

CIMS Balloon Pump : A Novel Left Ventricle Assist Device (LVAD)

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1) Background

In the UK, death from heart failure (HF) is at 24,000 in 2001, while new cases of HF is estimated to be at 63,500 every year. The probability of death within one year of diagnosis is 40%, if untreated ⁽¹⁾.

Heart failure treatment varies from lifestyle change, pharmacological treatment or surgical intervention. For advanced stages HF patients, heart transplant is the gold standard treatment. However, since donors are scarce resulting only 3000 operation/year worldwide, the next best treatment is *mechanical heart assist device*.

3) Chronic Intermittent Mech. Support (CIMS)

It has been reported that with prolonged mechanical support and pharmacological treatment a specific cohort of patient is able to develop and sustain HF reversal ⁽³⁾.

Chronic Intermittent Mechanical Support (CIMS) is a modality treatment that targets a specific cohort of patient suffering Dilated Cardiomyopathy (DC) or congestive heart failure (CHF). The treatment focuses on treating the patient by lowering the load on the patient's heart and increasing oxygen supply to the myocardium. It is designed for continuous activation, although it can be turned on and off depending on the patient's condition. It will be placed in the ascending aorta, thus being a left ventricle assist device (LVAD). CIMS advantages are:

- Easy to implant
- Long term usage
- Ambulatory (easy to carry around)
- Can be turned on/off & console removed
- Promoting heart recovery
- Relatively cheaper than IRBP
- Earlier (less aggressive) intervention.

The CIMS uses balloon pump, a displacement-type heart assist device counterpulsed like an Intra Aortic Balloon Pump (IABP).

CIMS is actuated by a percutaneous gas driveline connected to a portable console and battery pack.

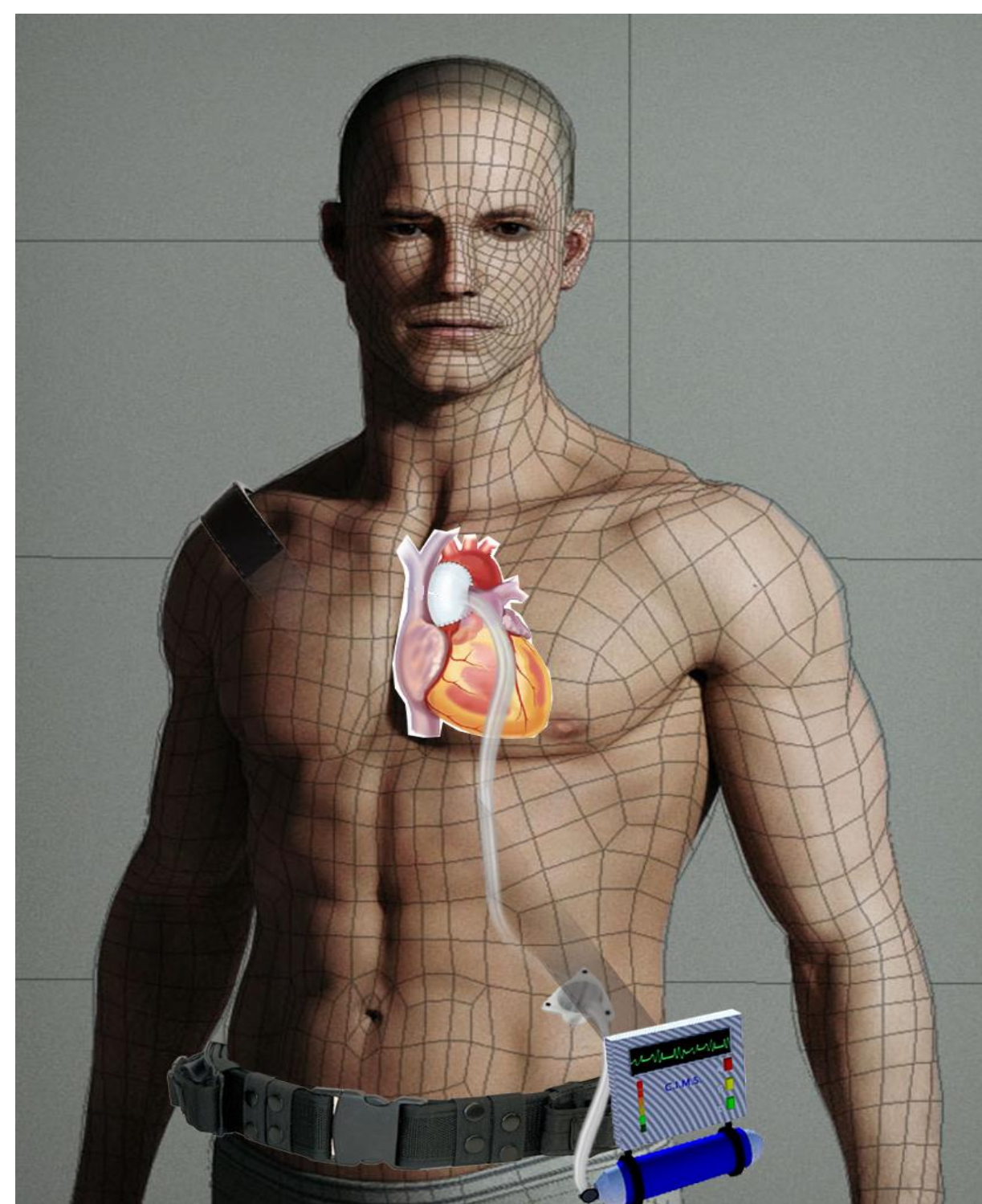


Figure 1: CIMS in concept

2) Aim & Objective

The aim of this study is to develop mechanical heart assist device specifically for left ventricle i.e. left ventricular assist device (LVAD) system that is able to restore heart health by reverse remodelling (self healing process). It is hypothesized reverse remodelling can be achieved by decreasing load faced by heart and increasing coronary perfusion. As such, objectives of this study are

- To develop a prototype of balloon pump
- To determine ventricular work reduction
- To optimize of balloon pump design, including for in-vivo experiment

In this poster, the first two objectives' result is presented.

4) IABP – the benchmark device

Intra aortic balloon pump (IABP) is a short term displacement type mechanical heart assist device used before or during a cardiac operation to increase coronary artery perfusion and unload the left ventricle.

IABP is placed in the descending aorta around 10 to 20mm distal of the subclavian artery. – usually via femoral artery cannulation. It is counterpulsed to increase aortic pressure during diastole; the balloon pump is inflated after the aortic valve is closed and deflated just before the start of the next systole. Example of counterpulsation is as per Figure 2.

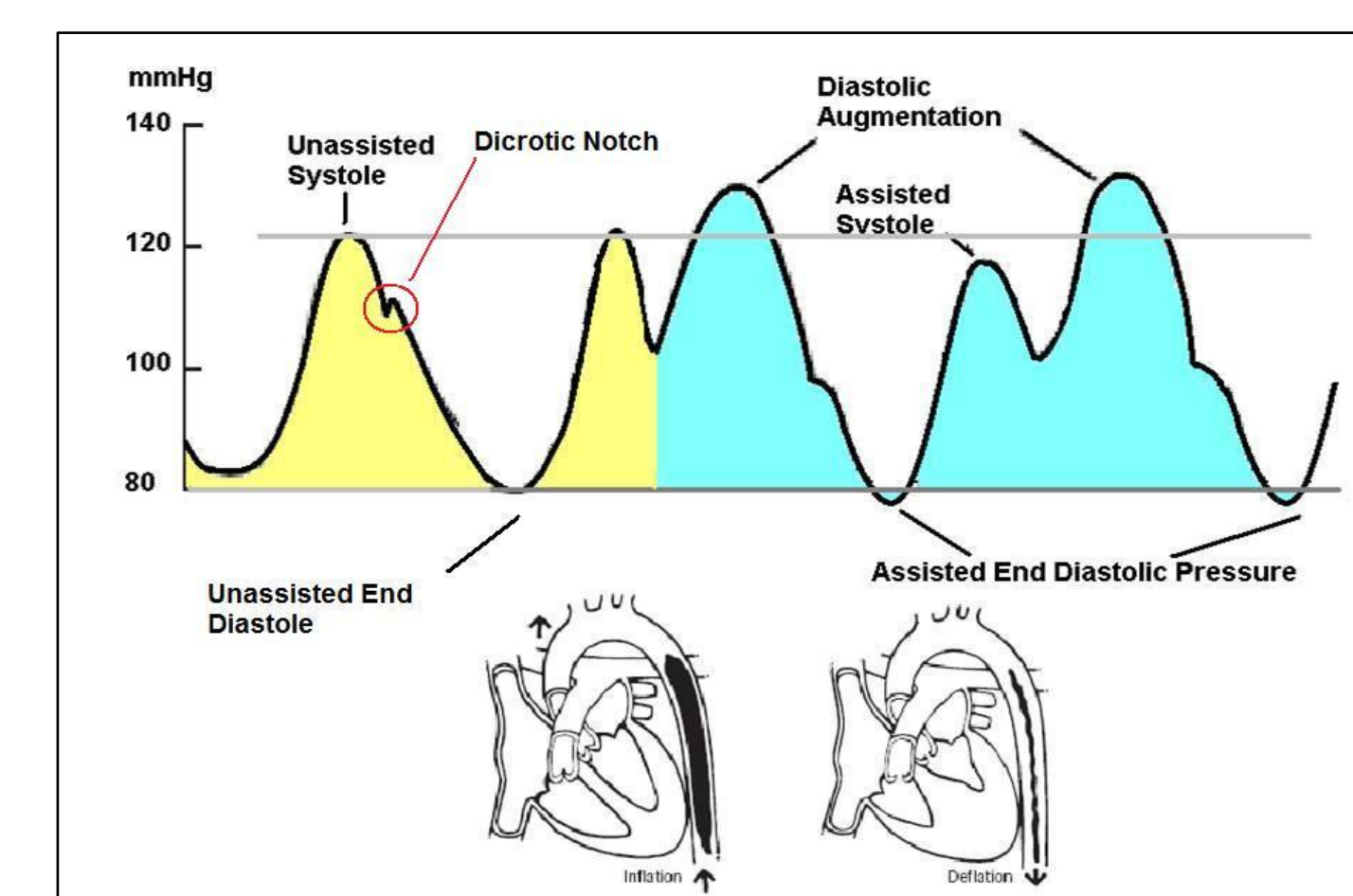


Figure 2: Counterpulsation effect on aortic pressure and activation of IABP

A major drawback due to femoral access, IABP recipients are bed bound and can suffer reduced perfusion of the cannulated leg.

5) Method

A prototype balloon pump was developed - the outer body has a hard casing with a flexible silicone membrane inside it. The CIMS balloon pump prototype is placed just distal of the aortic valve in a human mock circulatory loop (MCL).

The MCL is capable of simulating a variety of heart condition by adjusting left ventricle (LV) silicone sack contraction and peripheral resistance.

Other than systemic circulation simulating LV and aortic flow, it is also equipped with left coronary artery (LCA) circulation. The LCA tube is placed just distal of the aortic valve and consists of a flow sensor, compliance syringe, pressure transducer and systolic resistor to simulate systolic compression of myocardium affecting the LCA.

The CIMS balloon pump is connected to an IABP driver console. Once HF condition is set on the MCL the CIMS balloon pump is activated at 1:1 ratio i.e. at every heart beat triggered at the aortic valve. Data was taken for non-assisted flow and assisted flow for 40 seconds. Several parameters were measured and student t-test was used to determine the significance of flow augmentation.



Figure 4 : Balloon Pump Prototype

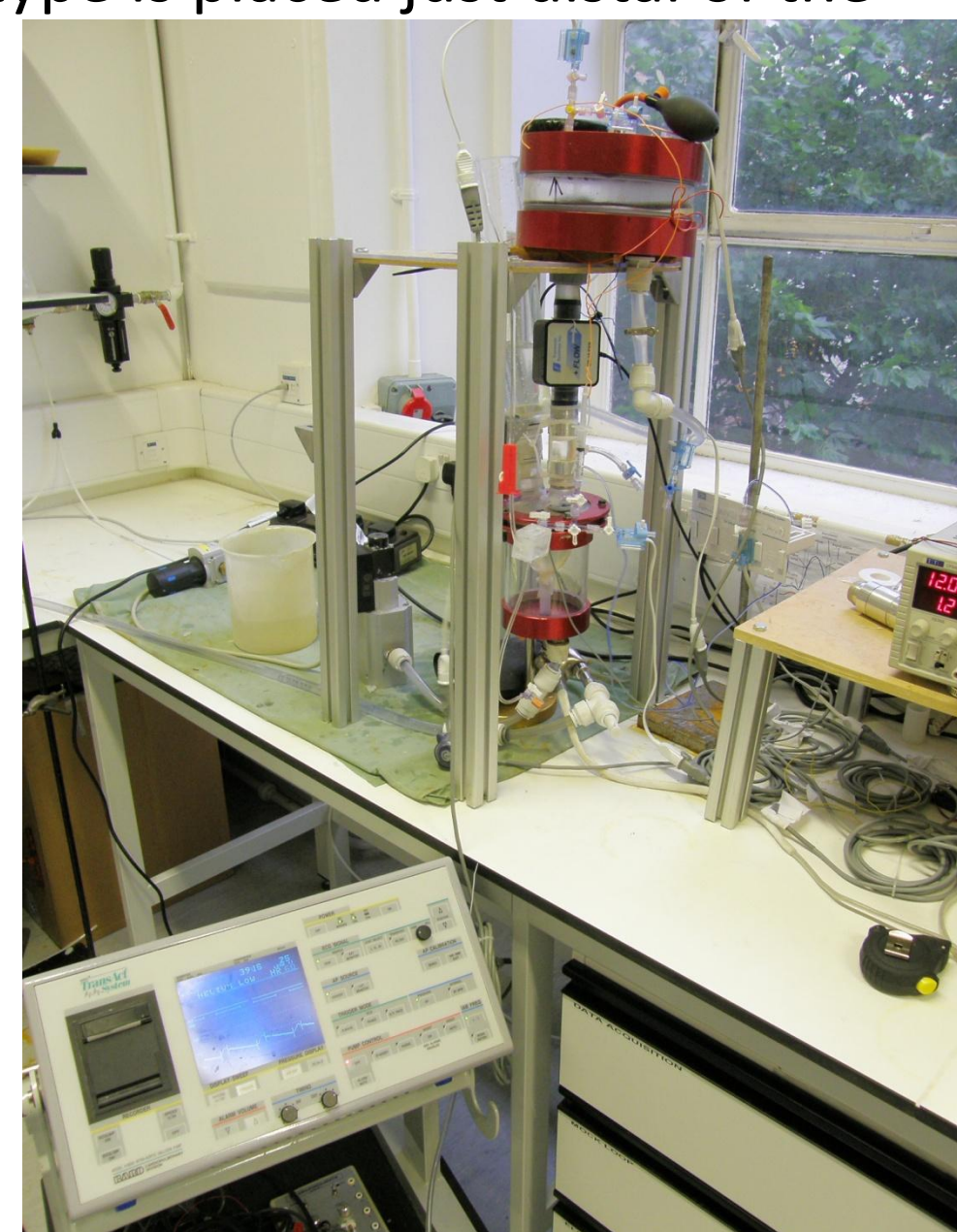


Figure 3: Mock Circulatory Loop with an IABP driver console

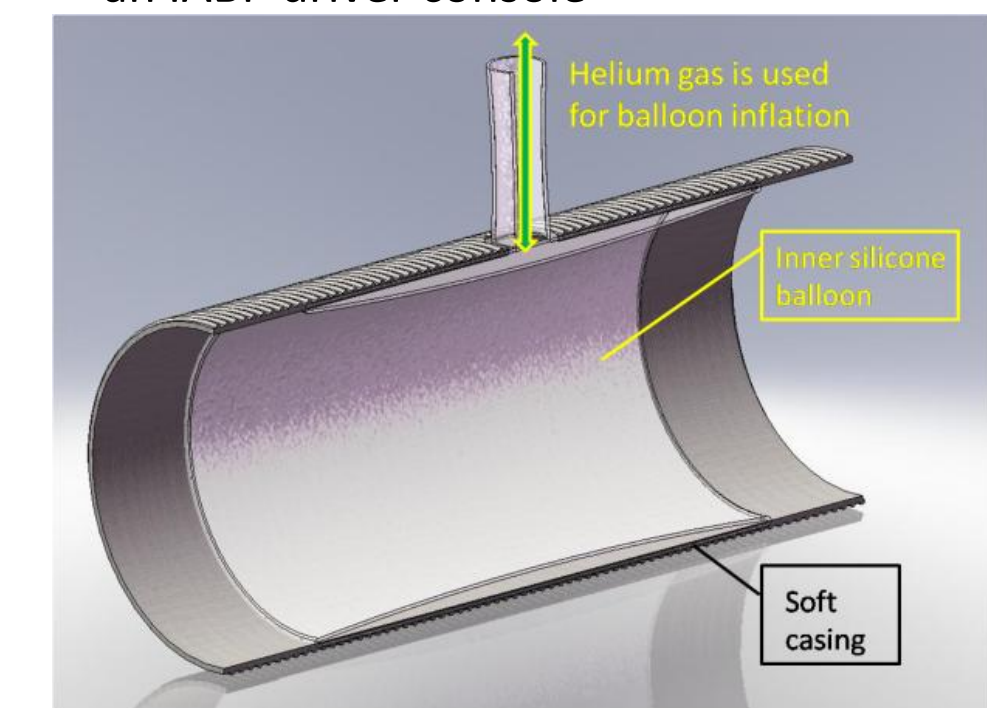


Figure 5: Concept design of in-vivo balloon pump

6) Result

The preliminary results using a CIMS balloon pump housing are very promising. A graph of aortic pressure, aortic flowrate and left coronary flowrate is presented in Figures 6 and 7 respectively. The numerical values (with standard deviations) for main parameters of interest appear in Table 1.

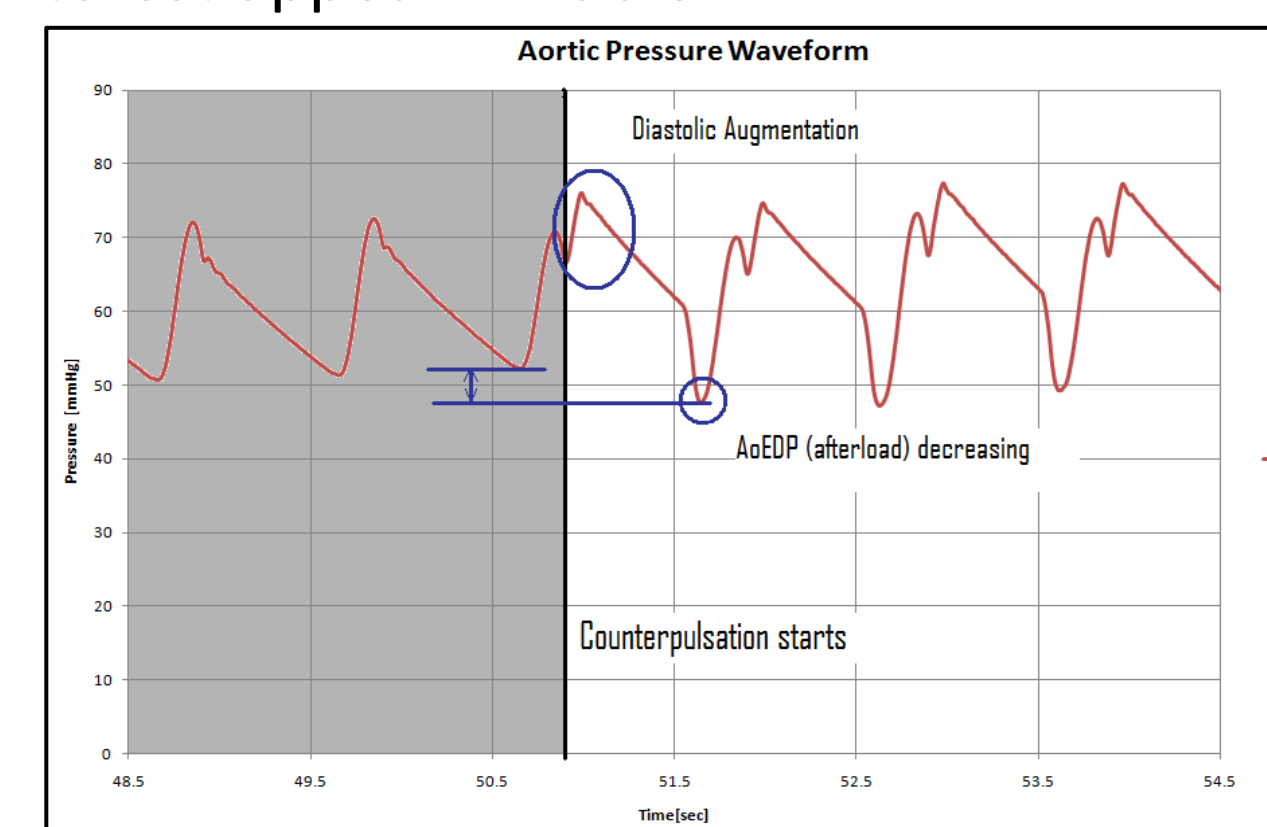


Figure 6: Aortic Pressure Waveform with augmentation

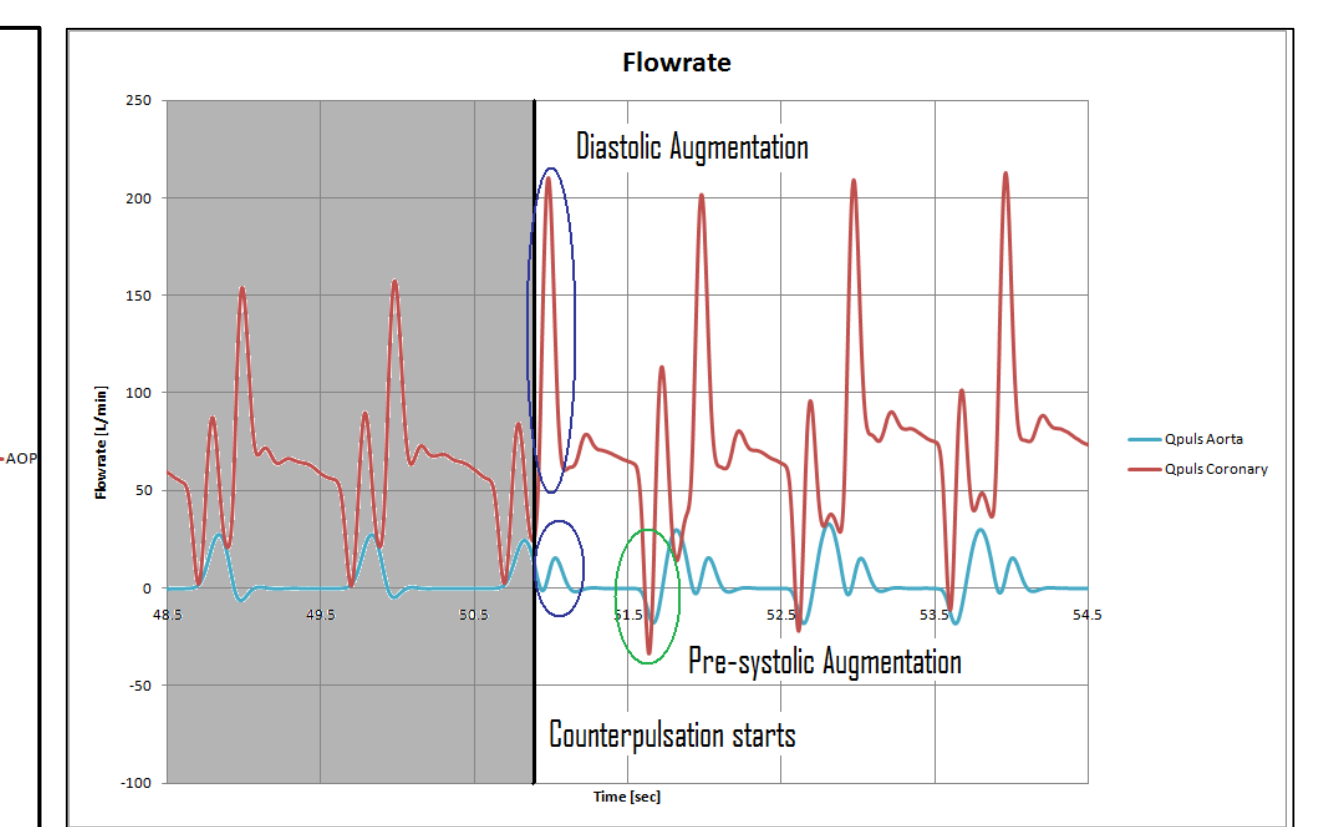


Figure 7: Aortic and coronary flowrate augmentation

	Cardiac Output (CO) [L/min]	Left Coronary Artery Flowrate [mL/min]	Aortic End Diastolic Pressure (Afterload) [mmHg]	LV Hydraulic Work [Watt]
Non-assisted	3.18 ± 0.03	65.4 ± 0.52	51 ± 0.52	0.5 ± 0.03
Assisted	3.4 ± 0.08	72.5 ± 0.87	48 ± 1.16	0.44 ± 0.08
Percentage of difference	6.71%	10.82%	-6.01%	-11.38%
p value	<0.001	<0.001	<0.001	<0.001

Table 1: Haemodynamics response due to balloon pump counterpulsation

7) Discussion & Conclusion

From the results it is evident that a device placed in the ascending aorta *decreases the heart's load and increases flow output* into coronary and peripheral circulations. The CIMS balloon pump increases aortic flowrate by only 0.22 L/min, but succeeds in lowering afterload resistance which the heart must overcome to eject blood in systole and in increasing the blood supply to the myocardium thus improving cardiac dynamics in both systole and diastole.

8) Future Work

Further testing will be carried out to investigate the effect of balloon pump compliance on flow augmentation. It is hypothesized that increased balloon pump compliance will give a more favourable haemodynamic response especially on systemic perfusion and decrease afterload.

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