Design of a Percutaneous Left Ventricular Assist Device

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Abstract: Percutaneous Left Ventricular Assist Device is used for short (1-2 weeks) of cardiac support and have strenuous design methodology as compared to conventional Left Ventricular Assist Device (LVAD). The aim of this study is (i) to design a micro-axial blood pump (ii) valídate the design using Computational Fluid Dynamics (CFD) and Systemic Mock Circulation Loop (SMCL), and (iii) flow visualization using Particle Image Velocimetry (PIV). The diameter of the impeller is 7.6 mm and length is 15 mm. One of the most important aspect of the design was the elimination of the bearing. The optimum parameters ascertained includes a wrap angle of 250^0, blade thickness of 0.5 mm and shroud clearance of 0.25 mm. The straightener and diffusor were eliminated to reduce the net surface area exposed to blood. The pump characteristics were obtained using a Systemic Mock Circulation Loop (SMCL), developed in-house. The dynamic response was recorded by varying arterial compliance from 0.5 mL/mm Hg to 2 mL/mm Hg in SMCL. The design showed a consistent pump characteristics over a range of arterial compliance and an optimum flow rate of 2.5L/min at 60mm Hg, whereas the maximum flow rate of 2.8L/min at 80 mm Hg. The flow characteristics obtained using PIV were in good agreement with the CFD results.

1 INTRODUCTION

Every year 17.9 million deaths are reported worldwide from Cardiovascular Disease (CVD), which is 31% of all deaths worldwide (Benjamin et al., 2019). The number of Heart Transplants performed worldwide in 2018 is approximately 3500 (Cook et al., 2015). Percutaneous Left Ventricular Assist Device (henceforth called PVAD) is used to support a failing heart. Unlike conventional Left Ventricular Assist Device (LVAD), the PVAD, is transplanted and used for a duration of only 6 to 14 days allowing the heart to recover (Casassus et al., 2015). Currently available PVAD's includes, Impella (2.5/CP/5.0) by Abiomed Corporations and HeartMate PHP by Thoratec Corporation. The Impella 2.5 (size 12 Fr) delivers a maximum flow rate of 2.5 L/min at 50,000 rpm whereas Impella 5.0 (size 21 Fr) delivers maximum flow rate of 5L/min at 33,000 rpm (Lima et al., 2016). The HeartMate PHP (size 21 Fr) delivers a maximum flow rate of 5L/min at 21,000 rpm (Van et al., 2016).

Three criteria are generally used for the design of the PVAD. They are: a) Flow rate and pressure head, which in this case is 2.5 L/min at 60 mm Hg b) reduction of the exposure time of the blood in the high shear regions, c) reduction of high shear region. PVAD design is an iterative process where authors have used conventional pump design theories to develop the initial design (Gregory et al., 2017), (Song et al., 2004) and (Yu H., 2015). Nevertheless these theories and calculations requires modifications to design PVAD, especially at various regions between hub and shroud, wrap angle of blades, shroud clearance, and changes in pump parameters when the diffusor is not used. The wrap angle, which governs the exposure time, clearance gap which governs the wall shear stress, and changes in design parameters to avoid high shear zones by eliminating the diffusor, are critical aspects to be considered while designing the PVAD.

The development of PVAD requires in vitro performance test to analyse flow rates, pressure variations, dynamic response with respect to conditions like preload and after-load. Identifying these parameters helps to validate the PVAD's initial design. Mock circulation loops (MCL) have been developed for a simple non-pulsatile prototypes as well as for a more complex pulsatile prototypes (Gregory et al., 2009). Though mock circulation loop

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represents the human arterial system, consisting of both pulmonary and systemic circulations, in this work only systemic circuit has been used to validate the PVAD (Vilchez et al., 2016). Gregory et al. has developed a Mock Circulation Loop (MCL) which has been widely used as a benchmark design, which includes peripheral resistance, compliance, inertance, systemic and pulmonary circuits, VAD connections and adjustable cardiac connections (Gregory et al., 2011). Pantalos et al. used MCL to mimic the Frank-Starling response under normal heart, diseased heart, and cardiac recovery conditions (Pantalos et. al., 2004). Timms et al. developed a MCL which represents pulsatile left and right ventricles (Timms et al., 2005)

In order to visualize the flow field in the pump region, for miniaturized rotary centrifugal (Day et al., 2004) and axial blood pumps (Apel et al., 2001), particle image velocimetry (PIV) has been widely used. Flow visualization can either be done using a single camera (in two dimensions), or using two cameras for a three dimensional visualization. Due to the small size of the percutaneous pumps, a region to provide an optical access has always been a challenge. Moreover the velocity gradients resolution in the clearance space between tip and the shroud requires a high resolution CCD camera, which is not covered in this study.

2 MATERIALS AND METHODS

2.1 Pump Design Theory

PVADs are micro axial pumps of less than 8 mm and their speed is inversely proportional to their size. Red blood cells which are 10 microns in size are the most affected part of the blood due to the high rotational speed of these pumps (Lund et al., 2016). Another major design parameter which affects the shear stress on RBCs is the clearance gap between the shroud and the impeller tip (Yu H., 2015). Moreover regions of vortices and stagnation in the pump can cause hemolysis and thrombosis (Gregory et al., 2017). Considering these major criteria, design of the PVAD is a cumbersome process compared to a conventional axial flow pump. The impeller geometry includes impeller hub and shroud diameter, inlet and outlet blade angles, wrap angle, clearance gap and blade profiles. The Design condition imposed for current PVAD is 2.5 L/min at a pressure head of 60 mm Hg. Cordier Diagram being the most common starting point for the selection of any pump in the conventional design theory was used, after which velocity triangles were used to calculate the blade angles at various locations of hub, shroud and points between them (Song et al., 2004), Since there lies infinite points between the hub and the shroud, we have selected a total three points at a span (T) of 0.25, 0.5, 0.75, thus making it a total five points to calculate the inlet and the outlet blade angles.

Table 1: Initial design parameters.

Location	Hub	T1	T2	T3	Shroud
β_1	24.3^0	22.8^0	21.4^0	20.2^0	19.1^0
β_2	36.2^0	32.1^0	28.9^0	26.3^0	24.1^0
Calculated parameters: De Haller Ratio (HR)= 0.75, Hub diameter (d)= 6 mm, Chord length (c)= 8 mm.					
Assumed parameters : Number of blades (Z), Wrap angle (θ), Clearance gap (c), Blade thickness (t).					

$$HR = \frac{Rel.velocity\ @\ outlet\ to\ impeller}{Rel.velcity\ @inlet\ to\ impeller} \quad (1)$$

$$\theta = Blade\ angle\ \{outlet - inlet\} \quad (2)$$

The de Haller ratio (HR) and angle of deflection (θ) provides an insight on the loading of the blades. A smaller de Haller ratio results in more blade loading. Normally, the de Haller ratio should be larger than 0.7 to avoid stalling of flow, where flow separation occurs on the suction side of the blade (Gregory et al., 2017). On the other hand, angle of deflection is directly proportional to the work done by the impeller. Table 1 shows the initial design parameters calculated from the conventional designed methodology. These design calculations does not give number of blades, wrap angle, clearance gap, blade thickness and the effect of variable hub diameter on the flow characteristics of impeller. So these initial design parameters were assumed as listed in Table 1 which is later optimized with an iterative design process using CFD results. The impeller of PVAD was modelled using BladeGen (ANSYS® Academic Research Mechanical, Release 18.1), the blade profile at the leading edge and trailing edge was estimated as an ellipse for smooth entry and exit.

2.2 CFD Study

Computational Fluid Dynamics study has proven to be an efficient method to get good insights of impeller designs and also for initial validation of the design (Song et al., 2004). The study used Ansys TurboGrid for meshing and Ansys CFX for solving the RANS

Table 2: Study for optimum wrap angle.

Wrap angle (θ)	Head (m)	Power (W)	O= H/P (m/W)
90^0	0.95 m	0.83 W	1.140 m/W
150^0	0.79 m	0.76 W	1.048 m/W
250^0	0.73 m	0.64 W	1.137 m/W
360^0	0.41 m	0.39 W	1.050 m/W

equations, which are commercial available software. (ANSYS Inc., Canonsburg, PA, USA). TurboGrid is an interactive hexahedral grid generation system, specifically designed for turbo machinery. It is preprogrammed with several templates tailored to the complex curvatures of various types of turbines, compressors and pumps. BladeGen files were imported to TurboGrid, which generates the flow domain for the impeller geometry. Tip clearance at shroud was directly given in TurboGrid which was varied from 0.1-0.25 mm, based on different models at different iteration steps. The meshing was further refined at trailing edge by keeping the trailing edge cut- off factor at 3.

The meshed data of fluid domain was then transferred to CFX, where the inlet boundary condition was kept as mass flow rate and the outlet was kept open to let the pressure develop over time. The flow domain was given a counterclockwise rotation and a no-slip boundary condition was applied to the walls. Rotational periodicity interface was used to reduce the computational time.

A frequently used turbulence model in the field of rotary blood pumps is the Shear Stress Transport (SST) model, which is regarded as an industry standard due to good validation results. K-Ɛ turbulent models used in conventional VAD's predicts fluid flow outside the boundary layer, but fails to capture near field flow regimes (Song et al., 2004) and (Demir et al., 2011). Since PVAD is micro-axial entity with high rotational speed, it is important to track the near boundary phenomenon and hence SST turbulent model has been used in our study.

Due to the very high rotational speed, N (nearly 12000 to 27000 rpm) and the small dimension of the pump, the computational time step must be very small in order to capture flow field adequately. Thus, time required for 1 revolution (t) is given by

$$t = \frac{60}{rpm} \times 1000\, ms \tag{3}$$

Table 3: Study for optimum chord length.

Chord length (mm)	Head (m)	Power (W)	O= H/P (m/W)
8 mm	0.7336 m	0.645 W	1.137 m/W
12 mm	0.878 m	0.86 W	1.02 m/W

Moreover, if the number of blades is 'z' and hence for a periodic fluid domain, time taken to spin one pitch (T_p) is given by

$$T_p = \frac{t}{z} \tag{4}$$

To capture more information about the flow field, we have further reduced the time step by a factor of 5, which solely depends on the amount of information needed and the computational power. So, the final time step (T_F) is given by

$$T_F = \frac{T_p}{5} \tag{5}$$

The total time taken is 0.8 sec. The streamlines are shown in figure 1a.

2.3 Design Iterations

Based upon initial parameters adopted from conventional design theory, a CFD model was generated and an initial analysis was carried out. Based on the CFD results, the design parameters were altered, and the process was repeated. Four assumed variable parameters which were not possible to be calculated from conventional pump theories, namely wrap angle (P1), clearance gap (P2), blade thickness (P3), and the number of blades (P4), were fixed with this approach. The number of blades is assumed to be two. More blades were not considered, as the net blood exposure surface area increases with number of blades, along with drive power requirements. The clearance gap is fixed to 0.25 mm due to the limitation in manufacturing. The blade thickness, should be as minimum as possible to increase the net flow area between the blades. As per the current manufacturing methods, a blade thickness of 0.5 mm has been chosen, which results in a unit head loss of 0.1 m/W, but an increase of 7.9 % of flow area was achieved. Different wrap angles of 90^0, 180^0, 250^0 and 360^0 were analysed, as shown in Table 2.

Table 3 shows the effect of chord length for one of the iterations on the pump characteristics.

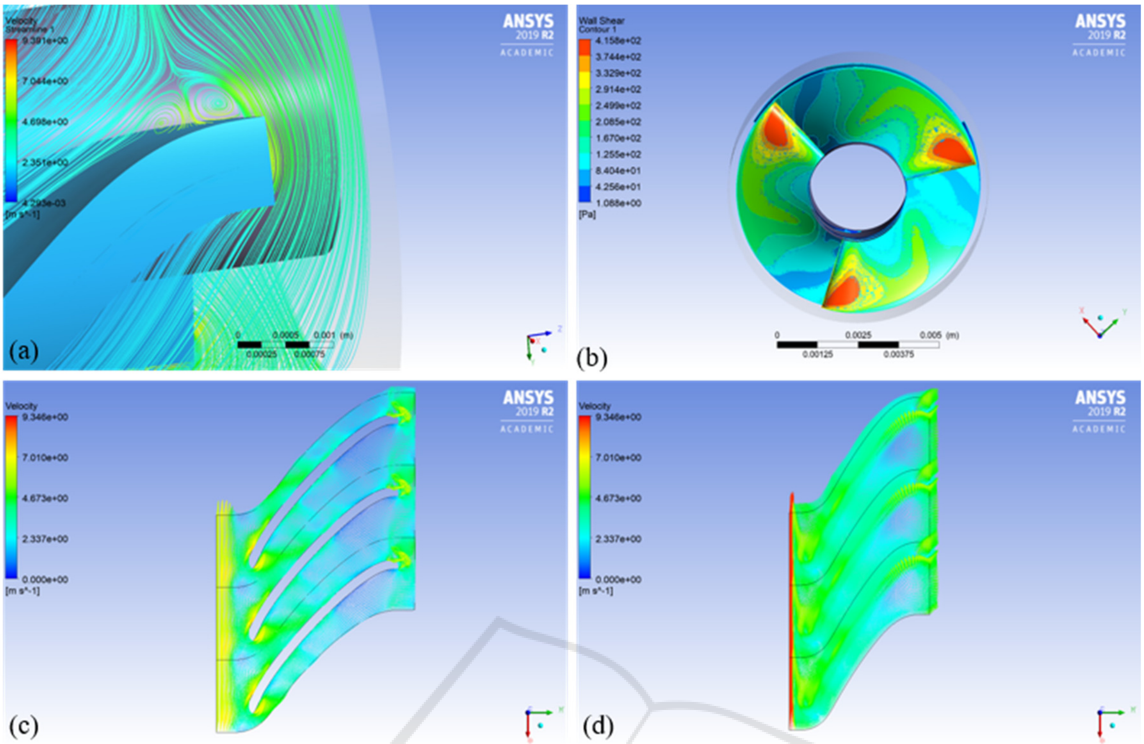

Figure 1: a) Vortices at trailing edge, b) shear stress distribution at leading edge, c) velocity vectors at 50% span, and d) velocity vectors at 95% span.

Head per unit power obtained from CFD has been used for comparisons. Maximum pressure rise increases with blade length. However, blade length affects the torque required to rotate the PVAD and an increase in length increases the exposure time of the RBC's causing an increase in damage to these cells.

The blade length from the leading edge (LE) to the trailing edge (TE) is fixed as 12mm to accommodate motor shaft, which is 7 mm in length. Figure 2c shows the geometry of the final design. The configuration does not include flow straightener or diffusor to reduce exposure time.

2.4 Prototyping and Assembly

The impeller illustrated in figure 2c is manufactured using additive manufacturing technology of PolyJet printer (Stratasys Systems, US), which has an accuracy of 16 microns. VeroClear material is used for the prototyping. A BLDC motor of 8 mm in diameter with 7mm shaft length (Faulhaber GmbH, Germany) was tight fitted with the impeller. The casing for the pump with 0.25 mm clearance was initially 3D printed and later on manufactured with glass for PIV experiment.

3 SYSTEMIC MOCK CIRCULATION LOOP

A mock circulation loop was designed and constructed as shown in figure 2b. A two-element Windkessel model is used to model the MCL (Catanho et al., 2012). Two compliance chambers to mimic aortic compliance and venous compliance were used. Aortic compliance (AoC) of 1.65 mL/mm Hg and a Venous Compliance (VoC) of 10 mL/mm Hg have been used (Timms et al., 2005). The compliance chamber is made of an acrylic cylinder, filled with air and sealed at the top at a desired pressure to produce the desired value of compliance. Table 4 shows the designed MCL parameters. The compliance is given by

$$C = \frac{V_{air}}{P_{air}} \tag{6}$$

Where V_{air} *and* P_{air} are the volume of air and pressure of air above water column in the chamber. From expression (6), it can be seen that the

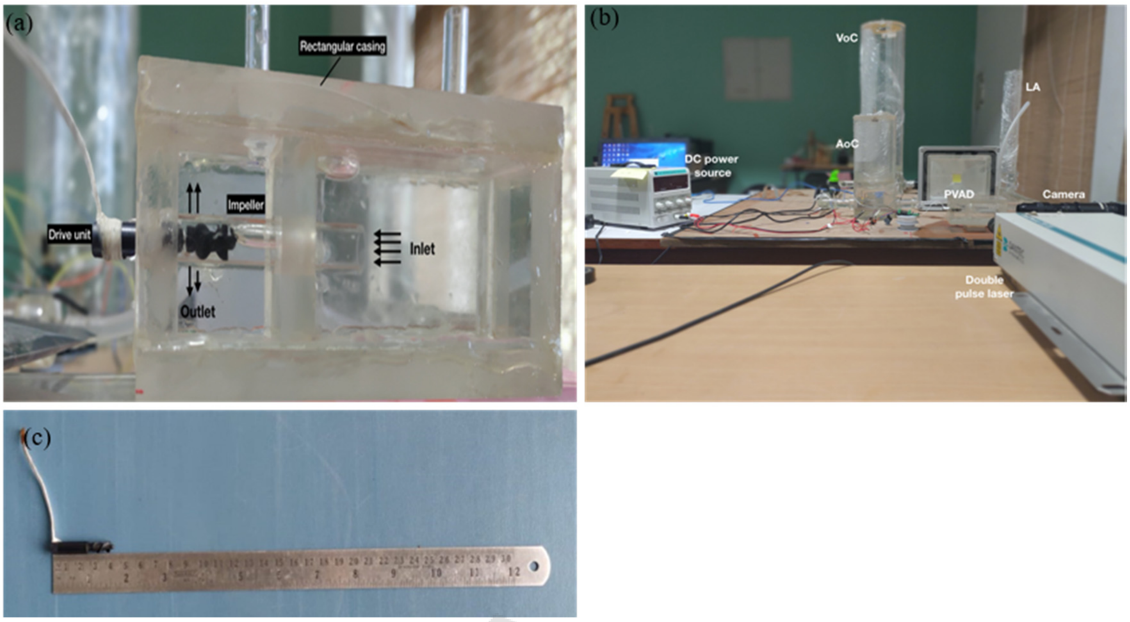

Figure 2: a) Pump Assembly inside rectangular acrylic casing, b) Systemic Mock Circulation Loop. (VoC: Venous Compliance Chamber) (AoC: Arterial Compliance Chamber) (LA: Left Atrium), and c) Impeller with motor

compliance can be varied either by varying volume of air or by varying the pressure exerted by air in the compliance chamber. The resistance of the blood vessels is modelled as a lumped parameter, adjusted by a flow control valve. To prevent interference with the pressure flow rate response of the MCL due to connecting tubes, the resistance of all the tubes combined is set at 0.06 mm Hg.s/mL (Gregory et al., 2017). Clear acrylic tubes of internal diameter of 20 mm were used for the arteries and veins to lower the frictional losses.

Table 4: Design parameters for systemic mock circulation loop.

Parameter	AoC	VoC	LA
Compliance	1.65 mL/mm Hg	10 mL/mm Hg	-
Diameter	100 mm	150 mm	40 mm
Height	250 mm	600 mm	400 mm
Pressure	Variable	Variable	atmospheric

An Arduino Uno is used to link the sensors with the workstation. Two MPX-5100 AP pressure sensors (NXP Semiconductors, Netherlands), are used, along with a non-invasive ultrasonic flow sensor - UF08B100 (Cynergy 3, UK).

4 PARTICLE IMAGE VELOCIMETRY

Particle Image Velocimetry was used as a flow visualization methodology. Due to the small size of the pump, there were several constraints, namely a) the observational area should be optically accessible, which was achieved by making a glass casing, b) the seeding particles should follow the flow field and should reflect the laser light in sufficient amount to be captured by the camera, for which hollow glass particles, coated with silver, of 10 micron diameter were used. In order to avoid the effect of the curvature, of pump casing, a rectangular acrylic casing was made to enclose the pump and was filled with a mixture of water-glycerol (35% glycerol and 65% water) to match the refractive index. The study was conducted in two parts, (i) the laser was illuminated in the vertical plane and the camera was placed in the front (figure 3a) and (ii) the laser was illuminated in the horizontal plane and the camera was placed at the top (figure (3b, 3c and 3d)).

Image acquisition is accomplished with a commercial available PIV system (Dantec Dynamics,

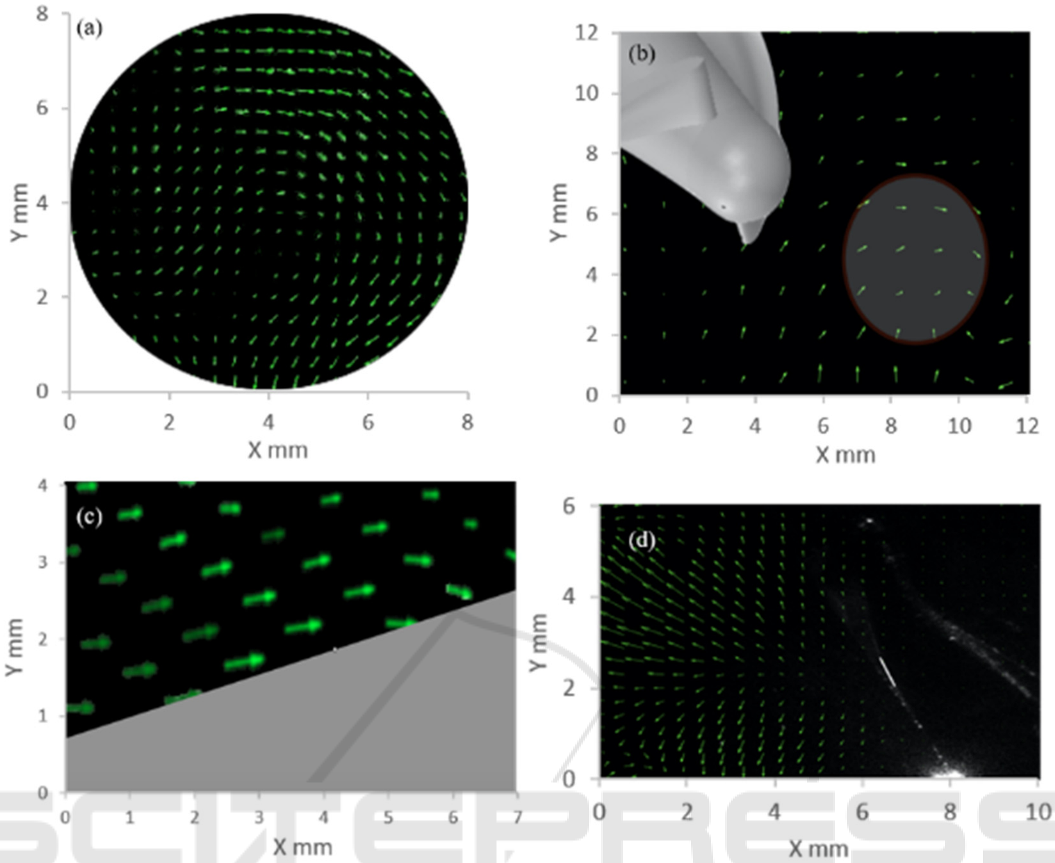

Figure 3: a) Inlet flow regimes, b) flow vortices at Leading edge, c) no vortices or stagnation at middle of the impeller, and f) bifurcation zone at the outlet.

GmbH, Germany) using a 400 mJ Nd:YAG laser at 532 nm. A CCD camera along with Navitar zoom 6000 lens was used to capture the flow field. Single frame double-pulse laser mode was used to arrest the motion of the impeller at high speed. PIVlabs toolbox in Matlab (The Mathworks, Inc., Natick, MA, USA) was used to analyse the flow fields (Thielicke et al., 2014). The impeller was painted black to minimise the pseudo reflections from impeller surface. Figure 3 explains the flow fields in various regions of the pump.

5 RESULTS AND DISCUSSIONS

A PVAD with diameter 7.6 mm and impeller length 15 mm has been successfully prototyped to achieve an optimum flow rate of 2.5 L/min at 60 mm Hg. There was a trade-off between pressure rise, power requirement and net blood exposed area when wrap angle and chord length is varied (Table 2 and Table 3). The increase in wrap angle from 90^0 to 250^0 have shown an increase in flow rate. The final prototype has a wrap angle of 250^0, to achieve 2.5 L/min of flow rate and chord length of 12 mm, to accommodate 7 mm of shaft length. The reduction in constant hub diameter of 5.8 mm to variable hub diameter of 3 mm at the leading edge and 5.8 mm at the trailing edge has increased the net flow rate at the same pump speed. Moreover, reducing the blade thickness from 1 mm to 0.5 mm has increased the flow area for the same size of PVAD. Figure 1a represents regions of vortices at the trailing edge possibly caused to the absence of the diffusor. The trailing edge angle of the impeller can further be modified to eliminate this recirculation region. Figure 1b shows that the shear stress distribution at the entry is below 400 Pa, which is within the acceptable limits (Song et al., 2004) and (Yu H., 2015). The highest shear stress regions were at the leading edge of the impeller when the fluid is expected to make its first contact.

Figure 1c represents the velocity vectors at 50%

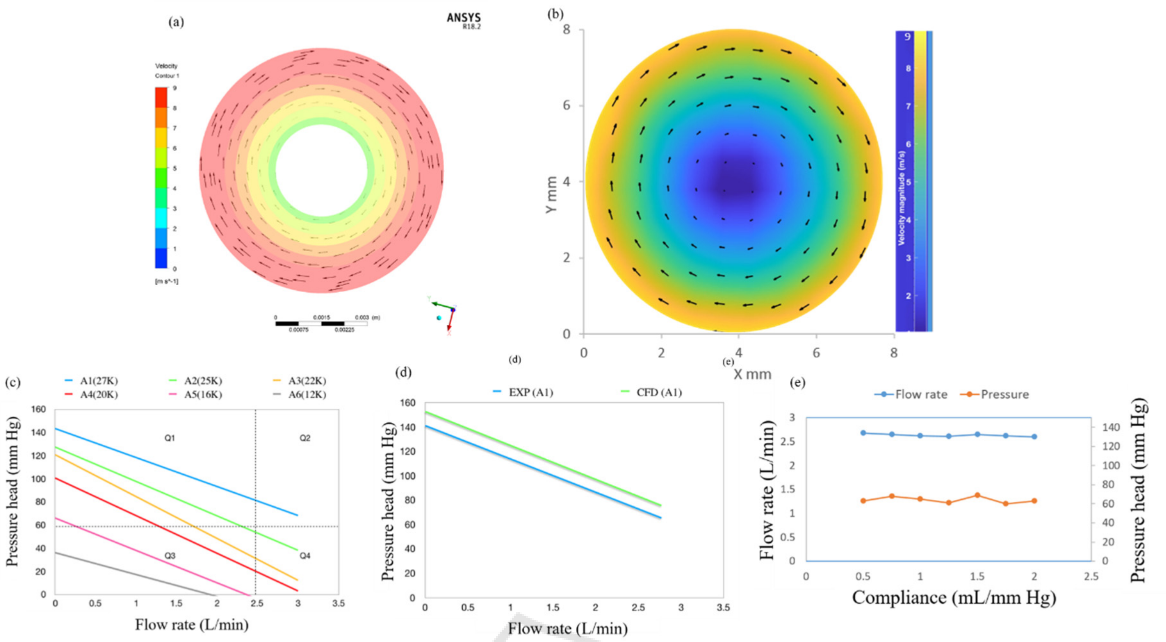

Figure 4: a) CFD results at inlet, b) PIV results at inlet, c) H-Q curve of designed PVAD at various speeds, d) Comparison of CFD and Experimental HQ curve, and e) Pump performance at different Arterial compliance value.

span, with a maximum velocity of 9.3 m/sec and figure 1d represents the leakage losses in the pump due to the clearance gap which are not accounted for in the conventional pump design theory being used.

Figure 3a and 3b illustrates the flow regime at the inlet to impeller under front and top view respectively, and shows recirculation at inlet as expected, due to the elimination of flow straightener. Figure 3c shows straight flow fields without any vortices at the middle section of the impeller. Figure 3d shows a bifurcation region at the outlet of impeller possibly due to sudden increase in flow area. The spatial resolution is 16 pixels which corresponds to approximately 0.125 mm.

Figure 4a illustrates the CFD velocity contour and vectors for the optimum design and figure 4b illustrates the experimental PIV contour and vectors. The maximum velocity is near the shroud and it decreases towards the centre. The difference between the CFD and the experimental results is less than 10%.

Figure 4c represents the H-Q curve for various conditions ranging from 27000 rpm (A1) to 12000 rpm (A6). It can be seen that the designed point is achieved with A1 condition. The region Q1 represents points at which pressure difference above 60 mm Hg can be achieved. Region Q2 refers to the extreme working region of the PVAD mainly during the condition of multiple organ failure. Region Q3 represents the working region under recovering heart condition and region Q4 refers to high flow rate conditions under low pressure.

Figure 4d is a comparison between experimental and CFD results. It can be seen that CFD has marginally over predicted the PVAD's performance. Figure 4e shows the pump performance by varying the Aortic Compliance, from (2 mL/mm Hg to 0.5 mL/mm Hg). The designed PVAD showed a consistent performance with less than 6% variation under diseased heart condition.

The results shown agree with the defined problem, that is, the PVAD developed is capable to deliver 2.5 L/min at 60 mm of Hg. These characteristics very well matches with the state of the art devices available as of now (Lima et al., 2016) and (Van et al., 2016). Moreover the size of the PVAD is within anatomical space constraint. Current limitation of this PVAD, due to unavailability of low power high rpm motors, is to deliver higher flow rates, upto 5 L/min, with same dimensions. The future work will be focused on a) testing the prototype with blood to measure Normalised Index of Hemolysis (NIH), to better interpret the trade-off between wrap angle and chord length and b) to insert the motor impeller assembly into a catheter and check dynamic response of PVAD with blood in SMCL.

6 CONCLUSION

In this study a Percutaneous Left Ventricular Assist Device (PVAD) is designed and validated via Systemic Mock Circulation Loop (SMCL), and Computational Fluid Dynamics (CFD). The flow field was visualized using Particle Image Velocimetry (PIV). The iterative design procedure successfully eliminates the variables one by one to reach an optimum design parameter using conventional pump theory. SMCL and PIV turns out to be insightful in an early stage development of PVAD to predict pump performance under varied arterial compliance and visualizing regions of vortices at various regions of the impeller. The PVAD showed consistent performance under diseased heart condition with a reduced arterial compliance.

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