NEW!

PhysioPump

zammi medical innovation

PULSATILE FLOW DEVICE

A healthy heart works at an average rate of 72 beats per minute, 104,000 a day and pumps the equivalent of 85 grams of blood with each beat.

All procedures requiring CPB, ECMO and VAD devices used for such procedures only generate linear flow. It is well documented that linear flow pumps generate potential health problems and delay in patient recovery, topic to be addressed later.

It is important to mention that pulsatile flow devices have been launched in the market, however, they failed to achieve the desired goal.

Currently, there are several studies and much research seeking the advancement of technology to obtain physiologic flow. To date have yet to prove their effectiveness in demonstrating efficient and conclusive results.

The World Heart Federation estimates 17.3 million people die each year of heart related problems worldwide. It is the fourth leading cause of death in developing countries and first in the developed world. The Federation predicts that by 2030 the number of deaths will reach 23 million per year.

PhysioPump is a physiological pulsatile flow device with innovative technology developed in Brazil.

DESCRIPTION

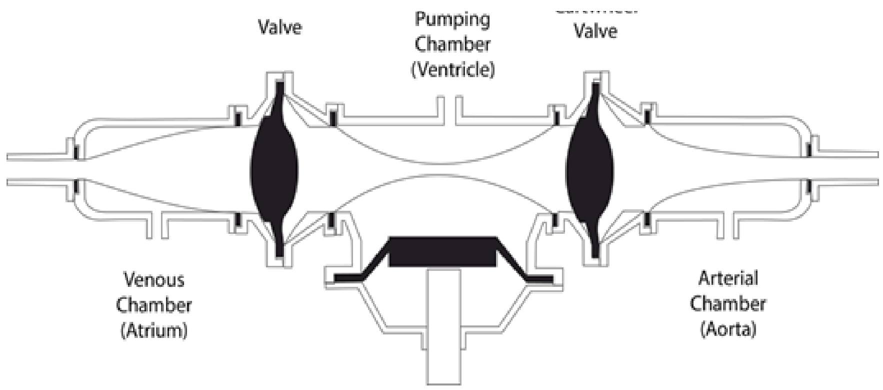
PhysioPump was developed at Zammi Instrumental with the objective to create a blood pump capable of producing physiological pulsatile flow for application in extracorporeal circulation. The starting point of the project was to assess the problems that other products were having, understand their approach and limitations.

Known problems pertaining to pulsatile flow devices:

- Lack of compliance and high resistance CEC circuit.
- Need for large-diameter arterial and venous cannula.
- Noisy drive.
- Filled chambers increases (chance of stasis, thromboembolic, and hemolysis events).
- Power/battery high consumption.
- Obstruction and clogging problems in unidirectional valves.
- Thrombogenicity.
- Fixed and low systemic volume.
- High frequency.

Limitation analyses were considered for the device design. PhysioPump (figure 1) was designed to replicate the reciprocating pumping, in analogy to the heart physiology, with a hydraulic-activated pumping chamber, two passive chambers that replicate the complacency of vascular system, input and output unidirectional valves with low pressure gradient working to ensure pulsatile flow with systolic and diastolic phase, producing a proportional pressure wave equivalent to the physiological pulse wave, figure 2. The ejected volume and cycle frequency are adjustable and produce cardiac output that may range from 600ml to 7000ml per minute.

Figure 1



Laboratory and animal tests showed that PhysioPump is feasible to meet the blood pumping needs for conventional extracorporeal circulation, circulatory assistance, and ECMO.

On the image below, figure 2, the curves observed in blue and red are the records of pressure waves before and after the pump working with 3/8" tubing with arterial output connected to a reinforced 24Fr arterial cannula. On the lower screen, the curves in yellow and green refer to the flow recorded before and after the pump, respectively. In white, the numbers record the arterial and venous blood temperature

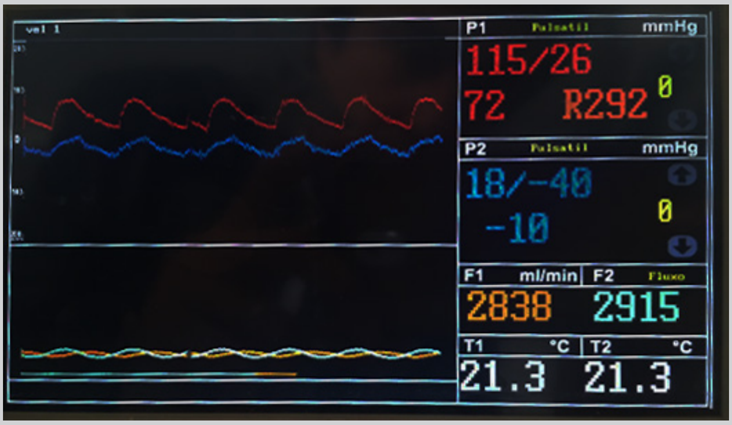
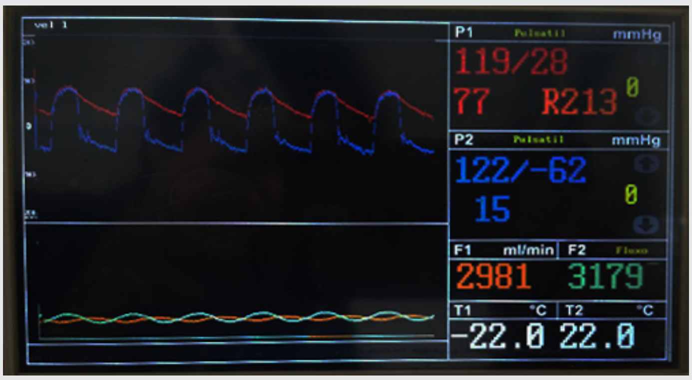


Figure 2. The red line is the pressure variation record generated by the PhysioPump pulse, the values in red 115/26 and 72 refer to systolic, diastolic pressures, and arterial line average values. Similarly, the line and values in blue, refer to the circuit venous line. The F1 and F2 captions on screen refer to arterial and venous flows, T1 and T2 are the temperature values for arterial and venous line. The R292 caption addressed a development functionality.

In figure 3, a pressure transducer installed inside the pumping chamber recorded the pressure curve in this chamber, shows similarity to the physiological ventricular pressure curve. At the same time, we can see the pressure on the output of the pump that is very similar to the aorta pressure waveform. This was obtained due to the arterial chamber that emulates the compliance of the aorta.

Figure 3. In the wave morphology comparison produced by the PhysioPump pumping chamber with the physiology description (taken from Guyton, Textbook of Medical Physiology, 1996).



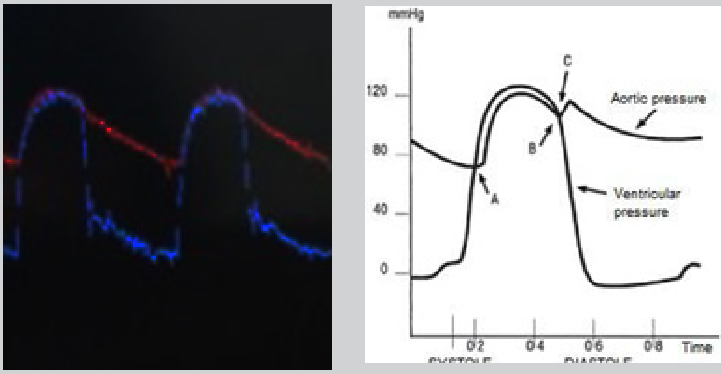


Figure 4. Image to the left was extracted from the screen of the pressure monitor, and shows the waveforms inside the pumping chamber (in blue) and arterial chamber (in red); The image on the right was extracted from Guyton, Textbook of Medical Physiology, 1996, and shows the correlation between the pressure waveforms from the left ventricle and the aorta. Note the similarity of the two images. As can be seen, PhysioPump reproduces the same pressure pattern as the heart.

The hemolysis analysis, as per standard ASTM 1841, showed a very low INH. The same test was extended for 140 consecutive hours. The results obtained in laboratory show that PhysioPump is less traumatic than conventional CEC pumps, be they centrifugal or roller pumps.

PHYSIOLOGICAL PULSATILE FLOW

Physiologically, blood flow is pulsatile and morphologically the result of the cardiac cycle.

Heart cycle is the term referring to events related to blood flow and pressure that occur from the beginning of a heartbeat to the next heartbeat. In short, we divide the cycle into two periods: relaxation called diastole, when the heart is distended by receiving blood, and contraction called systole, when it ejects blood.

Contraction and relaxation of the heart chambers results in pressure changes within the heart chambers that produce blood movement through the cardiovascular system.

This cycle produces a large variation in blood pressure, ie the pressure wave. At each cardiac cycle, an amount of blood is ejected into the arteries (stroke volume) and the frequency of the cycles produces cardiac output, the intensity of which produces blood flow in the arteries and at the same time determines a counter-flow force called resistance.

The relationship between flow and resistance determines blood pressure. Blood pressure has wave morphology with peak pressure (systolic pressure) and wave depression (diastolic pressure). The difference in systolic and diastolic pressure is the arterial pulse.

CONTINUOUS FLOW X PULSATILE FLOW

For years, multinational companies and several start-ups, have invested in the development of pulsatile flow devices, as they believe this to be the most efficient. However, no device developed could reproduce the physiological pulsatile flow.

Numerous studies have been published comparing pulsatile (non-physiological) flow devices with continuous flow devices. Although not physiological, pulsatile flow obtained better clinical results. It is reasonable to suppose that the flow that most closely approximates the natural blood flow is the most appropriate, namely, Pulsatile Flow.

However, after years of investment in research into the development of pulsatile and unsuccessful flow devices, most companies have opted to invest in continuous flow because they find it more advantageous to the mechanical part of the device (small size device, longer system durability, better energy efficiency, greater confidence to medical staff and patient, silent drive, and more...)

However, as for the clinical part, it is known that the pulsatile flow has advantages such as: attenuates neurohormonal response, reduces vascular resistance, increases visceral blood flow, improves renal function among others.

Thus, it is observed that, at the moment, there is a tendency to incorporate pulsatile flow into continuous flow devices resulting in a device having the mechanical advantages of continuous flow and the clinical advantages of pulsatile flow.

In any case, the objective of obtaining a pulsatile flow as close as physiological was not achieved.

According to the clinical study "Comparison of continuous-flow and pulsatile-flow left ventricular assist devices is there any advantage to pulsatility", streaming offers advantages such as smaller device size, higher system reliability and durability.

However, in long procedures continuous flow has a low rate of ventricular recovery associated with lack of pulsatility, increased pressure gradient in the aortic valve, and decreased compliance in small arterial vessels.

The conclusion of this study is that pulsatile flow devices may be beneficial and potentially necessary in long-term procedures and that the best solution may be to incorporate pulsatility into continuous flow devices while maintaining their benefits.

The conclusion of the Study "Arterial Pulsatility and Aortic Valve Function under Continuous Flow Left Ventricular Assist Device Support, Continuous Speed vs. Varying Speed Pump Assistance", stresses that several studies show the advantages and benefits of pulsatile flow. In this study, a pulsatility in a continuous flow velocity variation (RPM) device was created suggesting that in the near future this technology may be applied to patients to reduce the long-term adverse effects generated by continuous flow.

Moreover, by analyzing these and other comparative studies between pulsatile flow and continuous flow, it is possible to conclude that current pulsatile flow, despite all clinical advantages, is not yet ideal because it has mechanical disadvantages and mainly because it is not a common physiological pulsatile flow.

The article, "NO PULSE: HOW DOCTORS REINVENTED THE HUMAM HEART", suggests that an artificial heart that spins at 10,000rpm and generates a continuous flow may be even better than the human heart (pulsatile). The publication suggests that not always copying nature is best, and gives as an example Leonardo da Vinci's attempt to fly by building bird-like wings.

In fact, both da Vinci's wings and current pulsatile flow didn't work, but both are far from the perfect copy of nature.

"Just as human flight was not possible until people gave up the idea of mimicking birds, permanently replacing the most vital of organs may not be possible without freeing our minds from the revealing heartbeat. "I think we are on the verge of solving the artificial heart problem now," he said. "All we had to do was get rid of the wrist."

What we can conclude is that after countless failed attempts to copy the human heart, the conclusion is that the great obstacle is the pulsatile flow. Without pulsatile flow, building a safe, long-lived artificial heart becomes much simpler. It is hard to believe but in fact, to solve a mechanical problem, they are trying to diminish the importance of pulsatile flow for humans.

Below are the Conclusion and Key Points from Chapter 10. "Pulsatile Cardiopulmonary Bypass" of the book: Cardiopulmonary Bypass - Principles and Practice.

KENNETH M. TAYLOR and TERRY GOURLAY

CONCLUSION

"Pulsatile flow in CPB remains a controversial issue (7). Pulsatile blood flow studies during CPB have focused on a broad spectrum of factors, ranging from cellular metabolism to organ functioning including both hemodynamic and metabolic responses. However, most of this work, particularly clinical studies, has been performed without truly physiological pulsatile blood flow, as a result of the lack of a device capable of providing such a flow pattern during CPB. Despite the evidence in its favor, pulsatile flow in CPB remains controversial. However, it is conceivable that producing a pulsatile pump capable of generating physiological pulsatile flow during CPB will solve this issue.

This leaves us a considerable opportunity for further investigation. Despite the safety issues raised in the second half of this chapter, it seems logical that a flow mode very similar to the natural state will have a better outcome. It remains to be seen whether it can be safely achieved within the constraints imposed by the size of the arterial cannulas. As technological development progresses, this controversy may not be too far away to be resolved."

KEY POINTS

- It has long been recognized that pulsatile flow is of physiological importance and that the reproduction of pulsatility during cardiopulmonary bypass may be beneficial. However, this reproduction is not totally safe because it presents technological obstacles.
- Just generating normal pulse pressure may not be enough to support normal circulatory physiology during cardiopulmonary bypass. Reproduction of "normal" physiological pulsatility is the goal.
- Non-pulsatile CPB induces a progressive increase in systemic vascular resistance, potentially compromising organ perfusion during cardiopulmonary bypass and possibly increasing myocardial oxygen demand after bypass.
- Mechanisms involved in increasing systemic vascular resistance include increased circulating catecholamines and vasopressin and activation of the renin-angiotensin system.
- Clinical research on animals generally revealed that both urine and renal blood flow are better preserved with the pulsatile system as compared to nonpulsatile circulation; although these studies did not notice significant improvements in the renal system with pulsatile flow. This is most likely because the pulsatile flow was not physiological enough.
- Pulsed extracorporeal circulation has been shown to reduce not only cerebral acidosis but also markers of brain injury and neurohumoral dysfunction. However, clinical studies have failed to produce better evidence.
- Research suggests that liver, pancreatic and intestinal functions are best preserved during pulsatile extracorporeal circulation; quite possibly due to a reduction in the development of mucosal ischemia, which may induce endotoxemia. The clinical implications of these findings remain unclear..
- The PhysioPump solves some of the mechanical problems of today's pulsatile flow devices, incorporate the mechanical qualities of continuous flows, and get as close to physiological pulsatile flow as possible.