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Development of a Novel Low-cost Lung Function Simulator

Abstract: In order to test medical devices, industry increasingly uses simulators closely reassembling the behaviour of physiological systems. In the context of respiratory therapy, most available simulators are designed based on a ventilated volume. This highly adjustable volume allowing for fast dynamical changes often leads to very cost-intensive test devices, particularly when incorporating realistic spontaneous breathing. Therefore, in this article we introduce a novel concept for a low-cost lung simulator, capable of mimicking the ventilation behaviour of the human lung at the Y-piece of a mechanical ventilator. The proposed design does not require any enclosed spaces to hold inhaled air nor expensive precise linear actuators adjusting its volume. Instead, the setup is designed based on the design of a mechanical ventilator, connecting the system with one port to the ventilator and then dividing the hose into two independent branches. Each branch has an integrated radial fan and a proportional valve, controlling the inspiratory and expiratory flow, individually. The mass flow and pressure are measured at the systems inlet port, representing the condition at patient airway. In contrast to existing setups, the proposed design is not limited by the physical properties of a volume such as fixed maximum size, allowing the simulation of various types of patients and conditions. Numerical simulations to evaluate this system design showed the ability to generate a realistic spontaneous breathing pattern. With a first experimental setup it was possible to prove the feasibility of this approach, by generating common flow curves during spontaneous breathing. Building on this design, the approach could eventually lead to a more accessible method for testing.

Keywords: lung function simulator, modelling, simulation, respiratory ventilation, mechanical ventilator

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1 Introduction

Mechanical ventilation is a key aspect in modern medicine, sustaining a proper gas exchange during respiratory insufficiency [1], [2]. The application of positive pressure used for mechanical ventilation often leads to severe complications, such as ventilation-induced lung injury (VILI), respiratory muscle weakness and sinusitis [1–3]. Therefore, great efforts are made developing lung protective ventilation strategies, resulting in a constantly improving range of ventilation modes, and underlying control algorithms [3]. In conjunction with the increasing complexity, especially regarding medical software, it is a major concern to maintain the reliability, efficacy and safety of medical ventilators. To verify the safety of medical devices, different models classified as computational modeling and simulation (CM&S), bench testing, animal studies and clinical trials are utilized in the development and during the regulatory process [4].

Despite the ongoing trend towards evaluating medical devices using CM&S, the other mentioned means of testing are still irreplaceable in the engineering practice [5]. This can be explained by the fact that CM&S has great potential for cost savings [4], [5]. However, it often does not produce as reliable results as bench testing due to lack of data to drive model development or unmodeled environmental impacts [5].

According to our investigation, there is currently only a small number of commercial devices available, simulating the lung to evaluate ventilators, only five of which can simulate an active breathing, such as the ASL-5000™ from Ingmar Medical and the TestChest® from Organix GmbH. These products, alike the human lung, consist of a volume in which the inspired air is stored. This volume can be actively increased e.g. by a linear actuator, to mimic different patients and generate a spontaneous breathing. Another approach on an active lung simulator called i-Lung introduced by [6] uses a piston cylinder system to create an airflow, but also is dependent on a latex bag as a lung equivalent.

This paper proposes a novel concept for a lung function simulator without requiring the precise, adjustable volume and the associated linear actuators. This is achieved by generating the airflow with radial fans instead of a dynamically adjustable reservoir. The advantage of this approach is the independence of a physical volume, which

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allows for high flexibility in the simulation, over a wide variety of patients of any age and conditions. The primary goal of this paper is to prove the basic capability of such a system to pneumatically generate a lung ventilation waveform of a spontaneously breathing patient in terms of flow going in and out of the patient.

2 Material and Methods

The design of the system was derived by using the functional analysis approach based on the requirement to control the flow in and out of the simulator with and without a ventilator attached to the system. The resulting design is shown in Figure 1. At the main port of the system the ventilator under test is attached to the lung simulator. At the port, two sensors are utilized to measure the systems in- and outgoing mass flow rate as well as the pressure, representing the condition at patient airway. Afterwards the system divides into two independent pneumatic branches each integrating a radial fan and a proportional valve. This way the airflow for the inspiration and expiration can be controlled independently. The radial fans are counter-rotating, thus one creating a negative pressure at the main port generating an inspiratory flow, while the other generates a positive pressure and thus an expiratory flow. To ensure an airflow is streaming through the desired branch, additional valves are required. These valves also enable a faster dynamic response of the system during transients.

In order to emulate the physiological behaviour of a patient, the mass flow rate through the main port of the device is controlled so that it follows a reference generated by a suitable mathematical model of the respiratory system. There is a vast amount of literature on describing ventilatory lung dynamics mathematically [7–9]. In general, the system design allows to adapt various models of the respiratory system as long as they are dependent on the flow rate of the patient. As a first implementation of the system the here applied model is a highly simplified but widely used linear single compartment model based on the approach of [10]. This model allows to describe the flow dependencies of a spontaneously breathing patient, based on the pressure generated by the respiratory muscles. The differential equation is given by:

$$P_{mus} = \frac{1}{C} V(t) + R \dot{V}(t) + P_{aw}, \quad (1)$$

where P_{mus} is the respiratory pressure generated by respiratory muscles as the driving force of the ventilation movement, P_{aw} the pressure at the patient airways, C the

Figure 1: Pneumatic circuit diagram of the resulting system design with solid lines for tubes and dashed lines for data cables.

¹ Device under test

compliance modeling the elasticity of the lung, R represents the airway resistance, $V(t)$ is the inspired volume and $\dot{V}(t)$ is the respiratory air flow.

As control loop technique, a proportional-integrated controller is used to control the flow rate as the process variable to follow a desired reference trajectory. The calculated flow is converted to a differential pressure in accordance to the Hagen–Poiseuille law, since the radial fans generate a differential pressure proportional to the input voltage.

2.1 Numerical Simulation

In order to pre-evaluate the concept a numerical simulation was developed, with the aim to collect information about the ability to simulate lung function of the system as a whole and of the chosen components in particular. Furthermore, the simulation was used for rapid control prototyping to develop and test suitable controllers as well as the chosen mathematical lung model. For this purpose, the Software MathWorks® Simscape Fluids™ was chosen. This software allows the simulation of physical models. In addition, Simscape Fluids™ provides rich component libraries for modelling fluid dynamic systems, containing all required components of the system approach.

Figure 2: Volumetric flow rate curves of two breathing cycles of the reference data created by the mathematical lung model (solid black line), the simulated data created by numerical simulation (grey dashed line) and the measured data created by the experimental setup (grey solid line), showing greatest inconsistencies after the switching points between inspiration and expiration phases (enlarged window).

2.2 Experimental Setup

An experimental setup was realized according to the system design shown in Figure 1, with the restriction that a check valve was used in the outlet branch instead of a proportional valve. The system was controlled by an Infineon XMC 4800 microcontroller programmed to generate a spontaneous respiratory flow curve, implementing the mentioned single compartment lung model and the control steps in C code. The online sampling time to calculate the reference flow curve was 1 ms. It was not possible to transmit the data in such a high rate, so that the recorded data was transmitted after the measurement with a sampling time of 10 ms. A complete list of components is given in Table 1.

Table 1: Used components for the experimental setup of the developed system

Component	Part
Mass flow meter	Sensirion SFM3000
Pressure sensor	Honeywell 26PC Series
Radial fans	Blower Unit
Proportional valve	Expiratory valve
Microcontroller	Infineon XMC4800

3 Results and Discussion

For a first evaluation of the system design, the systems capability of generating a realistic spontaneous breathing pattern was tested. Therefore the respiratory muscle pressure data from [7] was used as an input to the lung model in eq. (1). The model is then forward simulated using an ODE-solver, thus generating the reference for the patient flow. For the parameters of the respiratory system $R = 0.18 \text{ Pa s/l}$ and $C = 1.84 \text{ l/kPa}$ were chosen in accordance to [8]. Two consecutive breaths, spanning 8 s, were simulated. The generated reference was used in the numerical simulation and the experimental setup, where the simulation of the model was run on the μC .

The resulting flow curves generated in simulation and on the testbed are depicted in Figure 2. Both curves from the numerical simulation (grey dashed line) and from the experimental setup (grey solid line) show good overall concordance with the reference curve from the mathematical lung model (black solid line). When integrating over the flow curves during the inspiration phase the inhaled tidal volume only differs by 0,4 ml for the numerical simulation and by 3,5 ml for the experimental setup, from the reference of 541,2 ml.

It is noticeable that in both scenarios the greatest deviations in the flow rate occur during the switching between the inspiration and expiration phase. This is most likely due to the switching behaviour of the proportional valves. During this phase the valve tends to chatter, due to

the currently used binary control of the valves. This results in the controller to not operate as intended. Once the flow reference increases the controller is capable of following the desired reference. The same phenomenon is apparent in the transition from inspiration to expiration at 6 s, but due to the steepness of the curve this effect is less severe. The usage of the valves as proportional valves probably suffices to solve this issue.

Despite the fact that there were some aberrations from our anticipated flow rate curve, we believe our findings demonstrate that it is possible to simulate a realistic spontaneous breathing pattern with the introduced system design, without an enclosed space to hold inhaled air.

4 Conclusion

This paper introduced a novel concept for a lung simulator capable of simulating the ventilation of a spontaneously breathing patient. Due to the use of radial fans instead of linear actuators and enclosed vessels, the presented concept could be the first step towards a more affordable, highly flexible solution for testing medical ventilators. The evaluation of the system design has shown that the presented concept of an alternative lung function simulator is able to provide an adequate simulation of a spontaneously breathing patient with minor restrictions.

Further research, studying the system behaviour in combination with a mechanical ventilation should be conducted to achieve a realistic system response to it. Apart from that a more adequate nonlinear mathematical model of the respiratory system could be adopted to achieve more realistic breathing curves. In the long term, it is already intended to expand the system's possibilities by simulating the lungs gas exchange processes. For this purpose a pressurized carbon dioxide reservoir together with an additional proportional valve could be connected to the expiration branch of the system.

Proceeding from this, the solution could eventually lead to a more easy and accessible method for testing ventilators and ventilation algorithms. System tests of these devices could be done at an earlier stage in the development process. This could potentially have a great impact on innovation, e.g. in the field of intelligent ventilation support, leading to a

reduction of VILI and therefore ultimately contribute to patient safety.

Author Statement

Conflict of interest: Florian Bautsch declares that he has no conflict of interests. Georg Männel and Philipp Rostalski have received research funds from Drägerwerk AG & Co. KGaA.

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