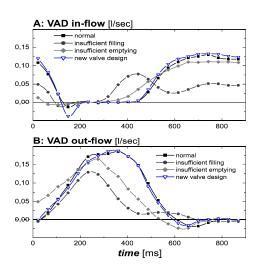
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Introduction: Acute cardiac insufficiency and heart failure requires immediate therapeutic intervention including the implantation of artificial hearts or ventricular assist devices (VAD) replacing or assisting the failing heart. A typical VAD system and its parallel connection to the cardiovascular system are illustrated in figure 1. The blood flow is maintained by bypassing the heart by connecting the inlet of the devices to the ventricular atrium and the outlet to the aorta or pulmonary artery. VAD implantation is often performed on a temporary basis to serve as bride-to-transplantation (temporary support until suitable transplant heart is available) or as bridge-to-recovery (temporary support to relieve load until heart recovers). The role of the ventricular assist device (VAD) in the management of heart failure is expanding, but there is still a high risk for complications. The most common described complications are bleeding, infection, tamponade, respiratory events, technical problems and neurologic events [1]. Thrombosis as shown in figure 1 (right) may be the reasons for neurologic events and could mean a high rate of morbidity and mortality. Most often fibrin or thrombus formation is generated near the inflow or outflow valve or in the pump chamber due to insufficient anticoagulation or a poorly adjusted system. In addition, particular flow characteristics inside the VADs such as vortex formation, flow reversal and thus increased residence times may also help to explain the high rate of thrombo-embolic events after VAD implantation. However, to date no systematic evaluation of flow patterns in VADs has been reported and the effect of operating conditions or device design (geometry of pump chamber and valve systems at inlet and outlet) on flow characteristics and thus VAD performance is poorly understood. It was therefore the purpose of this study to use flow sensitive 4D MRI for a detailed analysis of local and global 3D flow dynamics in a clinical routine VAD under different system adjustments and with a new valve design.

Methods: A routinely clinical used PVAD (MEDOS AG, Stolberg, Germany) was integrated into an MR-compatible mock loop. Periodic pressure waveforms were transferred to the VAD circuit to generate pulsatile flow within the VAD model system (figure 2). All MR experiments were performed using a 3T MRI system (TRIO, Siemens, Germany) using time-resolved 3D phase contrast MRI (flow sensitive 4D-MRI) [2]. Measurements were prospectively gated to the RR-interval simulated by the pump system and 21 time frames with a temporal resolution of 42.4ms were collected within the flow cycle [3]. Flow sensitive 3D MRI was performed to measure time-resolved threedirectional flow velocities in the entire device under ideal conditions (full fill, full empty), insufficient filling and a insufficient emptying of the pump chamber. In addition, a completely new valve design was evaluated for the first time. A patient monitor (SIRECUST SIEMENS) was used to monitor the pressure conditions at the inlet and outlet in the mock loop. Advanced computer aided 3D flow visualization methods were employed to derive a comprehensive picture of flow dynamics within the VAD system under this different conditions.

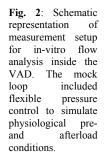
Results: With the combination of the mock loop and the real time pressure monitoring we were able to adjust physiological pressure conditions at the in- and outlet (~80mmHg afterload, 5-8 mmHg preload). 3D visualization revealed locally accelerated flow and vortex formation inside the VAD (figure 3). Flow pattern changes for different operating conditions were clearly identified and included impaired out-flow and pump chamber emptying. Most noticeably, the new valve design clearly improved VAD function and reduced valve insufficiency in the inflow cannula. Figure 4 shows the quantified time resolved flow during one pump cycle under different operating conditions and additional with the novel valve design.

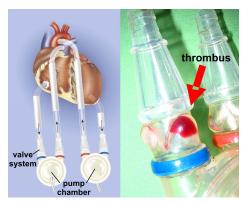
Fig 4: Quantified time resolved flow during one VAD pump cycle near the valve region at the inlet (A) and outlet (B). Note the considerably impaired performance for insufficient emptying (diamonds) and particularly insufficient filling (circles). The VADs with standard (squares) and novel (open rectangles) valve design demonstrated almost identical flow behavior.



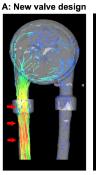
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Fig. 1: Biventricular cardiac support with PVADs connecting left the (right) ventricle with the ascending aorta (pulmonary artery). Complications that can result in device failure include thrombus formation in the bulb of the inflow valve system.





pressure monitoring control MR-scanner triager signal



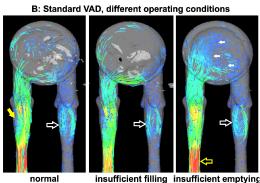


Fig. 3: 3D flow characteristics inside the VAD during the peak outflow phase (systole). The gray shaded area represents an iso-surface rendering of the magnitude data and shows the VAD geometry including pump chamber and valve systems at in- and outlet. A: A novel valve design using a differently shaped valve support region resulted in improved VAD performance. In addition to improved filling of the out-flow cannula (red arrows compared to solid yellow arrow), vortex formation proximal to the in-flow valve was virtually eliminated. B: The effect of different operating conditions in the same VAD clearly resulted in considerable differences in VAD function. Compared to normal operating conditions, insufficient VAD filling resulted in reduced filling and velocities during out-flow. Insufficient emptying lead to impaired clearing of the pump chamber (small white arrows) while marinating high out-flow velocities (open yellow arrow). Vortex formation proximal to the inlet valve was clearly visible for all operating conditions (open white arrows)

Discussion: Complex flow patterns, valve insufficiency or vortex formation and locally accelerated flow point towards the potential of the presented methodology to further deepen the understanding of VADs and complications such as thrombus generation within the device. The results of this study provide insight into the mechanisms underlying possible thrombus formation inside a VAD. Furthermore, these insights may form the basis to optimize the device's adjustments, the design and its need for anticoagulation.

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