DEVELOPMENT OF THE INTEGRATED HEART LUNG ASSIST DEVICE FOR NEXT-GENERATION EXTRACORPOREAL MEMBRANE OXYGENATION

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INTRODUCTION

Percutaneous cardiopulmonary support (PCPS) using a membrane oxygenator and a centrifugal blood pump has become a good therapeutic option for heart-lung support for cardiac and/or respiratory failure patients. Many problems, however, remain regarding currently available PCPS equipment, including complexity in setup, bulky apparatus, plasma leakage from the microporous membrane oxygenator, and thrombogenic properties. We have been developing a novel integrated heart-lung assist device (IHLAD) to overcome these problems and to extend the application of the system [1-3]. The device has a composite structure consisting of a centrifugal pump surrounded by a cylindrically woven hollow-fiber oxygenator. Gas transfer in the hollow-fiber oxygenator is influenced by a number of factors, including the materials and the dimensions of the hollow-fiber, spatial porosity distributions, the gas/blood velocity ratio, and so on. It is also significantly important to have spatially uniform flow distribution in the hollow-fiber unit to realize the maximum gas-transfer rate. The previous prototype employs a separating partition between the impeller and the hollow-fiber unit with a single window, but it was suggested that the existence of a shortcut from the impeller exit to the device outlet deteriorated the gas-transfer efficiency of the membrane oxygenator.

The present study deals with the design progress of IHLAD in relation to flow path design with the intent of realizing uniform flow distribution in the hollow-fiber unit by implementing a vaned diffuser between the impeller and the hollow-fiber unit. The effects of a newly designed diffuser on gas-transfer performance, hydrodynamic characteristics, and the flow distribution were investigated. The optimization of the diffuser vane profiles was also carried out based on the fluid dynamic study of the device.

DESCRIPTION OF THE INTEGRATED HEART LUNG ASSIST DEVICE (IHLAD)

The photograph and the cross sectional view of the IHLAD are depicted in Fig. 1 and Fig. 2, respectively.

The impeller of the centrifugal pump is located in the center of the device surrounded by the hollow-fiber unit of the cylindrical structure. The gas exchange unit of IHLAD consists of a special hollow-fiber membrane made of polyolefin. The micropores of the fiber are blind-ended at the blood contacting surface to form a thin dense layer to eliminate direct blood-gas contact. Between the impeller and the hollow-fiber unit, the circular vaned diffuser is installed in the new prototype. The diffuser is composed of seven curved vanes located between the impeller and the inner surface of the hollow-fiber unit. The purpose of using the diffuser is to divide the flow path entering the hollow-fiber unit into equally resistant passages, and to transfer the dynamic energy imparted by the impeller rotation to static pressure, with least energy losses at gradually diverging passages.

The number of diffuser vanes (seven) was selected to be different from that of the impeller blades (six) so as to avoid subharmonics of excitation of the impeller passages and the diffuser passages, which are caused by large pressure fluctuations occurring when an impeller blade passes a diffuser vane. Such subharmonics are believed to cause many kinds of vibration problems [4].

EVALUATION OF THE DEVICE PERFORMANCE

The gas-exchange performance of the new prototype IHLAD was evaluated in an ex vivo animal study of cardiopulmonary bypass using an adult goat. The IHLAD was installed paracorporeally via the right thoracotomy in the manner of a venoarterial bypass, and oxygen and carbon dioxide transfer rates were evaluated by simultaneous samplings of blood at the inlet and outlet ports at various blood and gas flow rates. The gas exchange characteristics of the IHLAD of oxygen and carbon dioxide are shown in Fig. and Fig., respectively. The oxygen-transfer rates of the new IHLAD using the diffuser were higher than those of the previous prototype, except for one measured point (Q=5 L/min at V/Q ratio = 5). A significant improvement in gas-transfer rates was observed especially at lower flow rates ranging 1 - 3 L/min. An enhancement of gas exchange at lower flow rates indicates that the diffuser worked to divide the flow path into equally distributed

paths. The carbon dioxide-transfer rate results also showed significant improvement, with the same trend as the oxygen-transfer rates.

Hydrodynamic characteristics were evaluated by measuring the pressure heads and flow rates at various pump speeds. The device was installed in a closed circuit containing the reservoir and the resistor. The flow rate was varied by adjusting the resistor. Flow rates were measure by a electromagnetic flowmeter (MFV-3100, Nihon Kohden, Tokyo, Japan). Saline at room temperature was used as the working fluid. Pressure was measured by the pressure transducers located at 10 centimeters upstream and downstream of the device, and the difference of between two was calculated to obtain the pressure head across the device. A slight decrease in the pressure head over the whole flow rate range was observed. The decrease in pressure head was attributed to the equal distribution of the flow paths, which would bring about the increase in the net flow area in the hollow-fiber unit and therefore increase the resistance of the unit. The diffuser itself, of course, made some contribution to the total resistance inside the device. The degree of blood-cell destruction by the IHLAD was not in a tolerable range, and the vane profile was modified. The number of vanes was decreased from seven to five, and the width of the diffuser passage was also decreased from 3 mm to 2 mm, with the intent of diminishing the chance of rotating stall, which was observed by flow visualization in the vicinity of the diffuser vanes. Rotating stall occurs as the result of mismatch of angles between the diffuser vanes and the fluid velocity entering the diffuser. The hemolysis testing was performed to compare the degree of erythrocyte destruction, and the results revealed that less amount of hemolysis was caused by the diffuser with five vanes. The effect of other design parameters such as the clearance between the impeller edge and the diffuser leading edge are currently under investigation.

CONCLUSION

Design changes of IHLAD were evaluated in terms of flow path in order to realize uniform flow distribution in the hollow-fiber unit by implementing a vaned diffuser between the impeller and the hollow-fiber unit. The effects of the newly designed diffuser on gas-transfer performance, hydrodynamic characteristics, and the flowing behavior were investigated. The vaned diffuser has brought about a significant improvement in gas-transfer performance without a large sacrifice in the pressure head. The observed flow toward the outlet port indicated that equally distributed flow was realized with the use of the vaned diffuser. The diffuser vane profile was optimized to decrease destruction of blood cell component by IHLAD. The progresses studied in this report have contributed to the efficacy of IHLAD as the next-generation heart lung support system.

REFERENCE

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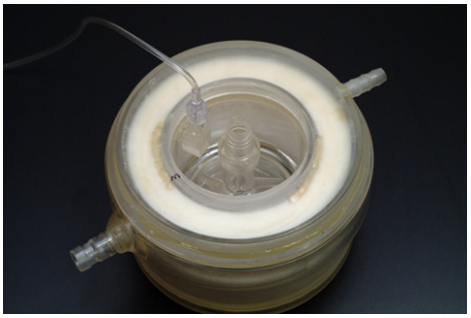

Fig.1 The Integrated Heart Lung Assist Device

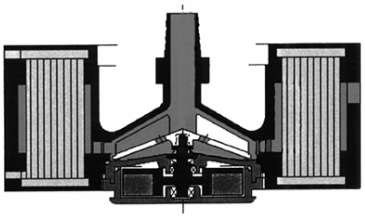

Fig.2 Cross Sectional View of the IHLAD

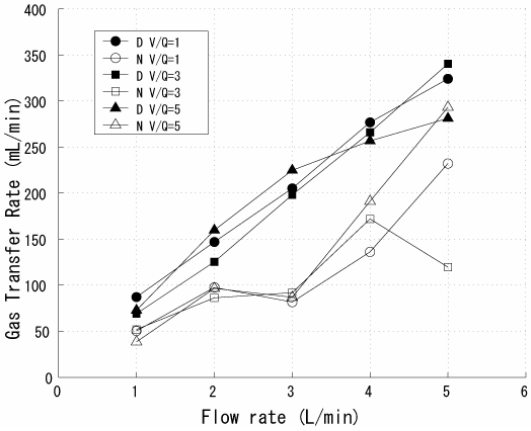

Fig.3 Transfer Rate of Oxygen

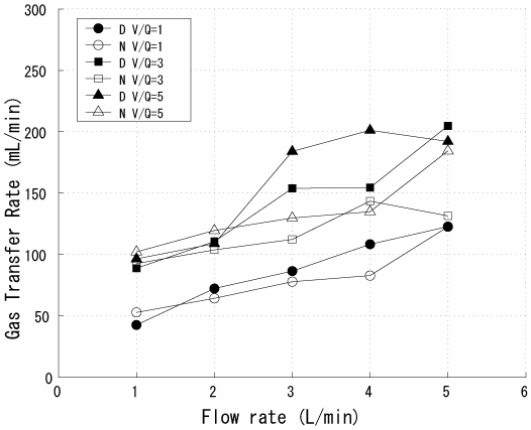

Fig.4 Transfer Rate of Carbon Dioxide