzer (accuracy ±0.01 slpm) and a Testo 512 (Testo, West Chester, PA, USA) differential pressure gauge with a range of 2 kPa (accuracy ±10 Pa) were used. Pressure differences developed on the sensor were measured in both directions of the flow from 0 L/min to ±80 L/min using the assembly depicted in Fig. 5. Direction of flow to the patient was considered as positive. Compressed medical grade dry air was used for the measurement.

2.4. Precision of tidal volume measurement

The precision and stability of tidal volume measurement using the CoroQuant flow sensor was determined during ventilation of lung models with various mechanical parameters and various ventilator settings. CoroVent ventilator (MICo Medical, Trebic, Czech Republic) was used for ventilation in volume-control mode with three pre-set tidal volumes (200, 300 and 500 mL), two ventilatory frequencies (15 and 20 breaths per minute) and two levels of positive end-expiratory pressure, PEEP (5 and 10 hPa). The lung model compliance was set to 10, 20 and 50 mL/hPa and the airway resistance to 5, 20 and 50 hPa·s/L. The delivered tidal volume was measured by CoroVent ventilator and using a VT900A Gas flow analyser. The results presented are mean values and standard deviations calculated from 30 consecutive breaths recorded for each combination of the ventilator settings and the lung model parameters. The linear regression was used to evaluate linearity and bias of the tidal volume measurement using the tested CoroQuant sensor.

3. Results

The designed CoroQuant sensors were manufactured using the plastic injection moulding. Polypropylene was chosen for the production of the sensor due to its biocompatibility and mechanical properties suitable both for the plastic injection mouldings and consequent chemical disinfection. The final products are depicted in Fig. 6. A CoroQuant sensor after its packaging and sterilization suitable for distribution into medical facilities is depicted in Fig. 7.

The pressure-flow characteristics of the manufactured sensor were measured for flow rates of −80 to 80 L/min. The results are presented in Fig. 8.

For implementation of the CoroQuant flow sensor to the CoroVent ventilator, it was necessary to generate the curve for recalculation of voltage measured on the pressure difference transducer to the actual gas flow rate. A differential pressure transducer with a range of ±2 kPa

![Fig. 1. Technical drawing of the CoroQuant sensor.](image1)

![Fig. 2. Technical drawing of the CoroQuant sensor – front view.](image2)
(MPXV7002DP, NXP Semiconductors, Eindhoven, the Netherlands) was used for the measurement; the transducer was built into the CoroVent lung ventilator unit. The output voltage of the sensor is from $+0.5\text{ V}$ to $+4.5\text{ V}$ and was recorded using the CoroVent service mode. The measurement was performed in both directions on three selected flow sensors. The average values presented in Fig. 9 were used for implementation in the CoroVent software.

The precision and stability of tidal volume measurement using CoroQuant sensor is presented in Fig. 10 where averages and standard deviations of 30 consecutive breaths are depicted for combinations of pre-set ventilatory parameters and various lung model characteristics. The trend confirms the linearity of the sensor; the coefficient of determination $R^2$ is 0.9992 for the linear approximation of the measured data with CoroQuant versus the reference values.

Fig. 10 also depicts limits of error of the tidal volume measurement allowed by the international standard ISO 80601-2-12:2011 for critical care ventilators (red curves), which is $4\text{ mL} + 15\%$ of real delivered tidal volume value. The tested sensors fulfill the requirements of the ISO standard very well.

4. Discussion

The designed and manufactured sensors CoroQuant are able to measure bidirectional flow of the breathing gas mixture in the range of flows from 0 to 80 L/min. When connected to the CoroVent ventilator, CoroQuant sensors are able to measure tidal volumes with relatively small error (Fig. 10) which very well meet the requirements for the precision of tidal volume measurement requested by the international standard ISO 80601-2-12. As the reported precision is suitable for medical applications that use mechanical ventilators, the manufactured sensors meet other criteria defined for the design, including possibility of fast and cheap mass production, rapid and inexpensive sterilization, biocompatibility and a possibility to be connected to standard patient circuit components using the standardized medical cone connectors.

During the development of the sensor, two possible principles of flow measurement were considered. The flow sensor with an inserted heated wire is relatively complex and not easy to manufacture. Another disadvantage is the fact that a heated wire inside the sensor can trap deposits from the patient’s airways. Deposits on the wire can affect the accuracy of the measurement significantly. The advantage of this principle is good sensitivity to small flow rates of the ventilation mixture (below 5 L/min). Another advantage is its low susceptibility to changes in the chemical composition of the measured gas mixture, which changes due to ventilator setting (e.g. by changing fraction of oxygen in the inspiratory gas) and differs between inspiration and expiration due to oxygen intake and CO$_2$ production within the human body.

The second principle of flow rate measurement considered for the design was the pneumotachographic principle that uses a resistive element. The advantages of this solution are the simplicity of the sensor design and low financial and time requirements for production. The main disadvantage of the solution is the lower accuracy of measurement at small flow rates. A pneumotachograph flow sensor with an inserted resistive element was finally chosen for the measuring system of the CoroVent lung ventilator. The main reason was the time required for the development of the flow sensor and the possibility of its fast and inexpensive production.
Initial design and optimization of CoroQuant sensor was conducted using the computational fluid dynamics modelling in COMSOL Multiphysics (COMSOL, Inc., Burlington, MA, USA). The technology of 3D printing was used for manufacturing and testing of the first samples of the CoroQuant sensors. During the optimization process, the location and shape of the resistance element inside the sensor’s body were identified as crucial for the resulting sensor characteristics. The final design of the sensor is the result of many experiments with different shapes of the resistance element. In the first phase, it was important to decide on the type of the resistance element. Among the prototypes produced there was a sensor with an orifice within it. This sensor has a parabolic pressure-flow characteristics. However, this solution had very low accuracy at lower flow rates, so it was abandoned after testing several differently shaped prototypes. Another solution was to make a sensor with a variable resistance element created from a flexible foil.

The foil gradually opens due to the increasing flow rate of the ventilation mixture. As a result, the pressure-flow characteristics becomes close to linear. This solution offers higher accuracy at low flow rates, but it is more difficult to manufacture sensors with identical properties. At the same time, the sensor is more susceptible to depositions from the patient’s airways that affect the precision of the measurement. Considering all the described complications, a sensor with a fixed resistive element described in the method section was selected as the final solution.

Further design and tests were aimed at optimization of the shape and position of the resistive element. After creating prototypes using 3D printing and creating the first components by plastic injection moulding, it was found that due to the presence of a bend of the ventilation circuit just behind the sensor (e.g., when connected to an L-piece), it is not possible to place the resistance element to the sensor tube randomly. Due to the specific shape of the ventilation circuit, it was necessary to prevent the so-called Coanda effect, which began to manifest itself on the moulded sensors. The reason for this phenomenon was the fact that the moulded sensors had very smooth inner walls, which caused the air stream to adhere to the sensor wall. This distorted the flow profile in the sensor and thus affected the pressure drop that did not correspond to the actual value of flow rate. Prototypes from a 3D printer did not have smooth walls, which prevented the Coanda effect occurrence.

As a result of a relatively low sensitivity of the sensor to low flow rates, the pressure difference developed on the resistive element is very small for small flow rates as occurs for example at the end of expiration when flow rate may exponentially become zero. Due to this property, a suitable pressure transducer for the pressure difference measurement
should be used. High precision in a small range of pressures, very low drift and high thermal stability are required.

As the design of the sensor was conducted during rapid development of an emergency lung ventilator, there are several possibilities for improvement. It would be appropriate to test modified resistive parts of the sensor with different curvatures and possible forms of the ends of the channels for sampling the pressure difference. By such improvements in shape, further increase in the accuracy of flow and tidal volume measurements could be achieved.

So that the CoroQuant sensor could be used as part of a patient circuit, a highly clarified random copolymer resin PP9074MED (Exxon-Mobil, Parkway Spring, TX, USA) designed for injection moulding of medical devices was used. The material is suitable for radiation of chemical (ethylene oxide) sterilization. CoroQuant sensors were sterilized before their distribution and were intended as single use only.

5. Conclusion

The sensor based on pneumotachographic principle, manufactured by the plastic injection moulding of polypropylene, meets the requirements for the precision of tidal volume measurement defined by the international standard for mechanical lung ventilators. The sensors were produced in the Covid-19 pandemic in the Czech Republic for use with the CoroVent ventilators, when no sensors for clinical use were available due to the increased demand for respiratory material. CoroVent ventilators with CoroQuant sensors were distributed to 27 hospitals in the Czech Republic for free upon the requests from the medical facilities, and started to be clinically used, thus preventing lack of lung ventilators in medical facilities in the Czech Republic.

CRediT authorship contribution statement

Ladislav Bís: Design of sensors, Mathematical simulations, Manufacturing, Laboratory experiments, Data processing, Formal analysis, Writing – review & editing. Karel Roubík: Conceptualization, Methodology, Formal analysis, Writing – review & editing. Both authors have read and agreed to the published version of the manuscript.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.measen.2022.100383.

References

[1] Emanuele Rezoagli, et al., Development of a critical care response-experiences from Italy during the Covid19 pandemic, Anesthesiol. Clin. (2021).
[2] W.D. Carroll, et al., European and United Kingdom COVID-19 pandemic experience: the same but different, Paediatr. Respirat. Rev. (2020).
[3] Iadre El Majid, et al., Preliminary design of an innovative, simple, and easy-to-build portable ventilator for COVID-19 patients, Euro-Mediterranean J.Environ. Integrat. 5 (2) (2020) 1–4.
[4] Rex A. Marley, Simon Kaycee, Lung-protective ventilation, Annu. Rev. Nurs. Res. 35 (2017) 37.
[5] Nanda Gopal Mandal, Measurement of volume and flow in gases, Anaesth. Intensive Care Med. 10 (1) (2009) 52–56.
[6] Karthikeyan Iyengar, et al., Challenges and solutions in meeting up the urgent requirement of ventilators for COVID-19 patients, Diabetes Metabol. Syndr.: Clin. Res. Rev. 14 (4) (2020) 499-501.
[7] ISO 80601-2-12, Medical Electrical Equipment – Part 2-12: Particular Requirements for Basic Safety and Essential Performance of Critical Care Ventilators, International Organization for Standardization, 2011.
[8] ISO 5356-1, Anaesthetic and Respiratory Equipment — Conical Connectors — Part 1: Cones and Sockets, International Organization for Standardization, 2015.