

Laser Doppler anemometry measurements of steady flow through two bi-leaflet prosthetic heart valves

Velocimetria laser de escoamento permanente através de duas próteses cardíacas de duplo folheto

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Abstract

Introduction: *In vitro* hydrodynamic characterization of prosthetic heart valves provides important information regarding their operation, especially if performed by noninvasive techniques of anemometry. Once velocity profiles for each valve are provided, it is possible to compare them in terms of hydrodynamic performance. In this first experimental study using laser doppler anemometry with mechanical valves, the simulations were performed at a steady flow workbench.

Objective: To compare unidimensional velocity profiles at the central plane of two bi-leaflet aortic prosthesis from St. Jude (AGN 21 – 751 and 21 AJ – 501 models) exposed to a steady flow regime, on four distinct sections, three downstream and one upstream.

Methods: To provide similar conditions for the flow through each prosthesis by a steady flow workbench (water, flow rate of 17L/min.) and, for the same sections and sweeps, to obtain the velocity profiles of each heart valve by unidimensional measurements.

Results: It was found that higher velocities correspond to the prosthesis with smaller inner diameter and instabilities of

flow are larger as the section of interest is closer to the valve. Regions of recirculation, stagnation of flow, low pressure, and flow peak velocities were also found.

Conclusions: Considering the hydrodynamic aspect and for every section measured, it could be concluded that the prosthesis model AGN 21 – 751 (Regent™) is superior to the 21 AJ – 501 model (Master Series). Based on the results, future studies can choose to focus on specific regions of these valves.

Descriptors: Heart valve prosthesis. Blood flow velocity. Laser-Doppler flowmetry.

Resumo

Introdução: A caracterização hidrodinâmica *in vitro* de próteses de válvulas cardíacas fornece informações importantes quanto ao seu funcionamento, sobretudo se realizada por meio de métodos não-invasivos de anemometria. Uma vez obtidos os perfis de velocidade para cada válvula, é possível compará-las quanto ao seu desempenho hidrodinâmico. Neste primeiro estudo experimental de anemometria laser com válvulas mecânicas,

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Abbreviations, acronyms & symbols	
1D	Unidimensional
2D	Bidimensional
3D	Tridimensional
LDA	Laser Doppler anemometer

as simulações foram realizadas em bancada de testes para escoamento permanente.

Objetivo: Comparar perfis de velocidade unidimensional no plano central de duas próteses aórticas de duplo folheto St. Jude (modelos AGN 21 – 751 e 21 AJ – 501) submetidas a um regime de fluxo permanente, para quatro seções distintas, três à jusante e uma à montante.

Métodos: Proporcionar condições de similaridade para o escoamento através de cada prótese, por meio de bancada hidrodinâmica para escoamento permanente (água, à vazão de 17 L/min.) e, por meio de anemometria laser unidimensional, obter os perfis de velocidades para as mesmas seções e varreduras.

Resultados: Verificou-se que as maiores velocidades correspondem à prótese de diâmetro interno menor e que as instabilidades do fluxo são maiores à medida que a seção de interesse encontra-se mais próxima da válvula. Também foram verificadas as regiões de recirculação, de estagnação do fluxo e de baixa pressão, além dos picos de velocidade para o escoamento em questão.

Conclusões: Sob o aspecto hidrodinâmico e para todas as seções de interesse, foi possível concluir a preferência da válvula de modelo AGN 21 – 751 (Regent™) sobre a 21 AJ – 501 (Master Series). Os resultados obtidos permitiram escolher, para os próximos trabalhos, um foco de estudo mais específico para regiões concretas dessas próteses.

Descritores: Próteses valvulares cardíacas. Velocidade do fluxo sanguíneo. Fluxometria por laser-Doppler.

INTRODUCTION

In vitro hydrodynamic characterization of prosthetic heart valves provides important information regarding their operation [1,2], especially if performed by noninvasive techniques of anemometry [3-8]. Regarding hydrodynamic performance, it is possible to compare the velocity profiles for each valve and develop new designs. Velocity profiles are different for every type of valve and regions of flow stagnation and separation could occur, inducing formation of thrombosis, tissue overgrowth and/or calcification as well as blood hemolysis due to shear stress [1,9,10]. ISO 5840:2005 standard offers a pattern for the hydrodynamic performance testing of prosthetic valves, considering a steady or pulsatile flow and allowing for the evaluation of these valves [11,12].

Nevertheless, the comparison between prosthetic heart valves is possible under some conditions of flow similarity, which is the specific objective of this study: to compare the velocity profiles of two St. Jude bi-leaflet aortic valves with a nominal diameter of 21 mm exposed to a steady flow regime. The 1D velocity profiles were obtained at the central plane of flow, on four distinct sections, three downstream and one upstream of the valves.

This first experimental study is due to an academic agreement established between UNICAMP (Medical School, Department of Surgery) and EPUSP (Polytechnic School, Mechanical Engineering Department). The study was developed at the Medicine Center and Experimental Surgery and the Biomedical and Environmental Engineering Laboratory, from the Medical School (UNICAMP) and Polytechnic School (EPUSP), respectively.

METHODS

The objective of this study was to compare, during a steady flow regime, the velocity profiles at the central plane of two St. Jude bi-leaflet aortic valves. For this reason, it was necessary to establish a suitable methodology for experimental hydrodynamic testing. An academic agreement celebrated between EPUSP and UNICAMP made it possible to use the 1D LDA system, the steady flow hydrodynamic workbench, and the valve prostheses.

The *in vitro* simulations presented in this paper did not have the purpose of reproducing the physiological conditions of the test fluid (blood analog properties of viscosity, density, and temperature), neither mimicking the physiological pressure and volumetric flow curves. The test fluid used was water at 27°C and a steady flow condition was imposed in order to compare the velocity profiles of the two prostheses under the same range of volumetric discharge. In order to meet the specific purpose of this study (velocity profiles comparison), the ISO 5840:2005 guidelines [11] were not considered for the hydrodynamic performance analysis in steady flow regime (i.e., the imposition of volumetric flow discharge from 5 to 30 L/min., varying every 5 L/min.), although the unique imposed flow rate was close to the mean value established in those guidelines. Similarly, the question of the “effective orifice area” of the prostheses, discussed in the standard as criteria for the hydrodynamic performance analysis, was not addressed here. These characteristics, as well as pulsatile testing, are convenient and will be the target of next studies [13,14].

The materials and methods used in this study are presented below.

Hydrodynamic workbench for steady flow regime

The experimental workbench for the hydrodynamic testing in steady flow regime was designed at the Biomedical and Environmental Engineering Laboratory of EPUSP and was adapted at the Medicine Center and Experimental Surgery of UNICAMP.

The workbench (Figure 1) consists of two reservoirs, an acrylic test chamber, sealing rings, three spherical valves, connections and pipes in PVC, and a positive displacement hydraulic pump with a nominal flow discharge of 360 gallons per hour (22.71 L/min). The same flow discharge was imposed for each experiment, allowing for the comparison of the velocity profiles obtained from the valves. An indirect method of volumetric flow measurement was used, by determining the effective flow of the pump once the steady state regime was performed on the hydrodynamic workbench.

The effective pump flow discharge was obtained through variations in observed volume in a chamber of the experimental workbench during a certain period of time measured by a chronometer. With the experimental workbench adjusted for steady flow and with the hydraulic circuit to the testing chamber blocked (changing the valve in Figure 1, n.1, to the closed position), the filling up of the superior reservoir up to a stipulated height for a registered period of time was observed. The water volume was determined through the internal area of the base of the superior reservoir. The effective pump flow discharge was obtained dividing this volume by the measured time.

The steady flow regime was performed when the water level in the reservoirs remained invariable. The same flow resistance in the hydraulic circuit (equivalent resistance) was

established for each experiment. Considering the differences between the two cardiac prostheses used, they offer distinct resistances to flow circulation, which implies different pressure distributions for each one (see the Results section). The equivalent flow resistance (total head loss) for each experiment was ensured by regulating the inferior spherical valve of the hydrodynamic workbench (Figure 1, n. 2). This spherical valve implies an adjustable flow resistance to the hydraulic circuit. To validate each experiment, the other two spherical valves (Figure 1, n. 1 and n. 3) remained, fully open and fully closed, respectively. In addition, the same total water volume was ensured on every testing. The effective flow value can be seen in the results section.

In order to use the LDA system, a test chamber was conceived in a specific region of the hydraulic circuit (Figure 1, Detail A). The design of this test chamber is shown in Figure 2. It consists of two pipes and an optical confinement (Figure 2, n. 1), both in acrylic, and seal rings. The prosthesis (Figure 2, n. 4) is positioned under pressure, by longitudinal assembling of the two pipes, which in turn slide within the test chamber orifices. The two pipes downstream and upstream of the prosthesis (respectively, n. 2 and n. 3 in Figure 2) have internal diameters of 21.20 mm (able to shelter the chosen prosthesis) and both pipes are 210 mm long (upstream pipe length allows for the developed flow to be measured; downstream pipe length offers LDA measurements on different sections). Each pipe has one orifice to acquire pressure (Figure 2, n. 5) based on the height of the water column so that differential pressure can be obtained. When the pipes are positioned, they lock the prosthesis inside them. In this condition, the orifices are located 40 mm upstream and 20 mm downstream of the prosthesis.



Fig. 1 - Steady flow hydrodynamic workbench photo
Highlighted: A (test chamber), 1 (top spherical valve), 2 (bottom spherical valve) and 3 (maintenance spherical valve)

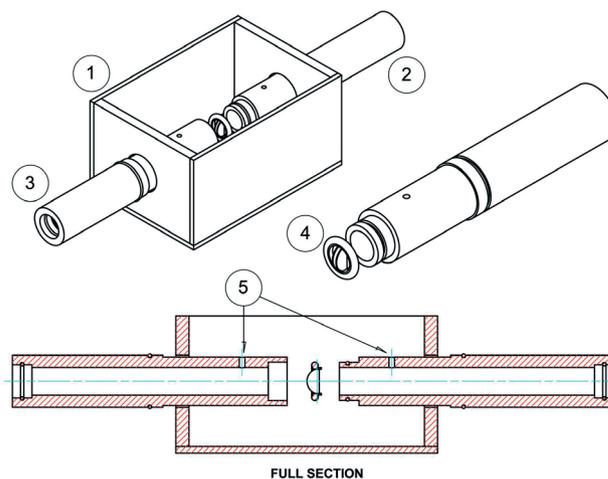


Fig. 2 - Workbench test chamber detail
Highlighted: 1 (optical confinement), 2 (upstream pipe), 3 (downstream pipe), 4 (bi-leaflet mechanical heart valve) and 5 (holes for differential pressure acquiring)

Prostheses used

The high frequency of valve replacement in the aortic position gave support to the choice of these prosthesis models in the research here presented [15-16].

Two St. Jude bi-leaflet prosthetic aortic valves, models 21 AGN – 751 (Regent™) and 21 AJ – 501 (Masters Series), [17] were used. Although the two valves have the same nominal diameter of 21 mm, they have internal diameters of 19.6 mm and 16.7 mm, respectively. These prostheses models are shown in Figure 3.

Considering dimensional variations of mechanical valves are negligible, only one prosthesis of each model was used in this study. So the results were considered independent of the number of samples. On the other hand, the internal diameter difference of the two prostheses (two different models) enabled the comparison and discussion of the results. Further studies are necessary to properly define the number of samples (prostheses).

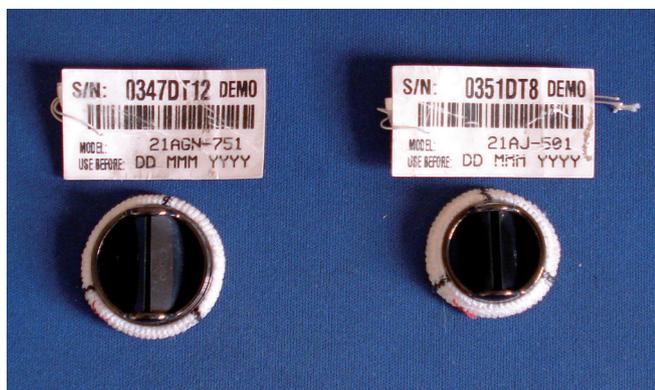


Fig. 3 - Aortic bi-leaflet prosthetic heart valves used
Highlighted: from left to right, models 21 AGN - 751 and 21 AJ - 501

LDA used: working principle and description

Before describing the LDA system used, its working principle is briefly discussed.

The laser Doppler anemometry system (or LDA) consists of a first stage of laser beam transmission so that pairs of laser beams converge into an intersection point, representing the point of interest to be measured (flow containing seeding particles). At the same time, another stage occurs, which is characterized by the detection of scattered light radiation from the small intersection volume (when particle motion is due to specific flow velocities). Then, these data can be conditioned and processed for a particular type of information, since the flashing light frequency (Doppler frequency) is proportional to the flow velocity at the measurement point.

In the transmission phase, the purpose is to have the pairs of laser beams converging in order to form a measuring

volume at a particular intersection point. Since it is usually possible to separate three laser-beam wavelengths (violet, blue, and green) generated by the source, each wavelength can be manipulated in pairs of beams in orthogonal planes and it can provide information on up to three velocity components simultaneously: in each plane and for a specific point. This is why LDA systems are suitable for accurate velocity measurements. The most well-known configuration is called backscattering. In this configuration, the probes perform two simultaneous functions. Firstly, they are responsible for the convergence of monochromatic pairs of laser beams into the measurement point (intersection volume) through the outer lens (focusing lens). Secondly, they receive the scattered light (from seeding particles) through the inner lens (reception phase).

When crossing the measurement volume, the seeding particles (contained in the flow) induce the scattering of light in varying intensity according to the flow velocity at that point. This returning light is redirected to the detection, signal conditioning, and processing phases. Finally, the results of the processing phase are manipulated and displayed using specific software. Thus, it is possible to know the velocity components of flow (1D, 2D, or 3D, depending on the system configuration) through sweeping points comprised of a linear sequence of measurement volumes.

In this study, the LDA system of the Laboratory of Surgical Technique and Experimental Surgery at UNICAMP was used. The equipment is from Dantec Dynamics and it is actually capable of 1D velocimetry measurements only. This LDA system is based on Argon ions laser (Innova 70 Coherent, nominal power of 4 W), which is refrigerated by air with a backscattering configuration. The BSA Flow Software, from the same company, was also used.

The scope of this study was the use of the 1D LDA system in order to obtain information about the horizontal plane of the flow. In addition, a manual traverse system was used for positioning the probe and, consequently, scanning the observed measurement points upstream and downstream of the prostheses.

RESULTS

The 1D measurement results (one section upstream and three sections downstream of the valves) obtained for the two St. Jude bi-leaflet prosthetic aortic valves through a steady flow are presented. Introductorily, the flow conditions, which were derived from the operating workbench, as well as the proper positioning of the LDA probe, are presented below.

Preliminary preparation

The prostheses were arranged in the test chamber as described in the methodology. The test fluid used was water at 27°C, with the addition of seeding particles of 20 µm in

diameter (Dantec Dynamics, Polyamide Seeding Particles).

Plastic hoses were conveniently connected with a manometer in order to acquire differential pressure from the pipes' orifices upstream and downstream of the prosthesis (Figure 2, n. 5).

As mentioned in the methods section, the flow used in the test chamber was the pump's effective flow, once both the same volume of water on the workbench and the steady flow regime on each experiment was established. The volumetric flow discharge was obtained indirectly: volume variation over measured time. This procedure was repeated three times and an arithmetic average was obtained. It was found that the flow rate imposed on the prosthesis was approximately 17 L/min. and this value represents the only possible flow discharge for the test chamber.

With the LDA system in operation, the manual traverse system was referenced so that the laser beams always reached the mean horizontal plane of the pipes. A controlled routine established, via software, for the operation of the LDA system allowed some variables of the spectral analyzer to be controlled during the experiments, such as: the acquisition rate (up to 10 KHz), the photomultiplier voltage (up to 1,000 V), the amplifier signal gain (35 dB), and the operating power (170 mW). As described in the methods section, the LDA system operated only as 1D, through a probe with a pair of laser beams for the green spectrum and with the following characteristics: wavelength (λ) of 514.5 nm, diameter of 1.35 mm, focal length of 160 mm, spacing of the laser beam pair in the focal lens (frontals) of 38 mm, and fringes spacing (at the intersection volume of the beams) of 2.182 μ m, with a total of 35 fringes.

After establishing the horizontal plane for the reference position, the probe was positioned in the sections and points of interest, as shown in Figure 4.

Following the flow direction, the first point of interest was

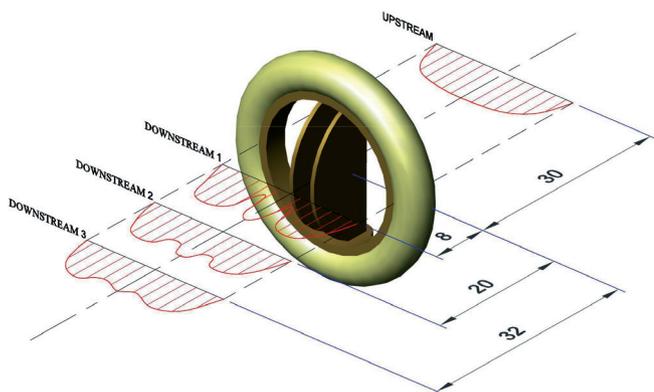


Fig. 4 - Measurement sections referenced at the prosthesis positioning Highlighted: in the flow direction, upstream at 30 mm, downstream 1 at 8 mm, downstream 2 at 20 mm and downstream 3 at 32 mm from the valve

at 30 mm before the prosthesis (Figure 4, upstream). Three other points of interest were located after the prosthesis at 8 mm (Figure 4, downstream 1), 20 mm (Figure 4, downstream 2), and 32 mm (Figure 4, downstream 3). Therefore, the 1D LDA measurements consisted of scans of four sections for each prosthesis: one upstream and three downstream of the valve.

Measurements in the hydrodynamic workbench

After each prosthesis was assembled in the test chamber (Figure 2), the steady flow was established, and the probe was conveniently positioned facing the measurement point (Figure 4), the LDA system was used to obtain the 1D velocity profiles at the central plane along the inner diameter of the pipes (21.20 mm) and for four sections along flow direction. Every new measurement at the point of interest was obtained by displacing the LDA probe longitudinally through 0.50 mm over the horizontal diameter plane.

Under 17L/min. of flow discharge, differential pressure was 42 mm of water column (or 3.09 mmHg) for assembling the prosthesis 21 AGN - 751 (internal diameter of 19.6 mm) and 63 mm of water column (or 4.63 mmHg) for the prosthesis 21 AJ - 501 (internal diameter of 16.7 mm).

Figures 5 to 8 show the measured velocity profiles for the two prosthetic valve models, under steady flow conditions with a volumetric discharge of 17 L/min, for each point of interest. The discussion of the results is presented in the next section.

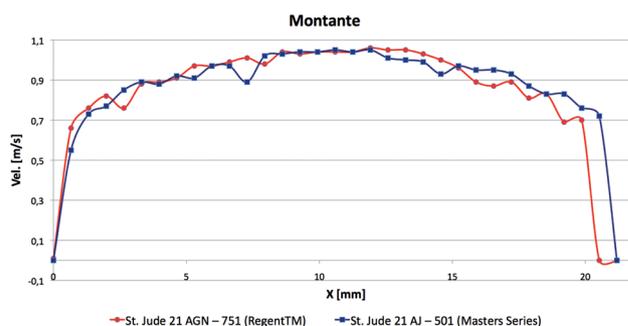


Fig. 5 - Velocity profiles at 30 mm upstream of the valves

DISCUSSION

As stated in the methods section, the scope of this study does not address the guidelines of ISO 5840:2005 for hydrodynamic performance analysis. It only consists of accomplishing a comparison of the velocity profiles obtained for two models of valves with different internal diameters, under a common condition (volumetric discharge of 17 L/min.). Therefore, the prostheses provide different

flow restrictions in the passage of the flow, which implies different localized head loss. According to the literature, a prosthesis with larger diameter offers a smaller head loss. To ensure that in each of the experiments the same equivalent resistance was imposed on the hydraulic circuit, we used a spherical valve (Figure 1, n. 2). In fact, when the prosthesis with smaller diameter was used, this specific spherical valve was kept more open.

Each velocity profile obtained at 30 mm upstream the valve allowed for the flow discharge to be estimated by integrating the velocity profile in the referenced area. This calculation confirms the previously measured value of 17 L/min. with an error margin of approximately 5%. However, the testing by means of this single flow discharge represents an intrinsic limitation of this study [18].

The results obtained using the 1D LDA correspond to those expected from the literature: for all of the downstream measurement sections, greater velocities correspond to the prosthesis with a smaller internal diameter (16.7 mm, St. Jude model 21 AJ – 501), with higher transversal gradients near the pipe wall. In terms of pressure measurements, the prosthesis with a larger internal diameter (19.6 mm, St. Jude model 21 AGN – 751) presented smaller values of differential pressure and, consequently, smaller local head loss (42 mm of water column, or 3.09 mmHg). This implies smaller resistance to the passage of flow, compared with the prosthesis with a smaller diameter. In terms of flow instabilities downstream the prosthesis, it was observed that they are greater in the section near the prosthesis (section 1, downstream). It was found that although certain symmetry of the velocity profiles occurs, this symmetry is not significant.

Some small negative values of velocity were measured with the LDA system. Recirculation zones were observed for both prosthesis models, St. Jude 21 AGN – 751 and St. Jude 21 AJ – 501, particularly in the downstream sections. Although negative values of velocity were expected in the prostheses surroundings, they were not expected at the farthest sections (downstream 2 and 3). The transversal gradients of velocity are much more pronounced in the case of the prosthetic valve with a larger diameter (St. Jude 21 AJ – 501), which is possible to observe by analyzing Figures 6 and 7. Similar future studies with measurements in more than one direction, i. e., 2D LDA measurements, will be used to validate the results obtained in this study.

In terms of hydrodynamics, the prosthesis with a larger internal diameter should be adopted, considering the smaller peak velocities in the aortic root and the smaller transversal velocity gradients in this case, with less probability of recirculation. This is in accordance with the adequate sizing of the effective orifice area criteria so that residual stenosis after valve implantation can be avoided, thereby minimizing the occurrence of elevated pressure gradients through the valve [19]. On the other hand, the occurrence of

unsatisfactory pressure gradient across the prosthesis should also be avoided, as it would result in an incomplete reduction of the left ventricular hypertrophy [20,21]. Manufacturers have developed models of valves for different sutures without addressing controversies about the proper diameter of the prosthesis according to the patient's aortic annulus [19,20] and relying on the experience of clinical practice favoring hemodynamic performance.

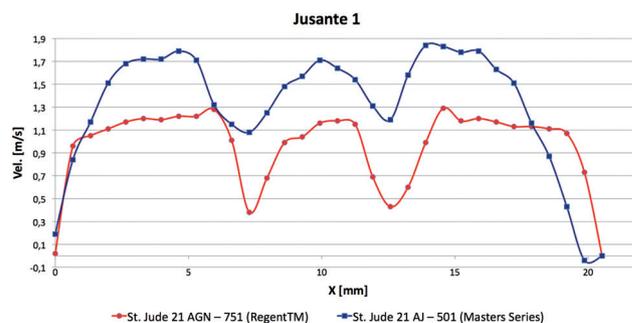


Fig. 6 - Velocity profiles at 8 mm downstream of the valves

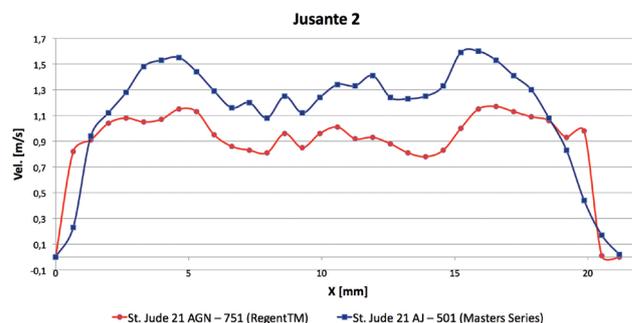


Fig. 7 - Velocity profiles at 20 mm downstream of the valves

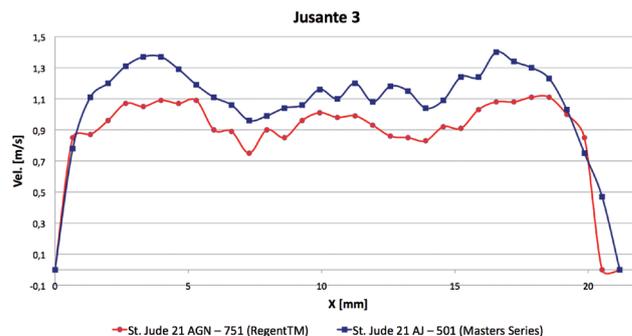


Fig. 8 - Velocity profiles at 32 mm downstream of the valves

This can be seen for the two St. Jude prostheses tested here. The AGN 21 - 751 (Regent™) model is designed for supra-annular suture and the AJ 21 - 501 (Masters Series) model for intra-annular suture. Currently, due to hemodynamic advantages, most surgeons employ the supra-annular positioning, even if there is a discrepancy among manufacturers regarding different internal diameter of the prostheses based on valves with the same nominal diameter [20-22]. For the prostheses studied here, which are from the same manufacturer, the choice of supra-annular prosthesis implies a valve with a larger inner diameter, although the two models have the same nominal diameter (21 mm). In fact, smaller peak velocities and a better hydrodynamic behavior were observed for all measurements of the supra-annular prosthesis 21 AGN – 751 (Regent™) points of interest (Figures 6 to 8). However, it is not possible to disregard some surgical priorities that can be more relevant in some cases than the hydrodynamic aspects for a certain group of patients [20].

Clearly, the present study has some limitations because it does not include other flow ranges besides 17 L / min. [11, 18] and the LDA system available is restricted to 1D measurements. It would be feasible to extend this study by using another type of pump and including additional spherical valves and a flowmeter in the hydrodynamic circuit, so that it is possible to adjust other values of volumetric discharge in steady flow regime. As explained in the methodology, this will be the focus of the next study, using a cardiac simulator (USP), where 2D laser anemometry will be used for velocity measurements [13,14].

CONCLUSION

For the two prosthetic valves tested according the hydrodynamic aspect considered, it was possible to verify the superiority of the prosthesis model AGN 21 - 751 (Regent™) comparing with model 21 AJ – 501 (Master Series). This choice implies the supra-annular positioning. The results permit to focus, in next work, the observations and measurements in some specific regions nearby the prosthesis where the flow recirculation and peak velocities occurs. According with was exposed in methods, for further testing will be possible include a statistical analysis based on a batch of valves and regarding some guidelines suggested by the ISO 5840:2005 standard.

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Author's roles & responsibilities	
OB	LDA equipment maintenance estimating; steady workbench design and manufacturing (except the test section of the prosthesis), test section CAD re-drafting; transferring and assembling of hydrodynamic workbench between USP and Unicamp; LDA training; LDA testing with the prostheses; paper writing, figures, graphs and resion; revisor replicas.
JPO:	Academic partnership coordinator and linked jobs between USP and UNICAMP, LDA trials monitoring; line of research guiding at USP; paper revision and revisor replicas.
FUVJ:	Workbench test section CAD drawings; test section manufacturing; LDA training; LDA testing with the prostheses; paper revision.
RWV:	Academic partnership coordinator and linked jobs between USP and UNICAMP, LDA trials monitoring; line of research guiding at Unicamp; paper review.
NA:	Responsible for resources finding, maintenance and re-structuring of Medicine Center and Experimental Surgery Laboratory (LDA system); responsible for the heart valves obtaining from St. Jude Medical Brazil.
FDBT:	Transferring and assembling of hydrodynamic workbench between USP and Unicamp; LDA training; LDA testing with the prostheses; testing photos.
ETC:	Responsible for the workbench test section building (by the Center for Biomedical Engineering, CEB, Unicamp) and enable the maintaining resources of the LDA equipment via CEB.
OPJ:	Responsible for the Cardiac Surgery discipline at Unicamp and agreeenting assignatures allowing the LDA maintenance.

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