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Assessment of Hydraulic Performance and Biocompatibility of a MagLev Centrifugal Pump System Designed for Pediatric Cardiac or Cardiopulmonary Support

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Abstract

The treatment of children with life-threatening cardiac and cardiopulmonary failure is a large and underappreciated public health concern. We have previously shown that the CentriMag is a magnetically levitated centrifugal pump system, having the utility for treating adults and large children (1,500 utilized worldwide). We present here the Pedi-VAS, a pump system whose design was modified from the CentriMag to meet the physiological requirements of young pediatric and neonatal patients. The PediVAS is comprised of a single-use centrifugal blood pump, reusable motor, and console, and is suitable for right ventricular assist device (RVAD), left ventricular assist device (LVAD), biventricular assist device (BVAD), or extracorporeal membrane oxygenator (ECMO) applications. It is designed to operate without bearings, seals and valves, and without regions of blood stasis, friction, or wear. The PediVAS pump is compatible with the CentriMag hardware, although the priming volume was reduced from 31 to 14 ml, and the port size reduced from 3/8 to 1/4 in. For the expected range of pediatric flow (0.3–3.0 L/min), the PediVAS exhibited superior hydraulic efficiency compared with the CentriMag. The PediVAS was evaluated in 14 pediatric animals for up to 30 days, demonstrating acceptable hydraulic function and hemocompatibility. The current results substantiate the performance and biocompatibility of the PediVAS cardiac assist system and are likely to support initiation of a US clinical trial in the future.

In contrast to advances in the development of cardiac support systems for adults, the development of such systems for children has lagged far behind. The most common indications for mechanical circulatory support in children is the temporary augmentation of cardiac performance during and after surgery for congenital heart disease,^{1–3} decompensated heart failure,^{4–8} or as a bridge to transplantation.⁹ Mechanical circulatory support potentially can enhance growth and development and improve survival.¹⁰ Unfortunately, despite recent studies pointing to favorable outcomes in children provided with ventricular support,^{11–13} the utilization of pediatric cardiac assist technology has been less than expected. Of the

36,000 children born with congenital heart defects each year, approximately 25% will ultimately require invasive cardiac therapy and 1,800 will ultimately die.¹⁴

Although it may be beneficial to provide circulatory support to infants and children for long-term support as a bridge to transplantation,^{12,15,16} the available clinical options to treat these children are, in fact, quite limited. This issue may be related to several factors: 1. In general, the pump components in adult systems are far too large relative to the size of the patient, thus requiring large priming volumes and excessive blood contact areas.¹⁷ Owing to the small size, variations in configuration, and fragility of these children's vasculature, novel cannulation approaches may be needed. 2. Because patient size may vary considerably with age, mechanical circulatory support systems, particularly those intended for long-term use, must safely produce a wide range of flow rates or provide exchangeable components to meet the changing flow requirements. 3. The prevalence of congenital cardiac malformations in pediatric patients with heart failure requires design engineers to consider the significant variations in underlying vascular anatomy.¹⁸ 4. In contrast to adult heart failure, pediatric heart failure is often characterized by right ventricular or biventricular cardiac dysfunction with respiratory failure. Thus, technologies for pediatric circulatory support need to be more versatile and complex than those systems designed for adults. The most commonly used technology currently for mechanical circulatory support in pediatric patients is the extracorporeal membrane oxygenator (ECMO).¹⁹ However, the use of ECMO is limited by moderate survival rates (approximately 40%), restriction of use to the acute setting (5–10 days) to avoid complications, and circuitry requiring labor intensive maintenance. The only Food and Drug Administration (FDA) approved device to date for pediatric ventricular assistance is the MicroMed DeBakey VAD child (MicroMed Cardiovascular, Inc., Houston, TX). However, this is an implantable device that is limited to children 5 years or older. An alternative cardiac support system, the Berlin Heart EXCOR VAD (Berlin Heart GmbH, Berlin, Germany), is capable of smaller priming volumes and has been used on a case per case basis in the United States.²⁰ The above factors demonstrate the complex requirements for pediatric systems and suggest a compelling rationale for continued research into the design and implementation of practical cardiac pump technology for children with severe heart failure.

Although several ventricular assist systems to treat neonatal and pediatric patients are currently under study,^{21–24} these systems are intended to be implantable and provide long-term support. Alternatively, there may be a significant benefit in providing short-term, extracorporeal devices which are designed to provide cardiac or cardiopulmonary support and serve as a bridge to decision until the pediatric patient can be successfully weaned to recovery or to an alternative long-term therapy. The Levitronix CentriMag VAS (Levitronix LLC, Waltham, MA) is a bearingless device that is in clinical use throughout world, with an estimated 1,500 patients treated. When used to treat pediatric patients, the device has been used principally as part of an ECMO circuit and to a lesser extent to provide left, right, or biventricular mechanical assistance. Although the CentriMag system has been effectively employed in larger children, the PediVAS, a structurally modified variation of the CentriMag VAS, has been specifically designed for support of these smaller pediatric and neonatal patients.²⁵ We present here early stage testing of this system in terms of its physiological performance and biocompatibility.

Methods

Design Features of the PediVAS Pump

The Levitronix CentriMag System is comprised of three core components: a single-use polycarbonate blood pump, a motor, and a drive console. In brief, the CentriMag pump is a continuous flow, centrifugal-type rotary blood pump. When used as a ventricular assist

system, blood from the failing heart is directed from the right or left ventricle or atrium to the inlet of the pump *via* an inlet cannula. Blood exits through the outlet of the pump through the outlet cannula ultimately to the systemic or pulmonary circulation. Unlike conventional centrifugal blood pumps that require a shaft, seal, and a set of bearings to function, the central design feature for the CentriMag is the “bearingless motor,” a technology combining drive, magnetic bearing, and pump rotor functions into a single unit without valves, seals, mechanical bearings, or moving parts aside from the magnetically levitated rotor. In such a configuration, the bearing forces are not generated by mechanical or magnetic bearings positioned separate from the motor block, but within the motor itself. Thus, the active motor generates not only the torque, but also the radial magnetic bearing force, which is needed for suspension of the rotor. Under normal operating conditions, the electromotive force produced by the motor windings drives the levitated rotor. Rotation of the rotor with integral vanes creates a vortex that accelerates the blood using axial and centrifugal force. The energy imparted by the rotor increases the velocity of blood along the direction of rotation through the pump outlet. The CentriMag system is capable of operating more than a range of speeds up to 5,500 rpm, generating flows up to 9.9 L/min under normal physiologic pressures and conditions.

The PediVAS (Levitronix LLC, Waltham, MA) is intended for neonates and pediatric patients with flows from 0.3 to 3.0 L/min at speeds up to 5,500 rpm. In the design of the PediVAS, the following system attributes were deemed essential: 1. high versatility, capable of operating as an left ventricular assist device (LVAD), right ventricular assist device (RVAD), or biventricular assist device (BiVAD); 2. capable of reducing priming volume by decreasing size of the volute and connectors; 3. compatible with CentriMag hardware/software; 4. suitable for use for both neonatal and pediatric cases; 5. capable of use with conventional ECMO techniques; 6. demonstrable optimal performance in the flow range of 0.3–3.0 LPM; 7. suitable for use during patient transport; and 8. possess hematologic performance and hydraulic efficiency equal to or better than the CentriMag System. The CentriMag characteristics retained included compatibility with the existing bearingless motor technology platform. Large gaps between the lower housing and the rotating impeller, similar to the CentriMag design, minimize stasis beneath the impeller and promote continuous washing of the surfaces. The pump is capable of functioning for weeks with low hemolysis and minimal thrombus formation. The priming volume has been minimized and the pump head designed for single use.

A comparison of the overall characteristics of the PediVAS and CentriMag is provided in Table 1 and demonstrated in schematic form in Figure 1. The PediVAS has a priming volume of 14 ml compared with 31 ml for the CentriMag pump. Both pumps operate using the same hardware (motors and consoles), and operate over the same range of speeds. The PediVAS is capable of generating flows up to 3.0 LPM compared with the CentriMag VAS which generates up to 9.9 LPM. To improve the hydraulic efficiency over the range of conditions expected in the pediatric setting, the PediVAS pump impeller was designed to incorporate a closed vane impeller. From an operational perspective, the PediVAS was designed to be compatible with existing ECMO circuits, protocols, monitoring techniques, and multiple oxygenators. The console retains the ability to sense and display pressure and flow information when the PediVAS is used. For ease of transport and use, the system was designed to be suitable for use for air or ground transport on fixed or rotor wing aircraft. The device was configured to be deployable in the left, right, or biventricular configuration with or without an oxygenator. Combined computational fluid dynamics (CFD) analysis and experimental testing were used to investigate the detailed fluid dynamics of the PediVAS and to characterize the positional behavior of the impeller over the entire operating range of speed, pressure, and flow.²³

Hemodynamic Performance of the CentriMag and PediVAS Pumps In Vitro

Because the bearingless motor technology employs a magnetic-bearing architecture with four actively controlled axes and two which are passively stabilized, changes in pressure load, flow rate, and speed can affect the axial position of the impeller. We characterized the positional behavior of the impeller over the predicted operating range. Using the Levitronix Magnetic Control Development Studio (MCDS) software, the axial position of the impeller was correlated with the magnetic flux signal strength measured by sensors within the motor. “FLX_ABS” is the dimensionless data value MCDS returns representing the magnetic flux strength from the permanent magnet contained within the impeller as measured from within the motor. By mechanically adjusting the impeller’s axial position and recording the FLX_ABS value, a calibration curve was created relating this value to axial position. Following this, the pump was run in a test loop flowing a blood analog (density = 1.054 gm/ml, viscosity = 3.9 cP at 37°C) over 3,500–5,500 rpm and flow rates of 0–3 L/min to ascertain hydraulic efficiency of the PediVAS compared with the CentriMag pump. Although much of the efficiency of a given centrifugal pump design is fixed by its impeller diameter and operating speed (two attributes which were fixed to maintain system compatibility), changes to the priming volume, impeller blade design, and recirculation (washing) regions were ascertained. Running the system at fixed rpm points, varying the pressure loads, and measuring the resultant flow and drive coil current provide the data necessary to produce a graphical series of H-Q and efficiency curves defining the performance envelope of the pump. The efficiency of the pump was calculated as follows:

$$\eta_{pump} = \frac{P_{hydro}}{P_{mech}}$$

$$P_{hydro} = (\Delta P)(Q)$$

where P_{hydro} and P_{mech} are the hydraulic and mechanical power, respectively. ΔP is the pressure drop across the pump inlet and outlet, and Q is the fluid flow rate.

$$P_{mech} = \left[\widehat{I}_{s1} \cdot C_m \cdot \frac{2 \cdot \pi}{60} \cdot (RPM) \right] - P_{Fe(RPM)}$$

where I_{s1} is the current supplied to the motor.

$$P_{Fe(RPM)} = C_{hysteresis} \cdot (RPM) + C_{eddycurrent} \cdot (RPM)^2$$

where “C” are constants representing power losses within the motor.

$$C_m = 9.8 [N \cdot mm/A] = 9.8 \times 10^{-3} [N \cdot m/A],$$

where C_m is a conversion factor to determine the torque to the rotor. The efficiency equation for the pump thus results in the following equation:

$$\eta_{pump} = \frac{\Delta P \cdot Q}{\widehat{I}_{s1} \cdot C_m \cdot (2\pi/60) \cdot (RPM) - C_{hysteresis} \cdot (RPM) - C_{eddycurrent} \cdot (RPM)^2}$$

In Vivo Animal Testing of the PediVAS

Surgical Implantation of PediVAS—We employed lambs weighing approximately 10–30 kg to test the performance and biocompatibility of the PediVAS *in vivo*. The animals were premedicated with atropine (5 mg subcutaneous), anesthetized with methohexital (10 mg/kg intravenously), and placed on warming pads. The left thorax of the animal was prepared for surgery using standard techniques. Hemodynamic monitoring was performed using a pediatric sized Swan-Ganz catheter and an arterial line. The chest was entered *via* thoracotomy through the fifth intercostal space. Four pledgets were sutured to the cardiac apex and used to attach the cannula fixation device. A bolus of heparin (150 U/kg) was given to achieve an ACT >400 seconds. A commercially available pediatric inflow cannula was placed into the left ventricle through a stab incision. The outflow cannula was secured to the descending thoracic aorta with a purse-string suture. The pump and extracorporeal circuit were primed with warm balanced electrolyte solution, connected to the cannulae, and the system was placed adjacent to the animal to minimize extracorporeal tubing lengths. After closure of the chest, each animal was allowed to recover from anesthesia, and spontaneously ventilate. Marcaine was used in the intercostal muscles and Banamine (25 mg intravenously) was used for analgesia. The animal was allowed to awaken immediately after surgery and supported with a vest and sling restraining system. The heparin was not reversed with protamine after the surgical procedure. No heparin was administered for 24–48 hours after surgery until the chest tube drainage was <50 ml/h. Afterwards, heparin was administered to maintain the ACT at approximately 180 seconds.

Hemodynamic/Biocompatibility Data—Baseline measurements of arterial and venous pressures, pulmonary artery and pulmonary capillary wedge pressures, and cardiac output were made. Animal and pump hemodynamic data including pump flow and speed (rpm) were continuously monitored and stored. Trends were plotted throughout each study. Hematologic measurements including: complete blood cell count (CBC) [white blood cell (WBC), red blood cell (RBC), Hct, Hgb, differential WBC], platelet count, plasma-free Hgb, a serum chemistry panel to assess general health status, arterial blood gases, and flow cytometric assessment of platelet activation. Acknowledging the paucity of flow cytometric assays to detect platelet activation in ovines, novel assays measuring p-selectin expression, platelet microaggregates, and Annexin V binding to platelets, previously developed by Johnson *et al.*²⁶ and similar assays to quantify platelet-leukocyte aggregation, were employed in this study.

Preoperative whole blood was collected from healthy ovines by jugular venipuncture using an 18-gauge 1½ in needle with syringe, discarding the first 3 ml. Blood (2.7 ml) was immediately added to monovette tubes containing 0.3 ml of 0.106 M trisodium citrate (Sarstedt, Newton, NC). Blood was collected postoperatively through indwelling vascular access lines by withdrawing 20 ml of blood, then the sample volume, and then reinfusing the blood initially collected. P-selectin expression was measured using the monoclonal antibody MCA2420 and was prepared as previously described for control samples evaluating monoclonal antibodies, while modifying the Tyrode's buffer to also contain 0.106 M sodium citrate, increasing the buffer volume to 25 µl from 20 µl, and omitting the 5 µl of the glycine-proline-arginine-proline (GPRP) peptide. P-selectin antibody binding to ovine platelets was analyzed and compared with isotype control antibody (Coli S69A) binding to ovine platelets. Platelet microaggregates were measured from MCA2420 and Coli S69A tubes.²⁶ Leukocyte platelet aggregate tubes were prepared with 120 µl of the Tyrode's buffer, 5 µl of 75 µg/ml GB20A (ovine platelet marker, Veterinary Medical Research & Development, Pullman, WA) or 5 µl of 75 µg/ml Coli S69A, 100 µl of blood, and 5 µl of 300 µg/ml goat anti-mouse phycoerythrin (Invitrogen, Carlsbad, CA) and incubated for 20 minutes. Samples were then washed and resuspended as previously described. Anti-ovine

CD 45 fluorescein isothiocyanate (10 μ l) (Serotec, Raleigh, NC) was added and incubated for 20 minutes. Ammonium chloride potassium buffer, 8.29 gm NH_4Cl , 1.0 gm KHCO_3 , 0.0372 gm disodium ethylenediamine tetra-acetic acid/L distilled H_2O ; (Sigma-Aldrich, St. Louis, MO) was added to lyse the RBCs and the samples were centrifuged and resuspended as before, washed with Tyrode's buffer with citrate, then fixed with 1% paraformaldehyde. A 2% fluorescent intensity threshold was set based on the isotype control antibody to leukocytes (CD45-positive cells); leukocytes with GB20A fluorescence above this threshold were considered leukocyte platelet aggregates. All data obtained were compared with baseline (preimplant) values to assess the influence of the device on these parameters. Statistical analyses were performed to compare data at defined postimplant periods and preimplant values using one-way analysis of variance (ANOVA) with *post hoc* testing of differences. All pumps were examined for thrombus at the time of explant along with any evidence of pannus or other tissue deposition.

Results

Hydraulic Efficiency of the PediVAS Pump System In Vitro

The pump efficiencies at each speed (rpm) setting were averaged for both the CentriMag and PediVAS pumps and plotted *versus* flow rate in Figure 2. Although both pumps demonstrate equivalent hydraulic efficiency (approximately 40% maximum), the PediVAS curve is shifted toward more efficient operation across the lower flow rates (0–3 LPM).

Use of the PediVAS Cardiac Support System in Animal Studies

We tested the PediVAS cardiac support system in 14 ovine animal studies (Figure 3), employing commercially available pediatric cannulae to connect the left ventricle to the pump inlet. The outlet cannulas were secured to the descending thoracic aorta for pump outflow. After being primed with warm physiologic saline, the pump and extracorporeal circuit were connected to the cannulae, and the system was placed adjacent to the animal to minimize extracorporeal tubing lengths. Assays were obtained during these *in vivo* tests to verify the level of hemolysis, overall biocompatibility, and preservation of organ function. Three cohorts of animal studies ($n = 14$) were carried out to evaluate hemodynamic capability and basic hemocompatibility of the pump. The first cohort (veno-arterial) of short-term studies was comprised of two animals in which preliminary protocol refinement and hemocompatibility studies were performed. The second cohort included seven animals that were used to assess performance of the first-generation prototype design of the pediatric pump for up to 30 days *in vivo*. The third cohort of five animals tested the performance of the final design of the pediatric pump for up to 30 days.

Cohort 1: Initial PediVAS Veno-Arterial Hemocompatibility Studies ($n = 2$)—

The first two animals were studied to assess basic hemocompatibility of the first-generation blood pump using a simple veno-arterial model. In each instance, the inlet and outlet cannulae of the PediVAS System were placed bilaterally in the internal carotid and jugular veins of the animal. This veno-arterial cannulation technique was employed to assess risk of thrombus formation within the pump and *in vivo* hemolysis. The implant duration for the two animals was 1 and 2 weeks. Basic hemocompatibility was demonstrated based on the absence of thrombus within the pump and acceptable hemolysis levels.

Cohort 2: First-Generation PediVAS In Vivo Endurance Studies ($n = 7$)—A

second cohort of animals was studied to characterize hemodynamic performance and *in vivo* reliability of the “first-generation pump” design for up to 30 days in the VAD configuration, employing commercially available cannulae. The inlet/outlet cannulae pairs ranged from 16F inlet/12F outlet to 12F inlet/8F outlet. Three of seven experiments were terminated at 30

days postimplant, whereas the remaining four studies were terminated nonelectively for reasons unrelated to the device (primarily bleeding or respiratory issues). No device malfunctions or failures were observed. Although this system performed satisfactorily, the *in vivo* results combined with observations based on bench testing suggested that the first-generation pump could be modified to further optimize efficiency for the low-flow, high-pressure setting of the pediatric application. Design changes were implemented to create an extended blade impeller, which increased the hydraulic power of the pump while improving the flow dynamics within the pump. In addition, the blade modifications improved the axial stability of the impeller during extreme operating conditions.

Cohort 3: Final-Generation PediVAS *In Vivo* Endurance Studies (n = 5)—The third series of experiments included five animals, and were carried out to evaluate *in vivo* performance of the final design of the pediatric pump before producing production quality components. This final pump design incorporated all of the design modifications described above. Three of the five animals were terminated at 30 days, whereas the remaining two animals were nonelectively terminated at implant and 24 hours postop for reasons unrelated to the device.

Assessment of Hemocompatibility—We demonstrate in Figure 4 the results of hemocompatibility studies performed on blood samples obtained from five sheep implanted for 30–33 days. Animals showed a transient postsurgical increase of fibrinogen from a normal level of about 200 mg/dl to that above 600 mg/dl. After the first postimplantation week, the fibrinogen concentration returned to the base level. Other blood parameters (hematocrit, total blood hemoglobin, total plasma protein) were slightly reduced but stable during the period of implantation. Plasma-free hemoglobin (plfHb) concentration was predominantly <10 mg/dl. Measures of platelet activation by flow cytometry including annexin V, platelet microaggregates, platelet leukocyte aggregates, and p-selectin were also assessed (Figure 5). The moderate preoperative elevation of platelet activation indices was likely related to blood collection technique. As expected, all of the platelet activation indices increased after the implant surgery. All of the indices returned to below or slightly elevated levels compared with the preoperative values by the conclusion of the study.

Pump Retrieval Observations—All pumps, cannulae, and tubing were inspected for thrombus formation after explant per our necropsy protocol. Except for intact ring thrombus at the barbed fitting, all pumps were free from thrombus.

Discussion

We have described herein the development of a novel centrifugal blood pump, the PediVAS, which is based on the CentriMag pump design and optimized for pediatric flow rates. The specific PediVAS modifications include a reduction of the inlet and outlet port size and priming volume, and refinement of the impeller design to improve performance in the target flow range (0.3–3.0 LPM). The PediVAS offers a flexible platform for bi- or univentricular support and is capable of mating with commercially available perfusion cannula or ECMO circuit tubing to provide either cardiac or cardiopulmonary support. Compared with currently available technology, the PediVAS embodies small size, low priming volume, excellent hemodynamic and hematologic performance, and the elimination of failure modes caused by seals and bearings. We believe that these characteristics are important in the design of cardiac support systems for neonatal and pediatric patients requiring cardiac or cardiopulmonary support in the range of flows from 0.3 to 3.0 L/min. Other advantages include the absence of valves, no flexing diaphragms, and better control of pump operation *via* a console that incorporates important safety features for this patient group.

Our initial experience in developing MagLev centrifugal pumps began with development of the HeartMate III VAS for Thoratec. The HeartMate III LVAS is a long-term, implantable system for adults based on our bearingless motor technology^{27,28} subsequently; Levitronix developed the CentriMag VAS, a temporary ventricular assist system for use up to 14 days in the United States and 30 days in Europe as a “bridge to decision.” The CentriMag system has undergone preclinical validation *in vitro* and *in vivo* as a VAD and ECMO pump for pediatric patients, and has been used in pediatric patients in Europe and other parts of the world. An FDA Investigated Device Exemption (IDE) has been submitted to gain experience in larger pediatric patients with CentriMag VAS in the United States. The PediVAS pump is unique, yet conceptually linked to the CentriMag, and has undergone validation *in vitro* to ascertain performance and hemocompatibility.²³ These results included a combined CFD analysis and experimental testing to investigate the detailed fluid dynamics of the pediatric blood pump over a range of relevant physiologic conditions and an evaluation of the system in a simulated ECMO circuit. In the current study, we demonstrate improvement of hydraulic efficiency in the pediatric flow range compared with the CentriMag, and have substantiated the physiological performance and biocompatibility of the device in 30-day implants using a pediatric ovine model.

To ascertain hemocompatibility, we assayed platelet activation indices through flow cytometry methods.²⁶ Healthy calves undergoing VAD implantation typically exhibit an elevation of platelet activation indices after surgery, which remain elevated above preoperative levels for the duration of support. The fact that calves undergoing VAD implant sham surgery exhibited only a transient elevation of platelet activation suggests that persistent elevation of platelet activation markers may be directly attributed to the device. Moreover, platelet activation indices in calves with thrombotic occlusions in the VAD trend to even higher levels when compared with calves without such occlusions.²⁹ We demonstrate here the time-resolved effect on platelet activation assayed with flow cytometry of PediVAS implantation in the ovine model. We specifically observe that platelet activation indices were elevated during the peri-implant period, but then returned to levels below (in the case of p-selectin and platelet microaggregates) or were only slightly elevated (in the case of Annexin V and platelet leukocyte aggregates) compared with preoperative values. The degree of activation was lower than that seen in calves, and when the level of platelet activation did increase after early perioperative period (as was the case with Annexin V), the elevation was not sustained. We note that the preoperative levels for p-selectin expression and platelet microaggregates were relatively high in this study compared with prior control studies²⁶ and suggest that this was likely to be a reflection of nonspecific stress effects on ovine platelets during preoperative blood collection.³⁰ These data demonstrate that the PediVAS possesses sufficient evidence of biocompatibility to allow progress toward an investigational clinical trial. Finally, hemolysis testing was performed *in vitro* for 6 hours comparing the results with the PediVAS pump to a Medtronic BioMedicus BP 50 device. The PediVAS plasma-free hemoglobin values were found to be approximately 50% that of the BP 50 Pump.

In summary, we have demonstrated that the PediVAS, a novel MagLev centrifugal pump system based on the CentriMag design, exhibits excellent performance and biocompatibility in the flow range characteristic of young children and infants. Based on the results to date, the design has been frozen and we will proceed to final preclinical studies, to support a regulatory application for a clinical trial with the PediVAS pump.

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Figure 1. Comparison of cross-sections of CentriMag (A) and PediVAS (B) pumps. Both pumps employ bearingless motor technology platform and possess large gaps between the lower housing and the rotating impeller to minimize stasis beneath the impeller. The PediVAS has a reduced priming volume (14 ml) compared with the CentriMag (31 ml) and exhibits a reduced maximum flow. To improve hydraulic efficiency of the PediVAS in the intended flow range, the impeller of the PediVAS was redesigned to incorporate a closed vane impeller.

Figure 2. Hydraulic efficiency of PediVAS compared with CentriMag pump systems. The pump was run in a test loop employing a blood analog at 3500–5500 RPM and flow rates of 0.3–3.0 LPM. Shown here is a comparison of the hydraulic efficiency of the CentriMag and the PediVAS pumps of low flow rates.

Figure 3.

In vivo implementation of Levitronix PediVAS in sheep model. Pediatric cannulae were used to connect the left ventricle to the pump inlet, and return flow from the pump to the descending thoracic aorta. After connection to the inlet/outlet pump ports, the system was placed adjacent to the animal to minimize extracorporeal tubing lengths and primed with warm physiologic saline.

Figure 4.
Pedivas hematological parameters including Hct, total Hb, and total blood protein and plasma-free hemoglobin, were stable.

Figure 5. Flow cytometric assays of platelet activation. Assays of Annexin V, platelet microaggregates, platelet leukocyte aggregates, and p-selectin were obtained during a 30-day period of observation after device implantation. These indices increased during the implant period but returned to levels below or slightly elevated compared with the preoperative levels.

Table 1

Comparison of Levitronix CentriMag and PediVAS Pumps

Parameter	CentriMag Pump	PediVAS Pump
Priming volume (ml)	31	14
Operating speed range (rpm)	0–5,500	0–5,500
Flow range (LPM)	0–9.9	0–3.0
Cannulae connection size (inch barb)	3/8	1/4
Impeller configuration	Open	Closed