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An Analysis on the Application of In-vitro Experimental Fluid Circulation Loop in the Evaluation of Cardiac and Cerebral Circulation Medical Devices

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ABSTRACT

Conventional medical-device evaluation often involves animal experiments and clinical investigations, both of which require substantial time and resources and are subject to ethical and practical constraints. Both require significant investment and a long period of time, have numerous ethical constraints, and once the testing plan is set, it is difficult to make changes. It is even more challenging to conduct innovative tests. With the acceleration of device updates, this verification model has become increasingly strained. Cardiovascular and cerebrovascular diseases impose a substantial clinical burden, and the performance of related medical devices directly affects treatment outcomes and postoperative recovery. The pressure on public health prevention and control is constantly increasing. At the clinical level, the performance of cardiovascular and cerebrovascular devices directly affects the treatment outcome and postoperative recovery quality of critically ill patients, and they are indispensable equipment in intensive care. The introduction of the extracorporeal circulation circuit system has opened up a new way for verification work. This system can simulate the real hemodynamic conditions of the human cardiovascular system, and the experimental parameters can be adjusted as needed, precisely compensating for the shortcomings of traditional methods. This article focuses on the engineering implementation and application of this platform. Based on experimental records and long-term practical experience, the author explains the hardware composition, operating characteristics, and simulation accuracy of the system, and combines detection examples of interventional and circulatory support devices to examine their actual test results. During the experiment, some problems have also been gradually exposed: there is still a deviation between physiological simulation and the real environment, the performance stability of the supporting consumables is poor, and the industry test standards have not yet been unified. These aspects constitute the key topics of discussion in this article. The above research results provide a basis for the structural optimization, parameter calibration, and standard formulation of the extracorporeal evaluation system, and have direct reference significance for the preclinical verification of similar medical devices.

KEYWORDS

Extracorporeal fluid circulation circuit; Cardiovascular and cerebral circulation; Medical apparatus and instruments; Haemodynamics; Separate assessment

1. INTRODUCTION

In recent years, the incidence groups and patterns of cardiovascular and cerebrovascular diseases have undergone significant changes. The disease characteristics that were previously prevalent among the elderly have gradually weakened, while the number of acute and severe cases among young and middle-aged individuals has been increasing year by year. The trend of younger onset has become more pronounced, further increasing the clinical treatment pressure. These diseases progress rapidly

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and have high uncertainty in prognosis. The treatment of severe cases heavily relies on the assistance of sophisticated medical equipment. For critical conditions such as acute cerebral vascular occlusion and severe cardiac function damage, interventional devices and extracorporeal circulation auxiliary equipment can quickly correct the disordered blood circulation state and effectively improve the survival rate of critically ill patients [1].

The advancement of bionic manufacturing and precision processing technologies has driven the continuous update and iteration of cardiovascular and cerebrovascular medical devices. Various new stents, embolic devices, and heart-assist devices have gradually been applied in complex and high-risk clinical scenarios. With the upgrade of device technology, industry assessment standards have been continuously tightened, with the focus shifting from basic function verification to the stability of the equipment in complex blood flow environments, clinical compatibility, and long-term use safety. Higher requirements have been placed on the early design and detailed testing of the devices.

Currently, Animal experiments and clinical investigations remain important components of conventional medical-device evaluation, but these approaches involve relatively long development cycles, substantial costs, biological variability, and ethical constraints. The traditional verification model has obvious shortcomings. The complete performance verification tests take several months and have a long development cycle, making it difficult to match the rapid product iteration rhythm of enterprises. At the same time, experimental animals have individual physiological differences, which can cause fluctuations in test data and poor stability and reusability of the results [2]. In addition, the strict ethical review constraints have restricted the conduct of innovative experiments, which has somewhat delayed the development and clinical translation progress of new devices.

Based on this, this paper relies on long-term experimental accumulation and measured data to systematically analyze the technical characteristics, application scenarios, and existing defects of this platform, providing a reference for industry technology optimization and the improvement of the assessment system.

2. THE COMPOSITION STRUCTURE OF THE FLUID CIRCULATION CIRCUIT IN THE IN VITRO EXPERIMENT AND ITS PHYSIOLOGICAL SIMULATION CAPABILITY

2.1. Overall Equipment Architecture And Selection of Simulation Medium

To accurately reproduce the true physiological state of blood flow in the human body, this study employs a modular architecture to construct a dedicated liquid circulation testing platform. By integrating core functional units—including power output, vascular compliance simulation, biomimetic vascular modeling, blood flow parameter acquisition, and temperature-controlled fluid storage—the platform forms a complete in vitro blood flow simulation system. These functional components work together synergistically to effectively replicate the hemodynamic characteristics of systemic and cerebral circulations, restoring realistic physiological blood flow conditions. Based on this experimental platform, systematic evaluation of cardiovascular and cerebrovascular medical devices for blood flow compatibility can be conducted, enabling objective assessment of how well devices match the human blood flow environment [3]. This provides standardized, controllable in vitro experimental support for device performance validation, ensuring test results truly reflect the devices' clinical applicability.

The selection of the simulation medium directly determines the simulation effect of blood flow. Most in vitro simulation experiments in worldwide use a glycerol-water mixed solution instead of human blood. This medium has a constant temperature viscosity of 3.39 cP, which is similar to the viscosity of healthy adult whole blood, and can meet the requirements for basic hemodynamic parameter detection. However, this medium can only simulate a single viscosity index of blood and cannot

reproduce the blood cell components and rheological properties. It is only suitable for pure physical parameter testing and cannot conduct biological interactive composite experiments. It is a prominent technical limitation in the current in vitro evaluation system.

2.2. Bionic Structure Design And System Physiological Simulation Accuracy

To reduce the differences between the in vitro test environment and the actual physiological environment of the human body, this study adopted an integrated silicone casting process to fabricate biomimetic pipelines. This process can precisely control structural parameters such as the pipe diameter and wall thickness, closely replicating the anatomical morphology and elastic characteristics of human blood vessels [4]. Compared to traditional spliced pipelines, the integrated molding structure can eliminate blood flow disturbances at interface positions and reduce system test errors. It is the optimal structural solution after multiple rounds of trial optimization.

The measured results show that the simulation accuracy of this platform meets the industry in vitro evaluation standards. The platform's aortic compliance can reach 1.75 mL/mmHg, which is within the normal physiological range of 1.5-2.0 mL/mmHg in the human body, and can fully reproduce the dilation and contraction changes of blood vessels during the cardiac cycle. The equipment can operate stably for a long time and simulate the normal blood pressure range of 80-120 mmHg in the human body. In terms of parameter matching, the pressure simulation error of the brain artery branch of the platform is controlled within ±7%, and the blood flow distribution ratio of the carotid artery and intracranial blood vessels and the clinical measured data deviate by less than 10%, which can meet the accuracy requirements of conventional medical device evaluations. It should be noted that the platform can only simulate the normal physiological blood flow state of the human body and cannot precisely replicate the abnormal blood flow environment caused by various cardiovascular diseases [5].

2.3. The Application Advantages And Applicable Scenarios of the in Vitro Experimental Platform

Compared to animal experiments, this in vitro testing platform has greater controllability of working conditions. During the test process, it can precisely lock onto a single research variable, avoiding data fluctuations caused by individual physiological heterogeneity of animals, effectively improving the stability and repeatability of the test data, and being suitable for the early performance screening and parameter optimization tests of medical devices.

This platform has no ethical review restrictions, lower test costs, and a wider range of adjustable parameters. It can support various tests such as the initial performance screening of new devices, comparison of multiple parameters, and long-term stability verification. In the complete process of device development, the in vitro platform cannot replace the clinical value of live experiments, but can be used as a pre-test method to quickly screen the optimal device structure and operating parameters, reducing the trial-and-error costs of subsequent live experiments and improving the overall development efficiency [6].

3. THE PRACTICAL APPLICATION OF THE EXTRACORPOREAL FLUID CIRCULATION CIRCUIT IN THE EVALUATION OF CARDIOVASCULAR AND NEUROLOGICAL MEDICAL DEVICES

The extracorporeal fluid circulation circuit has evolved from a single blood flow simulation device to a standardized evaluation platform for the refined development of medical devices. Based on years of practical experience, the core applications of this platform focus on three aspects: hemodynamic assessment of interventional devices, biocompatibility testing of circulatory assist devices, and

verification of fluid simulation results. This chapter, by combining measured data and experimental cases, elaborates on the practical application value of the platform.

3.1. Evaluation of the Hemodynamic Effects of Interventional Devices

Interventional devices such as coronary stents, intracranial aneurysm stents, embolic devices, and artificial heart valves are the core treatment equipment for high-risk cardiovascular and cerebrovascular diseases in clinical practice. After being implanted, these devices will directly alter the blood flow distribution in the affected area. The effect of blood flow optimization directly affects the postoperative rehabilitation quality and long-term prognosis of patients. Therefore, hemodynamic assessment is a core testing item before the device's market launch and an important quantitative basis for determining the clinical effectiveness of the device [7].

This study adopts an individualized simulation assessment method. Based on the preoperative medical imaging of patients, a cerebral vascular anatomical model is reconstructed. After connecting to the circulation circuit, the patient-specific physiological blood flow environment is replicated. Compared with the general standardized model, the individualized simulation scenario is more in line with clinical real cases, and the assessment data has higher reference value. During the experiment, parameters such as blood pressure, blood flow velocity, and blood flow direction in the lesion area can be collected in real time, and the blood flow regulation and lesion isolation effects of the device can be quantitatively evaluated intuitively.

The data from the control trial show that there are significant differences in the blood flow optimization effects of different intervention schemes. Simply implanting a blood flow guiding device can reduce the average blood flow velocity inside the aneurysm by 42%, which can slightly improve the abnormal blood flow in the lesion area, but cannot completely avoid the various clinical risks caused by abnormal blood flow. After using a combined intervention scheme of blood flow guiding device and liquid embolic material, the blood flow velocity inside the aneurysm can be reduced by up to 67%, and the effect of lesion blood flow stasis and vascular remodeling quality are significantly improved [8]. The intervention effect is significantly better than that of the single-device treatment mode.

The above quantitative data can be directly used for device performance comparison, clinical indication screening, and treatment plan optimization. At the same time, the platform can capture the dynamic changes of blood shear stress, and abnormal shear stress is an important factor inducing vascular damage and thrombosis. Relevant measured data can guide the R&D personnel to optimize the device structure and surface processing, improving the device's blood flow compatibility and safety. In addition, in vitro pre-test can reduce the consumption of live test samples, compress the R&D cycle and test cost, and has high industrial application value.

3.2. Performance and Biocompatibility Testing of Circulatory Assist Devices

Ventricular assist devices, aortic balloon counterpulsation, ECMO accessory tubing, and other circulatory assist devices have direct contact with human blood for a long time. The blood compatibility of the equipment directly determines the clinical safety of use and is the core indicator for evaluating the performance of the devices. Among various influencing factors, the impact of the device's operating mode and working conditions on blood stability is the most prominent.

To clarify the influence of the operating mode on the blood compatibility of the device, this study used the NIH hemolysis index as the evaluation standard and conducted a 6-hour continuous working condition control trial. The results showed that the hemolysis index of the device in the pulsatile flow mode was 59.6 ± 14.5 mg/100L, while that in the non-pulsatile steady-state flow mode was 37.3 ± 12.4 mg/100L. The degree of blood damage in the pulsatile flow condition was significantly higher [9]. This result confirmed that choosing a reasonable operating mode can effectively reduce the risk

of blood damage and provide data support for the calibration of device working conditions. This trial focused only on the single variable of operating mode and did not include factors such as pipeline friction and test duration. The research conclusion is only applicable to the set working conditions.

This platform can adjust parameters such as circulation resistance, vascular compliance, and pulsation frequency to simulate the pathological blood flow environment of patients with different heart function impairments and restore the clinical real lesion scenarios. The results of the parameter optimization trial of this study showed that after precisely adjusting the equipment speed and pulsation rhythm, the blood flow of the model brachiocephalic artery could be increased from 0.63 L/min to 0.77 L/min, effectively improving the blood perfusion effect of peripheral tissues. This indicates that precise parameter adjustment can significantly improve the working efficiency of circulatory assist devices and provide practical basis for individualized parameter settings in clinical practice.

3.3. Review the Results of Fluid Simulation And Improve The Evaluation System for The Instruments

Computational fluid dynamics simulations are widely used in the preliminary research and development of cardiovascular and brain medical devices, featuring high efficiency, no loss, and low cost [10]. They are mostly applied to the optimization of device structures and the analysis of blood flow mechanisms. However, pure simulation calculations inherently have inherent errors. Issues such as boundary condition setting, material parameter selection, and meshing accuracy details can all lead to deviations in the simulation results from the actual working conditions, making it difficult for them to independently support the performance evaluation of high-precision devices.

The measured data of the extracorporeal circulation circuit is objective and repeatable, and can be used as benchmark data to correct the errors in the simulation model. In this study, after calibration and optimization using the measured data, the average deviation between the blood flow distribution simulation results and the measured data was reduced to 2.4% ± 1.70%, significantly improving the prediction accuracy of the simulation model. Currently, the industry commonly adopts a combined evaluation mode of "simulation prediction + physical verification", effectively compensating for the deficiencies of a single evaluation method and enhancing the scientificity of device performance evaluation. This is the mainstream development direction for future medical device evaluation [11].

4. THE LIMITATIONS OF THE EXTERNAL FLUID CIRCULATION CIRCUIT APPLICATION

The extracorporeal fluid circulation circuit has become the core tool for in vitro evaluation of cardiovascular and neurological medical devices. However, when considering the practical operation and current application status of the industry, this technology has not yet achieved large-scale and standardized application. There are still many shortcomings in simulation technology, consumable performance, and industry norms, which restrict the improvement of evaluation accuracy and the promotion and implementation of the industry.

4.1. The Physiological Simulation Dimension Has Limitations And Cannot Fully Reproduce The Complete Biological Mechanisms

This platform can precisely reproduce physical parameters such as blood flow pressure, flow velocity, and circulation resistance, meeting the basic requirements for evaluating the mechanical performance of medical devices.The human circulatory system combines both fluid movement and biological metabolism, and multiple physiological mechanisms are involved in its regulation [12]. The overall system is extremely complex. Ordinary fluid simulation models can only observe the surface flow state of blood. This method cannot replicate the physiological regulation process of the human body

or truly reproduce the running details of the internal blood circulation. Therefore, simple physical simulation has obvious deficiencies.

In my opinion, the generation of vascular damage and thrombosis is not caused by changes in the physical flow of blood, but by the disruption of internal biological regulation in the human body. The balance of vascular endothelial metabolism, body inflammatory response, and coagulation function will directly affect the integrity and stability of the blood vessels. When studying blood-contacting medical devices, we mainly refer to these biological changes to determine the safety of the equipment's long-term use and evaluate the compatibility between the equipment and human blood [13].

At present, most extracorporeal circulation simulation devices only conduct physical simulation tests on the fluid characteristics of blood. These devices lack key physiological components such as human cells, bioactive factors, etc., and have a significant gap from the real internal environment of the human body. Due to the lack of core biological components, this simulation system cannot reproduce the various biological reactions that occur between the device, blood, and blood vessel tissues after the device enters the human body. The extracorporeal simulation data is therefore (one-sided) and cannot be fully equivalent to the real physiological performance of the human body. We must face this issue in our research and reasonably view the reference value of the results of extracorporeal experiments.

The test data from this platform can only reflect the performance of the device in an isolated physical environment and differs from the actual physiological state of the human body. This is the core reason why in vitro tests cannot replace in vivo tests and clinical trials [14].

4.2. The Performance of the Biomimetic Consumables is Insufficient, And During Long-Term Experiments, Parameter Drift Is Prone To Occu

Conventional test consumables such as silicone tubing and 3D-printed biomimetic blood vessels can meet the short-term basic assessment needs and have the advantages of low cost and ease of use. However, in long-term and high-precision stability tests, the performance deficiencies of these consumables are more prominent, and they cannot meet the requirements of long-term experiments.

The elasticity, surface smoothness and fatigue resistance of the existing biomimetic consumables all have a gap compared to the original human blood vessels. During the long-term operation of the equipment, the consumables are continuously washed by blood flow and subjected to pressure, which will cause aging, micro-deformation, and surface wear, directly changing the core test parameters such as vascular compliance and blood flow shear force, causing data drift and reducing the credibility of long-term control experiments. The author has observed such problems in multiple long-term experiments, and the performance attenuation of the consumables is the main technical bottleneck in the long-term performance assessment of current devices.

4.3. The Absence of Industry-Wide Standards and the Poor Universality of Experimental Data

The technical flaws can be gradually improved through material iterations and equipment upgrades. However, the absence of industry standards is the core issue restricting the large-scale application of this technology. Currently, a major challenge is the lack of universally harmonized standards for in-vitro circulatory-loop testing. Differences in system configuration, operating conditions, measurement protocols, and data-processing methods reduce the comparability of results obtained across laboratories. There are no unified norms for equipment selection, operating conditions setting, operation procedures, and data determination [15].

Universities, research institutions, and enterprise laboratories mostly adopt self-built testing systems, and the test parameters and operation procedures are not uniform. Data obtained from the same batch

of equipment tested on different platforms vary significantly, making it impossible to conduct horizontal industry comparisons. The data interoperability and universality are poor. The absence of industry standards not only hinders academic exchanges and technology transfer but also prevents this technology from being included in the standardized and compliant assessment system, limiting the industry-wide popularization of the technology.

5. CONCLUSION

The extracorporeal fluid circulation circuit has significant application advantages in the evaluation of cardiovascular and cerebrovascular medical devices. This platform has no ethical constraints, low testing costs, stable data, and adjustable working conditions. It can efficiently complete core tasks such as hemodynamic assessment of interventional devices, biocompatibility testing of circulatory assist devices, and verification of simulation models. This effectively compensates for the shortcomings of traditional live experiments, which have long cycles, high costs, and numerous restrictions. In vitro testing support is the main value of this platform. The early development of devices, structural optimization, and parameter calibration can all benefit from it. However, the shortcomings are also obvious: it can only reproduce the physical-level blood flow parameters, but the biological regulatory mechanisms cannot be replicated, and the physiological simulation dimension is also relatively simple. The durability and biocompatibility of biomimetic materials do not meet the standards. As the long-term testing progresses, the data deviation becomes more and more obvious. In addition, the lack of harmonized testing protocols and evaluation criteria limits data comparability across different experimental platforms and laboratories, thereby hindering broader standardization of in-vitro circulatory-loop assessment.

In the future, technological upgrades can be promoted from two aspects: technical optimization and industry standardization. Technically, relying on new biomimetic materials and bio-factor coupling technology to enrich the simulation dimensions of the platform, narrowing the gap between the in vitro environment and the real physiological environment of the human body, and improving the test accuracy. At the industry level, integrating multiple scientific research resources, unifying test conditions, operation procedures, and evaluation standards, and establishing a standardized in vitro evaluation system. The coordinated advancement of technological innovation and standardization construction can fully leverage the technical advantages of the extracorporeal fluid circulation circuit, providing support for the innovative research and standardized development of cardiovascular and cerebrovascular circulation medical devices.

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