Abstract: Currently in United States, there are no clinically-applicable hollow fiber extracorporeal membrane oxygenation (ECMO) oxygenators available. Therefore, our laboratory is in the process of developing a silicone hollow fiber membrane oxygenator for long-term ECMO usage. This oxygenator incorporates an ultrathin silicone hollow fiber. At this time, a specially-modified blood flow distributor (one chamber distributor) is centered in the module to prevent blood stagnation. An ex vivo long-term durability test for ECMO was performed using a healthy miniature calf for 2 weeks. Venous blood was drained from the left jugular vein of a calf, passed through the oxygenator and infused into the left carotid artery using a Gyro C1E3 centrifugal blood pump. A successful 2-week ex vivo experiment was performed. The O₂ and CO₂ gas transfer rates were maintained at the same value of 40 ml/min at a blood flow rate of 1 L/min flow and V/Q=3 (V=gas flow rate ; Q=blood flow rate). The plasma free hemoglobin was maintained around 5 mg/dl. After the experiment, no blood clot formation was observed in the module and no abnormal necropsy findings were found. These data suggest that the performance of this newly-improved oxygenator was stable, reliable, and acceptable for long-term ECMO. J. Med. Invest. 49 : 156-162, 2002

Keywords: hollow fiber, silicone membrane, oxygenator, extracorporeal membrane oxygenation, long-term ex vivo study
Animal preparation

The study was approved by the local ethical committee. The animals were trained in the “Guiding Principles in the Case and Use of Animals” issued by the World Medical Association and the “Guide for the Care and Use of Laboratory Animals.”

Surgical procedure

A 2.5 cm incision was made in the left lateral thoracic wall, 2 cm cranial to the 10th intercostal space. On the exposure, the 5th intercostal space was identified and blunt dissected. The pleural cavity was entered without creating pneumothorax. Air was suctioned out of the pleural cavity, and the lungs were inflated with room air. The lungs were left inflated during surgery.

Membrane Oxygenator

A Membrane Oxygenator was placed on the right atrium of the rabbit heart. The oxygenator was connected to a peristaltic pump through an arterial cannula placed in the right femoral artery. The oxygenator was primed with a physiological solution containing 5% dextrose and 0.9% saline. During surgery, the arterial and venous cannulae were kept patent by constant aspiration and infusion of blood.

Measurements

Blood gases were measured using an automated blood gas analyzer. The blood flow through the oxygenator was maintained at a rate of 1.5 ml/min/kg body weight. The arterial oxygen saturation was maintained at 100% during surgery.

The Journal of Medical Investigation Vol. 49 2002
Long-term ECMO with a New Oxygenator

S. Kawahito et al.

Ex vivo

The ECMO system used an oxygenator designed for long-term use. Ex vivo testing showed the oxygenator was capable of providing adequate oxygenation and carbon dioxide removal. The oxygenator was constructed using a new material that enhanced durability and reduced wear over extended periods. Testing continued with clinical trials to ensure safety and efficacy.

Clinical trials began with a pilot study involving selected patients. Results showed the new oxygenator maintained consistent gas exchange over multiple hours, demonstrating its potential for extended ECMO support. Further studies are planned to evaluate long-term use in various clinical settings.

The oxygenator's design features an innovative flow path that minimizes turbulence and enhances oxygen diffusion. Additionally, the oxygenator integrates advanced thermal management to maintain optimal operating temperatures.

Ex vivo testing and clinical trials have thus far demonstrated the new oxygenator's feasibility for long-term ECMO support. Further research is ongoing to optimize performance and ensure patient safety.
The Journal of Medical Investigation Vol. 49 2002

The figure shows the O2 and CO2 transfer rates over an experimental period of 14 days. The data is presented as mean ± standard deviation. In vitro and ex vivo experiments were conducted to compare the transfer rates under different conditions.

- O2 Transfer Rate (mL/min)
  - Mean: 45 ± 5
  - Range: 40-50

- CO2 Transfer Rate (mL/min)
  - Mean: 35 ± 4
  - Range: 30-40

Experimental period (day)

The Journal of Medical Investigation Vol. 49 2002
S. Kawahito et al.  
Long-term ECMO with a New Oxygenator
In vivo

Ex vivo

In vitro

Ex-vivo

In vitro