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.  

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 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 chambers, (e) aortic flow sensor, (f) PHP across the aortic valve

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

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:

\[ E(t) = \frac{K}{2} \left( t - t_o \right) - \frac{1}{2} \left( 1 - C_d \frac{4}{3} \left( \frac{t - t_o}{t_o} \right)^{3/2} \right) \]

\[ E(t) = E(t) + E(t) \frac{V_p}{L} (x(t) - V_o) + \gamma \left( e^{\gamma(t-t_o)} - 1 \right) \]

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

HeartMate PHP at 20.5k RPM, HR-PCI
- Upon activation Heartmate PHP shifted PV loops gradually towards left reducing EDV and SV as a function of the pump speed.

HeartMate PHP at 20.5k RPM, CS
- 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

<table>
<thead>
<tr>
<th>Test Condition (RPM)</th>
<th>Speed (mm Hg)</th>
<th>MAP (mm Hg)</th>
<th>Total CO (LPM)</th>
<th>EDV (ml)</th>
<th>SV (ml)</th>
<th>SW (LPM)</th>
<th>PVA (mm Hg x L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HR-PCI</td>
<td></td>
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<tr>
<td>Baseline</td>
<td>16k</td>
<td>4.6±0.5</td>
<td>158±1</td>
<td>89±2</td>
<td>10.1±0.3</td>
<td>11.6±0.2</td>
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<tr>
<td></td>
<td>(n=3)</td>
<td></td>
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<tr>
<td>18k</td>
<td>4.8±0.3</td>
<td>157±2</td>
<td>83±2</td>
<td>9.4±0.3</td>
<td>10.9±0.2</td>
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<tr>
<td>20.5k</td>
<td>5.1±0.3</td>
<td>150±2</td>
<td>72±3</td>
<td>8.1±0.2</td>
<td>9.8±0.1</td>
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<tr>
<td>CS</td>
<td>66±2</td>
<td>3.5±0.4</td>
<td>156±6</td>
<td>57±7</td>
<td>5.1±0.5</td>
<td>7.5±0.6</td>
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<tr>
<td></td>
<td>(n=3)</td>
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<tr>
<td>18k</td>
<td>3.9±0.5</td>
<td>147±9</td>
<td>38±7</td>
<td>3.3±0.6</td>
<td>5.9±0.5</td>
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<tr>
<td>20.5k</td>
<td>4.2±0.4</td>
<td>141±12</td>
<td>27±3</td>
<td>2.3±0.3</td>
<td>5.0±0.4</td>
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</tr>
</tbody>
</table>

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

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

Disclosures
- All of the authors are employees of Thoratec Corporation.