

Structural Design and Performance of the First Hepatic Portal Blood Flow Blocker

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Research article

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Structural design and performance of the first hepatic portal blood flow blocker

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Abstract:

Laparoscopic surgery has been gradually promoted by people because of its advantages of small trauma and quick recovery. However, the operation is difficult, the first hepatic portal should be completely fastened during the operation. In this paper, through the study of the existing structure of the blocker, a kind of blood flow blocker for the first hepatic hilum blocking under laparoscope is designed. All kinds of parameters were calibrated through equation calculation, and the pressure guiding the blood flow blocking of hepatic portal during operation was calculated. The dynamic analysis was carried out with ANSYS software, and it was found that the fluid movement state was most uniform when the airflow velocity reached 8m/s. The experimental apparatus was set up to simulate the process of hepatic portal vein being blocked in vitro, then the feasibility of blocking effect was evaluated. Finally, it is concluded that the designed blood flow blocking device can have good blocking effect on blood vessels.

Key words: laparoscopic surgery; blood flow blocker; parameter calculation; ANSYS; simulation experiment

1. Background

Liver tumors have always been a common multiple diseases, requiring liver resection to achieve therapeutic results^[1]. In the course of surgery, liver tissue cutting is often accompanied by different degrees of bleeding, the amount of blood loss directly affects the postoperative morbidity and mortality^[2]. Laparoscopic hepatectomy pays more attention to intraoperative bleeding, because in the process of surgery, the limited operating space leads to unclear vision, which makes it impossible to perform the operation directly. Thus, the operation can only be performed through screen images, and conventional methods of hemostasis cannot be adopted^[3]. How to control bleeding in laparoscopic surgery has become a more serious problem. During laparoscopic surgery, if the bleeding can be effectively reduced, the scope of surgical treatment will be expanded accordingly, and the success rate will be higher. So it's important to design a device that can reduce or even block bleeding during laparoscopic surgery.

At present, both domestic and foreign laparoscopic hepatic portal blood flow blockers are still in the initial stage, and there is no mature product technology, which is dependent on the measures used in open surgery to block, and some simple props are used in the operation. On the market, appropriate hemostasis can be carried out with some instruments of breaking liver, such as microwave knife, argon coagulation device, ultrasonic knife, laparoscopic multifunctional surgical anatomic device and so on^[3]. These instruments of cutting liver in surgery also play a role in blood flow blocking. Most of them are used to stop bleeding by instantly crusting the section under high temperature generated by electric energy. However, these methods are only for local control, unable to achieve fundamental blood flow blocking, and most operations need to be performed successfully

in the environment of open surgery, which will still affect the surgical process. The key point of this study is how to design a blocking device that can be inserted into the human body, make use of the particularity of the location of the first hepatic hilum to perform fundamental blood flow blocking of the first hepatic portal and improve the success rate of laparoscopic surgery.

In this paper, combined with laparoscopic liver clinical surgery, the first hepatic portal blood flow blocker is designed. This filling blocking device makes use of the pressure generated by fluid entering the airbag, making the airbag expand rapidly and squeezing the vascular space to achieve the blocking effect. In addition, the dynamic pressure required by the device was calculated by using fluid mechanics, and the fluid velocity was calculated by deducing and calculating by energy conservation equation and momentum conservation equation in combination with ANSYS software analysis. Finally, the feasibility of the device was evaluated by simulating the flow state of blood vessels and blood under normal and blocked conditions in vitro.

Methods

2. Introduction to the structure

In this paper, a filling blood flow blocker is designed by summarizing the deficiency of existing blood flow blockers. The filling blocker takes advantage of the pressure of fluid entering the airbag, causing the airbag to expand rapidly, squeezing the surrounding vessel space to stop the flow. Compared with the common blocking, this method has a great improvement in the method by using the nature of the material itself to extrude. The airbag blocking uses the pressure of the fluid to exert pressure. The process of applying pressure is gentle and the adjustable space is large. Moreover, the materials are all flexible materials with good elasticity, which reduces the direct

damage of the materials to the human body.

2.1 Structure design

Adhering to the principles of convenient operation, simple and safe structure, and strong control, through observation in clinical surgery, the designed structure is columnar, which is easy to penetrate into the human body.

The first hepatic portal is located at the lower right part of the liver, and the distance from the puncture site to hepatic porta; is about 10-15cm, while the maximum diameter of the puncture is 12mm. Therefore, in the design process, the device should be able to enter the human body smoothly, so the diameter should not exceed 12mm. In order to ensure the effective effect of the object, the diameter was set to 12mm, and the outer casing for puncture was set to 15mm. The overall structure is shown in **Fig1**.

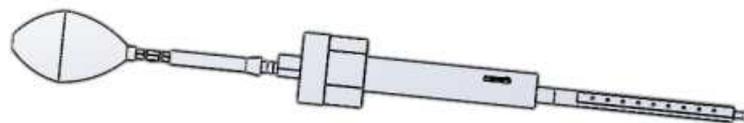


Fig1.Structure diagram of blood flow blocker

2.2. Description of the parts

The power unit of the blood flow blocker uses a balloon, which consists of a rubber balloon and a control valve and a one-way valve. There are connecting holes in front and rear of the balloon, one end is used to connect the one-way valve to maintain communication with the atmosphere, and the other end is connected to the air supply pipe through the control valve. The one-way valve ensures the stable input of gas, which can be obtained by squeezing the balloon. After the balloon is released, it will automatically recover due to atmospheric pressure, saving the step of gas storage (liquid), which is more convenient and fast. Control valve controls the direction of gas flow and can

discharge excess gas, so that the gas into the device does not return, which keeps the internal pressure in balance. The balloon which has a good restorative is an important characteristic of the power plant, which facilitates repeated operation until vascular occlusion is achieved.

The gas that comes in through the power plant needs to be passed inside, so you need to have the right structure to do that. After the conduction device enters the human body, it will have a certain displacement with the change of internal organs, so the device itself needs to have a good fixation effect to play a good role in the operation. The designed conduction device is mainly composed of screw cap, outer casing, conduit, fixing part and spring. The outer casing, as the carrier of the catheter, sends the catheter and other parts into the human body through puncture. The coordination between the screw cap and the outer casing can effectively reduce the displacement of the fixator and the catheter, so that their positions are relatively fixed. As the main component, the catheter is connected to the power device through a rubber pipe at one end, which is connected with a multi-section round table, and is closely connected by the friction force of rubber. The other end is connected with the airbag and provides power for it. The fixator is slightly shorter than the catheter and has the same groove below as the outer casing. The free end of the airbag can be secured by dislocation of the two grooves. The two springs are placed below the catheter and the fixer respectively to automatically reset the device.

The porous airbag is made of a soft plastic material that can form a wrap around the target location to meet the operating environment at normal temperature. The outer layer of the airbag is a layer of medical rubber which is easy to expand under pressure. When the air pressure is generated inside the bag, the gas is exported through the porous hole. The barrier of the medical rubber makes itself expand, and the volume increases gradually, reducing the space around the part, so as to block the blood flow^[4]. The medical soft glue material also has the characteristic which is safer and more reliable.

Results

3 Parameter setting

3.1 Speed setting

The gas is produced by squeezing the balloon and entering the porous balloon via a conduction device. The porous balloon passes gas through various apertures and transports the gas to the external deformable rubber membrane. Due to the location of pore size, the gas flow velocity generated is different, the different flow velocity leads to different deformation of rubber mold, so a suitable flow velocity is needed to ensure the stability of internal fluid movement, but also to let the fluid flow evenly to each hole.

The complexity of the fluid movement process determines the complexity of the calculation. Based on the basic equations of energy conservation, momentum conservation and mass conservation, the flow velocity of the fluid is calculated and analyzed.

Pretreatment: Assume that the fluid is incompressible.

After a series of calculation, the simulation study combined with ANSYS software shows that when the flow velocity reaches 8m/s, the fluid flow through the pore has the best effect, and the flow velocity has the best effect on the filling of the porous balloon.

3.2 Output pressure setting

The gas velocity in the flow passage is mainly determined by the pressure provided by the power device. The greater the pressure is, the greater the flow velocity will be. Bernoulli equation is adopted to analyze and calculate the output pressure of the power device to ensure that the flow velocity of each hole into the porous balloon is relatively stable.

In the process of flow through the conduction device, the pressure will decrease due to the friction between the air flow and the inner wall of the device and the change of pipe structure. Therefore, this pressure drop is calculated by hydromechanics, and this loss is compensated by increasing the pressure at the output.

Pretreatment: Assume the air is an incompressible ideal gas, the environment is the first hepatic portal, and the initial pressure inside and outside the power unit is 1MPa. Under this condition, mechanical calculation is carried out for the internal fluid. **Fig2** shows the simplified channel of the device.

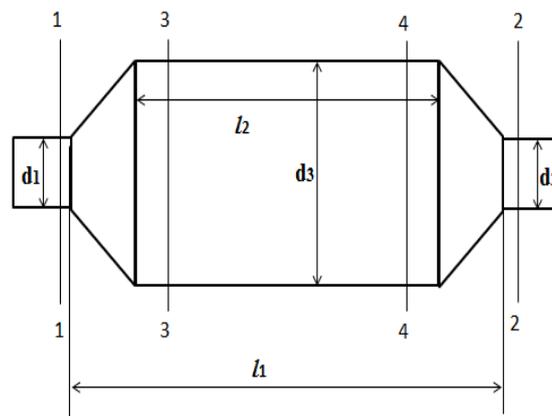


Fig2.Fluid channel simplification

Bernoulli equation is used to calculate:

$$Z_1 + \frac{P_1}{\rho g} + \alpha_1 \frac{v_1^2}{2g} = Z_2 + \frac{P_2}{\rho g} + \alpha_2 \frac{v_2^2}{2g} + \Delta h \quad (1)$$

Pressure drop loss in the whole process: $\Delta P = \rho g \Delta h = 286.05 \text{ Pa}$. Atmospheric pressure (i.e. external pressure of the device) under normal condition is taken as $P_2 = 1.013 \times 10^5 \text{ Pa}$. Finally, it is calculated that the initial pressure of the power unit needs to reach $1.016 \times 10^5 \text{ Pa}$. Since the internal pressure will be increased after each pressurization, the subsequent output pressure needs to be

continuously pressurized during the use of the device, it must not be lower than 286Pa each time to achieve continuous gas injection, so as to ensure the relatively stable flow velocity of the fluid.

3.3 Block pressure calculation

The above has calculated the initial pressure provided by the power plant, and also calculated each need more than the last increase of the pressure, to achieve the effect of blocking porta, it is impossible to apply pressure again and again without limit, in order to provide an estimate of the blocking pressure to subsequent operators of the device, and prevent damage blood vessels, this paper carried out the first hepatic portal to block the calculation of the pressure.

To block the first hepatic portal is to focus on blocking the hepatic portal vein and hepatic artery^[5]. In the process of blood flow of hepatic portal vein and hepatic artery, the pressure is applied to the outer wall of the vessel to reduce the flow velocity of blood. Complete blocking is not needed in the process of liver surgery, as long as the blood flow velocity drops significantly, a small amount of blood flow will not affect the blocking effect. The diameter of hepatic artery is about 2-5mm, and the blood flow velocity is about 0.19m/s, so the pressure drop is smaller than that of hepatic portal vein. Therefore, in the calculation of blocking pressure, we can directly select the blocking pressure required by hepatic portal vein, and block other relatively small vessels while blocking hepatic portal vein.

Pretreatment: Blood was treated as an incompressible fluid, and a simulation diagram of hepatic portal flow was established. The Y-axis direction was the direction of blood flow. As shown in Fig3.

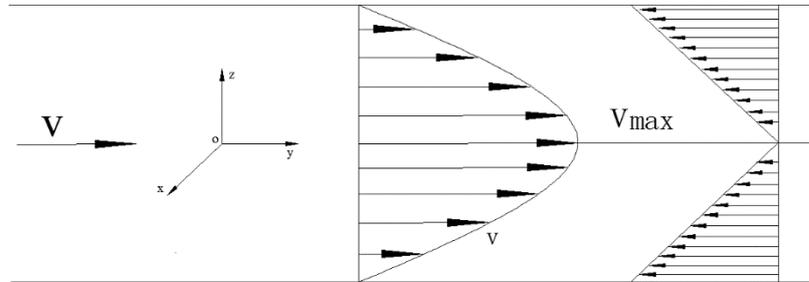


Fig3.Simulation of hepatic portal vein flow

Establish force balance equation:

$$f_y - \frac{1}{\rho} \frac{\partial p}{\partial y} + \nu \left(\frac{\partial^2 v_y}{\partial x^2} + \frac{\partial^2 v_y}{\partial y^2} + \frac{\partial^2 v_y}{\partial z^2} \right) = (2) \frac{\partial v_y}{\partial t} + \frac{\partial v_y}{\partial x} v_x + \frac{\partial v_y}{\partial y} v_y + \frac{\partial v_y}{\partial z} v_z \quad (2)$$

After a series of calculation can be derived for the pressure variation $\Delta p=27.9\text{Pa}$. The male portal vein pressure is 1640Pa , so at least 1667.9Pa is required for blocking. The male portal vein pressure is slightly higher, so the pressure of blocking the male hepatic portal vein can be applied to the female patients relatively. Therefore, the operator can carry out subsequent pressurization operation according to this estimated value to prevent excessive or insufficient pressurization, which has guiding significance for practical operation.

4 Dynamic analysis

The motion state of the fluid in the airbag is based on the motion effect generated after the gas is delivered to the airbag by the conduction part of the power device under the ideal state. By studying the motion state of the fluid, we can predict the possible deformation of the airbag, and then select the appropriate flow rate for filling. According to the research, CFD (Computational

Fluid Dynamics), namely Computational Fluid Dynamics^[6], is adopted to analyze the Fluid dispersion process of the airbag and its exits, and the changes generated by various parts of the airbag can be obtained.

4.1 Modeling

The key structure of the blood flow blocker is the airbag structure which is in direct contact with the patient, the motion state of the fluid inside the airbag directly affects the expansion state of the external structure. Therefore, in the design process of blood flow blocking device, the analysis of the balloon structure becomes the most important. At present, the state analysis of fluid movement changes inside the airbag can be carried out mainly through ANSYS CFD software. Under given conditions, the process and movement trend of fluid flowing through the airbag and then flowing out from different outlets can directly reflect the blocking effect of the device. Modeling with SolidWorks, as shown in **Fig4**.



Fig4.Structure diagram of airbag

ANSYS CFD fluid analysis software was used to reconstruct the model of the airbag. The geometry software in Workbench was used for reconstruction, and the Fill tool was used to Fill cavity of the airbag^[7]. First, select the boundary line of channel to form a closed surface. After selecting the generate button, the filling effect as shown in the figure below is formed. The green

part is pipeline of fluid movement, as shown in **Fig5**.

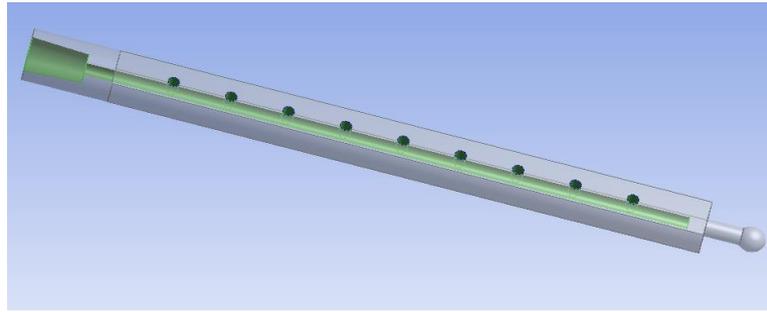


Fig5.Fluid channel finite element model

4.2 Meshing

The first step of grid division is determination of cell length, which directly determines the density and number of grids. The larger the cell length is, the smaller the number of grids will be, and the larger the gap between grids will be. The calculation results may not fully reflect actual stress situation, or even ignore calculation of some danger points^[8].

Based on Saint Venant's theory, we can use encrypted local key points to divide the grid. The channel inside the airbag is tubular, and exit part is locally encrypted to improve accuracy and reduce unnecessary errors. The tetrahedral mesh is adopted here to facilitate calculation.

The tetrahedral unstructured grid was used to divide the flow field area of the fluid channel, and some key parts were encrypted, as shown in **Fig6**. The final number of flow channel grids was about 100,000, and the quality of the divided grids was tested and evaluated by the unit quality standard, as shown in **Fig7**.

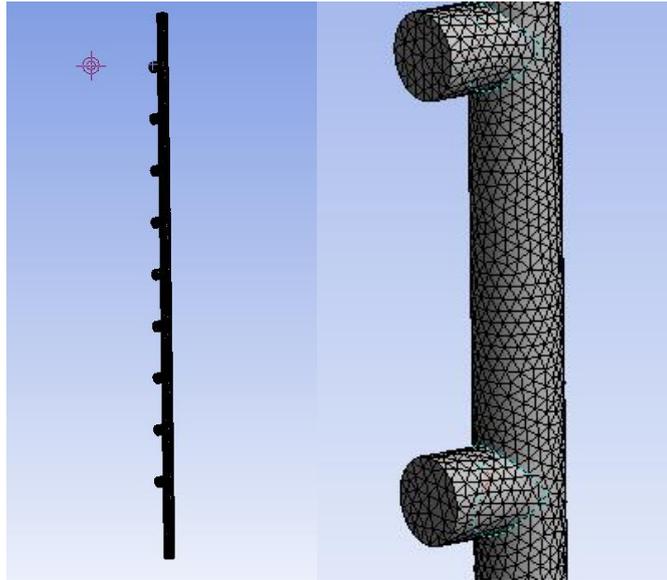


Fig6.Grid division and local enlargement

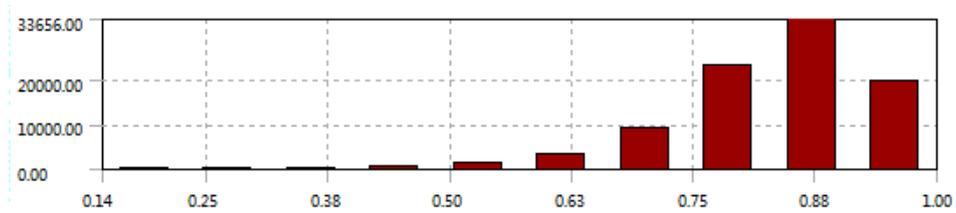


Fig7.Grid quality detection for fluid channels

Most of the mesh quality is more than 0.8, which can meet general calculation requirements^[9].

4.3 Simulation results

When ANSYS is used for fluid mechanics analysis, after the device is modeled and meshing is divided, the boundary conditions for experimental analysis need to be set, which are mainly based on the range of fluid movement inside the balloon, including: inlet boundary conditions, outlet boundary conditions, and wall boundary conditions. Through analyzing the calculation of above parameters, the boundary condition of ANSYS analysis is set, and the outlet boundary condition is set as the default pressure, the export of boundary condition were set to inlet flow 2, 4, 6, 8, 10 m/s, 5 groups of different flow velocity of the air inside the balloon channel under the motion state of

comparison, and qualitative evaluation of the best airflow velocity analysis is applicable to the balloon.

Fig8 shows the velocity cloud diagram and velocity vector diagram generated by gas passing through various apertures of porous balloon at the velocity of 8m/s. The graphs at other velocities have been omitted. The experimental velocity was set as 2m/s, 4m/s, 6m/s, 8m/s and 10m/s. The color of picture indicated the difference of velocity, the velocity vector diagram shows the change of velocity direction of the flow through the channel under a given condition.

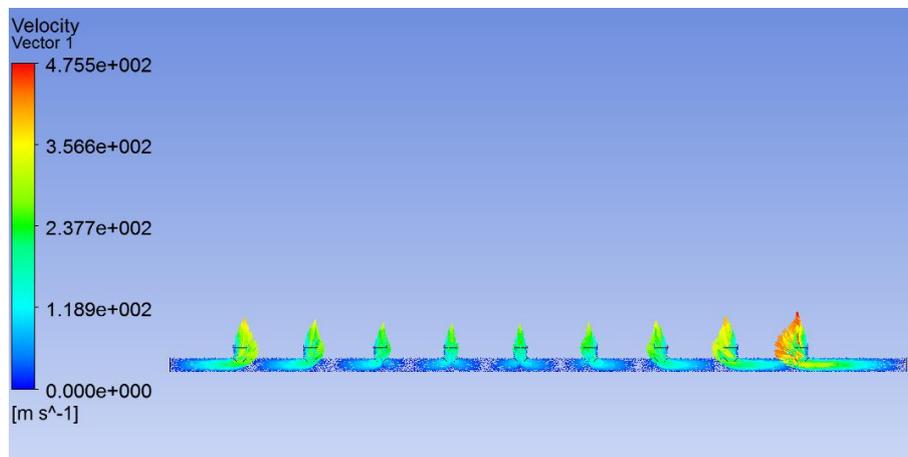


Fig8.Velocity vector diagram

By comparing the experimental results of figure above and omitted figure, it can be seen that the overall movement trend is the closest at a speed of 8m/s, which is favorable for gas filling, and the velocity trend is quite obvious. At the speeds of 2m/s and 4m/s, the overall movement trend is not particularly strong, which may lead to the fact that the gas flow rate may be too slow during the restart process, and the airbag cannot expand rapidly, not as effective as it should be. When the velocity exceeds a certain limit (10m/s), the local velocity increases obviously, but the overall velocity does not have much upward trend. Since the gas velocity directly affects the effect of inflation, overspeed is also a waste. In addition, too fast speed may also directly affect the physical

changes of materials during the aeration process. Based on the study of 8m/s velocity, it can be found that the velocity change of whole structure is relatively gentle and can meet the speed requirement of the device, which is more reasonable.

5 Simulation experiment

In order to better verify the rationality of the device, the rationality and practicability of design structure were verified by in vitro simulation experiments. The most direct way to verify the blocking effect of the blood flow blocker is to block the corresponding blood vessels by simulating the blocker, observe the change of blood flow velocity and the expansion of the porous balloon, and judge whether the blood flow velocity is reduced to a reasonable range and the overall expansion effect of the balloon to meet the requirements of the operation. The rationality of device can be effectively evaluated by simulating the flow mode of blood and the basic characteristics of blood vessels and applying reasonable pressure to it to achieve the desired purpose.

5.1 Selection of experimental materials

1. Blood is prone to biochemical changes in vitro, resulting in a series of physical and chemical properties will be changed. After a series of comparison, we chose milk which is very similar to the physical and chemical properties of blood as a substitute. The density of milk was 1.03, the average specific gravity was 1.032, and the relative viscosity was about 3, which was very close to the physical and chemical properties of blood.

2. This experiment is to simulate the blocking of the first hepatic portal. Since the first hepatic portal mainly contains multiple blood vessels, the portal vein with the largest diameter is selected to simulate experiment. The diameter of the portal vein is between 6-10mm and the

thickness of the outer wall is about 1mm. In the experiment, the silicone catheter with the diameter of 8mm and the thickness of the outer wall is 1mm was selected as the substitute of the blood vessel in vitro. The 1500mL drainage bag is used to hold fluid and control blood flow by controlling the outlet valve. **Fig9** shows the catheter and drainage bag.

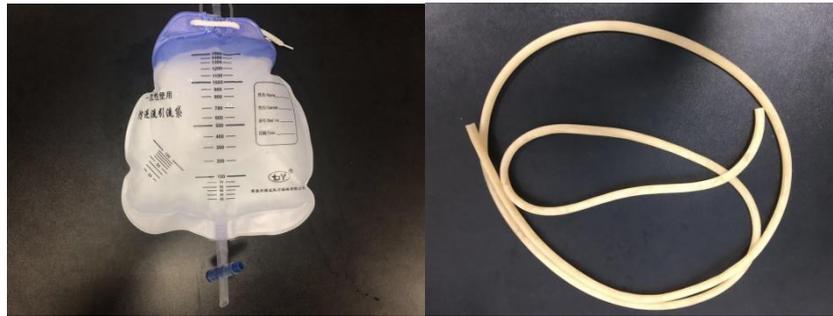


Fig9.Silicone catheter and drainage bag

3. The flowmeter selected for the experiment is the glass rotameter, as shown in **Fig10**, which can directly measure the velocity of fluid. Fluid flows in from below and out from above, and the flow rate can be read out by observing the height of the float, thus using the continuity equation to calculate the flow velocity. According to the portal vein flow rate of 1.1L/min, a rotameter with a range of 10-100L is selected.



Fig10.Glass rotameter

4. Aluminum alloy steel frame can be used to fix the height of the drainage bag. The bottom

of the drainage bag is connected with a silicone catheter to simulate blood vessels, and the height of the drainage bag is adjusted to provide a certain speed of fluid with gravitational potential energy.

5.2 Experimental steps

5.2.1 Setup of experimental equipment

Hepatic portal vein blood pressure was measured at about 1650Pa and blood flow velocity was 0.2m/s. The feasibility of the device was tested by in vitro experiments designed to simulate the pressure and flow rate of blood vessels. The height of the fluid can be calculated from the hepatic portal blood pressure at about 0.16m, which is basically consistent with the pressure in the blood vessel. Then the velocity of the free-falling body at this height can be calculated as 0.18m/s, which is similar to the blood flow velocity. Therefore, the experimental platform built is shown in **Fig11**.



Fig11.Experimental device platform

5.2.2. Experimental operation

The flow velocity of the portal vein was 0.2m/s, the experiment kept the same flow velocity, the internal diameter of the silicone catheter was 8mm, it can be calculated that the flow rate is 36.2L/h, which is in line with the range of the rotor flowmeter. Connect the other end of the catheter

to the inlet of the rotameter, turn on the switch of the drainage bag, observe the reading of the rotameter by adjusting the height, fix the drainage bag and close the switch when it is adjusted to 36L/h.

The catheter fitted with the blood flow blocker is completely wrapped around the catheter and the adjusting device is installed. Because the designed blocker is enlarged, a metal rod is bound to the outside of the silicone catheter. Open the switch of drainage bag and let the fluid start to flow. At the same time, squeeze the power device by hand. The front airbag expands, and the flow velocity in the catheter gradually slows down, recording the change of flow velocity after each pressure. Constantly adjust the height of the drainage bag, test the fluid velocity changes at different heights, and conduct a control experiment with diluted milk. The recorded data are shown in **Tables1** and **2**.

Table1

Speed of milk flowing down from different heights

Height/m	0.4	0.5	0.6	0.7
Flow/L · h ⁻¹	36	39	52	61
Velocity/m · s ⁻¹	0.199	0.216	0.288	0.337

Table2

Speed of diluted milk flowing down from different heights

Height/m	0.3	0.4	0.5	0.6
Flow/L · h ⁻¹	36	42	51	60
Velocity/m · s ⁻¹	0.199	0.232	0.282	0.332

5.3 Experimental results and analysis

The recorded data were processed to analyze the variation trend of velocity of milk under the

action of blood flow blocker at different heights, as shown in the annex to **Fig12**.

The initial velocity varies with the height of the drainage bag. After blocking by the blocker, the fluid flow velocity decreases significantly within 0-8 seconds, and the meter reading is basically maintained below 8L/h. Compared with the initial flow rate, this data is reduced by more than 85%, and the simulated catheter flow rate is effectively controlled. This proves that in the case of high blood flow rate, the blocker can also have an obvious blocking effect on blood vessels, and finally maintain a stable low-speed condition, creating a stable environment for surgery. At present, we can only rely on the operation experience of doctors to control the hepatic hilum blocking, without quantitative control.

Studies have shown that men and women have certain differences in blood density, and there are significant differences in blood density at different time periods. The viscosity also increases when the blood is dense, and decreases when the blood is less dense. This will affect the actual flow rate of occlusion, but has no significant impact on the effect of occlusion, so the blocker can still effectively block the blood flow to achieve a safe surgical condition.

6 Discussion

However, in the process of simulation experiment, the simulation device used in the experiment still has a certain gap with the human body in structure. The use of gas can control the flow velocity of blood, but it cannot completely block the flow of blood. These results suggest that gas is effective in reducing the speed of blood vessels, but further structural improvements are needed to completely block blood flow.

7 Conclusion

In this paper, a blood flow blocking device is designed for the bleeding problems in laparoscopic surgery, through SolidWorks software to structure model, through calculation of the basic equation and analysis of ANSYS, the appropriate velocity is obtained, the output pressure of the power plant was obtained through analysis and calculation, in order to facilitate the operator of the subsequent operation, the blocking pressure is calculated.

In order to verify the rationality and practicability of the design structure, after the completion of the plant design, through 3D printing, print out the material object, has carried on the simulation experiment in vitro, and a series of analysis were made to the data, it is concluded that the blocking effect of the blood flow blocking device plays an obvious role in the experiment, the flow speed of fluid is greatly reduced. And the time of speed change is relatively short, which can achieve the blocking effect in a short time. Through the adjustment of the control valve, the blood flow velocity can be effectively changed, real-time control of blood flow velocity.

List of abbreviations

CFD: Computational Fluid Dynamics

Declarations

Ethics approval and consent to participate

This article does not involve any ethics.

Consent for publication

No personal data is involved in this article.

Availability of data and materials

All data generated or analysed during this study are included in this published article (and its supplementary information files).

The datasets generated during and/or analysed during the current study are available in the [NAME] repository.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

GQS was the initiator of the project and SSY was the writer of the paper. All the authors participated in the research and experiment of the project, All the authors contributed equally to the article. All authors read and approved the final manuscript.

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Figures

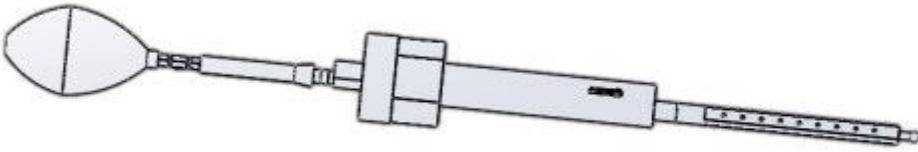


Figure 1

Structure diagram of blood flow blocker

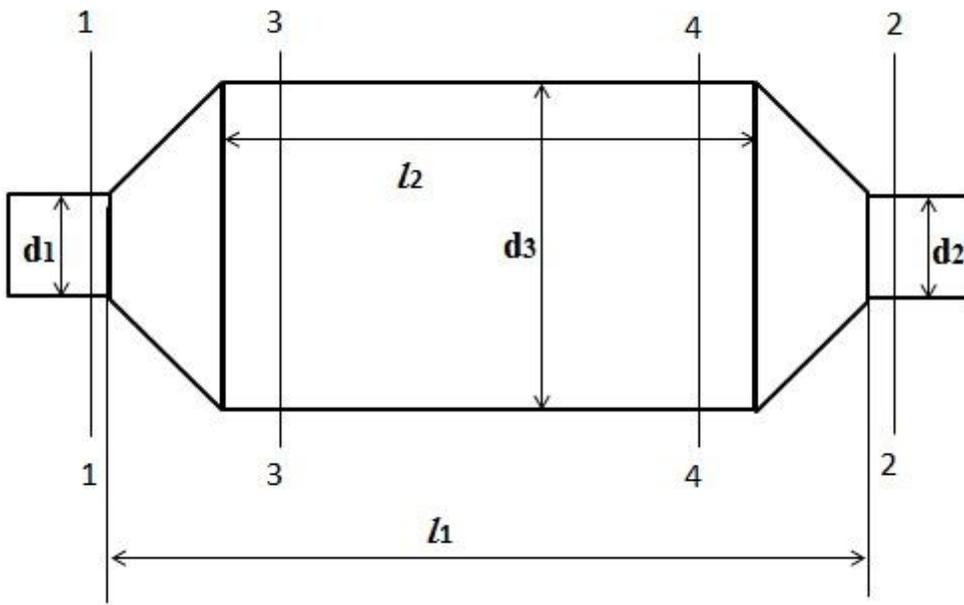


Figure 2

Fluid channel simplification

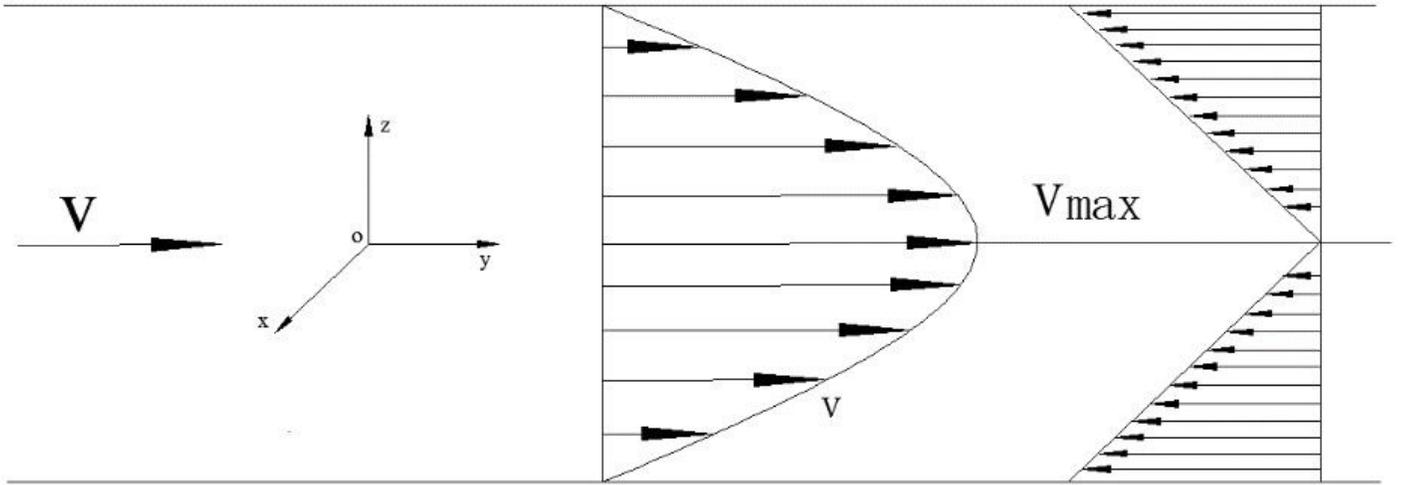


Figure 3

Simulation of hepatic portal vein flow



Figure 4

Structure diagram of airbag

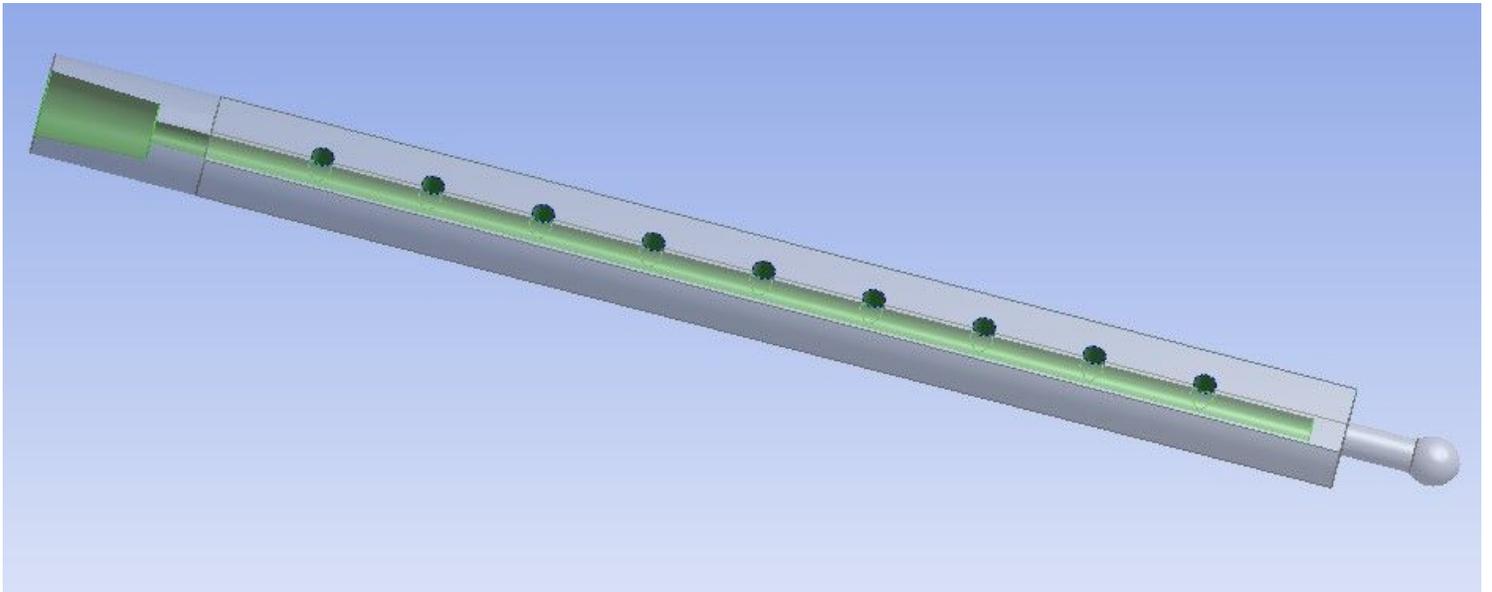


Figure 5

Fluid channel finite element model

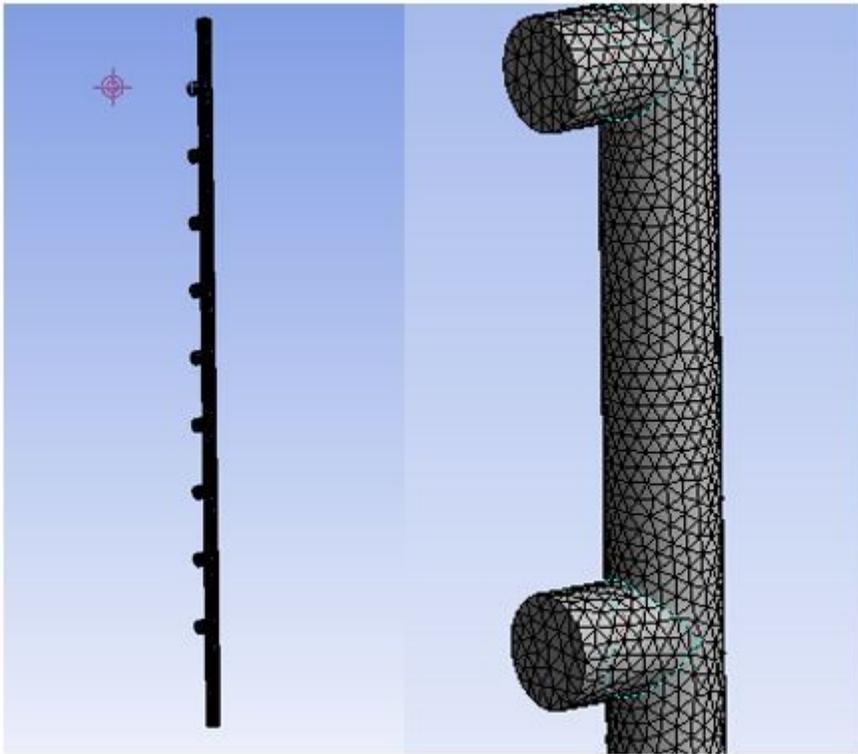


Figure 6

Grid division and local enlargement

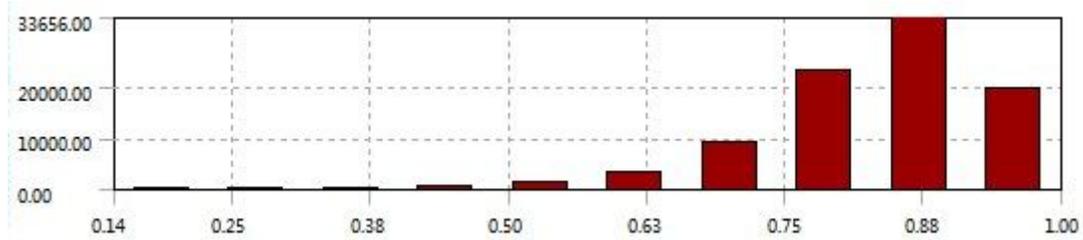


Figure 7

Grid quality detection for fluid channels

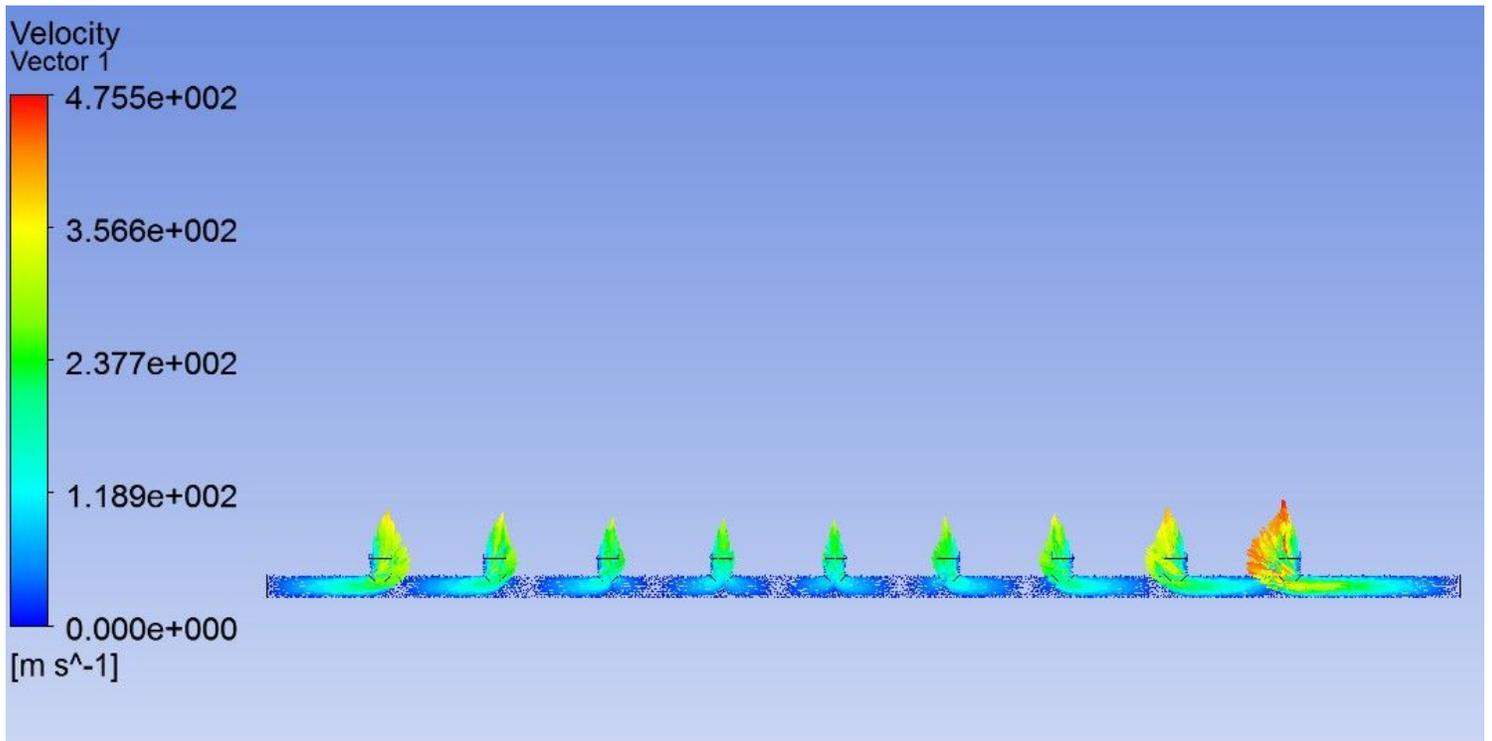


Figure 8

Velocity vector diagram

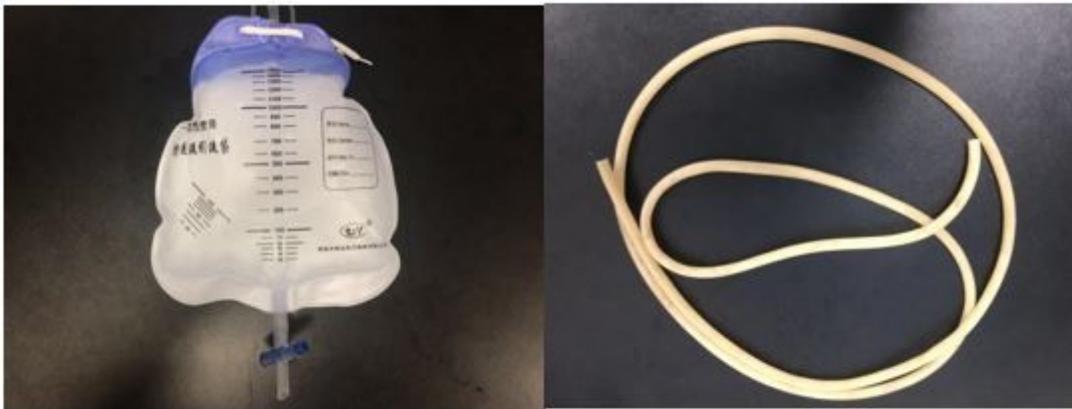


Figure 9

Silicone catheter and drainage bag



Figure 10

Glass rotameter



Figure 11

Experimental device platform