Physico-Mathematical Substantiation of the Effectiveness of a New Model of an Artificial Mechanical Single-Leaf Heart Valve in the Tricuspid Position

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The effectiveness of a new artificial mechanical single-leaf heart valve presented in the Utility Model Patent No. 202285 was substantiated. Its effectiveness was compared with that of a PAHV-2 heart valve prosthesis from OOO Special Design Bureau of Medical Technology (Russia). Hemodynamic values for the native tricuspid heart valve were taken as reference values. 3D models of the valves and the working environment were created in SOLIDWORKS software (Dassault Systèmes, France). Hemodynamic calculations were performed using the SOLIDWORKS Flow Simulation extension. Downstream blood flow velocity and pressure gradient profile images were generated in MATLAB (MathWorks, USA).

Introduction

The cardiovascular system (CVS) is one of the major and most loaded systems in the human body. The CVS is constantly overloaded during life due to work, stress, sports, aging, etc.

Valve defects constitute a common cause of cardiac failure. If valves are afflicted by stenosis, they develop large pressure drops, which can produce serious reductions in systemic pressure or pulmonary artery pressure, inevitably creating large loading on the heart. Cardiac failure can develop simply as a result of aging or can be produced by a variety of different specific pathologies. Surgical intervention is one of the most effective methods of treating cardiovascular diseases. It includes heart valve prosthetization [1, 2].

The commonest and most dangerous conditions are diseases of the aortic and mitral valves of the heart, though impaired functioning of the tricuspid valve (TV) is also commonly seen.

Impairments of the functioning of the TV can result from failure of this structure. Tricuspid failure (TF) is a heart disease in which incomplete closure of the valve leaflets occurs and the TV loses its closing function, leading to regurgitation of blood from the right ventricle into the right atrium during systole. The commonest cause of TF is right ventricular dilation. TF is usually asymptomatic, though severe TF can produce pulsation of the neck veins, a holosystolic murmur, right ventricular cardiac failure, and atrial fibrillation. TF can be diagnosed by physical examination or echocardiography. The course of TF is usually benign and does not require treatment, though some patients with particularly severe cases and missed cases of TF require annuloplasty, valve reconstruction, or valve replacement [1, 3].

The aim of the present work was to seek physical-mathematical substantiation of the effectiveness of an artificial mechanical single-leaf heart valve model in SOLIDWORKS and MATLAB software.

Materials and Methods

The following software were used in the study:

- SOLIDWORKS (Dassault Systèmes, France) - CAD software providing industrial enterprises with automation at the stages of design and technical preparation for manufacture; it was used here for mathematical modeling of artificial heart valve (AV) operation in a medium identical to that in which the native TV operates;

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— MATLAB (MathWorks, USA), a suite of applied programs for solving technical computation tasks, used here to create convenient downstream blood flow velocity and pressure gradient profile images using different AV models as compared with the native TV.

Calculations in SOLIDWORKS Flow Simulation were run on the basis of the Navier–Stokes equation and the laws of conservation of mass, momentum, and energy:

$$\begin{split} \frac{\partial P}{\partial t} + \frac{\partial}{\partial x_k} (\rho u_k) &= 0; \\ \frac{\partial \rho u_i}{\partial t} + \frac{\partial}{\partial x_k} (\rho u_i u_k - \tau_{i,k}) + \frac{\partial P}{\partial x_i} &= S_i; \\ \frac{\partial \rho E}{\partial t} + \frac{\partial}{\partial x_k} \Big[(\rho E + P) u_k + q_k - \tau_{i,k} u_i \Big] &= S_k u_k + Q_H, \end{split}$$

where ρ is density, u is velocity, P is flow medium pressure, t is time, S is the external mass force acting per unit mass of flow medium, E is the total energy per unit mass of flow medium, Q_H is heat production (or absorption) per unit volume, q is the distributed heat flow, and τ is the viscous shear stress tensor. Subscripts designate summation in the three coordinate directions [4, 5].

Hemodynamic parameters were calculated for the AV in SOLIDWORKS by modeling a conical tube whose structural geometrical parameters approximated the native values of the right ventricle [6].

Calculation of hemodynamic blood flow parameters and operation in MATLAB used Newton's formula for

friction between layers in a viscous fluid and the Poiseuille equation, along with the Reynolds number:

$$F_{\text{frict}} = \eta S \frac{d\vartheta}{dx};$$

$$V = \frac{\pi r^4 (P_1 - P_2)}{8\eta L} t;$$

$$Re = \frac{\rho \vartheta d}{\eta},$$

where η is blood viscosity, S is the area of contact of the blood flow layers, $d\vartheta/dx$ is the blood flow velocity gradient (shear rate), V is blood volume, r is tube radius, $(P_1 - P_2)$ is the pressure drop, L is tube length, t is time, ρ is blood density, ϑ is blood flow velocity, and d is tube diameter [5, 7].

Methods for studying AV by computer modeling have now come into greater use, as they provide for primary investigation of designs, correcting all shortcomings without the expense of creating real prototypes. Satisfactory computer calculation results indicate when it is appropriate to make a prototype and run hydrodynamic bench studies [8].

The design of the artificial mechanical single-leaf heart valve (AMSLV) developed here is shown in Fig. 1. The main innovations in the design are the housing in the shape of a Reuleaux triangle, the leaf made from synthetic fluorinated rubber, and a compression spring in a tube. The design of the attachment unit and the materials selected provide for full-flow functioning of the AV, simple assembly of the valve without any need for heating or compressing the housing or specialized instruments; the attachment unit has a satisfactory strength, indicating reliability [9].

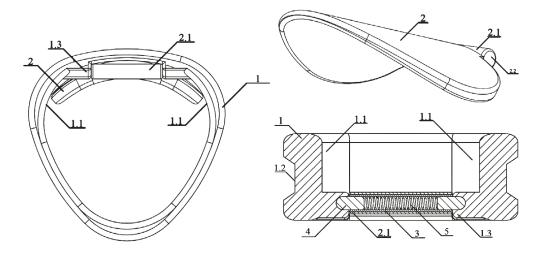


Fig. 1. Design for the single-leaf mechanical heart valve developed here: 1) housing; 1.1) inner support ledges; 1.2) groove; 1.3) slots; 2) leaf; 2.1) fastening; 2.2) aperture; 3) tube; 4) spring; 5) pin [9].

It should be noted that the AMSLV has design advantages over the PAHV-2, as the ratio of housing aperture area to flow area is 33% in the PAHV-2, giving a full-flow coefficient of 0.67, while the ratio for the AMSLV is 11%, giving a full-flow coefficient of 0.89. Furthermore, the design of the leaf attachment unit gives a more homogeneous flow, with properties close to those of the operation of the native valve [9, 10].

Results

Figure 2 shows SOLIDWORKS calculations of blood flow velocity through the AV.

Analysis of the image of the blood flow velocity distribution on operation of the PAHV-2 valve shows splitting of the central blood flow into two peripheral flows, which leads to a nonuniform velocity gradient distribution. This flow is due to the internal position of the axis of rotation of the leaf at the center of the housing. The hemodynamic parameters of the PAHV-2 are far from the properties of the operation of the native tricuspid valve leaf. This characteristic of valve operation can increase the risk of forming turbulent flows and thrombi.

Analysis showed that operation of the AMSLV formed a single central laminar flow, indicating the absence of turbulent movements, due to displacement of the axis of the leaf attachment to the base of the housing.

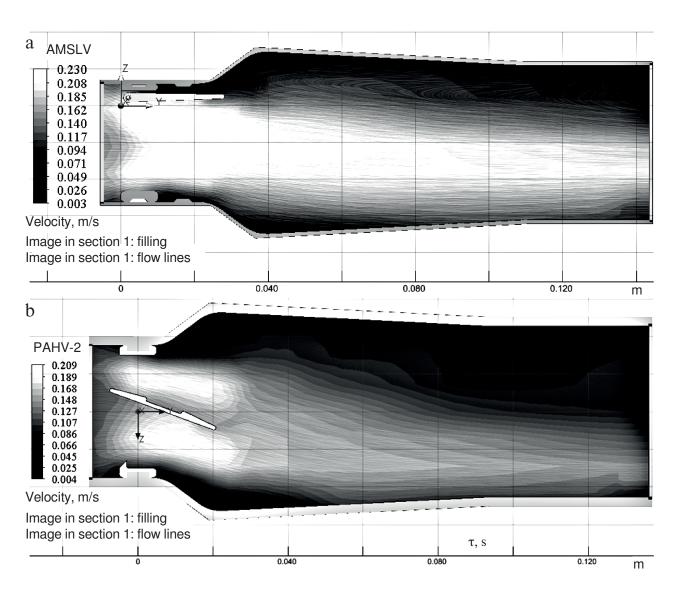


Fig. 2. Downstream blood flow velocity profiles: a) AMSLV; b) PAHV-2.

Parameter	PAHV-2	AMSLV	Native TV
Maximum blood flow velocity, cm/s	20.90 ± 0.77	23.00 ± 0.57	20.00 ± 0.60
Mean blood flow velocity, cm/s	13.75 ± 1.13	15.09 ± 0.99	15.00 ± 1.05
Minimum blood flow velocity, cm/s	6.60 ± 0.21	7.10 ± 0.29	10.00 ± 0.3
Reynolds number	2856.87	2515.89	2650.16
Presence of vortexes (turbulent flows)	+	_	_
Presence of peripheral flows	+	_	_

TABLE 1. Results of Measurement of Hemodynamic Parameters of Valves

The hemodynamic parameters of the AMSLV are close to those of the native TV. The obtained results are compared with the data for healthy TV in Table 1.

Analysis of parameters for the PAHV-2 showed a clear deviation from the values for the TV due to the formation of two peripheral flows and the turbulent nature of the blood flow due to the position of the axis of rotation of the leaf at the center of the housing.

Analysis of Table 1 showed that the parameters of the AMSLV, in contrast to those of the PAHV-2, were closer to those of the native TV, particularly the distribution of blood flow velocity and creation of a laminar cross section in the blood. These values were achieved because the AMSLV produces a full-flow section and because of its flexible leaf, simulating the operation of native leaves.

Conclusions

This study obtained physical-mathematical substantiation of the operating effectiveness of a new artificial mechanical single-leaf heart valve model for prosthetization of the tricuspid valve of the heart. The studies showed that:

- the parameters of the AMSLV were similar to published values for operation of the TV;
- the hemodynamic parameters of the AMSLV were better than those of the PAHV-2 in a comparative analysis with the TV, which is evidence that the AMSLV design developed here has the advantage;
- the satisfactory results from studies of the AMSLV provide evidence that a material prototype should be built and its operability tested on the hydrodynamics bench.

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