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DESIGN AND 3D-MODEL OF A DYNAMIC BUBBLE TRAP FOR CARDIOPULMONARY BYPASS

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The use of extracorporeal circulation systems (cardiopulmonary bypass pumps, ECMO) can lead to brain and coronary artery microembolism, which significantly reduces postoperative rehabilitation and often leads to severe complications. Microembolism occurs when oxygen or air microbubbles (MBs) enter the arterial system of patients. Existing CPB pumps come with built-in bubble trap systems but cannot remove bubbles in the circuit. ECMO devices have arterial filters but cannot reliably filter out <40 μm bubbles in a wide flow range. We have proposed an alternative method that involves the use of an efficient dynamic bubble trap (DBT) for both large and small bubbles. The design includes development of two DBT variants for hemodynamic conditions of adult and pediatric patients. The device is installed in the CPB pump and ECMO outlet lines. It provides sufficient bubble separation from the lines in a blood flow of 3.0–5.0 L/min for adults and 0.5–2.0 L/min for children. The developed computer models have shown that MBs smaller than 10 μm can be filtered. The use of this device will greatly reduce the likelihood of air embolism and provide the opportunity to reconsider the concept of expensive arterial filters.

Keywords: cardiopulmonary bypass, microbubbles, ECMO.

INTRODUCTION

Air embolism (AE) is accompanied by blockage of microvessels of vital organs and can occur when using both cardiopulmonary bypass pumps (CPB pumps, heart-lung machines, HL machines) and extracorporeal circulatory support systems. Until now, AE remains a severe problem, the most critical for brain microvessels [1–3].

There are many studies reporting postoperative neuropsychological complications after the use of mechanical circulatory assist devices (MCAD) associated with cerebral microischemia [4, 5]. AE with varying degrees occurs in almost all cardiopulmonary bypass (CPB) surgeries [6]. It is very important to quickly identify and eliminate the cause of air in the circuit, because the patient is often completely dependent on ECMO or CPB. Moreover, the air embolism mechanism is not only associated with microvascular occlusion, but can also be combined with the triggering of thrombosis at the blood-gas interface [7].

The most common cause of air aspiration is the inlet section of venous drainage line at the cannulation site. Unlike the situation when air enters the intake line, where they are trapped by the oxygenator, the presence of air in the return line is a more serious problem. In this case, air is often sucked into the oxygenator, which can occur if the oxygenator capacity exceeds the patient's oxygen requirements, and blood pressure becomes lower than the gas pressure on different sides of the oxygenator membrane [8, 9]. Another reason is reduction in blood level in the venous reservoir below the critical level when using the perfusion technique.

In addition, during open heart surgeries with CPB, errors by perfusionists are not excluded. For example, due to reduction in blood level in the venous reservoir below the critical level, errors during blood sampling for analysis and incomplete air removal when filling the CPB circuits. The highest number of ingress of microbubbles (MBs) into the arterial line is possible during complex surgeries like aortic valve replacement [10]. Also, one should not exclude technical breakdowns in devices leading to circuit line rupture, blood cavitation and microbubble ingress from the venous reservoir into the arterial line due to active blood drainage using suctions.

Despite their small size, MBs are differentiated. Some researchers divide bubbles into: very small (<50 μm), which refers to MBs; small (50–100 mm); medium (100–150 μm); large (150–300 μm); very large (>300 μm) [11]. Others refer to MBs as all objects that can be measured by the current registration systems in the circuit of MCAD machines (from 5–10 μm to 250–500 μm) [12].

Modern MCAD devices provide protection against massive air embolism using arterial filters. These filters provide only limited effectiveness in removing MBs; they do not completely remove 25–40 μm MBs, depend-

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ing on pore size [8, 13, 14], which can enter the bypass circuit both from the operating field and during perfusion interventions. Reduced size of filtration pores can lead to increased hydrodynamic resistance, damage to blood cells and platelet aggregation [8]. In our studies we consider predominantly 40–50 μm MBs.

In [8], a comprehensive assessment of MBs filtration in different oxygenation systems was carried out. The variation in efficiency of bubble trap systems was from 80% to 99%. It was shown that most of the MBs not captured by the filter ranged from 10 to 30 μm.

Reducing the number of MBs in the circuit of extracorporeal circulatory systems remains an important factor in patient safety, and the development of effective MBs separation devices remains a crucial task.

Fig. 1. Appearance of the DBT for an adult patient and a pediatric patient

MATERIALS AND METHODS

The *aim* of the work is to create an easy-to-use device for maximum separation of >10 μm gas bubbles and significant reduction of <10 μm MBs from MCAD circuit to improve the efficiency of circulatory assist devices. The design of two dynamic bubble trap (DBT) models, which are installed at the outlet of the arterial line by CPB and ECMO (Fig. 1), has been proposed. The devices trap bubbles at 3.0–5.0 L/min flow rates for adults and 0.5–2.0 L/min for pediatric patient.

How the DBT works

The DBT is an elongated cylindrical tube of biocompatible polymer that is connected to the outlet line of a CPB or ECMO machine instead of a filter. The DBT consists of a flow swirl unit, a bubble centering unit and an MBs separation unit (Fig. 2).

I. The flow swirl unit receives and expands blood flow by means of a conical inlet fitting, twisting around the axis with a helix (1).
II. The bubble centering unit is represented by a housing () extending into the outlet fitting (2).
III. The bubble separation unit is represented by a thin separating tube (3) with a small diameter at the separator outlet, positioned exactly along the axis of the device.

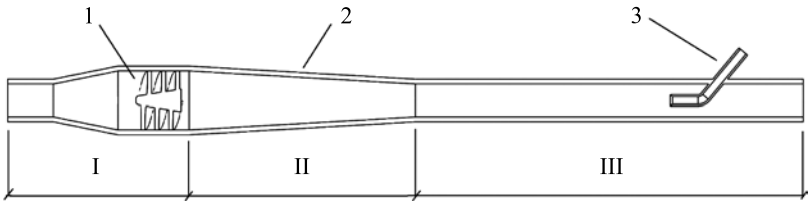

Fig. 2. Schematic diagram of the DBT. I, flow swirl unit; II, bubble centering unit; III, bubble separation chamber. 1, helix; 2, housing, 3, bubble outlet tube

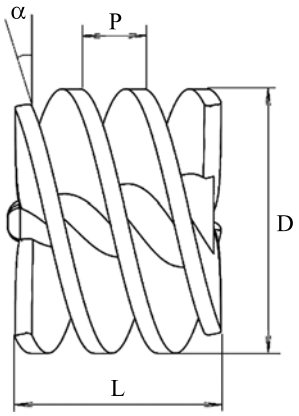

Fig. 3. Sketch of the helix

The *flow swirl unit* is designed for swirling around the axis of the blood flow using an iconic shaped helix in the inlet part of the housing. The helix (Fig. 3) has variable parameters such as inlet angle α, thread pitch P, diameter D and length L, which are calculated for flow parameters.

The blades are designed to convert part of linear flow into radial flow. The conical shape of the central body of the helix, expanding along the flow path, shifts it further away from the DBT axis. At the same time, by reducing the cross-sectional area of the helix channels from inlet to outlet, the velocity, according to partial deduction from Bernoulli's law, increases particle velocity, which

dramatically increases the centrifugal force of flow at the helix outlet. At the helix outlet, the maximum flow rate is reached, and an accelerating flow mode is formed. At the outlet of the helix, in the swirling flow due to centrifugal forces, an axisymmetric area is formed with a pressure drop from the periphery to the axis of the device. Under the generated pressure gradient, the bubbles rush from high pressure zone to low pressure zone, i.e. to the axis of the device, along which they move due to the linear component of the flow velocity. The effect depends on many geometrical factors, both on helix parameters and on angle of the cone-shaped body part.

The bubbles are then captured by a thin-walled, small-diameter tube connected to the venous reservoir and located at the separator outlet exactly along the axis of the device. In this way, a small portion of the blood, together with the micro and macro bubbles collected along the axis, circulates from the DBT to the venous reservoir of the air outlet due to the pressure differential. The operating principle of the design is shown in the fluid flow model (Fig. 4). The blood flow entering the DBT contains bubbles of different diameters. The inlet fitting has a conical expansion of the line. The diameter of this extension corresponds to the diameter of the helix used and allows for sufficient centripetal force in the blood flow. In the figure, it can be noted that the large bubbles are located on the separator axis at the helix outlet, while the MBs are centered some distance from it. This is due to the lower mass of the MBs.

With this in mind, the minimum size of centered MBs is determined by the total length of the block. The main study in this stage of device development comes down to determining the coordinates at which <10 μm bubbles are centered. This will allow the MBs separation tube to be positioned more efficiently.

Computer model of the device and stand

In the adult and pediatric models, according to analytical and mathematical calculations, the helix parameters were: 18 mm diameter, 20 mm length, 1.3 thread pitch, 3 blades and 17° entry angle. The lines were 10 mm and 6 mm in diameters, respectively. The bubble outlet tube has an inner diameter of 2.4 mm, which will allow taking no more than 10–15% of the blood volume. The bubble centering points of different diameters were analyzed on the models. Based on the results of the studies, the optimal distance from the helix where the outlet tube of the bubble outlet is located was chosen to be equal to the MBs centering coordinates to ensure effective operation of the DBT.

For this purpose, a 3D mathematical model of viscous fluid flow in DBT cavities was developed in COMSOL-Multiphysics software. The calculation boundary conditions were 100 mmHg pressure at the DBT outlet and 8 mmHg pressure in the tube, which corresponds to the average venous value. We applied multiphase simulation mode of blood and air flow. The flow rate averaged 5 L/min for adult and 1 L/min for pediatric circulation parameters. A 10^{-4} pressure convergence residual was defined as the convergence criterion. A k-ε turbulence model was used to simulate the flow field. A fairly fine mesh consisting of tetrahedral cells with a total number of 90,000 elements was obtained. An example of a multiphase flow simulation is shown in Fig. 5, where one can see the movement of 50 μm, 10 μm and 5 μm bubbles in the DBT model for a 5 L/min flow rate. As can be seen from the figure, smaller diameter MBs are more likely to pass the tube.

The developed DBT models were produced by 3D printing and examined on the a hydrodynamic stand

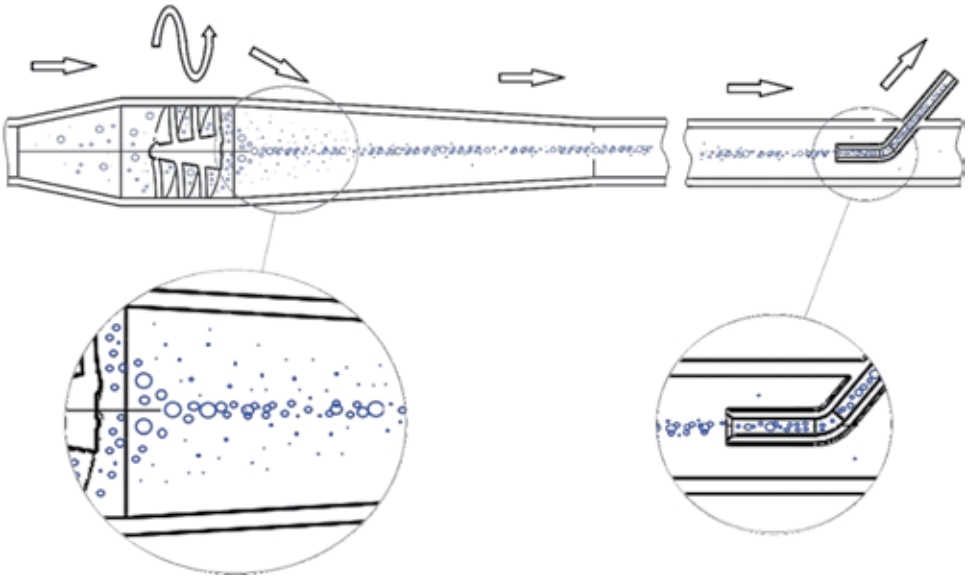

Fig. 4. DBT operating principal. The principle of centering the bubbles and getting them into the tube is shown

shown in Fig. 6. The stand includes a Rotaflow pump (Maquet, Germany), which sets the flow rate recorded by an ultrasonic flow meter (2). Bubbles are discharged from the DBT into a reservoir (8) filled with liquid. Bubbles of different diameters are introduced into the circuit through a port (5), by means of a syringe (6). The bubbles that have not reached the outlet tube are detected by the sensor (9). Pressure is regulated by the system hydraulic resistance (3), and is detected at the DBT inlet and outlet by pressure transducers (4, 10).

Flow rates in the aorta and pump were measured using ultrasonic flowmeter Transonic Systems Inc., USA. Pressure transducers (Edwards Life Sciences, USA). To record hemodynamic parameters, we used multichannel module ANGIOTON (Biosoft-M, Russia) with recording on a personal computer in Pumpax software (Biosoft-M). The stand was filled with 35% glycerol – saline mixture 4.0 ± 0.3 cP to reproduce physiological blood circulation conditions. The studies quantified the presence of MBs without/with the use of DBT.

RESULTS

Computer studies obtained the following data for adult and pediatric model costs.

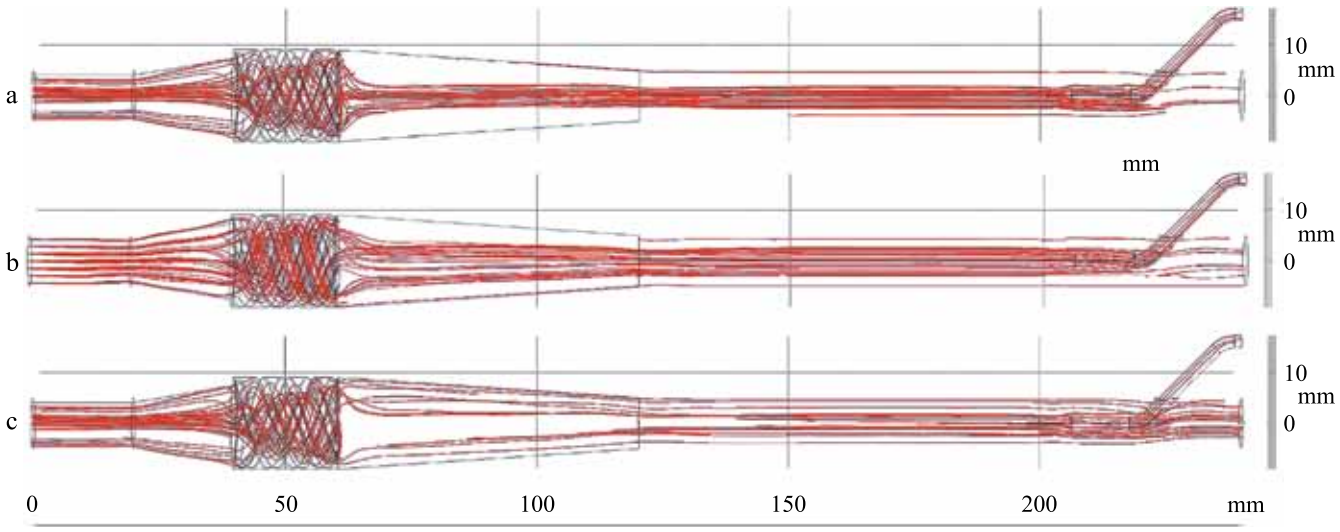

Fig. 5. Simulation of the DBT for a 5 L/min flow rate with 50 μm (a), 25 μm (b), and 5 μm (c) microbubbles

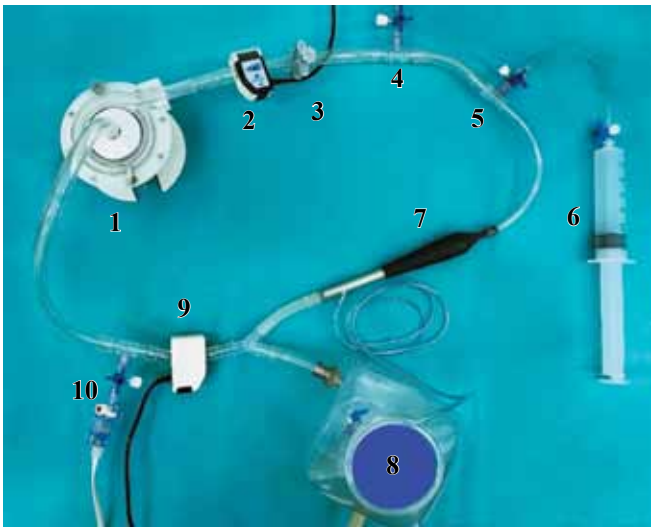

Fig. 6. Hydrodynamic stand for the DBT investigation: 1, Rotaflow pump; 2, flow meter; 3, system hydraulic resistance; 4, pressure transducer at the DBT inlet; 5, bubble input port; 6, bubble generation device; 7, DBT model; 8, bubble intake tank; 9, bubble counting sensor; 10, pressure transducer at the DBT outlet

As can be seen from the figure, MBs are centered much further away from the helix exit. The distance from the helix to the centering of 10 μm MBs for the adult and pediatric versions, were 133 mm and 86 mm, respectively. In view of the values obtained, the distance between the helix and the bubble outlet tube was chosen to be 143 mm and 96 mm, with a 10 mm margin, while the total length of the DBT models was 245 mm and 225 mm for the adult and child versions, respectively. Based on the data obtained from the computer model studies, experimental models of the DBT system were assembled and tested on a hydrodynamic stand.

As a result of studies on the hydrodynamic stand at a low pressure drop (90 mmHg for 3.0–5.0 L/min and 0.5–2.0 L/min blood flow), bubble counts before and after using DBT were obtained as shown in Fig. 8.

For these flow rate ranges in the two models, one can observe a significant decrease (by 3–4-fold) in the total number of MBs and >10 μm bubbles by a factor of 10 or more. There is, however, a decrease in efficiency at the boundaries of the studied flow rates of 0.5, 2.0,

3.0 and 5.0 L/min. Upon reaching the boundary ranges of the study, the number of recorded MBs began to increase. For low flow levels, this was due to a decrease in the pressure gradient and less exposure to MBs. For high flow rates, linear velocity of MBs along the DBT axis increases, which shifts their centering coordinates. There is also a fairly large pressure drop on the DBT (over 100 mmHg, at >5 L/min flow rate in the adult patient model and >2 L/min in the pediatric patient model). Therefore, work was continued to optimize the DBT in terms of reducing pressure drop while maintaining or improving MF separation efficiency.

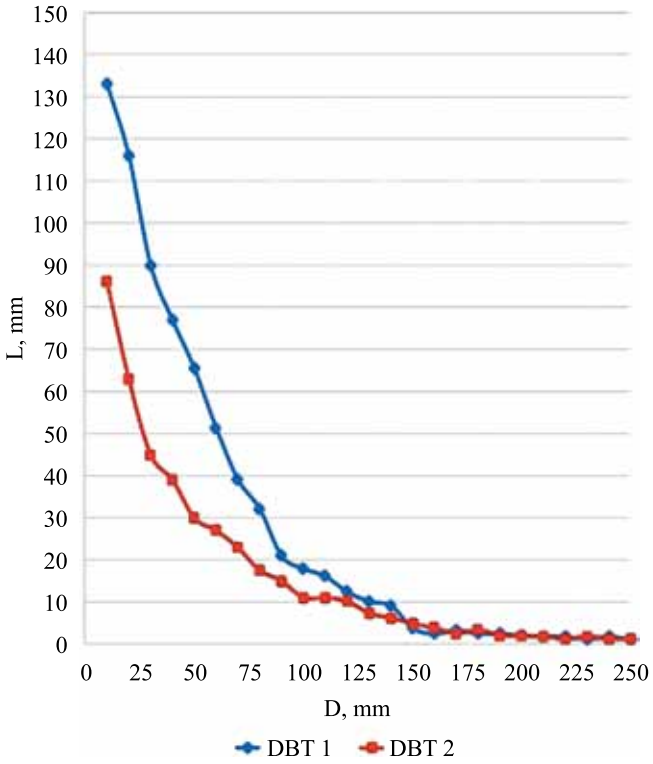

Fig. 7. Dependence of bubble centering distance L on bubble diameter D

CONCLUSION

DBT tests have shown that the use of a DBT reduces the probability of AE by a factor of 3–4 on average. The microbubble separation efficiency depends on the geometric dimensions of the DBT, the flow swirl angle and the outlet cross-section of the helix swirling channels. Adult and pediatric DBT designs were selected based on preliminary studies. Preliminary analysis revealed the directions for further promising improvement of microbubble separation parameters and DBT optimization. The use of this device will reduce the effect of microembolism, make cardiopulmonary bypass safer and provides the opportunity to reconsider the concept of using expensive arterial filters.

The authors declare no conflict of interest.

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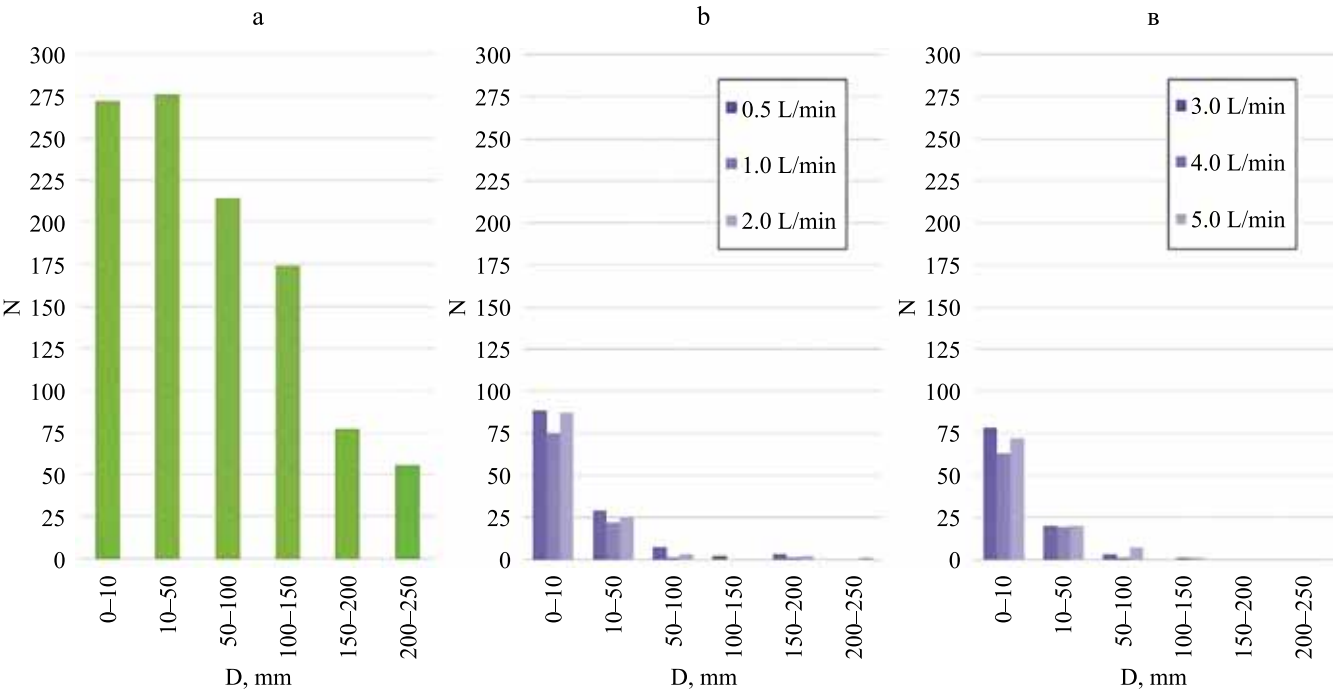

Fig. 8. Separation of bubbles of different diameters at different flow rates for the investigated DBT models: a, composition of bubbles when entering the circuit; b, performance of the pediatric model; c, performance of the adult model

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