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Research on Design Method of Voltage Injection Test Circuit of Active Implantable Neurostimulator

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***Abstract*—A design method of electrode-tissue interface equivalent circuit for the voltage injection test of active implantable neurostimulator (INS) is presented and analyzed. In this proposed method, characteristic frequencies of the equivalent circuit are determined, based on the published data of human tissue permittivity and conductivity. The equivalent circuit structure is defined, according to "electrode-tissue" interface model. Appropriate values of electronic components are matched by simulation. In addition, a method of replacing the electrode-tissue interface equivalent circuit with purely resistance is also proposed. According to ISO14708-3, voltage injection tests are carried out with these different equivalent circuits and INS. Results showed that these design methods can meet test requirements with no significant difference. This study explored convenient and universal methods for the voltage injection test of INS, which is useful to improve the guarantee of the electromagnetic compatibility (EMC) safety of the INS.**

***Clinical Relevance*— This study is helpful to realize the convenient EMC test of INS, and provide guarantee for the safety of clinical use.**

I. INTRODUCTION

An active implantable neuro-stimulator (INS) is an important medical device used to improve patient symptoms and enhance the quality of life by stimulating the target nerve by electrical pulses. It is sensitive to electromagnetic field (EM), and the interaction between the INS and EM may cause INS work in abnormal conditions, result in inappropriate therapy, even lead to serious injury. In recent years, with the increasing use of electronic devices, the EM in which patients with INS are located becomes complex and common. The risk associated with these interactions between active implantable medical devices and EM becomes an ongoing concern of patients, manufacturers and regulators. In order to evaluate the EMC performances of active implantable medical devices and ensure the safety of clinical use, several ISO standards have been developed [1-2]. These standards guide manufactures to make their products comply with certain requirements to achieve an appropriate level of EM compatibility in uncontrolled EM.

In ISO 14708-3:2017, a voltage injection test for INS is described and used for a Spinal Cord Stimulator (SCS) in the chapter 27--“Protection of the active implantable medical device from electromagnetic nonionizing radiation”. Since different INS systems have different functionality and different types of leads and are implanted in different parts of human body, the voltage injection test devices are different. The most important difference between different injection voltage test devices is the "electrode-tissue" interface equivalent circuit. Though one specific tissue equivalent circuit board with known materials and dimensions is described in this standard, the clear guidance of the design methods of voltage injection test for INS systems is lack. How to design the electrode-tissue interface equivalent circuit for specific products, and how to evaluate the design methods and voltage injection test results are the problems faced by manufacturers, regulators and even patients.

In this paper, our research presents a design method of electrode-tissue interface equivalent circuit for the voltage injection test of INS. The proposed method calculates parameters based on the published data of human tissue permittivity and conductivity and defines the equivalent circuit structures combined with the models described in ISO standards. This method attempts to achieve a convenient and universal design pattern for the requirements of voltage injection test of different INS systems. Circuits designed by this method and others are applied in experiments with a SCS and a deep brain stimulator (DBS). The results show that the circuit designed by this method can meet the test requirements and test results have no significant difference with those circuits presented in ISO standards. Our research can provide reference for manufacturers and regulators, help to improve the test method and evaluation of voltage injection of INS, and help to realize convenient EMC test.

II. DESIGN

A. *Electrode-tissue interface model in voltage injection test*

The test schematic diagram of voltage injection test is shown in Fig.1. As suggested in ISO14708-3:2017, the whole test circuit consists of three parts: the electrode-tissue interface model, the low pass filter and the lead interface. The electrode-tissue interface model simulates the impedance of the electrode-tissue interface and matches signal generator output to the circuit. The low pass filter is designed to separate

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the injected signal from the output waveforms of the INS. The lead interface simulates the impedance of therapy leads and is connected to an INS. During the test, the test signal generator injects voltage signal which should meet the requirements listed in standards into the electrode-tissue interface model. The INS output stimulation is selected. The oscilloscope is connected to the electrode-tissue interface model and the low pass filter to monitor signals.

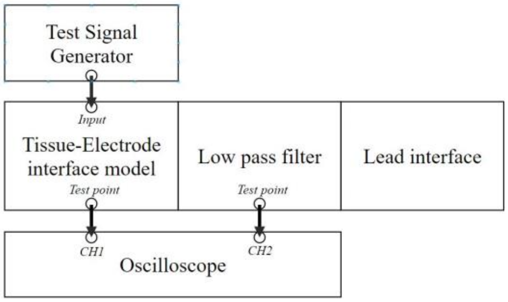

Figure 1. The test schematic diagram of voltage injection test.

The electrode-tissue interface plays an important role in the study of electrical interactions between electrodes where the stimulation signals output and human tissue. Accurate electrode-tissue equivalent circuit is of great significance to simulate the working condition of the INS after implantation. What's more, the in vivo impedance of electrode-tissue interface always reflects some changes of interface components and it should be considered during clinical stimulation parameter selection and chronic animal research studies [3].

However, in vivo impedance measurements are very difficult [4]. Since the electrode-tissue interface model in voltage injection test is only used to simulate the certain impedance to regulate the injected signal. We can explore some convenient design method of electrode-tissue interface equivalent circuits.

B. Design methods

Instead of measuring impedance of electrode-tissue interface in vivo, our design methods use known data to fit the equivalent circuit structure and parameters. The design flow chart is shown in Fig.2.

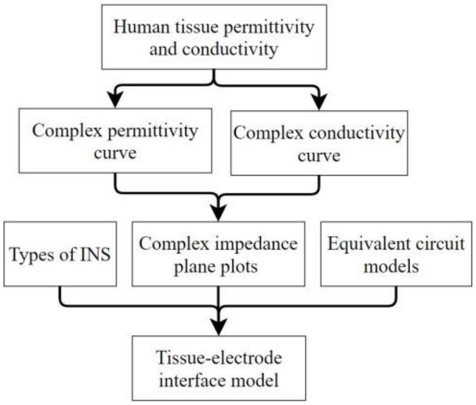

Figure 2. The design flow chart of electrode-tissue interface equivalent circuit.

The published data of human tissue permittivity and conductivity are from the database set up by "IT'IS Foundation". The Foundation for Research on Information Technologies in Society (IT'IS) is an independent, nonprofit research foundation dedicated to improving and advancing the quality of people's lives by enhancing the safety and quality of emerging electromagnetic technologies [5].

According to the Cole-Cole equation [6], the complex permittivity and the complex conductivity can be represented by (1) and (2).

$$\varepsilon_\omega = \varepsilon' + j\varepsilon''. \tag{1}$$

In (1), ε_ω is the complex permittivity, the ε' is the real part of ε_ω , the $\varepsilon'' = (\sigma - \sigma_l) / (\omega\varepsilon_0)$ is the imaginary part of ε_ω, σ_l can be determined by low frequency limit conductivity and ε_0 is dielectric constant of vacuum.

$$\sigma_\omega = \sigma' + j\sigma'' . \tag{2}$$

In (2), σ_ω is the complex conductivity, the σ' is the real part of σ_ω, the $\sigma'' = (\varepsilon - \varepsilon_h)(\omega\varepsilon_0)$ is the imaginary part of σ_ω, and ε_h can be determined by high frequency permittivity.

Based on (1) and (2), the complex impedance plane plots can be drawn, and the characteristic frequencies of the equivalent circuit are determined.

However, in our complex impedance plane plots, Warburg impedance may appear in low frequency region. Then we can take the common equivalent circuits and the INS systems need to be tested into consideration. Referring to the five element model proposed in the standards and the impedance of the actual implantation position of the INS system, we can use some relevant software to match the appropriate parameters. At last the electrode-tissue interface equivalent circuit is designed.

III. EXPERIMENT

In this section, experiments are carried out to compare the injection voltage test results of different types of electrode-tissue interface equivalent circuits. An SCS system and a DBS system are tested in experiments, and these experiments are in accordance with ISO 14708-3:2017. The frequency range of the injected signal is 16.6Hz to 80MHz.

A. Test configuration

Test configuration includes:

- A qualified SCS with output-only (non-sensing) functionality and a percutaneous lead with 16 electrodes. The length of the lead is 60cm.
- A qualified DBS with output-only (non-sensing) functionality and a percutaneous lead with 8 electrodes. The length of the lead is 60cm.
- A voltage injection testing device with 17 test channels (16 electrodes and enclosure) for SCS, the electrode-tissue interface equivalent circuits are designed as recommended in ISO 14708-3.
- A voltage injection testing device with 17 test channels (16 electrodes and enclosure) for SCS, 17

electrode-tissue interface equivalent circuits are replaced by 17 purely resistance.

- A voltage injection testing device with 17 test channels (16 electrodes and enclosure) for DBS, the electrode-tissue interface equivalent circuits are designed by the method proposed in this paper.
- A voltage injection testing device with 17 test channels (16 electrodes and enclosure) for DBS, 17 electrode-tissue interface equivalent circuits are replaced by 17 purely resistance.
- Test principle of voltage injection test is shown in Fig.3: oscilloscope, signal generator, voltage injection testing devices with different electrode-tissue interface equivalent circuits as shown in Fig.4, and INS.
- Test signal is selected according to ISO14708-3:2017: Table 104 and Table 105.

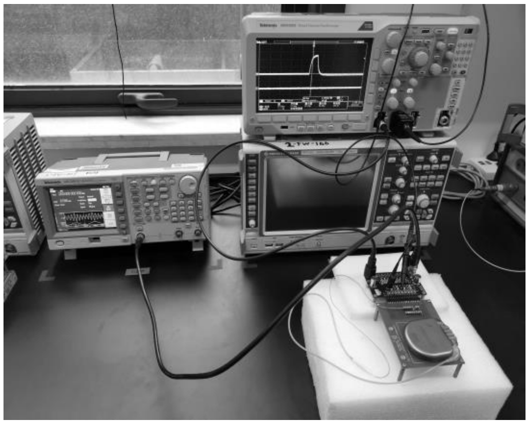

Figure 3. Test principle of voltage injection test

Figure 4. Voltage injection testing device .

B. *Comparative experiment between the circuit in ISO14708 and the pure resistance equivalent circuit*

Based on the SCS system, the comparative experiment is conducted. The SCS works in the bipolar mode and the electrode 4 is programmed as an anode (+). The voltage of the output signal of the SCS is 1.5V. The electrode-tissue interface equivalent circuit for SCS presented in ISO 14708 is at the top of Fig.5, and the purely resistance is shown at the bottom of Fig.5. In the Fig.5, the R1 is 60.4 ohms, the R2 is 90.9 ohms, the R3 is150 ohms, the C1 is 240 pF, C2 is 56nF, and the R is 249 ohms.

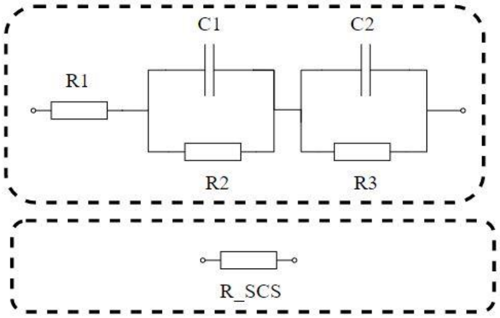

Figure 5. The electrode-tissue interface equivalent circuit for SCS

Test signals are applied to the equivalent circuits, and the output waveforms of SCS are monitored by oscilloscope. When the frequency of test signal is from 5kHz to 300kHz, we get the obvious result of output signal interference. The results are similar to the reference [7]. By calculating the variation, we find the maximum variation of the output signal interference in each equivalent circuit. Results obtained from the electrode-tissue interface equivalent circuit for SCS designed in ISO14708 show that the maximum variation is 20%, when the frequency is 30kHz. For example, the most obvious result of output signal interference is shown in Fig.6. Results obtained from purely resistance for SCS show that the maximum variation is 18%, when the frequency is 30kHz.

This experiment shows that the both equivalent circuits can meet the requirements of voltage injection test described in ISO 14708-3:2017. What's more, the test results of both equivalent circuits have good consistency. The purely resistance can be used to replace the electrode-tissue interface equivalent circuit to accomplish the voltage injection test of SCS.

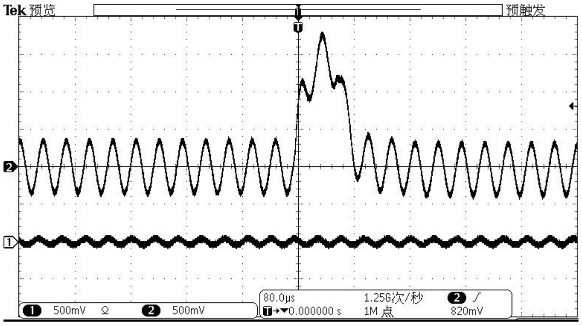

Figure 6. Example of the most obvious result of output signal interference. (The frequency of test signal is 30kHz)

C. *Comparative experiment between the circuit designed by our method and the pure resistance equivalent circuit*

Based on the DBS system, the comparative experiment is conducted. The DBS works in the bipolar mode and the electrode 5 is programmed as an anode (+), and the electrode 6 is programmed as a cathode (-). The voltage of the output signal of the DBS is 1.5V. The structure of the electrode-tissue interface equivalent circuit for DBS designed by our method is similar to the Fig.5, but the values of components are different.

The value of R1 becomes 249 ohms and the values of other components remain unchanged. Since the characteristic frequencies of electrode-tissue interface equivalent circuit calculated for DBS are in the same order of magnitude with the characteristic frequencies of the electrode-tissue interface equivalent circuit for SCS. The purely resistance applied in the test for DBS is 996 ohms.

Test signals are applied to the equivalent circuits, and the output waveforms of DBS are monitored by oscilloscope. When the frequency of test signal is from 5kHz to 300kHz, we get the obvious result of output signal interference. The results are also similar to the reference [7]. The maximum variation of the output signal interference in each equivalent circuit are obtained. when the experiment is conducted with our circuit, the maximum variation is 23%, and the frequency is 100kHz. the most obvious result of output signal interference is shown in Fig.7. Results obtained from purely resistance for DBS show that the maximum variation is 21%, when the frequency is 30kHz.

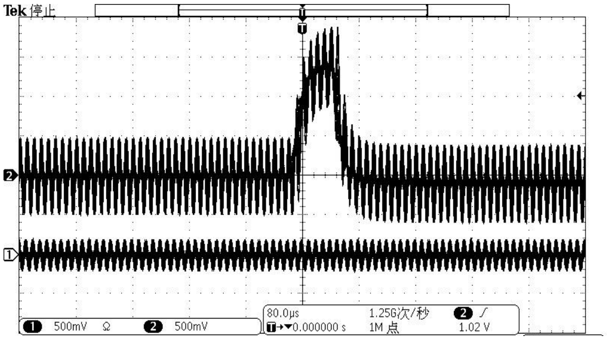

Figure 7. Example of the most obvious result of output signal interference. (The frequency of test signal is 100kHz).

This experiment shows that the equivalent circuits designed by our method can meet the requirements of voltage injection test described in ISO 14708-3:2017, and it has good consistency with the purely resistance equivalent circuits. Our method can be used to design the electrode-tissue interface equivalent circuit to accomplish the voltage injection test of DBS even other INS systems.

IV. CONCLUSION

The design method of electrode-tissue interface equivalent circuit for the voltage injection test of INS presented in this paper is helpful to realize convenient EMC test, and improve the guarantee the safety of the INS. Based on the published database and the references of ISO standards, the structure of the electrode-tissue interface equivalent circuit and the appropriate values can be determined. Experiments of voltage injection test with an SCS, a DBS and several equivalent circuits are carried out. The results confirmed the effectiveness of the equivalent circuit designed by the proposed method. The results also indicate that the purely resistance can be used to replace the electrode-tissue interface equivalent circuit. And the output signal interference has no significant difference. This paper explores convenient and universal methods for the voltage injection test of INS, which can provide references for manufacturers, and help regulators implement effective monitoring to promote the development of the industry.

STATEMENT

There are no experimental procedures involving human subjects or animals in this work..

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