

Messung des stationären Vorwärtsflusses einer Transkatheter-Aortenklappenprothese mittels Particle Image Velocimetry

Measurement of Steady Flow through a Transcatheter Aortic Valve Replacement by means of Particle Image Velocimetry

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TAVR, PIV, ISO5840, hemodynamics, testing of heart valves

Abstract

Cardiovascular diseases are among the most common diseases with a high mortality rate, including aortic valve stenosis and insufficiency. For patients with an increased risk for open heart surgery, the minimally invasive implantation of a transcatheter aortic valve replacement (TAVR) has become the treatment of choice. During the procedure, the prosthetic heart valve is placed inside the aortic root in the region of the stenosed native valve.

Anatomically, the aortic root is formed from three bulges called sinus. It is commonly assumed, that long-term outcomes after TAVR are influenced by hemodynamic factors. Therefore, the analysis of the velocity field surrounding the TAVR device in the aortic root is highly relevant. In particular, the occurrence of recirculation areas and unphysiological shear rates are of central interest. Numerical and experimental methods allow a detailed investigation of the flow phenomena in the aortic root, but should be mutually investigated for validity of the results.

We have conducted previous studies, in which pulsatile flow conditions were both numerically simulated by means of computational fluid dynamics (CFD) and, additionally, measured using particle image velocimetry (PIV). Nevertheless, the validation of pulsatile flow phenomena is challenging, especially when matching the initial conditions and the boundary conditions between experiments and simulations. For this reason, the ISO 5840 suggests a steady-state forward flow assessment of TAVR for validation and research purposes.

Within the current work, we demonstrate the development of a test bench that allows the steady-state flow through a TAVI implant to be experimentally investigated by means of PIV. The test bench was composed of a circulation system, driven by a centrifugal pump, a reservoir and a test chamber, including the TAVR mounting. A PIV system from Dantec-Dynamics was used to measure the flow fields.

First, we measured a Hagen-Poiseuille profile inside a straight tube, at a flow rate of 3.9 l/min. The averaged velocity profile along the flow direction measured by means of PIV showed minor differences compared to the analytical solution. The amplitude of the velocity corresponded closely. The absolute deviation was 0.0091 m/s on average and 0.0266 m/s at maximum over the whole profile.

Secondly, PIV measurements on the aortic root model including the TAVR prototype were done at four different Reynolds numbers. We observed that the maximum velocity measured

with PIV decreased when the volume flow was reduced. Furthermore we saw similar jet formations as well as vortex structures in all measurement configurations. It was noticeable that the main vortex got bigger with smaller Reynolds numbers.

In this work, we have shown the development of a test bench for the experimental investigations of steady-state fluid flow through a TAVR device by means of PIV. Due to the simplification by neglecting the temporal variation and flow in laminar Regimen, the complexity of the hemodynamic situation is reduced, allowing an initial validation workaround. This can help and drive the development of new numerical methods such as physically driven neural networks.

Introduction

The minimally invasive implantation of a transcatheter aortic valve replacement (TAVR) has become the standard of care for patients with severe aortic stenosis who are at high risk for open heart surgery due to various comorbidities [1].

The expansion of the patient cohort to younger patients requires a prolonged durability of the prosthetic heart valves [2,3]. Therefore, flow-induced complications, such as thrombosis, are becoming a focus of research [4].

In 2021, the ISO 5840 standard was revised to incorporate new research findings into the quality assurance of heart valves, including those in the field of fluid mechanics [5].

Quality assurance should make it possible to assess the risks of implants for the patient. This will enhance patient safety, should assist the physician in implant selection, and drive the development of new generations of implants.

According to the new ISO 5840 standard, an assessment of the thrombogenic and hemolytic potential of the valve replacement must be performed. Experimental methods such as Particle Image Velocimetry (PIV) and numerical methods such as Computational Fluid Dynamics (CFD) are mentioned to determine the risk of thrombus formation regarding a TAVR. Additionally, the use of experimentally determined measured values for the validation of flow simulations is emphasized [5].

In addition to pulse duplicator measurements, which can be found in numerous publications, measurement of steady-state forward flow is also recommended in the ISO 5840-1 [5].

Regarding numerical methods, the simplification due to the neglect of the temporal variability leads to a reduction in computational time and modeling level for numerical methods, and thus, can help leverage the development of suitable numerical methods such as physical driven neural networks.

Particle Image Velocimetry Measurement of TAVR

Flow Loop

The developed flow loop used for flow field assessment of steady state forward flow in TAVR is illustrated in figure 1. The aortic root model was connected to acrylic pipes on both ends to ensure straightness and a fully developed flow at the inlet of the aortic root for Reynolds number up to $Re_{max, laminar} = 1300$. The entrance length was approximately 180 cm long, $75D$, where D is the pipe diameter of 2.4 cm. The exit length was approximately 120 cm, $50D$, which was intended to prevent disturbances induced by the pipe elbow from influencing the upstream flow of the heart valve. An impeller pump (Nirostar 2000-A, ZUWA-Zumpe GmbH, Laufen, Germany) was implemented to drive the fluid flow. The reservoir integrated an inline heat exchanger (ED v2, Julabo, Seelbach, Germany) to keep the fluid temperature constant at $t = 37^{\circ}\text{C}$, resulting in a constant viscosity. The reservoir was also used to fill the flow loop

and mix the test fluid. A stagnation chamber was positioned downstream to damp pulsatility of the flow.

A flow straightener was located between the stagnation chamber and the acrylic pipe. It was composed of a diffusor, a bundle of tubes, a metallic grid and a nozzle. The flow straightener was implemented to reduce pressure and velocity fluctuations as well as secondary flow before entering the acrylic pipe. The flowrate was measured by using the inline ultrasonic flow sensor LEVIFLOW LFS-50 (Levitronix, Zurich, Switzerland).

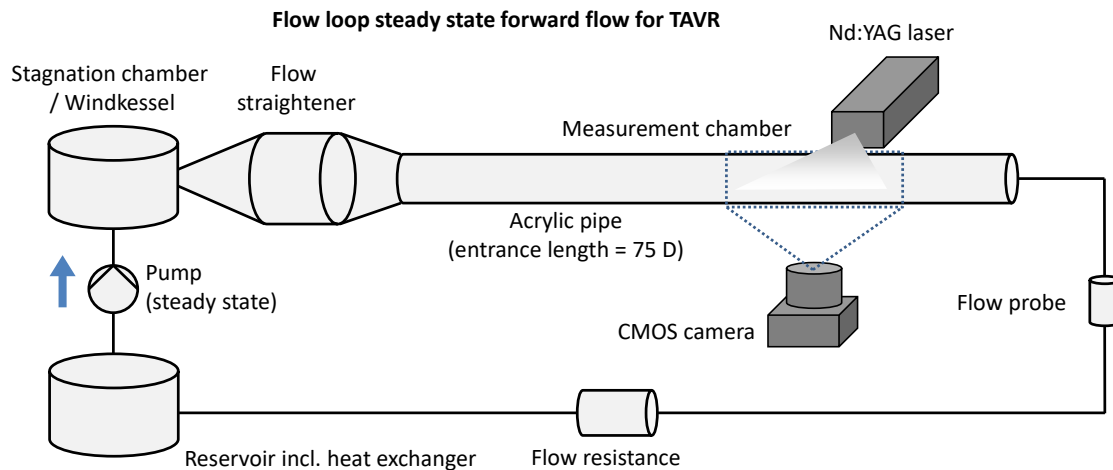


Figure. 1: Schematic illustration of the flow loop used for steady forward flow testing of TAVR

The Newtonian blood analog fluid was composed of 0.9% sodium chloride solution (NaCl solution) and glycerol (mixing ratio glycerol/total mixture = 0.506) resulting in a fluid density of $\rho = 1,1 \text{ g/cm}^3$ and a kinematic viscosity of $\nu = 3.5 \text{ cSt}$ [6], as recommended in ISO 5840 [5]. Two measurements were performed; the first one within a straight tube without implant as a reference (Hagen-Poiseuille flow) and a second one within a TAVR implanted in an aortic root model. The flow rate was adjusted during each experiment to match the specified Reynolds numbers, see tables 1 and 2.

Table 1: Hydraulic parameter set for steady state flow (Hagen-Poiseuille flow), Reynolds number Re , pipe diameter $d = 24 \text{ mm}$ and kinematic viscosity $\nu = 3.5 \cdot 10^{-6} \text{ m}^2/\text{s}$

Re	Flowrate [ml/s]	U_{mean} [m/s]
approx. 980	3.9	0.144

Table 2: Hydraulic parameter set for steady state TAVR flow; Reynolds number Re , pipe diameter $d = 24 \text{ mm}$ and kinematic viscosity $\nu = 3.5 \cdot 10^{-6} \text{ m}^2/\text{s}$

Re	Flowrate [ml/s]	U_{mean} [m/s]
1430	5.7	0.21
1180	4.7	0.17
930	3.7	0.14
680	2.7	0.10

Heart Valve model

For the experiments, a TAVR-Prototype developed by our (Institute for ImplantTechnology e.V.) was used. The TAVR consisted of a Nitinol frame, which was laser cutted, by means of femto-second laser cutting techniques (*StarCut Tube L600*, Coherent Inc., Santa Clara, California, USA). The TAVR had a leaflet from porcine pericardium, sutured to the Nitinol

stent frame. The aortic root model was fabricated from a transparent silicone (Sylgard 184 Silicone Elastomer; The Dow Chemical Company, Midland, MI, USA) with a refractive index of $n = 1.410$. The molds required for silicone casting were additively manufactured by means of 3D-printing (Objet30, Stratasys Ltd., Rehovot, Israel). A detailed description of the geometry of the aortic root model was published in Borowski et al. [7].

PIV System

The PIV system included a ND:YAG laser (wavelength $\lambda = 532$ nm, repetition rate of 8–15 Hz max. energy 145 mJ; Litron Laser Ltd., UK) as illumination source. The laser beam was expanded by means of light sheet optics, to a 1 mm thick light sheet.

The test fluid was seeded with fluorescent polystyrol particles (micro particles GmbH, Berlin, Germany) as tracer particles (diameter of particles $d_p = 10$ μm). Due to a density of $\rho_p = 1.05$ g/cm the tracer particles were buoyancy neutral and could follow the flow without slip. The fluorescent light of the tracer particles ($\lambda = 607$ nm) was detected by CMOS cameras (EoSens 12CXP, Mikrotron, Deutschland) equipped with long-pass filters (590 nm edge wave length, AHF Analysetechnik, Tübingen, Deutschland). The camera system and laser light sheet were aligned and the camera system was calibrated using a calibration target and linear transformation function.

During the measurements a particle density of 5-10 particles per interrogation area (IA) was adjusted ($IA = 64$ Px). For each single measurement, 100 double images were taken. The mean value of the 100 double images was subtracted from each captured particle image, so that the background had no influence on the calculation of the velocity from the particle images. An adaptive cross-correlation algorithm was used to calculate the velocity fields from the acquired particle images, allowing for a 50% overlap of the IA . The mean of the resulting 100 vector maps were finally computed.

Results

First, we measured a Hagen-Poiseuille profile. To do so, we inserted a straight tube with the same inlet and outlet length into the test bench instead of the aortic root and the TAVR. The measured results at a flow rate of 3.9 l/min were compared with the theoretical analytical solution, see figure 2. The measured values of the velocity profile measured by PIV were averaged over the IA s along the flow direction.

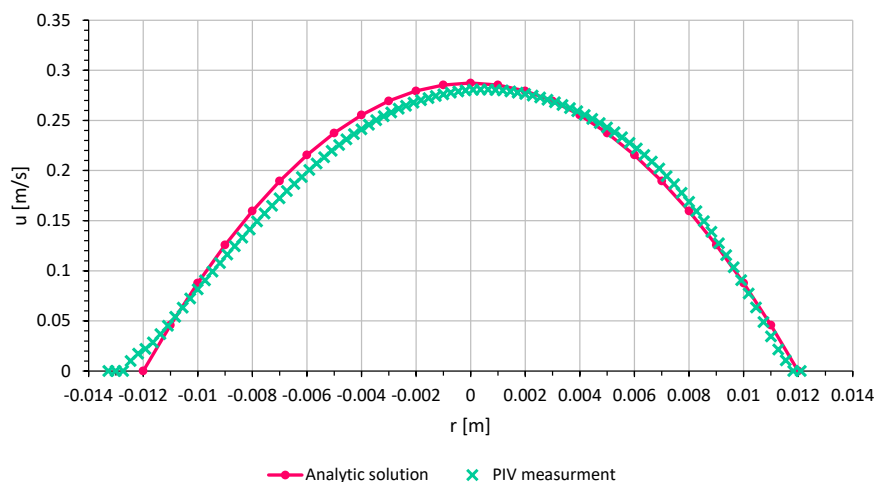


Figure 2: Measured velocities across the radius (r) of the tube compared with the analytical solution of a fully developed laminar profile for a flow of 3.9 l/min. The velocity $u(r)$ was obtained by means of spatial averaging over the measuring plane for different r ($\Delta r = 0.27\text{mm}$)

The PIV profile shows a shifted occurrence compared to the analytical solution. The amplitude of the velocity corresponds closely. The absolute deviation was 0.0091 m/s on average and 0.0266 m/s at maximum over the whole profile.

The results of the PIV measurement with the aortic root model including the TAVR prototype are shown below. The plot represents the velocity measurements in XY-plane of the measured section. The magnitudes of the measured velocity components as well as from the velocity field derived streamlines are shown in figure 3.

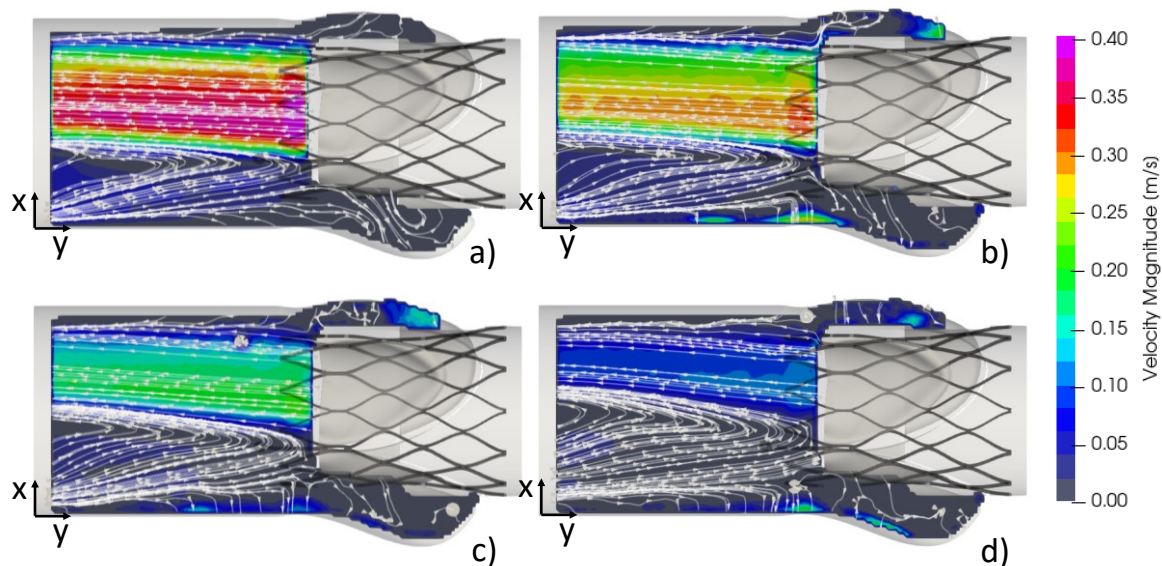


Figure. 3: Measured velocities in downstream direction of a TAVR during steady flow at a) $Re = 1430$ b) $Re = 1180$ c) $Re = 930$ d) $Re = 680$

As expected, the maximum velocity measured with PIV decreased when the volume flow was reduced. Similar jet characteristics as well as vortex formations can be seen at all measurement configurations. In each case, the jet showed a skewness leading away from the sinus investigated, here in the negative y-direction. It is also noticeable that the main vortex was bigger with smaller Reynolds numbers.

Discussion

The measured Hagen-Poiseuille profile showed a mild skew. This may be due to the concentric deviations of the inner diameter of the tube over the length of the tube. These imperfections should be compensated upon future work.

Nevertheless, the presented experimental setup allows the determination of the exact inlet profile for the validation of e.g. numerical methods. The measurements of the TAVI under different Reynolds numbers allow the validation of the flow field in a measurement plane with two velocity components. The advantage of the test setup clearly lies in the simplified flow situation where both pulsatile conditions and transient phenomena (at low Re) do not occur, which is particularly important for reduction of the computational time and modeling level for numerical methods and thus can drive the development of appropriate numerical methods such as physics informed neural networks. Aside from that, this test bench setup has disadvantages with respect to the hydrodynamic characterization of a TAVR, so that the opening and closing behavior cannot be evaluated. Due to the increasing vortex formation with decreasing Reynolds number, a matching of the Reynolds number of CFD simulation needs to be ensured when using experimental data.

Conclusion

The presented work demonstrates the development of a test bench to experimentally study steady-state flow through a TAVI implant by using PIV. The test bench consists of a circulation system driven by a centrifugal pump, a reservoir, and a test chamber containing the TAVR. A PIV system from Dantec-Dynamics was used to measure the flow fields. For comparison, measurements were made both with TAVR and in a straight pipe.

Future plans are to extend the PIV measurement system so that tomographic PIV can be used to measure three velocity components within the volume.

Simplification by neglecting temporal variability leads to a reduction in computational time and modeling level for numerical methods, and thus this steady state forward flow test setup can drive the development of new numerical methods such as physically driven neural networks.

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