Intra-Aortic cardiac support device LifeheART for End-Stage Heart Failure

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Objective:

This study aims to compare the performance of LifeheART, a new implantable Left Ventricular Assist Device (LVAD) (Oran, 2017)*, with state-of-art clinically approved LVADs. LifeheART may provide effective cardiac assistance with reduced blood trauma, by its low-speed axial impeller, and be less surgically invasive, by being intra-aortic and wireless powered. LifeheART has a shaftless pump placed in series with the heart, implanted within the aorta avoiding a heart bypass, that preserves the native cardiac function. LifeheART has a larger impeller diameter and significantly lower rotational speeds (<3000 RPM) than current devices (>5000 RPM).

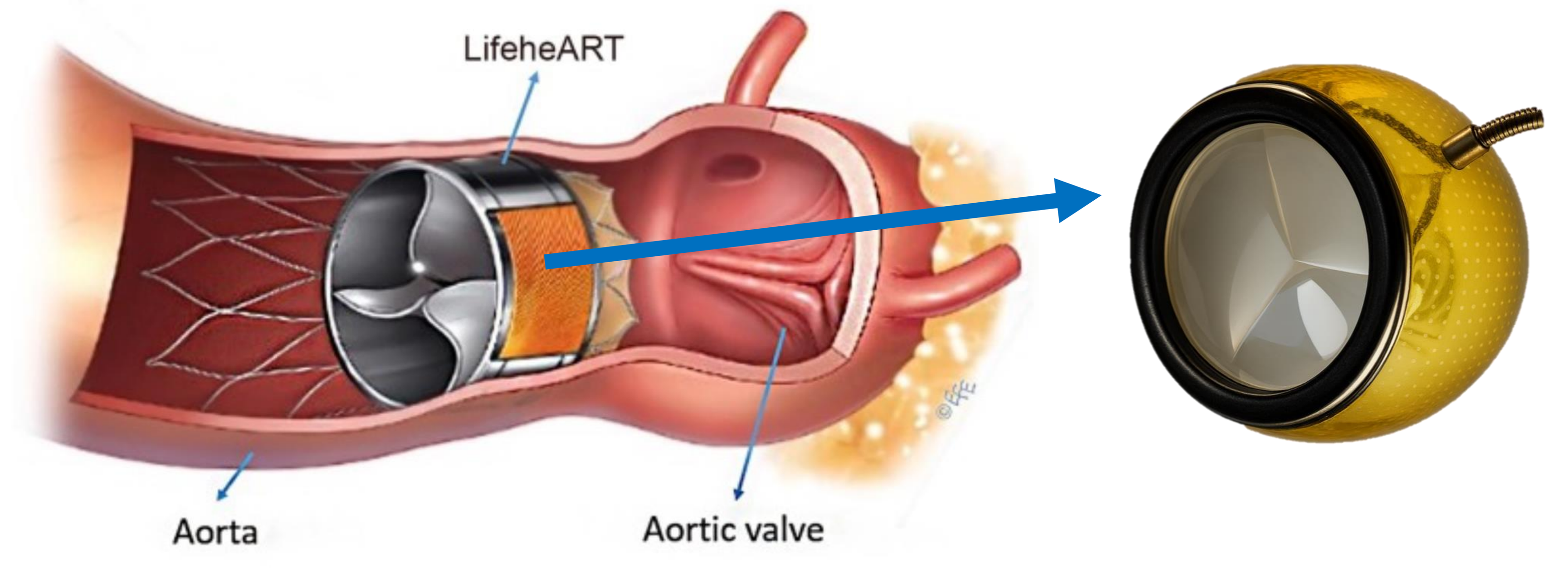


Figure 1. The Intra-aortic LVAD (LifeheART) concept and LifeheART prototype

Method:

LifeheART utilises an axial shaftless pump that operates in series with the heart and implanted within the aorta avoiding heart bypass, and preserves native cardiac function. The pump is optimised using Computational Fluid Dynamics (CFD) and Taguchi optimisation method to allow its implantation inside the aorta while meeting the required cardiac outcome. The optimised design has larger impeller diameter (>25mm) and significantly lower rotational speeds (< 3000 RPM) relative to the available clinically approve devices. A prototype of the optimised design has been tested in a Cardiovascular Mock Circulation Loop (MCL) to test its cardia outcome for operating conditions for different patient activities. Flow visualization using Particle Image Velocimetry (PIV) is carried out to provide detailed analysis of flow velocity profiles at the pump outlet. The in-vitro experimental results are used to validated the CFD model that is used to evaluate the device cardiac performance, power consumption, shear stress distribution and the blood damage index.

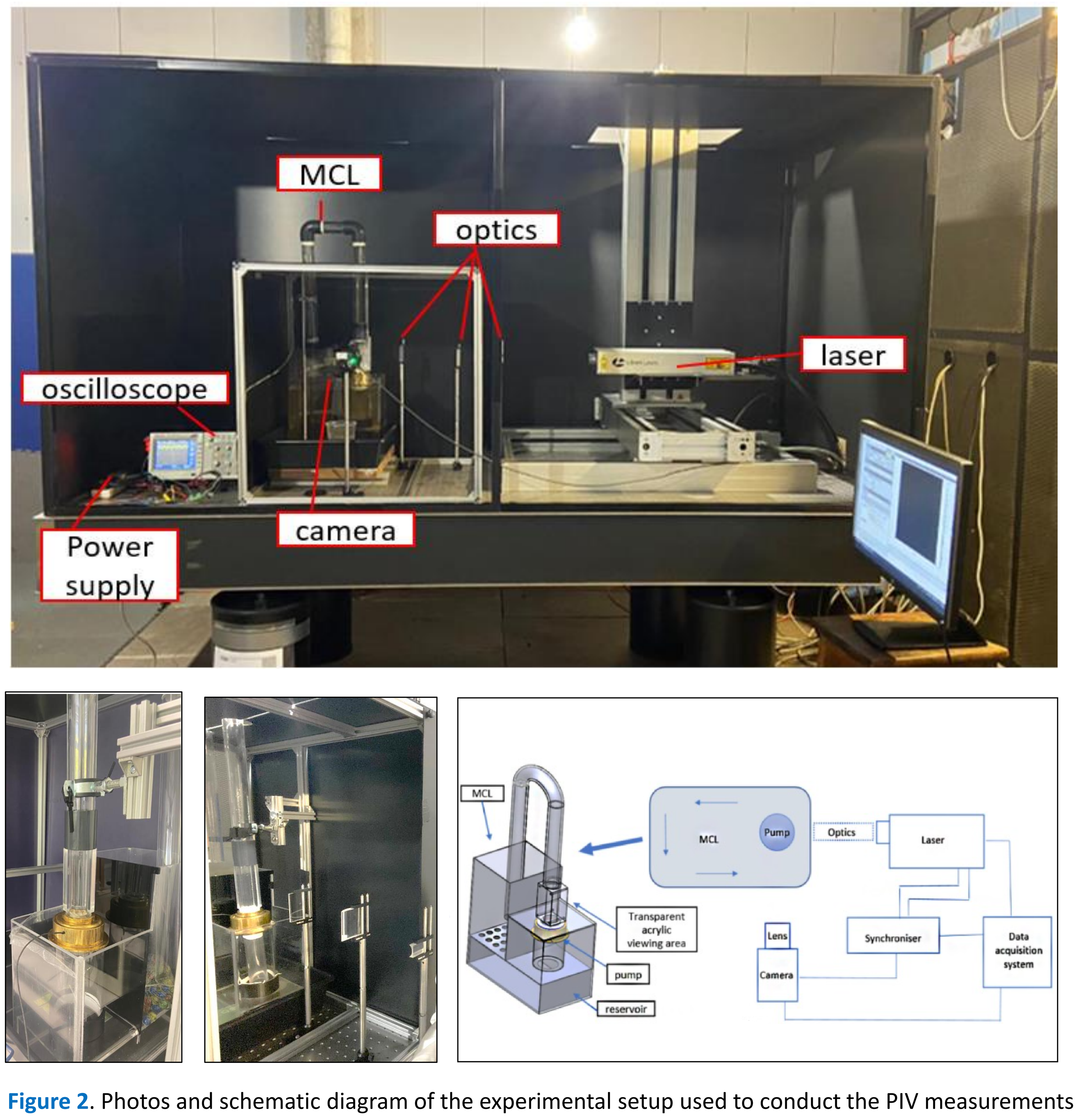


Figure 2. Photos and schematic diagram of the experimental setup used to conduct the PIV measurements on the LifeheART prototype.

Results and discussions

PIV measurements confirm the accuracy of the CFD model, showing agreement in the velocity vector map and a steady output [4.5L/min] (fig.3). The validated results show that the compact LifeheART pump provides the same hemodynamic hydraulic head at a significantly reduced wall shear stress (WSS) and blood damage index (<40Pa-averageWSS) compared to current clinically approved LVADs (>80Pa-avarage) (fig.4). These improvements are attributed to the low-speed, large-diameter, and short length of the pump with streamlined internal geometry. Moreover, its low energy consumption enables compatibility with wireless power transfer, offering the potential to eliminate driveline-associated infections.

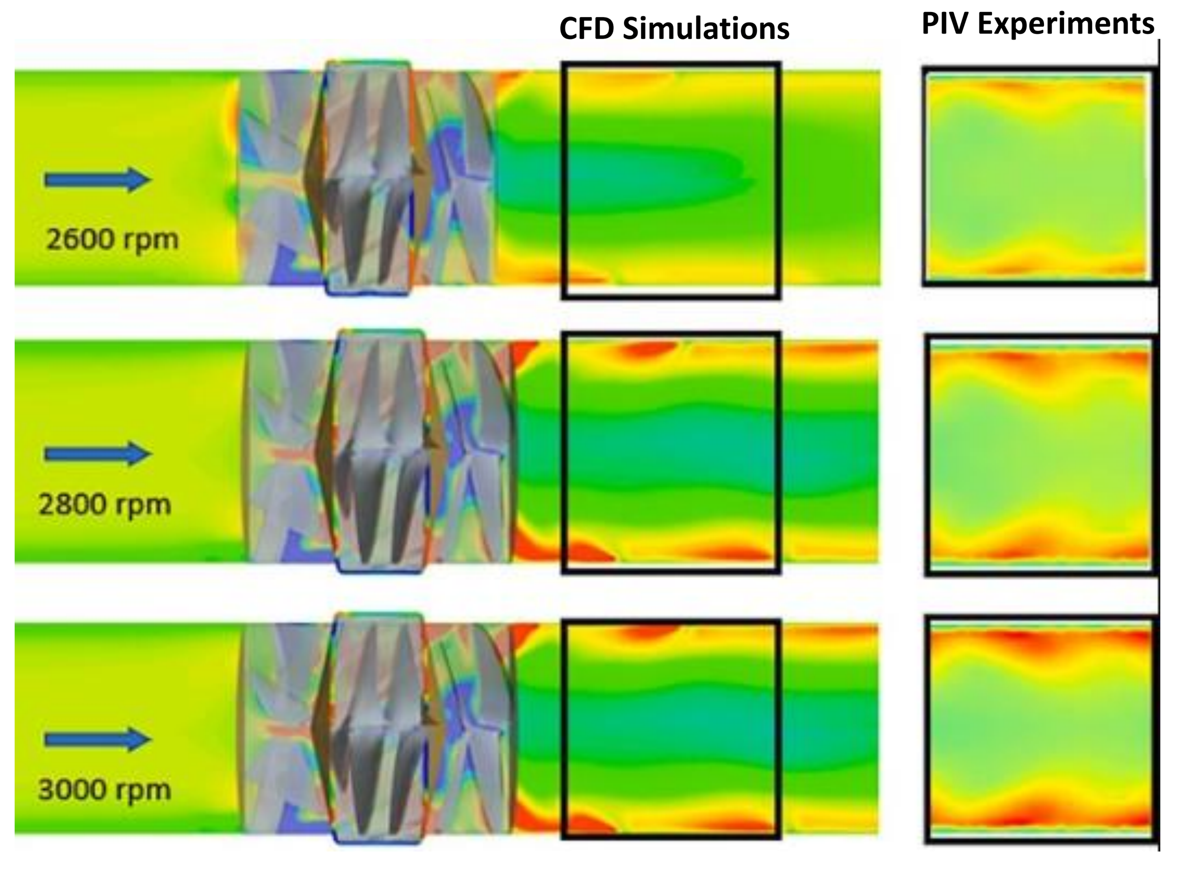


Figure 3. Radial and Axial Velocity Distribution at the LifeheART Pump Exit: Comparison Between PIV Experiments and CFD Simulations.

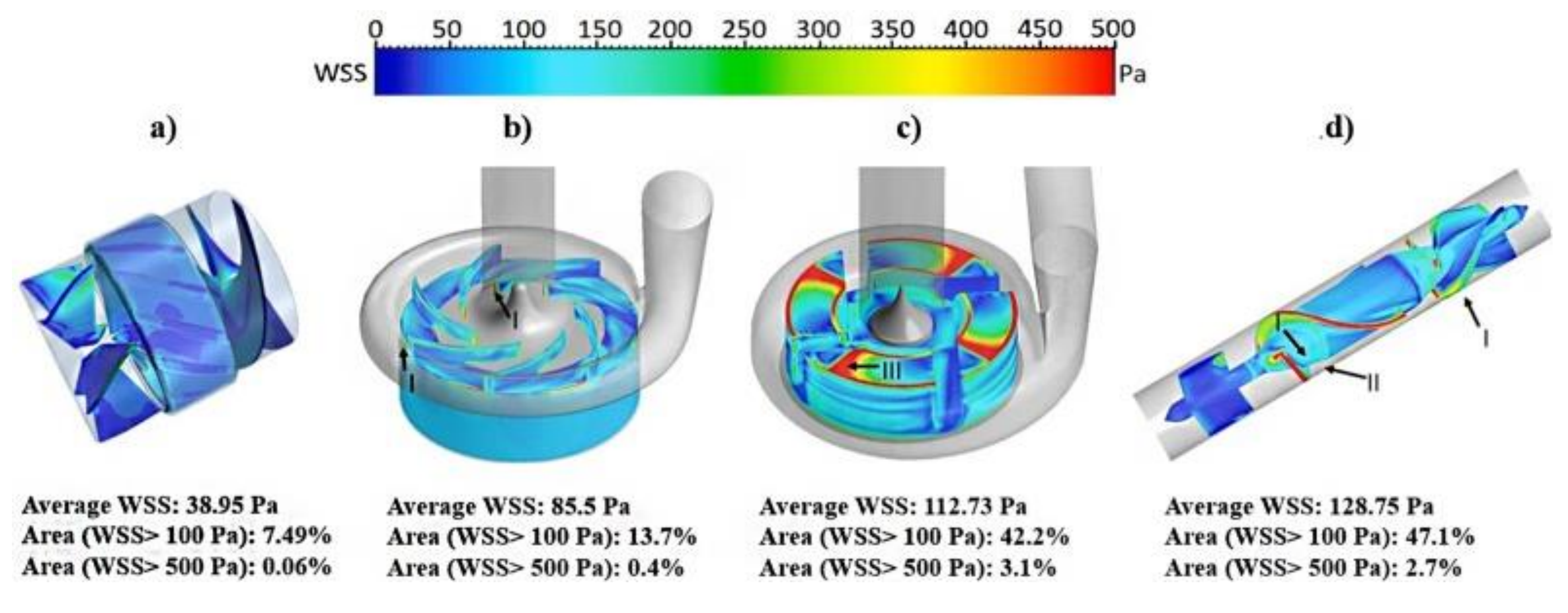
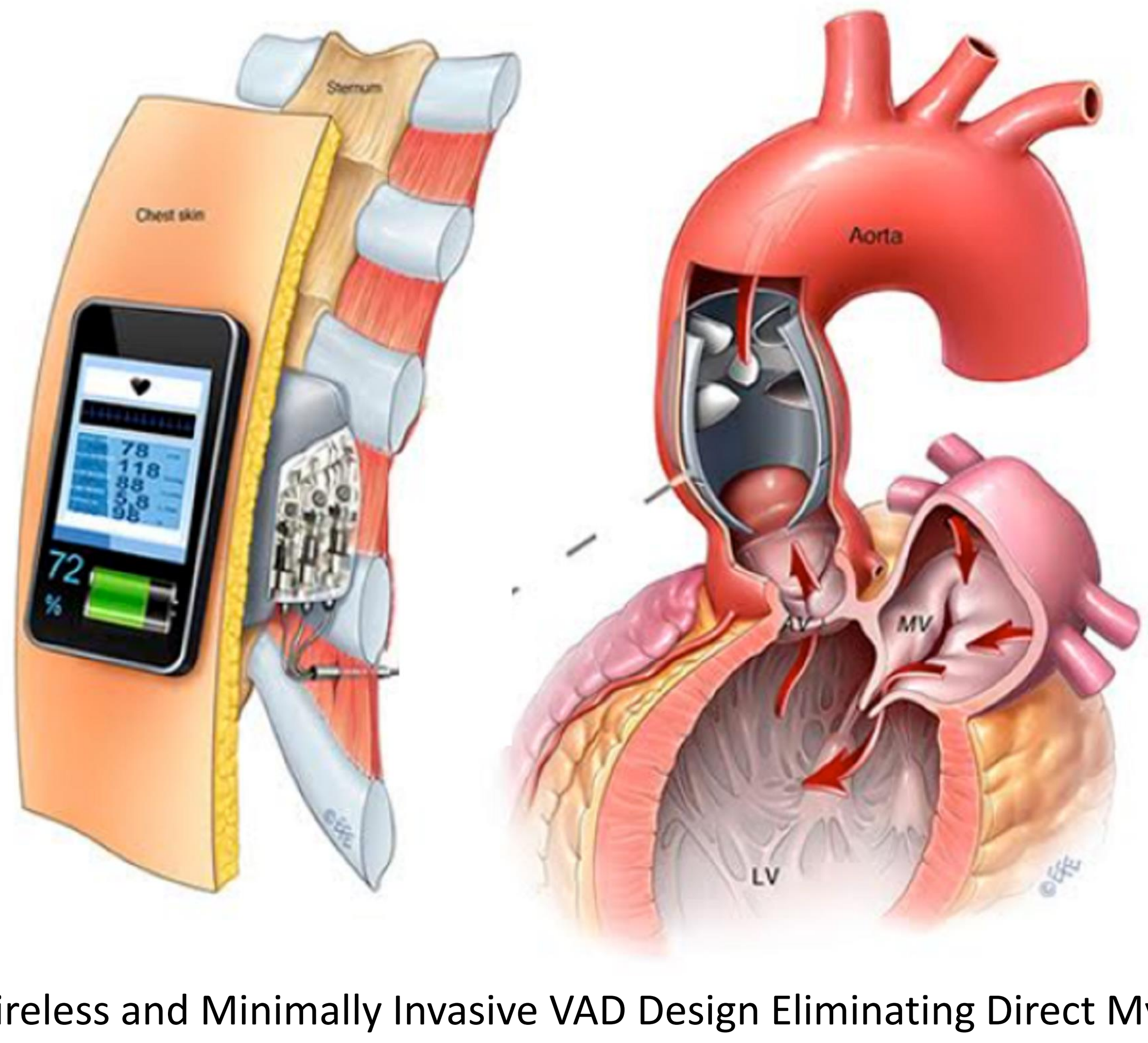


Figure 4. Illustrates the distribution of wall shear stress (WSS) on the impeller surfaces with an aortic pressure of 120 mmHg: (a) LifeheART from this study; (b) CH-VAD; (c) HVAD; and (d) HM II, as reported by Zhang et al. (2020)**.

The LifeheART device exhibits significantly lower WSS and reduced blood damage potential compared to current devices, including the CH-VAD (a design similar to the HeartMate 3, as cited by Wiegmann et al., 2019, and Thamsen et al., 2020). Specifically, the WSS value of the LifeheART is approximately twice as low as that of the CH-VAD. This superior performance is evident in the area exposed to high shear: only 7.49% of the LifeheART's surface area has a WSS value above 100{Pa}, which is roughly half the 13.7% seen in the CH-VAD, and dramatically lower than the 42.2% for HVAD and 47.1% for HM II. The reduction is even more significant at extreme shear levels, with the LifeheART exhibiting an area with WSS exceeding 500{Pa} of just 0.056%, compared to 0.4% for the CH-VAD.

Conclusion:

LifeheART represents a promising advancement in LVAD technology, offering effective circulatory support with a strong focus on patient safety and quality of life. Its intra-aortic configuration supports the native heart function, reduces mechanical blood trauma, and removes the cause of driveline-associated infections using a wireless power transfer. The favourable hemodynamic and hemocompatibility results support continued development and preclinical testing toward future clinical use.



LifeheART: Wireless and Minimally Invasive VAD Design Eliminating Direct Myocardial Incision and External Cable Entry.

*Oran B., Oran E., 2017. "Endovascular permanent heart assist device", US Patent 9,555,175.

**Thamsen, B., Gülan, U., Wiegmann, L., Loosli, C., Daners, M. S., Kurtcuoglu, V., ... & Meboldt, M. (2020). Assessment of the flow field in the HeartMate 3 using three-dimensional particle tracking velocimetry and comparison to computational fluid dynamics. *ASAIO Journal*, *66*(2), 173-182.