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Presentation of a New High Performance Hollow Fibre for Oxygenators

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Abstract: This paper shows the development of a new hollow fibre for medical applications in oxygenators. It shows how thin fibres can theoretically be made theory and how they perform in practice.

Keywords: *ECMO; ARDS, oxygenator, hollow fibre*

I. INTRODUCTION

Extracorporeal membrane oxygenation (ECMO) systems are mainly used in hospitals to treat patients with acute respiratory distress syndrome (ARDS). Even more challenging is the treatment of infants with ECMO therapy. One of the major problem is the priming volume of the oxygenator. A research group at the TH Köln accomplished a research project named MemO2 to develop a new hollow fibre. This new hollow fibre has a much thinner outer diameter, which allows reducing the priming volume. Due to the lower priming volume, a better tolerance of thetreatment is expected.

II. PROBLEM IDENTIFICATION AND BASIC PRINCIPLE

The mortality rate of infant ECMO therapy is still about 39 percent [1]. On its way through the oxygenator, blood is exposed to various stresses that it does not encounter in the human circulatory system. Blood is exposed to different flow and pressure conditions, several exogenous materials (such as polypropylene, polyethylene, and polymethylpentene) as well as unused shear forces that damage the vulnerable structure of the blood and lead to hemolysis [2]. Furthermore, the damage to the thrombocytes increases the tendency of the patient to bleed. This is especially relevant for the recovery chances of patients after ECMO. If too many thrombocytes are harmed during ECMO, a donation of thrombocytes is required to restore the patient's coagulation performance [3]. But the most challenging problem is a decreasing number of erythrocytes, which decreases the oxygen-carrying capacity, and leads to a shortage in cellular respiration [4].

This is why the biomedical engineering research group at the TH Kölnhas developed new solutions to improve technical ECMO systems and make ECMO treatment of infants more secure.

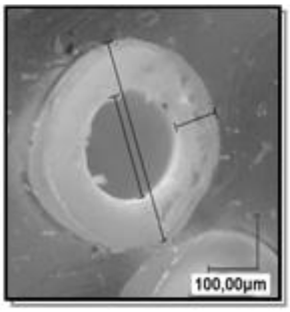

Fig. 1: Measurement of the diameter of the hollow fiber

III. METHODOLOGY

The biomedical engineering research group at the TH Kölnused the theoretical models of Hagen-Poiseuille and Ergun to develop a theoretical model to calculate the minimum hollow fibre diameter of current modules from a leading manufacturer. In addition, these models were validated and adjusted through experimental investigations. The researchers mainly focused on the reduction of pressure ratios and shear forces in the oxygenator because these parameters are directly affected by a change in the diameter of the hollow fibres [5].

To verify the calculated values and, if necessary, introduce a correction factor, experiments were conducted. To ensure reproducibility, several experiments were carried out in the laboratory of A.A. Kashefi-Khorasani at the RWTH Aachen [6].

During the experiments, the following equipment was used:

- Flowmeter Transonic T101
- Pressure measurement Siemens SIRECUST 404-1
- Temperature control of Stoeckert
- Roller pump CPB S3 of Stoeckert
- Heat exchanger Haake
- U-tube pressure assistance

For all experiments, structure and performance were identical. The experiments were constructed as shown in Figure 2.

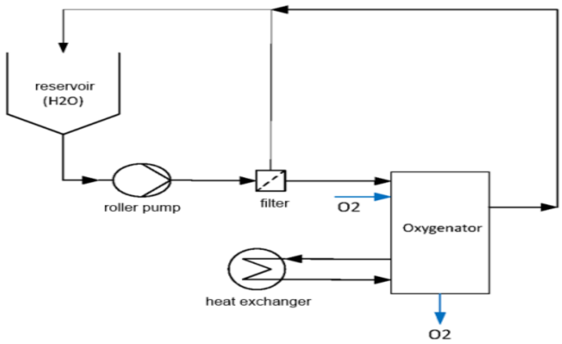

Fig. 2: Schematic structure of the testing bench [5]

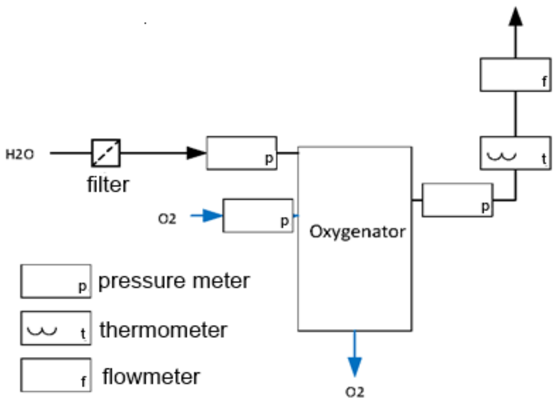

Fig. 3: Constructions of sensory devices (measurement) [5]

For the experiment series, three different modules (adult/child/infant) were tested with the following gas/blood flow settings (see Table 1, Table 2 and Table 3).

Table 1:Setting of blood/gas flow for the adult oxygenator module

QGas [l/min]	**0**	**1**	**3**	**5**	**7**	**10**	**14**
QH_2O [l/min]	**1**	**3**	**5**	**7**			

Table 2:Setting of blood/gas flow for the child oxygenator module

QGas [l/min]	**0**	**1**	**2**	**2.4**	**2.8**	**4.8**	**5.6**
QH_2O [l/min]	**0**	**1**	**1.5**	**2**	**2.4**	**2.8**	

Table 3: Setting of blood/gas flow for the infant oxygenator module

QGas [l/min]	**0**	**0.6**	**0.8**	**1**	**1.6**	**2**
QH_2O [l/min]	**0**	**0.6**	**0.8**	**1**		

IV. INITIAL RESULTS AND DISCUSSIONS

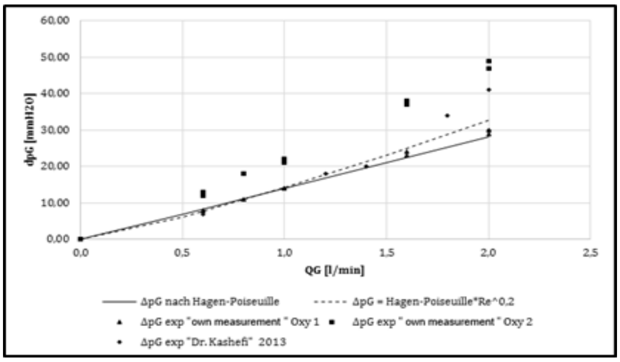

Fig. 4: ΔpG represented experimentally and theoretically in the infant module [5]

The results of the previous experiments and calculations for the gas-side pressure drop of the models for adults, children and infants are shown in Figure 4, Figure 5 and Figure 6. The graphs show that the measurements of the calculations according to the Hagen-Poiseuille model differ from the experiments at the TH Köln and an experiment by Kashefi-Khorasani that was conducted in 2013. The measured values show an exponential curve, which increases the deviation from the linear behaviour of Hagen-Poiseuille with increasing gas flow (QG).

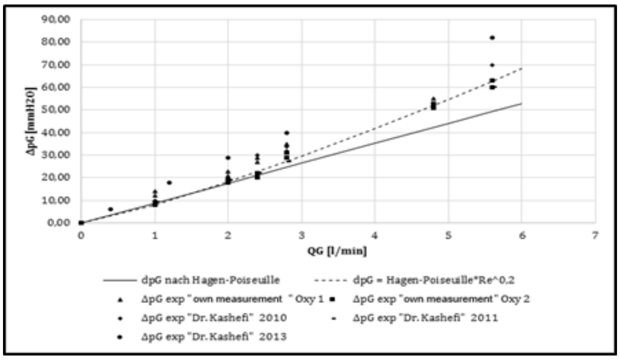

Fig. 5: ΔpG represented experimentally and theoretically in the child module [5]

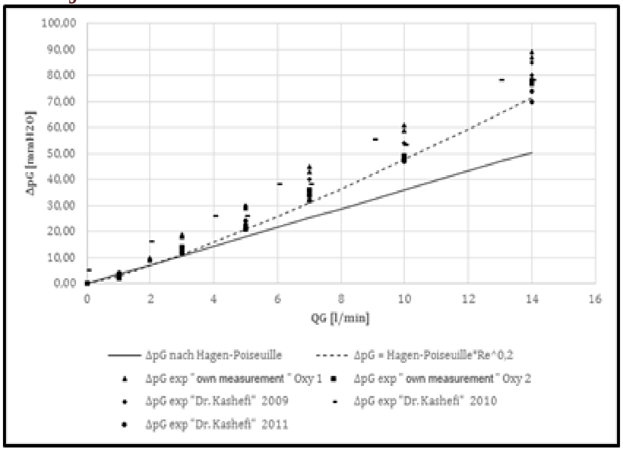

Fig. 6: ΔpG represented experimentally and theoretically in the adult module [5]

The mentioned difference can have various causes for example, with increasing volume flow, the inlet turbulence increases in the pod and also within the hollow fibres. Production characteristics can also influence the loss of pressure. The hollow fibres are held together in the form of a mat by using warp yarns. It cannot be precluded that the warp yarns force constrictions that reduce the hollow fibre diameter in the experiment. In addition, the production process of the fibre potting may influence the inlet effects because of the oblique sectional area that resulted from oblique cutting of the hollow fibres.

Furthermore, variations in the diameters of the hollow fibres influence the loss of pressure. The company Membrana quotes the outer diameter of the hollow fibres with PP at 380 ± 20 µm [7]. Since the outer diameter of the hollow fibres has an effect on the amount of fibres, these 20 µm might also affect the gas-side loss of pressure. The described influences can hardly be proven individually because of their interactions; therefore, they can only be considered together.

For the mathematical model, the authors adjusted the formula by adding an empirically determined correction factor of Re0.2 (Equation 1) to fit the model results to the experimental results. Experimentally evaluated oxygenators, a Reynolds number in the gas phase, results in less than 50 at maximum gas flow rate. Inside the hollow fibres, therefore, the flow can be considered as a laminar flow.

In the theoretical treatment (ΔpG), the equation of Hagen - Poiseuille is applied (Equation 1) for the gas -side pressure drop. This equation describes ΔpG in tubes in laminar stationary currents that are dependent on the gas flow rate (Q˙_G), the number of hollow fibres (N), the length of the hollow fibres (lHF), the inner diameter of the fibres, and the dynamic viscosity of the gas (□ G).

In the Reynolds number, material data and the influence of the flow rate are both considered dimensionless numbers. The exponent 0.2 takes into account the exponential increase in the loss of pressure with increasing gas flow. With this correction n factor, the calculation can be regarded as validated.

Equation 1: Equation of the model with correction factor [5]

$$\Delta p_G = \dot{Q}_G \cdot \frac{128 \cdot \eta_G \cdot l_{HF}}{\pi \cdot d_i^4 \cdot N} \cdot Re^{0.2}$$

The blood-side loss of pressure is calculated based on the model by Ergun [6]. In this calculation, values of the oxygenator and the integrated heat exchanger both are included. The results of the experiments and calculations are shown in Figure 7, Figure 8 and Figure 9.

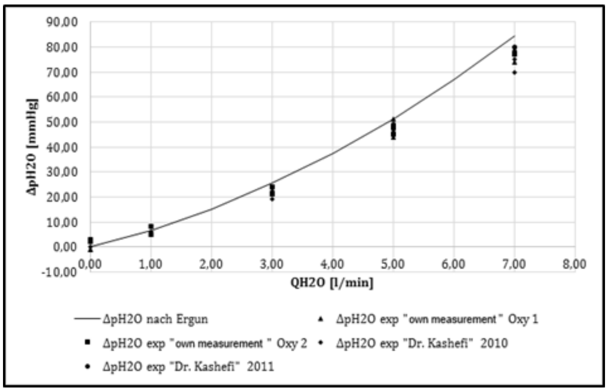

Fig. 7: ΔpH2O represented experimentally and theoretically in the infant module [5]

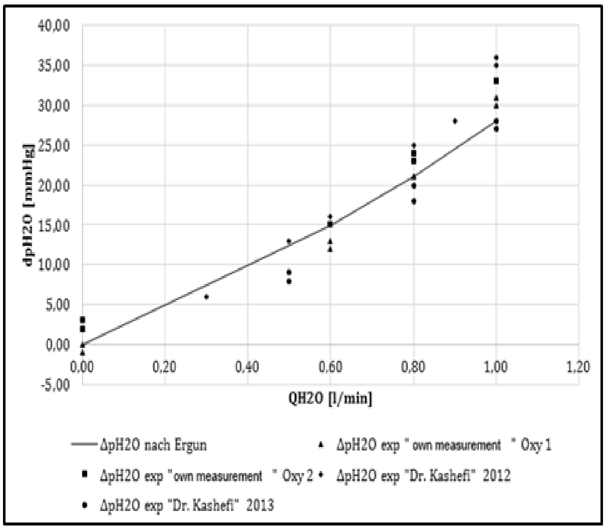

Fig. 8: ΔpH2O represented experimentally and theoretically in the child module [5]

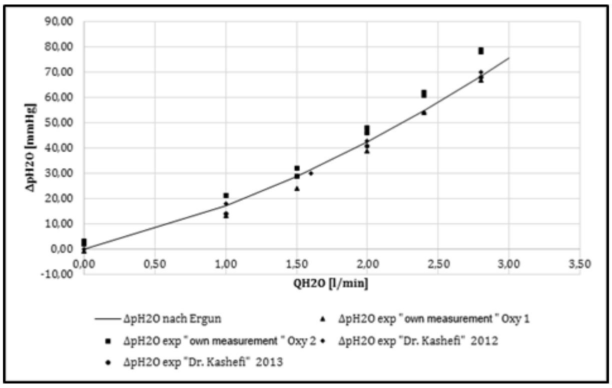

Fig. 9: ΔpH2O represented experimentally and theoretically in the adult module [5]

The figures show that the model by Ergun is a good approximation for all experimentally used module types with a PP hollow fibre. Therefore, there is no need for a correction factor and the model is considered validated.

In the second equation, the fluid with its dynamic viscosity (η) and the characteristics of the oxygenator are both taken into account. In the first part of the equation, the oxygenator variables, such as the number of fibres (N) and the outer fibre diameter (do), are used. The volume flow of liquids ($\dot{Q}_L$) is also included in the calculation.

Equation 1: Equation of loss of blood pressure[6]

$$\Delta p_B = \frac{128\cdot\eta\cdot\mu_{Mod}\cdot L_{eff}}{\pi\cdot d_o^4\cdot N}\left(\frac{1-\varepsilon_{Mod}}{\varepsilon_{Mod}}\right)^3 \dot{Q}_L + 1.1136\frac{\mu_{Mod}\cdot L_{eff}}{d_o}\cdot\frac{1-\varepsilon_{Mod}}{\varepsilon_{Mod}}\cdot\frac{\rho}{2}\cdot\bar{v}_{Mod}^2$$

Theso-called indirect factor (μ_{Mod}) refersto the fact thatthe fluidpasses throughthe oxygenator. Itis notrectilinear, but undulated to flow past the hollow fibres (Figure 10).

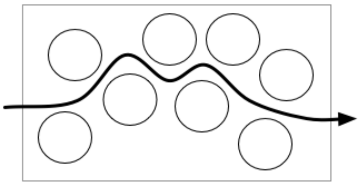

Fig. 10: Schematic representation of the flow detour [5]

It can be calculated as follows:

Equation 2 [5]

$$\mu_{Mod} = \frac{\Delta p\cdot\varepsilon_{Mod}^3\cdot d_o^2}{32\cdot\bar{v}_0\cdot\left(1-\varepsilon_{Mod}+\frac{d_a}{D_o-D_i}\right)^2\cdot L_{eff}\cdot\eta}$$

The calculation needs the loss of pressure(Δp),which has to be determined experimentally. It is measured at the lowest possible flow rate in order to allow a well-developed flow around the hollow fibres. D_i and D_o each indicate the inner and outer diameters of the module.

The effective length of the module(L_{eff}) is the module length minus the potting ($L_{eff} = L_{Mod} - l_{Pot}$).The calculation of the medium speed in the fibre'souterspace ($\bar{v}_{Mod}$) used in Equation 2can be calculated in the following manner:

Equation 4 [5]

$$\bar{v}_{Mod} = \frac{\dot{Q}}{\frac{\pi}{4}\cdot(D_o^2-D_i^2)\cdot(1-N\frac{d_o^2}{D_o^2-D_i^2})} = \frac{\bar{v}_0}{\varepsilon_{Mod}}$$

$\bar{v}_0$ is the so-called velocity in the empty oxygenator. The module porosity (ε_{Mod}) indicates the proportion of the void volume in the context of the total volume of the module (see Equation 5).

Equation 5 [5]

$$\varepsilon_{Mod} = 1 - N\frac{d_a}{D_o^2-D_i^2}$$

Based on defined limits for the gas-side loss of pressure and the shearing rate that affect the blood, three new possible fibre diameter dimensions were determined for the micro-porous polypropylene (PP) membranes, shown in Table 4.

Table 1: Minimum diameter for PP hollow fibres

Module	Adult	Children	Infant
D_i/D_o [µm]	155/232	100/150	80/120

V. RESULTS AND DISCUSSIONS

After the production of the hollow fibre at the Faserinstitut Bremen, the biomedical engineering lab at the TH Köln carried out the final testing. The fibre is currently in a patent process. Figure 11 shows an example of an SEM image of the new fibre with an outer diameter of 120 µm.

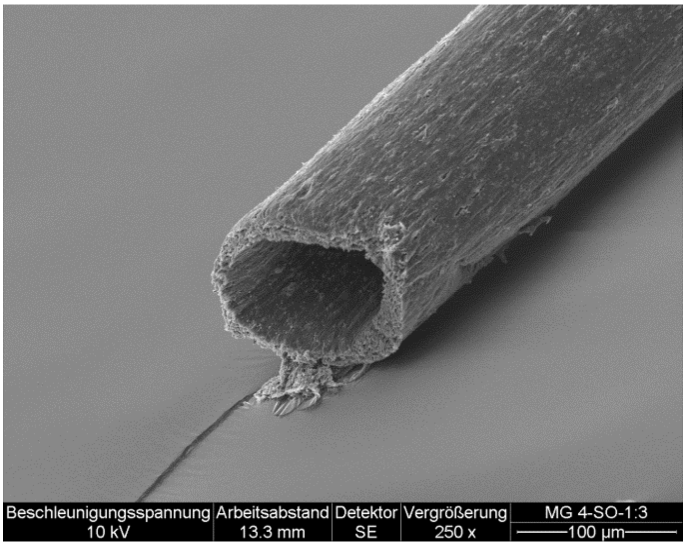

Fig. 11: SEM image of the new fiber

The blood tests based on ISO 7199 and the AAMI standard "Association for the Advancement of Medical Instrumentation" led to the following results regarding the gas transfer performance.

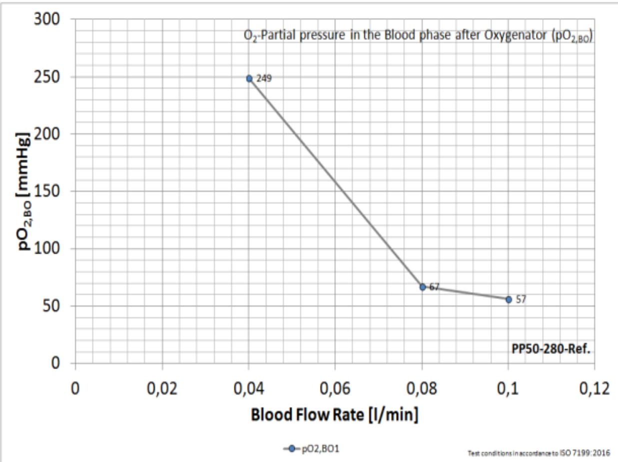

Fig. 12: O_2 gas transfer performance Ref. module

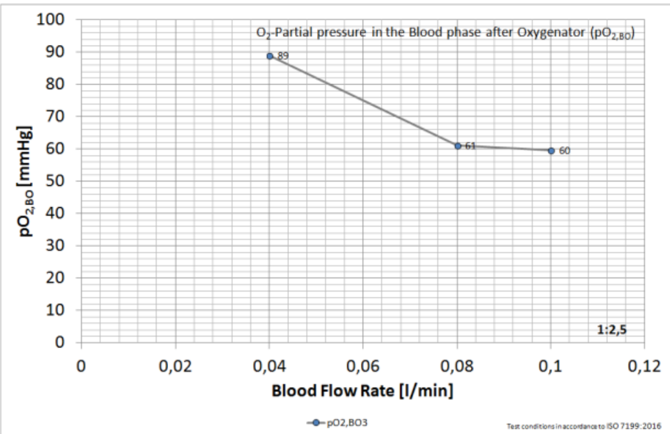

Fig. 13: O_2 gas transfer performance new fibre. module

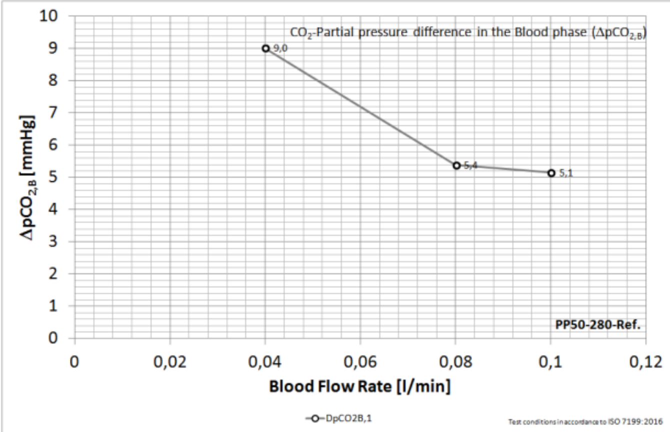

Fig. 14: CO_2 gas transfer performance Ref. module

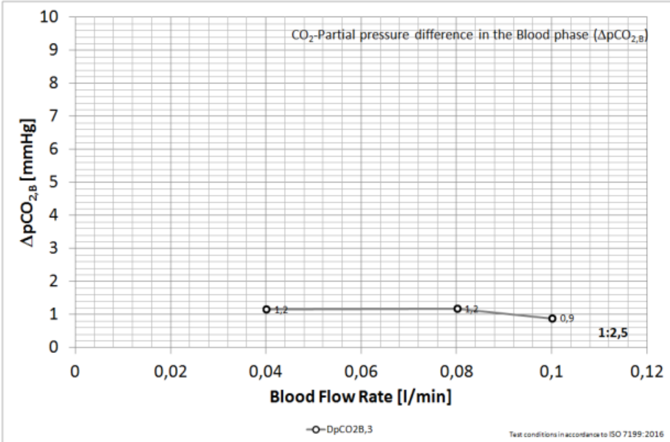

Fig. 15: CO_2 gas transfer performance new fibre. module

CONCLUSIONS

More research needs to be carried out to improve the gas transfer. In particular, the CO_2 transfer must be improved. In the next step, the pore geometry should be adapted and improved. This means that the priming volume is not only reduced by the geometrical effect, but furthermore the total surface area of the membrane can be minimized. As a result, less blood comes into contact with less external surfaces.

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