Original research

Our new tornado-compatible aortic valve prosthesis: notable results of hydrodynamic testing and experimental trials

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Aims A shortcoming common to all existing designs of mechanical cardiac valve prostheses is an increased trombogenicity caused, among other factors, by the lack of hydrodynamic compatibility between the luminal part of the prosthesis and the patterned blood flow. The aim of the study is to design and test our new mechanical aortic valve prosthesis to exclude life-long anticoagulation treatment.

Materials and methods Standard hydrodynamic tests of the new prosthetic valve have been carried out for comparing with the other existing valve designs. A new method for the heart valve prosthesis testing in a tornado-like flow has been developed. The valve function has been verified in a swine excluding the anticoagulation treatment during the period of time exceeding six months.

Results The significant advantage of the new prosthesis in the standard hydrodynamic tests has been demonstrated. The tests in the tornado-like flow have shown that only this prosthesis allows maintaining the pattern, the head and flow rate characteristics of the tornado-like jet. Upon implanting the new prosthesis in the aortic position in a swine, the good performance of the valve without anticoagulation therapy has been confirmed in the course of more than six months.

Conclusion Obtained has been the evidence of the merits of the new mechanical aortic valve owing to the due consideration of the hydrodynamic peculiarities of the aortic blood flow and the creation of the design providing the proper hydrodynamic compatibility.

Keywords Mechanical aortic valve prosthesis • Tornado-like vortex flow • Heart flow rate

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Introduction

A 50 year-long history of the development of mechanical prosthetic cardiac valves includes a great variety of original engineering concepts, but it should be noted that to the present day there has been no design of mechanical prostheses available which is really capable to completely replace the cardiac valve function and at the same time avoid aggressive anticoagulant therapy which affects quality of life of recipients [1,2].

The authors hereof assume that a conflict between a prosthetic cardiac valve and a recipient organism is provoked by a complex of causes, among which mentioned should be the following factors: inadequate (poor) quality of prosthetic valve materials, failure in cardiac contractility mechanics, provocation of hyperplasia on the prosthesis sewing ring and destruction of the specific hydrodynamic pattern of the blood flow. The latter manifests itself as a damage and activation of blood formed elements involved in coagulation cascade, along with a damage of endothelium due to high linear velocities and effects of flow splitting in separation and stagnation regions. In this case, none of the authors undertakes to identify the most critical factor among those listed above, since the mechanisms and developments of complications in cardiac valve replacement surgery are still imperfectly understood.

A preliminary assessment of functional properties of all mechanical prosthetic cardiac valves is provided with the use of hydrodynamic test benches both under stationary and pulsating turbulent water flow conditions. Test results reflect in every case those significant flow distortions which may occur on some valve components located within the flow core. It appears as a considerable increase in shear stresses and liner velocities, when flowing along the leaflets, as well as separation and stagnation regions within a space downstream of an artificial valve, and in the testing process all distortions take place to a variable degree for all existing models of the mechanical cardiac valve prostheses. We have succeeded in the development of a radically new mechanical prosthesis, which is designed with due consideration of the specific fluid dynamics pattern in the blood circulation segment between the left ventricle and the aorta, that determines the hydrodynamic compatibility of the offered prosthetic cardiac valve. Our new prosthetic valve has received the name Tornado-Compatible Aortic Valve Prosthesis (TCV).

Starting in 1992, the Bakoulev Scientific Center for Cardiovascular Surgery at the Russian Academy of Medical Sciences has been conducting research on the specific hydrodynamic pattern of the blood flow in the heart chambers and the aorta [3]. As a result, our suggestion has been proven that the blood flow generated in the left ventricle shows a structure of self-organizing tornado-like flows which are described by exact solutions to non-stationary equations in fluid dynamics published in 1986 for this sort of flows [4]. A tornado-like vortex represents an axially-symmetric structurally-organized swirl flow, the streamlines of which are directed along a converging spiral and do not intersect each other. Such a structural pattern is responsible for a laminar separation-free fluid flow, which may exist in a pipe with a curvilinear axis. This blood flow regime provides for integrity and intactness of blood cells and endothelial lining of blood vessels, while the biologically active systems in blood and the blood vessel walls (the coagulation and complement system) remain inactivated.

A flow of this class features high head and flow rate characteristics at a low hydrodynamic resistance because of the convergence, the specific organization of the labile three-dimensional boundary layer and extra gradients which occur in the flow core due to its rotational movement. The self-organization of the flow appears subject to the necessary and sufficient conditions resulting from the exact solutions of the above mentioned equations. The said conditions imply the necessity to initiate longitudinal movement of fluid, the channel convergence along the streamlines, the mechanism of flow swirling and the availability of the conditions for the formation of the labile three-dimensional boundary layer to provide full contact of fluid with the channel wall or other fixed external surface. The tornado-like flows are stable by virtue of rotational inertia, but if an obstacle in the flow core appears, it causes local changes in structural parameters in the flow (the ratio between the longitudinal, radial and azimuthal components of the velocity) and leads to a partial or full disruption of the flow structure and transformation of the flow into a turbulent one with all associated unfavorable consequences as follows: an increase in its hydrodynamic resistance and shearing stresses as well as formation of separation and stagnation regions therein [5]. These phenomena in the blood flow initiate an activation of coagulation; they cause damages to the blood formed elements, induce increased shearing stresses at the blood vessel walls and start re-distribution of the blood stream through the branches located in the vicinity of the flow disturbance zone [6]. The totality of all above phenomena dictates the necessity to receive a long-life anticoagulation treatment for every patient who underwent an implantation of a cardiac prosthetic device, if its design ignores the specific organization of the blood flow.

A number of attempts have been made in order to adapt the geometry of the flowing channel of an artificial cardiac valve to that of the biological swirl blood flow. For this purpose, our engineering concept developed for the Cardiomed [7] and trileaflet heart valves with intraluminal disposition of the leaflets [8, 916] has provided for the rotation of the paired leaflets about the channel axis, but we have faced the problem of a significant distortion of the flow structural pattern either due to the triangular shape of the lumen cross-sectional area with the valve open or due to placement of the leaflets within the flow that provides a hindrance to fluid stream. The Bakoulev Scientific Center for Cardiovascular Surgery has offered an absolutely new model of the mechanical aortic valve prosthesis (Patent RU 2434604 C1), the lumen of which is shaped as a circular-type cross-section throughout the full length of the flow-exposed prosthetic body portion and is free of any obstacles which might distort the blood flow pattern. The prosthetic valve consists of a body and three leaflets attached to the external body surface with the use of hinges (see Figure 1 below). The profile of the leaflets is designed so that the lumen cross-sectional area, as viewed from the flowing-through part, is of circular type with the valve open, and the other side of the leaflets has a contour following the curvature of the surface of the sinuses of Valsalva. This provides the proper matching of the aortic stream to the blood flow in the coronary arteries with the valve closed.

Figure 1. Tornado-compatible aortic valve prosthesis (TCV) in closed and open position, respectively.

The aim of our study was to conduct comprehensive tests of the TCV developed by us and assess implantability of the valve in experiments without administration of anticoagulation therapy.

Methods and results

1. Standard hydrodynamic testing

The hydrodynamic bench tests were carried out in the Testing Laboratory operated by the Bakoulev Scientific Center for Cardiovascular Surgery. The test benches have been properly certified by the Russian National Agency ROSTEST, and the said test facilities have been found to be in full conformity with the requirements of the Russian National Standard GOST 26997-2003. The hydrodynamic testing of cardiac prosthetic devices was conducted under the conditions both of the stationary and pulsating flow. For the purpose of testing, water was used as the test medium. The testing conditions were in accordance with the Russian National Standard GOST 26997-2003 requirements.

a) Testing in stationary flow

Model	Effective orifice area (mm²)	Leakages (l/min at 120 mm hg)
TCV (Ø23)	340	1,0
Roscardics (Ø25)	310	1,2
NeoCor (Ø26)	230	0,1
CorBeat (Ø25)	305	1,0
CardioMed (Ø25)	290	>>1.0
LICS (Ø30)	310	0,6
Reference: applicable testing requirements according to the above GOST	-	<1.8

b) Testing in pulsating flow

Model	Stroke volume (ml/stroke)	Backflow leakage (ml/stroke)	Functional characteristics (visual examination)
TCV (Ø23)	108	4,7	Sat.
MICS (Ø23)	100	2,5	Sat.
TriCardics (Ø23)	75	4,5	Sat.
CorBeat (Ø25)	105	2,5	Sat.
RosCardics (Ø25)	85	4,5	Sat.
NeoCor (Ø25)	102	2,5	Sat.
Cardiomed (Ø25)	96	5,5	Sat.
Reference: applicable test requirements according to the above GOST	>70	<10	

b) Durability testing

The TCV item was tested on an accelerated life test bench in the Testing Lab responsible for testing of implantable CVP items at the Bakoulev Scientific Center for Cardiovascular Surgery. During the accelerated durability testing, 400 000 000 cycles were completed that corresponded to 10 years of the CVP performance in a patient body. Upon testing, no damages or wear of the prosthesis moving parts, which could result in a risk of disintegration of the valve or failure in its performance, were reported. Upon testing completion, the prosthetic valve surfaces subject to friction were examined at magnification x40.

2. Testing in tornado-like flow

The type of the flow of the test fluid has a significant influence on hydrodynamic properties of the investigated mechanical cardiac valve prosthesis. Following the suggestion, L. Bockeria et al. [10] published their own data that an insertion of a vane consisting of inclined blades into the flowing-through channel of the stationary flow test bench provoked a non-systematic change in the measured functional properties of a tested object.

Therefore, the challenge of that stage of the study was designing a new test bench that should be capable of generating a stationary tornado-like jet stream.

The newly designed test bench comprises two vessels (a feeding vessel and a receiver) arranged one above another (see Figure 2 below). Water freely leaves the upper feeding vessel. A tested valve is to be inserted in line with the jet stream which is formed at the outlet nozzle of the vessel. The nozzle is designed as a confusor channel, the profile of which is computed in accordance with the exact solutions to the above mentioned equations. For the purpose of the computation, a bore diameter of the tested valve and the required ratio between the outlet size and the length of the channel to be equal to 1/5 are taken as initial parameters.

Figure 2. Test bench for testing CVP in stationary tornado-like flow (left: external appearance; middle: attachment of confusor to bottom of feeding vessel; right: confusor channel).

Water, upon leaving the feeding vessel, self-organizes into a tornado-like jet stream within the confusor channel. This jet stream differs from the turbulent one in the following: no surface disturbances are available; the jet shows glass-like transparency; no disturbances occur at the location of the water jet falling in the receiving vessel despite the fact that twisting of the jet stream is visually detected due to the fluid rotational motion in the receiving vessel. The visual characteristics of the tornado-like jet exhibit significant differences from those of the jet formed with the use of a pipe-like channel with the same cross-section and length parameters. An efflux time of a specified volume of fluid via the confusor channel is with certainty known to be less than it is the case with an efflux of the same fluid volume through a pipe (s. Figure 3 below).

Figure 3. Glass-like transparent jet stream at outlet of confusor channel without valve inserted (left) vs. jet stream at outlet of the pipe with the same cross-sectional area (right).

A comparative test of 5 major designs of the mechanical cardiac valve prostheses of the same size was carried out to cover the following items: a caged ball valve, a disc-type cardiac prosthesis (MICS), a bileaflet valve (Cardiomed), a trileaflet valve prosthesis (CorBeat) and a trileaflet TCV (tornado-compatible aortic valve prosthesis). The results of the comparative test are given in Figures 4 and 5 as well as shown in Table 3 below.

During the said experimental testing, 190 l water was made to flow from the upper into the lower vessel under a head pressure ranging from 50 to 5 mm hg.

For the purpose of a quantitative assessment of a degree of influence of the design of each valve on parameters of the exiting liquid, an efflux time of the same liquid volume between the two recorded heights of the liquid columns in the upper vessel was measured for different designs of the prostheses tested (s. Figure 6).

Figure 4. Destruction of tornado-like jet when flowing over the mechanical aortic valve body: top left: caged ball valve; top right: disc valve MICS; bottom left: bileaflet valve Cardiomed; bottom right: trileaflet valve CorBeat.

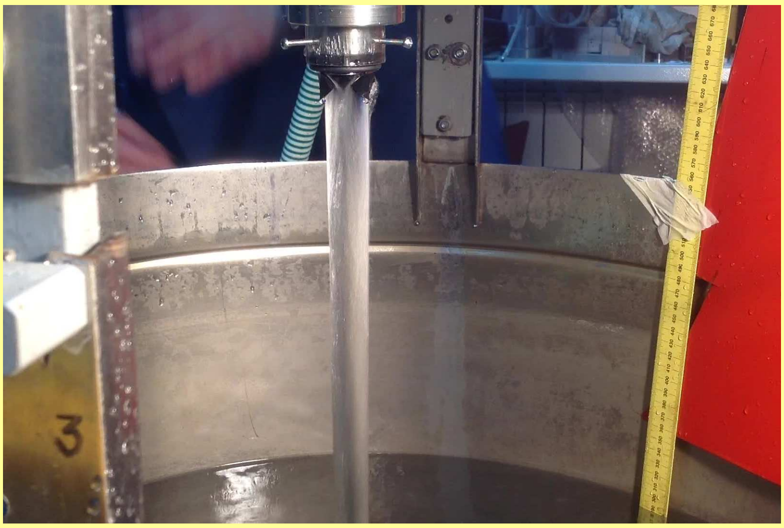
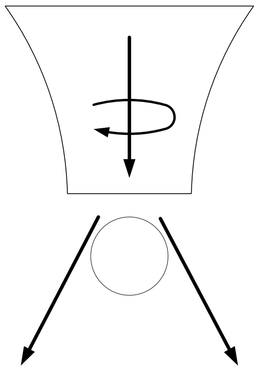
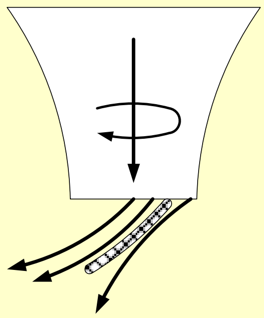
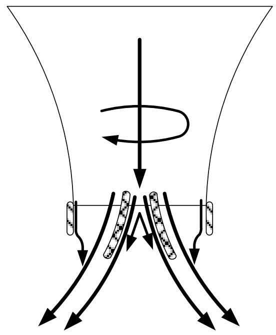
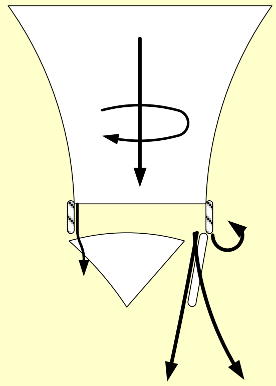
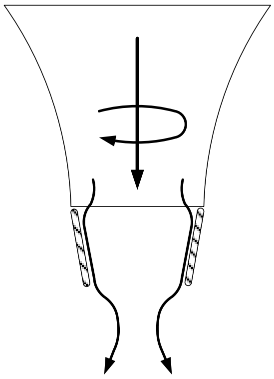
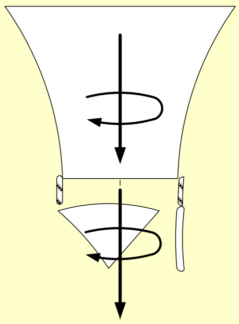


Figure 5. Maintenance of the tornado-like jet pattern at outlet of confusor channel with cardiac prosthetic device TCV inserted therein.

Table 3. Patterns of flow around a prosthetic aortic valve body by falling tornado-like jet stream

Type of prosthetic valve	Front view	Reported
Caged ball valve CBV		Complete destruction of the swirl flow; backflows within the area under the ball and disintegration of the water jet stream.
Disc valve MICS		Complete destruction of the swirl flow; the water jet is attracted to the surface of the disc (the Coandă effect); the main jet stream shifts towards an inclination of a leaflet; the typical jet compression takes place in the area of the bottom edge of the body.
Bileaflet valve Cardiomed		Complete destruction of the swirl flow; the water jet is attracted to the surface of the leaflets (the Coandă effect); there is a flow separation between the leaflets; the main stream is shifted towards an inclination of the leaflets; the typical jet compression takes place in the area of the bottom edge of the body.
Trileaflet valve CorBeat		Complete destruction of the swirl flow; the water jet is attracted to the surface of the leaflets (the Coandă effect); there is a fragmentation of the flow and there are return flows within the hinge region; breaking-through diverging streams in the shape of a cone between the leaflets occur; the typical jet compression occurs in the area of the bottom edge of the body.

Bioprosthetic frame valve BioLab		Complete destruction of the swirl flow; the water jet is attracted to the surface of the leaflets (the Coandă effect); the jet compression takes place in the area of the bottom edge of the body that is typical for a conical extension.
Cardiac prosthetic device TCV		The flow pattern shown herein is observed because the TCV internal surface geometric shape is a perfect geometric extension of the surface of the swirling apparatus.

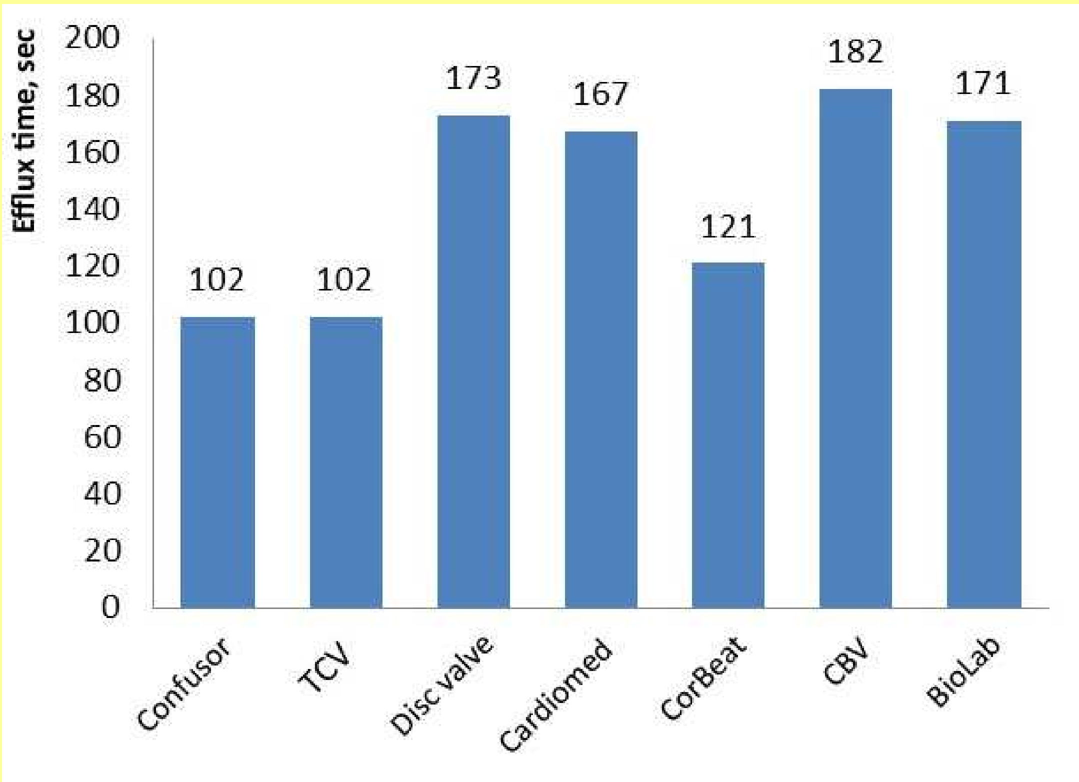


Figure 6. Efflux time of the same liquid volume between two recorded heights of the liquid columns: efflux via free confusor channel vs. efflux via flowing channel with inserted prosthetic devices of different designs.

As is evident from the above presented data, the maintenance of the pattern of the flow in its passage through the TCV does not produce an increase in the efflux time, and, consequently, it does not create any resistance to the out-streaming jet. Reported is that all the other designs of the prosthetic valves contribute to a resistance to the out-streaming jet to one degree or another.

During cardiac valve surgery, it is not infrequently the case when the internal architectonics of the left ventricular cavity is disrupted that leads to a destruction of the swirl flow, so that the aortic valve prosthesis is washed by a non-swirl flow.

We performed a study in order to establish how the swirl-free flow interacts with the same set of the cardiac prosthetic valves. For the purpose of the experimental study, instead of the confusor we installed a cylindrical extension piece with a diameter equal to that of the confusor outlet diameter, and the length of the extension was more than 5 diameters. Results of that hydrodynamic trial are given in Figure 7 below.

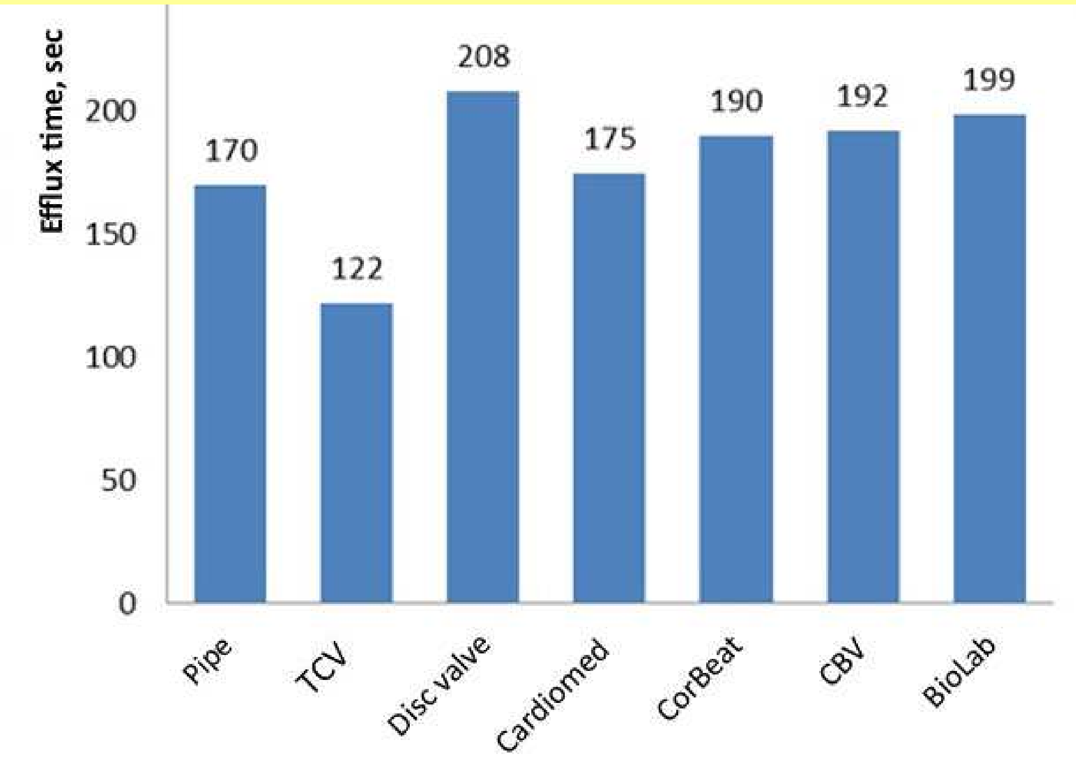


Figure 7. Efflux time of the same liquid volume between the two recorded heights of the liquid columns: efflux via free pipe channel vs. efflux via channel with inserted valve prosthesis of different designs.

During the above experimental study, it was reliably established that in case of the test with the TCV inserted, the resistance to outflow was considerably decreased, but not increased, that is evident from the data represented herein. The other valve models demonstrated their resistance to the flow to one extent or another.

The reported data unambiguously demonstrate that the stream jet pattern downstream of the TCV remains essentially intact that is the evidence for the hydrodynamic compatibility between the structural pattern of the intracardiac and the aortic blood flow and the tornado-like jet stream structure.

The offered testing methodology makes it possible to assess the behavior of a cardiac prosthesis under the conditions of a falling non-plunging tornado-like jet. It is well known that in case of the heart and large blood vessels we always deal with the plunging jet. However, when it is considered that, according to the exact solutions, a tornado-like jet stream shows its clear boundaries determined by the respective flow streamline directions, and under due consideration of the fact that the secondary streams, accompanying the evolution of the jet, are also swirled, but in the opposite direction, i.e., the jets in question are physically separated, all this lends credence to our methodology which may be utilized as an assessment technique in evaluating hydrodynamic compatibility of a prosthetic cardiac valve.

3. Chronic experimental prosthetic valve testing

Up to the present, upon an implantation of mechanical cardiac prostheses (especially in aortic position) it has been an imperative to provide a long-life anticoagulation management. Otherwise thrombosis is always initiated because of the presence of some prosthetic valve components washed by the blood flow so that it may lead to thromboembolism of brain and other abdominal organs [11-15]. The aim of the chronic experimental testing is an assessment of the valve performance in vivo, excluding anticoagulation management treatment.

A TCV in the aortic position was implanted in a swine with a weight of 45 kg with artificial blood circulation using cold chemical cardioplegia. The implantation procedure was in full compliance with the generally accepted guidelines on aortic valve prosthetic device implantation. Upon the cardiac surgery, the animal received warfarin dosing to provide INR at a level about 2.5 for 1.5 month that was in conformity with the commonly used clinical practice. Upon expiration of that period of time, warfarin was replaced by aspirin received as dosage of 100 mg/day for one month, whereupon any further medication was stopped. The prosthetic device performance was monitored with echocardiography. Noted was a good functioning of the prosthetic valve; the prosthetic device gradient showed an insignificant increase with the animal body size growth.

Discussion and conclusions

The experience accumulated in engineering and clinical applications of the cardiac prosthetic devices has shown that the replacement of diseased or damaged natural heart valves is an effective and sometimes the only solution to save the patient's life. But at the same time, considering a good progress in cardiac prosthetic device research & development and taking into account a great variety of the prosthetic valve designs available, every cardiac surgery expert is facing now the need to choose the right valve for the right patient to provide the most favorable performance of the valve prosthesis in patients. So far a cardiac surgeon in decision-making has operated with the terms like anatomical, biological compatibility and hemocompatibility of the cardiac prosthetic devices [16]. Hereby we insist on the necessity to introduce a new criterion for this purpose: it is the hydrodynamic compatibility of prostheses functioning in the blood flow.

The existing concepts of blood circulation are not capable of properly considering the blood flow pattern as a criterion in favor of a mechanical cardiac prosthesis type. Therefore, the conventional hydrodynamic studies and tests of the cardiac prosthetic devices are of empirical nature and cannot correlate with real quantitative criteria featuring the blood flow regime in a human body. The factual evidence that the blood flow refers to the class of self-organizing tornado-like flows and may be quantified by the exact solutions to the hydrodynamic non-stationary equations for the said flow class makes it possible to develop an absolutely new design of the cardiac prosthesis avoiding any conflict with the biological blood flow, with lowering risks of activation of the coagulation and triggering action of the other systems connected with the blood flow.

Such approach has allowed us to offer our radically new design of the cardiac prosthesis which has demonstrated its superior performance both in standard hydrodynamic testing in accordance with the applicable standard requirements and specific testing, where an interaction between the new prosthetic valve and the simulated tornado-like jet stream has been evaluated. The factual evidence that the TCV improves the flow regime under the turbulent flow conditions attests that this prosthesis may be applied in those cases, when it is known in advance that we are dealing with a failure of the mechanism of the generation of the tornado-like jet stream within the left ventricular cavity, for instance, in the event of a double-prosthetic repair in a patient. Moreover, the TCV implanted provides a means for administration of a low-level anticoagulation or even full avoidance of a long-life anticoagulation treatment that is inevitable in case of implantation of the conventional mechanical prostheses of other designs and that significantly impairs quality of life in patients upon prosthetic valve replacement.

As a result of our investigations on the hydrodynamic pattern of the blood flow in the left ventricle and the aorta and as a consequence of devising quantitative approaches to analyses of the specific blood flow hydrodynamics, a new design of the mechanical aortic valve prosthesis, which features hydrodynamic compatibility and allows avoiding anticoagulation management therapy, has been offered for application in practice by our R & D team.

Statement on ethical issues

Research involving people and/or animals is in full compliance with current national and international ethical standards.

Conflict of interest

None declared.

Author contributions

All authors analyzed the data and contributed to the writing of the manuscript. All authors read the ICMJE criteria for authorship and approved the final manuscript.

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