DOI: 10.15825/1995-1191-2024-4-133-139

DEVELOPMENT OF AN EXTRACORPOREAL PUMP FOR ECMO SYSTEMS

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Objective: today, extracorporeal membrane oxygenation (ECMO) systems remain the main type of short-term circulatory support in various clinical situations. One of the main elements of this system is a blood pump. The objective of this study is to develop the first domestic centrifugal pump for use in ECMO systems. **Materials and methods.** Based on a systematic literature review, the main medical and technical requirements for an extracorporeal centrifugal pump were formulated. To create 3D mathematical models of the outer casing of the pump and all its internal components, calculations were performed in CAD software package SolidWorks (SolidWorks Corp., USA). Hydrodynamic test benches were designed and developed to evaluate the performance of the centrifugal pump mockup. The pump was studied to obtain its head-capacity curve (HCC) and hemolytic characteristics. **Results.** 3D modeling of geometrical parameters of the pump flow impeller was performed. Fluid flow was assessed in the rotor rotation range at speeds from 3000 to 7000 rpm. Hydrodynamic bench tests were performed under conditions simulating the resistance of the oxygenator and connecting cannulas. The HCC was obtained based on the given medical and technical requirements for the operating flow range from 1 to 5 l/min at pressure drops of 200 to 400 mm Hg. **Conclusion.** Based on results from the 3D modeling and bench experiments, a model of extracorporeal centrifugal pump was obtained, which showed its efficiency during the first trials. Further experimental studies will be conducted to obtain the energy and biological characteristics of the developed device.

Keywords: 3D computer model, centrifugal pump, extracorporeal pump, head-capacity curve, hemolysis, ECMO.

INTRODUCTION

Recent advancements in technology have led to significant improvements in extracorporeal membrane oxygenation (ECMO) systems, which have become essential in the management of patients with pulmonary, cardiac, and cardiopulmonary insufficiency. These systems have become more efficient, compact, and even portable [1–2].

The centrifugal pump (CP) is a key component of the extracorporeal circuit in ECMO systems.

It plays a crucial role in maintaining hemodynamic stability by compensating for circulatory failure or partially replacing the heart's pumping function.

Additionally, the CP ensures blood flow through the membrane oxygenator, enabling oxygenation and the removal of carbon dioxide, thus substituting pulmonary function.

The increase in ECMO procedures performed in intensive care units (ICUs) and cardiac resuscitation units over the years has resulted in improved survival rates for critically ill patients.

The development and integration of a Russian-made CP into these systems will further enhance the quality and accessibility of high-tech medical services.

MATERIALS AND METHODS

An analytical review of bibliographic sources on the development of extracorporeal pumps for ECMO systems highlights the following key medical and technical requirements for the CP:

– Body length: up to 80 mm;
– Maximum external diameter: 50 mm;
– Impeller diameter: up to 30 mm;
– Weight: up to 50 g.

The developed pump incorporates a built-in long cylindrical electric motor [3].

The new CP is seated and magnetically coupled, ensuring unobstructed motor operation. The pump head is securely fixed to the motor, with an annular flow section designed to adequately cool the motor under various operating conditions.

The device being developed is a flask-shaped structure that contains an 8-bladed closed impeller mounted on a hinged support. The impeller, with a diameter nearly equal to that of the motor, is positioned between the pump inlet and the motor housing. Centrifugal pumps designed for artificial circulation typically feature impellers with relatively large diameters, around 50 mm

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(e.g., Rotaflow, Maquet, Germany), which allows for pumping blood at low rotational speeds. According to preliminary calculations, the pump head must provide sufficient peripheral speed for an impeller of approximately 30 mm in diameter.

However, this speed could potentially be excessive, increasing shear stress on erythrocytes. The resulting tangential stress in the blood flow layer and the stress proportional to the velocity gradient from erythrocyte momentum exchange may lead to complications [4]. Thus, one of the key areas requiring further development is the detailed calculation of the impeller design, with a focus on minimizing rotor speed.

3D modeling methods

The SolidWorks program (Dassault Systèmes, France) was used to create a 3D model of the CP. Through computer flow simulation, a theoretical head-capacity curve (HCC) was developed to analyze the pump model. A review of literature on computer modeling of pump flow revealed that the key focus lies in constructing an accurate computational mesh and selecting an appropriate turbulence model. Inaccuracies in turbulence modeling can lead to significant errors in calculations [5, 6].

To achieve more accurate characteristics, software methods were employed to calculate flow hydrodynamics within the pump cavities. The primary simulation parameters involved stress analysis and flow velocity estimation, aiming to minimize stagnation and recirculation zones. Theoretical data derived from simulations were then compared with actual results obtained from the pump mock-up on a hydrodynamic bench. This bench simulated the conditions of the ECMO procedure using the LivaNova oxygenator (INSPIRE, USA). The operating characteristics of the RotaFlow centrifugal pump, which is widely used in medical practice [7], were considered when selecting the most appropriate pump operating parameters for the mode.

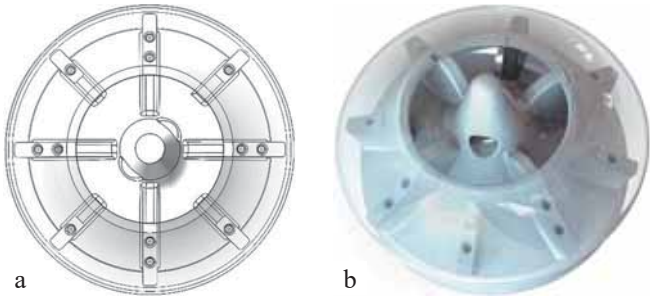


Fig. 1. a, modification of the 8-blade impeller structure; b, 3D model of the impeller

Developed design of the centrifugal pump impeller

The impeller features a configuration of 4 primary radial vanes, with four additional intermediate vanes positioned between them. These intermediate vanes mirror the shape of the primary vanes but are only half their length. Both the inlet and outlet angles of the blades are oriented perpendicular to the axis. Adjustments to the blade twist angles did not yield notable improvements in hydrodynamic performance and introduced unnecessary complexity to the manufacturing process. The final 8-blade impeller configuration is illustrated in Fig. 1, a, with the corresponding 3D computational model shown in Fig. 1, b.

The proposed CP design includes four inlet channels leading to the impeller, each subdivided by short guide blades. The cross-sectional areas at the inlet and outlet of the impeller flow path are proportionate, and the streamlined channel geometry enables unobstructed fluid transfer. The exponential contour of the duct promotes laminar flow within the pump and ensures optimal alignment with the pump casing.

At the swivel support level, the impeller is equipped with perforations that facilitate flushing of the pump. This design feature effectively reduces thrombogenicity without causing any measurable decline in hydraulic performance.

Computational fluid dynamics

In addition to experimental evaluation, the pump design was analyzed using computational fluid dynamics with SolidWorks (Dassault Systèmes, France) and Ansys (ANSYS Inc., USA) software. A computational mesh comprising approximately 220,000 elements was generated to represent the entire flow domain. For the simulations, blood was modeled as a Newtonian fluid with a dynamic viscosity of 5.0 mPa·s and a density of 1055 kg/m^3. Representative results are shown in Fig. 2, illustrating the pressure distribution and flow streamlines within the pump.

The computed HCC was obtained and is presented alongside experimental results to facilitate comparison with bench test data from the pump's operation in a closed-loop circulation circuit.

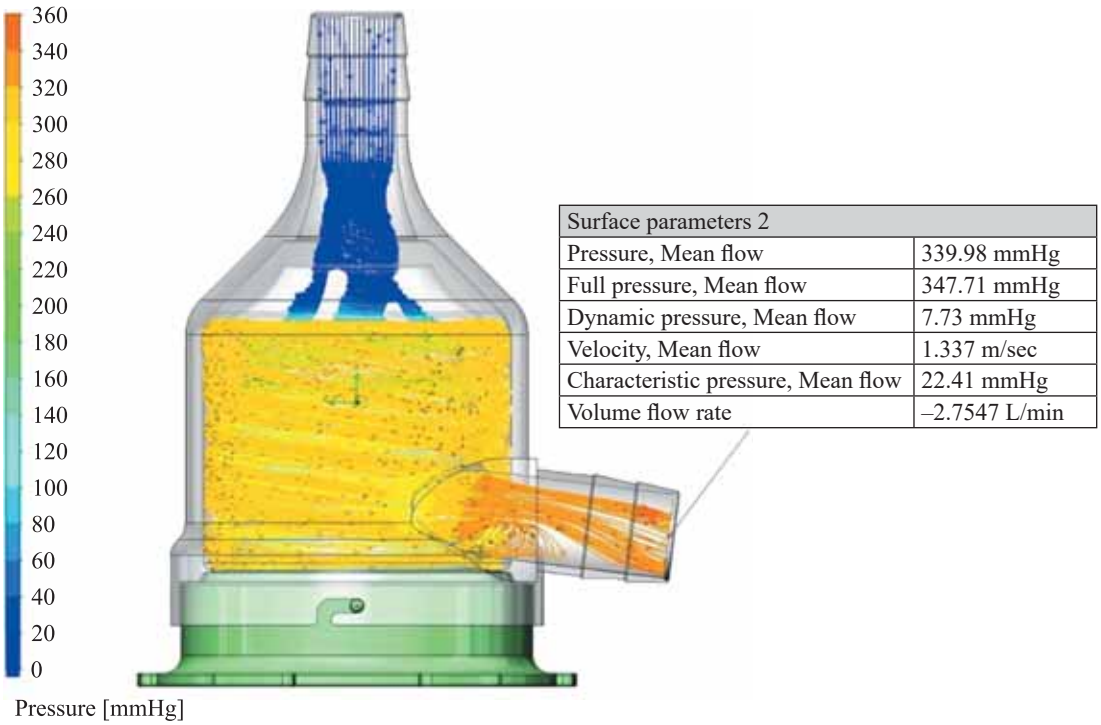
Computational and mathematical analyses revealed a slight reduction in impeller efficiency, estimated at 5–7%, primarily due to the presence of recirculating flow and the resulting hydrodynamic losses. Numerical simulations indicated elevated flow velocity on the rear side of the impeller and within the orifices. Recirculation through these orifices ranged from 0.3 to 1.0 L/min per orifice, depending on rotational speed and differential pressure.

The total internal volume of the pump was 16 mL. Flow transitions remained smooth throughout the helical outlet region. Under ECMO operating conditions (pressure of 350 mmHg and flow rate of 5 L/min), peak tangential shear stress was 125 Pa, while average shear stress was approximately 40 Pa.

Prototype centrifugal pump

Based on preliminary computer simulations, a three-dimensional model of the centrifugal pump (CP) was developed, as shown in Fig. 3, a. Using this model, the prototype components were fabricated with a large-format medical 3D printer, the Formlabs 3BL (USA). The parts were produced via stereolithography (SLA), a laser-based 3D printing technology, using Gorky Liquid (Surgical) – a biocompatible, sterilizable surgical photopolymer – with a printing precision of 25 μm. The rotor features a working section mounted on a disk supported by a ball bearing, which also houses a magnet for the drive mechanism. The fully assembled prototype pump, prepared for bench testing, is depicted in Fig. 3, b.

The assembly includes a 4-pole magnet paired with a closure ring made from Steel 10, as well as a custom-fabricated support ball composed of durable aluminum oxide (Al_2O_3), also known as corundum or alundum. The CP housing features an outlet fitting with an internal diameter of 3/8 inch. The impeller is rotated externally via a magnetic coupling mechanism.



Surface parameters 2	
Pressure, Mean flow	339.98 mmHg
Full pressure, Mean flow	347.71 mmHg
Dynamic pressure, Mean flow	7.73 mmHg
Velocity, Mean flow	1.337 m/sec
Characteristic pressure, Mean flow	22.41 mmHg
Volume flow rate	–2.7547 L/min

Fig. 2. Particle trajectories at 7000 rpm impeller speed, 2.7 L/min flow and 340 mmHg pressure (ECMO mode)

Fig. 3. a, 3D model of the designed pump; b, model of the designed pump

Experimental study of HCC

The prototype testing was carried out in two sequential phases. The first phase involved validating the HCC derived from closed-loop computational simulations [8, 9]. Constant rotational speed studies were conducted within a circulatory test loop designed to emulate essential physiological elements such as vascular resistance, fluid inertia, and aortic compliance. The pump was driven using a Deltastream drive (Medos, Germany), as illustrated in Fig. 4. Distilled water served as the working fluid. Pump speeds ranging from 3000 to 7000 RPM were sufficient to achieve extracorporeal membrane oxygenation (ECMO) operating conditions. However, when the speed exceeded 8500 RPM, the impeller made

contact with the pump housing due to increased hydraulic lift forces.

In the second phase of testing, a hydrodynamic perfusion bench, described in detail in [10], was assembled. This bench replicates the configuration of an ECMO system and includes the pump, an oxygenator with an integrated heat exchanger, and an additional oxygenator. The latter is connected to a 5% CO_2 gas mixture and functions as a simulated "patient" (see Fig. 5).

For the pump efficiency study, anticoagulated donor blood diluted to a hematocrit of 25% was circulated through the system. This dilution was chosen to meet the minimum circuit volume requirement of approximately 700 mL.

Hemolysis parameters were assessed (N = 4) by calculating the normalized hemolysis index (NIH) using Formula, as described in [4].

Fig. 4. Evaluation of the HCC of the fabricated centrifugal pump head

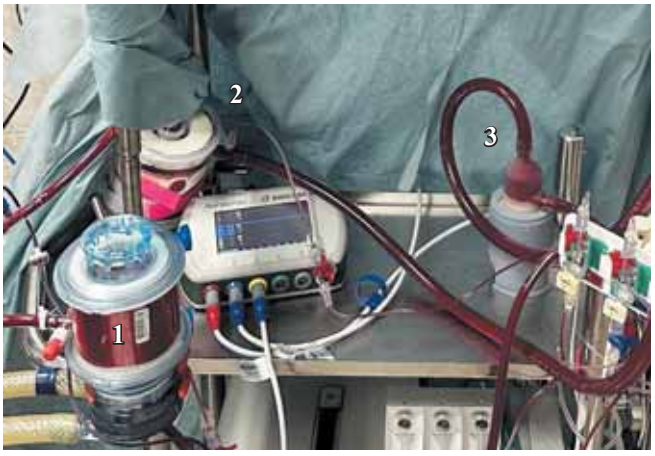


Fig. 5. Evaluation of oxygenating properties and hemolysis in ECMO mode (1, LivaNova oxygenator (INSPIRE, USA); 2, deoxygenator; 3, developed centrifugal pump)

$$\text{N.I.H. g / 100 l} = \Delta\text{freeHb} \times V \times \frac{100 - Ht}{100} \times \frac{100}{Q \times T},$$

where: Δfree Hb – increase in free plasma hemoglobin (g/L) during the sampling interval, V – circuit volume (L), Q – blood flow rate (L/min), Ht – hematocrit (%), T – pump operation time (min).

Throughout the experiment, the temperature of the circulating fluid was maintained at a constant 37.5 °C. The total duration of the tests was 6 hours. Upon completion of the experiments, the pumps were inspected for evidence of clot formation.

RESULTS

The HCC, presented in Fig. 6, demonstrates an agreement between the predicted and experimental results, with a deviation of 2.5 ± 0.5%.

The successful demonstration of the prototype centrifugal pump's operability and efficiency enabled progression to the second stage: a series of studies evaluating oxygenation performance and hemolysis under ECMO conditions. The pump effectively circulated blood through two oxygenators, achieving high levels of oxygen saturation.

The NIH of the pump was measured at 0.001 ± 0.001 g/100 L at the start of the experiment and 0.002 ± 0.001 g/100 L at the end – values that fall within acceptable limits for the given operating conditions. The blood hematocrit decreased from 25 ± 2% to 24 ± 2%, based on averaged data.

DISCUSSION

Calculations and experimental tests of the CP prototype showed a high correlation with the specified medical and technical requirements. Despite its small size, the pump delivers sufficient hydraulic power to achieve a pressure drop of 300–400 mmHg at a flow rate of 5–6 L/min.

The actual pressure drop deviated from theoretical predictions by no more than 3%. The HCC exhibited a banded structure, which is typical for CP performance profiles. In ECMO mode, the rotor operated at 6000–6500 rpm, which is much lower than the operational speed of the clinically used Deltastream pump (Medos, USA) [11].

The developed impeller design effectively minimized vortex formation and eliminated fluid stagnation zones. The calculated average tangential shear stress was approximately 40 Pa, remaining well below the erythrocyte damage threshold of 150 Pa [4]. Given the 500–600 RPM reduction in rotor speed compared to standard clinical devices, hemolysis levels observed in future experiments are expected to remain within acceptable limits.

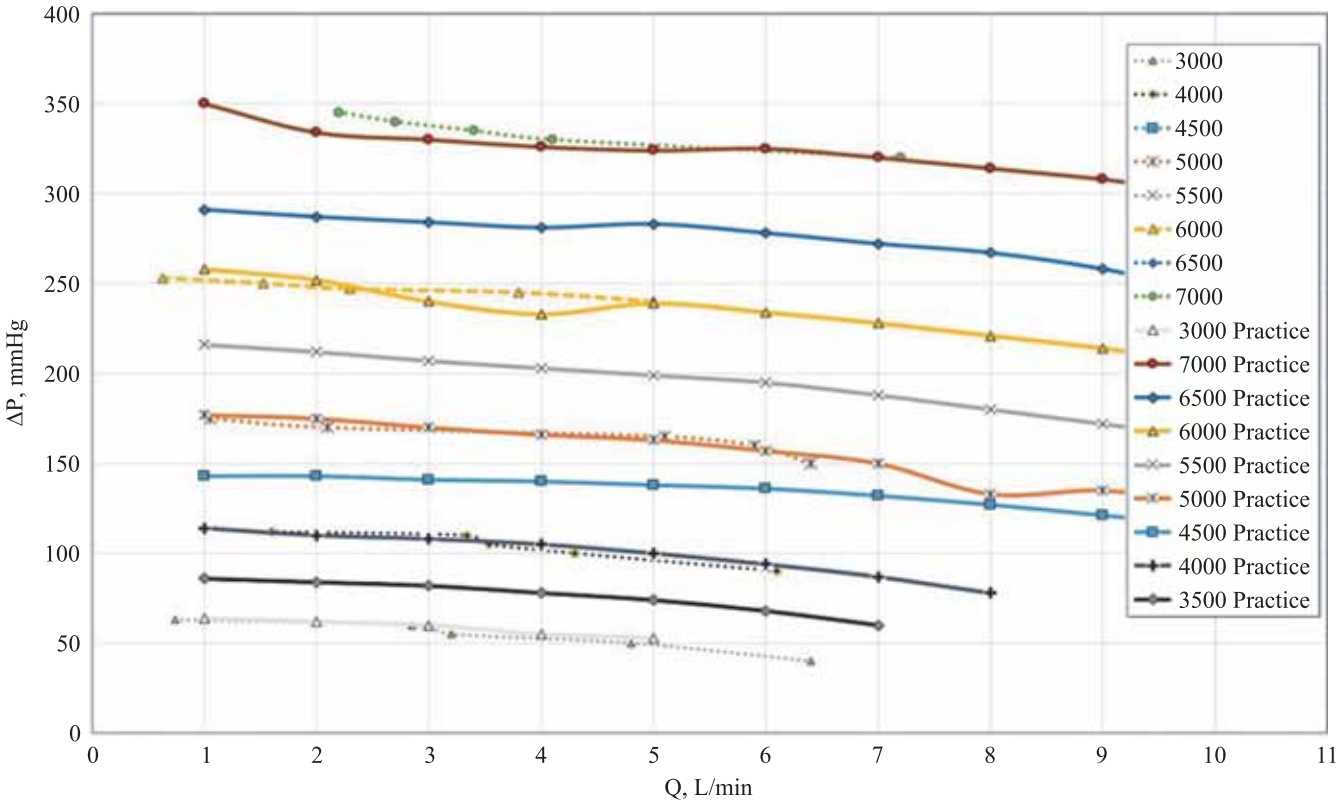


Fig. 6. Head-capacity curve of the pump. Dotted line indicates computer modeling, solid line shows bench test results

The use of straight vanes in the impeller design simplifies the manufacturing process of the pump. Evaluation of the proposed vane configuration showed an increase in head pressure while maintaining consistent fluid velocity throughout the flow path. The HCC of this model also indicates enhanced sensitivity to preload, which contributes to increased pulsatility – particularly beneficial in applications involving oxygenators and small-diameter cannulas.

The inclusion of additional ports proved to be an effective modification, facilitating improved pump flushing and enhancing non-thrombogenic properties without any significant compromise in hydraulic performance. A slight increase in impeller torque – up to 7% – was recorded, corresponding to a reduction in impeller efficiency by the same margin. This decrease is attributed to the presence of recirculation zones, which introduce hydrodynamic losses.

Numerical simulations confirmed elevated flow and velocity on the rear side of the impeller and within the added orifices, with secondary flow rates ranging from 0.3 to 1.0 L/min, depending on the head and flow rate.

In the final design, a closed impeller configuration was selected to minimize internal leakage flow while allowing for a larger operational clearance. During perfusion bench experiments, where the pump was integrated into a simulated ECMO circuit, the device showed good overall biocompatibility and low blood damage over a 6-hour test period (N = 4).

The maximum recorded value of NIH was 0.003 g/100 L, attributed primarily to limitations in the precision of the 3D printing process. No blood clots were observed during or after the experiments. The pump effectively overcame the combined resistance of two oxygenators, which totaled approximately 200 mmHg.

CONCLUSION

The presented results indicate that the developed centrifugal pump prototype exhibits strong potential for use in ECMO systems. Its hydraulic performance meets the requirements for conventional auxiliary circulatory support systems. Future work will focus on rotor optimization, comparative evaluation of alternative designs, development of a low-volume pump variant, and adaptation of the experimental models for production by casting.

The authors declare no conflict of interest.

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The article was submitted to the journal on 14.08.2024