Acta Scientific MEDICAL SCIENCES (ISSN: 2582-0931)

Volume 9 Issue 10 October 2025

Research Article

Various Types of Coating of the Mechanical Circulation Support Pump Impact on Hemolytic and Homeostatic Blood Parameters

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DOI: 10.31080/ASMS.2025.09.2156

Received: February 17, 2025

Published: September 11, 2025

Abstract

Mechanical circulatory support can lead to hemolysis, thrombosis, bleeding, and other complications. The aim of the study was to determine the degree of influence of various types of coating of the disk pump for mechanical circulatory support on hemolytic blood parameters.

Materials and Methods: *In vitro* studies were conducted on a specialized device that simulated a large circle of blood circulation. Human donated blood was used for the study.

Results and Discussion: It was found that using an uncoated and diamond-coated disc pump, an increase in the level of FreeHb in blood plasma was noted from a baseline value of 0.01 g/l to 0.12 g/l and from 0.02 to 0.09 g/l, respectively. In studies, where a disk pump with a surface treated by electron beam with a silicon-carbon coated was used, the concentration of FreeHb in blood plasma remained at the background level.

Conclusion: It is shown that a disk pump with a surface treated by electron beam with a silicon-carbon coated caused the smallest changes of the studied blood parameters.

Keywords: Disc Pump; Coating; FreeHb; Hemolysis

Introduction

Left ventricular bypass mechanical circulatory support (MCS) devices have been effectively used for the treatment of end-stage chronic heart failure over the past three decades [1-5].

A key element of the left ventricular bypass (LVB) MCS apparatus is a pump that connects to the left ventricle of the heart and the descending or ascending aorta of a patient suffering from chronic heart failure (CHF) [6]. MCS devices also include hardware and software systems that provide control of the heart pump [7].

At the same time, one of the main problems of therapy with MCS is the degree of its effect on the patient's body. Thus, relatively long-term such therapy causes a number of complications: hemolysis, thromboembolic complications, and bleeding, which in turn cause functional disorders in many organs and body systems [1,3].

An important factor influencing hemolysis and the rate of thrombosis is the surface coating of the inner walls of the pump [8]. However, in the available literature, we have not found any works devoted to the study of the role of the pump wall surface in maintaining the homeostatic and hemolytic parameters of the pumped blood.

These questions served as the basis for the present work.

Research Methods

An *in vitro* study was performed in which the effect of a titanium disc pump without a coating, with a diamond-like coating and with a silicon-carbon coating of the inner surface (a-C:H:SiOx) on hemolytic and homeostatic parameters of the blood system (n = 6) was studied, the study was conducted on a specialized set simulating a large circulatory system (Figure 1). Fresh human donor blood was used for the study (storage did not exceed 24 hours).

Figure 1: General view of the stand for studying the effect of a disk-type circulatory aid device on the parameters of donated blood. Symbols: 1 - blood tank; 2 - Tygon tubes; 3 - Biosoft-M device for pressure measurement; 4 - software on a laptop; 5 - flow meter; 6 - heat exchanger; 7 - screw clamp; 8 - disc pump.

The set consisted of several key parts: an elastic reservoir (1) capable of holding up to one liter of liquid designed to simulate blood; connecting tubes made of Tygon material (2) and a device for regulating the temperature of the liquid, which was installed in the middle of the flow of incoming and outgoing liquid (6). In order to remove air bubbles in the system, the pump was started from with a speed of 500 rpm. Next, half of the Ringer's solution (250 ml) was drained and 450 ml of donor blood was added to the system. The device operated at 2000-2500 rpm with a capacity of 5 ± 0.5 liters/min. In order to create hydraulic resistance, a screw clamp was used for metered compression of the discharge line (7). The disc pump (8) operated in a constant flow mode. The temperature was maintained at 37 °C using a heat exchanger (6).

Before each experiment, a background blood sample (sample zero) was taken to determine the baseline level of controlled blood parameters.

After the pump was connected, blood samples were taken every 30 minutes for 4 hours.

A modified hemolysis index (MIH) and a normalized hemolysis index (NIH) were used to accurately determine the hemolytic effect of the pump.

$$MIH = \Delta freeHb * V * \frac{100 - Ht}{100} * \frac{10^6}{Q * T * Hb}, where:$$

MIH is customary to calculate according to the formula [9]:

Hb - the total concentration of hemoglobin in the blood at time zero (mg/l).

Δ free Hb - an increase in the level of free plasma hemoglobin (mg/l) during the sampling time interval; V - the volume of the contour (l); Q - the flow rate (l/min); Ht - the hematocrit (%); T - the sampling time interval (min).

In most works, the following formula is used in NIH calculations [10]:

$$NIH\left(\frac{mg}{100L}\right) = \Delta freeHb * V * \frac{100 - Ht}{100} * \frac{100}{Q * T}$$

The following blood system parameters were determined: concentrations of bilirubin (ctBil), lactate (cLac), hematocrit (Hct), lactate dehydrogenase (LDH, L-lactate), hydrogen index (pH), free hemoglobin (FreeHb), as well as concentrations of electrolytes of potassium (K^+), calcium (Ca^{2+}), sodium (Na^+) and chlorine (Cl^-).

Results

On an set simulating a large circle of blood circulation (I), 3 variants of experiments were conducted, the duration of which in each variant was 240 minutes.

In the first variant, a titanium MCS disc pump without a special biocompatible coating was used; in the second variant, a titanium MCS disc pump with a diamond-like coating was used; and in the third, an MCS disc pump with a silicon-carbon film coating (a-C:H:SiOx). In these studies, the disc pump operated at 2500 rpm with a capacity of 5 ± 0.5 liters/min.

The results of studies of the effect of coating on blood parameters are presented in Table 1. As can be seen, when using a disc pump with an unpolished and uncoated surface (A) and with a surface after manual grinding with a diamond-like coating (B), after 4 hours of operation, there was a significant increase in the level of free hemoglobin in blood plasma. This is typical for enhancing the hemolysis process. The remaining plasma parameters of the donated blood remained virtually unchanged.

Parameter	Disc pump without surface grinding and coating A		Disc pump with surface after manual grinding with applied diamond-like coating B		Disc pump with an electron beam-treated surface with a-C:H:SiOx coating C	
	Of	After	Of	After	Of	After
Hematocrit, Hct, %	23,1 ± 0,3	22,9 ± 0,6	24,4 ± 1,2	24,1 ± 1,1	23,5 ± 1,0	23,4 ± 1,1
Hemoglobin, ctHb, g/L	74,0 ± 0,5	73,6 ± 1,5	76,0 ± 1,0	76,0 ± 1,1	74,1 ± 4,0	74,1 ± 0,6
The level of free hemoglobin, FreeHb, g/L	0,01 ± 0,01	0,12 ± 0,04*	0,02 ± 0,01	0,09 ± 0,02*	0,03 ± 0,01	0,03 ± 0,01
Bilirubin, ctBil, mM/L	9,0 ± 1,2	9,1 ± 1,4	7,1 ± 0,1	8,7 ± 1,5	8,0 ± 2,0	8,3 ± 0,6
Lactate, cLac, mM/L	1,6 ± 0,1	1,9 ± 0,3	0,9 ± 0,1	1,0 ± 0,1	1,2 ± 0,7	1,5 ± 0,3
Potassium, K^+, mM/L	2,0 ± 0,1	2,1 ± 0,3	1,3 ± 0,2	1,3 ± 0,1	2,2 ± 0,9	2,2 ± 0,1
Sodium, Na^+, mM/L	150 ± 1,2	149 ± 1,4	151 ± 1,5	152 ± 1,8	150 ± 0,4	150 ± 0,6
Chlorine, Cl^-, mM/L	123 ± 0,6	123 ± 1,3	117 ± 1,2	118 ± 1,6	123 ± 0,5	123 ± 0,1
pH	7,0 ± 0,06	6,9 ± 0,1	7,0 ± 0,06	7,0 ± 0,1	7,0 ± 0,06	7,0 ± 0,1

Table 1: The effect of a titanium disc pump with a different coating on the parameters of the blood system *in vitro* (M ± m).

Note: * - here and further: significant differences from 0 samples before connecting the pump.

The results of testing a disk pump with an electron beam treated with a silicon-carbon film coating were the best (C), since the concentration of free hemoglobin in the blood, like other studied parameters, remained at the background level.

When studying platelet adhesion on the surface of the samples, discs coated with a-C:H:SiOx and discs without such a coating were compared. When scanning the surface of the discs using electron microscopy (Mira3 from Tescan) and counting the number of platelets using the standard method using 20 randomly selected fields of vision, it turned out that platelets form a continuous layer on the surface of the disc pump without treatment, forming clusters in areas with pronounced roughness (Figure 2a), whereas on the surface of the modified disc pump, after electron beam treatment and deposition of a-C:H:SiOx films, there are separate thrombocytes with clear circular contours that practically do not form clusters (Figure 2b). This indicates an extremely low thrombogenic activity of such a surface.

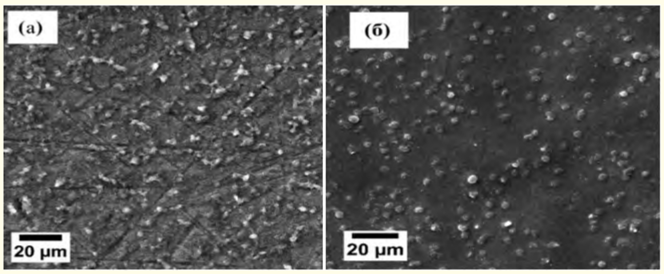

Figure 2: Images of the surface using scanning electron microscopy after the platelet adhesion test, where: (a) is an unmodified surface of a titanium prototype, (b) is a titanium prototype modified by electron beam processing and application of a-C:H:SiOx films.

Thus, the treatment of the sample surface by the electron beam method followed by the application of a-C:H:SiOx coating leads to its structural improvement, which contributes to the preservation of hemolytic and homeostatic blood parameters without significant disorders and the acquisition of antithrombotic properties.

To study the dynamics of hemolytic and homeostatic blood parameters, *in vitro* experiments were conducted with prolonged use of a disk pump, the surface of which was treated with an electron beam coated with silicon-carbon film coating in an operating mode of 2500 rpm (Table 2).

In bench experiments, it was found that the tendency to a slight increase in the level of FreeHb in the plasma of donated blood began at 150 minutes of pump operation, although these changes were unreliable, and within 4 hours the free hemoglobin index did not exceed the level of 0.04 g/l. In parallel with the trend towards an increase in FreeHb, there was a slight unreliable increase in the concentration of ctBil from a baseline value of 7.5 ± 1.1 to 8.6 ± 0.9 mmol/l and cLac from 1.6 ± 0.2 to 2.0 ± 0.2 mmol/l, respectively.

The concentrations of Na^+ and Cl^- did not change during the entire experiment, and the concentration of K^+ from the 150th minute, in parallel with an increase in the level of free hemoglobin, began to increase, but within the reference values. And only from the 180th minute. there was a significant increase in the concentration of potassium in plasma. These data indicated the occurrence of partial hemolysis with the release of potassium from destroyed erythrocytes into plasma.

Thus, the use of a disc pump with a-C:H:SiOx coating at a rotor rotation speed of 2500 rpm in the experiment on the stand did not cause significant violations of blood parameters for 4 hours.

Parameter	**Blood sample (minutes)**								
	0 (0)	**1 (30)**	**2 (60)**	**3 (90)**	**4 (120)**	**5 (150)**	**6 (180)**	**7 (210)**	**8 (240)**
Hematocrit, Hct, %	24,3 ± 2,1	24,1 ± 1,9	24,1 ± 1,9	24 ± 2,1	24,2 ± 2,1	24,2 ± 2,1	24,2 ± 2,1	24,3 ± 2,1	24,3 ± 2,1
Hemoglobin, ctHb, g/L	76,1 ± 7,1	75,5 ± 6,6	75,5 ± 6,6	75 ± 7,2	75,3 ± 7,1	75,8 ± 7,2	75,5 ± 7,2	75,3 ± 7,1	75,5 ± 6,9
The level of free hemoglobin, FreeHb, g/L	0,03 ± 0,01	0,02 ± 0,01	0,03 ± 0,01	0,03 ± 0,01	0,03 ± 0,01	0,04 ± 0,01	0,03 ± 0,01	0,04 ± 0,01	0,04 ± 0,01
Bilirubin, ctBil, mM/L	7,5 ± 1,1	7,3 ± 1,2	7,8 ± 0,9	6,1 ± 0,9	8,0 ± 1,1	8,1 ± 1,1	6,8 ± 0,9	8,5 ± 1,1	8,6 ± 0,9
Lactate, cLac, mM/L	1,6 ± 0,2	1,6 ± 0,2	1,6 ± 0,2	1,5 ± 0,2	1,5 ± 0,2	1,9 ± 0,2	1,9 ± 0,3	2,0 ± 0,2	2,0 ± 0,1
Potassium, K^+, mM/L	2,1 ± 0,3	2,0 ± 0,3	2,0 ± 0,3	2,2 ± 0,3	2,6 ± 0,1	3,0 ± 0,4	3,3 ± 0,1*	3,9 ± 0,1*	4,2 ± 0,1*

Sodium, Na^+, mM/L	149,8 ± 0,8	149,5 ± 0,6	149,3 ± 0,8	149,1 ± 0,6	149,1 ± 0,6	149,8 ± 0,4	150,8 ± 1,4	151 ± 1,4	150,8 ± 1,4
Chlorine, Cl^-, mM/L	116,1 ± 2,9	116,1 ± 2,5	116,5 ± 2,5	116,3 ± 2,5	117 ± 2,7	116,6 ± 2,7	116,5 ± 2,9	116,1 ± 2,7	116,1 ± 1,1
pH	7 ± 0,01	7 ± 0,03	7 ± 0,01	7 ± 0,02	7 ± 0,01	7 ± 0,01	7 ± 0,02	7 ± 0,02	7 ± 0,02

Table 2: Blood system parameters during the examination of the disk-type auxiliary circulation pump on the stand for 4 hours.

Discussion and Conclusion

Damage to the erythrocyte membrane is affected by the threshold potential, at which the erythrocyte membrane collapses, and the exposure time. It is believed that the peak potential of shear stress in the blood flow is at around 120 Pa [11], beyond this boundary, the erythrocyte membrane collapses. G. Wright's study claims that red blood cells are very resistant to many forces, with the exception of shear stress [12].

In addition to the threshold potential, damage to the erythrocyte membrane is affected by the time of exposure to a physical factor. In many cases, the time of exposure of a physical factor to the blood system can be tracked only in a delayed period, for example, several months after the implantation of the pump.

In the studies of Ravichandran A.K., out of 100 patients with an implanted pump, 18 had hemolysis, increased LDH and bilirubin levels a year after implantation, which was accompanied by a significant increase in mortality [13]. It is likely that the study of the content of bilirubin, LDH, free hemoglobin and the number of red blood cells in the blood when using MPC pumps in experiments requires a longer follow-up - 15-30 days.

The collected data allow us to conclude that with short-term use, the MPC disc pump does not significantly affect the red blood system and can be used for short-term extracorporeal connections. One of the indicators of the degree of hemolysis is the normalized (NIH) and modified (MIH) hemolysis indices. In a study by Dmitrieva., *et al*. the NIH was 0.005738, and the MIH was 0.573773, which was considered the norm [14]. According to Bourque, MIH is equal to 2.1, 3.5 and 2.3, which was also considered the norm [15]. The NIH value in Nakazawa's analysis was 0.0028 [9].

Based on the data obtained, the range of hemolysis indices in our experiments for NIH ranged from 0.0028 to 0.005738; for MIH, from 0.573773 to 3.5, which is lower than in the cited studies.

Thus, a disc pump with an electron beam treated with a silicon-carbon coating caused the least disturbances in the hemolytic and homeostatic parameters of the blood under study.

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