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# Fatigue Test of Helical Nervous Electrodes and Weak Point Analysis of Helical Nervous Electrodes Design

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***Abstract*—Due to the increasing number of both implantation and removal of the helical nervous electrodes, the safety and the reliability of the electrode becomes an important issue in its clinical application，particularly its fatigue failure caused by body movement. Utilizing fatigue testing, we evaluated the weak points of the helical electrode. Our data analysis for fatigue cycles recorded by the fatigue test equipment showed that the adhesive strength between the silicone and suture, and the load of the electrode were essential for the mechanical durability of the electrode. The locations of the weak points and improvements for helical electrode design were given. The suggestions of decreasing damages to the nerves in clinical use will be helpful to the surgeons.**

***Keywords*— helical electrode; fatigue test; weak point**

## I. INTRODUCTION

Implantable peripheral neurostimulation therapy is effective for a number of neuro-disorder diseases, such as vagus nerve stimulation (VNS) for refractory epilepsy, depression and chronic heart failure [1-2]. As an important part of peripheral neuro-stimulator, electrode design, besides its functions, has focused on two aspects since its beginning: decreasing damage and increasing mechanical durability. Cuff and Helical electrodes are two main electrodes in clinical use. Cuff electrodes are relatively easy to implant and remove, but can cause nerve constriction and compression, which must be avoided during and after its implantation [3]. On the contrary, helical electrodes greatly reduce the neural damage, while its removal may cause injury to the nerves [4]. As a long-term implantation, the use of helical electrodes is more common in peripheral nerve stimulation applications. Commercially, Cyberonics uses the helical structure electrodes for the VNS Therapy system. To date, there are more than 67,000 patients using the helix electrodes for their diseases [5].

With the increasing clinical cases of implantation and removal of helical nervous electrodes, the injuries to the nerves during the surgeries have attracted more attention. Firstly, during the stimulation process, if insulation discontinuity of the electrodes happened, aberrant spread of current may cause severe discomfort [6]. Secondly, side effects, which comprise voice alteration, hoarseness, throat or neck discomfort, headache, cough, and dyspnea, always occur during stimulation [7-8]. Lastly, dense scar tissue encased the electrodes makes the dissection and removal difficult [9-10]. Commonly used options include cutting off the distal lead which connect the electrode and the generator, but not removing the electrodes [11]. However, complete removal of the helix electrodes is extremely desirable. For instance, MRI body scan can cause injury on the surrounding nerves and tissues because of the heat induced in the implanted electrodes [12].

Although successful removal has been reported and attempts to minimize tissue trauma in the process of surgical operation are in progress, few researches concentrate on evaluating the safety and reliability of the electrodes and/or improving the helix design in clinical use [13-14]. Since the patients frequently rotate their necks, the damages depicted in the second paragraph may occur. We now conduct a fatigue experiment of the helix electrodes to emulate the neck's movement, for either discovering weak points of the electrode or improving the electrode design. Furthermore, we analyze the influencing factors of the weak points, which may provide technical support for the surgeons to use the helical electrodes.

## II. STRUCTURE AND METHODS

### A. Structure of Helical Electrode

The helical electrodes transmit stimulating current pulses from the generator to the nerves. It is comprised of three different parts. The first part is a three-turn long helical coil of flexible, insulating, biocompatible layer of silicone. The second one is a platinum-iridium (Pt-Ir) alloy ribbon coil for electrical contact, which is located on the inside of the silicone's middle turn and welded with four-filar MP35N alloy coils to connect the lead. The third one is a length of polyester suture threading the ribbon and silicone, which allows manipulation of the helix electrode onto the nerve. The schematic of the helical electrode is shown in Fig. 1. Because

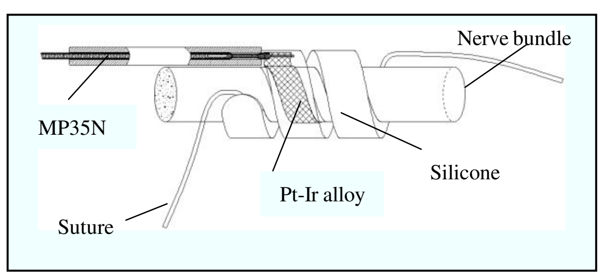


Figure 1. Helical electrode diagram

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of different materials of each part, high adhesive strength of the whole electrode is hardly achieved. If any separations occurred, the security will be reduced.

In order to find out the weak points of the helical structure, improve the production process, and design better performance helical electrode, all the samples used in the following tests are made in our laboratory. The helical silicone coil is 0.6mm thick, and the material is a kind of unrestricted healthcare product from Nusil Silicone Technology. The Pt-Ir alloy ribbon coil is 10mm long, 1mm wide, 0.025mm thick and from Goodfellow Cambridge Limited. The suture, 26mm long and 0.15mm in diameter, is a medical polyester line from Jinhuan Medical. Through the fatigue experiments, either the cause of the separations or the weak connections of the electrode will be detected.

### B. *Fatigue Test*

To exclude the possible influences of tissue fluids on the adhesive strength, all the sample electrodes have been soaked in normal saline for ten days.

The fatigue test equipment, which consists of an actuator, a motor driver, a microcontroller, a monitoring circuit and a LCD panel, has been developed in our laboratory. As shown in Fig. 2, the sample is fastened on the fixture by wrapping the suture around it, while the fixture is fixed on the actuator. The load of different weights is hung on the other side of the suture. The actuator is driven by a two phase step motor that is controlled by a microcontroller through a motor driver. When the actuator rotates in bidirectional direction, the fixture will do the same movement and the suture will wrap or unwrap around the fixture. So the helix structure can completely stretch or return to the original shape. With the reciprocating rotation of the actuator and the fixture, the fatigue test of the sample electrode is carried out. When any separations of the sample occur, the cycles of the actuator's rotation will be recorded by the monitoring unit and displayed on the LCD panel.

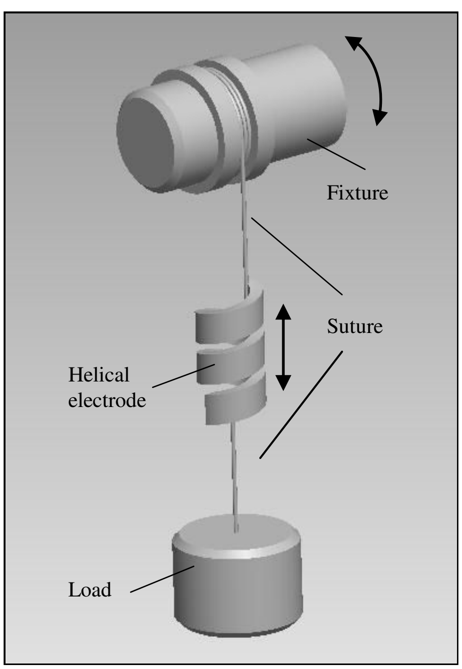

Figure 2. Illustration of the fatigue test

The fatigue test elaborated above is based on the emulation of the surgical procedure, i.e. the way of the surgeon operating the helical electrode, and the daily movements of the patients' necks. In order to find out the locations and influence factors of the electrodes' weak points, two different experiments are designed in this paper.

Because of the interrelation between the suture to the silicone and Pt-Ir alloy, the effect of the adhesive strength between the suture and the silicone is firstly evaluated. Different pretreatments present different adhesive strength, so the sutures of the sample electrodes with and without coupling agent pretreatment need to be compared. The operation conditions of the fatigue test equipment in the first experiment are as follows:

1) The force is 2 N, i.e. the load is 200 grams. 2N force is an evaluation criterion used in implantable pacing lead. It is a performance requirement of the guide steel wire inserting into or pulling out from the electrode catheter [15].

2) 135 degrees, the rotation angle of the motor is proven appropriate for the stretching length of the electrode through the preliminary tests. 0.2Hz, the cycle of the motor's rotation, guarantees sufficient stretch and recovery time.

3) For ensuring the 2N force is exerted upon the helical electrode completely, the tensile state maintains 0.5s at the end of each cycle.

Second, the impact of different loads is evaluated. 200 grams and 500 grams, i.e. 2N and 5N tractions are exerted upon the electrodes. Same as the first experiment, the rotation angle and the rotation cycle of the motor are 135 degrees and 0.2Hz respectively. All the sutures used in the second test have no coupling agent pretreatment.

## III. RESULTS

A separation in our experiment presents adhesive failures among different materials of the helical electrode. As shown in Fig.3, the locations of all the separations focus on the area around the holes which are used to thread the suture through the Pt-Ir alloy ribbon. It shows that the hole is a weak point of the helical electrode. More details are shown below:

### A. *Effect of the Suture*

As shown in Fig.3 (a), whether the suture is overlaid the coupling agent or not, the separations are nearly the same. However, as shown in Fig.4, the fatigue strength is different. The average fatigue cycles of the sample electrodes with (n=4) and without (n=4) coupling agent pretreatment sutures are 51,304 and 26,694 respectively. And the fatigue cycles of all the four electrodes with coupling agent coating sutures are above 47,000, which is an evaluation criterion used in implantable pacing lead, while the fatigue cycles of the electrodes without coupling agent coating sutures are all below this criterion. It demonstrates that the coupling agent coating obviously increases the fatigue cycles.

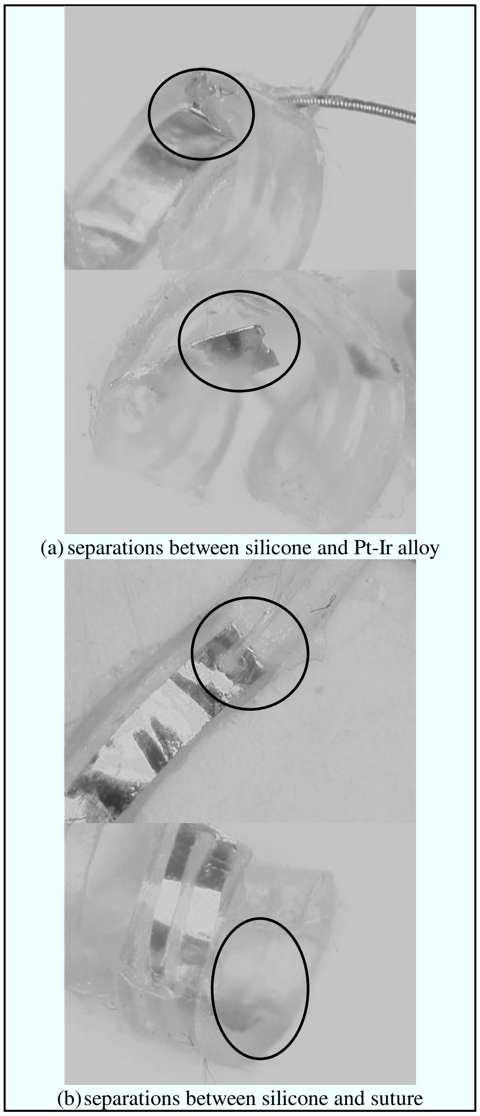


Figure 3. Graph of separations. *All the separations marked with black circles are around the holes that located in the Pt-It alloy ribbons. The holes are used to thread the sutures through the ribbons.*

## B. Effect of the load

As shown in Fig.3, when the load is 500 grams, separations between the silicone to the suture and Pt-Ir alloy both appeared. Specifically, one connection between the silicone and the Pt-Ir alloy ribbon, as well as three connections between the silicone and the suture are destroyed. The fatigue cycles of 500-grams load (n=4) are obviously less than the 200-grams load (n=4), which the average fatigue cycles of the electrodes with 200 grams and 500 grams load are 26,694 and 476 respectively (Fig. 4).

Different fatigue cycles indicate that the adhesive strength between the silicone and the suture, and the load of the helical electrode are essential factors of the adhesive strength between the silicone and Pt-Ir alloy ribbon, which is an important issue to evaluate the reliability of the electrode. The guidance of the suture is required in the process of implantation and removal of the electrode. If the connection between the suture and the silicone is destroyed, the operation will be difficult to handle and the surgeons have no alternative but to operate the silicone, while the silicone can be easily encased by fibrosis, making dissection difficult and potentially harmful. Physical damages to the patients may also occur because of the sharp edge of the Pt-Ir ribbon, which is separated from the silicone.

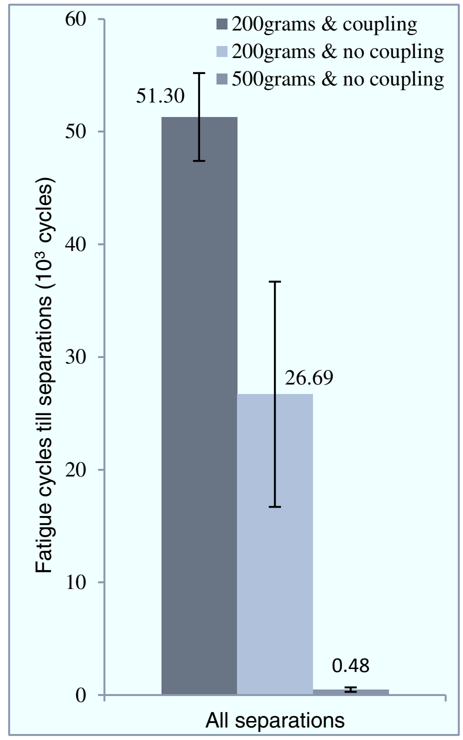


Figure 4. Fatigue cycles of different pretreatments&different loads. *When the load is 200 grams, the fatigue cycles of the sample electrodes with pretreatment sutures (n=4) are 47324, 52300, 49300, 56290, and the fatigue cycles of sample electrodes without pretreatment sutures (n=4) are 14602,35510, 34290, 22372. When the load is 500 grams, the the fatigue cycles of the sample electrodes without pretreatment sutures (n=4) are 245, 408, 539, 713.*

## IV. Discussion And Conclusion

The weak point of a helical electrode is critical and complicated. In our experiments, the separation between silicone and Pt-Ir alloy, and the separation between silicone and suture may bring side effects which are hard to bear for the patients, and also make the surgeons difficult to operate. A neuroma was found between the two helical electrodes in a 19 year-old Caucasian woman. Tran suspected the separation of the Pt-Ir alloy ribbon may be the reason for the traction injury to the nerve [16]. Leijten and Van Rijen reported a case: A man only got stimulation when he was supine with his head turned to the left. The authors concluded that the reason of this case was the disruption in the electrode's insulation [17]. As the hole which is used to thread the suture through the Pt-Ir alloy ribbon is a weak point of the helical electrode, engineers and surgeons must concentrate on this area. Lack of detailed data on human body environment and reevaluating fatigue strength after improvement made the experimental results in this paper not universal, but the analysis of the separations could provide useful experience for clinical use and improvements for helical electrode design.

In conclusion, based on a fatigue test method in this paper, the weak points of the helical electrode were detected and clarified. The damages of the separations for helical electrode's design were discussed. After improvements, higher reliability could be expected. The findings may be helpful to the surgeons when they implant or remove the helical electrodes.

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