Evaluation of Navel Materials that constitute parts of an Intravascular Lung Assist Device

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1. Introduction

The intravascular oxygenator(IVOX) is a new generation of gas exchange device.[1,2] The IVOX consists of micropolypropylene hollow fibers with a thin continuous silicone coating and is designed for placement in the vena cava through a femoral or jugular venotomy. IVOX is a potentially useful alternative to the extracorporeal circuit that should that should be less expensive and less laboratory intensive than extracorporeal membrane oxygenators (ECMOs). However, the device has limited gas exchange capabilities, primarily because of the insufficient surface area, which is limited by the venacaval size.[3] A key step for the advancement of IVOX clinically used long term is to develop a novel membrane material with excellent gas transfer.

In this study, the fabrication of a novel hollow fiber is described. The gas transfer and blood compatibility of the hollow fiber have been investigated.

2. Results and Discussion

The hollow fibers were prepared by a dry/wet phase inversion process. A spinning solution was filtered and subsequently degassed. The solution and bore fluid were extruded through a spinneret die to form a hollow fiber at room temperature.

The fibers were passed through a short air gap, coagulated methanol at room temperature, and collected. After spinning, the fibers were cut into lengths of~120 cm, rinsed with methanol for 12 hr, and air-dried for 12 hr at room temperature. They were finally dried in a vacuum oven at 150℃ for 15 hr to remove all residual solvent.

The experimental closed loop fluid circuit consists of 3/8-inch inner diameter biocompatibility cylindrical shell, a deoxygenator (Baxter Healthcare Corporation), an electromagnetic blood flow meter, a roller pump (Cobe Cardiovascular, Inc.) and the membrane oxygenator. A gas blender (Sechrist Industries, Inc.) was connected to the deoxygenator with tubing. The blood temperature was maintained at 37 ℃ with a heat exchanger.

We fabricated a novel hollow fiber for a membrane oxygenator. The fibers prepared by a dry/wet phase inversion process. The process requires time for evaporation of a volatile solvent from the spinning solution. In this study, several seconds are available during dry phase separation. The separation process occurs immediately in the air gap prior to coagulation, and the outer surface skin layer of the hollow fiber is simultaneously formed. The fiber is then immersed in a non solvent coagulant, thus undergoing wet phase separation.

For the evaluation of in vitro blood compatibility, platelet adhesion to the hollow fiber was measured by SEM. Pseudo formation, deformation, and aggregation of platelets were not activated. The number of platelets on the fiber was 1.0 $\mu g/cm^2$, which was one-fifth and one-seventh less than the values measured on PDMS and silicone coated fibers, respe

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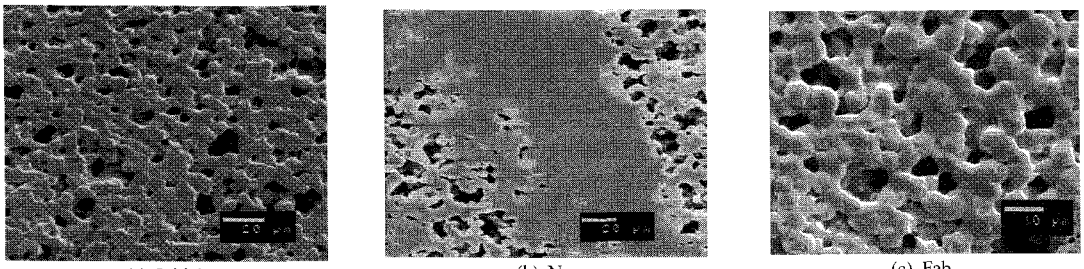
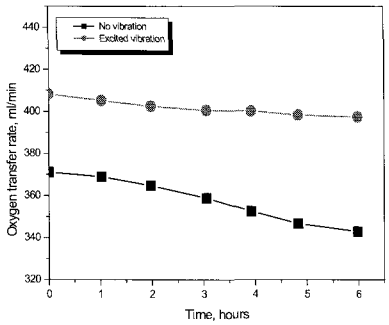
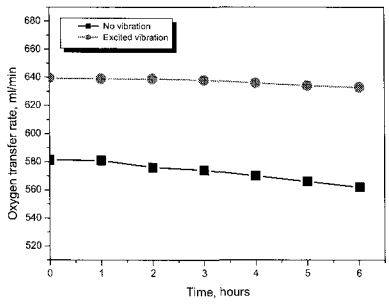


(a) Initial (b) No (c) Fab.

Fig. 1 Scanning electron photographs of surface of polypropylene membrane.



(a) No. of hollow fiber = 100



(b) No. of hollow fiber = 450

Fig. 2 Oxygenation performance of the various module types, with time at excited frequency 7Hz.

ctively, indicating good blood compatibility.

The gas transfer rates of O_2 and CO_2 exhibited significantly higher values than those obtained in the presently available membranes for oxygenators, such as the PDMS hollow fiber, and were comparable with those found with a silicone layer coated hollow fiber with similar membrane structure used in the IVOX device by Mortensen.[1)]

3. Conclusion

A novel hollow fiber was developed for use in an intravascular oxygenator. It was also found that the membranes exhibited suppression of complement activation as well as excellent in vitro blood compatibility. These results suggest that the hollow fiber is a promising membrane material for use in an IVOX device.

Acknowledgements

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References

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