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In vitro investigation of axial mechanical support devices implanted in the novel convergent cavopulmonary connection Fontan

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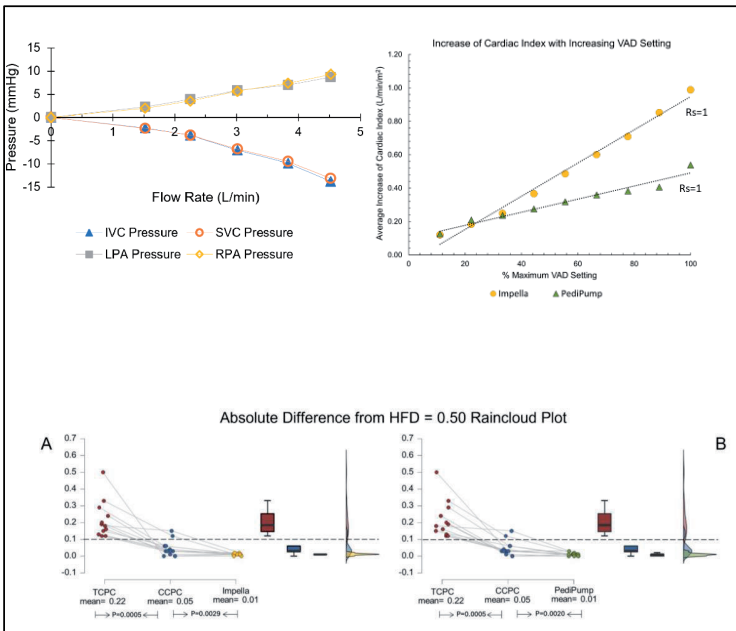
In Vitro Investigation of Axial Mechanical Support Devices Implanted in the Novel Convergent Cavopulmonary Connection (CCPC) Fontan

Summary

- 12 TCPC and CCPC models tested in a in-vitro benchtop model using two MCS devices(Impella RP® and PediPump)
- SVC and IVC pressures, HFD and CI were compared with and without MCS
- Significant decrease in CVP, and improvement in CI and HFD noted with CCPC and MCS
- The CCPC provides a feasible MCS solution by increasing cardiac index, balancing HFD, and decompressing central venous pressure in the Fontan Circulation.



CCPC, Convergent Cavopulmonary Connection; CI, Cardiac Index; CVP, Central Venous Pressure; HFD, Hepatic Flow Distribution; IVC, Inferior Vena Cava; LPA, Left Pulmonary Artery; RPA, Right Pulmonary Artery; Superior Vena Cava; TCPC, Total Cavopulmonary Connection

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Abstract

OBJECTIVES: The 2 opposing inflows and 2 outflows in a total cavopulmonary connection make mechanical circulatory support (MCS) extremely challenging. We have previously reported a novel convergent cavopulmonary connection (CCPC) Fontan design that improves baseline characteristics and provides a single inflow and outflow, thus simplifying MCS. This study aims to assess the feasibility of MCS of this novel configuration using axial flow pumps in an *in vitro* benchtop model.

METHODS: Three-dimensional segmentations of 12 single-ventricle patients (body surface area 0.5–1.75 m^2) were generated from cardiovascular magnetic resonance images. The CCPC models were designed by connecting the inferior vena cava and superior vena cava to a shared conduit ascending to the pulmonary arteries, optimized *in silico*. The 12 total cavopulmonary connection and their corresponding CCPC models underwent *in vitro* benchtop characterization. Two MCS devices were used, the Impella RP® and the PediPump.

RESULTS: MCS successfully and symmetrically reduced the pressure in both vena cavae by >20 mmHg. The devices improved the hepatic flow distribution balance of all CCPC models (Impella RP® $P = 0.045$, PediPump $P = 0.055$).

CONCLUSIONS: The CCPC Fontan design provides a feasible MCS solution for a failing Fontan by balancing hepatic flow distribution and symmetrically decompressing the central venous pressure. Cardiac index may also improve with MCS. Additional studies are needed to evaluate this concept for managing Fontan failure.

Keywords: Fontan redesign • Mechanical circulatory support • Flow loop • Cardiac index • Hepatic flow distribution • Convergent cavopulmonary connection

ABBREVIATIONS

CCPC	Convergent cavopulmonary connection
HFD	Hepatic Flow Distribution
IVC	Inferior vena cava
LPA	Left pulmonary artery
MCS	Mechanical circulatory support
PAs	Pulmonary arteries
RPA	Right pulmonary artery
SVC	Superior vena cava
TCPC	Total cavopulmonary connection
VADs	Ventricle assist devices

INTRODUCTION

With significant improvement in outcomes of staged single-ventricle palliation pathway, patients with Fontan circulation are now surviving into adulthood; however, many develop circulatory failure [1]. The Fontan circulation creates passive venous return to the pulmonary bed to compensate for the lack of a subpulmonary ventricle (Fig. 1A), and the consequent increase in central venous pressure leads to a multitude of issues [2]. Over time, elevated venous pressures and altered haemodynamics create multi-organ dysfunction leading to protein-losing enteropathy, stroke, cyanosis due to pulmonary arterio-venous malformations associated with poor hepatic flow distribution (HFD), hepatic fibrosis and renal insufficiency, which can lead to mortality due to heart failure, thromboembolic events and sudden unexplained cardiac death [1, 3]. Other than heart transplant, interventions for Fontan failure, are at best palliative and temporary [4, 5].

Efficacious and accessible mechanical circulatory support (MCS) for patients with failing Fontan physiology is urgently needed. However, the collision of the superior vena cava (SVC) and inferior vena cava (IVC) inflows in the total cavopulmonary connection (TCPC) potentially leads to vortical flow formation and energy loss [6]. Any MCS to help promote forward flow would therefore require 2 inflows (SVC and IVC), which are not currently incorporated into device designs. Additionally, 2 outflows [left pulmonary artery (LPA) and right pulmonary artery (RPA) branches] are oriented at opposite ends further complicating MCS. The requirement for multiple inflows makes insertion of MCS in this circuit very challenging, fraught with recirculation [7] highlighting the need for novel pumps [8].

Due to the lack of a uniform solution, varying circulatory support strategies have been used with varying results [9–12]. Supporting the systemic ventricle using ventricle assist devices (VADs), which may lead to improvements in systemic cardiac output, but fails to adequately decompress the high central venous pressure [10, 13–15]. Except for isolated reports of successful right (subpulmonary) heart support [11, 12] requiring complete revision of the Fontan circuit, implantation of a device in the IVC alone generates increased pressure in the SVC due to the counter flow generated by the TCPC design or recirculation leading to inefficiencies [5, 16].

We have previously described a novel alternative to the TCPC called the convergent cavopulmonary connection (CCPC) [17] which converges both SVC and IVC flows and directs the total caval return to the pulmonary arteries (PAs) through a common conduit (Fig. 1B). The CCPC design demonstrates several advantages; first, due to complete mixing of SVC and IVC blood, a balanced HFD is observed. The second more important benefit is that the converged venous limb offers a single inflow and outflow, therefore providing an ideal platform for insertion of MCS devices.

Given the urgent need for circulatory support solutions for the growing and ageing Fontan population, this study sought to investigate the feasibility of providing MCS with the CCPC configuration of the Fontan. We hypothesize that the CCPC designs will allow easy institution of MCS, allow symmetrical and uniform decompression of both SVC and IVC pressures with a single device; as well as improve HFD compared to the TCPC designs.

MATERIALS AND METHODS

Ethics statement

The study was approved by the Children's National Hospitals Institutional Review Board (# 00008714, approved 8/2/2017). A waiver of informed consent was obtained.

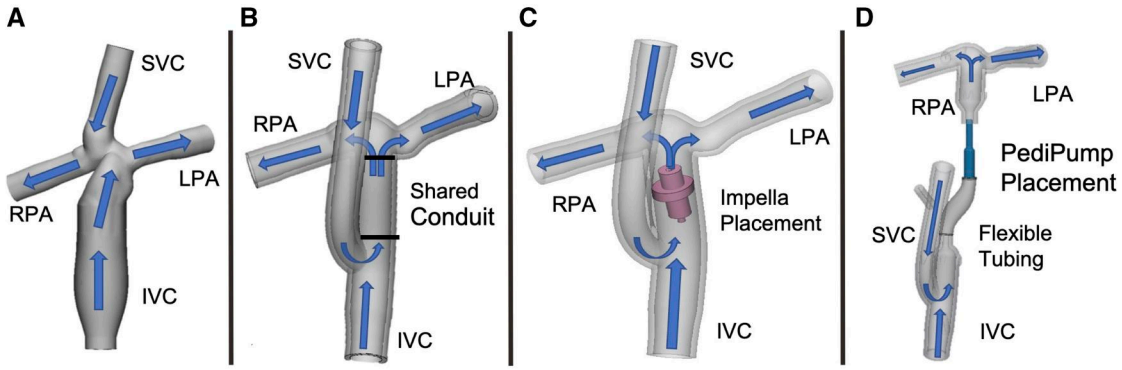


Figure 1: Example of the (**A**) TCPC Fontan and the (**B**) CCPC Fontan. (**C**) Virtual placement of the modified Impella RP® VAD in the CCPC model. (**D**) Virtual placement of the PediPump VAD in the CCPC model with tubing attacments. CCPC: convergent cavopulmonary connection; IVC: inferior vena cava; LPA: left pulmonary artery; RPA: right pulmonary artery; SVC: superior vena cava; TCPC: total cavopulmonary connection; VAD: ventricle assist device.

Table 1: Baseline details of 12 patients whose cardiac Magnetic Resonace Imaging data were used for the design of convergent cavopulmonary connection models

Patient no.	Type of native conduit	BSA (m^2)	Cardiac index (l/min/m)
1	Extracardiac	1.45	2.67
2	Extracardiac	0.80	1.59
3	Extracardiac	0.72	2.34
4	Intra-extracardiac	0.64	2.44
5	Bidirectional glenn	0.71	2.70
6	Bidirectional glenn	0.52	1.40
7	Lateral tunnel	1.54	2.92
8	Lateral tunnel	1.64	2.35
9	Lateral tunnel	1.65	2.60
10	Lateral tunnel	0.89	2.83
11	Lateral tunnel	1.44	2.98
12	Lateral tunnel	1.73	3.07

BSA: body surface area.

CCPC model design and printing

Twelve cardiac magnetic resonance scans from patients with single ventricles at either the second or third stage of staged palliation were used to create digital models of the heart and chest. Each model's derived specifications, including type of Fontan, body surface area and cardiac index, are detailed in Table 1. Digital models were derived from both contrast and non-contrast magnetic resonance angiography (resolution 1 mm × 1 mm × 1 mm to 1.4 mm × 1.4 mm × 1.4 mm), along with patient-specific, phase contrast-informed flow boundary conditions using standard lab procedures described in previous studies [18–21]. Mimics (Materialise, Leuven, Belgium) software was used to segment the heart and anatomy, then exported as stereolithography files.

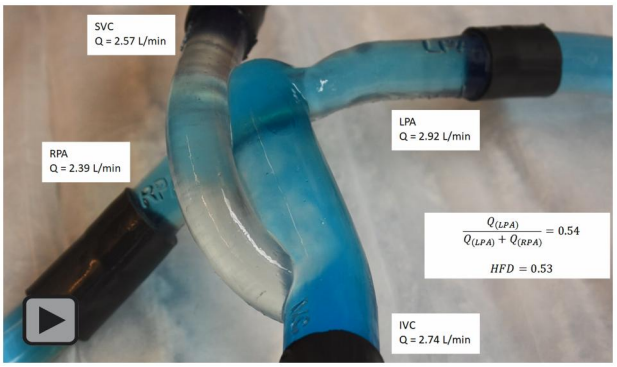
Computational fluid dynamics analysis was used to calculate the PL, HFD and % subphysiologic wall shear stress [18] of the TCPC configuration in these patients. Computer simulations were then used to create the CCPC models, which were optimized to fit in the chest cavity and meet thresholds for these 3 parameters [17]. To prepare the models for printing, the TCPC and CCPC vessels were digitally extended to accommodate tubing attachment. The CCPC vessels were split halfway along the shared conduit, with alignment keys added to the outer surface, to allow for device placement. CCPC and TCPC vessels were printed in Nylon 12 using offsite selective laser sintering printing (Xometry, Gaithersburg, MD).

Flow loop setup

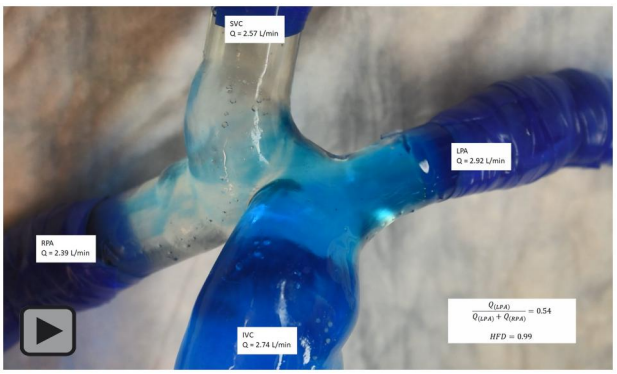
In vitro testing was similar to our previous work with Fontan models [19, 21, 22]. The 24 models (12 TCPC and their 12 corresponding CCPC) were tested on a custom mock circulatory flow loop (Supplementary Material, Fig. S1) to collect haemodynamic end points, including pressure, flow rate and HFD. A solution of 60% water and 40% glycerine was used to mimic blood viscosity. A 12-V diaphragm pump (Flojet 04300143A Electric Pump, Xylem Inc., DC) was used to recreate the patients' cardiac output and was held at a constant rate throughout testing. The model was placed in a closed loop with the diaphragm pump and MCS device in series, allowing for increased flow consequent to increasing MCS device support through the diaphragm pump diastole (and not the entire cardiac cycle) and therefore is expected to underestimate the increase in overall cardiac output with MCS.

Four ultrasonic flow metres (Onicon, Largo, FL) were used to measure the flow of the inlets at the IVC and SVC and the outlets at the LPA and RPA. Ball valves were used to achieve the patient-specific distribution of flow amongst the vessels as observed in their clinical cardiac magnetic resonance. Absolute pressure measurements were collected with pressure transducers (Utah Medical, Midvale, UT). All data were collected with a LabVIEW data acquisition card (National Instruments, Austin, TX).

HFD was measured as the proportion of IVC flow entering the LPA. Measurements within the flow loop setup were based on published methodology [23, 24]. 1% Brilliant Blue Tracer Dye (Cole Palmer, IL, USA) was injected upstream of the IVC. The injection of the tracer dye was controlled with a programmable syringe pump (Harvard Pumps, Holliston, MA). To avoid oversaturation of the solution, the target absorbance range of the output was 0.075–0.200. 20 ml of working solution was drawn from access ports in the LPA and RPA. The concentration of tracer dye was measured using a Nanodrop Spectrophotometer (Thermo Fisher, Waltham, MA), and the absorbance was measured at 628 nm. HFD was calculated using Equation (1), which used the concentration of dye in the LPA and RPA. Videos 1 and 2 provide



Video 1: Visualization of the tracer dye in a clear TCPC.



Video 2: Visualization of the tracer dye in a clear CCPC.

visualization of the tracer dye in a clear TCPC and CCPC model, respectively.

$$\mathrm{HFD} = \frac{[\mathrm{LPA}]}{[\mathrm{LPA}] + [\mathrm{RPA}]}. \quad (1)$$

Circulatory support device integration

Two different pumps were used to provide MCS in the CCPC designs: Impella RP® and PediPump. While baseline data from native TCPC configurations were used for comparison, due to the design limitations of the TCPC, it cannot be effectively supported using a single MCS [7, 25]. Therefore, MCS in TCPC circuits was not done.

An Impella RP® (Abiomed, Danvers, MA) was modified to fit within the printed models (Fig. 1C). The VAD length was reduced to 3 cm by customizing the outflow of the pump. To eliminate recirculation, a custom ring for each model was three-dimensional printed (Formlabs, Boston, MA), occluding the conduit. The VAD was then sealed into the model with the power cable running down the IVC and exiting via a silicone-sealed gasket. The CCPC models were tested with the Impella RP® boosting the baseline cardiac output supplied by the pump, and changes in pressure and flow rate at the IVC, SVC, LPA and RPA were measured. The VAD was tested at varying power settings ranging from 0 (off) up to 9, the maximum power setting determined by the development of negative pressures in the inlet vessels.

A PediPump (Perfusion Solutions, Euclid, OH) accommodation required splitting of the shared conduit and three-dimensional printing clear reducing endcaps (Formlabs, Boston, MA). The VAD was then connected to the shared conduit of the CCPC with PVC tubing (Fig. 1D). The minimum RPM was established at the beginning of testing (6000–7000 rpm) and was then increased in 1000 RPM intervals until negative pressures developed in the IVC and SVC. The pressure and flow rates of the IVC, SVC, LPA and RPA were collected.

Statistical analysis

Repeat measure analysis of variance was utilized for analysing the effect of increasing pump speeds on pressure (CVP) and flows (Cardiac Index). We also analysed the cardiac index relationship with increasing pump support using linear mixed-effect models with a random case effect to account for the repeated measures. This model was also used to compare PediPump and Impella. Spearman rho correlation was used to study the relationship between device RPMs and flow (cardiac index).

HFD was characterized as optimal (% flow to either lung between 35% and 65%) or suboptimal (% flow to either lung $<35\%$ or $>65\%$). Wilcoxon signed-rank test was used for HFD comparisons between groups. Distribution of optimal versus suboptimal HFD was compared between groups using an exact McNemar's test. Raincloud plots to visually display the central tendencies and distributions were created. The statistical analysis was performed and visualized in JASP (JASP team 2022, Version 0.16.4.0, Amsterdam, Netherlands) and SAS V9.4 (SAS Institute Inc., Cary, NC).

RESULTS

Impact of circulatory device on convergent cavopulmonary connection venous pressure

Both pumps reduced the pressures in the SVC and IVC symmetrically and led to an increase in PA pressures (Fig. 2) ($P < 0.001$). The Impella RP® reduced the IVC and SVC pressures by 12–20 mmHg. The PA pressures increased by 7–9 mmHg. The PediPump reduced the pressure in the IVC and SVC by 5–7 mmHg while increasing the PA pressures by 5–13 mmHg (Fig. 2) ($P < 0.001$) (Supplementary Material, Table S1).

Impact of Fontan geometry and circulatory device on hepatic flow distribution

A balanced HFD with equal flow going to the LPA and the RPA was defined as 0.50 (±0.15). Figure 3 visualizes the change in HFD when transitioning from the TCPC models to the optimized CCPC models. While the mean (standard deviation) HFD of the 12 TCPC models was 0.39 (0.22), only 4 (33%) were balanced. The CCPC design improved the HFD for all 12 models compared to their respective TCPC designs ($P = 0.0078$). The mean (standard deviation) absolute deviation from a perfectly balanced HFD of 0.5 was noted to be 0.22 (0.11), 0.05 (0.04), 0.01 (0.01) and 0.01 (0.01) for TCPC, CCPC, CCPC with Impella and CCPC with PediPump, respectively. This was statistically significant for CCPC with Impella when compared to TCPC ($P = 0.045$). This is demonstrated visually in the raincloud plot where variability of HFD goes almost to 0, demonstrating the lack of anatomic influence

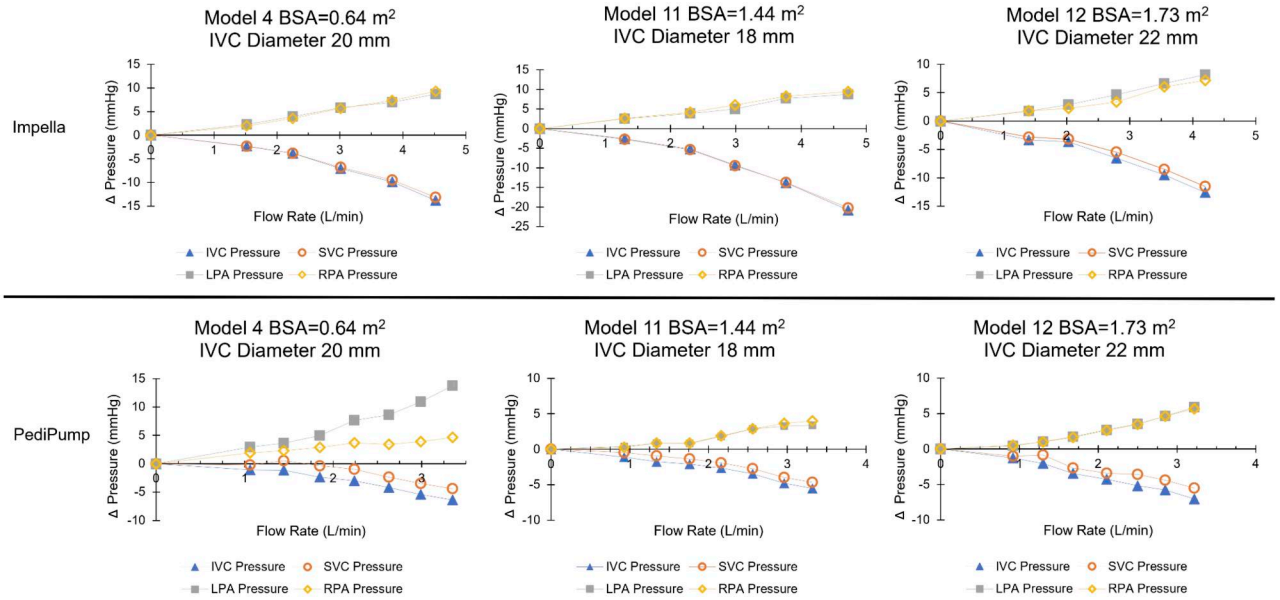


Figure 2: Impact of the Impella RP® (top) and PediPump (bottom) on CCPC venous pressure from small (BSA = 0.64 m^2), medium (BSA = 1.44 m^2) and large (BSA = 1.73 m^2) models. BSA: body surface area; CCPC: convergent cavopulmonary connection; IVC: inferior vena cava; LPA: left pulmonary artery; RPA: right pulmonary artery; SVC: superior vena cava.

on the HFD in a CCPC with a circulatory assist device (Fig. 4) (Supplementary Material, Table S2).

Impact of circulatory device on total flows

Supplementary Material, Fig. S2 presents the mean increase in total flow cardiac index as the device's power is increased when in series with the main pump. The Impella RP® was operated based on the proprietary settings, from 0 (off) to 9 (max), while the PediPump was operated from 6000 to 14 000 rpm. The 2 devices were compared in relation to their percentage of maximum output. Both devices demonstrated a linear correlation, with increasing cardiac index of the models in proportion to the increasing VAD settings ($R = 1$) ($P < 0.01$), which increased significantly compared to baseline with increasing device speeds ($P < 0.001$). The comparison of the cardiac index with increasing pump support revealed a positive association between the cardiac index and pump % of max ($P < 0.0001$) for both pumps (PediPump and Impella). These associations did not differ between the 2 pumps (interaction test $P = 0.1267$). However, the overall mean for Impella was 0.20 (Standard Error = 0.03) higher than PediPump, $P < 0.0001$.

The Impella RP®, operating within the CCPC model, was able to generate >4 l/min flow when the Impella RP® inlet and outlet were separated by an occlusion plug. Without occlusion, the Impella RP® was only able to generate 0.9 l/min actual flow (Supplementary Material, Fig. S3).

DISCUSSION

This study investigated the effects of mechanical circulatory devices implanted in a novel CCPC-type Fontan model using a benchtop mock circulatory loop setup. Data collected demonstrated that the inclusion of a single MCS device within the CCPC leads to improvements in HFD and symmetrical decompression of both the SVC and the IVC with insertion of a single mechanical pump. An increase in cardiac output may also be seen.

With the current TCPC-type Fontan designs and circulatory support options, it is difficult to decompress both SVC and IVC venous beds and increase total cardiac output [25, 26]. Mechanical support in the Fontan, while improving haemodynamics, can also generate high pressures in the PAs [26] or paradoxical increase in the SVC pressure [5]. While there are separate efforts underway to improve the efficiency of the native Fontan TCPC pathway and development of novel MCS devices for a failing Fontan, our aims have focused on combining both objectives. Our proposed CCPC design can achieve both aims by converging SVC and IVC flows, eliminating inflow competition and potentially creating not only a more efficient Fontan circulation at baseline; but also simplifying MCS therapy for a failing Fontan by providing a platform for device placement without competing inflows and outflows [17]. This is a much simpler solution with less cannula material compared to a double-inflow, double-outflow device concept [27].

The combination of the novel CCPC shape with circulatory assist devices was efficacious, without any observable adverse haemodynamic outcomes seen when utilizing a TCPC design. For example, while previous studies with axial pump devices were able to decrease the IVC pressure, a paradoxical increase in SVC pressure was observed [7]. Our benchtop testing demonstrates that within the CCPC model, an axial flow MCS device can adequately reduce the venous pressures of the IVC and SVC symmetrically and also increase pressure in the PAs. While it is difficult to predict which patients may require circulatory support, and when, the timing of placement of a CCPC would trend with timing of placement of a TCPC.

Balancing HFD is a unique challenge to the TCPC design. Formation of pulmonary arterio-venous malformations appears to be linked to poor HFD in patients following TCPC operation [4]. Creating the shared conduit in the CCPC model allows for the mixing of the IVC and SVC blood streams before splitting at the PAs. We have previously demonstrated improvement in the

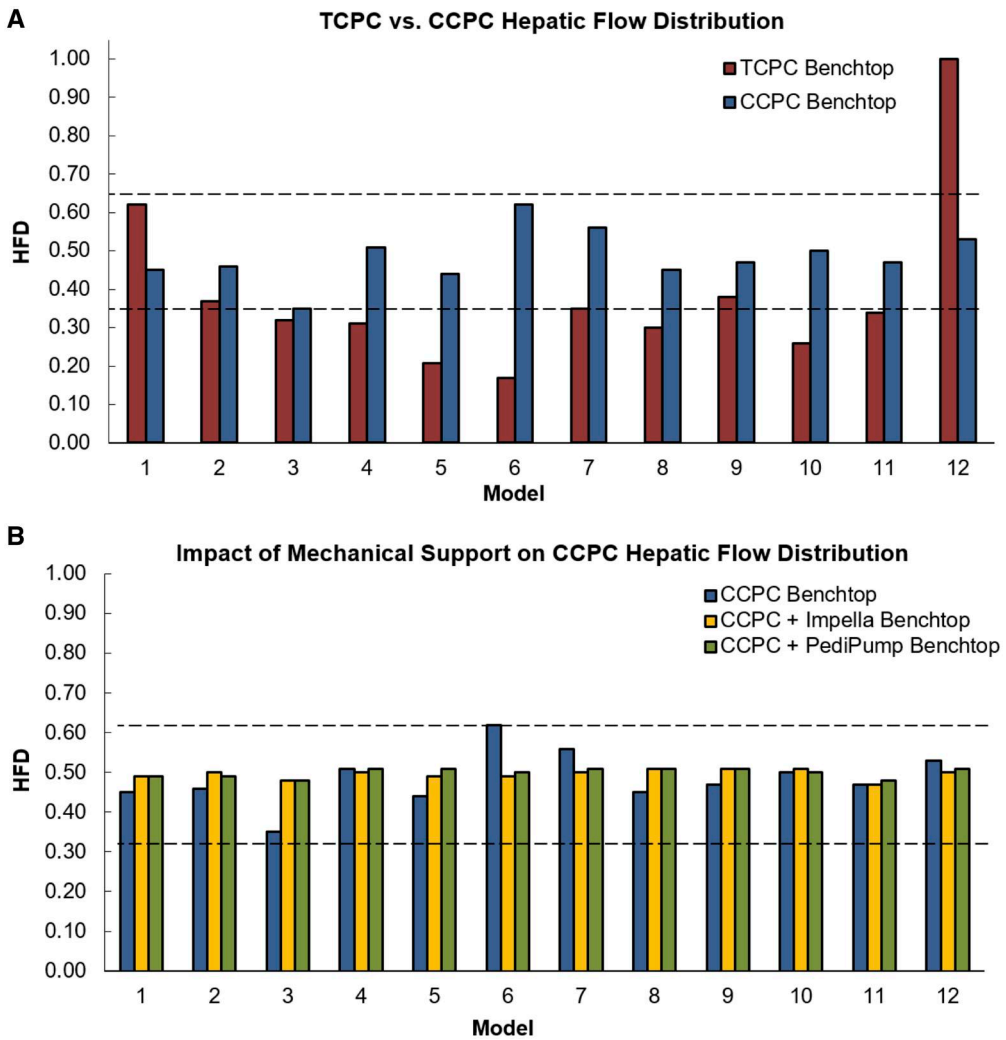


Figure 3: (**A**) Benchtop measurements of hepatic flow distribution (HFD) in the TCPC and CCPC models. (**B**) Benchtop HFD measurements of the CCPC models without and with the mechanical circulatory devices. Dashed lines indicate the target HFD range of 0.50 ± 0.10. CCPC: convergent cavopulmonary connection; TCPC: total cavopulmonary connection.

HFD with CCPC models compared to TCPC [17]. This study shows that addition of a VAD leads to further improved mixing and balancing the HFD.

The use of MCS devices in Fontan patients has been attempted with mixed results. Often, implantation of the devices requires major revision of the Fontan, which carries an increased risk to the patient [9]. Prêtre *et al.* [12] describe the use of the Berlin heart by combining both the IVC and SVC flows before passing through the extracorporeal pump and outputting blood into the IVC [12]. Karner *et al.* [11] successfully reduced the central venous pressure within 2 weeks from 29 mmHg pre-implantation to 13 mmHg. Lacour-Gayet *et al.* [15] demonstrated the ability of an axial flow pump in a shared conduit to reduce IVC and SVC pressure in an idealized Fontan design. Additionally, the problem of circulatory support during staged palliation is a complex issue which deserves innovative exploration for all steps of the stages [28].

Our prior work has shown that the common limb of the CCPC design is most efficient when the SVC flow is converged low and at a perpendicular angle to the IVC [17]. This has the dual advantage of providing a common limb, which is about 18–20 mm in diameter and about 30 mm in length, as space for an MCS device placement. While there are no existing devices on the market that can function within this graft design, development of these pumps is an area of interest. Given the benefits of the novel CCPC configuration, it is possible that adoption of the CCPC conduit design for Fontan creation instead of TCPC may not only improve baseline Fontan performance but also provide a platform for easily incorporating mechanical circulatory devices for blood propulsion in the common limb of the conduit to overcome the Fontan paradox.

*We are exploring novel biomaterials/conduits for construction of the CCPC designs as well as in vivo studies, which will modulate pump performance in turn; thus, this work is iterative.

Limitations

We acknowledge that our study has several limitations. This is an experimental feasibility study providing the proof of the concept of the CCPC design and MCS therapy and requires further investigation to make this approach clinically feasible. Recirculation within the conduit upon placement of the Impella RP® requires incorporation of an occluder device between the pump inflows

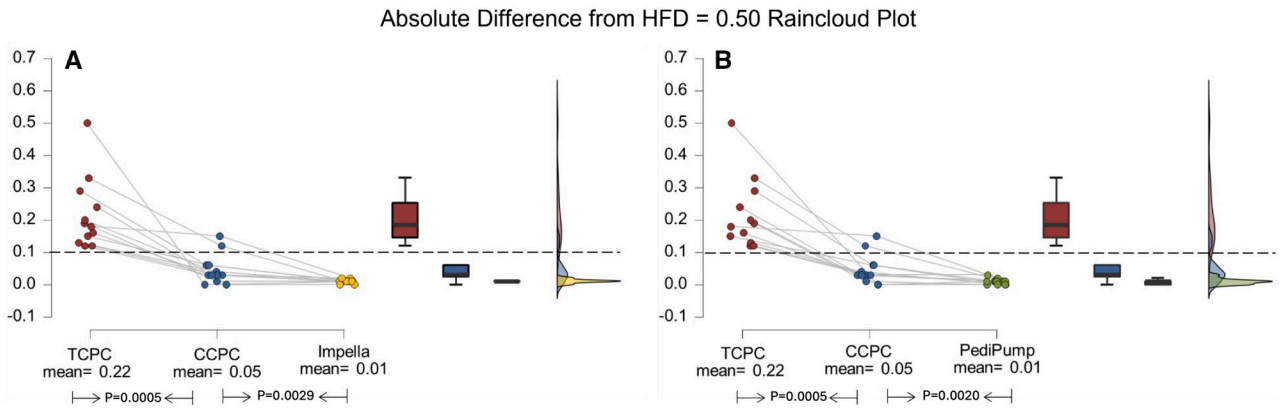


Figure 4: (**A**) Raincloud plots of the absolute difference from a balanced HFD of 0.50 comparing the TCPC models, CCPC models and the CCPC models with Impella RP® device. (**B**) The TCPC models, CCPC models and the CCPC models with PediPump device. The dashed line indicates the targeted design threshold for HFD balance of 0.50 ± 0.10. CCPC: convergent cavopulmonary connection; HFD: hepatic flow distribution; TCPC: total cavopulmonary connection.

and outflows [29], which would clinically create an area of stasis in the conduit prone to thrombosis. The mock circulatory loop, while allowing theoretical testing of the haemodynamics in the cavopulmonary circuit, is more reliable for testing HFD and venous pressure decrease but is not ideal for assessing overall systemic cardiac output increase. Future work will focus on creating a mock flow loop that better mimics physiological venous return mechanisms to accurately collect cardiac output and pressure data. The rigid walls of the models do not consider the dynamic vascular resistance or compliance of an organic system.

The CCPC design has demonstrated potential benefits for improving the haemodynamics of Fontan patients within *in vitro* studies. Further work including preclinical animal studies would be essential for investigating the *in vivo* implications of the CCPC graft design and MCS are required to observe efficacy and drawbacks of this approach within a living circulatory system. Although our experiment and results are still exploratory, they would support that the CCPC with circulatory support device would likely be an effective therapy for the subgroup of failed Fontans with elevated central venous pressures, consistent with recent clinical multi-site evidence [30].

CONCLUSION

This *in vitro* investigation demonstrates the feasibility of axial flow pumps within a modified CCPC Fontan design with beneficial effects on the HFD and easy decompression of both the IVC and SVC with a single device. Utilization of the CCPC Fontan design and development of high redundancy pumps for the common limb can potentially solve the Fontan paradox.

SUPPLEMENTARY MATERIAL

Supplementary material is available at *EJCTS* online.

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Conflict of interest: none declared.

DATA AVAILABILITY

The data underlying this article are available in the article and in its online supplementary material.

Author contributions

Vincent Cleveland: Data curation; Formal analysis; Methodology; Project administration; Resources; Software; Visualization; Writing—original draft. **Jacqueline Contento:** Data curation; Formal analysis; Investigation; Methodology; Project administration; Software; Validation; Visualization; Writing—review & editing. **Paige Mass:** Data curation; Formal analysis; Investigation; Methodology; Project administration; Resources; Software; Validation; Visualization; Writing—review & editing. **Priyanka Hardikar:** Investigation; Methodology; Software; Writing—original draft. **Qiyuan Wu:** Investigation; Software; Validation. **Xiaolong Liu:** Investigation; Software; Validation. **Seda Aslan:** Investigation; Methodology; Software. **Yue-Hin Loke:** Resources; Supervision; Validation; Visualization; Writing—review & editing. **Scott Lunos:** Formal analysis. **Axel Krieger:** Funding acquisition; Methodology; Project administration; Resources; Supervision; Validation; Visualization; Writing—review & editing. **Laura Olivieri:** Conceptualization; Funding acquisition; Project administration; Resources; Supervision; Writing—original draft; Writing—review & editing. **Pranava Sinha:** Conceptualization; Funding acquisition; Methodology; Project administration; Resources; Supervision; Visualization; Writing—original draft; Writing—review & editing.

Reviewer information

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