# USE OF EXTERNAL PRESSURE APPLICATION TO AUGMENT FONTAN HEMODYNAMICS

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## Motivation

- The incidence of patients born with functional univentricular physiology is approximately 2 per every 1000 births. Without surgical intervention, the combination of cardiac anomalies is fatal within the first 2 weeks of life.
- The Fontan procedure has remained the prominent means of surgical palliation for these patients with modifications and staging evolving over the past three decades.
- The total cavopulmonary connection (TCPC) is an example of the extracardiac Fontan first described by de Leval et al. This procedure connects the inferior vena cava (IVC) and superior vena cava (SVC) directly to the main right pulmonary artery. The resulting Fontan configuration of the univentricular anatomy leads to an increased workload on the systemic ventricle due to a loss of kinetic energy from the lack of a subpulmonary ventricle (Figure 1).
- Improved management strategies and continued research of the Fontan physiology and its response to treatment may reduce the risk of developing late stage morbidity. Research indicates that an afterload reducing agent improves ventricular-vascular interactions and Fontan hemodynamics.
- Few therapeutic alternatives exist for the failing Fontan patient beyond medical therapy and ultimately heart transplantation.
- To address this need for novel therapeutic options, we are developing an external pulsation system as a long-term clinical management strategy.
- The inflation and deflation of these trousers applies circumferential pressure to the lower extremities which translates into a forward propulsion of blood and an increase in venous return pressure (Figure 2).

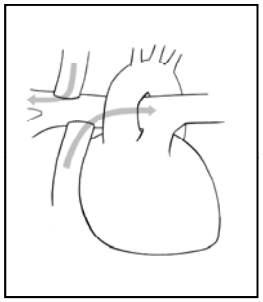
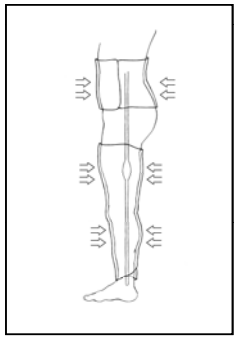


**Figure 1: Fontan Total Cavopulmonary Connection.** Direct connection from the great veins (IVC and SVC) to the pulmonary arteries.



- The external pulsation is designed to provide mechanical pressure augmentation of blood flow from the IVC to the lungs, thus enhancing cardiovascular hemodynamics through improved systemic pressure, increased ventricular filling, and augmented cardiac output.
- In order to assess the feasibility in design we executed a clinical study using commercially available MAS trousers on Fontan patients. We hypothesized that routinely administered, non-invasive, external pulsation will: 1) enhance flow from the great veins through the lungs, and 2) will improve functional and exercise capacity in these patients with single ventricle physiology.

**Figure 2: External pressure application to lower limbs and abdomen using MAS trousers.** Hypothesized forward propulsion of blood, illustrated as a bolus in the mid-thigh above, due to external pressure to augment Fontan circulatory hemodynamic.

## Methods

- VCU Investigational Review Board (IRB) approval was obtained for this study (HM #11906).
- The study population consisted of volunteer subjects aged 10 to 45 years who are recruited by staff and participating personnel. All subjects had a previously scheduled, dual-sided, cardiac catheterization.
- Two sets of MAS trousers (David Clark Company Incorporated, Worcester, MA, U.S. Patent No. 3933150) were procured and retrofitted for the pulsation studies: an adult size and a pediatric size (Figure 3).
- The pressure compartments on these MAS trousers were individual such that the abdominal sections were interchangeable as well as the lower extremity sections
- System pressure application was provided via two means of airflow, coarse and fine adjustments, laid in series to the pressure garment.
- Bulk airflow to generate pressures accurate within approximately 10 mmHg originated from a standard air pump (Intertek Listed, Model: HB-505B).
- The pressure gage was added to the system in parallel to airflow through the trousers compartments, downstream of the pump and upstream of the patient.

## Methods(*continued*)

- The subjects (n=2) were placed in the supine position with the MAST garment applied but not inflated.
- Baseline measurements of blood pressure, cardiac output, respirations, right atrial pressure / central venous pressure, and pulmonary capillary wedge pressure, $O_2$ sat, and heart rate were taken. Based on the patient's diastolic pressure, we determined three separate pressure points to evaluate, up to 20 mmHg above their diastolic pressure.
- The MAS trousers were inflated and a circumferential pressure was applied to the lower extremities similar to a blood pressure cuff. This pressure was held for 20 to 40 seconds and then released for 10 seconds and then was applied again. These intermittently applied pressures at the first pressure point occurred for 3 to 5 minutes. Clinical measurements were ongoing.
- A brief rest period was provided between selected pressure point cycles.

## Clinical Results

- The three external pressures were applied to the lower limbs of the both patients and abdominal section of patient 1 were determined based upon mean baseline calculations (Table 1).
- As external pressure was applied, real-time aortic augmentation was visually perceptible (Figure 5A,5B).
- Patient 1 developed measurable pressure augmentations during all three external pressure levels; increase in cardiac pressure ranged from approximately 9-15 mmHg in systolic blood pressure, 4-10 mmHg in diastolic blood pressure, and 5-11 mmHg in calculated MAP.
- Patient 2 also developed detectable pressure rises during cycles of external pressure application demonstrating systolic pressure augmentation of approximately 10 -13 mmHg, diastolic increase of 5-7.5 mmHg and improvements to calculated VMAP of 3 – 9 mmHg.
- Patient 1 demonstrated a linear average aortic pressure response to external pulsation (Figure 6A). Patient 2 demonstrated an uncharacteristic response, however average aortic pressure augmentation was achieved (Figure 6B).
- Results from this clinical trial with two patients (n=2) indicate that MAS trousers successfully augmented venous return, systemic pressure, cardiac output, and blood pressure.

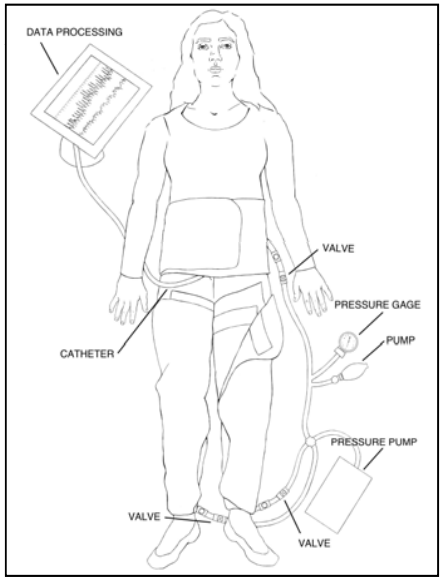



**Figure 3: Sketch of retrofitted MAS trousers used for pulsation clinical trials.**

## Clinical Results(*continued*)

**Table 1: Patient baseline pressure measurements and applied external pressure data.**

| Patient | Age | Gender | Cardiac Anatomy | Baseline Aortic Pressures (mmHg) | | | 1st Pressure Point (mmHg) | 2nd Pressure Point (mmHg) | 3rd Pressure Point (mmHg) |
|---|---|---|---|---|---|---|---|---|---|
| | | | | Systolic BP | Diastolic BP | MAP | | | |
| 1 | 37 | female | Extra-Cardiac Fontan | 94 | 47 | 63 | 37 | 47 | 57 |
| 2 | 24 | male | Intra-Atrial Fontan | 117 | 79 | 92 | 69 | 79 | 89 |

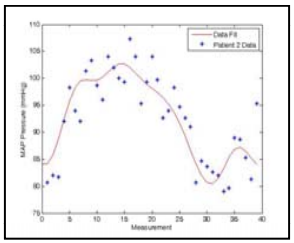


**Figure 4: Aortic pressure augmentation to patient 2 during a selected cycle with external pressure augmentation at the 2nd pressure point.** External pulsation effects can be seen through aortic pressure augmentation. Measurements correspond to pressure calculations as a function of time with regard to patient heart rate.

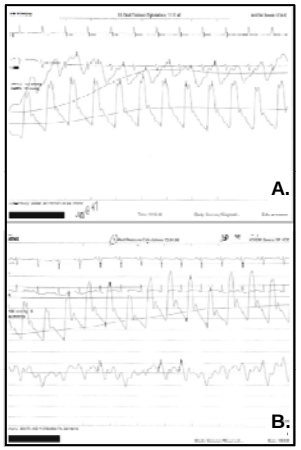



**Figure 5: Sample pressure data from external pressure augmentation obtained during cardiac catheterization.**: A)Patient 1 during upstroke of external pressure at 2nd pressure point. B) Patient 2 during upstroke of external pressure application at 1st pressure point.

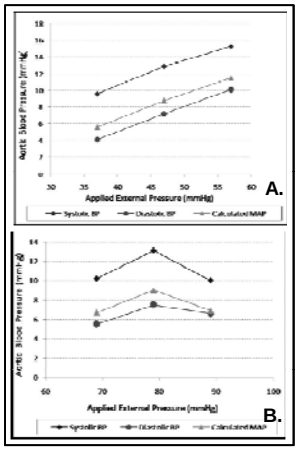



**Figure 6: Average aortic augmentation to baseline pressure as a function of applied external pressure.** A) Patient 1 demonstrated a linear response. B) Patient 2 demonstrated an uncharacteristic augmentation response.

## Conclusions

This study presented the results from a clinical trail (n=2) designed to evaluate the performance of external pressure application to the lower limbs designed to augment Fontan hemodynamics. There is evidence to suggest that pressure application to the lower extremities redistributes blood volume to the thorax thus resulting in an increase in both venous return and stroke volume.

Data from the clinical trials provide evidence that the external mechanical compression of lower vasculature increased venous pressure in both patients. Additional trials will be done to substantiate our conclusions and provide support to our efforts in designing our new medical device.

## Acknowledgements

The Thomas F. and Katie Jeffress Memorial Trust, American Heart Association Beginning Grant-in-Aid, the National Science Foundation BRIGE Award, the 2009 Oak Ridge Associated Universities (ORAU) Ralph E. Powe Junior Faculty Award, and the U.S. Department of Education GAANN Interdisciplinary Graduate Engineering Education and Research (I-GEEAR) fellowship awards (S.S. Bhavsar).