Reliability Evaluation of Ventricular Assist Devices

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Abstract
Reliability is a prerequisite for the clinical use of ventricular assist devices; a key factor that affects the safety of patients, and determines the expected clinical efficacy for patients. In this paper, the load/stress analysis and acceptance criteria of reliability evaluation for ventricular assist devices are discussed. The load/stress analysis defines the test stress, and the test requirements of the system. Physiological parameters, which can be viewed as stress tests, were analyzed. The thresholds under minimum, normal, and maximum loading conditions were determined. Lumped parameter models under three threshold conditions were established. Peripheral resistance and arterial compliance were adjusted by comparing the difference between the aortic pressure, left atrial pressure and cardiac output. The reliability evaluation platform was built based on simulated parameters. In the aspect of acceptance criteria, the potential failures have been analyzed, and each failure has been classified under four classes. The method for analyzing performance degradation after a reliability evaluation is given. The aim of this paper is to standardize the reliability evaluation platform and protocol of ventricular assist devices and to improve the consistency of reliability evaluation.

Key words: Ventricular Assist Device, Reliability, Load/Stress Analysis, Lumped Parameter Models, Acceptance Criteria

Evaluación de la Fiabilidad de los Dispositivos de Asistencia Ventricular

Resumen
La confiabilidad es un requisito previo para el uso clínico de los dispositivos de asistencia ventricular; un factor clave que afecta la seguridad de los pacientes y determina la eficacia clínica esperada para los pacientes. En este documento, se analizan los criterios de aceptación y análisis de carga / estrés de la evaluación de confiabilidad para dispositivos de asistencia ventricular. El análisis de carga / tensión define la tensión de prueba y los requisitos de prueba del sistema. Se analizaron los parámetros fisiológicos, que pueden verse como pruebas de estrés. Se determinaron los umbrales en condiciones de carga mínima, normal y máxima. Se establecieron modelos de parámetros agrupados bajo tres condiciones de umbral. La resistencia periférica y el cumplimiento arterial se ajustaron comparando la diferencia entre la presión aórtica, la presión auricular izquierda y el gasto cardiaco. La plataforma de evaluación de confiabilidad fue construida en base a parámetros simulados. En el aspecto de los criterios de aceptación, las fallas potenciales se han analizado y cada falla se ha clasificado en cuatro clases. Se proporciona el método para analizar la degradación del rendimiento después de una evaluación de confiabilidad. El objetivo de este documento es estandarizar la plataforma de evaluación de confiabilidad y el protocolo de los dispositivos de asistencia ventricular y mejorar la consistencia de la evaluación de confiabilidad.

Palabras clave: Dispositivo de Asistencia Ventricular, Confiabilidad, Análisis de Carga / Tensión, Modelos de Parámetros Agrupados, Criterios de Aceptación

1. Introduction
According to the Chinese cardiovascular diseases report from 2015, the prevalence of chronic heart failure (HF) in the Chinese population aged 35-74 years was 0.9% in men and 1.0% in women[1]. By December 2016,
only 2,149 heart transplants had been completed in mainland China, and a large proportion of patients could not receive transplants because there were no donors. Therefore, it is of great social significance to develop long-term, implantable, ventricular assist devices (VADs). Basically, the quality of VADs directly affects the rehabilitation of patients’ heart function, and even their lives[2]. At present, however, VADs still have some issues, such as device failure after implantation or device incapacitation due to poor reliability of the system, which have affected the survival rate of patients[3]. Therefore, reliability is an important part of product quality evaluation and pre-market review. The load/stress analysis and the acceptance criteria are the two core areas of the reliability test.

Previous studies on the reliability evaluation of VADs are concentrated in the summary papers of Pantalos[4] and Lee[5]. At the same time, the manufacturers of VADs have also reported their own reliability test protocol. This literature has preliminarily discussed the testing period, sample size determination, risk analysis, and test environment for the reliability test of VADs. For example, in 2014, HeartWare reported the results of its reliability test [6], which lasted six years and was conducted on a customized reliability test bench that could generate pulsatile flow, and record relevant pressure and flow information in real time for evaluation.

Acceptance criteria are used for quantitative evaluation of the reliability test, which mainly include failure pattern identification and classification during the test, and the maintenance of basic performance afterward. Yamane et al. [7] have introduced a specification of technical guidance for VADs, compiled by the Ministry of Health in Japan. This paper specifies the prerequisites for a product to be marketed in Japan. The reliability should be higher than 60% (recommended 80%), and the confidence level of the system must reach 80% during 6 months or after a 2 year test. Kitano et al.[8] have introduced a reliability test for the Evaheart blood pump in Japan. According to the design structure; the H-Q curve, sealing and bearing wear-resistance have been specially evaluated after the test. Stonehouse et al.[9] have introduced a test for the VentrAssist system, from WalaCor Co. Ltd. As of July 9th 2007, the total testing time of all 13 circulating pumps is 29.36 years. At the same time, the paper has also introduced its work on the determination of acceptance criteria, suggesting that electrical characteristics, wear and corrosion, leakage volume and P-Q curve should all be evaluated after the reliability test.

At present, although VADs are developing rapidly, in the aspect of quality evaluation, no complete, systematic reliability test protocol has been presented. The lack of testing protocol and models leads to a lack of in-depth evaluation on their reliability, which seriously constrains the marketing potential of the devices. This paper hopes to establish a standard reliability test protocol and platforms, so as to enhance the ability of scientific evaluation on the reliability of VADs, and to improve the consistency of evaluation.

2. Experimental Section

2.1 Reliability test conditions of ventricular assist devices

Reliability is defined as the ability of a system to carry out essential performance within a specified period of time, under every possible condition. The reliability test for VADs needs to be carried out under the various physiological and hemodynamic conditions which act on them during their operation. The key requirement of a reliability test is to simulate the hemodynamic state of the human body under various physiological and pathological conditions.

In order to meet the different hemodynamic requirements of patients and their activities, the reliability test platform must be able to operate normally, within a certain range of physiological conditions, for a long time (2 years or more). Physiological conditions can be understood as the patient’s physiological state, such as sleep, daily activities and movement, corresponding to the minimum, moderate and maximum loading. Physiological parameters measured in each state include heart rate, stroke volume, mean atrial pressure (representing ventricular preloading), and mean arterial pressure (representing ventricular afterloading). At the same time, vascular compliance and peripheral resistance should conform to the normal range of the physiological state. The physiological and hemodynamic parameters of patients have been obtained from published clinical literature [10-12] (Table 1). Among them, heart rate, stroke volume, left atrial pressure, vascular compliance and peripheral resistance represent the corresponding parameters of environmental stress in vitro, while systemic flow (Qs), mean aortic pressure, rotational speed and the power consumption of VADs represent the corresponding "evaluation indexes". Based on the above considerations, the reliability test was carried out under the following physiological loadings and requirements, in which the rotational speed was determined according to the load conditions of the test bench.

Table 1. Conditions for reliability test of VADs

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Minimum loading (sleep)</th>
<th>Moderate loading (daily activities)</th>
<th>Maximum loading (movement)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration (hour)</td>
<td>8</td>
<td>15</td>
<td>1</td>
</tr>
<tr>
<td>Heart rate (bpm)</td>
<td>50</td>
<td>70</td>
<td>130</td>
</tr>
</tbody>
</table>
Inlet pressure (mmHg) 24
Aortic pressure (mmHg) 80 90 100
(adjustable rotational speed)
Aortic pressure (mmHg) 80-100
(fixed rotational speed)
Ventricular pressure pulsating quantity (mmHg) >60
Auxiliary flow (L/min) 2-4 4-6 6-8
Peripheral resistance of systemic circulation Determined by simulation results
Vascular compliance of systemic circulation Determined by simulation results
Temperature (℃) 37
Rotational speed (rpm) Self-defined

2.2 Platform model for reliability test of VADs

The VADs and the hemodynamic parameters of the circulatory system determine the system responses coordinately. The evaluation on the stability of VADs needs to be carried out under a condition similar to physiological state[13]. Therefore, to establish an appropriate platform, a mathematical model of the circulatory system should be created to determine the parameters of peripheral resistance and compliance under different physiological states. Because the systemic circulation is closely related to the VADs, the model only contains the left ventricular and systemic circulation sections. According to the theory of the lumped parameter model, voltage is used to represent blood pressure, current is used to represent blood flow, resistance is used to represent vascular resistance, capacitance is used to represent vascular compliance, and inductance is used to represent blood flow inertia. The lumped parameter model of the simplified 5-stage circulatory system is shown in Figure 1.

![Figure 1. Lumped parameter model of circulatory system](image)

The lumped parameter model of the circulatory system consists of three parts: the left atrium, the left ventricle and the systemic circulation. The state variables and their physiological indicators are shown in Table 1. The hemodynamic parameters and their physiological indicators are shown in Table 2.

<table>
<thead>
<tr>
<th>State variable</th>
<th>Physiological Indicator</th>
<th>Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>X₁</td>
<td>Left ventricular pressure</td>
<td>mmHg</td>
</tr>
<tr>
<td>X₂</td>
<td>Left atrial pressure</td>
<td>mmHg</td>
</tr>
<tr>
<td>X₃</td>
<td>Arterial pressure</td>
<td>mmHg</td>
</tr>
<tr>
<td>X₄</td>
<td>Aortic pressure</td>
<td>mmHg</td>
</tr>
<tr>
<td>X₅</td>
<td>Arterial flow rate</td>
<td>ml/s</td>
</tr>
</tbody>
</table>
Table 3. Parameter list of lumped parameter model of circulatory system

<table>
<thead>
<tr>
<th>Model parameter</th>
<th>Physiological Indicator</th>
<th>Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>CA</td>
<td>Aortic compliance</td>
<td>ml/mmHg</td>
</tr>
<tr>
<td>CR</td>
<td>Left atrial compliance</td>
<td>ml/mmHg</td>
</tr>
<tr>
<td>CS</td>
<td>Systemic circulation compliance</td>
<td>ml/mmHg</td>
</tr>
<tr>
<td>C(t)</td>
<td>Left ventricular compliance</td>
<td>ml/mmHg</td>
</tr>
<tr>
<td>DA</td>
<td>Aortic valve</td>
<td>--</td>
</tr>
<tr>
<td>DM</td>
<td>Mitral valve</td>
<td>--</td>
</tr>
<tr>
<td>LM</td>
<td>Systemic circulation blood inertia</td>
<td>mmHg.s^2/ml</td>
</tr>
<tr>
<td>RA</td>
<td>Aortic valve resistance</td>
<td>mmHg.s/ml</td>
</tr>
<tr>
<td>RC</td>
<td>Aortic resistance</td>
<td>mmHg.s/ml</td>
</tr>
<tr>
<td>RM</td>
<td>Mitral valve resistance</td>
<td>mmHg.s/ml</td>
</tr>
<tr>
<td>RS</td>
<td>Peripheral resistance</td>
<td>mmHg.s/ml</td>
</tr>
</tbody>
</table>

The systolic characteristics of the left ventricle in the lumped parameter model are simulated by the left ventricular elastic function $E(t)$, which is defined as the reciprocal of the left ventricular compliance $C(t)$. The left ventricular elastic function describes the relationship between left ventricular pressure and volume. Suga et al.[14] have pointed out that the left ventricular elastic function can be defined by Formula (1).

$$ E(t) = \frac{1}{C(t)} = \frac{P_{LV}(t)}{V_{LV(t)} - V_0} $$

Where, $E(t)$ is left ventricular elasticity; $P_{LV}(t)$ is left ventricular pressure (mmHg); $V_{LV(t)}$ is left ventricular volume (ml); $V_0$ is left ventricular volume (ml) when left ventricular pressure is 0mmHg.

Although Formula (1) defines the physical significance of the elastic function, it cannot be used to directly calculate the left ventricle elasticity because the left ventricular pressure and the left ventricle volume are unknown. Therefore, Formula (2) was used to calculate the left ventricular elasticity in this paper.

$$ E(t) = (E_{max} - E_{min})E_n(t_n) + E_{min} $$

Where, $E_{max}$ is the maximum value of left ventricular elasticity (mmHg/ml); $E_{min}$ is the minimum value of left ventricular elasticity (mmHg/ml); $E_n(t)$ is the normalized left ventricular elasticity function (mmHg/ml).

The maximum and minimum values of the left ventricular elastic function are determined by the pressure-volume relationship of the left ventricular in end-systolic and end-diastolic, respectively. $E_n(t)$ represents the normalized left ventricular elastic function. In this paper, the normalized left ventricular elastic function was established by using a bimodal function[15], as shown in Formula (3).

$$ E_n(t_n) = 1.55 \left[ \frac{1.9}{1 + \left( \frac{t_n}{50} \right)^{1.7}} \right] \left[ \frac{1}{1 + \left( \frac{t_n}{110} \right)^{2.19}} \right] $$

$$ t_n = \frac{T}{T_{max}} $$

$$ T_{max} = 0.15t_c + 0.2 $$

$$ t_c = \frac{60}{HR} $$

Where, $t_c$ is cardiac cycle (ms), and HR is heart rate.
The heart valve state divides the cardiac cycle into four periods: isovolumic contraction period, ejection period, isovolumic relaxation period, and filling period, as shown in Table 3.

### Table 4. Valve state in cardiac cycle

<table>
<thead>
<tr>
<th>Period</th>
<th>Mitral valve state</th>
<th>Aortic valve state</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isovolumic contraction period</td>
<td>OFF</td>
<td>OFF</td>
</tr>
<tr>
<td>Ejection period</td>
<td>OFF</td>
<td>ON</td>
</tr>
<tr>
<td>Isovolumic relaxation period</td>
<td>OFF</td>
<td>OFF</td>
</tr>
<tr>
<td>Filling period</td>
<td>ON</td>
<td>OFF</td>
</tr>
</tbody>
</table>

According to the state of the valve, the differential equations of the lumped parameter model of the circulatory system during different periods are established. The equations are arranged according to the form of $X = A(t)X$ to obtain the spatial state equation $s$ of the circulatory system, where $X = [x_1 x_2 x_3 x_4 x_5]^T$ represents the state variable matrix of the coupled model. The coefficient matrix $A(t)$ of the coupled model is determined by the structure of the lumped parameter model during different periods.

1. **Isovolumic periods.** Isovolumic periods include the isovolumic contraction period and isovolumic relaxation period. During the isovolumic period, the aortic and mitral valves close, and the aortic flow rate is 0 ml/s. On this basis, the coefficient matrix of the spatial state equation of the lumped parameter model during the isovolumic period was obtained, as shown in Formula (4):

$$A(t) = \begin{bmatrix} \frac{-C(t)}{C(t)} & 0 & 0 & 0 & 0 \\ 0 & \frac{-1}{R_{SCR}} & \frac{1}{R_{SCR}} & 0 & 0 \\ 0 & \frac{1}{R_{SCR}} & \frac{-1}{R_{SCR}} & 0 & \frac{1}{CS} \\ 0 & 0 & 0 & \frac{-1}{CA} & \frac{1}{RA} \\ 0 & 0 & \frac{-1}{LS} & \frac{1}{LS} & \frac{-1}{RS} \end{bmatrix}$$

2. **Ejection period.** During the ejection period, the aortic valve opens and the mitral valve closes. Blood flows from the left ventricle into the aorta. On this basis, the coefficient matrix of the model state equation during the ejection period was established, as shown in Formula (5):

$$A(t) = \begin{bmatrix} \frac{-C(t)}{C(t)} & \frac{-1}{RA \cdot C(t)} & 0 & 0 & \frac{1}{RA \cdot C(t)} & 0 \\ 0 & \frac{-1}{RA \cdot C(t)} & \frac{1}{RA \cdot C(t)} & 0 & 0 & 0 \\ 0 & \frac{1}{RA \cdot C(t)} & \frac{-1}{RA \cdot C(t)} & 0 & \frac{1}{CS} & \frac{-1}{CA} \\ \frac{1}{RA \cdot CA} & 0 & 0 & \frac{-1}{LS} & \frac{1}{LS} & \frac{-1}{RS} \end{bmatrix}$$

3. **Filling period.** During the filling period, the left ventricle dilates, the aortic valve closes, and the mitral valve opens. Blood flows from the left atrium to the left ventricle through the mitral valve. On this basis, the coefficient matrix of the model state equation during the filling period was established, as shown in Formula (6):

$$A(t) = \begin{bmatrix} \frac{-C(t)}{RM \cdot C(t)} & \frac{-1}{RM \cdot C(t)} & \frac{1}{RM \cdot C(t)} & \frac{1}{RM \cdot C(t)} & 0 & 0 \\ \frac{1}{RM \cdot CR} & \frac{-1}{RM \cdot CR} & \frac{-1}{RM \cdot CR} & 0 & \frac{1}{CS} & \frac{-1}{CA} \\ \frac{1}{RA \cdot CA} & 0 & 0 & \frac{-1}{LS} & \frac{1}{LS} & \frac{-1}{RS} \end{bmatrix}$$
2.3 Parameter determination of the circulatory system

In order to determine the peripheral resistance and compliance parameters of the circulatory system under three test conditions, a numerical simulation was carried out for the mathematical model of the circulatory system. The two parameters; peripheral resistance and arterial compliance, were adjusted by comparing the difference between the aortic pressure, left atrial pressure and cardiac output of the models and the target values. The numerical simulation was conducted by MATLAB, and the simulation time was 4s. The results are shown in Figures 2-4.

Figures 2-4 show that the heart stroke and aortic pressure of the cardiovascular system increase gradually from the minimum to the maximum loading, while the left atrial pressure and the ventricular preloading remain unchanged, which is consistent with the three working states required by the system. The corresponding peripheral resistance and arterial compliance are shown in Table 5. Therefore, the peripheral resistance and arterial compliance can be used to guide the construction of the reliability test bench for ventricular assist devices.
Figure 4. Maximum loading

Table 5 Peripheral resistance and arterial compliance of circulatory system under three states

<table>
<thead>
<tr>
<th>Working state</th>
<th>Peripheral resistance (mmHg·S/ml)</th>
<th>Arterial compliance (ml/mmHg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimum loading</td>
<td>2.5</td>
<td>2.0</td>
</tr>
<tr>
<td>Moderate loading</td>
<td>1.0</td>
<td>3.3</td>
</tr>
<tr>
<td>Maximum loading</td>
<td>0.7</td>
<td>3.5</td>
</tr>
</tbody>
</table>

Derived from the fluid resistance formula of straight pipe (Poiseuille Law),

\[ R = \frac{8\eta l}{\pi r^4} \]  

(7)

Where \( R \) is peripheral resistance, \( r \) is the radius of the pipe, \( l \) is the length of the pipe, and \( \eta \) is the viscosity coefficient of the fluid. According to the Formula (7), the length of the pipe can be determined according to the hydrodynamic viscosity and the inner diameter of the pipe. Since the platform needs to produce three working states in which the flow resistance of the pipe increases gradually, the length of the pipe is calculated according to the peripheral resistance under the maximum loading state. This is to calculate the length of the pipeline according to Formula (7), to achieve pipe resistance under moderate and the minimum loading through the damper valve.

Human blood vessels have great elasticity, during the cardiac ejection period, the artery will gradually expand to accommodate the blood pumped from the heart, thus reducing the peak systolic pressure. During the diastolic period, the artery will gradually contract, keeping the blood pressure stable, and allowing blood to flow continuously, thus maintaining the continuity of blood perfusion in peripheral organs. However, the pipe elasticity in the stability test platform is much lower than that in the blood vessels, so a systemic compliance chamber was designed to simulate the arterial compliance of the circulatory system. Compliance refers to the changes in vascular diameter due to periodic pressure changes, which is defined according to ISO 7198:2016 as the percentage of changes in the diameter of blood vessels caused by pressure changes per 100mmHg, as shown in Formula (8).

\[ C = \frac{d_{p1}-d_{p2}}{d_{p1}(p_1-p_2)} \]  

(8)

Due to the cylindrical compliance chamber adopted for vascular compliance, the diameter of the chamber remains unchanged, and the height of the liquid level in the chamber can be changed. Therefore, Formula (8) is modified to describe compliance as a percentage of changes in the height of the liquid level, as shown in Formula (9). According to the compliance of the circulatory system as determined by the mathematical model, the percentage of changes in the height of the liquid level under different working conditions is determined. Then, by modifying the pressure value above the liquid level in the compliance chamber, the percentage of changes in the height of the liquid level is adjusted to produce different compliance.
3. Results

3.1 Construction of reliability test platform

According to the mathematical model established above, we designed the reliability test platform of VADs, as shown in Figure 5. The left atrium is an open container made of polymethyl methacrylate to provide preloading to the left ventricle. The left ventricle is a sealed container composed of a flexible diaphragm and a rigid chamber (as shown in Figure 5), and the linear motor simulates the motion of the left ventricle by reciprocating with the flexible diaphragm. The linear motor makes contact with the flexible diaphragm during the entry motion to simulate the active contraction mechanism of the left ventricle. The linear motor is separated from the flexible diaphragm during the returning motion, and the sealing container expands naturally under the action of inertial fluid to simulate the passive filling mechanism of the left ventricle.

The SV, HR and the systolic/diastolic ratio (Sys/Dia) are simulated by changing the motion stroke, the motion cycle, and the entry time/return time ratio of the linear motor. The simulated aortic and mitral valves are passive components, of which the switching states are determined according to the pressures between ventricle and artery and between ventricle and atrium to ensure the one-way flow of fluid in the circulatory system. The characteristic impedance of the vascular system simulates the vascular resistance of the ascending aorta. Due to the high compliance of the systemic circulation artery system, the compliance chamber was used to simulate aortic compliance. To simulate human body temperature, a temperature control system was composed of a heating rod, temperature sensor and temperature controller. Flow and pressure sensors were used in the test bench to detect the signals of ventricular pressure, aortic pressure, the inlet pressure of the ventricular assist device, systemic flow rate and pump flow rate.

3.2 Operation of reliability test platform

In order to make the platform work properly, a phosphate buffer solution was used as a test solution to simulate the blood viscosity. The temperature of the test solution was controlled at 37±1℃ by the temperature control system. To inhibit microbial growth, an ultraviolet sterilizer was added into the pipes of the system. The test system was equipped with a UPS emergency power supply for at least 4 hours of power supply. The system recorded the rotational speed, flow rate and power consumption of the blood pump, and the water temperature and pressure of the system in real time via testing software. The system used 0.9% NaCl solution as a test liquid. In addition, the testing software needed to control the rotational speed of the blood pump, the natural heartbeat frequency and other parameters, which were adjusted three times a day to simulate the variance of human activities.

3.3 Verification of reliability test

3.3.1 In-process acceptance criteria: failure mode analysis

Acceptance criteria, which are used to quantitatively describe the success or failure of reliability test, are the
Acceptance criteria mainly include the in-process and after-process acceptance criteria. The in-process criteria are mainly used to identify and classify possible failure patterns in the test, and to determine the hazard level. The after-process criteria mainly consider whether the basic performance of the system is maintained (derogated) after the reliability test.

According to the direct or indirect influence of failure on the VADs, the in-process acceptance criteria divide the failure into four categories according to the hazard level (severity), which are catastrophic failure, critical failure, marginal failure and minor failure, see table 6. To facilitate a reliability test, we give the name and specification of every failure. If a catastrophic or critical failure occurs, the test is considered to be a failure. For marginal and minor failures, they should be analyzed to find the cause, and the frequency of occurrence should be clearly listed in the results.

Table 6. Failure mode and specification of VADs during reliability test

<table>
<thead>
<tr>
<th>Failure mode</th>
<th>Definition of System Failure</th>
<th>Failure name</th>
<th>Failure specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catastrophic</td>
<td>a failure resulting in complete loss of the capability of the system to perform its primary function. A failure that occurs without sufficient warning, resulting in serious injury or death.</td>
<td>Failure of blood pump or controller</td>
<td>Blood pump stopped running, restarting or replacing the controller doesn’t make it start or work properly.</td>
</tr>
<tr>
<td>Critical Failure</td>
<td>a failure of the system to perform safely as stated or implied. Without intervention, the failure will result in serious injury or death.</td>
<td>Flow rate out of range</td>
<td>Flow rate exceeding range value (±10%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Rotation speed out of range</td>
<td>Flow rate exceeding range value (±30%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Power out of range</td>
<td>Blood pump power of normal range</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Controller failure</td>
<td>System initialization error, blood pump not connected, controller fault alarm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Other failure</td>
<td>Specified by manufacture</td>
</tr>
<tr>
<td>Marginal Failure</td>
<td>a failure that compromises a backup safety system, or the system fails into a fail-safe state. A failure that results in reduced system capability or causes minor injury.</td>
<td>Power</td>
<td>a continuous increase in power consumption, but not more than the normal range</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Backup system failure</td>
<td>Controller cannot store trend and event data</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Trend and event data stored in the controller cannot be downloaded through an external monitor</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Settings and patient information cannot be saved to other controllers</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Other failure</td>
<td>blood pump temperature runs out of control, main battery failure, other alarms, instantaneous pressure changes exceeds alarm threshold, controller hardware fails but does not affect the function of driving the pump</td>
</tr>
<tr>
<td>Minor Failure</td>
<td>a failure that necessitates unscheduled maintenance or results in cosmetic damage to the system; or a failure that is not serious enough to cause injury.</td>
<td>Display failure</td>
<td>Controller display color or brightness changes, but does not affect observation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Component aging</td>
<td>Failure of Lamp (incorrect or not on)</td>
</tr>
</tbody>
</table>

3.3.2 In-process reliability test verification

For verification of the reliability test system, the test environment under three physiological conditions (minimum, normal, and maximum loading) was carried out by adjusting characteristics such as aortic compliance, peripheral resistance, ventricular pulsatile ability and heart rate.

The hemodynamic result from the test system is shown in Figure 6. The pressure range of the left ventricle is
about 25-90mmHg, in which the minimum end-diastolic pressure is about 25mmHg. This result is consistent with the normal state of the natural heart, while the aortic pressure fluctuates up and down, and the pulse pressure is about 20mmHg. There is a phase difference between the aortic pressure waveform and the left ventricular pressure waveform, which is different from that in the natural circulatory system but exists in many experimental systems. As can be seen from the Figure, the average flow of the system under normal condition is about 5.86L/min. In addition, from the aortic and ventricular pressure waveforms, we can see that the cardiac cycle is about 0.85, that is, the heart rate is about 70 beats per minute. It can be seen from the aortic flow waveform that the end-ejection flow is less than zero, indicating that aortic reflux exists, but is quite small, which is the same phenomenon in normal physiological situations.

Compared with normal loading, the aortic pressure is lower under the minimum loading condition, only about 80mmHg. The ventricular end-diastolic pressure is increased to more than 20mmHg, suggesting that the ventricle can not be fully unloaded. At this moment, the peak aortic flow is only about 4L/min, which is less than half it would be under normal circumstances.

![Figure 6](image6.png)

**Figure 6.** Macro hemodynamic diagram of the reliability test system under three loading conditions, in which LAP (left atrial pressure), LVP (left ventricular pressure), AOP (aortic pressure), TF (total flow) and PF (pump flow).

3.3.3 Real-time 24-hour result and data processing

The real-time, 24-hour data that was collected is shown in Figure 7 a), from which three loading states can be distinguished. At each loading state, the data fluctuates within a certain range of the baseline. When the three loadings of the system are switched, the state of the system will fall out of balance temporarily, which leads to the collected data exceeding the effective data range. In the actual data processing, the data collected 10 seconds after the test bench switches state is ignored. The processing flowcharts are shown in Figure 7 a. In the reliability test, the test platform generates a huge amount of data, so we use a program to process data automatically. The algorithm can be seen in figure 7 b). The algorithm can plot every day’s result as a figure, meanwhile identifying data that doesn’t meet the required criteria.
4. Discussion

4.1 In-process reliability test verification

4.1.1 Consideration for rotational speed and flow rate of blood pump

The possibility of brain death due to sudden cardiac arrest also increases sharply over time. The brain death rate is less than 10% within 1 min of cardiac arrest, about 40% within 4 min, about 60% within 6 min, over 80%, and the brain may already be dead, within 8 min, and almost 100% after 10 min or more. Based on the above considerations, the mean flow is taken as an index to evaluate the fatal failure of the system. As a closed-loop control system, the actual rotational speed should be consistent with the set rotational speed. To simulate the actual situation of natural heartbeat, the pulse flow will repeatedly impact the blood pump in the durability test, which will lead to the deviation of the actual rotational speed. Under normal conditions, the circuit will constantly make self-adaptive adjustments to ensure that the rotational speed fluctuates within a certain range, but if the instantaneous rotational speed deviates from the target value too much and cannot be adjusted, it indicates that there may be a control risk. Therefore, the instantaneous rotational speed and flow rate are also taken as indexes to evaluate the fatal failure potential of the system.

4.1.2 Consideration for power

The input power fluctuates according to the difference between input and output pressures, and the fluctuation degree varies with the pressure difference. If there is no obvious noise or tremble in the pump body, but the power increases sharply, it indicates that there may be some abnormal states inside, such as the rubbing of the rotor and resonance of the pump body. These abnormal states will eventually lead to damage of the device. Therefore, power being out of range is also defined as a fatal failure.

4.2 After-process acceptance criteria: Performance maintenance (degradation)

The subsequent performance of reliability test (failure) analysis is an important approach to product reliability analysis. In previous, relevant reports on the durability testing of ventricular assist devices, researchers only paid attention to the relevant test data, and ignored the analysis of product performance afterward. The fact is that, through the data of the product test during and after the reliability test, and in conjunction with failure analysis after the test, its influence on the fluid performance parameters of VADs and the degree of mechanical damage caused by long-term operation can be grasped. Therefore, the following tests are recommended to be conducted after the reliability test.

4.2.1 Pressure-Flow, Power-Flow curve

The characteristic curve can represent the working performance of a pump completely, intuitively and accurately, and is the most intuitionistic data to evaluate the VADs. After the reliability test, we can find out whether the device has a problem of performance degradation or not by comparing it with the initial curve.
Meanwhile, in normal conditions, the power fluctuates according to the difference between input and output pressure. If there is no obvious noise or vibration of VADs, but the power increases sharply, it indicates that the VADs may be in an abnormal state, such as the increase of damping and the resonance of the pump body. In this way, the abnormal state will eventually lead to device damage.

Figure 8. Pressure-flow and power-flow curves of VADs measured before and after the reliability test. A and B are the test results of two groups of VADs

Figure 8 shows the pressure-flow and power-flow curves of VAD measured before and after the reliability test. In the figure, the black indicates the results before the reliability test starts, and the red indicates the results after. It can be seen that the pressure-flow curve before the VADs test is basically the same as that after, and the maximum deviation of all points is not more than (±5.0%). However, after the test, under the same working conditions, the power consumption of the pump has increased to a certain extent. In particular, the power of VAD equipment, marked A, increases by 46.4% under some operating conditions. This result may indicate that the pump body is in an abnormal condition. Therefore, it is necessary to pay special attention to this kind of situation.

4.2.2 Chemical corrosion

Under normal conditions, the circulation fluid is sealed within the channel of the blood pump, and no other material precipitates. If other ferromagnetic material ions or other metal ions are detected in the circulation fluid, it indicates that the sealing of the pump body is problematic. When the circulation liquid makes contact with magnetic steel and other unexpected parts it corrodes the corresponding metal. This kind of risk may not be immediately presented, but over time the influence on the product can be fatal. Therefore, the metal ion analysis of the circulating fluid (using ICP-MS, for example) should be carried out after the reliability test. The analysis results should be compared with the blank solution and focus on whether the target metal ions such as lead, neodymium, platinum and iridium appeared in the solution after the test.

Figure 9. ICP-MS spectrum of circulation fluid A before reliability test(red) and After reliability test (green)
As can be seen in figure 9, since we use a phosphate buffer solution as the circulation solution, a lot of metal ion can be detected in the spectrum. However, compared with the blank solution, the spectrum is basically same, and no target metal ions are found in the spectrum.

4.2.3 Wear

Wear failure is a common failure in the operation of ventricular auxiliary devices, which seriously affects the safety, reliability and efficiency of their operation. It is suggested that observation of the appearance and macro and micro characteristics of wear traces, and the testing of the strength and chemical components of the contact parts should be carried out and after the reliability test, so that the properties, causes and influencing factors of wear failure of rotor parts can be discussed.

Figure 10. A stator surface photograph, B rotor surface photograph, C surface roughness test result

Figure 10 is the surface photograph of the contact parts (rotor and stator) after the reliability test. If the surface roughness of the two parts is very poor, it will lead to the increase of friction resistance and poor sealing. Through the contour scanning of the friction surface, the wear data of the contact surface can be found, and then the reliability performance of the product can be evaluated.

5 Conclusion

In this study, the test model and test bench has been set up to facilitate the reliability testing of VADs. The hemodynamic characteristics of the circulatory system under three conditions (minimum, normal, and maximum loading) have been provided and simulated in the test platform. At the same time, the acceptance criteria of the reliability test have been given, and the potential causes of failure for VADs have been analyzed, and each failure has been classified according to catastrophic failure, critical failure, marginal failure and minor failure. The significance of evaluating the characteristic curve, leakage and wear after reliability testing has been discussed. The test protocol according to the above considerations can scientifically simulate and undergo all of the environmental stress shocks experienced by VADs after implantation into the human body, and the evaluative criteria contain all of the possible failure states.

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References


