

Особенности проектирования устройства искусственного желудочка сердца: обзор работ

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Рассматривается проблема проектирования устройства механической поддержки/замены работы сердца – искусственного желудочка сердца (ИЖС). Актуальность исследований в этой области обусловлена высоким процентом населения, страдающим заболеваниями сердца. Причиной каждой пятой смерти в мире является сердечная недостаточность. На сегодняшний день создан ряд моделей ИЖС, некоторые из них успешно применяются в медицинской практике. За годы исследований в этой области сформировалась общая концепция разработки устройства ИЖС: установлены требования к системам, выработаны подходы к решению задач, получены определенные результаты и выявлены имеющиеся недостатки систем ИЖС. Стремительно развивающиеся технологии дают все больше возможностей для решения существующих задач. Работа представляет собой анализ состояния проблемы разработки систем ИЖС на сегодняшний день. Систематизированы биомедицинские и технические требования, предъявляемые к системам ИЖС, проведена классификация проблем, возникающих в процессе проектирования, и обсуждены тенденции новых разработок в этой области.

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Left ventricular assist device (lvad) design features: literature review

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bogdanova.bmstu@gmail.comgoukov_am@mail.ru**Introduction**

More than 8 million people in our country suffer from heart failure. About one million of these people die each year [1]. The problem of ventricular assist device creating - a mechanical device used for partial or complete replacement of heart function - is investigated for a long time (according to [2] just in our country since the 1970s). Today plenty of encouraging results are received. There is a number of VAD models which are successfully applied to patients with heart failure. After implantation, patients conduct a way of life that is normal in many respects: they are in the family, often they have an opportunity to work in their former specialty. Some of them live with the device about 8 years [3]. According to [4] for 2010 the estimated total number of long-term devices implanted in the United States per year is over 1,700 (the population of the U.S. is 305 million), compared with over 430 per year in Europe (the population of Europe is 731 million). Unfortunately, people who need a heart transplant are much more.

The principle of VAD is that being connected to the left ventricle with one cannula and to the ascending aorta with the other cannula the pump fully or partially replaces the function of the natural heart. This scheme allows the use of VAD in two ways: as a "bridge to transplantation" when the device is used temporarily until the donor heart is found, and a "bridge to recovery", when through the use of VAD the function of the heart muscle is recovered.

VAD system can be divided into three subsystems: blood pump, power supply system and control system (Fig. 1).

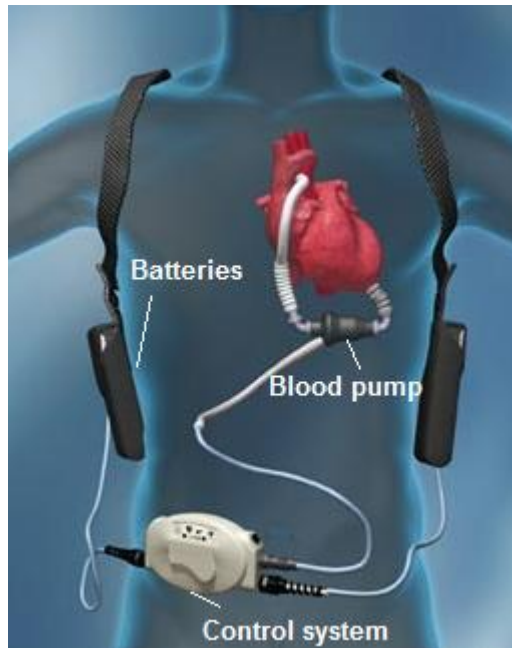


Fig. 1. VAD subsystems [5]

Each subsystem can be the subject of separate study. Special role in the development of VAD plays medical side of the issue. Successful research and development require interaction with qualified professionals in this field. The development of VAD is a multidisciplinary problem which demands fulfilment of a number of requirements.

One of the most active programs in implantation of long-term systems of artificial circulatory support is guided by German Heart Center in Berlin (DHZB) [3].

The well-known VAD commercial models were created by Berlin Heart (Germany), HeartWare Int. (USA), Thoratec (USA), Abiomed Inc. (USA) etc.

Works devoted to VAD systems can be classified in field of research, according to the above subsystems. Concerning the blood pump - a large number of works is devoted to the study of blood behavior in the pump chamber: to modeling questions [6-24], with an emphasis on red blood cells damage - hemolysis [10, 20, 23, 27-32]. Much less works are devoted to the research of rotor (impeller) dynamics of the blood pump [33-36]. Application of magnetic bearings in VAD and magnetic levitation control tasks of are addressed in [33-39]. Biomedical part of design, associated with the selection and development of biocompatible materials is considered in [26, 32, 40-43]. Features of power supply systems and control of VAD mode work are given in works [26, 44-50].

The integrated approach to VAD development with an emphasis on design phases is presented in the works [7, 51]. In [2] the problem of artificial heart creation in Russia on 2006 is clearly reflected. The most comprehensive systematic review of existing VAD systems with description of specifications is given in the work [54], as well as in [24, 26, 55-57]. Brief review of existing methodologies and

approaches to the design of artificial heart (AH) and circulatory support system (CSS) are presented in the works [58, 59]. The problem of creation of mechatronic modules of AH and CSS systems is studied in [60, 61].

With the purpose of further research in the development of VAD system, this work is the study of up to date problem state. The main part of the work consists of three sections. The first section is devoted to the study of blood pump. The second and the third sections are devoted to power supply system and control system respectively. Based on this analysis, the requirements to VAD development are generalized, main issues are underlined and new solutions are proposed in conclusion.

Purpose of investigation. The work is devoted to studying the features of VAD design with the purpose of further research on their optimization and improvement.

1 Blood Pump

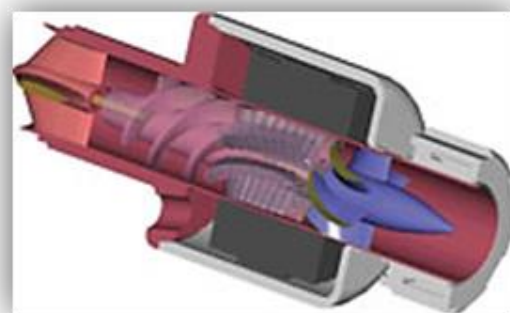
Depending on the pump type there are pulsatile, centrifugal and axial VAD [26, 54] (Fig. 2).



a)



b)



c)

Fig. 2. VAD types: a) pulsatile [62]; b) centrifugal [63]; c) axial [64]

Pulsatile (volume) pumps are Novacor® (Fig. 2, a), Excor®; centrifugal pumps are HeartWare® (Fig. 2, b), Levitronix CentriMag®, Levacor™; axial pumps are DeBackey® (HeartAssist 5) (Fig. 2, c), HeartMate II®, Incor®, Jarvik 2000 etc. [26]. The trends of recent research in this area are associated with the development of the rotary pump models exclusively [14-16, 33-35, 37, 51, 53-56, 65-70]. The operation concept of pulsatile pumps is based on alternate filling of the working chamber with blood and subsequent blood replacement. Disadvantages of this design are the big size of the pump, the fragility of the membrane, the use of valves which can fail when pollution.

VADs are distinguished by location of the pump: inside or outside the body (extracorporeally). An example of an external pump is the model Levitronix CentriMag®, as well as Hemopump®, Abiomed

BVS 5000™ etc. A clear disadvantage of such models is limited mobility of the patient, that is why following VAD models are created with the possibility of implantation.

CFD. Simulation of blood flow in the pump chamber is performed using hydrodynamic analysis - Computational Fluid Dynamics (CFD). CFD has been used since the 1960s to analyze fluid flows [51]. With the help of CFD they define the parameters of blood flow, such as: shear stress, pressure drop, velocity distribution, presence of stagnation zones, pressure distribution, hydraulic performance and other. CFD allows to estimate the selected geometry of the blood pump in a short time and at the initial development stage. Different numerical approaches can be applied in CFD:

- finite difference;
- finite volume;
- finite elements;
- smoothed particle hydrodynamics;
- method using of cumulative distribution function.

There are many mathematical modules allowing to carry out simulation of fluid and gas flow: CFX-TASCflow (finite volume), STAR-CD (finite volume), FLUENT (finite volume), SIMPLE algorithm (finite volume), SMAC algorithm (finite difference), Comsol Multiphysics (finite elements), XNS (finite elements) [51]. Modern software packages allow to take into account various effects including turbulence, temperature and thermal phenomena, fluid viscosity as well as to use a model of non-Newtonian fluid in the analysis of the blood dynamics – hemodynamics [7, 72].

The disadvantage of commercial solvers is that the code remains hidden from the user. A developer has no opportunity to look inside the program. In this sense self-developed solvers have the advantage and suggest a more flexible approach to modeling, including optimizing estimated time. Thus, the results given in references [51, 71], are obtained by their own finite element CFD code. But self-developed codes obviously have less user-friendly graphical user interface in comparison with commercial tools [51]. However, it is necessary to distinguish from the commercial finite element software Comsol Multiphysics. In Comsol Multiphysics problem statement is clearly visible when using any module, i.e. for user available are both the equations, describing the process, and the boundary conditions in an explicit form. For example, in ANSYS mathematical statement is hidden from the user behind the element choice. The engineer doesn't see the equations and boundary conditions in that format in which physicists and mathematics got used to see them. In ANSYS the choice of the element means the choice of the equations

describing process. In Comsol Multiphysics the choice of the element doesn't oblige you to anything, the equations are set separately at the choice of the module or at setting of their coefficients and constants [73].

Though blood also is non-Newtonian multiphase suspension consisting of plasma, white (leukocytes) and red (erythrocytes) blood cells and platelets [52] simulation of blood flow in large vessels is based on an assumption that blood is homogeneous incompressible Newtonian fluid with constant viscosity. There is a number of justifications of such assumption. Blood is considered homogeneous if it flows through the vessels with a diameter more than two orders of magnitude greater than the size of a red blood cell. This is usually the case for VADs (diameter of human red blood cell $\sim 7\text{-}8\text{ }\mu\text{m}$ [74]; diameter of abductor cannulas $\sim 25\text{ mm}$; the radial clearance between the screw and the housing is a function of the external screw diameter and the inner diameter of the hub of screw, and for sizes 30 mm and 15 mm it is 0,375-0,75 mm respectively [76]). It is a question of red blood cells because their quantity in usual conditions is three orders of magnitude greater than the quantity of leukocytes and more than one order greater than the quantity of platelets. The maintenance of red blood cells determines the rheological properties of blood. In hemorheology it is known that at shear rates above 100 s^{-1} blood behaves as a Newtonian fluid (more precisely as pseudo-Newtonian). In VADs the prevalent the shear rates are typically two orders of magnitude higher 100 s^{-1} [51]. Based on the assumption above the blood flow is described by the basic equations of hydrodynamics – Navier-Stokes equations [6-20, 23, 24, 26-28, 51, 53].

Blood damage. The first problem demanding the decision in VAD development is blood damage – hemolysis. The non-physical blood behavior in pump chamber leads to hemolysis. Under high shear stress, turbulence, strokes at walls of the pump chamber the shell of red blood cells brakes or stretches with pores formation, through which hemoglobin is released. Indicator of hemolysis is one of the most important characteristics of VAD.

One of the opportunities of hemodynamics is hemolysis prediction. For hemolysis prediction Giersiepen suggested an empirical dependence in the form of a model, corresponding to the equation (1), in which is the plasma-free hemoglobin compared to overall amount of hemoglobin in blood, τ is the shear stress (because of non-physiological flow in the pump), t is exposure time and C , a , b are coefficients was proposed

$$\frac{\Delta Hb}{Hb} = C\tau^a \Delta t^b. \quad (1)$$

Giersiepen's model is widely used in studies of the hemolysis phenomenon. Other approaches are given in [23, 51]. In work [7] the author gives full algorithm of hemolysis indicator definition. Blood

contact with foreign materials, roughness and coating of flow channel surface, adhesive behavior, as well as stagnation zones promote activation of platelets that leads to thrombosis. Except for detection of stagnation zones during the CFD [7], complexity of the thrombogenesis phenomenon makes it difficult for prediction. One of challenges of VAD development is the analysis and selection of biocompatible materials, as well as determination of requirements to surfaces of flow channel. The first model of platelet aggregation was formulated by Fogelson A.L. in 1992 [19, 20]. The full model consists of the system of coupled differential equations. There are other methods for thrombosis prediction [11, 75, 80], for example, similar hemolysis prediction, using the power transcendental equation [27], however, uniform standard approach for thrombosis prediction does not exist yet. Currently, coating with athrombogenic properties are prepared essentially by using heparin - natural sulfated polysaccharide. Such materials include, for example, one of the most successful commercial products Carmeda [77]. Additionally, bioinert polymer coating based on poly-*p*-xylylene and its derivatives are also used [26]. To the surfaces contacting with blood belongs not only flow channel of the pump, but also adductor and abductor cannulas.

Miniaturization. Rotor speed, significantly affecting the indicator of hemolysis, relates to the size of the pump. Capacity of existing commercial VAD models (HeartWare®, Levitronix CentriMag®, HeartMate III®, DeBackey®, Incor®, Heart Mate II®) designed for long-term use is in average $9 \text{ L} \cdot \text{min}^{-1}$. Volume flow of Impella® and its modifications changes from $2,5\text{-}5 \text{ L} \cdot \text{min}^{-1}$ as Impella® is a short-term mechanical system of heart function support. For $2,5 \text{ L} \cdot \text{min}^{-1}$ and a diameter of the pumping chamber equal to 4,2 mm rotation speed is 51,000 rpm [78]. At the same time Incor® at flow rate $10 \text{ L} \cdot \text{min}^{-1}$ and the diameter of the pumping chamber 30 mm has maximum rotor speed equal to 10,000 rpm. It should be noted that axial pumps are characterized by bigger rotor speeds, than centrifugal ones [26]. Of course, the smaller the dimensions of the pump are less feelable it is in the body.

Implantation configuration. Size, weight and configuration of the blood pump are chosen not only for reasons of blood safety and effectiveness of the device, but also for reasons of anatomical preferences. VADs must be easily implanted. Implantation of the mechanical heart support device should be safe for the patient and comfortable to the surgeon. General availability of such operation will be defined not only by cost, but also by complexity and risk level. Almost all used VAD commercial models are implanted by sternotomy. Difference make CircuLite® Synergy – the hybrid of the centrifugal and axial pump (the diagonal pump) and Impella®. Input cannula of the CircuLite® Synergy is connected to the left atrium and the output cannula is connected to the right subclavian artery. CircuLite® Synergy was appeared on the market recently. The European certification by data [79] was planned for 2012. Impella® is implanted endovascular through a femoral artery which makes such operation close to usual procedure [69, 78].

Reliability. Severity of complications which can develop in case of VAD failure puts rigid requirements for reliability and nonfailure work throughout all the operating life of the device. The key moment of pump part analysis is the analysis of rotordynamics.

In previous VADs models hydrodynamic jewelled tilting bearings, immersed in blood, perform as a support [26, 32]. In new generations of VADs they actively began to apply magnetic bearings. In ball bearings blood can't be used as lubricants, because high shear stress in a small ball-race clearance damages red blood cells. Application of other types of lubricants provokes platelets activation which leads to the thrombogenesis. Centrifugal pumps, as a rule, are used with hydrodynamic bearings with the minimum gap in which the main destruction of blood red cells can happen due to significant shear stress [80]. In addition, widespread industrial experience with hydrodynamic bearings has high bearing failure rates [33].

Magnetic suspension has the advantages of non-contact support: high durability due to the absence of friction and a bigger clearance, allowing the rotor to rotate at higher speeds with the uprise of not-too-high shear stress. The use of magnetic bearings in VADs reduces indicators of hemolysis and thrombosis and increases lifetime of the device, but it requires more rigid control. The PID control of the VAD magnetic suspension is spread [34, 36, 38, 81], as well as sliding mode control [34], PI control [70, 82], optimal [82, 83] and suboptimal control [39]. Magnetic levitated rotor is one of the examples of nonlinear systems, intensive studies of which are dedicated to finding optimal stable control.

2 Power supply system

The power source is necessary for functioning of VADs.

Infection. Modern VAD models suggest several options of power supply systems. The most widespread way of energy transmission is through the wires, which are passing through patient skin and connecting pump part to a network or batteries, being outside. Power supply from the network doesn't provide a sufficient level of mobility for normal activity for the patient. In this sense the use of accumulators, which are set in a backpack or on a belt is much more convenient. But such option of power supply in principle is dangerous, because the place of wires entrance is a source of infections, which almost in 100 percent of cases getting into the human organism lead to a fatal case.

The second option - wireless power transmission. In addition to medical features associated with the exception of infection, non-contact power transmission provides more freedom of movement for the patient. Moreover it allows power transmission from an implanted battery or using wireless power transmission channel [44-50].

For power transmission at a distance, there are two technologies: TETS (a transcutaneous energy transformer system) and FREE-D (free-range resonant electrical energy delivery). In both cases coils wound of litzendraht are used [84].

VADs power supply from implanted batteries technology is currently used only in conjunction with power supply through the wireless channel of energy transmission as accumulators, because modern implanted batteries don't have sufficient capacity for long-term work without replacement, and replacement is made by an invasive way. For a continuous power supply of VADs it is necessary to have a source with power up to 10 Watts (a nominal mode, with the flow rate $10 \text{ L} \cdot \text{min}^{-1}$) [26]. Currently, by Jarvik Heart company input of power and control wires through the mastoid bone of the skull was proposed (VAD model – Jarvik 2000) [55]. This method solves the infection problem rather effectively, but possible problems of the input unit survival have to be noted, as well as the need to lay wires of considerable length from the patient's head to supply elements located on the belt.

The following requirements are imposed to power supplies: compactness, safety, biocompatibility (for implanted supplies), reliability, long period of work [26]. The problem of VAD power supply should be solved globally because exactly this problem raises a question of normal activity and mobility of the patient.

3 Control of VADs work

Along with biomedical and design-technology tasks there are problems of effective control of VADs work.

Cardiac cycle consists of two phases: systole and diastole. Unsteady flow of blood with some approximation is taken periodic in time. From these considerations, the first models of VADs are of pulsatile type, for example, Novacor®, Abiomed BVS 5000®, HeartMate® and create pulsating flow [7, 9, 26, 54, 85]. Big sizes of pulsatile pumps (Fig. 3) resulted in need of VADs creation with constant blood flow.

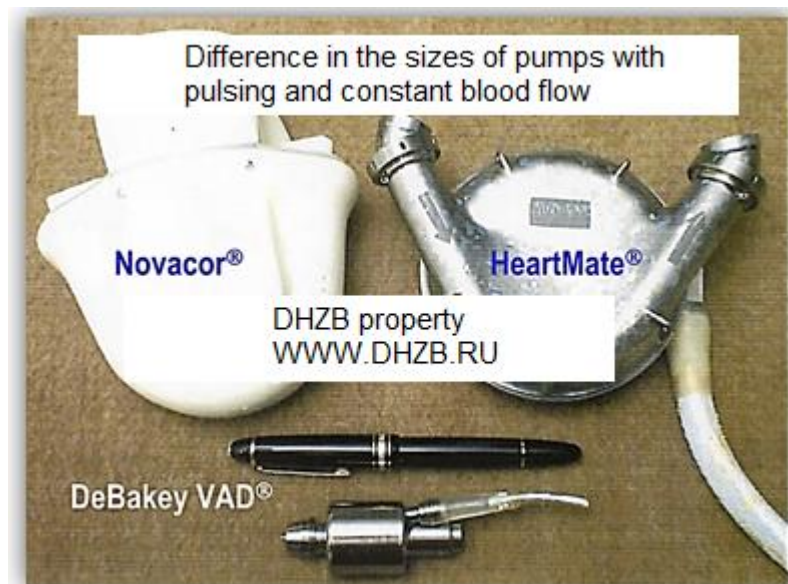


Fig. 3. Pumps with pulsating flow Novacor®, HeartMate®. Pumps with constant flow: DeBailey® [3]

All used pump models possess the flow rate, allowing to provide different operating modes of heart (high activity, normal mode, dream period). The necessary quantity of high-speed modes and smooth regulation of rotor rotation speed is provided. For this purpose for the control system [26]:

- **the main parameters determining heart intensity of the heart are established;**
- **parameters for continuous monitoring of the organism and heart operation control are chosen;**
- **system of parameters which will provide individual settings of control system and satisfy specific features of an organism; these parameters must be controlled periodically with a significant time period, in order to monitor their changes over time.**

Optimal management of VADs operation is vital for the patient.

Summary and Conclusions

The development of VAD system is a complex multidisciplinary technical and biomedical task. Considered features of VADs development in total allow to formulate the main requirements imposed to developers [7, 9, 14-16, 26, 32, 36, 86]:

- numerical simulation of hemodynamics (hemolysis);
- taking into account hemocompatibility (thrombosis);
- maximum miniaturization and selection of new materials;
- implantation configuration (ease of surgery);

- ensuring reliability of all the subsystems (long mechanical life);
- protection/prevention of infection.

All these requirements are anyway connected with each other or follow one from another. Finally, all of them are aimed to achievement of the only goal – improvement of life quality. Thus the cost of systems has to be adequate [51, 87]. Therefore the provided list can be expanded by two more points:

- quality of life;
- costs.

Currently VADs are far from widespread application owing to their imperfection: blood damage, existence of percutaneous power and control wires, heavy energy sources, which need to be carried constantly with oneself and extremely high cost. However, modern technologies open great opportunities for improvement in this area.

One of these achievements is 3D-printing. Rapid prototyping allows to create a prototype from almost any material (steel, titanium and other alloys, plastic, glass, wood, etc.) quickly. It reduces considerably production time: the model is printed in few hours, is tested, in case of need is refined – so, the working cycle is repeated until development is brought to perfection. In addition, it significantly reduces development costs due to lack of need for technical production and due to early detection of the development errors [88, 89].

Advantages of magnetic bearings allow to achieve smaller blood damage. The problem of optimal stable control can be solved with the help of synergetic control theory which is based on principles and methods of directed self-organization, allowing to take into account nonlinear properties of the object [90]. In the last decades the synergetic method of nonlinear objects control systems synthesis became widespread due to its advantages [90-96].

Application of new fluid flow models, development of an optimal blood pump design, application of new biocompatible materials and wireless power transmission realization can also contribute to improvement of current results.

Publications with keywords: [control design](#), [computational fluid dynamics](#), [rotordynamics](#), [magnetic bearings](#), [hemocompatibility](#), [mechanical heart support system](#), [ventricular assist device](#), [heart failure](#)
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