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New Aortic Valve Prosthesis - A Concept and Realization of Mechanical Valve Prosthesis Compatible with the Flow in Aorta

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Abstract **-** A new type of mechanical aortic valve prosthesis- Tornado-compatible valve (TCV) - is worked out basing on the principle of hydrodynamic compatibility with the swirling Tornado-like blood flow present in the heart cavities and main arteries. The design and profile of the TCV were calculated basing on the exact solution of the non stationary hydrodynamic equations for the class of self organizing Tornado-like flows of viscous medium. According to the results of standard hydrodynamic testing, TCV has shown the best functional characteristics as compared to other types of aortic valve prostheses used currently in the cardiac surgery. A special test was performed to study the interaction of TCV and other prostheses with the Tornado-like jet, generated artificially in the experimental stand. It has been shown that all existing valve prosthesis designs except TCV destroy completely the structure of the swirling Tornado-like jet augmenting significantly a hydrodynamic resistance to the flow. When testing in a turbulent flow TCV decreases significantly the resistance of the channel. The result of successful TCV implantation in the animal experiment for more than half a year is reported. TCV preserve its functionality even without any anticoagulant therapy.

Keywords**:** Mechanical aortic valve prosthesis, Tornado-like flow, Blood flow in the heart and main arteries.

1. Introduction

50-year-old history of mechanical heart valve prostheses includes many original technical solutions, none of which up to this day can fully restore the function of the valve and get rid of aggressive anticoagulant therapy, significantly affecting the quality of patient's life.

Causes of conflict between the recipient's body and prosthesis authors see as a complex of reasons. There are the materials quality, violation of a cardiac mechanics, hyperplasia on the cuff of the prosthesis and a distortion of the hydrodynamic structure of the blood flow. This latter factor can present itself in injury and activation of the blood elements involved in the coagulation cascade as well as endothelial injury due to higher values of the linear velocity and the formation of stagnant and separation zones just near the mechanical prosthesis. However, none of the authors have chosen a leading factor from this list, since the mechanisms and the development of complications of prosthetic heart valves have been insufficiently studied.

Preliminary assessment of the functional properties of mechanical heart valve prostheses is conducted on hydrodynamic stands producing the stationary or pulsating turbulent water flow. Test results in all cases demonstrate a substantial distortions of the flow on the valve's elements protruding into the flow core. This is manifested in a significant increase in shear stress and linear flow velocities in the valve's lumen, the appearance of separation and stagnant zones in the space behind the valve. These distortions occur in varying degrees during testing of all existing models of mechanical heart valve prostheses (D. Bluestein, et al., 2000). We managed to create a fundamentally new mechanical prosthesis which design takes into account the hydrodynamic structure of blood flow in the area between the left ventricle and the aorta. This determines the hydrodynamic compatibility of the proposed prosthesis that was named the Tornado-compatible aortic valve prosthesis (TCV).

Studies of the hydrodynamic structure of the blood flow in the chambers of the heart and aorta have been performed in the Bakulev Center for Cardiovascular surgery since 1992 (Bockeria, et al., 2013). These studies have shown that blood flow, generated in the left ventricle of the heart corresponds to the structure of self-organizing tornado-like flows described by the exact solution of non-stationary hydrodynamic equations for this class of flows that was published by Kiknadze and Krasnov (1986). Tornado-like flow is a structurally organized axis-symmetric swirling flow, which streamlines do not intersect and are directed along the converging helix. This structure provides laminarized no separated flow, which can be carried out in a channel with a curvilinear axis. Such a flow ensures the safety of the cellular elements of the blood and endothelial lining of blood vessels, and the biologically active systems of the blood and vessel wall (coagulation , complement, etc.) remain in an inactive state.

High pressure-flow rate characteristics, low hydrodynamic resistance due to the convergence, special organization of the three-dimensional movable boundary layer and additional gradients arising in the flow core due to its rotation are inherent to the streams of this class. Self-organization of such flows occurs under the necessary and sufficient conditions following from the exact solutions. These conditions are the necessity of initial longitudinal medium displacement, channel convergence along the flow, presence of swirling mechanism and the presence of conditions for the formation of three-dimensional movable boundary layer which provides an interface with the channel walls or the immovable media outside the flow borders. Tornado-like flows are stable because of inertia of rotation, but the emergence of obstacles in the flow core causes local changes in the structural parameters of the flow (the ratio of the longitudinal , radial and azimuthal velocity components) that leads to a partial or total destruction of the flow structure and its transformation into a turbulent flow with all its attendant adverse effects - increase in hydrodynamic resistance , shear stress , the formation of separated and stagnant zones . These cause the blood cells injury and activation of the clotting, the occurrence of elevated shear stresses on the walls of blood vessels, blood flow redistribution through the branches located near the area of the flow disturbance. The combination of these effects determines the need for lifelong anticoagulant therapy in all patients with implanted mechanical heart valve prostheses, which design does not take into account the features of structural organization of the blood flow.

A number of attempts have been made to adapt the geometry of the flow channel of prosthetic heart valve to swirling blood flow. For example a cusps rotation around the channel axis is provided in the MEDENG valve, also a tricuspid valve was developed, providing a central flux through the prosthesis, but the cross section of the lumen within the opened valve had a triangular shape and significantly distorts the flow pattern. Therefore these attempts were not successive since there were no any quantitative criteria of the flow swirling.

A new model of a mechanical aortic valve was developed (patent RU 2434604 C1), the lumen of which is circular in cross-section throughout the streamlined part of the prosthesis and is completely free from any kind of obstacles that can disrupt the flow pattern. The valve consists of a body and three cusps attached to the outer hull lines with rotary joints (Fig. 1). Cusps profile is arranged so that the cross section of the lumen in the valve’s open state is circular, and the reverse side of the cusps surface follows the curvature of the sinuses, which allows the hydrodynamic interface of the flow in the aorta with the flow in the coronary arteries when the valve is closed. The lumen profile along the flow axis corresponds to the Tornado-like streamlines direction according to the exact solution and known dimension of the left ventricular cavity.

Fig. 1 Tornado-compatible aortic valve prosthesis (TCV).

The aim of this study was to conduct extensive testing and evaluation of the TCV valve, and to assess the possibility of its implantation in the animal experiment without anticoagulant therapy.

2. Methods and Results

2.1. Standard Hydrodynamic Testing

Tests were carried out on the laboratory bench certified in Russian official and corresponding to Russian standard GOST 26997-2003 harmonized with international standards. Tests were performed under steady and pulsatile flow conditions. The working fluid used was the water. The available Russian valve models were compared. The testing results are summarized in Tables 1 & 2.

Table 1. Testing under a steady flow conditions.

Design	Effective orifice area (мм^2)	Reverse leakage (l/min at 120 mm Hg)
TCV (Ø23)	**340**	**1,0**
MIKS* (Ø25)	310	1,2
Biological# (Ø26)	230	0,1
CORBIT*** (Ø25)	305	1,0
MEDENG** (Ø25)	290	>>1.0
LIKS* (Ø30)	310	0,6
Standard demand		<1.8

*Disk valve; **Bicuspid mechanical valve;
***Tricuspid mechanical valve; #Biological pericardium valve made on the carcass

Table 2. Testing under a pulsating flow conditions.

Design	Stroke volume (ml)	Reverse leakage (ml/beat)	Visual control
TCV (Ø23)	**108**	**4,7**	satisfactory
MIKS* (Ø23)	100	2,5	satisfactory
TRICARDIKS*** (Ø23)	75	4,5	satisfactory
CORBIT*** (Ø25)	105	2,5	satisfactory
MIKS* (Ø25)	85	4,5	satisfactory
Biological# (Ø25)	102	2,5	satisfactory
MEDENG** (Ø25)	96	5,5	satisfactory
Standard demand	>70	<10	

*Disk valve; **Bicuspid mechanical valve;
***Tricuspid mechanical valve; #Biological pericardium valve made on the carcass

Durability testing: The TCV valve was tested on the stand for endurance testing. Operating time in the amount of 400 million cycles (equivalent to 10 years) did not cause any damage or wear of moving parts of the valve, capable of creating a risk of violating its integrity. Friction surfaces were investigated with magnification x40.

2.2. Tests in Tornado-like Flow

The flow type of the working fluid in the testing bench has a significant impact on the hydrodynamic characteristics of mechanical heart valve prosthesis. Thus Bockeria et al. (2008) has reported that the installation of the impeller with inclined blades in the flow passage inside the line of the test stand in a stationary flow leads to the non-systematic change of the functional properties and characteristics of the prosthesis.

Therefore, the goal at this stage of research was to design a stand in which it would be possible to generate a stationary tornado-like jet. Stand consisted of two reservoirs, arranged one above the other (Fig.2). The water flowed freely from the upper reservoir. The valve was placed coaxially with the jet formed at the outlet . The outlet channel was designed as a convergent channel which profile corresponds to the Tornado-like jet streamlines, calculated in accordance with the exact solution. Initial parameters of calculating included flow diameter of the valve prosthesis, and the demand ratio of outlet channel diameter to its length , equal to 1 /5 (Fig.3) . The water flowing out from the supply vessel self-organizes acquiring the tornado-like hydrodynamic structure due to the profile of the convergent channel.

Fig. 2. Hydrodynamic stand for valve testing in the free-falling jet (left), converging channel for Tornado-like jet generating fitted in the bottom of upper tank (middle), the lumen of converging channel (right).

The resulting stream is different from the turbulent flow by the absence of surface perturbations, continuous convergence, "glass" transparency of the jet as it falls in the receiving tank, absence of disturbances arise in the receiving reservoir, although the swirling of jet is visible, and is manifested in the rotation of the liquid in the receiving tank (Fig. 3).

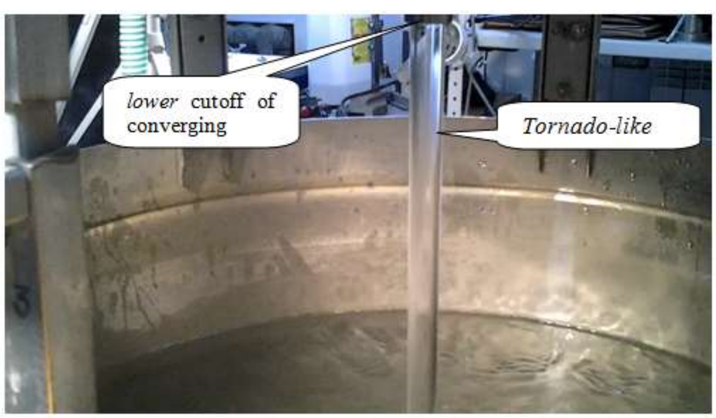

Fig. 3. “Glass” transparent jet, obtained on the outlet of converged channel.

A comparative testing of five basic designs of mechanical heart valve prostheses was performed: caged-ball valve, disc valve (MIKS), bicuspid valve (MEDENG), tricuspid valve (CORBIT) and tricuspid valve TCV. T test results are shown in Fig. 4.

Fig. 4. The degree of Tornado-like jet conservation after Bicuspid (MEDENG)(left) and TCV (right) mechanical valve prostheses.

To quantify the impact of the valve design on the parameters of tornado-like jet the efflux time was measured of a fixed volume of water. In the experiment, from the upper to the lower tank 190 liters of water were passed, and the pressure was varied from 50 to 5 mmHg. Efflux time of water between two fixed values of the column of liquid through the hollow convergent channel, and the channel containing valve prosthesis is shown in Fig. 5. As it is seen the preserving of structure of the flux occurs only when it passes through the TCV, and the efflux time does not increase, which means that this valve does not create any resistance to the flowing jet. All other designs create an additional resistance to the flow and completely destroy its structure.

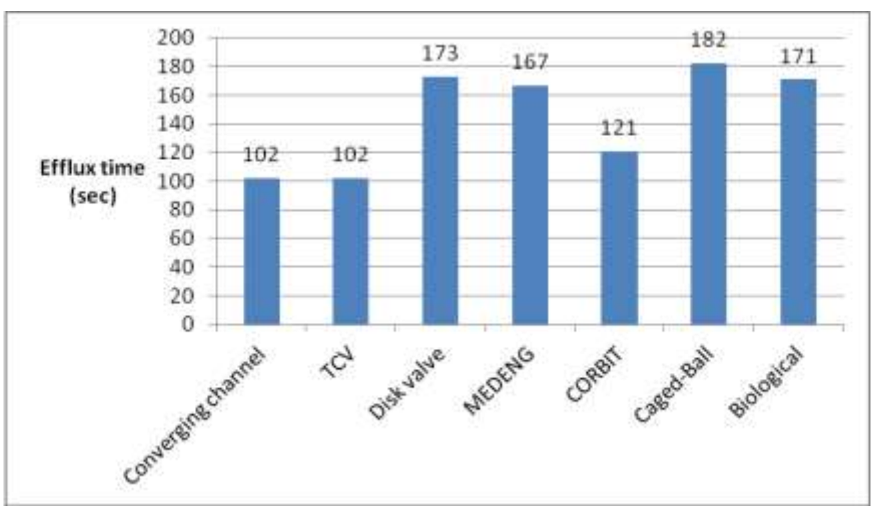

Fig. 5. The efflux time of the fixed volume of water at the same pressure passing through hollow converging channel and the channel containing valve prosthesis.

Study of interaction of the mechanical valve prosthesis with tornado-like jet allows assessment of the hydrodynamic compatibility, when the mechanism of tornado-like jet generating in the left ventricular cavity is not affected. However, the combined lesions of the valve apparatus or the presence of mechanical mitral valve can deteriorate the internal architectonics of the left ventricular cavity and the mechanics of cardiac contraction . As a result, the stream formed in the cavity may be turbulent, and the flow passing through the aortic valve prosthesis has no particular structure.

We have performed a study of the interaction of turbulent flow with the same set of valve prostheses. For the experiment, instead of the converged output, the upper reservoir was fitted with a cylindrical straight tube with a diameter equal to the diameter of the converged channel outlet, and its length was more than 5 diameters. The test results are shown in Fig. 6.

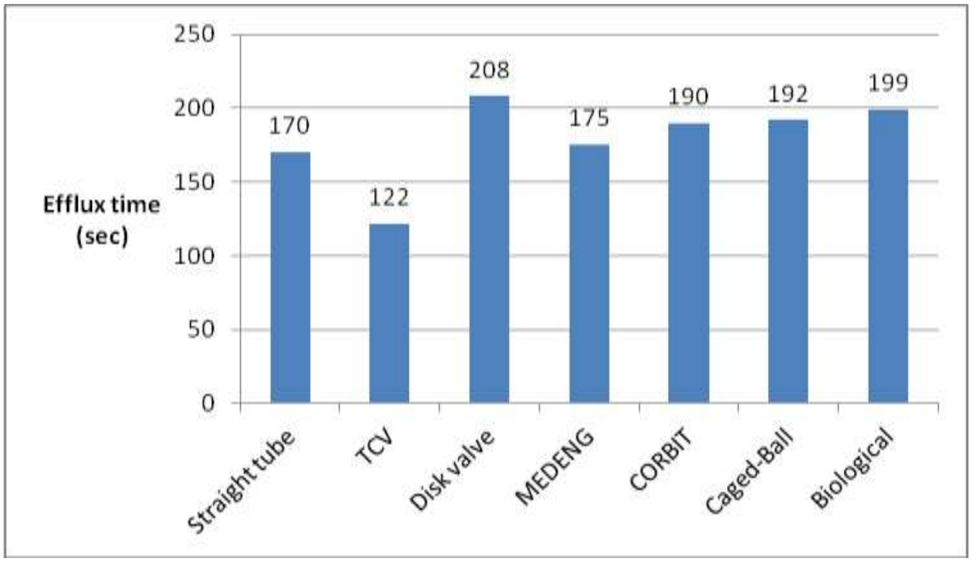

Fig. 6. The efflux time of the fixed volume of water at the same pressure passing through hollow straight tube and the tube containing valve prosthesis.

In conducting this experiment, it was found that when installing the valve TCV, channel resistance did not increase, but significantly decreased. All other models tested augment the flow resistance.

The proposed methodology allows us to estimate the interaction of the valve with the free- falling tornado-like jet. It is known that in the heart and major vessels, it is always a submerged jet . However , the exact solution indicates that tornado-like jet, even when it is submerged, has clear boundaries due to streamlines directions in accordance with the exact solutions, while the secondary flows, accompanying the evolution of the jet are also twisted in the opposite direction , ie these jets are physically separated . Therefore this technique can be considered as a method for evaluating the hydrodynamic compatibility of mechanical aortic valve prosthesis. The presented data clearly indicate almost fully intact jet structure after the valve TCV, which testifies to its hydrodynamic compatibility with tornado-like flow of blood present in the heart and aorta.

2.3. TVC Valve Testing in the Animal Experiment

Until now, the implantation of mechanical heart valve prostheses (especially in the aortic position) required mandatory lifelong anticoagulant therapy. In the opposite case, the valve elements streamlined by blood always initiate the process of thrombus formation, leading to thromboembolism of the brain and other internal organs. The purpose of this test was to evaluate the function of the valve in vivo in the absence of anticoagulant therapy.

TCV valve was implanted in pig weighing 45 kg in the aortic position using extracorporeal circulation and pharmacoligical-cold cardioplegia. Implantation technique was fully consistent with generally accepted principles of aortic valve prostheses implantation. During 1.5 months after the surgery animal received a dose of Warfarin providing INR value of about 2.5 , which corresponds to the standard clinical procedure . After this period, the Warfarin was replaced by Aspirin 100 mg / day for another month, and then any therapy was canceled. Valve function was monitored by echocardiography. The satisfactory functioning of the valve was observed, the valve pressure gradient slightly increased as the animal grew up. Now the experiment continues.

3. Discussion

The accumulated experience of the valve prosthetics proved that replacing diseased heart valves is effective and remains the only way to save the patient's life. However, the success achieved in the field of valve replacement and manifold designs of used mechanical prostheses give the necessity of choice of prosthesis, the most appropriate to conditions of functioning in the real blood flow. Until now, the choice of prosthetic was based on terms of anatomical compatibility, biocompatibility and hemocompatibility. We insist on the necessity of introducing the term of hydrodynamic compatibility for prosthesis being in contact with the blood flow.

Existing knowledge about the blood flow is not sufficient to take it into account when designing the optimized mechanical valve prosthesis, since the full quantitative description of the flow structure in the heart and aorta is not available still now. Therefore hydrodynamic research and testing of prosthetic heart valves were empirical and did not correlate with the valid quantitative criteria characterizing the state of the blood flow in the human body. Established fact that the flow of blood belongs to a class of self-organizing tornado-like flows and can be at least partially quantified using the exact solution of nonstationary hydrodynamic equations for such flows, enables construction of a prosthesis that does not conflict with the blood flow, reducing the activation of the coagulation system and other systems related to the blood movement.

This approach allowed us to develop a fundamentally new design that has demonstrated superior performance both in routine standards-compliant tests, and in the special test evaluated the interaction of the valve prosthesis and tornado-like jet. The fact that the TCV improved flow conditions in the turbulent flow gives evidence that it may be applied even in cases where the mechanism of tornado-like jet formation in the left ventricular cavity is deteriorated, for example at bivalvular prosthetics. Using TCV will significantly reduce or eliminate lifelong anticoagulant therapy inherent in the use of existing mechanical prostheses that significantly improve the quality of life of patients after surgery.

4. Conclusion

The study of the hydrodynamic structure of blood flow in the left ventricle and the aorta and the development of quantitative approaches to its analysis allowed a proposal of new mechanical aortic heart valve prosthesis (TCV), differing from previous models by the hydrodynamic compatibility and possibility to eliminate the anticoagulant therapy after the surgery.

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