DEVELOPMENT OF A NOVEL ARTIFICIAL LUNG AND KIDNEY ASSIST DEVICE – FROM FIBER SPECIFICATIONS TO DEVICE DESIGN

Ana Martins Costa (1), Frank Halfwerk (1, 2), Bettina Wiegmann (3, 4, 5), Jan-Niklas Thiel (6), Michael Neidlin (6), Jutta Arens (1)

1. Engineering Organ Support Technologies, University of Twente, Netherlands; 2. Medisch Spectrum Twente, Netherlands; 3. Hannover Medical School, Germany; 4. Implant Research and Development (NIFE), Germany, 5. German Center for Lung Research, Germany, 6. Department of Cardiovascular Engineering, Institute of Applied Medical Engineering, RWTH Aachen University

Introduction

A novel artificial lung and kidney assist device is being developed combining gas exchange and dialysis fibers (RenOx). The RenOx development accounts for 1) fiber specifications to maintain lung and kidney support in a new integrated membrane bundle, and 2) device design considering user requirements and optimal blood flow distribution. Our previous work indicated that lung support can be maintained when 25% of gas exchange fibers are replaced by dialysis fiber layers in an oxygenator. However, the effect of utilizing dialysis fibers in an unconventional outside-in mode in the RenOx (blood flow outside the fibers) still needed to be evaluated. Moreover, these fiber specifications should be considered for the RenOx design.

Objectives

First, this study evaluated RenOx fiber specifications on the efficiency of commercial dialyzer membranes utilized outside-in regarding solute clearance and ultrafiltration coefficient. Secondly, we describe device development steps comprising the optimization of device's blood flow path, design of device parts, and prototyping.

Methods

First, the performance of commercial dialyzers utilized outside-in and in conventional inside-out mode was compared during standardized tests with full blood adapting the ISO 8637:2016. Clearance of urea and creatinine was compared for continuous hemodialysis and hemofiltration. Also, fluid removal was evaluated in terms of dialyzer's ultrafiltration coefficient. Second, for the RenOx development, design requirements specifications were derived based on interviews with users. These specifications were accounted for the design of device concepts. The RenOx's blood flow path design was optimized by means of computational fluid dynamics (CFD) simulations, blood directing angle (50° to 10°) and by considering existing patented blood path designs.

Results

Regarding RenOx fiber specifications, our results show that hemodialyzer's fibers utilized outside-in achieved equal clearance of urea and creatinine as traditional inside-out dialysis fibers. Measured clearance doses (25 mL/kg$_{patient}$/h) were comparable to the levels required for continuous renal replacement therapy. However, ultrafiltration coefficient in outside-in mode was about 4 times lower than for inside-out. Regarding RenOx development, translation of requirements and fiber specifications resulted in the need for a device with estimated total surface area of 2 m^2 (75% gas exchange fibers = 1.5 m^2, and 25% dialysis fibers = 0.5 m^2) to support 80 kg adult patients. The RenOx blood path design was optimized to guide blood through an inlet and outlet angle that improves blood flow distribution and velocity in the bundle, Fig. 1. This approach was innovative compared to patented models. Device housing was designed considering sealing of gas, blood, and dialysis compartments and the possibility to easily remove the membrane bundle for analysis after tests.

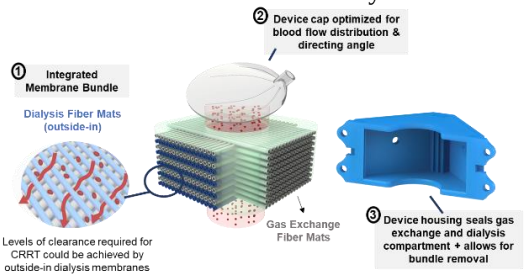

Figure 1: Development of novel lung & kidney assist device.

Discussion

Outside-in dialysis fibers could provide sufficient continuous clearance by hemodialysis and hemofiltration in in-vitro tests, but dedicated membranes with an outside selective layer would be needed for improved filtration rates. The estimated surface area for the RenOx of 2 m^2 is comparable to the size of state-of-the-art adult oxygenators. By replacing 25% of gas exchange fibers by dialyzers fibers, the RenOx will still be a compact oxygenator while providing additional kidney support.

Conclusions

A new membrane oxygenator with combined kidney function (RenOx) is under development. Our previous research indicates that a membrane bundle combining 75% of gas exchange fibers and 25% of outside-in dialysis fibers can provide lung and kidney support. In addition, first RenOx prototypes with optimized blood flow distribution are being prepared for further in-vitro and in-vivo testing.

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