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Application Research of Accelerated Life Test in Ultrasonic Knife System

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Abstract

Ultrasound knife, also known as ultrasonic cutting hemostatic knife, is a new type of surgical equipment that began to be applied in clinical surgery in the late 1980s. Ultrasound scalpels are currently widely used in China. However, most of the ultrasound scalpels used in hospital clinical practice are imported from abroad, and there are fewer ultrasound scalpels developed and produced domestically. The reason is that the research and development technology of ultrasound scalpels abroad is closed, and the verification and evaluation of the lifespan of ultrasound scalpels is difficult. This article will conduct research on the application of accelerated life testing for a certain type of ultrasonic knife system in China, propose a comprehensive verification method for the reliable life of the ultrasonic knife system, select appropriate acceleration stress and application method, calculate the acceleration factor through the corresponding acceleration model, design an accelerated life testing plan for a certain type of ultrasonic knife system, and finally verify the reliable life through conducting experiments.

Keywords

Ultrasound Knife System; Reliable Lifespan; Accelerated Life Test; Acceleration Factor.

1. Introduction

The scientific name of ultrasonic knife is Ultrasounic-Harmonic Scalpel (UHS). UHS appeared in the late 1950s and began to be used in clinical surgery after 1980s as a new surgical equipment[1]. Most of the ultrasonic knives used in clinical use in hospitals come from Haoyu ultrasonic knife produced by Johnson & Johnson in the United States, SonSurg ultrasonic knife produced by Olympus in Japan, CUSA series ultrasonic knife produced by Valleylab in the United States, Soering ultrasonic knife treatment system produced by Soering in Germany, etc[2]. Domestic research and development of ultrasonic knife system is less, the main reason is that foreign ultrasonic knife research and development technology is closed, domestic investment in this part of the technology is less, the direct introduction of foreign ultrasonic knife is more convenient; In addition, there is little research work on the reliability analysis and life prediction of ultrasonic knife system, and the reliability level and evaluation of domestic ultrasonic knife need to be further studied.

At present, Han Weining[3] has discussed the surgical effect and the impact on prognosis of breast cancer patients who have completed the treatment with ultrasound knife. Bai Bo[4] discussed the application value of Focus ultrasound knife in thyroid cancer surgery. Shen-Han Lee et al[5]. designed a prospective randomized controlled trial. The utility and results of Harmonic Focus of ultrasonic coagulation shear device (UCSD) were compared with those of electrothermal bipolar vessel occluders (EBVS) Ligasure Small Jaw (NCT01765686) in thyroidectomy. CAI Dingding[2],

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Yao Yaming[6], Sun Wei et al[7]. analyzed the daily maintenance and fault handling of Haoyun ultrasonic knife, put forward the maintenance and maintenance measures of ultrasonic knife before, during and after operation, and analyzed the common faults of ultrasonic knife and how to deal with the faults. These studies mainly have two aspects, one is the clinical application of ultrasonic knife; The second is the daily maintenance and fault handling of ultrasonic knife. However, there are few studies on the reliability analysis and life prediction of ultrasonic knives.

The research on statistical analysis of Accelerated Life Testing (ALT) began in the 1960s, with the first development being constant stress accelerated life testing. Nelson[8] studied the model of constant stress accelerated life testing and statistical analysis methods such as graph analysis, least squares, and maximum likelihood estimation. Since its inception, accelerated life testing has been in a state of research and application. In the initial stage, accelerated life testing was mostly used to verify the reliable life of major equipment (such as weapons, aerospace, etc.). In 1994, with funding from NASA, the National Research Council under the US Academy of Sciences and Engineering established the “Long term Degradation Assessment Research Group for Materials and Structures Based on Accelerated Test Methods” to study the degradation of various advanced materials, Propose an accelerated testing and analysis method for quantifying the material and structural life of new generation spacecraft, with the core content of using accelerated life testing methods to test and predict the degradation of materials in various possible operating environments of spacecraft. With the development of science and technology and the improvement of the level of researchers in the field, the application fields of accelerated life testing are becoming more and more widespread. Li Jing[9] proposes a comprehensive evaluation method for the working life of highly reliable electronic products based on the characteristics of long lifespan and high reliability of electronic devices. If traditional methods are used for life testing, there will be problems such as small samples, complex failure mechanisms, long testing cycles, and high costs; Zhang Yatao et al[10]. used the method of simultaneously changing the load and swing frequency for accelerated life testing, and established a grey neural network prediction model with PV value and wear degradation data as input parameters and life value as output parameters to predict the life of self-lubricating joint bearings; Liu Bo and Li Zhenhui[11] conducted a temperature vibration dual dimensional accelerated life test on the high-voltage jumper cable of the high-speed train unit. They established an accelerated life model with the function of temperature stress and vibration stress and the logarithmic function of a certain life characteristic. The unknown parameters in the model were solved using the maximum likelihood function method to obtain the service life of the cable at room temperature and normal vibration frequency.

The basic elements of accelerated life testing include accelerated stress, stress application method, acceleration model, and acceleration factor. Accelerated stress mainly includes the comprehensive stress of temperature, thermal cycling, vibration/shock, voltage, vibration/shock, and thermal cycling. Other special stresses can also be applied, such as the time pulse frequency of microprocessors, voltage or power fluctuations, pollutants or solvents, or the comprehensive stress of these special stresses. There are three types of stress application methods: constant stress application, step stress application, and sequential stress application. Therefore, according to the different stress application methods, accelerated life tests can be divided into constant plus life test, step plus life test, and sequential plus life test, with constant plus life test being the most commonly used. There are three common acceleration models: the Arrhenius model, commonly used to describe the relationship between temperature accelerated stress and product life characteristics; The inverse power law model is commonly used to describe the relationship between product life characteristics and stress levels when mechanical or electrical stress is used as accelerating stress; The Eileen model is commonly used to describe two different stresses (one of which is temperature stress) as accelerated stresses for accelerated testing. The acceleration factor reflects the severity level of stress level on product failure operations in the acceleration test, and therefore also reflects the conversion law between the life information obtained in the acceleration test and the life information under actual usage conditions. The above four elements have a certain order, and the accelerated stress should be determined first.

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Secondly, the stress application method and acceleration model can be determined synchronously, and then the acceleration factor can be determined based on the acceleration model. After the four elements are determined in sequence, the accelerated life test scheme can be designed, and then the equipment can be called for accelerated life test.

This article will conduct accelerated life test application research on a certain model of ultrasonic knife system in China, and propose a comprehensive verification method for the reliable life of the ultrasonic knife system. Firstly, analyze the structural composition, functional performance, and working environment of the ultrasonic knife system, and select the appropriate acceleration stress; Determine the appropriate stress application method based on the test environment conditions, equipment performance requirements, and advantages and disadvantages of the application method; At the same time, select the acceleration model based on the previously determined stress type; Then calculate the acceleration factor, design an accelerated life test plan for a certain model of ultrasonic knife system, and finally verify its reliable life by calling equipment to conduct accelerated life tests.

2. Analysis of Test Methods

2.1 Accelerated Life Test Analysis

Both life testing and accelerated life testing are commonly used domestically and internationally to evaluate the actual lifespan of weapons and equipment. Among them, life test refers to a technical approach to simulate the use of equipment on-site or through a laboratory, load the equipment with real environmental stresses and loads, obtain data on product failure or performance degradation, and quantify life indicators through statistical analysis of these data. The evaluation results of life testing are relatively true and reliable, but the testing cycle of this method is generally longer and the cost is high. Accelerated life testing is a technical method that accelerates the process of product failure or performance degradation by increasing the test stress level without changing the failure distribution of the tested product. By statistically analyzing the data obtained under accelerated stress, it predicts the normal service life indicators of the product. This method can greatly shorten the test time, improve the test efficiency, and reduce the test cost[12].

The implementation steps for accelerated life testing are as follows:

1) Select the tested product;

2) Analyze the structure, function, and working profile of the tested product to understand its working environment;

3) Select appropriate accelerated stress;

4) Determine the appropriate stress application method based on the test environment conditions and the performance requirements of the equipment itself;

5) Select the corresponding acceleration model based on the accelerated stress;

6) Calculate the acceleration factor;

7) Calculate the equivalent time of the test;

8) Design an accelerated life test plan for the tested product;

9) Conduct accelerated life testing;

10) Extract data and analyze experiments;

11) Conduct life assessment through outcome products;

In the above steps, the focus is on steps 3 to 6, which correspond to the four basic elements of accelerated life testing: accelerated stress, stress application method, acceleration model, and acceleration factor.

Accelerated stress mainly includes the comprehensive stress of temperature, thermal cycling, vibration/shock, voltage, vibration/shock, and thermal cycling. Other special stresses can also be applied, such as the time pulse frequency of microprocessors, voltage or power fluctuations,

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pollutants or solvents, or the comprehensive stress of these special stresses. Among them, temperature accelerated stress is widely used.

The stress application method is determined by combining the working environment of the product, the equipment and instruments present in the laboratory, etc. Generally, constant stress is most commonly applied and the effect is also the best.

The accelerated life test model is a life stress model, in which the acceleration mechanism and acceleration effect of accelerated stress on various failure modes are different. The acceleration model is used to describe the relationship between the reliability characteristic quantities of failure modes (such as average life, characteristic life, failure rate, etc.) and the accelerated stress level. There are three common models:

1) The Arrhenius model is used for constant temperature stress, which is based on the influence of temperature on the failure mechanism;

2) The inverse power law model can be applied when there are other stresses in the experiment besides constant temperature stress (such as electrical stress, mechanical stress, chemical stress (corrosion), and other stress models);

3) The Eileen model is adopted when the accelerated stress is a combined effect of temperature and humidity, which mainly evolved from quantum mechanics.

Among them, the Arrhenius model is the most widely used. The Arrhenius model is commonly used to describe the relationship between temperature accelerated stress and product life characteristics, namely:

$$\eta = A\exp\left[\frac{E_a}{kT}\right] \tag{1}$$

In the formula:

T--Temperature accelerated stress level;

A--The characteristic values of product life under temperature accelerated stress S, such as average life, p-percentile reliable life, etc;

H--The life characteristics of the product under the action of temperature acceleration stress S, such as average life, p quantile reliable life, etc.

Ea--Activation energy (eV), related to the material in which the failure mode occurs;

k--Boltzmann constant, k=8.6171×10-5ev/℃.

By taking logarithms on both sides of equation (1), a linearized Arrhenius model can be obtained:

$$\ln\eta = \gamma_0 + \gamma_1 \times \varphi(T) \tag{2}$$

In the formula: $\gamma_0 = \ln A$; $\gamma_1 = E_a/k$; $\varphi(T) = 1/T$.

In the accelerated life test, the acceleration factor reflects the severity level of the stress level on product failure during the accelerated test, thus also reflecting the conversion law between the life information obtained in the accelerated test and the life information under actual usage conditions.

If the reliable life of the product at stress level S_i and stress level S_j is t_i and t_j, respectively, then:

$$k_{i,j} = t_j/t_i \tag{3}$$

Is the Accelerated Factor (AF) of the accelerated stress level S_i and stress level S_j.

From equations (3), it can be seen that the acceleration factor is defined as the ratio of reliable life, thus essentially reflecting the relative speed of the failure process of the product at two different stress levels.

In electronic products, the life distribution follows the exponential distribution, so the acceleration factor of the exponential distribution is:

$$k_{i,j} = \lambda_j / \lambda_i \quad (4)$$

2.2 Time Compression Acceleration Test Analysis

The time compression test is an accelerated test that can only take into account (increase) the duration of the test, when the test product should be in actual working condition or in a working condition that can be characterized by damage but can be recovered. This accelerated test is suitable for situations where the product's operating stress and cumulative damage are significantly higher than other operating modes (non-operating or standby). In order to apply the above principle, it is required that the cumulative damage produced by the product under the action of lower stress is not different from the cumulative damage produced under the action of higher stress, which is difficult to objectively judge.

Time compression is achieved by increasing the “startup time” and reducing the “stop time” (for example, non-working time) to compress the work cycle. In addition, if the product is exposed to a wide range of stresses, then the maximum stress (principal stress) will cause the greatest damage, compared to the principal stress, some of the use of the product will cause negligible damage to the product, then it can be assumed that the product exposure to stress below the specified damage stress threshold will cause negligible damage and can be excluded from the test plan. This is especially true for mechanical fatigue, which is often used to accelerate the test of structural fatigue.

Advantages of time compression testing: Products with a small or short operating time compared to calendar time can be tested in a reasonable test time relative to the life of the test. For tests where nominal stress is applied and the test time is relatively short, it is not necessary to increase the stress, so it is not necessary to determine the acceleration factor of the experiment, otherwise there is a risk of over-stressing the product under test.

The disadvantage of time compression testing: focusing on the working time of the product means that only failure modes related to the working environment are considered, and failure modes occurring in a “non-working” environment may be ignored. The stress of these failure modes on the product may be much less than the stress of the product during use, but the time applied is quite long, so that the cumulative damage caused by the product is equal to or greater than that caused by the stress of the product use, so the damage to the product may be more serious. For products whose working time is less than the shutdown time, it is necessary to combine the acceleration test during the working period and the shutdown period, such as corrosion test and humidity test [13].

3. Analysis of Time Compression Accelerated Test

3.1 Introduction to the Structure and Function of a Certain Model of Ultrasonic Knife System

3.1.1 Structural composition

A certain type of ultrasonic knife system is composed of 4 components, which are divided into ultrasonic generator, ultrasonic transducer, ultrasonic knife and foot switch, because of the failure of 4 components in the working process, no matter which part will cause product failure. Therefore, the basic reliability and mission reliability models of products are series models. The ultrasonic knife system of this model belongs to the series model, so the failure rate λ_s of the whole machine is the sum of the failure rate λ_i of each component.

The focus of this model of ultrasonic knife system is on the ultrasonic generator, so this accelerated life test is mainly carried out for the ultrasonic generator. The core of the ultrasonic generator is composed of two circuit boards, which are divided into a main board and a display board. The basic reliability and task reliability models of this component are also cascaded models.

3.1.2 Function Introduction

The electrical energy in the ultrasonic generator is converted into mechanical vibration through an ultrasonic transducer, causing the ultrasonic blade to vibrate at a frequency around 55.5kHz, with an amplitude not exceeding 100 μm.

The vibrating ultrasonic blade contacts the tissue, causing the protein hydrogen bonds of the tissue to be cleaved, and the tissue protein cells to deform and form viscous coagulants. Achieve cutting and hemostasis with minimal tissue damage.

The ultrasonic generator has 5 output gears, corresponding to 1-5 gears, and each gear controls the output power and current.

3.2 Parameter Selection for Accelerated Life Test of Ultrasonic Generators

3.2.1 Accelerated Stress and Selection of Application Method

The acceleration stress mentioned earlier includes typical acceleration stresses such as temperature, thermal cycling, vibration/shock, voltage, vibration/shock, and the combined stress of thermal cycling. Considering that the product is a medical device and generally only works in hospitals, the geographical environment in hospitals is good, and vibration/impact is not considered; The power supply inside the hospital is also in a stable state, and the voltage is not considered. The thermal cycle is similar to high and low temperature changes, which refers to the periodic changes between two temperature points, while the temperature in hospitals is usually stable and the equipment is almost never in a thermal cycle state.

Taking into account all factors, temperature was selected as the accelerated stress for this accelerated life test, and a single stress accelerated life test was conducted. Before conducting the accelerated life test, multiple high-temperature bottoming tests were conducted on the ultrasonic generator, and a temperature stress of 60 ℃ was selected.

According to the previous discussion, the constant stress accelerated life test is superior to the step stress accelerated life test and the sequential stress accelerated life test. Ultimately, this test is set as the constant stress accelerated life test.

3.2.2 Acceleration Model and Calculation of Acceleration Factors

The accelerated stress in this experiment was selected as a constant temperature stress, so the accelerated model adopts the Arrhenius model.

The core of the ultrasonic generator consists of two circuit boards and belongs to electronic products. Its failure distribution belongs to an exponential distribution, and the acceleration factor is the ratio of the failure rates at the corresponding acceleration stress level. Therefore, before obtaining the acceleration factor, it is necessary to calculate the failure rates of the ultrasonic generator under two temperature stresses.

Table 1. The failure rate(10-6/h) of each section of the ultrasonic generator at different temperatures

Project	Temperature (℃)	
	25	60
Motherboard	13.72	21.22
Display board	21.85	48.85
Total	35.57	70.07

According to the "GJB 299C-2006 Electronic Equipment Reliability Prediction Manual"[14], the reliability prediction method of component stress analysis was used to predict the failure rates of each section of the ultrasonic generator at 25 ℃ and 60 ℃, as shown in Table 1.

In the table, the failure rate of the ultrasonic generator at 25℃ is 35.57×10-6/h, and the failure rate at 60℃ is 70.07×10-6/h. So we get the acceleration factor k=1.97, rounded to 2.

3.2.3 Determination of Accelerated Life Test Time

According to the requirements of the product task book, under normal environment (room temperature 25 ± 2 ℃, flat ground position), the core circuit board of the ultrasonic generator has a lifespan of ≥ 5 years. During these 5 years, the equipment is used 5 days a week, 3 times a day, and works for 0.5 hours/time. The total 5-year working time is 1950 hours, and the non working time is 41850 hours. The non working state here includes standby, storage, and other states.

When the equipment is not in working condition, it is in good condition and the environment is normal. There is no damage stress such as high temperature, vibration, voltage, etc., and the cumulative damage results can be ignored. Therefore, this accelerated life test also introduces a time compression accelerated test, which requires an ultrasonic generator with a service life of 5 years. The actual service time is 1950 hours, and conducting a test of 1950 hours can ensure the appropriate margin of the ultrasonic generator, Prove the reliability of the ultrasonic generator.

The previous text concluded that the acceleration factor at 60 ℃ is taken as 2. The equivalent duration of this accelerated life test is 975 hours, and it is expected to be completed in 40 days (24-hour test throughout the day).

3.3 Implementation Procedures and Judgment Rules for Accelerated Life Test

3.3.1 Accelerated Life Test Implementation Procedure

1) Pre processing: Place the test prototype under normal environmental (or reference) conditions until it reaches temperature stability.

2) Initial testing: Conduct initial testing on the test sample under standard atmospheric conditions.

3) Test: The test prototype is placed in the test box without moving, and the temperature of the test box is adjusted to 60 ℃ at a temperature change rate of no more than 10 ℃/min. After insulation for 1 hour, three test prototypes are powered on and operated under the test condition of 60 ℃ for 40 days. During the test, an intermediate test is conducted once a day.

4) Recovery: Restore the temperature of the test chamber to standard atmospheric conditions at a rate of no more than 10 ℃/min until the test sample reaches temperature stability.

5) Final inspection: Conduct post test inspection on the test prototype under standard atmospheric conditions.

3.3.2 Fault Determination and Qualification Criteria in Accelerated Life Test

During the accelerated life test process of the ultrasonic generator, the faults that occur can be divided into two types: non responsible faults and responsible faults. The fault determination method is as follows:

1) Determination of non responsible faults

During the accelerated life test process of the product, the following situations can be considered as non responsible faults:

① product faults caused by misoperation;

② Product failures caused by testing equipment, testing devices, or auxiliary equipment;

③ The failure of the tested product caused by environmental and working conditions that exceed the product's operating limits.

2) Determination of responsible faults.

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Except for faults that can be determined as non responsible, other faults can be determined as responsible faults, such as structural damage, abnormal performance testing, etc. [8].

After the accelerated life test of the ultrasonic generator is completed, if the test results of the prototype meet the following requirements, it is deemed qualified:

1) The appearance and structure are intact before and after the test;

2) The functional performance testing before and after the test meets the requirements;

3) The functional performance test in the experiment meets the requirements.

The standard for qualified appearance and structure is to avoid the following situations:

1) damage, deformation, and cracking of the product structure;

2) Surface coating blistering, wrinkling, peeling, corrosion, and deterioration;

3) Loose or detached fasteners;

4) The moving parts are stuck;

5) Wire detachment.

3.4 Analysis of Accelerated Life Test Results

During this accelerated life test, three prototypes were subjected to functional testing and data recording. The following data analysis will be conducted from four aspects.

1) Analysis of Excitation Frequency Data for Ultrasonic Knife System

The electrical energy in the ultrasonic generator is converted into mechanical vibration through an ultrasonic transducer, causing the ultrasonic blade to vibrate at a frequency near 55.5kHz, with an excitation frequency range of 55.5kHz ± 1kHz. The excitation frequency diagrams of the three prototypes are shown in Fig. 1.

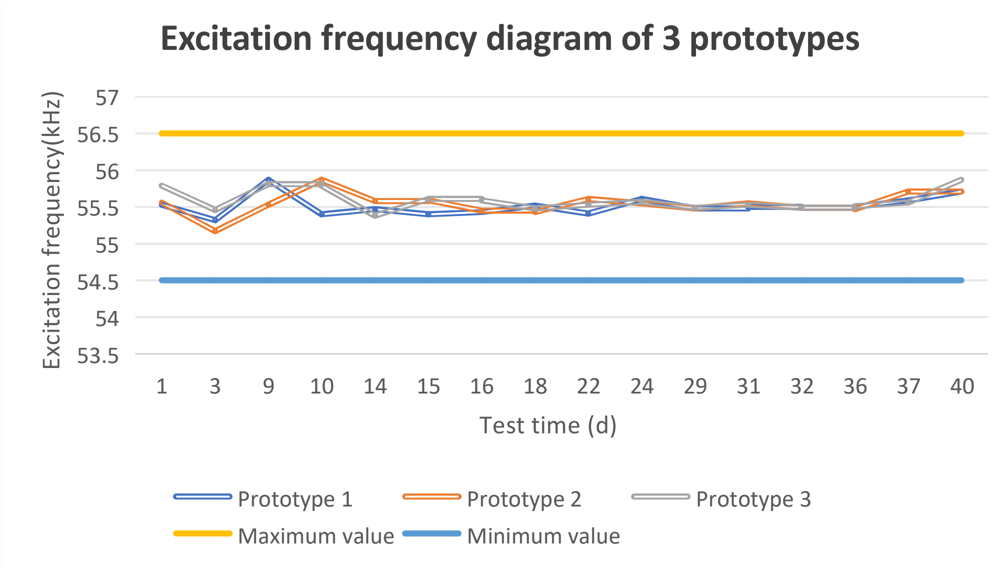

Fig. 1 Excitation frequency diagram of 3 prototypes

From Fig. 1, it can be seen that in this accelerated life test, the excitation frequencies of all three prototypes are within the allowable range, which meets the functional requirements of the equipment.

2) Analysis of Output Power Data of Ultrasonic Knife System in Gear 1

The output power range of the first gear of this model of ultrasonic knife system is 25W ± 10%. The output power diagram of the first gear of the three prototypes is shown in Fig. 2.

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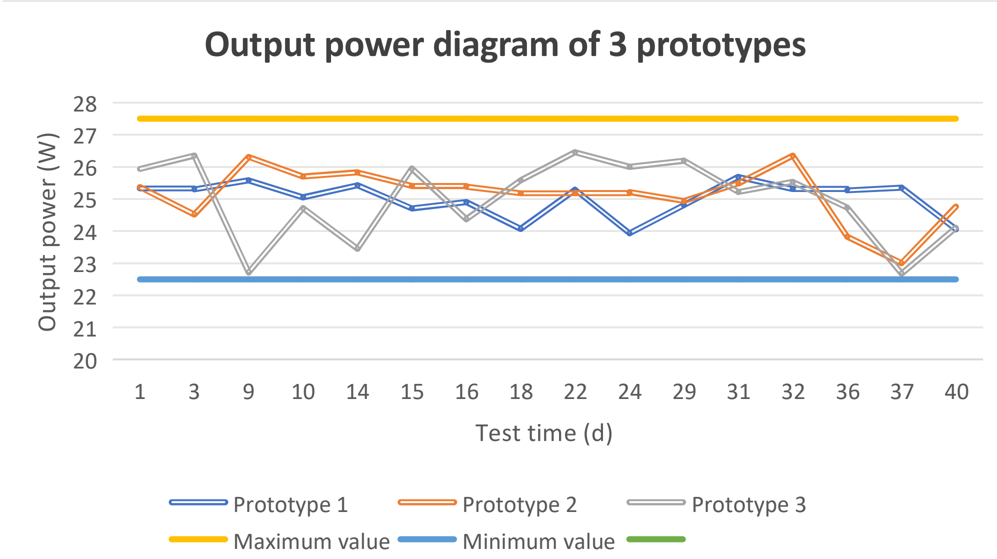

Fig. 2 Output power diagram of 3 prototypes

From Fig. 2, it can be seen that in this accelerated life test, the output power of the first gear of the three prototypes is within the allowable range, which meets the functional requirements of the equipment.

3) Analysis of Output Current Data of Ultrasonic Knife System in Gear 1

The output power range of the first gear of this model of ultrasonic knife system is 230mA ± 5%. The output current diagram of the first gear of the three prototypes is shown in Fig. 3.

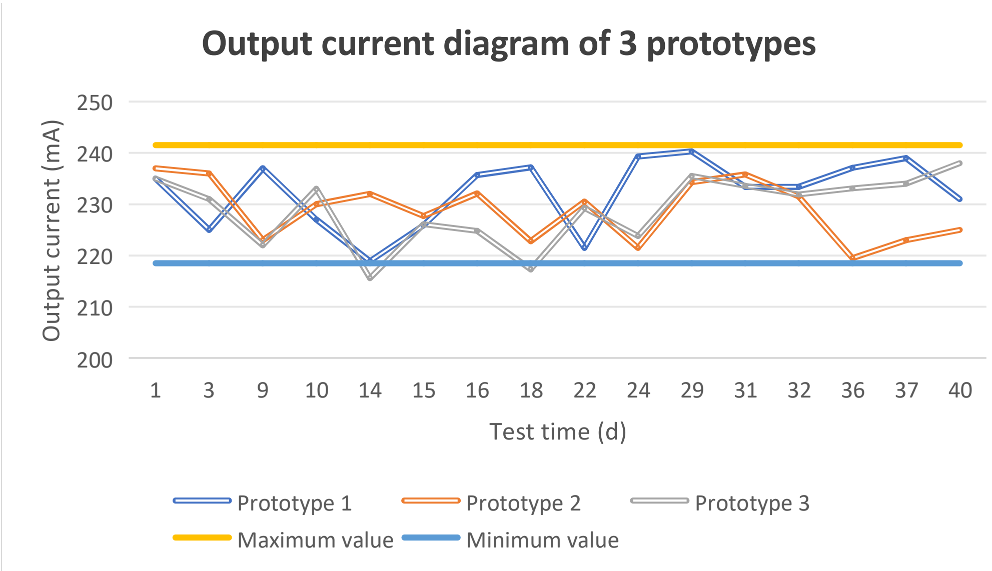

Fig. 3 Output current diagram of 3 prototypes

From Fig. 3, it can be seen that in this accelerated life test, the output current of the first gear of prototype 1 and prototype 2 is within the allowable range, which meets the functional requirements of the equipment. Prototype 3 was found to be below the minimum value during 14 and 18 days of testing. Through comparative analysis of data before and after, as well as multiple functional tests, it was determined that the cause was a misoperation by the recording personnel. Therefore, prototype 3 meets the functional requirements of the equipment.

4) Analysis of static (no-load) electrical power data of ultrasonic knife system

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The static electrical power range of this model of ultrasonic knife system does not exceed 12W. The static electrical power diagrams of the three prototypes are shown in Fig. 4.

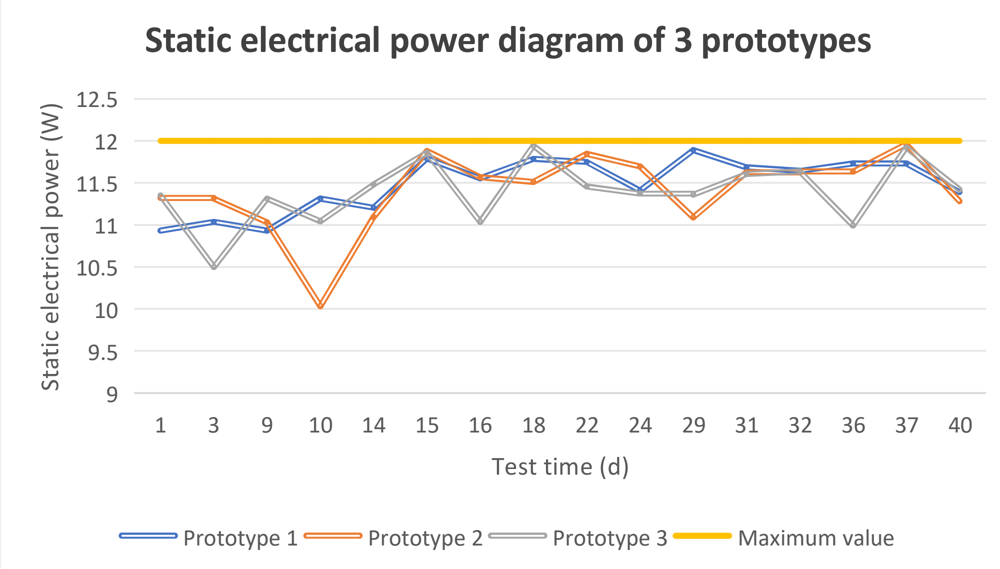

Fig. 4 Static electrical power diagram of 3 prototypes

From Fig. 4, it can be seen that in this accelerated life test, the static electrical power of all three prototypes is within the allowable range, which meets the functional requirements of the equipment.

Based on the above analysis of the experimental data of the ultrasonic knife system for this model and combined with the functional test results of the prototype conducted multiple times after the experiment, it is found that all functions of the equipment are normal after this accelerated life test, meeting the target requirements designed in the ultrasonic knife task book for this model.

4. Conclusion

On the basis of analyzing the development research and application fields of accelerated life testing, this article conducts accelerated life testing research on a certain type of ultrasonic knife system based on its reliable life indicators. A comprehensive verification method for the reliable life of the ultrasonic knife system is proposed, which combines the functional design requirements of the ultrasonic knife system, designs an accelerated life testing plan, and conducts accelerated life testing according to the plan, Based on the data analysis recorded in the experiment, it is determined that the ultrasonic knife system of this model meets the design requirements. The comprehensive verification method proposed in this article has important reference significance in the field of medical equipment, and has a certain guiding role in the reliable life verification of traditional Chinese medicine treatment equipment in this field.

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