 DOI: 10.5301/ijao.5000293

SHORT COMMUNICATION

Gas exchange efficiency of an oxygenator with integrated pulsatile displacement blood pump for neonatal patients

Peter C. Schlanstein, Ralf Borchardt*, Ilona Mager, Thomas Schmitz-Rode, Ulrich Steinseifer, Jutta Arens*

Department of Cardiovascular Engineering, Institute of Applied Medical Engineering, Helmholtz Institute, RWTH Aachen University - Germany

* Both authors contributed equally to this manuscript

Oxygenators have been used in neonatal extracorporeal membrane oxygenation (ECMO) since the 1970s. The need to develop a more effective oxygenator for this patient cohort exists due to their size and blood volume limitations. This study sought to validate the next design iteration of a novel oxygenator for neonatal ECMO with an integrated pulsatile displacement pump, thereby superseding an additional blood pump. Pulsating blood flow within the oxygenator is generated by synchronized active air flow expansion and contraction of integrated silicone pump tubes and hose pinching valves located at the oxygenator inlet and outlet. The current redesign improved upon previous prototypes by optimizing silicone pump tube distribution within the oxygenator fiber bundle; introduction of an oval shaped inner fiber bundle core, and housing; and a higher fiber packing density, all of which in combination reduced the priming volume by about 50% (50 to 27 mL and 41 to 20 mL, respectively). Gas exchange efficiency was tested for two new oxygenators manufactured with different fiber materials: one with coating and one with smaller pore size, both capable of long-term use (OXYPLUS® and CELGARD®). Results demonstrated that the oxygen transfer for both oxygenators was 5.3-24.7 ml_{O2}/min for blood flow ranges of 100-500 ml_{blood}/min. Carbon dioxide transfer for both oxygenators was 3.7-26.3 ml_{CO2}/min for the same blood flow range. These preliminary results validated the oxygenator redesign by demonstrating an increase in packing density and thus in gas transfer, an increase in pumping capacity and a reduction in priming volume.

Keywords: *Oxygenators, Pulsatile flow, Extracorporeal membrane oxygenation*

Accepted: December 16, 2013

INTRODUCTION

Extracorporeal membrane oxygenation (ECMO) has been utilized since the beginning of the 1970s (1) to provide effective pulmonary and cardiac life support to a wide range of patients. The most common cohort for ECMO is the smallest of patients: young pediatrics and neonates (0 to 30 days of age). Since the founding of the Extracorporeal Life Support Organization (ELSO) in 1989, over 21000 cases of ECMO in neonatal patients have been reported. A majority (19000) of these cases reflect patients that required ECMO for respiratory failure, most commonly due to congenital diaphragm hernia or meconium aspiration syndrome (2-5). A smaller number of neonate patients required cardiac ECMO for combined heart-lung assistance during the surgical correction of severe cardiac malformations and congenital heart defects (1, 3).

The basic extracorporeal circuit (ECC) for ECMO consists of an oxygenator for gas exchange and a blood pump to overcome the ECC pressure for veno-venous ECMO for lung assist (ECLA) or the combined ECC and arterial pressures for veno-arterial ECMO during heart-lung support (ECLS). In 2010 we developed and tested as a proof of concept an oxygenator with integrated collapsible and expandable silicone pump tubes acting as a membrane displacement pump (Pump-Oxygenator-v1) (6). However, we observed problems in positioning the silicone pump tubes in the fiber bundle. This has led to a low fiber package density and thus to a low gas transfer and a high priming volume. Additionally, the pumping capacity was lower than the expected 500 ml_{blood}/min. Therefore, this paper focuses on the redesign of the pump-oxygenator (Pump-Oxygenator-v2), aiming for a manufacturing method for reproducible silicone pump tube positioning, a balanced gas exchange and pump capacities, and a reduced priming volume.

MATERIALS AND METHODS

Oxygenator design

The initial design Pump-Oxygenator-v1 is characterized by a fiber bundle without inner core, inhomogeneous distribution of the silicone pump tubes within the fiber bundle, and a low fiber package density (upper Fig. 1). Therefore, the redesigned Pump-Oxygenator-v2 includes an oval shaped core upon which the fiber bundle with inlayed silicone pump tubes is coiled. The invention of a special coiling and positioning device for both fiber mats and silicone pump tubes enabled the implementation of a reproducible manufacturing process for a homogenous pump-oxygenator bundle (bottom Fig. 1).

To run the pump-oxygenator, three fluid flow ways are needed (Fig. 2):

1. Gas exchange: A constant O_2 gas flow (white arrows) enters the oxygenator fibers from the left top and exits the oxygenator housing (with up taken CO_2) at the bottom.
2. Pumping: All silicone pump tubes are connected (connectors) to the upper chamber that is connected to the "pulsator", a device that creates negative and positive air pulses (segmented black arrows) which cause the collapse and expansion of the silicone pump tubes.

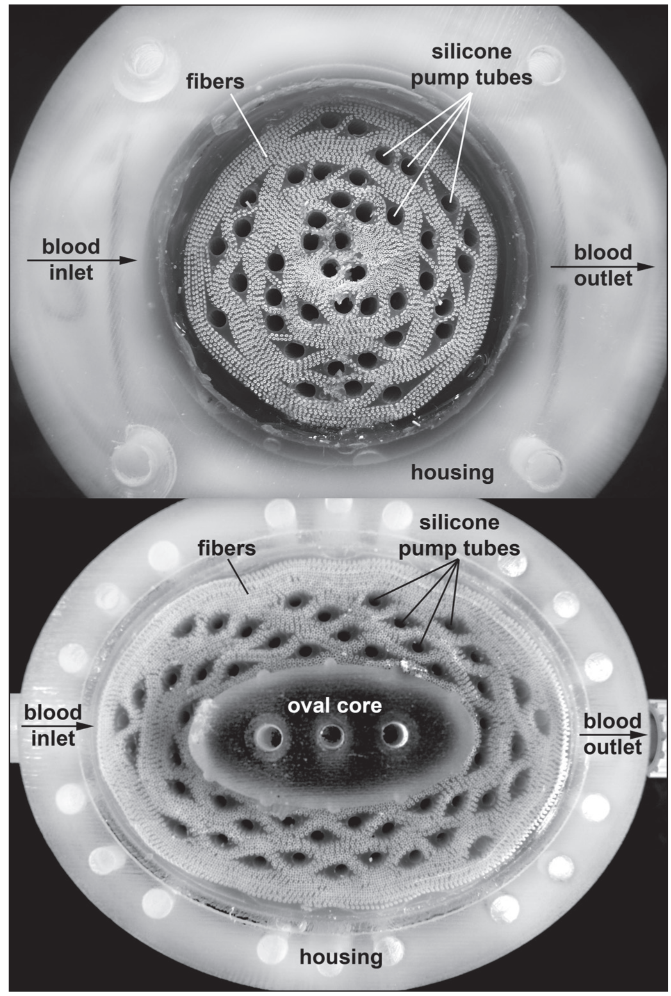

Fig. 1 - *Top view of the round shaped Pump-Oxygenator-v1 (upper view) and the oval shaped Pump-Oxygenator-v2 (bottom view) with integrated silicone tubes inside the housing.*

3. Blood flow: A pulsatile pumping action is imparted on the blood due to the repetitive expansion and contraction of the silicone tubes. Two active pinch valves (S206; Zimmer Automation, Rosengarten, Germany) are placed in the circuit, one at the blood inlet and one at the blood outlet. The valves are synchronized to the air pulses thus persuading blood flow through the oxygenator (gray arrows).

Materials

In this study, two different types of oxygenator hollow fibers were used:

– OXYPLUS® (Polymethylpentene, ID/OD 300/380 µm, fully closed outer surface, 1700 mm mat length, 35 mm fiber length) (Membrana GmbH, Wuppertal, Germany).

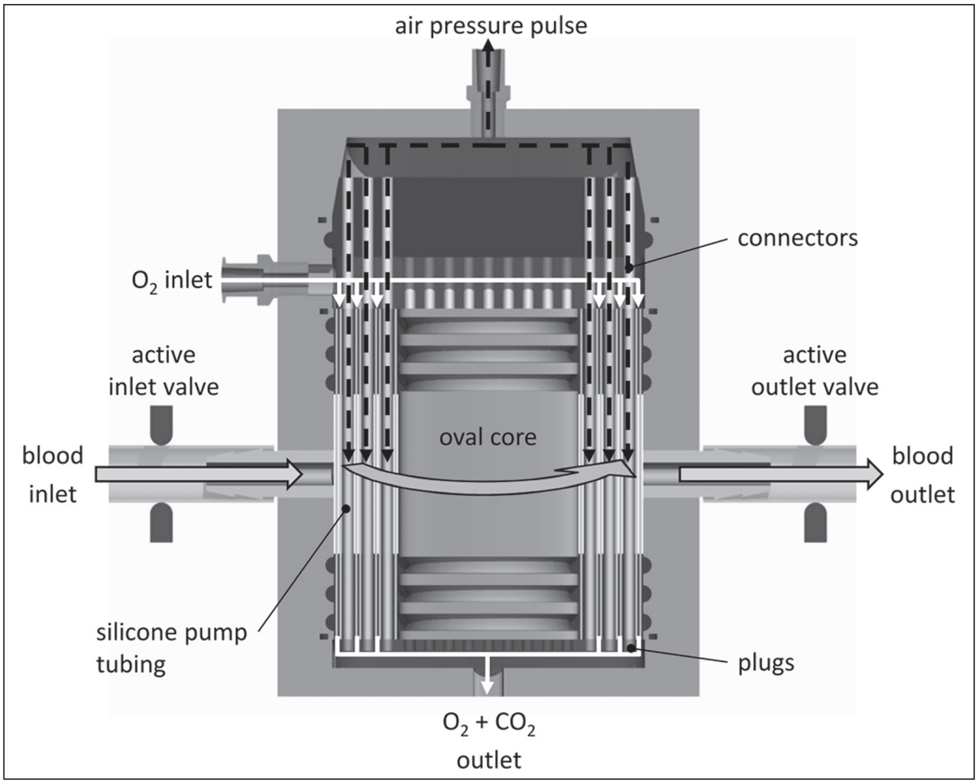

Fig. 2 - *Schematic cross section view (in longitudinal direction) of the Pump-Oxygenator-v2. Fluid pathways are illustrated as follows: O_2 flow way (white arrows), air pressure flow way (segmented black arrows), and blood flow way (gray arrows).*

- CELGARD® (Polypropylene, ID/OD 150/210 µm, small pore size of 0.03 µm, 2200 mm mat length, 32 mm fiber length) (Membrana GmbH, Wuppertal, Germany).
- Both are intended to prevent plasma leakage and can be used in long-term applications.

Other materials used:
- Thin-walled silicone tubes (RAUMEDIC-SIK 8635 silicone, ID/OD 2.0/2.3 mm, n = 60; Raumedic, Münchberg, Germany) to implement the pumping function.
- Potting material ELASTOSIL® 625 (Wacker Chemie, Munich, Germany).
- Housing components were manufactured by rapid prototyping (Objet Geometries, Billerica, MA, USA) from FullCure 720 material.

In vitro testing

To test the initial gas exchange efficiency of Pump-Oxygenator-v2, *in vitro* tests were completed in accordance to the DIN EN ISO 12022 and ISO 7199 standards for blood gas exchangers. Venous blood parameters at the oxygenator inlet were generated for the tests.

Measurements performed:
- Blood gas analysis with ABL800 flex (Radiometer, Willich, Germany) from inlet (n = 2) and outlet (n = 4) blood samples.
- Ultrasonic blood flow measurement with integrated bubble detection with H7XL flow sensor and HT110 flow meter (Transonic Systems, Ithaca, NY, USA).
- Blood pressure measurement at inlet and outlet with DPT-6000 pressure sensors (CODAN pvb Critical Care, Forstinning, Germany).
- Priming volume was measured during the priming procedure.

RESULTS

The results of initial gas exchange and pressure drop of Pump-Oxygenator-v2 are presented in Figure 3. The OXY-PLUS and CELGARD oxygenators show an approximately linear increase in oxygen transfer (max. 22.8 and 24.7 ml_{O2}/min, respectively), in carbon dioxide transfer (max. 26.3 and 24.0 ml_{CO2}/min, respectively), and in mean blood pressure losses (max. 84.1 and 49.1 mmHg, respectively). The pressure

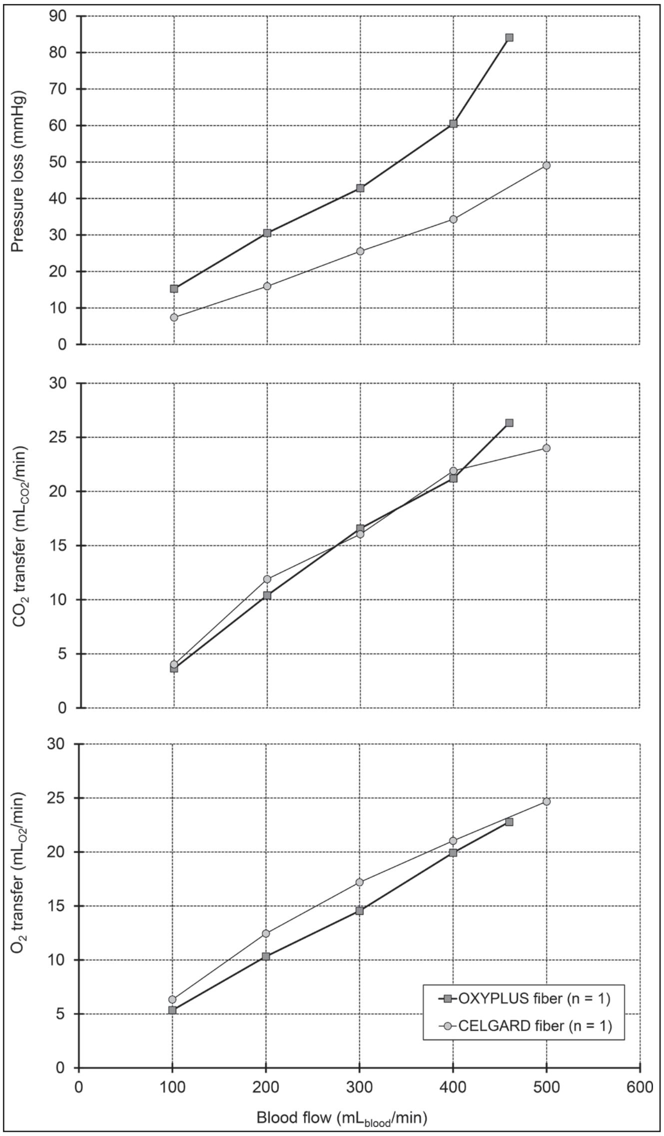

Fig. 3 - *Oxygen transfer rate (bottom view), carbon dioxide transfer rate (middle view), and mean blood pressure loss (upper view) of Pump-Oxygenator-v2.*

losses of the OXYPLUS oxygenator are 1.7 to 2.1 times higher than for the CELGARD oxygenator.

Experimental results demonstrate the OXYPLUS and CELGARD oxygenator pumping capacity at a maximum blood flow of 460 and 500 ml_{blood}/min, respectively. Outlined in Tab. I is the priming volume of the redesigned Pump-Oxygenator-v2. For a better classification of the priming volume, we also provide the gas exchange surface area and number of silicone pump tubes for the initial design Pump-Oxygenator-v1 and the Dideco Kids D100, an oxygenator of comparable size for blood flows up to 700 ml/min (6).

TABLE I - SPECIFICATION OF TESTED PUMP-OXYGENATORS (VERSION 1 AND 2) AND DIDECO KIDS D100

Oxygenator, Fiber material	Priming volume (mL)	Membrane surface (m^2)	Silicone tubes (n)
Pump-Oxygenator-v2, OXYPLUS®	20	0.24	60
Pump-Oxygenator-v1, OXYPLUS®	41*	0.26*	40*
Pump-Oxygenator-v2, CELGARD®	27	0.23	60
Pump-Oxygenator-v1, CELGARD®	50*	0.21*	40*
Dideco Kids D100 by Sorin**	31***	0.22	-

*Taken from Borchardt 2010 (6); ** an oxygenator of comparable size, blood flow up to 700 ml/min; product specifications published by Sorin (www.sorin.com/sites/default/files/product/files/2012/05/14/09294-47_KIDS_2012.pdf) (Accessed January 6, 2014); *** includes heat exchanger but no pump.

During testing, no bubbles were detected from the ultrasonic blood flow sensor integrated with a bubble detector.

DISCUSSION

Comparing Pump-Oxygenator-v1 and -v2, Fig. 1 shows the improved homogeneous silicone pump tube distribution. We were able to increase the number of pump tubes in the fiber bundle; in spite of this, the priming volume was decreased and thus the packing density was increased (Tab. I). For the initial design, Pump-Oxygenator-v1, oxygen transfer was limited to 16 ml_{O2}/min (6). The oxygen transfer rate of the redesigned Pump-Oxygenator-v2 was increased by a higher package density. The oxygen transfer of the CELGARD oxygenator is slightly higher than the OXYPLUS oxygenator. Both fiber materials are porous polymers; however, the OXYPLUS fibers have a leak-proof coating that decreases the danger of plasma leakage but could also cause a decrease in gas diffusion and correlated gas transfer. Both oxygenators show a consistent level of oxygenation that increases linearly with increasing blood flow. The oxygen transfer level is lower, however, when compared to the commercial oxygenator, Dideco Kids D100, which has a transfer of 34 ml_{O2}/min for 500 ml_{blood}/min blood flow.

For the initial design, Pump-Oxygenator-v1, carbon dioxide transfer was limited to 12 ml_{CO2}/min (6). The carbon dioxide transfer rates of the redesigned Pump-Oxygenator-v2 are higher and are about the same range within blood flows of 100 ml_{blood}/min to 400 ml_{blood}/min. With the gas:blood flow ratio of 2:1, carbon dioxide transfer rates of both oxygenators are slightly higher than the carbon dioxide transfer rate of the Dideco Kids D100 which has a transfer of 23 ml_{CO2}/min for 500 ml_{blood}/min blood flow.

These preliminary results from handmade laboratory prototypes show that a sufficient gas exchange can be guaranteed by the redesigned Pump-Oxygenator-v2 under the tested blood flow conditions for both fiber materials.

The priming volume of both Pump-Oxygenator-v2 prototypes was reduced by approximately 50% compared to the Pump-Oxygenator-v1 and is only 65% to 87% of the Dideco Kids D100 (without blood pump, but with heat exchanger). One reason for the reduction in the priming volume is the higher packing density and the well distributed silicone tubes over the entire cross section of the fiber bundle. Priming volume of the OXYPLUS oxygenator is even lower than the CELGARD oxygenator, with approximately the same membrane surface area (Tab. I).

The Pump-Oxygenator-v1 pumping capacity was limited to below 400 ml_{blood}/min (6). The pumping capacity of the redesigned Pump-Oxygenator-v2 could be increased by the number of silicone tubes. However, the OXYPLUS oxygenator with higher mean blood pressure losses and lower priming volume was not capable of pumping 500 ml_{blood}/min. The mean blood pressure losses show a difference between the OXYPLUS and CELGARD oxygenators (at maximum blood flows 84.1 and 49.1 mmHg, respectively) that indicates up to 2.1 times higher blood flow resistance in the OXYPLUS oxygenator. However, when comparing the mean pressure losses to that of the Dideco Kids D100 (175 mmHg at maximum blood flow of 700 ml_{blood}/min), both oxygenators show clearly lower flow resistance and thus lower blood pressure losses.

CONCLUSIONS

The approach of homogeneous pump tube distribution was able to increase the packing density, and thus increase the gas transfer and decrease the priming volume, for both fiber materials. Additionally, more pump tubes could be integrated, which led to a higher pumping capacity. The next steps will be to investigate a limit value of negative pressure before degassing of the fibers occurs (for both fiber materials), address the limitations associated with only two performed gas exchange tests for statistical validation, and analyze the hemolytic behavior of the system.

Financial Support: This work was performed in the course of a research and development project with the Dritte Patentportfolio Beteiligungsgesellschaft mbH & Co. KG, Schönefeld (Germany) who is also the owner of the underlying international patent.

Conflict of Interest: No author has any proprietary interest in the manuscript.

Meeting Presentations: The data were presented by Peter Christian Schlanstein at the 27th ESAO Congress in Skopje, Republic of Macedonia on September 9, 2010, with the title "Investigation of the influence of pulsating silicone tubes inside an oxygenator on gas exchange."

Address for correspondence:
Peter Christian Schlanstein
Department of Cardiovascular Engineering / CVE
AME – Institute of Applied Medical Engineering
Hemholtz Institute
Pauwelsstr. 20, D-52074 Aachen, Germany
schlanstein@hia.rwth-aachen.de

REFERENCES

1. Bartlett RH. Extracorporeal life support: history and new directions. ASAIO J. 2005;51(5):487-489.
2. Cook LN. Update on extracorporeal membrane oxygenation. Paediatr Respir Rev. 2004;5Suppl A:S329-S337.
3. Conrad SA, Rycus PT, Dalton H. Extracorporeal Life Support Registry Report 2004. ASAIO J. 2005;51(1):4-10.
4. Brown KL, Sriram S, Ridout D, et al. Extracorporeal membrane oxygenation and term neonatal respiratory failure deaths in the United Kingdom compared with the United States: 1999 to 2005. Pediatr Crit Care Med. 2010;11(1):60-65.
5. Schaible T, Hermle D, Loersch F, Demirakca S, Reinshagen K, Varnholt V. A 20-year experience on neonatal extracorporeal membrane oxygenation in a referral center. Intensive Care Med. 2010;36(7):1229-1234.
6. Borchardt R, Schlanstein P, Arens J, et al. Description of a flow optimized oxygenator with integrated pulsatile pump. Artif Organs. 2010;34(11):904-910.