Effect of thrombus formation on heat emission in Sputnik RBP

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Introduction

End-stage heart failure (HF) is a major cause of mortality, morbidity and disability worldwide. Nowadays, a surgical and medical treatment of HF has a positive trend. But heart transplantation remains an optimal treatment of end-stage HF. A shortage of donor organs has made this therapy available only for limited number of patients (1). This problem required a development of ventricular assist devices (VADs) for critically ilium patients. The first devices had large dimension, but by the aid of engineering and technology developers have the opportunity to reduce the dimensions of VADs (2, 3). This feature allows the use of VADs for treatment of patients with small body surface area. However, the miniaturization of pump components may lead to a high hemolysis level (4, 5). Thrombus formation remains a serious problem of axial and centrifugal ventricular assist devices (6-8).

A typical construction of axial VAD consists of a flow straightener, an inlet bearing, an impeller, an outlet bearing and a diffuser in series, and a stator (9, 10). Mechanical friction between the pump components in such devices is accompanied by heat generation, which depends on the pump design (11).

Conversion of electrical energy to thermal energy is inherent for any motor under normal operation mode (12). Heat dissipation occurs due to thermal emissions from pump housing and heat transmission of blood moving through a device. Herewith excessive heat generation can adversely affect the blood hemolysis level and the protein denaturation increasing the probability of thrombus formation (13). As a result the pump failure probability increases. This problem can be solved only by emergency surgery with full replacement of implanted VAD (14, 15).

Currently, the influence of thrombosis on a rotary blood pump heat generation is not fully investigated. Therefore, in vitro tests were conducted in hydraulic closed loop using the rotary blood pump of the Sputnik VAD to determine the nature of heat generation for different conditions which are typical for implantable systems. Since 2012 the Sputnik VAD successfully used to replace of left ventricular function for patients with HF. This VAD is the axial and continuous flow pump.

Materials and Methods

The Sputnik VAD construction is comprised of movable element (impeller) and stationary elements (flow straightener, diffuser, inlet and outlet bearings). An electrical motor allows you to rotate the pump at a speed from 5000 to 10000 rpm, providing a flow of up to 10 L/min (16). Sputnik VAD produces necessary head pressure-flow rate (H-Q) curves (17). This blood pump has a length of 82 mm, outside full diameter of 34 mm and weight of 246 g.

Experiments to compare the influence of thrombus formation on the VAD heat generation was carried out under following conditions: non-thrombosis, inlet (flow straightener) thrombosis, outlet (diffuser) thrombosis. The platinum-based silicone Ecoflex 00-10 (Smooth-On, USA) was used as a material for simulation of thrombus formation. For thrombus formation manufacture silicone components A and B was mixing in equal amounts. Degasing of resulting compound was conducted in vacuum chamber during 10 minutes. Further the silicone was applied on inner surface of flow straightener and diffuser. By hot air gun at 200 °C silicone instantly fixed. After complete polymerization the Ecoflex silicone is a very soft, durable and stretchable material without tacky surface. Thrombus with a volume of 0.5 cc was used in tests. Figure 1 shows an artificial clot in the diffuser (A, B) and flow straightener (C, D) before and after the tests. In total 27 hours of tests were performed for each thrombus formation.

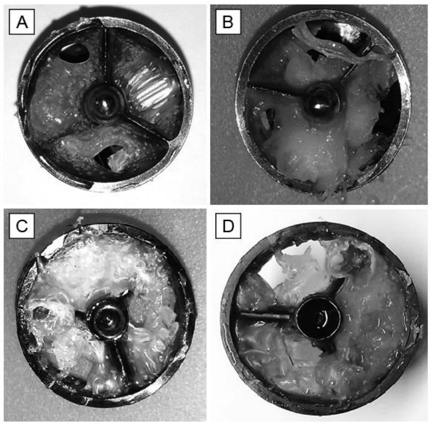

Figure 1: Image of the diffuser (A, B) and flow straightener (C, D) thrombosis at the beginning (A, C) and at the end of all tests (B, D).

The experiments were conducted on a special test bench, which consists of a hydraulic loop, temperature measuring and recording devices (infrared camera and thermocouple unit) and control units including pump controller, power source and personal computer. The pump body during the tests was placed inside a viscoelastic silicone cover with a volume of 1400 cc, which properties are similar to the soft tissues properties (18). Pump location inside the cover limits the heat dissipation into environment during the tests.

Temperature change of the Sputnik VAD body surface was measured by thermocouple-thermometer TPI 343 (TPI, USA). The data was recorded every 2 minutes. Temperature sensors were fixed tightly for more accurate recording of the pump surface temperature: one sensor – on the pump body at the stator location, and another sensor – at the pump outlet. This location of sensors allowed recording the heat emission level during stator operation and the temperature change at the pump outlet.

As an additional device for temperature change measurement a thermal imaging camera THT-47 (HT Italia, Italy) was used. This infrared camera is designed for rapid detection of heat map emitted by the test unit. THT Link software was used to analyze the obtained data.

Different test fluids were used to analyze viscosity influence on the pump heating. On the initial test stage distilled water with dynamic viscosity of 0.00085 Pa·s at 23 °C was taken. Aqueous glycerol solution (dynamic viscosity of 0.003 Pa·s at 23 °C) was used as fluid with blood viscosity. The test fluid volume in hydraulic loop was 6150 cc. On the second test stage test fluid was heated up to 37 °C during 90 minutes in a special bath by a heat regulator. Constant bath temperature was maintained for the duration of the experiment. Aqueous glycerol solution with dynamic viscosity of 0.006 Pa·s at 23 °C was used. It is noted that viscosity of fluid being heated decreases. Thus, aqueous glycerol solution with dynamic viscosity of 0.006 Pa·s at 23 °C after heating to 37 °C has viscosity equal to blood viscosity (19).

The experiments by test bench were carried out for each system configuration separately. Differences consist in four parameters: the pump speed (5000, 7000 and 9000 rpm), the viscosity of test fluid (distilled water or aqueous glycerol solution), the presence or absence thrombosis and its location and the test fluid temperature (room temperature – 23 °C or body temperature – 37°C). When using the aqueous glycerol solution with dynamic viscosity of 0.003 Pa·s at 23 °C, diffuser thrombosis and test fluid heating to body temperature the system configuration is «blood viscosity, outlet thrombosis, 37 °C».

Results

Experiments without heating the test fluid

The thermal map of the Sputnik VAD surface was obtained by infrared camera with aqueous glycerol solution with dynamic viscosity of 0.003 Pa·s as test fluid, pump reference speed of 5000 rpm and non-thrombosis (Fig. 2A). Figure shows areas with high temperature corresponding to the stator area. Also the output bearing was slightly heated in compare to the input bearing. There was no zone of excessive heat generation at the flow straightener area. Heat map of the pump surface is shown in Figure 2B for the pump inlet thrombosis case. The maximum temperature of the pump surface was located in the area between the inlet bearing and stator and amounted to 25.8 °C. In this case the heat emission level at the pump inlet is higher compared to the pump outlet. This pattern is caused by thrombus location on the flow straightener. It should be noted the difference of the pump surface heat map in absence and presence of thrombus formation: hot spots in Figure 2A are shifted to the left (the pump inlet), whereas hot spots in Figure 2B are located at the pump center. Heat map obtained in the experiments with diffuser thrombosis is shown in Figure 2C. The minimum temperature of the pump surface was 24.1 °C, maximum temperature was achieved at the diffuser area and equal to 29.1 °C. In addition, there is a driveline cable connection in this pump body area, which emits a small amount of heat during pump operation.

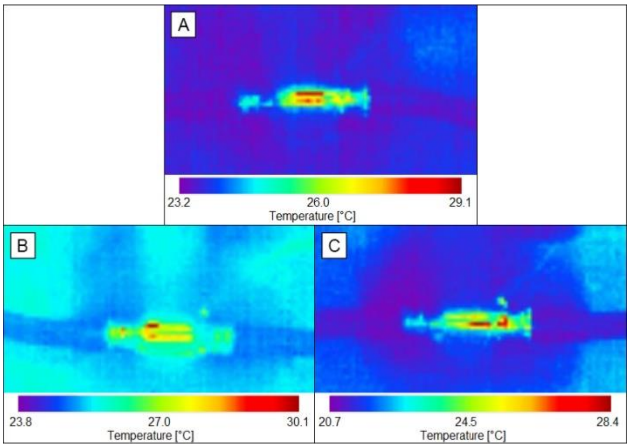

Figure 2: Thermal map of the Sputnik VAD surface at speed of 5000 rpm, using test fluid with blood viscosity and different thrombus clamping; where A – non-thrombosis, B – inlet thrombosis, C – outlet thrombosis.

For the same system configuration a temperature increase at the stator area surface and at the pump outlet measured using thermocouple sensors was equal to 0.7 °C for non-thrombosis, 1.2 °C for the inlet thrombosis and 1 °C for the outlet thrombosis. Consequently, for 5000 rpm the influence of the stator thermal energy to the total pump heat generation is minimized. Temperature change curves increase gradually, without spikes during 50 minutes, and then curves change to linearity range with a constant temperature value.

The temperature distribution obtained along the pump axis for reference speed of 9000 rpm is shown in Figure 3. For clarity the location of main pump components relative to coordinate origin is shown by vertical lines and numbers. Nature of the distribution is similar to the same data at the pump speed of 5000 and 7000 rpm. The differences are in maximum and average temperature values. For non-thrombosis case measured maximum temperature value of 26.7 °C is in the stator area. Conversion of stator electrical energy to thermal energy had a major influence on the total heat map of the pump. For inlet thrombosis case maximum temperature value was located in the area between the inlet bearing and stator, moreover characteristic temperature rise is observed before the thrombus, which is accompanied by a further sharp drop of measured temperature value. For outlet thrombosis case maximum temperature value of 27.9 °C was located in the thrombosis area. The temperature average at 9000 rpm for non-thrombosis system configuration was 24.4 °C, for inlet thrombosis – 24.6 °C and for outlet thrombosis – 24.5 °C.

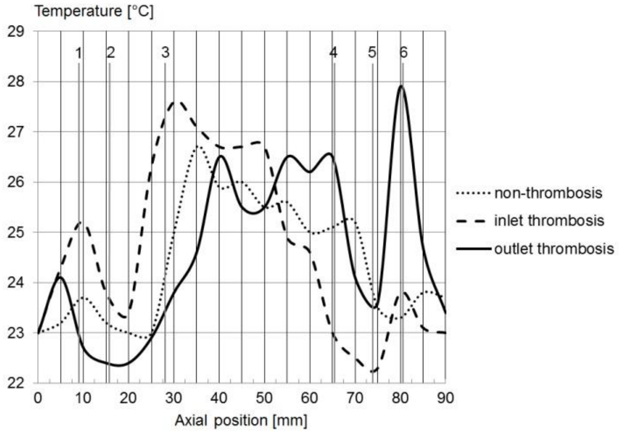

Figure 3: Temperature distribution along the pump axis for 9000 rpm, using test fluid with blood viscosity and different thrombus clamping; where 1-2 – flow straightener zone, 2-5 – impeller zone, 3-4 – motor zone, 5-6 – diffuser zone.

Curves obtained by thermocouple at 9000 rpm have different shape: temperature change curves of the stator area at the test start are compact and linearly increases with time, but the outlet temperature curves have a sharp discontinuity of temperature at the test start. At the reference pump speed of 9000 rpm maximum outlet temperature was higher than the stator temperature. Therefore, test fluid temperature was higher than the stator area surface temperature. As a result, electric stator energy is converted to thermal energy and contributes to heating of the test fluid.

Experiments with heating the test fluid

To determine the pump heat generation nature at human body temperature the test fluid was heated to 37 °C. After changing a single parameter of system configuration each subsequent experiment was started only after test fluid and pump body cooling to room temperature followed by heating to 37 °C. The pump outlet temperature change obtained by thermocouple is shown in Figure 4. The minimal temperature increase was 1.6 °C for «distilled water, outlet thrombosis, room temperature» configuration, maximum temperature increase was 5.1 °C for «blood viscosity, non-thrombosis, room temperature» configuration. Temperature increase is typical for all curves in the first 40-50 minutes of testing, further growth was slowing down and curves moved to flat area with a constant temperature spans.

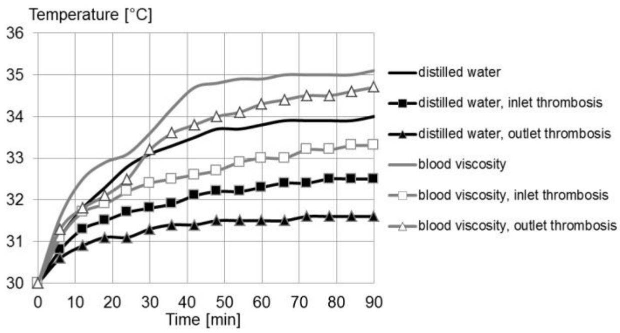

Figure 4: Temperature change curves at the pump outlet for different system configuration at the pump speed of 7000 rpm.

Temperature distribution curves for various reference speeds and thrombus presence at the inlet part of the pump are shown in Figure 5. The curves have a similar structure: temperature decreases first and then increases, reaching a maximum value in zone 1-2; in the stator area there is a decline up to diffuser reaching a minimum value; in zones 5-6 curves sharply increase and converge on the same parallel at 80 mm point; outlet temperature falls again. By reference to previously results it can be inferred that zone with maximum temperature includes a thrombus formation.

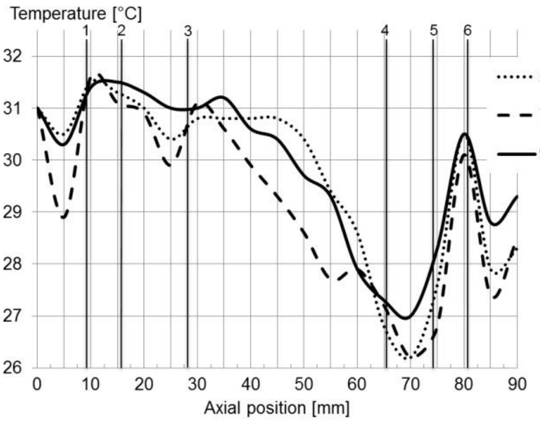

Figure 5: Temperature distribution along the pump axis for inlet thrombosis, using test fluid with blood viscosity and at different pump speeds; where 1-2 – flow straightener zone, 2-5 – impeller zone, 3-4 – motor zone, 5-6 – diffuser zone.

Conclusion and discussion

To determine relationship between the Sputnik VAD thrombosis and the pump heat generation numerous and continuous tests were conducted at in vitro bench. Temperature of the pump surface was increased in all trials regardless of reference pump speed, test fluid viscosity or thrombosis presence. At 5000 rpm conversion of stator electric energy to thermal energy provides the main contribution to the total pump heat emission. Whereas at

7000 and 9000 rpm pump surface temperature value depends more on pump rotational speed and test fluid viscosity. Results obtained at room temperature with great probability allow determining the presence and location of thrombosis. Pump surface areas with high temperature corresponded to thrombus presence in this pump part.

When the test fluid is heated up to human body temperature, identification of thrombus formation by visual analysis of heat map is complicated. This problem is associated with excessive test fluid heating and, therefore, elastic tubes surface heating. Temperature distribution curves along the pump axis were constructed to solve this task. Sites of pump, in which maximum temperature was measured, corresponds to thrombosis areas.

Data obtained on the laboratory bench gives an insight into the nature of released pump heat. However, a living organism is a very complex structure with many nuances. Therefore, understanding of human body heat transfer will allow developing a precise experimental model that will make possible obtaining accurate data of interaction with VAD. Most likely the overall blood temperature of the human organism does not increase during the VAD operation. But short-term or localized heat emission inside the pump with blood moving through it may cause thrombosis. In this case temperature value is the most important parameter. There is an increase of hemolysis rate consequently resulting to thrombus formation and potential death of patient already at the temperature of 40 °C (20). In spite of numerous studies on pump thrombosis detection (21), main causes and possible solutions (21), this problem remains important in the development of ventricular assist devices. Furthermore, study of the thrombosis problem is extremely important in implantation of tissue engineering structures based on carbon nanotubes in the area of defects in heart tissues and blood vessels.

Understanding of the pump heat generation will allow improving the design of axial and centrifugal VADs and reducing the probability of thrombosis.

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