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A new Design of the Miniature Force Sensor Based on Strain Gages for Ablation Catheter

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1 Background

Recently, the radiofrequency ablation catheter is widely used in the treatment of atrial fibrillation. Radiofrequency catheter tip is inserted through femoral vein puncture and pushed to the heart cavity. The radio frequency energy is applied to the ablation lesion on the inner wall of the heart, and then the heart cells die to achieve the aim of treatment ^[1]. During the treatment, however, the patients need repeated ablation because of the ineffective ablation, and the complications may occur. Continuous pulmonary vein lesion and isolation of wall is very important to increase the success of surgery ^[2]. Research ^[3] shows that the contact force between catheter tip and the tissue of inner heart is a key factor influencing the lesion size.

In order to monitor the contact force, many force sensors have been studied. Fukuda ^[4] used semiconductor strain gage outside of the catheter to monitor the contact force. Peirs ^[5] monitored the contact force by optical technology.

The disadvantages of the current sensors are using special expensive signal detecting and analyzing instrument, such as Endosense (SMART touch), which will increase the cost tremendously. For clinical application, it is necessary to develop a low cost sensor with enough accuracy which can also be used in the catheter for contact force measurement.

This paper focuses on designing a novel force-voltage transferring sensor. The sensor consists of a Ni-Ti alloy tube and several strain gages. With the compact design of a spiral structure, it can reduce the overall cost while keeping a good performance at the same time. The price of SMART touch catheter is 4, 348 dollars. The proposed design will be as much as 20-30 percent below SMART's price.

2 Design of the force sensor

2.1 Structure of the elastomer

The diameter of the cardiac catheter is usually 6-15 Fr (2-4.5 mm). In order to fit inside the blood vessel, the miniature force sensor should be able to be integrated with the catheter easily. The structure of the proposed force sensor consists of five components as shown in Fig.1: a) the electrode head, b) the holder, c) the strain gages, d) the elastomer, and e) the protective coating. The holder is manufactured using Ni-Ti alloy which has good elasticity. The feature of its linear deformation can ensure the sensor's accuracy.

The electrode is used for RF ablation, and it provides a reflective surface. The elastomer deformation of the holder is transferred to the distal force measuring to the voltage detection by analyzing the resistance of the three strain gages.

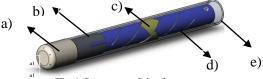


Fig.1 Structure of the force sensor

Because the miniature sensor is used for measuring the catheter tip contact force, the design of the sensor should be in accordance with the requirements of its application area. Its structure design is similar to the spring structure. The elastomer is showed in Fig.2. The elastomer is expected to withstand force of magnitude 0-1N.



Fig.2 Structure and size of the elastomer

2.2 Finite Element Analysis

The design must guarantee that the elastomer will not be damaged when exposed to a force with 1N. The force sensor should be effective within the working range of requirements and an adequate linear response. The diameter of the elastomer is 1.95mm and the length is 17mm. In order to optimize the geometry of the flexure, a finite-element modeling of the force-deformation transferring component is established and analyzed. The parameters of the force-deformation transferring component are optimized in ABAQUS (finite element analysis software). The final simulation and experiment results are shown in Fig.3.

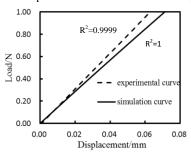


Fig.3 Simulation vs. experimental results

It is necessary to consider the scope of optimum contact force in the process of application before the design of elastomer. Interventional cardiologists have identified that the optimum contact force required to achieve a good and safe ablation line in RF procedures is around 0.2-0.3N ^[6]. Therefore, the design must ensure that the sensor will not be damaged when exposed to 1N.

2.3 The experiment verification

As shown in Fig.4, the experiment platform is established. The platform is composed of a digital angle level, a balance and a computer.



Fig.4 Experiment platform

As the tip of the catheter is lowered, the pressure on the contact surface increases gradually. The values of the balance output are 7.1g, 12.5g, 18.0g, 22.2g and 29.1g, respectively. Correspondingly, the computer records the voltage value according to the three strain gages under the action of each force value. The voltage corresponding to all the force values at the 45° is also recorded. The same procedure was repeated for a set of controls, and the contact force between the catheter and the balance was recorded during the experiment. At the same time, the three strain gages in the computer corresponding to the voltage signal is also recorded. The force values corresponding to the voltage values are found according to the look-up table.

3 Result

3.1The Finite Element Analysis

The result of simulation demonstrates that the force-deformation transferring sensor is linearly deformed when extra axial loads up to 1N. The stress contours of the structure under 1N is shown in Fig.5. Its maximum stress is $102.9 \; \text{Mpa}$, less than the yield strength of Ni-Ti alloy $(406 \; \text{Mpa})$.

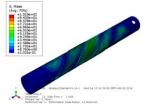


Fig.5 Stress contours of the force-deformation transferring component under axial load of 1N

3.2 The experiment verification

Table 1 shows the comparison of two sets of the experimental data. It indicates that the design of the catheter force sensor is accurate, and look-up table method is feasible.

Tab1 Comparing the load of the catheter with the horizontal plane at 45°

| contact force | | | | | |
|------------------|------|------|-------|-------|------|
| experiment /g | 6.1 | 12.3 | 18.1 | 24.2 | 30.2 |
| look-up table /g | 5.8 | 12.1 | 18.4 | 25 | 29.8 |
| error | 4.9% | 1.6% | -1.7% | -3.3% | 1.3% |

4 Interpretation

A miniature force sensor was developed and applied to the ablation catheter, which can accomplish the micro deformation with precise gages. The proposed design will greatly reduce the cost of ablation catheter due to its simplicity and accuracy. The experimental results indicate that the sensor works with fairly good linearity. It has the potential to be used in an intracardiac radiofrequency ablation surgery. The future of our main work is to develop a real-time and precise force feedback system.

5 Acknowledgment

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