PUMPLESS IN VITRO OXYGENATOR HAEMOLYSIS SETUP

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Introduction

In vitro haemolysis tests according to ASTM F 1841-2019 are commonly used to determine the haemolysis of extracorporeal membrane oxygenation (ECMO) devices. However, haemolysis testing for blood oxygenators remains a challenge [1], as current circuits typically require an additional blood pump, which is a primary source of haemolysis. [2]
Based on identified requirements, we propose a novel haemolysis test circuit that operates pump-free to increase the haemolytic signal of oxygenators.

Materials and Methods

Based on the identified limitations of haemolysis tests with oxygenators, we derived and synthesised requirements for a novel test circuit to overcome as many limitations as possible. The identified design requirements are presented below. Oxygenators specifically designed for ECCO2R therapy or paediatric ECMO therapy are designed for low blood flow perfusion. In paediatric ECMO, blood flows in neonates are typically between 0.080 L/kg/min and 0.120 L/kg/min and can be up to 1.7 L/min in infants weighing up to 15 kg [3], while blood flows in ECCO2R are between 0.5 L/min and a maximum of 2.0 L/min [4]. Schöps et al. demonstrated that specific haemolysis in centrifugal pumps is higher at low flow than at high flow [5], suggesting that a haemolysis test circuit that operates pump-free is required to eliminate pump haemolysis and thus improve the haemolysis signal of the oxygenator. To test different oxygenators used in low flow areas, the blood flow of the test circuit must be variably adaptable to the application under test (0.1 L/min to 4 L/min). To reduce the autologous haemolytic signal of the circuit, we reduce sections with causes of high shear rate. Further requirements result from the ASTM F 1841-2019 standard and relate to reproducibility and continuous flow.

Results

A pressure-driven setup was developed to perfuse a test oxygenator continuously without a blood pump. The experimental setup consists of pressurised cylinders that contain water and blood bags. The blood bags are connected by tubes for blood. A predefined pressure builds up in the pressure chambers using gas valves that are controlled by a Raspberry Pi controller. The blood transport tubes are connected via Y-connections and blood flow is regulated via clamp valves in a cross-circuit configuration. A controlled pressure build-up in the chambers compresses the blood bags and enables a controlled blood flow. Level sensors signal to the control unit when the gas and clamp valves for the blood tubes need to be changed to fill the blood bags alternately. The cross circuit guarantees unidirectional flow in the test object and frequent mixing in the reservoirs as they are filled from top but drained from the bottom.

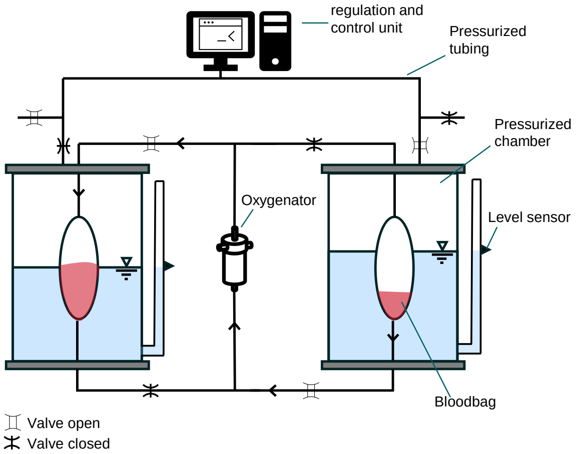

Figure 1: Experimental haemolysis setup

Discussion

The experimental setup represents a novel approach to haemolysis testing, offering the capability to test haemolysis in oxygenators used in low flow areas without having a haemolysis signal either from a resistance adjusting clamp in blood pump testing or from a blood pump in the testing of other components. This unique haemolysis test circuit presents a promising alternative for standard haemolysis tests, potentially leading to the standardization of the experimental procedure. However, challenges persist, including the need to further streamline the test setup and conduct more in vitro haemolysis tests to validate its effectiveness thoroughly.

References

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