Tiny Hearts and Lungs Get an Assist

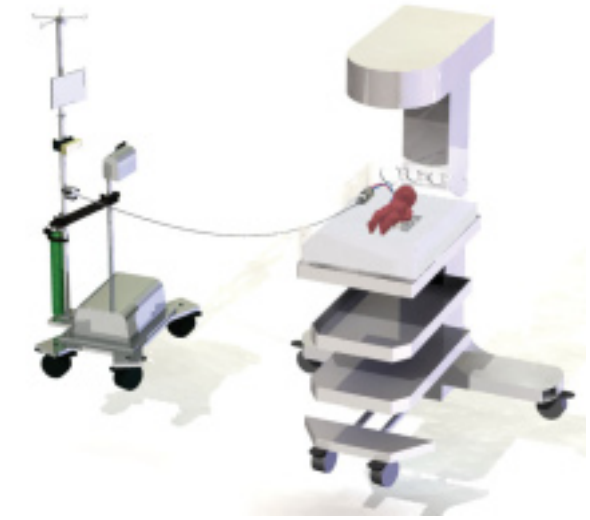
Designers use simulation to improve pediatric circulatory support techniques.

By Mark Gartner, Ension, Inc., Pennsylvania, U.S.A.

Blood-contacting portion of Ension pCAS with integrated blood pump and blood oxygenator components

In the United States, approximately two percent of all newborns require some form of corrective surgery for a cardiac or respiratory anomaly. A smaller yet significant number of these children require extended cardiopulmonary assistance for periods of days or weeks due to underdeveloped anatomy or as support until corrective surgery can be performed. The circulatory support technique known as extracorporeal membrane oxygenation (ECMO) has been used in more than 31,000 neonatal and pediatric patients worldwide with an overall survival rate exceeding 66 percent. However, with an international patient volume of less than 700 cases per year, technology investment has been limited. As a result, the devices used in ECMO have remained virtually unchanged since 1976.

In an attempt to stimulate advancement of pediatric circulatory assist devices and techniques, including ECMO, the National Heart, Lung and Blood Institute (part of the U.S. National Institutes of Health) awarded five contracts to develop a range of technologies aimed at improving the options for care of these smallest of patients. Ension, Inc. was awarded one of these contracts to develop a next-generation ECMO system that focused on ameliorating the shortcomings associated with current technology.



Ension Pediatric Cardiopulmonary Assist System (pCAS)

Ension's contract award led to the development of its pediatric cardiopulmonary assist system (pCAS). The pCAS device is mainly composed of an integrated blood pump and membrane oxygenator connected directly to the patient's circulatory system. Venous blood is removed from the patient and pumped through the pCAS device, where oxygen is added and carbon dioxide is removed. This oxygenated blood is then returned to the patient via an artery.

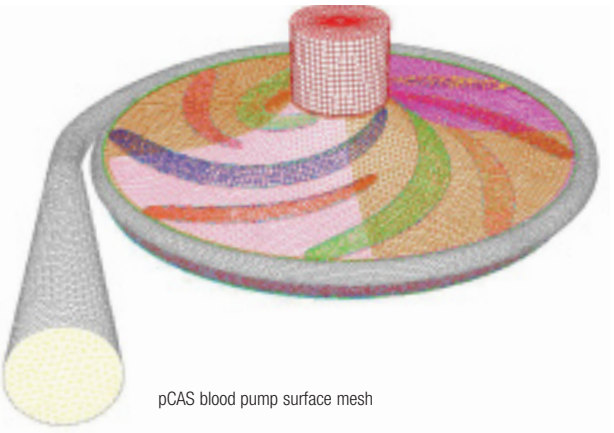
Extraordinary care must be exercised during the design of any blood-contacting component so that areas of flow recirculation, stagnation, excessive shear stress and residence time — all of which can damage the blood itself — are eliminated. Thus Ension designers desired to both predict the hemodynamic and mass transfer performance of pCAS prototypes and provide an estimation of device-induced blood damage prior to actual fabrication. As a result, the use of computational fluid dynamics (CFD) was proposed to aid in the design and analysis of the blood pump and membrane oxygenator portions of the pCAS. Due to the complexity involved in simulating the flow and mass transfer of blood, ANSYS, Inc. was engaged in a consulting role to assist with several facets of the program, including preparation of the initial CFD simulation files for the pump and implementation of user-defined function (UDF) routines.

Hybrid hexahedral and tetrahedral meshes of both the pCAS blood pump and membrane oxygenator were

created using the GAMBIT pre-processor. After the completion of meshing, the miniature centrifugal pump component was modeled with the FLUENT software package, using the moving reference frame formulation to simulate pump rotation. Supplementary test conditions were simulated by Ension and verified against experimental results. Ension then modeled the pCAS hollow-fiber membrane oxygenator component using the porous media model in FLUENT software. A porous media approach was required because of the disparate length scales present in the device. In this instance, the microporous hollow fibers, which number about 3,000 in a pCAS prototype, possess a diameter of about 0.3 mm; however, the diameter of the pCAS oxygenator itself is over 50 mm. This physical characteristic, coupled with the lack of geometric symmetry, meant that direct numerical simulation of flow and mass transfer in the membrane oxygenator was impractical. Therefore, the porous media model was used to model the area containing the fibers.

After achieving a converged and experimentally validated flow solution, a correlation-based model for blood oxygenation and a basic diffusion model for carbon dioxide removal were implemented using the FLUENT UDF capability. UDFs allowed specification of important parameters such as blood temperature, pH and hematocrit, which is the proportion of blood volume occupied by red blood cells. This UDF enabled Ension to predict the spatial concentrations for both oxygen and carbon dioxide throughout the flow domain and also allowed for the evaluation of changes in device geometry prior to the complex and time-consuming fabrication process. Plots of the oxygen delivery and carbon dioxide removal versus the blood flow rate demonstrated good agreement between CFD-based mass transfer prediction and experimental data derived from a benchtop mock circulatory loop.

The last area of computational investigation was an estimation of device-induced blood damage in the pump. Blood hemolysis — the rupture of red blood cells — is a key factor affecting the success or failure of any blood-contacting device. Even moderate levels of hemolysis



pCAS blood pump surface mesh

reduce the total amount of oxygen the blood can carry and can cause other kinds of deterioration. Hemolysis is usually calculated using particle tracking techniques, as a function of shear stress history and exposure time for a red blood cell. Once the converged and validated fluid flow solution was obtained, Ension used the discrete phase model (DPM) in the FLUENT product to track the hemolysis along the particle tracks traveling from the pump inlet to the outlet. A UDF was written to perform the necessary calculations along each particle track, which ultimately provided a prediction for the amount of blood damage experienced per pass through the device.

The predicted blood hemolysis again showed good agreement with experimental data for the pump speed and corresponding blood flow rate being studied. In the final analysis, a comprehensive CFD model was realized using the GAMBIT pre-processor, FLUENT simulation software and associated UDF functionality. The model served as a flexible tool that Ension could use as an adjunct to other methods for pCAS performance optimization. ■

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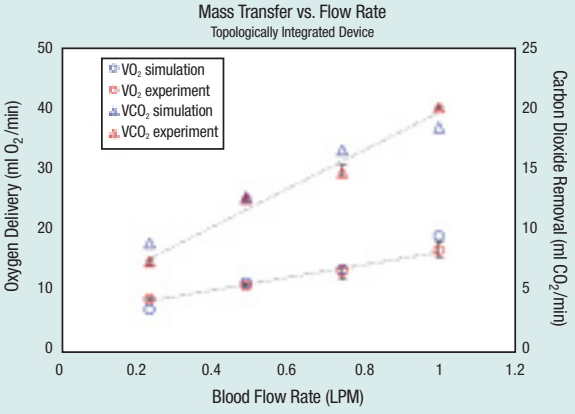
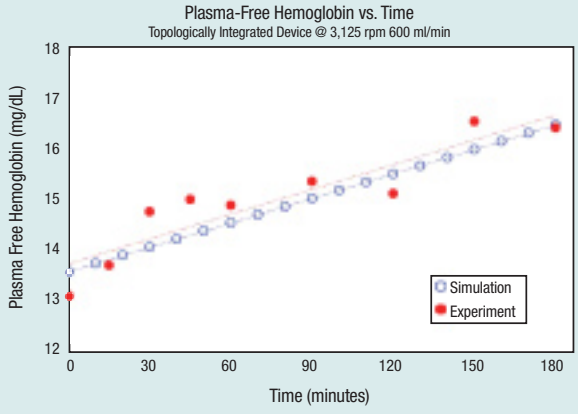


Predicted versus experimental mass transfer (oxygenation and carbon dioxide) for Ension's pediatric cardiopulmonary assist system



Simulation-predicted blood hemolysis versus experimental values for a cardiac assist device developed by Ension