Autonomous Fontan pump: Computational feasibility study

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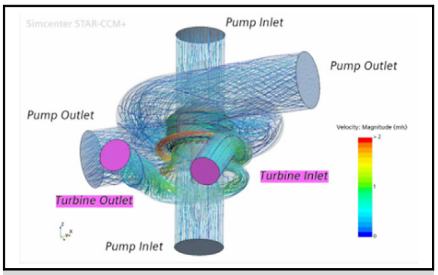
ABSTRACT

Objective: After Fontan palliation, patients with single-ventricle physiology are committed to chronic circulatory inefficiency for the duration of their lives. This is due in large part to the lack of a subpulmonary ventricle. A low-pressure rise cavopulmonary assist device can address the subpulmonary deficit and offset the Fontan paradox. We investigated the feasibility of a Fontan pump that is self-powered by tapping reserve pressure energy in the systemic arterial circulation.

Methods: A double-inlet, double-outlet rotary pump was designed to augment Fontan flow through the total cavopulmonary connection. Pump power is supplied by a systemic arterial shunt and radial turbine, with a closed-loop shunt return to the common atrium (Q_P:Q_S 1:1). Computational fluid dynamic analysis and lumped parameter modeling of pump impact on the Fontan circulation was performed.

Results: Findings indicate that a pump that can augment all 4 limbs of total cavopulmonary connection flow (superior vena cava/inferior vena cava inflow; left pulmonary artery/right pulmonary artery outflow) using a systemic arterial shunt powered turbine at a predicted cavopulmonary pressure rise of +2.5 mm Hg. Systemic shunt flow is 1.43 lumped parameter model, 22% cardiac output. Systemic venous pressure is reduced by 1.4 mm Hg with improved ventricular preload and cardiac output.

Conclusions: It may be possible to tap reserve pressure energy in the systemic circulation to improve Fontan circulatory efficiency. Further studies are warranted to optimize, fabricate, and test pump designs for hydraulic performance and hemocompatibility. Potential benefits of an autonomous Fontan pump include durable physiologic shift toward biventricular health, freedom from external power, autoregulating function and exercise responsiveness, and improved quality and duration of life. (JTCVS Open 2024;21:257-66)



Three-dimensional streamline plot AFP.

CENTRAL MESSAGE

A low-pressure cavopulmonary pump powered internally by the high-pressure systemic arterial circulation can autonomously offset the Fontan paradox.

PERSPECTIVE

In a Fontan circulation, the absence of a subpulmonary ventricle creates chronic circulatory inefficiency that culminates in Fontan failure and attrition. Cavopulmonary assist can offset the Fontan paradox by reinstating a subpulmonary power source. A cavopulmonary pump powered internally by a systemic arterial shunt may significantly improve late Fontan outcomes.

See Discussion on page 267.

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Abbreviations and Acronyms

AFP = autonomous Fontan pump
CFD = computational fluid dynamics
CO = cardiac output
IVC = inferior vena cava
LPA = left pulmonary artery
LPM = lumped parameter model
MCS = mechanical circulatory support
RPA = right pulmonary artery
SVC = superior vena cava
TCPC = total cavopulmonary connection

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Current treatment of single-ventricle heart disease consists of a staged surgical approach that culminates in a Fontan circulation. A Fontan circulation can be defined as a circulation that lacks a subpulmonary ventricle. Although this strategy offers the benefit of decades of life to most patients, it is palliative, not curative. The long-term consequences of the lack of a subpulmonary ventricle underpin the Fontan paradox: systemic venous hypertension, associated with pulmonary arterial hypotension, preload deprivation, and subnormal cardiac output (CO).[1] It is now well documented that all affected individuals will develop progressive Fontan-associated disease, eventually leading to circulatory failure and premature death.[2]

Although single-ventricle palliation and long-term survival of patients with single-ventricle physiology has improved considerably over time, there have been no therapies identified that can prevent chronic Fontan-associated disease progression and Fontan failure. With an increase in survivors, Fontan failure now represents an enigmatic clinical problem with no known solution.[3] From a surgical perspective, any Fontan pathway optimization, no matter how effective it may be, remains associated with a cavopulmonary pressure *loss*. There is no passive flow optimization that can result in a cavopulmonary pressure *gain*. A biventricular replacement (heart transplant) with restitution of a subpulmonary ventricle is the only method available to provide a gain, but is associated with limitations and trade-offs of its own.

To address this problem, research has been underway to develop technologies to partially or fully restore subpulmonary pump function within a Fontan circulation.[4] Because the Fontan circulation lacks a subpulmonary pump, a logical solution is to reinstate a subpulmonary power source to shift the physiology toward a more stable biventricular-like circulation. However, this is a major bioengineering challenge; the pump requirements are unique and vastly different from those of systemic mechanical circulatory support (MCS) devices. Adding to the technical challenges, MCS support is associated with significant morbidity and reduction in quality of life. The social burden of percutaneous drivelines, external system control components, and exogenous power dependence understandably limit the clinical attractiveness of MCS therapy.

Because cavopulmonary assist requires a uniquely low pressure rise, we and others have recognized the potential of adding pressure energy to the cavopulmonary circulation by tapping reserve pressure energy from the systemic arterial circulation, effectively transferring hydraulic power from a high-pressure source to augment flow in the low-pressure Fontan circuit. Some groups have focused on the use of systemic-to-pulmonary arterial shunts to augment Fontan cavopulmonary flow via entrainment or jet-venturi flow augmentation, and others have considered mechanical devices. Our group is developing a motorized cavopulmonary pump for the Fontan circulation based on the von Karman viscous pump principal.[5,6] It offers a multidirectional solution to cavopulmonary flow augmentation in a fail-safe design. The aim of this study was to use computational methods to determine the feasibility of an autonomous Fontan pump (AFP) based on the von Karman pump platform. If successful, it could resolve the burdens associated with need for external components and exogenous power while simultaneously improving Fontan circulatory efficiency and health long term.

MATERIAL AND METHODS

Autonomous Fontan Pump Design

A conjoined pump and turbine powered internally by a systemic arterial shunt was developed based on a double-inlet double-outlet centrifugal pump with superior vena cava (SVC)/inferior vena cava (IVC) inflow and left pulmonary artery (LPA)/right pulmonary artery (RPA) outflow. A shunt-driven turbine was integrated with the IVC end of the pump rotor (Figure 1). The device was scaled for adolescent or young adults (SVC/IVC inlet diameter 14 mm, LPA/RPA outlet diameter 16 mm). The following operating (boundary) conditions were applied: (1) SVC flow 2.5 L/min; (2) IVC flow 2.5 L/min; (3) pressure rise to LPA and RPA greater than 2 mm Hg; (4) shunt inflow pressure 96 mm Hg; and (5) shunt flow rate 1.42 L/min (28% CO).

The geometry of the pump and turbine were produced using CFturbo turbomachinery design software (CFturbo GmbH) (Figure E1). CFturbo creates turbomachinery blading and volutes based on well-established methodologies.[7-11] Rhino-3D was then applied as a general 3-dimensional computer-aided design system (Rhino-3D, TLM Inc). The IVC-side impeller is shrouded, with a radial inflow turbine integrated with the outer shroud surface. A double-pump volute discharges systemic venous flow to the LPA and RPA. The turbine features an inlet stator, as well as an inlet and discharge volute. Turbine egress is returned to the common atrium (Q_P:Q_S 1:1) as a left-to-left shunt (Figure 2).

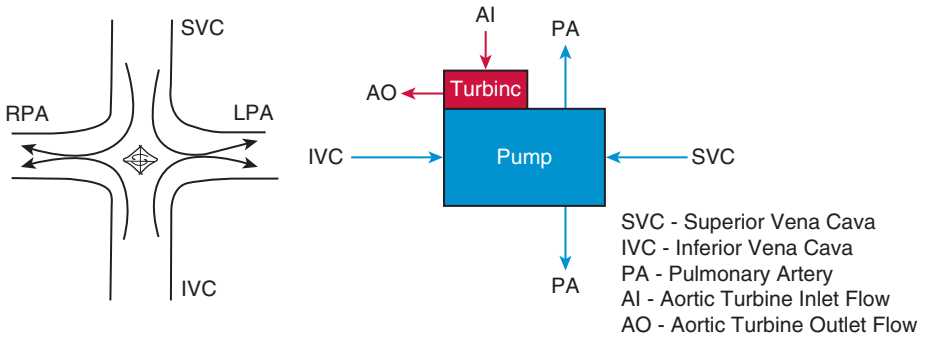


FIGURE 1. Viscous Fontan pump (*left*) and self-powered Fontan pump (*right*) conceptual models.

Computational Fluid Dynamic Analysis

Upon completion of the geometric design, a computational fluid dynamics (CFD) analysis was performed using STAR-CCM + software (Siemens PLM). Fluid density was assigned at 1060 kg/m^3. Viscosity was modeled as a constant value and through the adaptation of a non-Newtonian viscosity model. All leakage paths and secondary flow paths were modeled to account for the mechanical losses of the outer stationary surfaces. Reynolds-Averaged Navier Stokes Equations were used, and a turbulence model was used to close the equations. Two models of blood viscosity were examined. The first used a simplistic constant value of 3.5 mPa-s. For the second, because blood is a non-Newtonian fluid where viscosity increases significantly in areas with reduced shear strain rates, we adopted the model implemented by Al-Azawy[12] that accounts for blood viscosity properties via the standard Carreau-Yasuda non-Newtonian viscosity model (Figure E2).

A computational mesh was developed composed of hexahedral and polyhedral elements for the entire interior flow domain, including prismatic elements that accurately model areas of high viscous stress. The final mesh was composed of 10,419,436 cells and 25,025,128 vertices (Figure E3). Once complete, an unsteady CFD analysis using STAR-CCM+ was executed. The SST-k-omega model was used to close the Reynolds-Averaged Navier Stokes model.[13] Calculations were performed for each of the 2 viscosity models using the CFD modeling assumptions listed in Table E1.

Lumped Parameter Modeling to Predict Circulatory Impact of Autonomous Fontan Pump

A lumped parameter model (LPM) of Fontan circulation (varying elastance model[14]) was applied to demonstrate the acute response of the circulation upon switching from a "good Fontan" (ie, a minimal gradient total cavopulmonary connection [TCPC]) to cavopulmonary assist provided by the AFP (Figure 3). Baseline represents the Fontan resting state: (1) body surface area 1.39 m^2; (2) heart rate 75 beats/min; (3) systemic vascular resistance indexed 26.55 mm Hg/(L/min)*m^2; (4) pulmonary vascular resistance indexed 1.38 mm Hg/(L/min)*m^2. For the cavopulmonary assist simulation, the TCPC loss is replaced with AFP gain, and turbine shunt runoff from the aorta to the common atrium is also incorporated. Because only 1 data point is known for the AFP, fixed values of turbine flow (1.43 L/min) and pump pressure rise (+2.53 mm Hg) derived from CFD studies were imposed.

RESULTS

Computational Fluid Dynamics Analysis

The results of the CFD analyses are shown qualitatively and quantitatively in Figure 4 and Table 1. The CFD solution predicts an AFP pressure rise of +2.53 mm Hg at a shunt flow of 1.43 L/min (22% CO) and rotor speed 1900

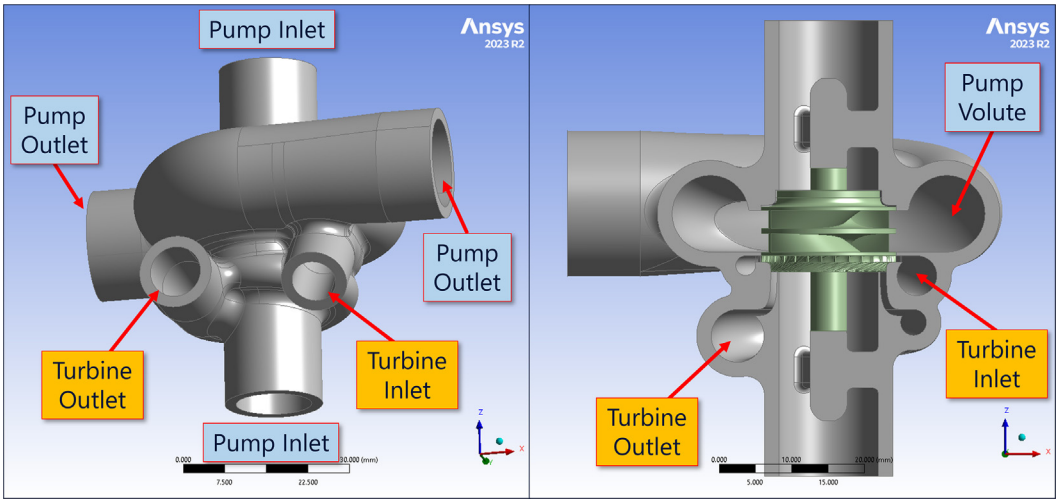


FIGURE 2. Geometry of AFP.

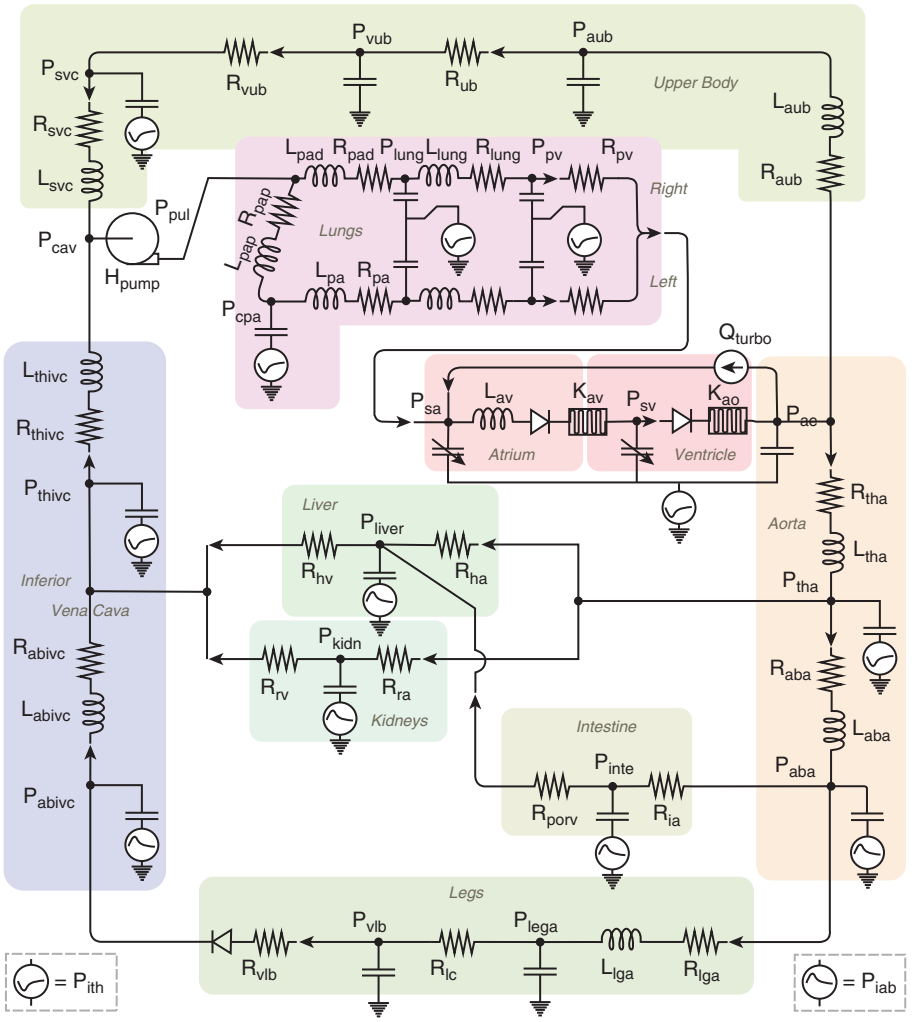


FIGURE 3. Schematic of LPM of Fontan circulation with AFP. Note Hpump in the TCPC and steady turbine flow (Qturbo) connection from aorta to common atrium. *LPM*, Lumped parameter model.

RPM. In general, patients will tolerate up to 25% shunt runoff. There is no significant difference between the different viscosity models, indicating high shear strain rates throughout the flow domain. In prior studies that we have performed, the CFD analyses conducted with the SST model underpredict pump pressure rise in comparison with in vitro mock loop testing.[15] If this observation holds with the AFP, it may be possible to further reduce shunt flow through the turbine to achieve equivalent performance. Additionally, in future iterations when an IVC/SVC inflow differential is factored into the design, because the IVC side of the pump will have higher efficiency due to its shrouded impeller (the SVC impeller is unshrouded due to high front cover leakage losses; the IVC side of the pump has no such passage, because this space is occupied by the radial turbine rotor), we expect that further improvement in pump performance with less shunt runoff through the turbine may be possible.

Lumped Parameter Modeling

In the LPM simulation, IVC/SVC pressure is reduced by 1.41 mm Hg and CO is improved secondary to an increase in atrial pressure and ventricular preload (Table 2 and Figure 5). However, CO is not increased as much as the turbine flow "steals" in terms of shunt runoff. As a result, there is a net reduction of aortic pressure and of flow delivered to the systemic circulation. A limitation of this model is that it cannot account for physiologic mechanisms (Frank-Starling mechanism, baroreceptor response). With a reduced mean systemic arterial pressure due to shunt runoff, the model does not reflect increased contractility secondary to improved preload and may underestimate potential improvement in CO (Video 1).

DISCUSSION

The findings of this study suggest that an AFP can provide a +2.5 mm Hg pressure rise within the Fontan TCPC

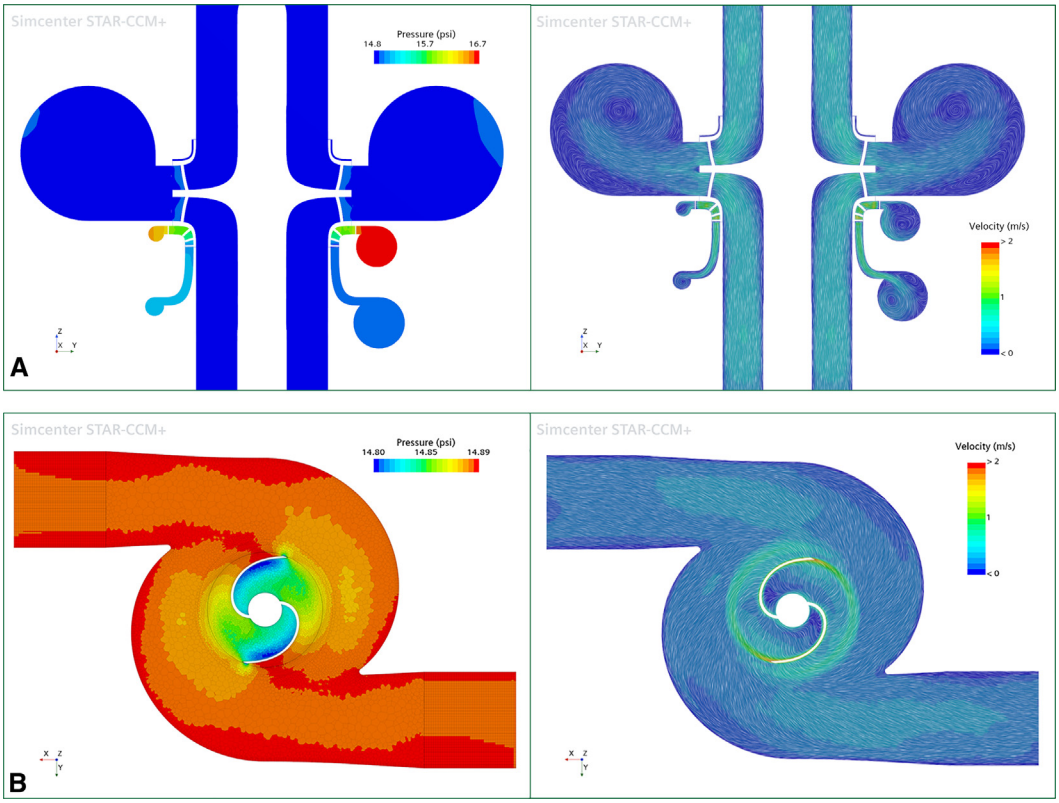


FIGURE 4. A, Cross-sectional plots of pressure and velocity through AFP. B, AFP pump volute flow plots.

under clinically acceptable operating parameters. Although this may at first seem to be a marginal gain, significant long-term benefits may include reduction in systemic venous pressure; increase in pulmonary arterial pressure; improved preload and CO; autoregulating pump performance in response to activity (ie, augmentation of shunt pressure and flow during exercise leading to increased cavopulmonary assist); 4-way TCPC flow augmentation with no back-pressure imposed anywhere in the circuit; no oxygen desaturation; and no pulmonary overcirculation. Additional compelling benefits that impact patient quality of life include freedom from external power requirement; no motor, wires, or batteries; elimination of percutaneous driveline and associated risk of infection or failure; autonomous self-regulation to activity; and maintenance-free (other than anticoagulation) service.

To elaborate further on the integration of CFD results within the LPM, the turbine flow and pump head results of CFD were imposed as inputs to the LPM. In the LPM results, systemic flow (Qs) matches the flow boundary condition on the pump in CFD, and the pressure gradient across the turbine (aortic pressure – atrial pressure) matches the pressure boundary condition on the turbine in CFD. Thus, the 0-D LPM is matched to the single operating point 3-dimensional CFD at the boundaries. This was accomplished by iteratively seeking an optimum combination of baseline patient vascular resistance and arterial and atrial pressures in the LPM. Because there are extra variables, this is not a unique solution; other solutions are expected to be generally similar, especially when considering additional restraints such as a realistic range of atrial pressure. The LPM does not account for baroreceptor response and

TABLE 1. Quantitative computational fluid dynamics results of autonomous Fontan pump flow

	Pump static head (mm Hg)	Turbine static head (mm Hg)	Total torque (N-m)	Turbine torque (N-m)	Pump volume flow (L/min)	Turbine volume flow (L/min)	Pump efficiency (%)	Turbine efficiency (%)
Constant viscosity	2.53	96.82	2.79e-5	5.88e-4	5.0	1.436	28.1	37.9
Non-Newtonian viscosity	2.47	96.78	1.95e-5	5.83e-4	5.0	1.433	27.3	37.6

TABLE 2. Lumped parameter model of results of an unsupported Fontan circulation (baseline) and a Fontan circulation with cavopulmonary assist (autonomous Fontan pump)

	Flow (L/min)			Mean pressure (mm Hg)				
	CO	Qturbo	Qs	Aortic	Caval	Gradient/head	PA	Atrial
Baseline	5.425	0	5.425	118.76	15.00	−0.60	14.40	9.02
AFP	6.437	1.436	5.001	109.17	13.59	+2.53	16.12	11.17

CO, Cardiac output; *Qturbo*, flow rate through turbine; *Qs*, systemic flow; *PA*, pulmonary artery; *AFP*, autonomous Fontan pump.

reflects the systemic and ventricular effects of the AFP only, all other things being equal.

Fontan Circuit Energetics

No matter how well optimized, all Fontan circuits are associated with a power loss. For example, a passive flow optimization may improve a Fontan circuit gradient from −3 mm Hg to −1 mm Hg, but it remains associated with a loss. Only a power source of some kind can provide a cavopulmonary pressure gain. A surprisingly modest pressure gain will significantly improve Fontan circulatory efficiency. To place this in context, consider the right-side circulatory energetics of Fontan physiology compared with biventricular physiology. In a normal biventricular circulation, in otherwise healthy individuals, the right artery to pulmonary artery mean pressure step-up is approximately +7 mm Hg (right artery mean 3-5 mm Hg; pulmonary artery mean 12-15 mm Hg). In a Fontan circulation, the systemic venous to pulmonary artery pressure differential is typically a −1 to 2 mm Hg loss. The difference between a Fontan cavopulmonary gradient (loss) and a normal biventricular circulation cavopulmonary gradient (gain) is approximately 10 mm Hg. By comparison, a +2 mm Hg gain provided by a cavopulmonary assist device may represent a 30% to 50% shift in Fontan efficiency toward biventricular equivalency and therefore may be highly clinically significant long term.

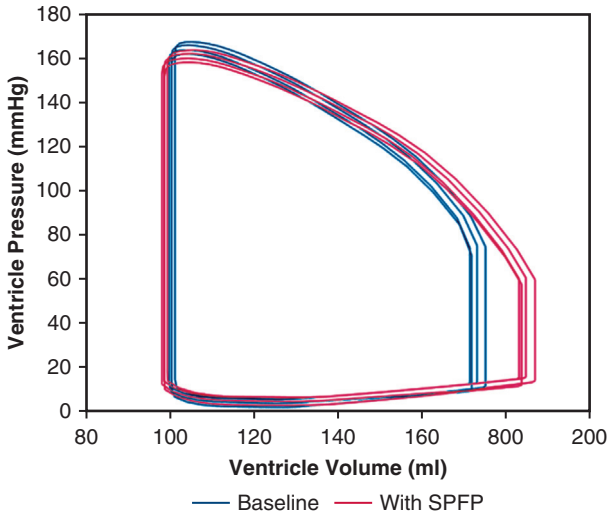


FIGURE 5. Pressure-volume loops from the 2 LPM simulations. *LPM*, Lumped parameter model; *SPFP*, self powered Fontan pump.

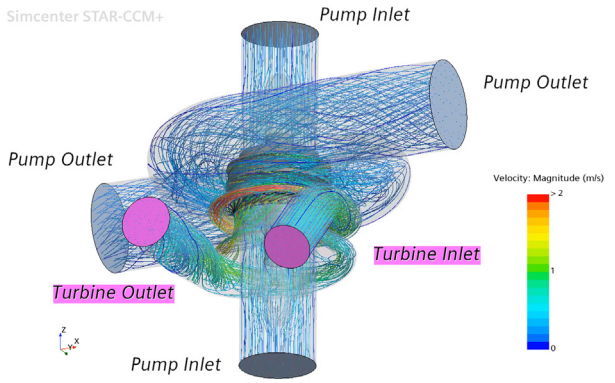
Clinical Correlates That Support a + 2 mm Hg Pressure Gain in the Fontan Circuit

A cavopulmonary assist device will function in the lowest pressure segment of the circulation, where the relative impact of any pressure change is an order of magnitude greater than in the systemic circulation. This makes sense clinically, where it is well known that the Fontan circuit is disproportionately sensitive to seemingly minor pressure gradient, including passive flow energy losses that may be clinically unmeasurable. In many cases, surgical revision of the Fontan pathway is warranted for gradients that exceed 2 mm Hg. In addition, conversion from an atriopulmonary Fontan to extracardiac conduit or lateral tunnel Fontan is associated with a 2 to 5 mm Hg improvement in Fontan circuit loss, with improved clinical status.[16] What these interventions have in common is an improvement in the Fontan circuit gradient by +2 mm Hg or so, which is consistent with the magnitude of pressure gain contemplated in this study.

Investigational Efforts to Tap Reserve Pressure Energy to Augment Total Cavopulmonary Connection Flow

Given the unresolved problem of late Fontan failure, several groups have explored innovative methods to internally augment Fontan cavopulmonary flow. Although these offer insight into a variety of approaches to this problem, they similarly shed light on the difficulty of producing a solution. Shunt nozzles and jet-venturi entrainment concepts have been most widely investigated.[17-19]

A turbine-powered mechanical pump has been proposed by Pekkan and colleagues[20] and was a key motivation for this study. The fundamental difference is that we are investigating a turbine drive applied to a 4-way TCPC pump opposed to a 1-way IVC pump. In our opinion, a 1-way IVC solution raises concern for backpressure in the opposing inflow territory (SVC). Paradoxically, the more effective a unidirectional IVC pump is, the more detrimental it is to the SVC territory. Long term, SVC hypertension may negatively impact brain health, promote the development of decompressing venovenous collaterals eventually leading to reverse/circular shunt, and increase



VIDEO 1. Autonomous Fontan pump. Video available at: https://www.jtcvs.org/article/S2666-2736(24)00183-9/fulltext.

thrombosis risk. The multi-directional concept that we propose will reduce both SVC and IVC pressure. Because it will augment 100% of systemic venous return, the demand on the pump is higher. In a more challenging double-inlet double-outlet configuration, the magnitude of IVC offload is unfortunately less. However, the trade-off of a lower performance 4-way solution is physiologically preferable and safer in the long term. Last, we considered whether to route turbine/shunt flow to the pulmonary or systemic circulation. Although egress into the pulmonary circulation may be simpler from a mechanical design standpoint, we favor closed-loop shunt return to the systemic circulation to avoid the volume-induced reduction in efficiency that would counteract the effective pressure rise delivered by the device.

Clinical Vision

Although conceptual and at the margins of meaningful pressure rise, an AFP has exciting potential to serve as a low-input Fontan circulatory "maintenance" therapy (vs "replacement" therapy with an externally powered cavopulmonary assist device) to enable a clinical management strategy that is more aligned with the principles and intent of biventricular therapy. It would be applied before end-stage Fontan failure with the intent to neutralize the progression of Fontan-associated disease and delay or prevent the timeline to Fontan failure or need for transplant. If applied in children or adolescents before somatic growth is complete, a commitment would be required to upsize the device. If more support is required, it could be exchanged to an externally powered cavopulmonary assist device. Chronic anticoagulation will be required. From the standpoint of MCS therapy, with a much lower morbidity profile in an autonomous maintenance-free device, long-term use may be less burdensome and more attractive. Based on its relative simplicity and maintenance free operation, the technology may have global applicability in under-resourced populations.

Although early-stage and speculative, the device is envisioned to be fabricated using medical grade titanium alloy. Dimensions of the inlets and outlets are currently at adolescent or adult scale. We expect that the pump can accommodate a patient with a body surface area of 1.6 m^2 or greater. Smaller versions potentially could be developed for use in younger patients. This pump will apply to lateral tunnel and extracardiac conduit types of Fontan operations. Surgical implant is similar to a Fontan conversion operation with the pump placed in situ in the TCPC. A fenestration would be contraindicated because of the potential for left-to-right shunting and reduction in CO. The presence of a second Glenn would require re-routing to the opposite SVC to prevent backpressure and risk of acquired circular shunt in the second Glenn. We do not envision any role in end-stage compassionate use situations; an AFP is intended to prevent chronic Fontan disease.

Limitations and Steps Forward

This is an early-stage proof-of-concept study for an implantable 4-way Fontan pump that is internally self-powered and requires no external energy. The study is focused on hydraulic feasibility based on advanced computational design and analysis. Rigorous CFD design and analysis offers a more cost- and time-effective approach because the manufacturing complexity for tight-tolerance pump components is expected to be considerable. Although the findings suggest that meaningful benefit is possible, device function is at the margin of hydraulic feasibility. But, when considered in the context of patients who are effectively committed for the duration of life to a chronic disease state with no possibility of halting the progression of Fontan-associated disease and with the compelling user-friendly and durable benefits that it may provide, further investigation is warranted.

CONCLUSIONS

For this analysis, the Fontan pathway obstruction risk (0 RPM) was waived to allow latitude to design for maximal hydraulic efficiency; this is a safety concern that will require further assessment. The margin for shunt runoff, scale and configuration for anatomic fit, and 70/30 IVC/SVC inflow differential also will need to be addressed. Volume overload is a concern that will require further assessment in mock circulatory loop studies that account for the complex interactions of ventricular function, systemic vascular resistance, shunt runoff, and systemic venous pressure. Future design optimization will focus on balancing the pump for differential systemic venous inflow (70% IVC; 30% SVC) and more effectively coupling turbine hydraulic

power to the IVC side of the pump without transmitting backpressure to the SVC territory. Thrombogenicity risk is unknown at this stage and can be rigorously assessed only after advanced mechanical development and in vitro validation provide reasonable assurance clinically acceptable hemodynamic performance. To draw valid conclusions, thrombogenicity assessment must be performed in advanced designs and highly refined prototypes. Thrombogenicity assessment in an early-stage prototype would increase the risk of false-positive findings. Preclinical device development will require high-precision advanced manufacturing, and development cost may be a limiting factor. Once hemodynamic performance and hemocompatibility are fully optimized, an objective determination can be made whether the magnitude of benefit outweighs the risk of implant and use.

Webcast

You can watch a Webcast of this AATS meeting presentation by going to: https://www.aats.org/resources/autonomous-fontan-pump-7195.

Conflict of Interest Statement

The authors reported no conflicts of interest.

The *Journal* policy requires editors and reviewers to disclose conflicts of interest and to decline handling or reviewing manuscripts for which they may have a conflict of interest. The editors and reviewers of this article have no conflicts of interest.

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Key Words: autonomous, cavopulmonary assist, Fontan circulation, subpulmonary pump

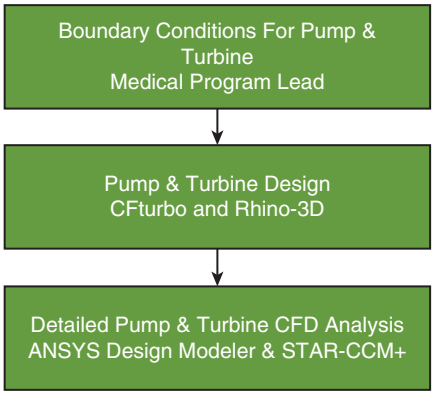

FIGURE E1. Design flow of AFP. *AFP*, Autonomous Fontan pump; *CFD*, computational fluid dynamics.

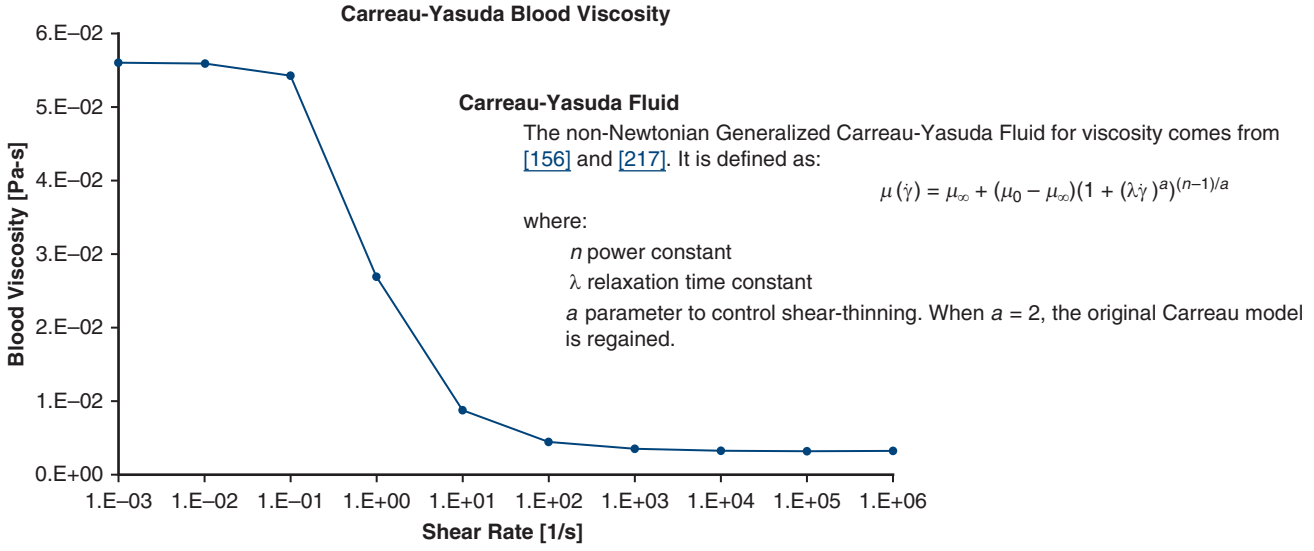

FIGURE E2. Non-Newtonian model of blood used in CFD analysis. *CFD*, Computational fluid dynamics.

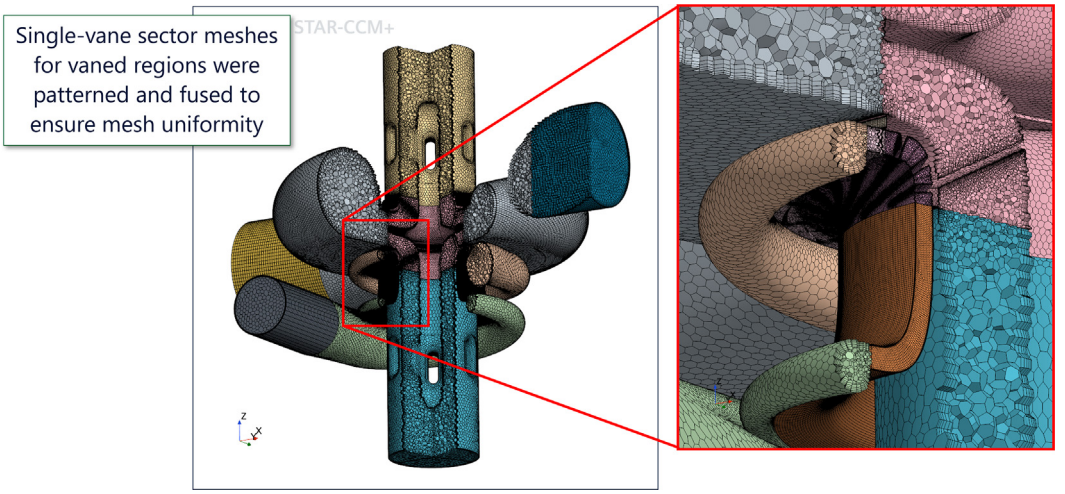

FIGURE E3. Computational mesh of the AFP flow domain. *AFP*, Autonomous Fontan pump.

TABLE E1. Computational fluid dynamics modeling assumptions for the autonomous Fontan pump

- Shear stress transport κ-ω turbulence model
- Segregated flow solver
- Blood as constant density fluid with constant or non-Newtonian viscosity (for different analyses)
- Boundary conditions
  - Volume flow of 2.5 L/min at each pump inlet, static pressure of 770 mm Hg at each pump outlet*
  - 1900 RPM rotating speed
  - Total pressure of 868 mm Hg at the turbine inlet, static pressure of 770 mm Hg at the turbine outlet
- Transient timestep of 8.772e-5 s (360 per revolution)
- 20 solver iterations per timestep
- Simulation ran until residual plots and monitor value plots (such as pressure, torque, and mass flow) were judged to have settled

*The absolute pressure (relative to absolute vacuum 0 mm Hg) of the pump outlets was 770 mm Hg: With standard atmospheric pressure of 760 mm Hg, this is clinically equivalent to a gauge pressure of 10 mm Hg, which is representative of mean pulmonary artery pressure in a "good" Fontan.