

## Long-Term Support

# The PediaFlow™ Pediatric Ventricular Assist Device

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The very limited options available to treat ventricular failure in patients with congenital and acquired heart diseases have motivated the development of a pediatric ventricular assist device (VAD). Our effort involves a consortium consisting of the University of Pittsburgh, Carnegie Mellon University, Children's Hospital of Pittsburgh, World Heart Corporation, and LaunchPoint Technologies, LLC. The overall aim of our program is to develop a highly reliable, biocompatible VAD for chronic support (6 months) of the unique and high-risk population of children between 3 kg and 15 kg (patients from birth to 2 years of age). The innovative pediatric VAD we are developing (PediaFlow™) is based on a miniature mixed-flow turbodynamic pump featuring magnetic levitation, with the design goal being to assure minimal blood trauma and risk of thrombosis. This article discusses the limitations of current pediatric cardiac assist treatment options and the work to date by our consortium toward the development of a pediatric VAD.

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Prolonged mechanical circulatory support with ventricular assist devices (VAD) is becoming increasingly commonplace in adult patients. These devices serve most often as bridges to transplantation and more recently as destination therapy.<sup>1,2</sup> Less often they have been used as bridges to myocardial recovery. In children, the use of VADs has been limited to sporadic reports in mostly adolescent children. The

reason for this is multifactorial, but raises some interesting questions about the differences in the requirements and challenges of VAD support in children versus adults. The following delineates some of these differences and outlines the direction our group has taken for solving these problems to develop VADs that can be routinely used in infants and toddlers.

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## Current State of Mechanical Circulatory Assistance in Children

Before endeavoring to develop VADs specifically for a pediatric population it is appropriate to ask: is there a need for mechanical circulatory assist in children? With an incidence approaching 1 per 100 live births, congenital heart disease is the most frequent birth defect in children. Of the approximately 36,000 babies born annually with congenital heart disease, most have defects that will resolve without treatment. Invasive treatment, however, is estimated to be required in 2.3 per 1,000 of children who would otherwise die in the first year of life. In the year 2000 over 25,000 cardiovascular operations for congenital heart disease were performed on patients less than 20 years of age with a mortality of 4.7%.<sup>3</sup> In addition to those children with congenital heart disease, acquired cardiomyopathy in children is reported to have an incidence of 0.11 per 10,000.<sup>4</sup> Cardiac transplantation has been an effective therapy for many of these children, yielding excellent long-term results. However, because the pool of available donor hearts is small and spread over a wide range of sizes, mortality while on a pediatric heart transplant list has been reported to be 23%.<sup>5</sup> While these statistics clearly state the need for mechanical circulatory assistance in children, they pale in comparison to the 264,900 adult deaths and 970,000 hospital discharges each year resulting from adult congestive heart failure.<sup>3</sup> With estimated direct and indirect costs of \$27.9 billion each year to care for these adult patients, it is not difficult to see why the focus of the assist device industry has been on serving the adult population.

The encouraging outcomes of VADs in adults raise a second question of the potential for these devices in children. With a lack of the newer technologies available to the adult patient, pediatric cardiac surgeons since the 1970s have routinely relied on the tools of cardiopulmonary bypass circuits for mechanical circulatory assist in children. This has included roller or centrifugal pumps usually coupled with a membrane oxygenator (extracorporeal membrane oxygenation, ECMO). While these pumps are generally considered less physiologic and less conducive to myocardial recovery, they have served this patient population well over the past 30 years.<sup>6,7</sup> It is interesting to note that when considering extracorporeal life support in general, far more neonates and children have received mechanical support than adults. The Extracorporeal Life Support Registry report of 2004<sup>8</sup> reports that of the nearly 29,000 patients receiving mechanical cardiopulmonary support since 1989, fully 94% were neonates and children. Of the 5,625 patients whose indication was purely cardiac support, 92% were children and neonates. The pediatric patients showed better survival rates and similar complication rates to their adult counterparts.<sup>8</sup> While the need for mechanical circulatory support in children in terms of volume is smaller than adults, it is reasonable to hypothesize that the outcomes in children receiving VAD support

would be equal to, if not better, than the results achieved in adults.

Given the successes of ECMO in children, why pursue VAD therapy as an additional option? First, the advantages of ECMO over VAD in the pediatric population must be acknowledged. Children with heart failure are more likely to be cyanotic or hypoxic, have pulmonary hypertension, and true biventricular failure.<sup>7</sup> These indications often require respiratory support in addition to cardiac support; thus the requirement for the membrane oxygenator. While ECMO can provide both respiratory and biventricular support to the child in cardiopulmonary failure, it has other significant advantages in this patient population. These advantages include that the ease of cannulation and availability of peripheral cannulation allow for its rapid deployment in a rescue situation. Also, ECMO is readily available at most institutions and uses relatively inexpensive materials.<sup>9</sup> Despite this extensive experience with ECMO in children, there are significant drawbacks. Of import is that it is indicated for short-term use (days or weeks) in an immobilized and heavily sedated patient with constant attention by trained personnel. There is no opportunity for physical therapy, increased levels of activity, or oral feeding. Most notably, there is a significant incidence of bleeding and thromboembolic complications that increase markedly with the duration of support.<sup>10</sup> These limitations to ECMO have resulted in lower rates of successful bridge to transplantation in children in comparison to adult patients being bridged with VADs.<sup>11-13</sup>

Despite the clear need for mechanical circulatory support in children and encouraging results received with the more dated ECMO technology, there are a number of obstacles to the routine use of VADs in children besides lack of availability. There are anatomic considerations in that these devices must be adaptable for a wide range of patient sizes, allow for different angles of VAD inflow and outflow cannulas, and accommodate the various congenital malformations resulting in the mixing of blood flow. Special physiologic considerations include a much wider range of blood flows to support a pediatric patient, as well as differences in the fragility and thrombotic properties of pediatric blood. VADs have been used successfully in children, including by our group, but generally in adolescents with a body surface area large enough to tolerate placement of the adult-sized pulsatile pumps.<sup>14,15</sup> Currently there are two pulsatile pumps available for children for which data is beginning to accumulate on their successful deployment in progressively smaller children.<sup>16-18</sup> Simultaneously, there has been a developing trend in adult circulatory assist for rotary instead of pulsatile VADs.<sup>19-21</sup> Because of the absence of valves and filling/emptying blood sac, rotary blood pumps are much smaller than similar pulsatile devices, providing better anatomic fit in smaller patients. Pulsatile devices also require a compliance chamber or a conduit to the external atmosphere, in addition to external power and control connections. Rotary VADs only require power and control connections, allowing for a substantial reduction in the size of the communicating lead. For the patient, the smaller lead likely contributes to a reduced exit site infection potential. The antithrombotic and overall

biocompatibility attributes of these pumps are still being determined.

## PediaFlow™ Rotary Blood Pump for Infants and Toddlers

In response to this identified need for pediatric mechanical circulatory support, and the unique obstacles to developing a device for this age group, the National Heart Lung and Blood Institute issued a Broad Agency Announcement entitled “Pediatric Circulatory Support” in November 2002 (BAA NHLBI-HV-04-01; <http://www.nhlbi.nih.gov/funding/inits/archive/rfp04-01.pdf>). This announcement solicited contract proposals to develop new circulatory support systems for infants and children with congenital and acquired cardiovascular disease with cardiopulmonary failure and circulatory collapse. The specified weight range was 2 kg to 25 kg. The following technical requirements were required to be met by applicants:

1. Be able to be routinely deployed and functioning in less than 1 hour after the decision to initiate support.
2. Minimize priming volumes.
3. Include cannulation strategies to accommodate potential variations in patient anatomy.
4. Minimize exposure to blood products.
5. Minimize risks of infection, bleeding, hemolysis, and thrombosis.
6. Be capable of providing support for up to 6 months, depending on the intended application.

Ultimately five grants were awarded as part of the National Heart Lung and Blood Institute pediatric circulatory support program, including our PediaFlow™ consortium consisting of the University of Pittsburgh, Carnegie Mellon University, Children’s Hospital of Pittsburgh, World Heart Corporation, and LaunchPoint Technologies, LLC. Other institutions receiving awards include: Ension, Inc and the University of Louisville; Jarvik, Inc and the University of Maryland; the Cleveland Clinic, and the Pennsylvania State University at Hershey. Each group has taken a somewhat different approach to developing a reliable VAD for children. The following outlines the plan and efforts of the University of Pittsburgh consortium to date.

### Clinical Design Requirements

Clinical design requirements for our pediatric VAD (PediaFlow™) include:

- Fully implantable with a single, small-caliber percutaneous lead crossing the skin for energy and data transmission;
- Suitable for up to 6 months continuous support of infants from birth to 2 years of age (3 kg to 15 kg, 0.3 L/min to 1.5 L/min flow rate range);
- Anticoagulation requirement limited to anti-platelet medications (with the option for warfarin if clinically indicated);
- A “smart” sensor-based hemodynamic controller will be

included to continuously monitor cardiac status for potential “bridge-to-recovery” applications. Our controller will also continuously monitor the performance of the PediaFlow™ and produce a flow pulse of programmable amplitude and frequency;

- Specially-designed pediatric cannulae sets suitable for both right ventricular and left ventricular support will be included.

### Design Strategy

Initially, the design team considered a range of options before narrowing potential designs. Based on the consortium’s previous experiences in developing adult rotary VADs, the team decided to develop a magnetically levitated impeller design. After much consideration, three pump topologies were considered for further optimization: (1) a symmetric dual-impeller centrifugal configuration, (2) an asymmetric single-impeller centrifugal configuration, and (3) a mixed-flow impeller configuration.

### Weighted Objectives Analysis

Preliminary analyses of turbodynamics, magnetic suspension, thermal dissipation, and rotor dynamics were conducted.<sup>22</sup> Based on preliminary design analysis, a weighted objective analysis was formulated and tested against each topology. This type of analysis facilitates objective comparisons of system configuration by identifying, ranking, and quantifying interdependent characteristics. Our weighted objectives analysis considered (Fig 1):

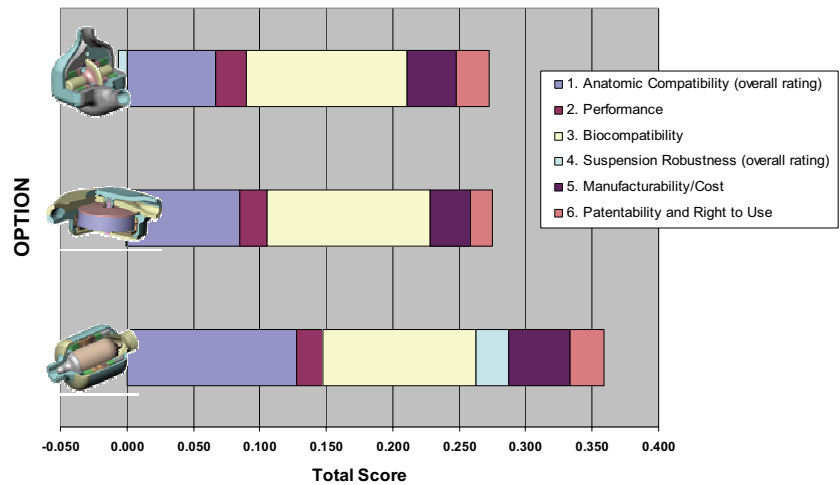
- Anatomic compatibility – maximum size, inlet/outlet direction, shape/form factor
- Biocompatibility – areas of local circulation, blood wetted surface area, number of blind crevices, number of wetted seams.
- Suspension robustness – critical speed margin, estimated shock tolerances, estimated performance of touchdown bearings, required sensor accuracy
- Manufacturability – number of components, number of seams/welds, machining complexity, tolerance of stack-up, estimated cost
- Fluid dynamics performance – pressure-flow characteristics, efficiency characteristics, blade numbers

A composite index was generated and used to quantitatively compare the three pump topology options. As a result of this analysis, the axial mixed-flow impeller pump configuration was selected for detailed design and fabrication of the first prototype.

### Pump and Motor

The PediaFlow™ pump will use a magnetically suspended impeller with both passive and active suspension. The six degrees of freedom of the rotor motion will be controlled as follows: two radial degrees of freedom and pitch and yaw are controlled by passive permanent magnetic bearings, where as the axial motion, unstable because of the radial bearings, will be actively controlled with a voice coil actuator and the roll

**Figure 1** The three design topologies considered and the weighted objectives analysis of each. Top: symmetric dual-impeller centrifugal configuration. Middle: an asymmetric single-impeller centrifugal configuration. Bottom: a mixed-flow impeller configuration.



motion driven by a DC brushless motor (Fig 2). This approach of combining passive and active suspension has been used by our team in earlier work on adult-sized heart pumps.<sup>19</sup> The motor and suspension design was carried out by successive refinement of component arrangement and geometry input into a MathCAD worksheet containing predictive analytical equations.<sup>23</sup> Similar to the fluid path design strategy described below, this approach allows multiple generations of designs to be analyzed and refined before construction of the first prototypes, substantially reducing development and construction costs.

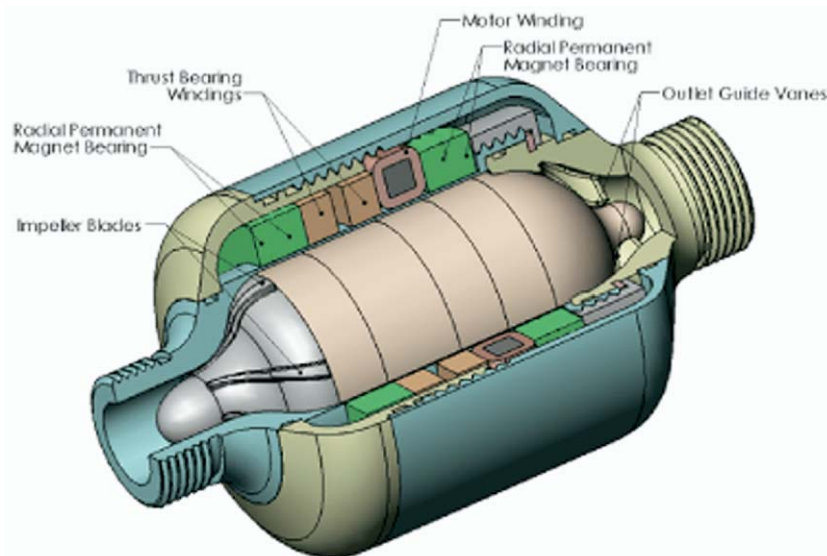
**Placement and Cannula**

For left ventricular assist, the PediaFlow™ pump will be implanted in the left upper quadrant, in the anterior abdominal wall behind the left rectus abdominus muscle. Inflow to the pump will be through a left apical cannulation with outflow to the ascending aorta. This optimal left ventricular pump location provides less compromise of the mediastinal and pulmonary structures while allowing the most flexibility with changes in the position of the child. This position also

takes advantage of the vascularity and accompanying anti-infective properties of the rectus muscle. This location will also provide for easy access for component change in the event of pump malfunction. The driveline will exit through a subcutaneous tunnel to the right costal margin traversing below the umbilicus, thereby optimizing the distance to reduce infection (Fig 3). We propose that the same pump could be used for either left or right heart assistance (or two pumps in tandem for biventricular support).

**Fluid Path**

The ultimate safety and efficacy of the PediaFlow™ VAD will depend on the biocompatibility of the flow path. This is corroborated by decades of historical experience with mechanical circulatory support, but is particularly challenging in the current application because of the demanding requirements for minimal anticoagulation over a wide range of operation. Deleterious flow conditions that may cause cell trauma or thrombosis must be avoided over flow conditions from near stall, as experienced during weaning, to the high



**Figure 2** Electrical-mechanical components of axial mixed flow pump design.



**Figure 3** Placement of PediaFlow™ as a left VAD in an infant. The pump sits extraperitoneal beneath the rectus abdominus muscle.

flow/high revolutions per minute experienced during needs for increased oxygen delivery.

The current PediaFlow™ design is being analyzed and optimized following the practice developed by members of our group in the development of adult rotary blood pumps,<sup>24–26</sup> and is based on a combination of mean-line semi-empirical analyses, and computational fluid dynamics analyses. Our primary goal for subsequent computational fluid dynamics optimization will be to analyze and identify the safe operating flow range of the existing design. This will require the incorporation of new blood damage models combined with robust multipoint design optimization. These blood damage models will incorporate blood damage and platelet physiology models for neonatal blood and will be derived based on information regarding neonatal blood rheology, blood coagulation, and platelet physiology as compared with adults.

### **Biocompatibility and Blood Contacting Materials**

As noted above, our efforts will be focused on optimizing the PediaFlow™ design with respect to biocompatibility with both blood and the surrounding tissue. To this end, our group has developed several unique devices to examine the effects of high shear stress environments on blood elements. These include a microchannel array to examine red blood cell elongation<sup>27</sup>; an apparatus to visualize flow effects at the impeller blade tips; and a unique apparatus, the blood shearing instrument, to simulate in vivo hemodynamic conditions ex-

pected with the PediaFlow™ pump and then refine predictive blood damage models to assist in pump optimization.<sup>28</sup> Ultimately, the data from these studies and others will be used to refine predictive blood damage models<sup>29</sup> that can then be incorporated into the pump optimization. This design method will also be extended to the development on cannula and anastomosis strategies. Thus far, through our work we have identified that pressure gradient, viscous dissipation (or another measure of scalar shear stress), flow deviation angle, and Peclet number are flow variables that prove useful in predicting blood damage. Pressure gradient and viscous dissipation are potentially the best indicators of hemolysis. Flow deviation angle, or confluency, is an accurate determinant of recirculation zones. Recirculation zones are problematic because they increase local shear stress, increase the flux of cells to the artificial surfaces of the pump, and usually result in flow stagnation where platelet agonists can accumulate. The Peclet number is a good indicator of the convective transport of cells, platelet agonists, coagulation proteins, and other blood borne proteins. Future work will include evaluating various blood damage models in tandem with assays of platelet activation, platelet micro-aggregate formation, leukocyte activation, and platelet-leukocyte aggregates. As this work proceeds, we believe that new models of blood damage and cellular activation in pediatric and neonatal blood will provide insight into the best possible flow path design for PediaFlow™ and help guide us to a more optimal design.

Materials selection will be based on two primary criteria:



**Figure 4** Rocker test system results of thrombus formation being conducted to assess material compatibility. The top two panels show the industry standard Ti Alloys covered with thrombus after rocker test. The bottom panel shows YTZP Zirconia Ceramic with little deposition after the same test.

biocompatibility and manufacturability. Commercially pure titanium and Ti-6Al-4V ELI are the most commonly used materials for rotary blood pumps. Two classes of materials have been considered as alternatives to these two alloys. The first class is injection moldable ceramics, while the second is alternative titanium-based alloys. Injection moldable ceramics could potentially reduce manufacturing costs. Because of the small size of the PediaFlow™ and demanding tolerances, investigations of surface finish, lay orientation, and tolerable junction size will be conducted. Additionally, we have identified over 30 potential coatings on which testing is being conducted (Fig 4).

### Thermal Modeling

Energy transfer in the form of heat is an important consideration for any intracorporeal VAD. High temperatures result in alterations of cellular functions and denaturation of blood proteins. The small size and lower cardiac output of children make this a particular consideration. Thermal modeling studies are being undertaken to ensure no greater than a 1°C rise in the temperature of the blood or the surrounding tissue.

### Physiologic Control

With the goal for implantation of our VAD in a growing child it will be necessary to optimize oxygen delivery or VAD output over a wide range of anatomic and physiologic conditions. Allowances must be made for growth, varying activity

levels, as well as potential recovery of the myocardium and weaning.

Two independent computer simulations of cardiovascular hemodynamics have been updated to improve accuracy and reliability. Parameters specific to the pediatric patient population are being compiled from the literature and our clinical experience for developing pediatric-specific simulations. Additional enhancements will include modifications for anatomic abnormalities, including septal defects, uni-ventricular hearts, and pulmonary hypertension. The simulation of ventricular suction is receiving concerted attention because this is of particular concern with rotary VADs. New models are being investigated to improve on those published by colleagues in the mid 1990s. Another particular focus is the development of flow and pressure estimators. Indwelling sensors in pediatric patients are a particular challenge, and obviating the need for this type of invasive monitoring should hasten recovery and allow for a device that can be easily controlled over a wide range of patient conditions.

### Testing

Bench-top testing will first be used to validate the predicted rotor-dynamic and flow-pressure performance. This in vitro testing will be carried out in a mock circulatory loop. This too will need to be designed and constructed specifically for pediatric circulation. Our design of a pediatric mock circulatory loop will be based on a novel “fluidic op amp” and will include consideration of the collapsing ventricle. In vivo testing will be carried out in an ovine model. During the final year of the PediaFlow™ contract, newborn lambs will be the animal model for in vivo testing.

### Conclusion

Recognizing the need for improved options and increased availability for mechanical circulatory assistance in infants and children, and the likelihood that these devices can be successfully deployed in this population with great success, our group has begun developing a small magnetically levitated rotary blood pump with target flows of 0.3 to 1.5 L/min. Building on previous experience in the design of adult-sized pumps, a team of engineers, biologic scientists, and clinicians has begun the process of updating and altering the anatomic and physiologic models used to develop VADs for the adult population to develop a VAD suited for the anatomy and physiology of a growing infant.

### References

1. Rose EA, Gelijns AC, Moskowitz AJ, et al: Long-term use of a left ventricular assist device for end-stage heart failure. *N Engl J Med* 345: 1435-1443, 2001
2. Stevenson, LW, Rose EA: Left ventricular assist devices: bridges to transplantation, recovery, and destination for whom? *Circulation* 108: 3059-3063, 2003
3. American Heart Association. Heart Disease and Stroke Statistics – 2005 Update. Dallas, TX, American Heart Association, 2004
4. Daubeney P, Nugent A, Davis AM, et al: Incidence and outcome of childhood cardiomyopathy in Australia: Results of a ten year population based study. *J Am Coll Cardiol* 33:496A, 1999 (suppl A) (abstr)

5. McGiffin DC, Naftel DC, Kirklin JK, et al., and the Pediatric Heart Transplant Study Group: Predicting outcome after listing for heart transplantation in children: Comparison of Kaplan-Meier and parametric competing risk analysis. *J Heart Lung Transplant* 16:713-722, 1997
6. Duncan BW: Mechanical circulatory support for infants and children with cardiac disease. *Ann Thorac Surg* 73:1670-1677, 2002
7. Duncan BW, Hraska V, Jonas RA, et al: Mechanical circulatory support in children with cardiac disease. *J Thorac Cardiovasc Surg* 117:529-541, 1999
8. Conrad SA, Rycus PT, Dalton H: Extracorporeal Life Support Registry Report 2004. *ASAIO J* 51:4-10, 2005
9. Deiwick M, Hoffmeier A, Tjan TD, et al: Heart failure in children – Mechanical assistance. *Thorac Cardiovasc Surg* 53:S135-S140, 2005 (suppl 2)
10. Kulik TJ, Moler FW, Palmisano JM, et al: Outcome-associated factors in pediatric patients treated with extracorporeal membrane oxygenator after cardiac surgery. *Circulation* 94:II63-68, 1996 (suppl 9)
11. Ibrahim AE, Duncan BW, Blume ED, et al: Long term follow-up of pediatric cardiac patients requiring mechanical circulatory support. *Ann Thorac Surg* 69:186-192, 2002
12. Levi D, Marelli D, Plunkett M, et al: Use of assist devices and ECMO to bridge pediatric patients with cardiomyopathy to transplantation. *J Heart Lung Transplant* 21:760-770, 2002
13. Bae JO, Frischer JS, Waich M, et al: Extracorporeal membrane oxygenation in pediatric cardiac transplantation. *J Pediatr Surg* 40:1051-1057, 2005
14. Reinhartz O, Copeland JG, Farrar DJ: Thoratec ventricular assist devices in children with less than 1.3 m<sup>2</sup> of body surface area. *ASAIO J* 49:727-730, 2003
15. Sharma MS, Webber SA, Gandhi SK, et al: Pulsatile paracorporeal assist devices in children and adolescents with biventricular failure. *ASAIO J* 51:490-494, 2005
16. Kaczmarek I, Mair H, Groetzner J, et al: Mechanical circulatory support in infants and adults with the MEDOS/HIA assist device. *Artif Organs* 29:857-860, 2005
17. Reinhartz O, Stiller B, Eilers R, et al: Current clinical status of pulsatile pediatric circulatory support. *ASAIO J* 48:455-459, 2002
18. Stiller B, Weng Y, Hubler M, et al: Pneumatic pulsatile ventricular assist devices in children under 1 year of age. *Eur J Cardiothorac Surg* 28: 234-239, 2005
19. Siegenthaler MP, Westaby S, Frazier OH, et al: Advanced heart failure: Feasibility study of a long-term continuous axial flow pump support. *Eur Heart J* 10:1031-1038, 2005
20. Goldstein DJ: Worldwide experience with the MicroMed DeBakey ventricular assist device as a bridge to transplantation. *Circulation* 108: II272-II277, 2003 (suppl 1)
21. Frazier OH, Myers TJ, Westaby S, et al: Use of the Jarvik 2000 left ventricular assist system as a bridge to heart transplantation or as destination therapy for patients with chronic heart failure. *Ann Surg* 237: 631-636, 2003
22. Wu J, Antaki JF, Wagner WR, et al: Elimination of adverse leakage flow in a miniature pediatric centrifugal blood pump by computational fluid dynamics – Based design optimization. *ASAIO J* 51:636-643, 2005
23. Noh MD, Antaki JF, Ricci M, et al: Magnetic levitation design for the PediaFlow™ ventricular assist device. *Advanced Intelligent Mechatronics. Proceedings of the 2005 IEEE/ASME International Conference*, pp 1077-1082
24. Chen C, Paden B, Antaki J, et al: A magnetic suspension theory and its application to the HeartQuest ventricular assist device. *Artif Organs* 26:947-951, 2002
25. Antaki JF, Boston JR, Choi S: Speed control system for implanted blood pumps. US Patent no. 5,888,242. Issued March 30, 1999
26. Antaki JF, Paden BE, Burgreen GW, et al: Magnetically suspended miniature fluid pump and method of making the same. US Patent no. 6,015,272. Issued January 18, 2000
27. Diao C, Wu J, Snyder TA, et al: Microscopic flow visualization of red blood cell trajectory in the blade tip clearance of a mini blood pump. *ASAIO J* 2005 (submitted).
28. Wu J, Antaki JF, Snyder TA, et al: Design optimization of blood shearing instrument by computational fluid dynamics. *Artif Organs* 29:482-489, 2005
29. Yeleswarapu KK, Antaki JF, Kameneva MV, et al: A mathematical model for shear-induced hemolysis. *Artif Organs* 19:576-582, 1995