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Original Article

Ventricular Assist Device Sputnik: Description, Technical Features and Characteristics

Sergey V. Selishchev, Dmitry V. Telyshev*

Department of Biomedical Systems, National Research University of Electronic Technology, Zelenograd, Moscow, Russian Federation

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In this paper, the first ventricular assist device (VAD) developed in Russia is described. This device is used to replace the function of left ventricle for patients with an acute heart failure. Basis of this VAD is the axial-flow pump, that assists a left ventricle pump blood to the aorta. Prior to the system development, diverse international design practices were scrutinized. Researches has shown that axial-flow blood pumps can be successfully used as a bridge to transplantation, a destination therapy or a bridge to recovery. The weight of implantable pump is about 200 g. The pump rotor speed can be varied within the range 5000...10000 rpm. Blood flow provided by the pump is up to 10 l/min. Components of the VAD include the microprocessor-based controller, four lithium-ion batteries, the charging unit, the notebook with installed control program and AC power adapter.

Introduction

About 8 million people in Russia suffer from a heart failure. About 30% of them have an acute heart failure (Classes III and IV of New York Heart Association functional classification of heart failure). In its turn, an acute heart failure is the most widespread reason of hospitalization and death from heart diseases. The only way to save the patient life at the end-stage heart failure is an implantation of donor's heart or a device, that can partially or fully replace heart function. Other solutions, such as usage of medications or therapeutic treatment, does not provide sufficient results [1]. In USA about 2000 hearts being transplanted each year. In Russia this sum is significantly smaller and is only reaches 100 transplantations. However, both these numbers stay almost unchanged yearly and remain much less than existing need for transplants [2].

Determining the solution to the donor's heart availability problem does not seem possible in the near future. Therefore, implantation of the device, that can partially or fully replace heart function, is the only way to treat a heart failure.

Ventricular assist devices (VADs) are partially replace heart function. Nowadays, most widespread type of VADs is an axial-flow or a centrifugal pump with nonpulsatile flow [3, 4, 5]. In 2009 in USA usage of such systems exceeded amount of donor heart transplantations [2]. Necessity for the solution of the acute heart failure problem and also usage of international experience with VAD formed the basis for the design of the Sputnik VAD.

Execution of the Sputnik VAD project started in 2009. The project is joint effort of:

- National Research University of Electronic Technology (MIET)
- OJSC Zelenograd Innovation-Technology Center of Medical Equipment (JSC ZITCMT)
- FSBI "Academician V.I. Shumakov Federal Research Center of Transplantology and Artificial Organs", Ministry of Health of the Russian Federation.
- DONA-M LLC.
- BIOSOFT-M LLC.

Materials and Methods

Operation principle

The Sputnik VAD design is based on an axial-flow blood

#Coresponding author: Dr. Dmitry V. Telyshev;
E-mail: telyshev@bmslab.miet.ru

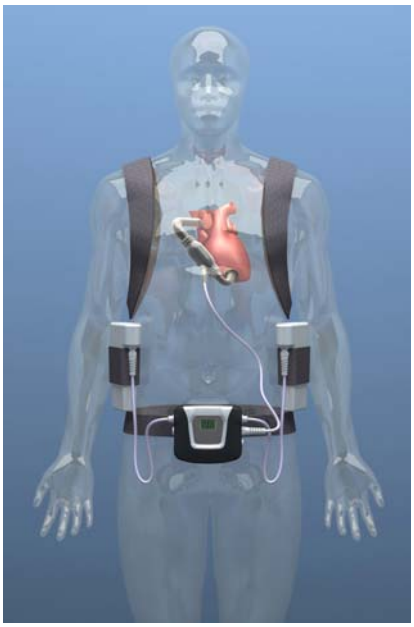

Figure 1: Wearable parts of the Sputnik VAD

pump with nonpulsatile flow. It can provide flow up to 10 l/min. An axial-flow pump was chosen due to clinically proven success of a nonpulsatile VAD usage: survivability of the patients with such systems exceed 70% two years after the device implantation [6]. Wearable parts of the Sputnik VAD are illustrated in Fig. 1.

The rotary type blood pump designed to produce blood flow to support a weak left ventricle of patient's heart. The pump includes a moving part, namely, impeller (rotor with four blades) and a stationary part, namely, flow straightener with three blades and diffuser. An external power supply is used to drive the pump. Two wearable batteries are connected to the driving unit, which, in its turn, connected to the pump by the percutaneous cable passing through the skin.

Implantable components

The blood flow through the VAD is driven by the pump impeller rotor that contain a permanent NdFeB magnet,

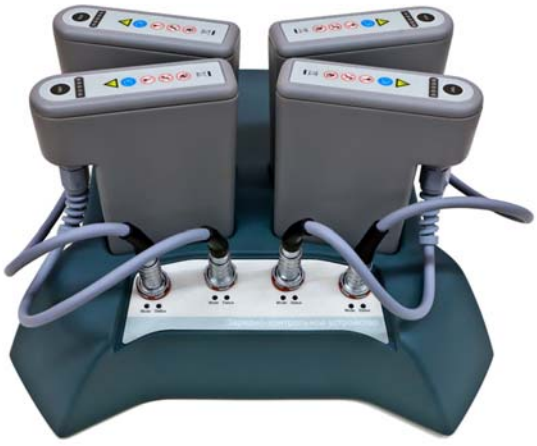

Figure 3: Charging unit with four batteries (front panel view)

which is actuated by a brushless DC motor. Stator of the motor located inside the thin-walled titanium housing with diameter of 16 mm. The weight of implantable pump is about 200 g. The flow straightener consist of three stationary blades 120^0 radially apart, straightening the incoming blood flow along the axial direction. The same characteristics of the straighteners have the Thoratec HeartMate II VAD (HMII; ThoratecCorp., Pleasanton, CA) and MicroMed HeartAssist 5 VAD (HA5; MicroMed Cardiovascular, Inc., Houston, TX) [7]. Three blades of the flow straightener direct flow into rotating impeller blades, minimizing eddy flow prior to entering into the impeller. Magnetic impeller has four blades (3 and 6 impeller blades for HMII and HA5, respectively [7]). The spinning direction of the impeller is clockwise (counterclockwise and clockwise directions for HMII and HA5, respectively [7]). After impeller, blood flow moves into the flow diffuser, which incorporates three twisted blades, located in the rotor output (HMII and HA5 have 3 and 6 diffuser blades, respectively [7]). The inlet and outlet support inflow and outflow needle bearings. Described design of an implantable pump allows to minimize a thrombosis and a hemocyte damage. The length of the implantable pump is 81 mm (the length of HMII and HA5

Figure 2: Blood pump profile

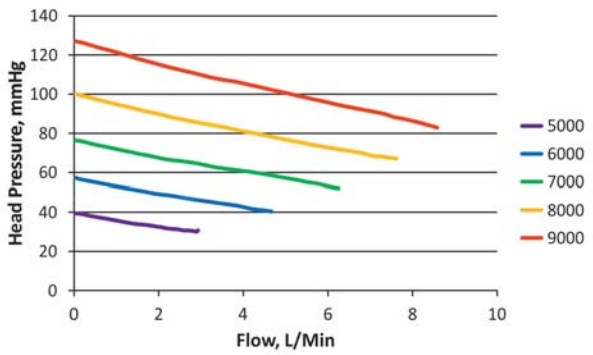

Figure 4: Flow-pressure (H-Q) curve of the Sputnik VAD

81 mm and 71 mm, respectively [7]) and the maximum diameter 34 mm (the maximum diameter of HMII and HA5 30 mm and 43 mm, respectively [7])

The blood pump profile is illustrated on Fig. 2. The tunneling trocar is used to lead the percutaneous cable of the implantable pump outward from the patient's tissue. Design of the implantable pump connection to a cardiovascular system includes inflow and outflow cannulas, felt ferrule and a vascular prosthesis, sewed to ascending aorta.

External components

The external components include microprocessor-based controller, lithium-ion batteries, the charging unit, the notebook with installed control program and AC power adapter.

The implantable pump is connected to the microprocessor-based controller (size: 130.6 cm × 10.6 cm × 3.7 cm, weight: 280 g) by the percutaneous lead with a silicone or polyvinylchloride jacket (diameter: < 5 cm, length: <170 cm). The microprocessor-based controller operates the pump, regulates the pump speed, manages power sources, store pump parameters data. The Sputnik VAD microprocessor-based controller design extensively described in [8]. The controller provides an audible alarm if one of the power supply is lost.

The system power supplying is carried out by two lithium-ion batteries (size: 161 cm × 110 cm × 34 cm, weight: 570 g) or by an AC network. The Sputnik VAD package contain set of four batteries. One pair of this batteries can provide up to 8 hours of the system support. The low-battery alarm on the microprocessor-based controller alerts the user when battery must be replaced and charged. The charging unit is used to charge the batteries (Fig. 3). This unit can monitor and charge up to four batteries at once. LED-indicators are used to display charge level of the batteries. Two dual-colored diodes used to show the battery charge level for the each channel. Maximum charging time of the Sputnik VAD lithium-ion battery is less than 5 hours. Forced air cooling via two integral fans is used to cool the charging unit.

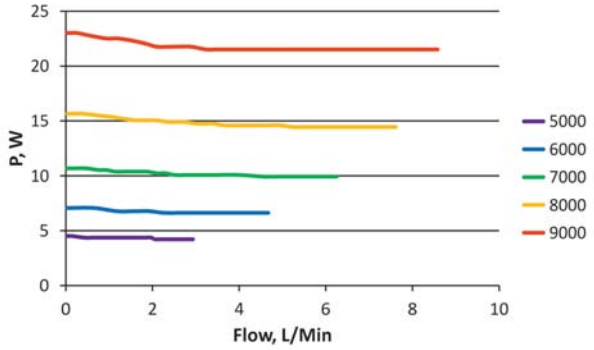

Figure 5: Flow- power uptake (P-Q) curve of the Sputnik VAD

The notebook with installed control program allows a user (e.g. doctor or technical expert) to:

- regulate prescribed value of the rotor speed installed in the VAD driving unit;

- monitor system parameters during intensive and recuperative stages of the patient's treatment;

- periodically monitor system parameters during clinical and ambulatory studies of the patient.

Results and Discussion

Results of the hydrodynamic pump evaluation (head pressure - pump flow and power uptake - pump flow) shown in Fig. 4 and 5. The pressure-flow characteristics were received during experiment with a basic hydraulic mock, like in [9]. The mock incorporate a flowmeter (ME-11PXL Clamp-on Tubing Flowsensors; Transonic Systems Inc., Ithaca, NY, USA), inlet and outlet pressure transducers (MPX5050GP; Freescale Semiconductor, Austin, Texas, United States), a resistance valve, reservoir and series of flexible polyvinyl chloride laboratory tubes (TYGON E-3603; Compagnie de Saint-Gobain, Courbevoie, Ile-de-France, France), with an inner diameter of 12.7 mm.

Over the 2009 to 2012 period, the experimental animal study was conducted [10]. During this study the prototype of the implantable pump VAD Sputnik was tested. The VAD was connected by a scheme "left ventricle – aorta" for two different configurations: paracorporeal and implanted in a thoracic cavity. In 4 out of 6 experiments longevity equaled 74.5 ± 29 days. One experiment was ended due to an intraoperative heart fibrillation. Last experiment lasted 8 days, but it was scheduled. Based on the results of the experiments there were none pump thrombosis and mechanical wear of bearings. Anatomical and histological examination of kidneys, liver and lungs did not spot occurence of an ischemic zone and thrombembolia.

On June 9, 2012, first implantation of the Sputnik VAD was successfully conducted [11]. The recipient was a 67 years old man. After one month in a clinic the patient was released, then he led normal life at home. Finally, on March 5, 2013, the Sputnik VAD was successfully replaced by a donor heart.

Conclusion

Over the 2009 to 2014 period, development studies, in vivo and in vitro studies, full range of certification tests and clinical testing of the Sputnik VAD were conducted in Russia [11]. Results, gained during studies, and successful practices of system clinical usage is a good basis for additional studies in the VAD field.

Currently, in MIET researches of a flow sensor integration into a VAD being conducted to provide an adaptive control of the system operation based on the physiological human needs. Mathematical simulation of a cardiovascular

system, considering a VAD implantation, is performed to examine the pump control task [12]. Also, studies were conducted with the objective of ensuring wireless transcutaneous energy transfer for VAD [13].

Acknowledgments

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