1995년도 춘계학술대회 논문집 제17권 제1호 95/5

Reliability Analysis of Korean Total Artificial Heart

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An electromechanical totally implantable artificial heart (TAH) has been developed in Department of Biomedical engineering, Seoul National University during last 10 years. Before clinical trial, the reliability of TAH is analyzed increasing the test time to demonstrate the National Institutes of Health (NIH)'s requirements.

In this paper, we describe the system setup of reliability test and the theoretical Weibull analysis with few or no failure and evaluate the current reliability of TAH. After detecting the one TAH failure according to the criteria of decreased flow rate, the TAH elements were inspected to suggest the possible failure mode.

Materials and Methods

Reliability Test Setup

The simple mock circulation loop used for the TAH is designed to simulate physiologic conditions, constant aortic pressure 90mmHg, constant pulmonary arterial pressure 40mmHg, as shown in Figure 1. The real time monitoring of flow rate using impeller type flow-meter (LD10-TA, STEC) is achieved by PC with 8 channel interface card. The data of minimum, mean, maximum flow rates including heart rate are stored into PC in every minute. The criteria of TAH failure is 10% decrease of mean flow rate for more than 1 minute under constant pressure.

Reliability Evaluation with Weibull distribution

Figure 1. Simple Mock Loops and Monitoring PC

The Weibull distribution is often used for product life estimation. Presented belows are the Weibull fraction failed, the reliability, the shape parameter, the scale parameter.

Fraction Failed

The Weibull cumulative distribution function for the population fraction failing by age t is

$F(t) = 1 - \exp[-(t/\alpha)^{\beta}]$ for $t \geq 0$

The scale parameter α (63.2 percentile failure time) is called the characteristic life. β is a shape parameter.

Reliability

The Weibull reliability function for the population fraction surviving beyond age t is

$R(t) = \exp[-(t/\alpha)^{\beta}]$ for $t \geq 0$

The Shape Parameter Value β

In practice, one does not know the exact value of β for a product. One may have historical data or engineering theory or experience that suggests a β. Various failure distributions can be made according to β. Values of β >1 correspond to increasing hazard rates (wear-out phenomena), and values =1 correspond to a constant hazard rate (exponential distribution).

Weibull Scale Parameter α

The usual (maximum likelihood) estimate of the Weibull scale parameter is

$$\hat{\alpha} = \left[\sum_{i=1}^{n} T_i^{\beta} / r \right]^{1/\beta}$$

T_i is an individual system test time. r is the number of failures.

The lower C% confidence limit for the Weibull scale parameter α is

$$\underset{\sim}{\alpha} = \hat{\alpha}\left\{2r / \chi^2(C;2r+2)\right\}^{1/\beta}$$

$$= \left\{2\sum_{i=1}^{n} T_i^{\beta} \Big/ \chi^2(C;2r+2)\right\}^{1/\beta}$$

where $\chi^2(C;2r+2)$ is the C^{th} percentile of the chi-square distribution with (2r+2) degrees of freedom.

Following above protocol, the reliability of any medical device could be evaluated for few or no failure data. The NIH proposed a guide line demonstrating 80% reliability at an 80% confidence level of a 2 year test program with 8-12 devices. This approach is consistent with a nearly 70% reliability of long term devices such as TAH after 5 year.

Inspection of Failed TAH

TAH has a brushless DC motor (Sierracin/ Magnedyne 566-18), planetary gear trains, the inner case, the outer case, two blood sacs of double membrane and four polymer valves as shown in Figure 2.

After detecting the failure of TAH #1, every components was decomposed for eye observation and microscopic inspection. The stereo microscope (Olympus SZH10) provides the surface view of the gear tooth. The lubricant was sampled for later chemical analysis.

Results

Table 1 shows 44 month of test time accumulated to data and one failure. The estimate for overall system reliability for 5 year operation of two confidence levels is shown in Table 2.

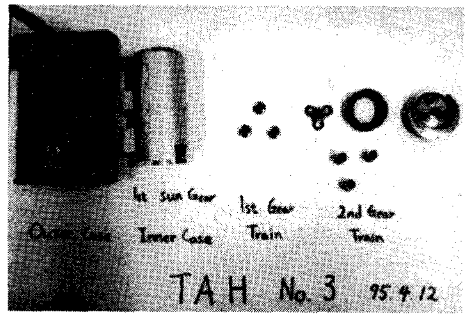

Figure 2. Mechanical Elements of TAH

Table 1. Mock Circulation Test Time of TAH

No.	*Start test time*	*Operation (month)*
1	1993.11	16 (failed)
2	1994.4	11
3	1994.5	10
4	1994.8	7

Table 2. Current Reliability (%) with Mission Time 60 month

Confidence Level (%)	*β =1*	*β. =1.3*	*β. = 1.5*
70	2.5	0.2	0.004
90	0.5	0.01	0.0006

Figure 3 shows an example of failure detection of 10% decreasing the mean flow rate from 5.6 l/min to 5.04 l/min in TAH #1.

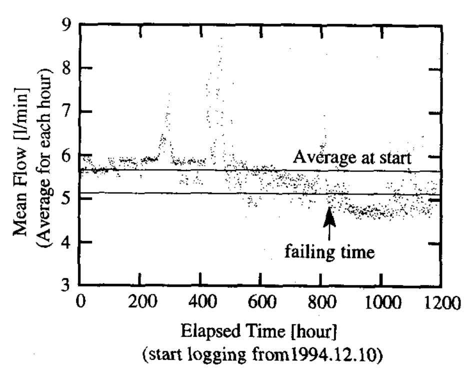

Figure 3. Flow rate of TAH #1

After failure occurring, TAH was disassembled to find the failing elements. Major reason of failure is the fracture of outer blood sacs that resulted in moving the lubricant to the space between the two membranes. Then it reduced the stroke volume of TAH. Arrows indicate the fractures of membranes in Figure 4.

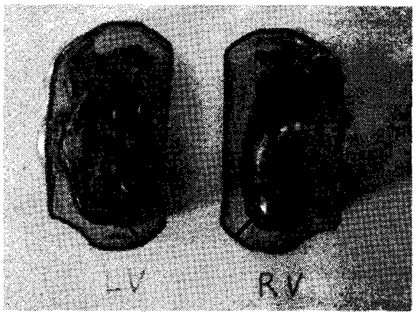

Figure 4. Fracture of Blood Sacs

Every gear was examined by the stereo microscope. Figure 5 shows the pitting of center surface and the plastic flow of end side that could result from the misalignment of gear train and the unstable rotation of the planetary gear. The abrasion of the cylinder type moving gear accompanied by advanced pitting was found as shown in Figure 6.

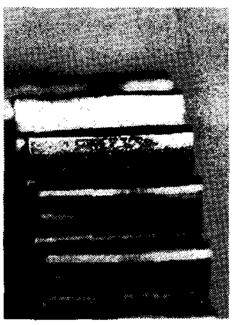

Figure 5. Tooth End Plane of 2nd Planetary Gear

Discussion

Estimation of system reliability from life time data before the occurrence of failures requires an assumption regarding shape parameter of Weibull distribution. The current reliability of TAH was evaluated through maximum likelihood estimate with conservative confidence level.

The reliability of current state is very low but adding more test setup and increasing test time will provide a suitable reliability for NIH guide line. The weak elements were discovered as the double membrane sacs

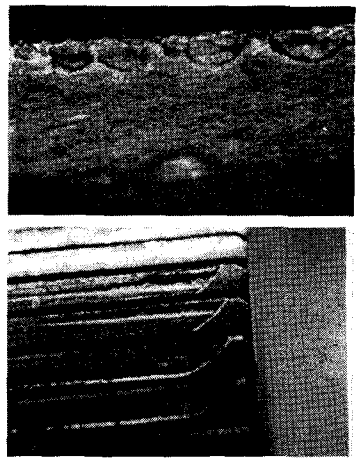

Figure 6. Moving Gear Tooth

and the moving gear. The increase of the TAH reliability and decrease of the failure rate will be achieved by design modification and quality control of these elements. Special considerations are needed to design of the proper gear train and the deformation of the blood sacs. The fatigue fracture due to the repeated large deformation and the stress concentration of membranes must be improved by selection of material and design of blood sacs and quality controlled manufacture.

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