"DESIGN AND CONSTRUCTION OF A NEW PULSE DUPLICATOR SYSTEM FOR IN VITRO EVALUATION OF PROSTHETIC HEART VALVES – CONCEPTION OF AN EXPERIMENTAL SETUP ON MITRAL POSITION"

Ovandir Bazan, ovandir.bazan@usp.br
Jayme Pinto Ortiz, jportiz@usp.br
University of São Paulo – Polytechnic School, Mechanical Engineering Department. Av. Prof. Mello de Moraes nº 2231, Cidade Universitária, São Paulo – SP, tel.: 55 – 11 – 3091-5335 / 9669.

***Abstract**. Since most complications related to operation of prosthetic heart valves are due to disturbances of flow, its hydrodynamic characterization is a useful aid in the design of new prostheses. Besides durability and biological response to implant, these prostheses should provide a favorable hemodynamic profile, considering that there is a great clinical interest focused on the haemolysis of blood. Haemolysis in heart valves can be induced primarily by cavitation in the closure of the prosthesis and by shear stress in the flow. Velocity and shear stress profiles as well as fluid stagnation and separation regions are different for each type of valve. In addition, damage of the blood cells could be expected in some flow conditions. Simulations of pulsatile flow in cardiac prosthesis began nearly 40 years ago, through the development of diferent mock human circulatory systems (simulating of the left ventricule), improving the interpretation of the clinical results. Brazil is one of the worldwide leaders of heart valves production, where about 8-10 thousand patients per year receive both biological and mechanical cardiac valve prostheses. A new design of a pulse duplicator system was developed at the Polytechnic School of the University of São Paulo (EPUSP), in the Mechanical Engineering Department (PME), to study prosthetic heart valves, based on the experience get with the mock circulatory system used in the Department of Bioengineering, Institute Dante Pazzanese of Cardiology (IDPC). This article describes the design and the partial construction of a new pulse duplicator system for heart valves simulations based on state-of-art studies. In this proposed design of a pulse duplicator system, an electric servo-motor controlled by computer emits, through a hydraulic piston, a pulse to the left ventricular chamber model, which is connected to two interchangeable heart valves accommodation, where aortic and mitral valves could be installed. The computer is also used for data acquisition and processing of the physical parameters like pressure, volumetric flow and temperature. Some results of flow, cardiac frequencies and pressures are evaluated according to physiologic ventricular states. To characterize, in the future, the hydrodynamic operation of mitral prosthetic valves (focus of this study), an experimental setup was mounted to provide measurements of volumetric flow, pressure and velociy fields on this valves. Therefore, a suitable working fluid, an eletromagnetic flow meter, pressure transducers, a temperature control system and a Laser Doppler Anemometer (LDA) are predicted on the pulse duplicator system designed. Optical access are conveniently provided on the design, making possible the use, in the future, of a LDA system. In order to improve the analysis of hydrodynamic shear stress and prediction of haemolysis, the experimental results may be used to calibrate a numerical model using 'Computational Fluid Dynamics' (CFD).*

***Keywords**: pulse duplicator system; experimental setup; mitral prosthetic valves.*

1. INTRODUCTION

The heart is the central pumping unity of the circulatory system, relying on arteries and veins as the blood leading system. The heart pumps around five liters of blood per minute and its valves open and close around 40 million times a year. The blood flow in arteries and veins has been object of study due to the traditional interest of spreading such flow and also the pressure pulse and, more recently, in the diagnosis of circulatory diseases.

Some of the circulatory system diseases are originated by the deficient operation of the heart valves, interfering seriously in the blood pumping capacity. Since the first successful heart valve prosthesis implant, around fifty different mechanical and biological models were designed. Currently, the worldwide most used valve has been the bileaflet mechanical valve, with 170,000 implants a year (Yoganathan *et al*., 2005). Anyway, the ideal project has not been achieved yet. All the heart valve prostheses result in stenosis of the valve orifice, due to its ring thickness. Besides, a certain transvalvular pressure gradient occurs in all the valves and has inverse relationship with the blood flow which crosses the valve ostium, apart from depending on the size, type and model of valve.

The structural failures in mechanical prosthesis are negligible, lasting during all the receptor life. In the case of biological prosthesis, the incidence of primary failures increases with time – especially in children and youth, since the calcification accelerates the tissue degeneration – and one of the aggravating circumstances is that the mortality risk increases when changing these prostheses. The mechanical prosthesis has its long durability advantage upon biological valves, but the patients who use them are subject to thrombosis and thromboembolism, even if they are conveniently treated with anticoagulants and platelet antiaggregants. The biological valves do not need to use anticoagulants, but its durability is limited because of the degeneration. It is expectable that the porcine bioprostheses last 15 years in aortic position and up to 10 years in mitral position, and they are also recommended for elderly patients and for the ones who cannot receive anticoagulants (Lemos and Stolf, 1992). Hence, there are advantages and disadvantages in the usage of biological or mechanical prosthesis, and both shall be available to the patient (Pio, 2002).

Once the most part of the complications relative to the operation of the prosthesis of heart valves is due to the flow disorders (Fung, 1997 and Berger *et al*., 1996), its hydrodynamic characterization is a very important aid in the project of new prosthesis (Yoganathan *et al*., 2004 and Dasi *et al*., 2009). Velocity and stresses profiles are different for each type of valve, where there may be stagnation regions and the separation of the fluid, allowing the formation of thrombosis, tissue overgrowth and / or calcifications, apart from blood haemolysis due to shear stress (Yoganathan *et al*., 2004 and Meyer *et al*., 2001).

Studies with simulations of pulsatile flow in heart prosthesis are very important, because they provide results of high clinic and scientific interest (Yoganathan *et al*., 2004). These studies are based on the development of various projects of benches pulse duplicators, such as "Yoganathan-FDA system", "Aachen pulse duplicator", "Sheffield pulse duplicator" and "Vivitro pulse duplicator", associated to measurement techniques to characterize the hydrodynamic operation of the valves in physiological or pathophysiological conditions (Meyer *et al*., 2001, De Paulis *et al*., 2005, Grigioni *et al*., 2004, Milo *et al*., 2003, Chew *et al*., 2001, FDA, 2010, Dasi *et al*., 2007, Meyer *et al*., 1997 and Woo and Yoganathan, 1986).

In the most updated workbench conceptions, apart from replicating the human physiology pulse, is often providing the geometry and the confinement of the valves as well as occurs in humans. This allows studying the flow direction and analyzing the influence of the hydrodynamic instabilities that are transferred from one valve to another (De Paulis *et al*., 2005, Grigioni *et al*., 2004 and Milo *et al*., 2003). Non-invasive velocimetry techniques are frequently used, such as *Particle Image Velocimetry* (or *PIV*) and *Laser Doppler Anemometer* (or *LDA*). *LDA* systems are able to map the flow of accurate and punctual manner, and providing the framework of the scales of turbulence (Yoganathan *et al*., 2005 and Pinotti, 2000), helping to characterize the possible haemolysis. To aid the analysis of hydrodynamic stress, the experimental results are frequently used to adjust a numerical model of *Computational Fluid Dynamics* (*CFD*), helping also when predicting the haemolysis indexes (Dasi *et al*., 2009 and Grigioni *et al*., 2004).

In 2009, a weekly following-up in the usage of pulsatile flow simulation workbench in the sector of Bioengineering, Institute Dante Pazzanese of Cardiology (IDPC), helped to know this type of equipment and handle it (Ortiz *et al*., 2009 and Fonseca *et al*., 2008). However, in order that group's investigations of Biomedical Engineering, Polytechnic School of the University of São Paulo (Leal *et al*., 2003 and Leal, 2001) been directed to specific scientific and clinical interest in the modeling of flow through prosthetic heart valves, it should meet all the requirements of ISO 5840: 2005 (Cardiovascular Implants - Cardiac Valve Prostheses) for pulsatile flow regime (ANS, 2005). Hence, it is deemed due a new workbench design, able to study the prosthesis performance in aortic and mitral positions. Now, the project is concluded and the experimental workbench is in building phase.

The purpose of this paper is to present the experimental workbench conception for hydrodynamic testing of prosthetic heart valves whose design stage has already been concluded. Some current stage details of the component mounting and manufacturing are presented as well.

The high frequency of valve replacement in mitral position, as well as the wide bibliography which reports the hydrodynamic studies in this position influenced our choice to restrict the focus of the paper and initially simulate mitral heart valve prosthesis (Arita *et al*., 2004). So, it is displayed a mounting plan of an experiment elaborated for the mitral prosthesis that shall be adopted when the workbench is in operation.

Nothing restricts that other studies on the same workbench may keep within the aortic position in the future.

2. A NEW PULSE DUPLICATOR SYSTEM

2.1. Methods

In order to achieve the proposed objectives (design and construction of the pulse duplicator workbench, beyond the conception of an experiment to test mitral valves), the methodology involves the total design of a pulse duplicator system (simulating the left side of the human heart physiology) and the determination of equipments and instrumentation that shall be incorporated to the mock system in the final phase of its construction in order to the experimental hydrodynamic simulation.

Afterwards, the results obtained in the experimental simulations shall be used in the adjustment of a computational model (Yoganathan *et al*., 2004) and compared with the physiological and patho-physiological human hemodynamic bibliography, to be verified, for each type of mitral valve, the problems that occur in them, particularly with regard to possible haemolysis of blood (Yoganathan *et al*., 2005, Dasi *et al*., 2009, Meyer *et al*., 1997, Pinotti, 2000 and Lu *et al*., 2001).

2.1.1. Experimental workbench for pulsatile flow

The definitive pulsatile workbench project at the Mechanical Department (PME/EPUSP) is based on the experience acquired when following up activities for the Institute Dante Pazzanese of Cardiology with artificial heart (Legendre,

2009) and in the bibliographical review carried out about the topic. Particularly, it meets the requirements of the international ISO 5840:2005 for pulsatile flow regime (ANS, 2005).

Regarding the workbench construction, processing techniques were used for component machining to comply with the parameters of adjustments and tolerances between different components and materials used.

Regarding the future workbench operation, the action heart "pumping" may be divided in two components: steady flow – in a single direction (Poiseuille flow) –, and another oscillatory that moves the flow from one side to another in the arterial tree. Therefore, the term "pulsatile" refers to the combination of steady and oscillatory flows. Furthermore, vascular flow is not permanent and occurs in flexible walls. This last feature makes the critical Reynolds' number knowledge difficult (transition from laminar to turbulent flow), which in the case of rigid walls it is around 2.300. In arteries, it is agreed that the Reynolds' number varies from 500 to 1000. After adjusting the pulse rate, similarity criteria will be defined for the physiological parameters based on the average instantaneous Reynolds number and Womersley number. As Reynolds' number represents a fraction between inertial and viscous forces, in case of pulsatile flow (due to simulation of cardiac cycle), the pulse rate is determined by the Womersley parameter, which relates the frequency of a pulsed wave and viscous forces.

2.1.2. Experimental setup for *in vitro* evaluation of prosthetic mitral heart valves

Considering the hydrodynamic experimentation of mitral heart valve prosthesis, as soon as the workbench is completely constructed, it shall incorporate the pressure, flow and temperature measurement equipment, as well as a data acquisition system, so that it can be calibrated with a physiological heart pulse. According to ISO 5840:2005 standard prescriptions, it is expected to perform hydrodynamic measurements for characterizing speed and tension profiles and mitral prosthesis, through a laser Doppler anemometry system (LDA).

Thus, the instrumentation includes four pressure transducers, a temperature controller, an ultrasonic flow meter (non-invasive, for not interfering in the flow), a data acquisition system and a LDA system. It also requires a computer to perform both servo motor control and data acquisition of the workbench.

The test flow to be used at the workbench shall be able to simulate both the viscosity and density which are characteristics of the blood. The importance of the refraction index verification of the test flow is that this coefficient is fundamental when directing laser beam.

In order to give subsides to results interpretation and help in the probable optimization of such prostheses, the information obtained in the experimental simulations shall be used to adjust a computational model (Bessa and Ortiz, 2009).

2.2. Results

According to the standard ISO 5840:2005, the new pulse duplicator workbench (PME/EPUSP) was designed to meet the interest in characterizing the flow in prosthetic heart valves. As well as the most modern worldwide known workbenches, it is used the deformable left ventricle and valve prostheses disposition in similar geometries to what happens *in vivo* (De Paulis *et al*., 2005, Grigioni *et al*., 2004 and Milo *et al*., 2003).

It is conceived that the disposition of components facilitates probable maintenances and has adjustments for cardiac debit, heart beating and ventricular stroke volume. The valves lodging local in the workbench is dimensioned to comply with all the standardized sizes of mitral and aortic prostheses. Currently, the study focus is on the mitral position.

In the project conception, some initial variables were equationed to allow the issuance of a pulse. Such initial variables are shown on Tab. 1. During the project, especially for allowing workbench versatibility and its applicability for various physiological pulses, it was provided that those variables could be adjusted when necessary, except for the piston diameter.

Table 1 – Pulse duplicator workbench project initial variables

Stroke volume (left ventricle model)	80 mL
Linear actuator displacement	28 mm
Piston diameter	60 mm
Estimated force at the piston shaft (including load losses)	115 N
Heart rate	70 bpm (beats per minute)
Total time per heart rate	820 ms
Phase time of ventricular ejection (stroke volume time)	270 ms
Cardiac output (flow at the workbench)	5.6 L/min

The principle of this workbench operation is based on the left ventricular function of the heart. In this project, it was designed the usage of two flows: the *working fluid* (responsible for the pulse transmission to the ventricle model) and the *test fluid* (simulating blood properties and course a hydraulic circuit in the workbench, passing through the prostheses).

Figure 1, shown below, presents in a schematic manner the main workbench components.

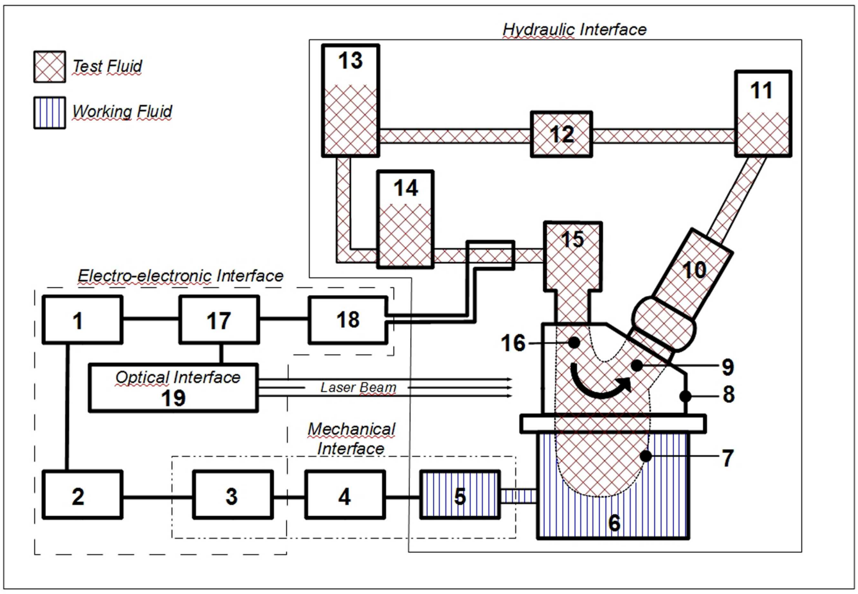

Figure 1 – Scheme of the main components of the experimental workbench.

According to the numbers referenced in Fig. 1, the main components of the workbench are as follows: 1. computer, 2. servo motor controller, 3. servo motor, 4. linear actuator, 5. hydraulic cylinder, 6. global reservoir, 7. deformable left ventricle, 8. heart valve prostheses fixation platform, 9. aortic valve, 10. aortic root model, 11. compliance, 12. peripheral resistance, 13. compliance, 14. atrium reservoir (where the temperature control system is located), 15. atrium model, 16. mitral valve, 17. data acquisition system, 18. ultrasonic flow meter and 19. laser Doppler anemometer.

The *working fluid* and the *test fluid* are separated by a flexible silicon membrane, delimiting the lower part of the left ventricle model. The other part of the ventricle is rigid, it delimits its upper zone, where the mitral and aortic prostheses are located. Such rigid higher part assigned "prostheses fixation platform" (refer to "8" on Figure 1) has optical accesses to allow the penetration of laser beams from the LDA system. So the whole ventricle model, composed of the flexible membrane and prostheses fixation platform, may be said "deformable left ventricle" (refer to "7" on Figure 1). Thus, the ventricular chamber is composed of inner walls of the flexible membrane and prostheses fixation platform.

For the operation of the workbench, a servo drive computer controlled is coupled to a linear actuator, which in turn transmits the reciprocating motion of a piston inside a cylinder. When the piston movement increases the pressure inside the global reservoir, a pulse is transmitted through the *working fluid* to the flexible membrane of the deformable left ventricle. This makes the membrane retracted, simulating the ventricular systole. At the same time, within the ventricular chamber, the membrane retraction transmits an additional pressure to the *test fluid* portion which is there and confined, since the heart valves are closed. With the increase of ventricular pressure in the chamber, the mitral valve remains closed, but when the system pressure is overcome, the aortic valve opens and allows the *test fluid* stored in the ventricular chamber can drain to other workbench components. It lasts until the end of the ventricular ejection. As to the cylinder piston returns and starts the ventricular diastoles, the pressure in ventricular chamber model decreases up to the moment it is lower than the system pressure. Then, the aortic valve closes and the mitral valve opens, making the *test fluid* stored in the atrium flows inside the ventricular chamber.

In the experimental workbench design, the geometries, dimensions and disposition of prostheses at the fixation platform were based on the anatomy of the heart left side. The housing of valves is also dimensioned to comply with the mounting of all nominal diameters standardized for aortic and mitral prosthesis according to the ISO 5840:2005. The pulse emitted by the piston may be adjusted to simulate certain heart elastance. The workbench has even two compliance modules, ventricular compliance and adjustable peripheral resistance. The prostheses fixation platform was designed so that optical access was willing to permit in the future the usage of the *LDA* system for both mitral and aortic positions. Figure 2, shown below, presents in mounting disposition the three-dimensional modeling of the main components designed.

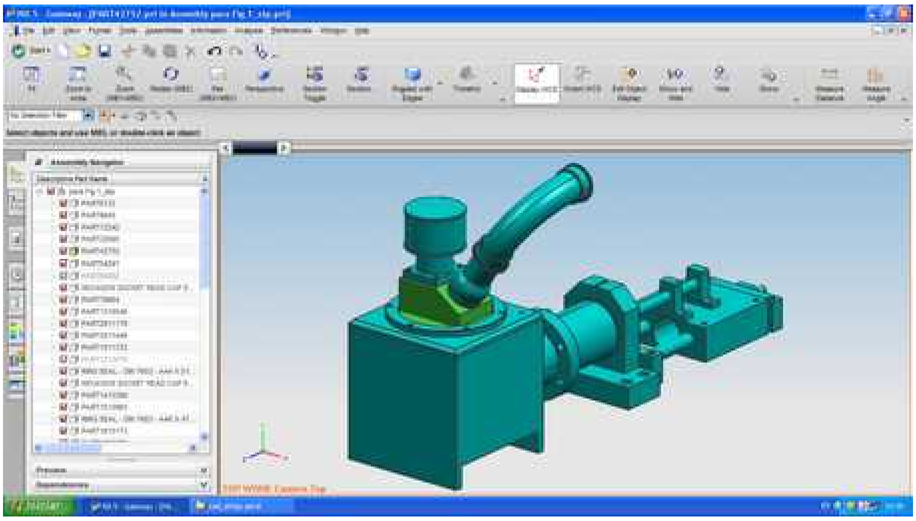

Figure 2 – Partial 3D model of the pulse duplicator system (PME/EPUSP).
Highlights: prostheses fixation platform. Modeling in Unigraphics/NX5
(PACE Laboratory / PME / EPUSP).

Currently, then the project phase is concluded, the experimental workbench is being constructed. In accordance with the project, several workbench components were made in acrylic, to allow the flow visualization of the working fluid and especially test fluid. In a special manner, the prostheses fixation platform, since the laser beams are in orthogonal disposition in it. Due to this attribution, it can also be called "*optical platform*". It is the most critical component of design and manufacturing, since it gathers many functions and cannot exceed some suitable dimensions to simulate small geometries of the left ventricle. It was designed and produced to comply with the interchangeability of prosthetic valves in several standardized sizes, to allow the test fluid tightness (with the external environment and the working fluid), facilitate the assembly of both aortic root and atrium model (see Figure 1 n.10 and n.15) and minimize the distortion by refraction of laser beams through choosing a more noble acrylic, the prediction of artificial polishing surface, interest regions with orthogonal plans and zones of little thickness.

Figure 3 and Fig. 4 show, respectively, a milling phase of the prostheses fixation platform (milling machine PME / EPUSP) and post-machining mounting of this component with both aortic root and atrium model.

Figure 3 – Milling operation of the prostheses fixation platform.
Milling machine (PME/EPUSP) in process of thinning out
the inclined plan (aortic root base).

Figure 4 – Both aortic root and atrium model assembled at the prostheses fixation platform. Arrangement: aortic root upon the platform inclined plan, atrium model at the higher left position.

Figure 5 shows the linear actuator machined and assembled, responsible for the transmission of the rotating movement of the servo motor in a linear dislocation to drive the piston. Figure 6, shown below, presents a photo of the partial assembly of the pulse duplicator system in which there are several components already manufactured.

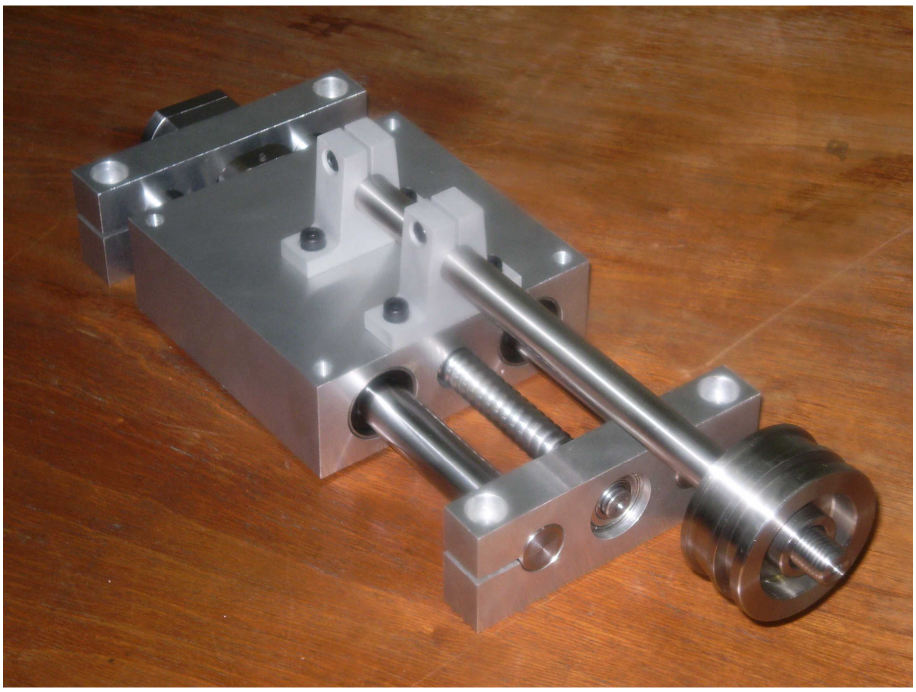

Figure 5 – Linear actuator manufactured and assembled. Assembly including the cylinder piston at the shaft end on the linear actuator top.

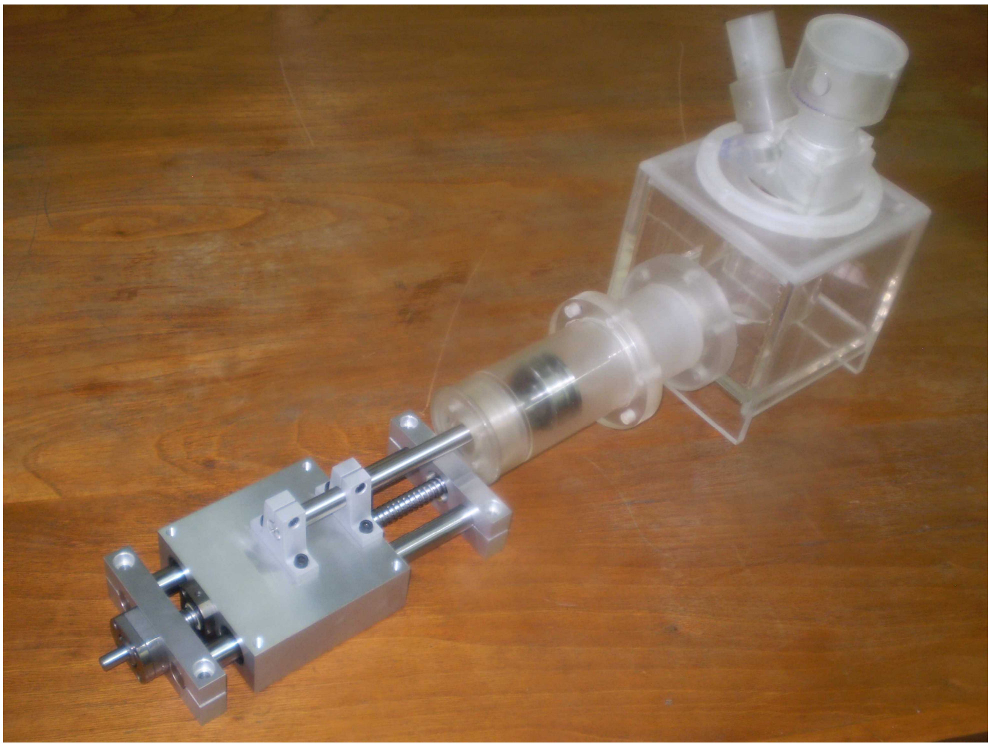

Figure 6 – Assembly photo of the workbench components manufactured (PME/EPUSP).
Components manufactured in correspondence with the undertaken design.

2.3. Experimental setup conception for evaluation of prosthetic mitral valves

According to the objectives proposed, a experimental setup involving testing and computational simulation of pulsatile flow through prosthetic mitral valves was conceived. The real implementation of this experiment may start as soon as the projected pulse duplicator workbench is completely constructed and instrumented. So when a physiological pulse is adjusted at the workbench, the pressure, velocity and shear stress fields shall be replicate through mitral valves simulations. These parameters shall be recorded in data acquisition and laser velocimetry. On the following stage, such experimental data shall be used to adjust a computational model that allows the interpretation of all the results. Such experimental setup conception is outlined below.

2.3.1. Preliminar preparing

As soon as the workbench is completely constructed, pressure, flow, velocity and temperature measurement equipment shall be provided in it, as well as a data acquisition system and a servo motor controlled by computer. The workbench shall be allocated at the Biomedical and Environmental Engineering Laboratory of the Mechanical Engineering Department.

According to the illustration on Figure 1, the working fluid shall occupy all the volume it comprehends the cylinder inner part and the internal walls of the global reservoir. The test fluid shall occupy the entire volume comprised by the inner walls of both the ventricular chamber and the system. They are disposed in the workbench mechanisms to escape and air dosage where the working fluid and the test fluid are confined. Based on the previous work experiences and related literature (Berger *et al*., 1996, Legendre, 2009 and Cherniauskas and Ortiz, 2009), we shall be based on a solution of 1/3 of glycerin, 1/3 of water and 1/3 of isopropyl alcohol (mass fraction).

As the initial focus of the study shall be based on the mitral position, the sensor's ultrasonic flow meter shall be put before the atrium model (cf. Figure 1, n.18), measuring the flow before passing by the prosthesis to be studied. The pressure transducers shall be arranged before and after the prostheses and the temperature controller is installed at the atrium reservoir (cf. Figure 1, n. 14).

Currently, through the collaboration established with the company Braile Biomédica S/A, biological heart prostheses and pressure transducers produced by this company are enabled.

2.3.2. Adjustment of physiological heart pulse

The first adjustment at the workbench shall be the ventricular stroke volume, from physiological data. For such, the servo motor positioning controlled by computer shall be established. Initially, a ventricular stroke volume of 80 mL, a heart rate of 70 bpm and a cardiac output of 5.6 L/min must be complied. Other adjustments shall be done to comply with the prescriptions of the standard ISO 5840:2005 for hydrodynamic testing of prosthetic heart valves in pulsatile flow regime.

The volume dosage of both air and test fluid in the compliances, as well as a pre-adjustment of the peripheral resistance shall establish initial conditions for putting the workbench in operation and, through flow and pressure data acquisition, adjust it step by step to the characteristics curves of a physiological heart pulse. These are the pre-requirements for flow measurements in mitral prostheses through the LDA system.

2.3.3. Measurements at the workbench

At this stage, it is expected to perform hydrodynamic measurements for the velocity, pressure and shear stress fields characterization at the mitral valve prostheses. Through academic agreement formally established between the Biomedical Environmental Engineering Laboratory (LAB), PME/EPUSP and Surgical Technique and Experimental Surgery Laboratory of Surgery Department, UNICAMP, the usage of the LDA system, whose manufacturer is the company Dantec Dynamics shall be ensured. Such equipment will be allocated at the LAB (PME/EPUSP) and engaged to the pulse duplicator system, to allow the incidence of laser beam at the prostheses fixation platform (for this purpose, assigned as "optical platform"), allowing the instantaneous measurements of the velocity fields.

Some preliminary tests shall be done in order to allocate and establish the movement of laser beams at the regions of interest: downstream of the prosthetic mitral valves. Preliminary tests also are performed in order to collect velocity profiles data and correlate them.

2.3.4. Computational modeling

The experimental results obtained will be used to adjust a numerical model of CFD (*Computational Fluid Dynamics*), using the *ANSYS (CFX/Fluent)*, available at the LAB (PME/EPUSP). Such computational model shall be highly useful to interpret the hydrodynamic shear stress data, which is an important parameter for the characterization of the haemolysis due to flow at the heart valve prostheses.

The computational model that will be obtained in future studies shall allow to study, through the academic agreement formally established between PME/EPUSP and the Surgery Department of UNICAMP, haemolysis indexes obtained and supposed project optimizations to new mitral prosthesis conceited.

3. ACKNOWLEDGMENTS

To the Polytechnic School of the University of Sao Paulo (EPUSP) and to the Mechanical Engineering Department (PME/EPUSP), for the infrastructure support.

To the Water Resources and Hydraulic Technologic Center (CTH) and to the Hydraulic Technologic Center Foundation (FCTH), for the infrastructure support.

To the Coordination for the Improvement of Higher Education Professionals (CAPES), for the PhD scholarship which lasted until January 31th, 2011.

4. REFERENCES

ANS, 2005, "American National Standard: Cardiovascular Implants – Cardiac Valve Prostheses", ISO 5840.

Arita, M., Tono, S., Kasegawa, H. and Umezu, M., 2004, "Multiple Purpose Simulator Using a Natural Porcine Mitral Valve, Asian Cardiovasc Thoracic Ann., Vol. 12, Nº 4, pp. 350-56.

Bessa, K.L. and Ortiz, J.P., 2009, "Flow visualization in arteriovenous fistula and aneurysm using computational fluid dynamics", J Visualization, Vol. 12, pp. 95-107.

Berger, S.A., Goldsmith, W. and Lewis, E.R., 1996, "An Introduction to bioengineering", Oxford University Press, New York, pp.133-70.

Cherniauskas, R. and Ortiz, J.P., 2009, "Fluido de trabalho para a simulação experimental de fluxo sanguíneo em aneurisma de aorta abdominal", Relatório de Iniciação Científica, Universidade de São Paulo - Escola Politécnica, São Paulo, 8 p.

Chew, Y.T., Chew, T.C., Low, H.T. and Lim, W.L., 2001, "Techniques in the Determination of the Flow Effectiveness of Prosthetic Heart Valves. In: Cardiovascular Techniques: Biomechanical Systems – Techniques and Applications", Vol. II., Ed. by Cornelius Leondes, CRC Press LLC, London, pp.70-117.

Dasi, L.P., Ge, L., Simon, H.A., Sotiropoulus, F. and Yoganathan, A P., 2007, "Vorticity dynamics of a bileaflet mechanical heart valve in an axisymmetric aorta", Phys Fluids, Vol. 19, pp. 105-117.

Dasi, L.P., Simont, H.A., Sucosky, P. and Yoganathan, A., 2009, "Fluid Mechanics of Artificial Heart Valves", Clin Exp Pharmacol Physiol, Vol. 36, Nº 2, pp. 225-37.

De Paulis, R., Schmitz, C., Scaffa, R., Nardi, P., Chiariello, L. and Reul, H., 2005, "In vitro evaluation of aortic valve prosthesis in a novel valved conduit with pseudosinuses of Valsalva", J Thorac Cardiovasc Surg., Vol. 130, pp. 1016-21.

FDA, 2010, "U.S. Food and Drug Administration: Draft Guidance for Industry and FDA Staff. Heart Valves - Investigational Device Exemption (IDE) and Premarket Approval (PMA) Applications", 3 Feb. 2010, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm193096.htm>.

Fonseca, J., Andrade, A., Nicolosi, D.E.C., Biscegli, J.F., Legendre, D., Bock, E. and Lucchi, J.C., 2008, "A New Technique to Control Brushless Motor for Blood Pump Application", Artif. Organs., Vol. 32, Nº 4, pp. 355-59.

Fung, Y.C., 1997, "Biomechanics: circulation", Ed. Springer, 2nd, New York, 577p.

Grigioni, M., Daniele, C., D'Avenio, G., Morbiducci, U., Del Gaudio, C., Abbate, M. and Di Meo, D., 2004, "Innovative Technologies for the Assessment of Cardovascular Medical Devices: State-of-the-Art Techniques for Artificial Heart Valve Testing", Expert Rev Med Devices, Review, Vol. 1, Nº 1, pp. 81-93.

Leal, E.B., 2001, "Simulador hidrodinânico para estudos 'in vitro' do sistema cardiovascular", Dissertação de mestrado, Universidade de São Paulo - Escola Politécnica, São Paulo, Brazil, 84p.

Leal, E.B., Ortiz, J.P. and Guerino, S.D., 2003, "Hydrodynamic simulator for studies in vitro of the cardiovascular system", Proceedings of the 17st COBEM, São Paulo, Brazil, pp. 41-50

Legendre, D.F., 2009, "Estudo de comportamento de fluxo através de modelo computacional de aneurisma de aorta infra-renal obtido por tomografia", Tese de doutorado, Universidade de São Paulo - Escola Politécnica, São Paulo, 183 p.

Lemos, P.C.P. and Stolf. N.A.G., 1992, "A prótese valvar cardíaca definitiva: meio século de procura", Arq Bras Cardiol., Vol. 58, Nº 1, pp. 15-24.

Lu, P.C., Lai, H.C. and Liu, J.S., 2001, "A reevaluation and discussion on the threshold limit for hemolysis in a turbulent shear flow", J Biomech., Vol. 34, pp. 1361-64.

Meyer, R.S., Deutsch, S., Bachmann, C.B. and Tarbell, J.M., 2001, "Laser Doppler Velocimetry and Flow Visualization Studies in the Regurgitant Leakage Flow Region of Three Mechanical Mitral Valves", Artif Organs, Vol. 25, Nº 4, pp. 292-99.

Meyer, R., Deutsch, S., Maymir, J. C., Geselowitz, D.B. and Tarbell, J.M., 1997, "Three-Component Laser Doppler Velocimetry Measurements in the Regurgitant Flow Region of a Bjork-Shiley Monostrut Mitral Valve", Ann Biomed Eng., Vol. 25, pp. 1081-91.

Milo, S., Rambod, E., Gutfinger, C. and Gharib, M., 2003, "Mitral mechanical heart valves: in vitro studies of their closure, vortex and microbubble formation with possible medical implications", Eur J Cardio-thorac Surg., Vol. 24, pp 364-70.

Ortiz, J.P., Bessa, K.L., Legendre, D.F., Fonseca, J., Cherniauskas, R. and Andrade, A., 2009, "Physical Modeling of the Cardiac Pump – Preliminaries Results", in: PCH Notícias & SHP News, Vol. 11, Nº 42, pp. 14-18.

Pinotti, M., 2000, "Is there Correlation between the Turbulent Eddies Size and Mechanical Hemolysis?", J. Braz. Soc. Mech. Sci., Vol. 22, Nº 4, 14 Mar. 2009, <http://www.scielo.br/scielo.php?script=sci_arttext&pid=S0100-73862000000400006>.

Pio, F., 2002, em DCI (Indústria), 12 Feb. 2009, <http://www.bv.fapesp.br/namidia/noticia/14726/valvula-cardiaca-mercado-us-10/>

Woo, Yi-Ren and Yoganathan, A.P., 1986, "Pulsatile flow velocity and shear stress measurements on the St. Jude bileaflet valve prosthesis", Scand J Thor Cardiovasc Surg., Vol. 20, Nº 1, pp. 15-28.

Yoganathan, A.P., Chandran, K.B. and Sotiropoulus, F., 2005, "Flow in prosthetic heart valves: state of the art and future directions", Ann Biomed Eng., Vol. 33, Nº 12, pp. 1689-94.

Yoganathan, A.P., Zhaoming, H. and Jones, S.C., 2004, "Fluid mechanics of heart valves", Ann Rev Biomed Eng., Vol. 6, pp. 331-62.

5. RESPONSIBILITY NOTICE

The authors are the only responsible for the printed material included in this paper.