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DEVELOPMENT OF A CANNULA DEVICE FOR GAS FRACTION REMOVAL IN SURGICAL DRAINS

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The development of low-traumatic surgical drains aimed at maximum possible separation of blood and air, is an important trend in modern medicine. The objective of this work is to create an inexpensive, user-friendly and low-traumatic dynamic blood aspiration system (DBAS). The system allows effective separation of blood and air when drawing blood from a wound under vacuum conditions required for blood aspiration. The operating principle of the system is to separate liquid and gas fractions of the blood-air mixture by modifying the blood intake cannula. The effect is achieved by applying the principles of centrifugal forces of a rotating blood-air flow combined with Archimedes lift forces.

Keywords: aspiration, CPB, cannula, blood drainage.

INTRODUCTION

Venous blood drainage is used in most surgical procedures [1, 2]. It was not generally used until the recent development of invasive cardiac surgery, along with the spread of open-heart surgeries that do not require blood transfusion [3]. Patients undergoing cardiac surgery with cardiopulmonary bypass (CPB) require large quantities of donor red blood cells [4]. Considerable evidence suggests that transfusions during cardiac surgery increase infectious and noninfectious risks [5–7]. Venous drainage is an acceptable method for patients to preserve their own blood. During the procedure, blood is aspirated from the wound cavities using a suction cannula connected to a blood suction system (roller or vacuum pump). In turn, the blood further enters the recirculation system represented by the collection reservoir and connecting tubes (Fig. 1).

According to experts, blood aspiration is the main factor traumatizing the blood and, along with the effect of air microbubbles getting into the blood circulation circuit, increases the patient's rehabilitation time after surgical intervention. In reviewing literature sources, it was noted that 79% (n = 15) of the authors believe that the vacuum drainage technique benefits the assisted circulation procedure and/or the patient. Reducing the number of transfusions helps to prevent blood bank overload [8–14]. The reduction is due to improved biochemical parameters and, therefore, there is no need to increase the volume of the venous reservoir to maintain the level of protection against air ingress into the system.

Reduced use of blood products helps to reduce postoperative complications, and the technique provides a reduction in total blood count, reducing hemodilution [3, 8–15] and maintaining hematocrit and hemoglobin at acceptable levels.

However, along with increased use of venous drainage, specific side effects of the procedure have been reported. Willcox et al., LaPietra et al., Davila et al., Burch and Locke have separately reported cases in in vitro studies where the venous drainage system returns air-laden blood to the patient [16–19]. This results in systematic microemboli. Microemboli often cause significant cerebral morbidity, usually manifesting as postoperative cognitive deficit or stroke [16].

Air embolism has been reported in other studies [10, 11, 20, 21]. It has been shown that venous vacuum drainage caused almost 10 times more embolisms in the arterial line compared to passive drainage, despite the use of appropriate equipment. The above-mentioned embolism is a consequence of microbubble formation in the liquid due to turbulence caused by high-pressure passage through a narrow tube. The same studies show that just by comparing the lengths of the vacuum and gravity methods, in the situation of air supply to the venous circuit through the venous line, the vacuum allows more air to enter the system.

There has been disagreement about the presence of high levels of hemolysis when using a vacuum. Most authors believe that hemolysis caused by negative pressure procedures was similar to hemolysis with passive drainage [3, 10, 11, 22]. However, comparing vacuum

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drainage with centrifugal pump drainage, Cirri et al. [23] showed that vacuum drainage causes a higher degree of hemolysis, which were also confirmed by Gregoretti et al. [24]. However, Lau et al. disagree, showing similar levels of hemolysis [25].

In the last decade, the efforts of many specialists working in the field of artificial blood circulation were aimed at developing new pumps, membrane oxygenators, which would reduce blood trauma during such operations. Nevertheless, despite certain successes in this direction, blood trauma is still a great danger, and this is mainly due to the traumatic effect of the blood aspiration system. This problem has become especially urgent recently when the age of patients undergoing open cavity surgery has significantly changed and the length of rehabilitation has increased. As a result, efficiency of blood drainage systems is an important part of the surgical process.

MATERIALS AND METHODS

The main causes of blood injury when using the existing blood aspiration systems include:

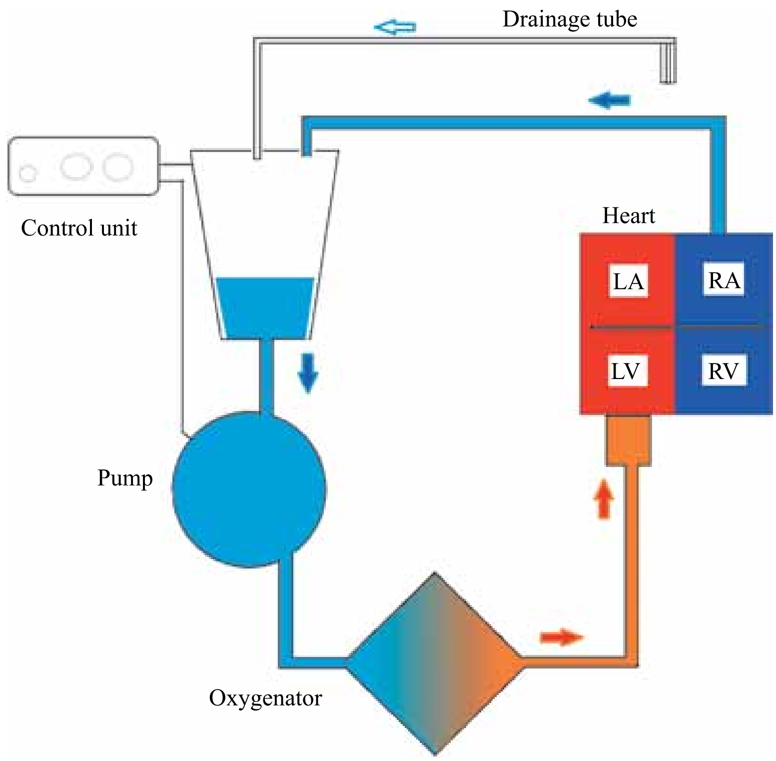

Fig. 1. Vacuum-assisted venous drainage. LA, left atrium; RA, right atrium; LV, left ventricle; RV, right ventricle

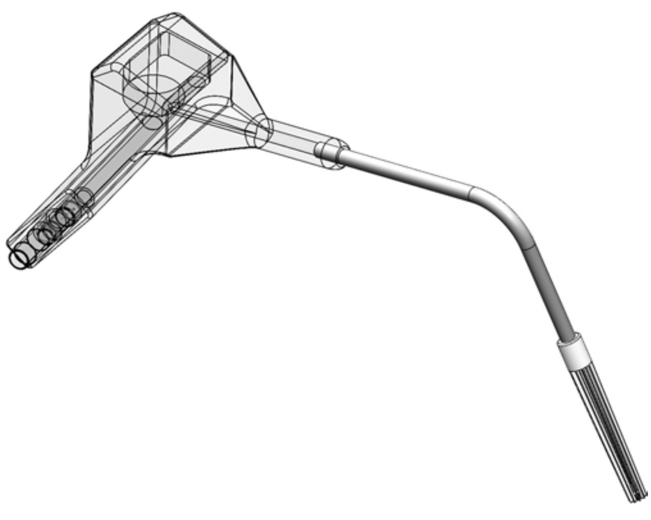

Fig. 2. Schematic representation of the modified separation cannula

– massive mixing of blood with air in the cannula, connecting tubes, and pump;
– high vacuum produced by the pump.

To reduce the influence of the above factors, an ergonomic and practical DBAS was developed. The appearance of the modified cannula is shown in Fig. 2. The system includes a mixture intake tube bearing a special nozzle and a cannula separation unit.

The separation unit, shown in Fig. 3, has a narrow part A, in which the mixture feed tube 1 is located. The wide part C, follows the narrow part through a smooth transition B. From the blood sampling nozzle through the tube, a liquid-air mixture enters the inlet tube of the separation unit, which is an extension of it. The mixture feed channel is directed to the thickened part C, in which a conical cavity 2, an air filtration zone 3 and two tubes of blood and air fraction withdrawal 4 and 5, located inside the handle of cannula D, are cut out.

One of the tubes 4 is a continuation of the conical part, and the liquid phase is discharged through it with a minimal air residue. The second tube 5 is parallel to the first one, but is connected to the filtration zone, which is vertically above the conical part. Through this tube, the air separated during flow through the conical part is removed. A bio-inert exchangeable sponge is installed in the filtration zone to optimize the separation process. The sponge is replaced by opening the top cover.

The conical part is located vertically with a narrowing downwards. With respect to the cross section of the cone, the inlet channel to it is located at an angle.

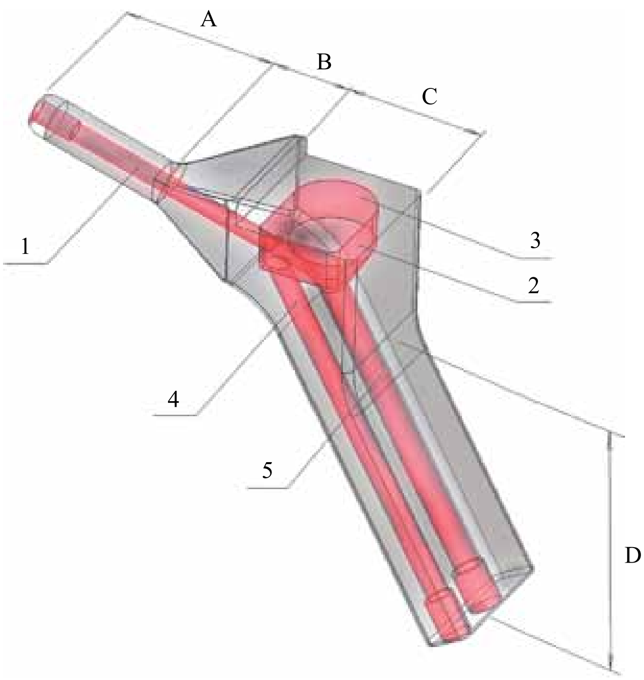

Fig. 3. Schematic representation of the separation unit

At the junction, the inlet channel is positioned such that the flow enters the conical part in a tangential line at the maximum radius of the cone cross section at the inlet. The wide section transitions into a handle designed to hold the system comfortably. The handle has slotted channels for the liquid and gas phases mentioned earlier. The channels end with outlet fittings, and are connected to a vacuum generation system. A sketch of the complete DBAS is shown in Fig. 4. Since the separation of blood and air must be performed as close to the wound as possible, the working chamber of the device is built into the handle of the drainage cannula (Fig. 3, D). Thus, after the separation process, blood is collected at the lower end of the working cyclone chamber and aspirated through a separate channel (Fig. 3, 5) using a roller pump (Fig. 4, 4).

In turn, air is collected in the upper part of the chamber and aspirated through another channel (Fig. 3, 4) by a vacuum roller pump (Fig. 4, 5). Blood and air are then fed separately into the cardiotomy tank (6).

How the device works

The blood-air mixture, under vacuum, is captured through the tip of the cannula from the wound and flows through the channel (Fig. 4). The mixture then enters the inlet of the cyclonic conical chamber at an angle to the vertical axis (Fig. 3). Rotation of the blood-air mixture is achieved, which is maintained by the conical expansion of the cyclone chamber. Blood is collected in the lower part of the nozzle, while air, due to centrifugal and Archimedes forces, is collected in the center of the rotating flow and rushes to the highest point. The forces acting on the air bubble can be considered in the coordinate system as shown in Fig. 5.

It can be seen from the figure that when an air bubble enters the cyclone chamber, its motion in the vertical direction along the axis is due to the applied vacuum P_1

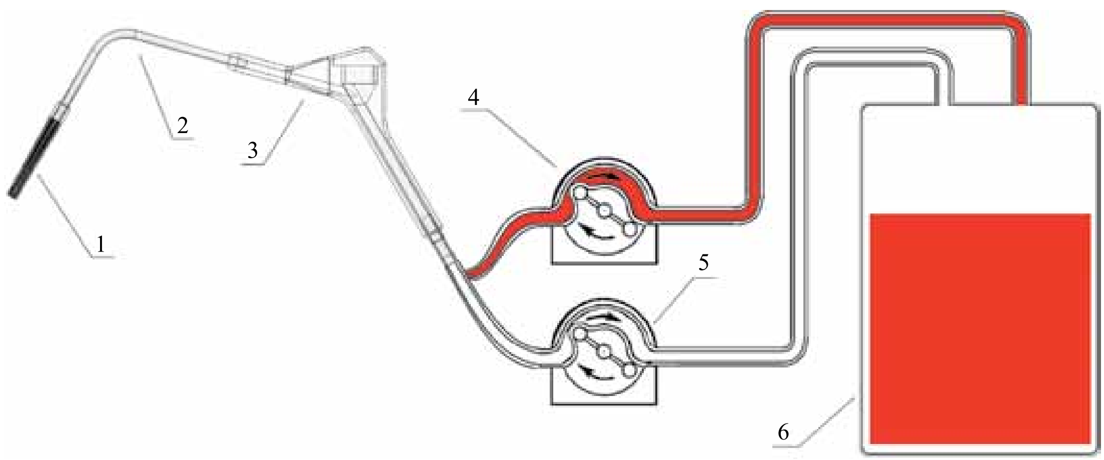

Fig. 4. Schematic representation of the dynamic blood aspiration system. 1, suction cannula; 2, liquid-air mixture supply tube; 3, separator; 4, roller blood pump; 5, roller air pump; 6, cardiotomy tank

from the liquid channel, the vacuum from the air channel P_2, the Archimedes force F_A, and viscous friction force F_T. It was decided to neglect the weight of the bubble due to the weak influence of this parameter in these conditions. Since the mixture intake channel enters the cyclone chamber at a tangent and vertical angle α, the vacuum in the *xy* plane can be considered as the projection of the flow force F_P on the *y* axis. In the *xy* plane, viscous friction force F_{Ty} will act on the bubble as a counterbalance to the motion of the bubble. We obtain the basic steady-state equation of bubble rising (1):

$$F_A - F_{Py} - F_{Ty} + F_2 = 0. \qquad (1)$$

In the case of absence or weak influence of vacuum P_2 and a decrease in force F_2, a solution of the system of equations gives the bubble ascent velocity and initial rotation velocity in the cyclone chamber (2):

$$\upsilon_y = \frac{1}{18}\frac{\rho g D_b^2}{\eta} - \frac{32}{3}\frac{LQ}{\pi d^2 D_b} \cdot \sin\alpha, \qquad (2)$$

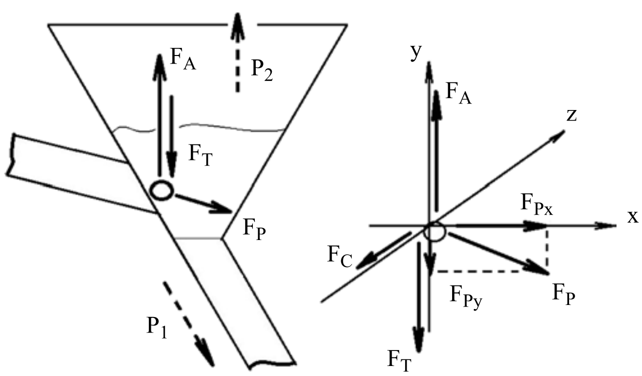

Fig. 5. The position of forces acting on air bubble

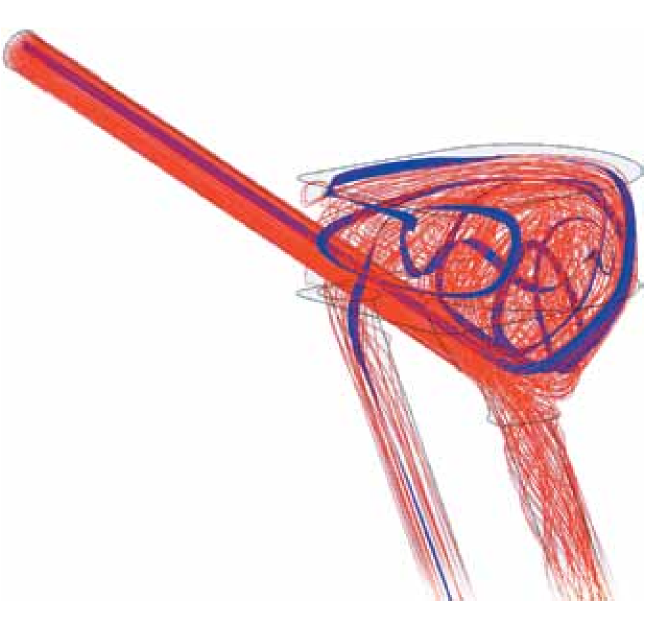

Fig. 6. An example of simulation of fraction flow in a 20 mm Hg vacuum with 4 mm air bubble diameter

where υ_y is the air bubble rising velocity, ρ is blood density, *g* is free fall acceleration, η is blood viscosity, α is the angle of blood intake channel entry into the cyclone chamber, *L* is the blood intake channel length, D_b is the diameter of the air bubble under study, and *Q* is the blood flow rate.

The rising rate, as follows from analysis of the equation, depends to a greater extent on the amount of blood flow that the pump produces and the angle α. Evaluating the relationship between vacuum and separation efficiency is part of the initial DBAS design process.

Computer model of the device

We developed a three-dimensional DBAS mathematical model of viscous liquid flow with the presence of liquid bubbles of different diameters using the COMSOL Multiphysics software. As a result of the studies, a picture of liquid and gas fraction motion was obtained, an example of which is shown in Fig. 6. The calculation boundary conditions included a vacuum value of up to 50 mm Hg. We applied a multiphase modeling mode of blood and air flow.

The criterion of amount of air fraction separated from liquid after flowing in the cyclone chamber was introduced as the required parameter. Convergence criterion 10^{-4} by pressure was defined as the convergence criterion. A k-ε turbulence model was used to simulate the flow field. A sufficiently fine grid consisting of tetrahedral cells consisting of 80,000 elements, was obtained.

The calculation example shows the mechanics of fraction movement, assuming a 0.5 l/min liquid flow rate. One can observe blue lines of trajectories of air bubbles up to 4 mm in diameter in the blood flow, shown by red lines. Calculation is made under the condition that air volume in the blood is equal to 10% of the total flow.

Most of the air flow with some amount of blood (not more than 0.05 l/min) is separated into the air channel. Volumetric flow was created under a 20 mm Hg vacuum condition. Thus, air and vacuum reduce the influence on further blood advancement into the cardiotomy tank. In the air channel, the blood is strongly affected by all thrombosis factors, but the volume of this fraction is reduced to a minimum.

Hydrodynamic bench

Initially, the efficiency of DBAS was assessed visually on a hydrodynamic bench by the nature of the air-bubble concentration zone and by the change in the composition of the air-liquid mixture after the intake tube (Fig. 7). However, in practice, due to the impossibility to observe air bubbles in a fairly wide range of changes, electronic microbubble counting devices were used.

The vacuum system is represented by two pumps – a roller pump, capable of developing the required vacuum for liquid and gas outlet channels, and a vacuum suction system.

The bench includes a roller pump (9), which sets the vacuum required for study and the liquid flow rate, measured by a flow sensor (6). Air is withdrawn into the vacuum suction tank (8) through a channel (3), and blood outlet through a channel (4). Bubbles of different diameters are injected into the cardiotomy tank (2) through a syringe (5) connected to the injection device, on which the volume of the supplied gas fraction is regulated. A cannula (1) is placed in the reservoir, which simulates the patient's wound.

Flow rate was measured using an ultrasonic flow sensor (Transonic Systems Inc., USA) (6), and pressure was measured using transducers (Edwards Lifesciences, USA) (7). To record hemodynamic parameters, we used multichannel module ANGIOTON (Biosoft-M, Russia) with recording on a personal computer using the Pumpax software program (Biosoft-M, Russia). Initially, water was used as the working fluid.

Standard 3/8″ silicone tubing was used to connect the various elements of the bench. During the study, the roller pump was operated on standard configurations for clinical use, to achieve flow rates ranging from 0 to 1 L/min.

RESULTS

The amount of vacuum required to drain the gas-liquid mixture was determined on the bench under pump flow conditions up to 1 L/min. Vacuum was measured

Fig. 7. Hydrodynamic bench. 1, cannula; 2, cardiotomy tank; 3, air channel; 4, liquid channel; 5, air supply device; 6, flow measurement / microbubble counting sensor; 7, vacuum measurement sensor; 8, vacuum suction tank; 9, roller pump

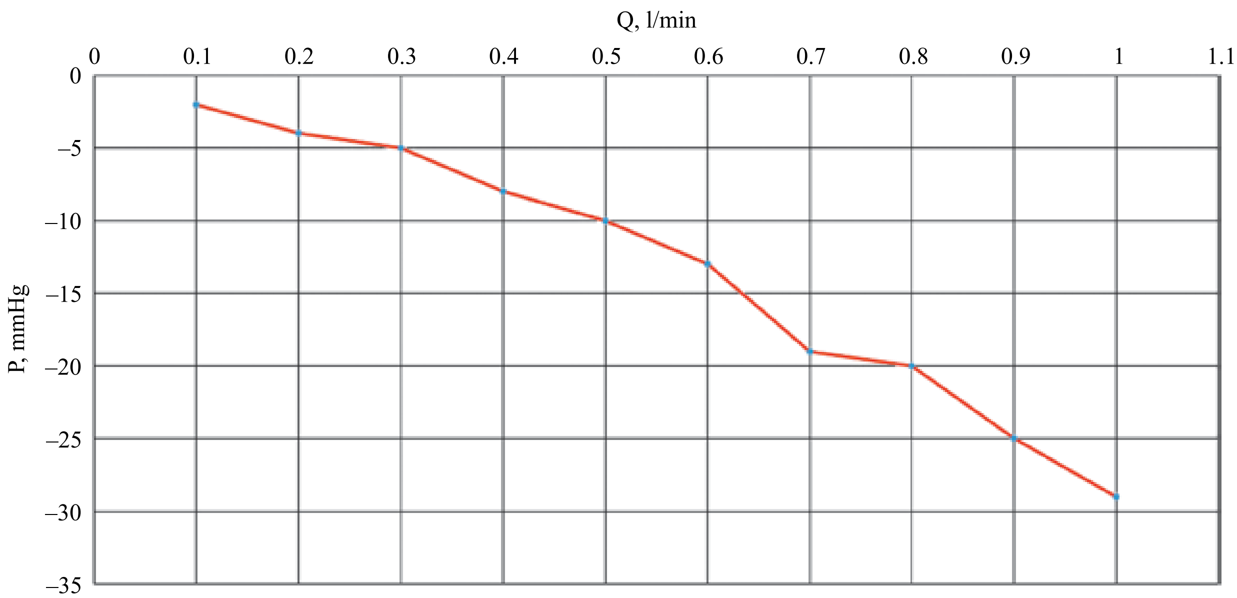

Fig. 8. A graph of flow rate versus applied vacuum

at the inlet of the roller pump. In this case, the variable was the percentage of air in the mixture from 0 to 50%. Fig. 8 shows the dependence of the required vacuum for drainage of various blood flow rates (at a constant roller pump flow rate).

As can be seen from Fig. 8, the vacuum changes from a weakly negative pressure, determined by the difference of the differential between the suction point and the pump inlet to a value of –29 mm Hg at a flow rate of 1 L/min. The picture of bubble separation at the calculated vacuum is shown in Fig. 9.

The obtained results confirm that in the process of gas-liquid mixture separation, efficiency simultaneously decreases both with increasing vacuum, which is known to significantly affect the injury by blood-forming elements, and with increasing volume of supplied air. The operating flow rate range used in surgical operations is up to 0.5 L/min with separation efficiency averaging more than 50% and under vacuum conditions not more than 10–15 mm Hg.

Given that blood viscosity (even in conditions of dilution during extracorporeal circulation) is 2–3 times higher than water ($\mu = 4.2 \times 10^{-3}$ kg/(m·s) and density $\rho = 1054$ kg/m^3), the required vacuum should be higher than in our measurements.

In the developed blood drainage device with pre-separation, it is necessary to choose capacities in blood and air suction lines. In basic drainage mode, the amount of air can be several times higher than the amount of blood. In this case, some of the air will enter the blood channel, flowing into the rotary pump, which constitutes the most dangerous mode in terms of hemolysis. To address the consequences of this mode, the air channel capacity can be increased several times relative to the blood suction channel capacity. Under airless blood drainage, blood will be drained through both channels. Under drainage with simple cannula use, air will also be drained through both channels.

CONCLUSION

We have proposed an alternative method that is based on the physical principles of centrifugal influence and Archimedes forces on air microbubbles for their effective removal from the blood suction system in surgical operations involving users of heart–lung machines. A dynamic blood aspiration system was developed to minimize gas fraction for blood return systems in the heart–lung machine circuit.

The authors declare no conflict of interest.

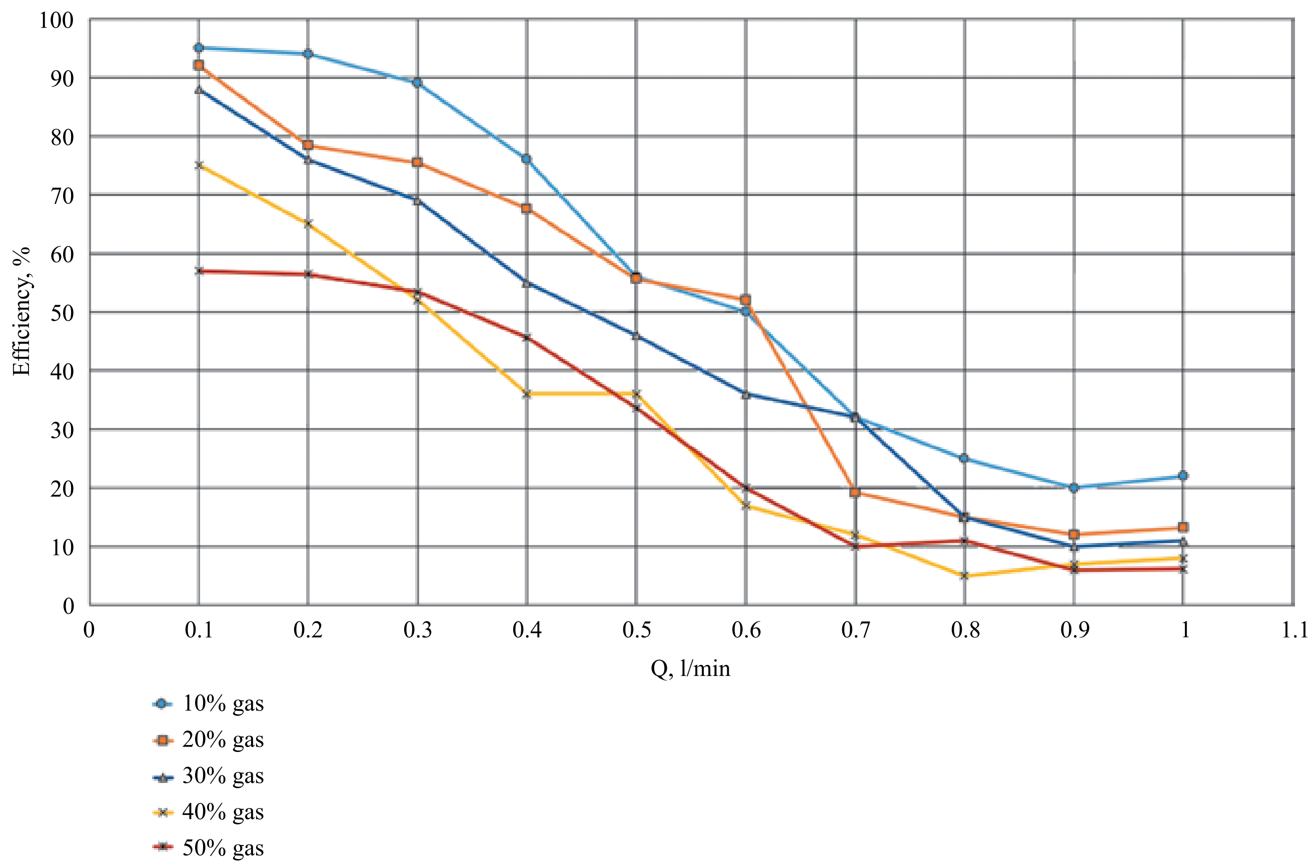

Fig. 9. Separation efficiency

REFERENCES

1. *Jones RE, Donald DE, Swan HJ, Harshbarger HG, Kirklin JW, Wood EH.* Apparatus of the Gibbon type for mechanical bypass of the heart and lungs; preliminary report. *Proc Staff Meet Mayo Clinic.* 1955; 30: 105–113.
2. *Miller BJ.* Laboratory work preceding the first clinical application of cardiopulmonary bypass. *Perfusion*. 2003; 18: 145–154.
3. *Hayashi Y, Kagisaki K, Yamaguchi T, Sakaguchi T, Naka Y, Sawa Y et al.* Clinical application of vacuum-assisted cardiopulmonary bypass with a pressure relief valve. *Eur J Cardiothorac Surg*. 2001; 20: 621–626.
4. *Mazer CD, Whitlock RP, Fergusson DA, Hall J, Belley-Cote E, Connolly K et al.* Restrictive or liberal red-cell transfusion for cardiac surgery. *N Engl J Med.* 2017; 377: 2133–2144.
5. *Vamvakas EC, Carven JH.* Transfusion and postoperative pneumonia in coronary artery bypass graft surgery: effect of the length of storage of transfused red cells. *Transfusion.* 1999; 39: 701–710.
6. *Karamlou T, Schultz JM, Silliman C, Sandquist C, You J, Shen I et al.* Using a miniaturized circuit and an asanguineous prime to reduce neutrophil-mediated organ dysfunction following infant cardiopulmonary bypass. *Ann Thorac Surg*. 2005; 80: 6–13; discussion 13–14.
7. *Vlaar AP, Juffermans NP.* Transfusion-related acute lung injury: a clinical review. *Lancet.* 2013; 382: 984–994.
8. *Taketani S, Sawa Y, Masai T, Ichikawa H, Kagisaki K, Yamaguchi T et al.* A novel technique for cardiopulmonary bypass using vacuum system for venous drainage with pressure relief valve: an experimental study. *Artif Organs*. 1998; 22 (4): 337–341.
9. *Chalegre ST, Salerno PR, Salerno LMVO, Melo ARS, Pinheiro AC, Frazão CS et al.* Drenagem venosa assistida a vácuo na circulação extracorpórea e necessidade de hemotransfusão: experiência de serviço. *Rev Bras Cir Cardiovasc*. 2011; 26 (1): 122–127.
10. *Zangrillo A, Garozzo FA, Biondi-Zoccai G, Pappalardo F, Monaco F, Crivellari M et al.* Miniaturized cardiopulmonary bypass improves short-term outcome in cardiac surgery: a meta-analysis of randomized controlled studies. *J Thorac Cardiovasc Surg*. 2010; 139 (5): 1162–1169.
11. *Nasso G, Costantini C, Petralia A, Del Prete A, Lopriore V, Fattouch K et al.* A new extracorporeal vacuum-assited device to optimize cardiopulmonary bypass. Comparison with the conventional system. *Interact Cardiovasc Thorac Surg*. 2011; 12 (4): 591–595.
12. *Banbury MK, White JA, Blackstone EH, Cosgrove 3rd DM.* Vacuum-assisted venous return reduces blood usage. *J Thorac Cardiovasc Surg*. 2003; 126 (3): 680–687.
13. *Bevilacqua S, Matteucci S, Ferrarini M, Kacila M, Ripoli A, Baroni A et al.* Biochemical evaluation of vacuum-assisted venous drainage: a randomized, prospective study. *Perfusion*. 2002; 17 (1): 57–61.
14. *Nakanishi K, Shichijo T, Shinkawa Y, Takeuchi S, Nakai M, Kato G et al.* Usefulness of vacuum-assisted cardiopulmonary bypass circuit for pediatric open-heart surgery in reducing homologous blood transfusion. *Eur J Cardiothorac Surg*. 2001; 20 (2): 233–238.
15. *Pappalardo F, Corno C, Franco A, Giardina, Scandroglio AM, Landoni G et al.* Reduction of hemodilution in small adults undergoing open heart surgery: a prospective randomized trial. *Perfusion*. 2007; 22 (5): 317–322.
16. *Willcox TW, Mitchell SJ, Gorman DF.* Venous air in the bypass circuit: a source of arterial line emboli exacerbated by vacuum-assisted drainage. *Ann Thorac Surg*. 1999; 68: 1285–1289.
17. *LaPietra A, Grossi EA, Pua BB, Esposito RA, Galloway AC, Derivaux CC et al.* Assisted venous drainage presents the risk of undetected air microembolism. *J Thorac Cardiovasc Surg*. 2000; 120: 856–863.
18. *Davila RM, Rawles T, Mack MJ.* Venoarterial air embolus: a complication of vacuum-assisted venous drainage. *Ann Thorac Surg*. 2001; 71: 1369–1371.
19. *Burch TM, Locke AQ.* Air lock and embolism upon attempted initiation of cardiopulmonary bypass while using vacuum-assisted venous drainage. *J Cardiothorac Vasc Anesth* 2012; 26: 468–470.
20. *Colangelo N, Torracca L, Lapenna E, Moriggia S, Crescenzi G, Alfieri O.* Vacuum-assisted venous drainage in extrathoracic cardiopulmonary bypass management during minimally invasive cardiac surgery. *Perfusion*. 2006; 21 (6): 361–365.
21. *Kiyama H, Imazeki T, Katayama Y, Murai N, Mukouyama M, Yamauti N.* Vacuum-assisted venous drainage in single-access minimally invasive cardiac surgery. *J Artif Organs*. 2003; 6 (1): 20–24.
22. *Murai N, Cho M, Okada S, Chiba T, Saito M, Shioguchi S et al.* Venous drainage method for cardiopulmonary bypass in single-access minimally invasive cardiac surgery: siphon and vacuum-assisted drainage. *J Artif Organs*. 2005; 8 (2): 91–94.
23. *Cirri S, Negri L, Babbini M, Latis G, Khlat B, Tarelli G et al.* Haemolysis due to active venous drainage during cardiopulmonary bypass: comparison of two different techniques. *Perfusion*. 2001; 16 (4): 313–318.
24. *Gregoretti S.* Suction-induced hemolysis at various vacuum pressures: implications for intraoperative blood salvage. *Transfusion*. 1996; 36 (1): 57–60.
25. *Lau CL, Posther KE, Stephenson GR, Lodge A, Lawson JH, Darling EM et al.* Mini-circuit cardiopulmonary bypass with vacuum assisted venous drainage. Feasibility of an asanguineous prime in the neonate. *Perfusion*. 1999; 14 (5): 389–396.

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