In Vitro Pulsatile Performance Evaluation of the HeartMate PHP™ (Percutaneous Heart Pump)

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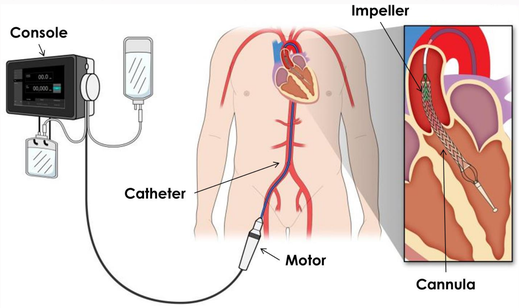
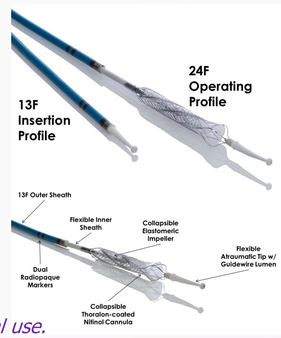
HeartMate PHP Overview

- The HeartMate PHP is a 13F catheter-based trans-aortic heart pump with a collapsible distal portion that expands to 24F to provide minimally invasive acute hemodynamic stabilization and left ventricular unloading in both prophylactic and emergent clinical settings.
- The HeartMate PHP is designed to maintain vital organ perfusion, augment coronary perfusion, reduce ventricular loading and myocardial oxygen consumption for High Risk Percutaneous Coronary Intervention (HR-PCI) and Cardiogenic Shock (CS) patients.*





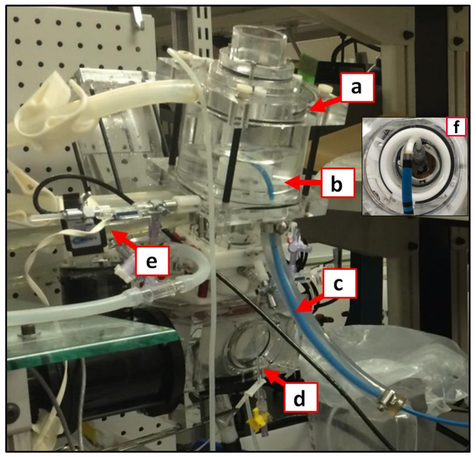
*Device in clinical investigation. Not available for commercial use.

Objective

- To evaluate the interaction of the HeartMate PHP with native cardiovascular system via in vitro pulsatile mock flow loop testing

Pulsatile Left Ventricle Simulator (PLVS)

- A custom-built pulsatile heart simulator adapted from Vivitro Pulse Duplicator (Vivitro Labs Inc., Canada) was tuned to generate physiological flow pressure waveforms while mimicking the preload sensitivity of the native heart.
- The HeartMate PHP expanded and mounted across the aortic valve.
- The systemic vascular impedance of the PLVS was adjusted to simulate typical pre-op hemodynamics HR-PCI and CS patients.
- Total cardiac output (CO) and pressures were measured with ultrasonic flow sensors and pressure transducers.
- Ventricular unloading is characterized by analyzing pressure-volume (PV) loops, and derived cardiac indices (See Table) at 16k, 18k and 20.5k RPM pump speeds.



PLVS: (a) aortic chamber, (b) aortic valve, (c) HeartMate PHP, (d) ventricle chamber, (e) aortic flow sensor, (f) PHP across the aortic valve

Frank-Starling Response of the PLVS

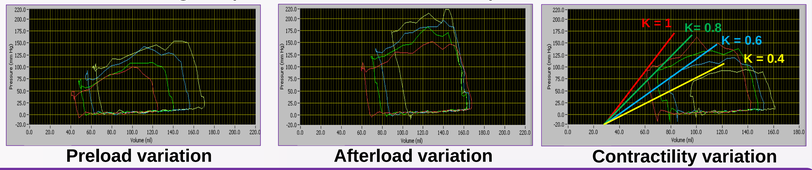
- PLVS allows left ventricle (LV) to adjust the stoke volume based on preload and afterload changes through a closed loop PID feedback control algorithm implemented in Labview (National Instruments, TX).
- LV pressure and volume relationship is prescribed through a time varying elastance function given below.

$$E(t) = \begin{cases} \frac{KE_{max}}{2} \times \left(1 - Cos\left[\frac{4}{3}\pi\frac{t}{t_{sys}}\right]\right) & 0 < \frac{t}{t_{sys}} < 0.75 \\ \frac{KE_{max}}{2} \times \left(Cos\left[4\pi\left(\frac{t}{t_{sys}} - \frac{3}{4}\right)\right] + 1\right) & 0.75 < \frac{t}{t_{sys}} < 1 \end{cases}$$

$$P_{LV}(t,x) = E(t) \times (V_{LV}(x) - V_o) + \gamma \times e^{\delta (V_{LV}(x) - V_o)}$$

$E(t)$: *time-varying elastance*
K : *contractility multiplier*
E_{max} : *maximum elastance*
t_{sys} : *systolic phase*
P_{LV} : *left ventricle pressure*
V_{LV} : *left ventricle volume*
V_o : *unloaded LV volume*
γ, δ : *diastolic filling coefficients*

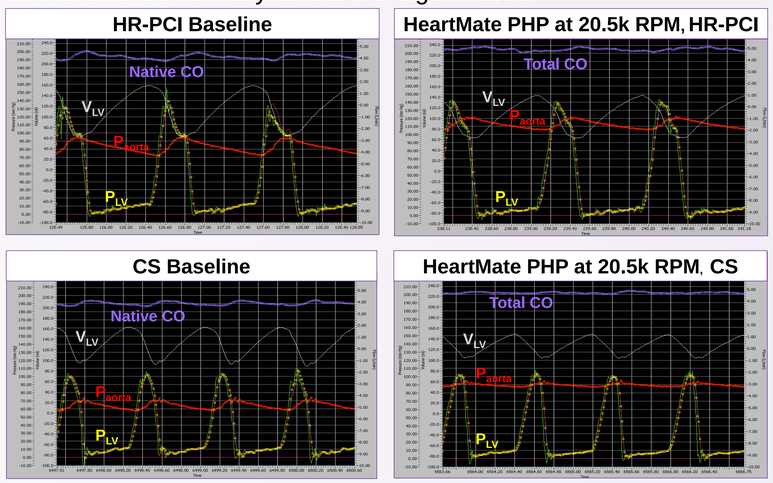
- Frank-Starling response is confirmed via preload-afterload variation.



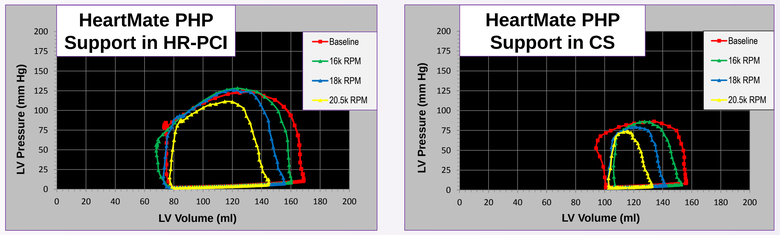
Preload variation | **Afterload variation** | **Contractility variation**

HeartMate PHP Pulsatile Hemodynamics

- Physiological aortic flow and pressure waveforms representative of HR-PCI and CS hemodynamics were generated.



- Upon activation Heartmate PHP shifted PV loops gradually towards left reducing EDV and SV as a function of the pump speed.



Left Ventricle Unloading Characteristics

Test Condition	Speed (RPM)	MAP (mm Hg)	Total CO (LPM)	EDV (ml)	SV (ml)	SW (mm Hg x L)	PVA (mm Hg x L)
HR-PCI (n=3)	Baseline	83±4	4.3±0.2	164±4	91±3	10.4±0.6	11.9±0.5
	16k	91±2	4.6±0.3	158±1	89±2	10.1±0.3	11.6±0.2
	18k	99±3	4.8±0.3	157±2	83±2	9.4±0.3	10.9±0.2
	20.5k	112±3	5.1±0.3	150±2	72±3	8.1±0.2	9.8±0.1
CS (n=3)	Baseline	66±2	3.5±0.4	156±6	57±7	5.1±0.5	7.5±0.6
	16k	75±1	3.7±0.4	151±8	47±6	4.1±0.5	6.5±0.3
	18k	83±2	3.9±0.5	147±9	38±7	3.3±0.6	5.9±0.5
	20.5k	95±4	4.2±0.4	141±12	27±3	2.3±0.3	5.0±0.4

MAP, Total CO, EDV, SV, SW, PVA *: Mean Aortic Pressure, Total Cardiac Output = native heart flow + PHP flow, End Diastolic Volume, Stroke Work, Pressure Volume Area [1]*

- The HeartMate PHP increased the total CO by 0.8±0.3 LPM and MP by 29±4 mm Hg from baseline HR-PCI hemodynamics at its maximum speed setting.
- The HeartMate PHP unloaded the ventricle by reducing all cardiac indices significantly (EDV: 9%, SV: 21%, SW: 22% and PVA: 17%, $p<0.05$) from baseline HR-PCI state.
- Under CS settings, the HeartMate PHP lowered the workload of the ventricle dramatically (lowering SV: 53%, SW: 54%, PVA: 33%, $p<0.05$), also resolved the hypotensive state by elevating MAP from 66±2 to 95±4 mm Hg and increased the total CO by 0.7 LPM from the baseline.

Summary

- This study demonstrates the systemic hemodynamic improvements and the effective ventricular unloading ability of the HeartMate PHP under clinically relevant pulsatile loading conditions of HR-PCI and CS.
- Results indicate that the HeartMate PHP restores the total cardiac output (+1 LPM) and boosts the aortic pressure (+30 mm Hg) to enhance the end organ perfusion and coronary perfusion, respectively.
- The HeartMate PHP reduced the total mechanical energy consumed by the native heart (SW, PVA) substantially, which correlates to a clinically meaningful reduction in the myocardial oxygen demand [1].
- It is worthwhile to note that the HeartMate PHP reduced the forward flow contribution of the native heart substantially (up to 90%) while maintaining the increased total CO mainly through the pump flow.

References

1. Suga H., “Ventricular pressure volume area as a predictor of cardiac oxygen consumption”, Am J Physio. 1981;240:H39-44

Disclosures

- All of the authors are employees of Thoratec Corporation.