Proceedings - 19th International Conference - IEEE/EMBS Oct. 30 - Nov. 2, 1997 Chicago, IL. USA

# ULTRASONIC DISTANCE DETECTION FOR A CLOSED-LOOP SPINAL CORD STIMULATION SYSTEM

E.A. Dijkstra*,#, J. Holsheimer#, W. Olthuis*, and P. Bergveld*

#Institute for Biomedical Technology, and *MESA Research Institute, Electrical Engineering,
University of Twente, P.O. Box 217, 7500 AE Enschede, The Netherlands
E-Mail: E.A.Dijkstra@el.utwente.nl

*Abstract* — **When stimulating the spinal cord at a constant strength, the current density in the spinal cord and thus the effects on chronic, intractable pain and vascular insufficiency will change with body position, due to the varying separation of the spinal cord and the stimulating electrode. The current density in the spinal cord has to remain between the perception and discomfort threshold (stimulation window) for a good therapeutic effect, i.e. that the patient does not suffer from pain. The stimulation window is very small. In current SCS systems the stimulus applied to the electrode is set at a constant value. A major improvement could be achieved when the distance between stimulation electrode and spinal cord could be measured and used to control the stimulus amplitude in a closed-loop system. An ultrasonic piezoelectric transducer was chosen to measure the distance between the electrode and the spinal cord.**

*Index Terms* — **Spinal cord stimulation, ultrasound, piezoelectric transducer.**

## I. INTRODUCTION

Spinal cord stimulation (SCS) is applied to patients suffering from chronic, intractable pain, and vascular insufficiency. SCS is based on electrical stimulation of neural structures on the posterior side of the spinal cord. The electrical field is applied by a selection from the contacts (usually four) integrated on an electrode (Fig. 1). The electrode is implanted in the epidural space at the posterior side of the spinal cord.

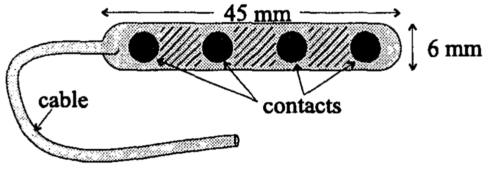

Fig. 1 Schematic representation of an electrode. The dashed area indicates the space for the transducer for distance detection.

Fig. 2 shows a schematic cross section of the spinal cord with the position of the electrode. An implantable pulse generator (IPG) generates the electrical stimulation pulses applied to the electrode via a cable. The IPG is implanted subcutaneously in the abdomen, and contains a lithium battery. With average use, most patients can expect the battery to last 2.5 to 4.5 years [1].

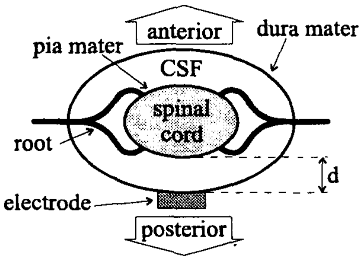

Fig. 2 Schematic cross section of the spinal cord.

### A. Anatomical Structure of the Spinal Cord

The spinal cord floats in the dural sac, a column of cerebrospinal fluid (CSF), surrounded by the dura mater. The CSF is optically clear. The spinal cord is surrounded by a thin smooth layer: the pia mater. At each vertebral level a pair of posterior and anterior roots leaves the spinal cord at both sides and they join lateral to the spinal cord (Fig. 2). This anatomical structure enables the spinal cord to move in the anterior and posterior direction, while little shift in a lateral direction is possible. The position of the spinal cord in the dural sac depends on the position and posture of a person.

In an MRI study by Holsheimer et al. [2] the dorsal CSF layer was measured in 26 subjects. This study showed that the CSF at T11 was approximately 2.2 mm larger when the subjects were in prone position than in supine position. At T12 this difference was approximately 3.4 mm. The thickness of the dorsal CSF layer varies between 1 and 10 mm, depending on the position of the patient and the vertebral level.

### B. The Stimulation Window

In current SCS Systems the stimulus applied to the electrode is set at a constant value. Therefore, the electrical field in the spinal cord will vary with the body position. However, the electrical field in the spinal cord has to remain between an upper (discomfort) and lower (perception) threshold for a good therapeutic effect, i.e. that the patient does not suffer from pain.

To keep the electrical field in the posterior spinal cord (almost) constant, the stimulus applied to the electrode has to be changed with the distance *d* between the spinal cord and the electrode. From an inhomogeneous, anisotropic volume conductor model of SCS it was calculated by Holsheimer et al. [3] that the perception threshold *P* can be written as:

$$P = 0.765 \cdot 10^{0.087d} - 0.57 \qquad (1)$$

Fig. 3 shows the perception threshold *P* and the discomfort threshold *D* (approximately 40% higher than *P*) as a function of the distance *d*. The applied stimulus has to be maintained between *P* and *D*, the stimulation window *ΔS*.

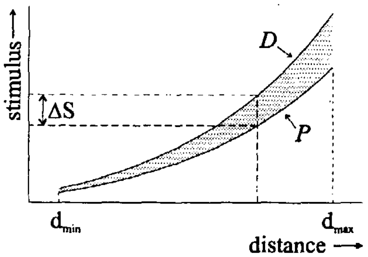

Fig. 3 The required stimulus (applied to the electrode) as a function of the distance between the electrode and the spinal cord for optimal stimulation. The dashed area indicates the stimulation window.

### C. *Improvement of the Current System & System Requirements*

In order to obtain a therapeutic effect, the stimulus has to remain in the dashed area (Fig. 3). Because the distance *d* may vary substantially, it is necessary to apply a distance-related stimulus. A major improvement of the current SCS system could be achieved when the distance between the electrode and the spinal cord could be measured and used to control the stimulus amplitude.

The distance measurement must be contactless, safe, harmless, and should be repeated regularly (once per minute). The distance between the electrode and the spinal cord varies between 1 and 10 mm, and the resolution of the measurement should be 0.5 mm, or less.

The distance detection system should have low power consumption, because a significantly increased power consumption reduces the battery lifetime. The transducer must be integrated on the electrode. This limits the size of the transducer to an area of 5×5 $\text{mm}^2$ and a thickness of 2 mm. Robustness is also an important requirement for an in-vivo used transducer.

## II. METHODS

Four methods for distance detection have been investigated [4]: Electrical, optical, opto-acoustic, and acoustic. According to the system requirements, the latter (using ultrasound) has been chosen to be implemented. This method needs just one element as a sensor and actuator, the size of the transducer can be kept small (4×4 $\text{mm}^2$), the delay times can be detected electronically, and piezoelectric transducers in pulsed mode have a low power dissipation.

### A. *Ultrasonic Distance Detection*

Ultrasonic distance detection is based on the time of flight of an ultrasonic pulse. This pulse can be generated and detected by a piezoelectric element. An ultrasonic pulse will be partially reflected on the interface of two media. The delay between emitting a pulse and receiving the reflected part is a measure for the distance between the transducer and the interface (spinal cord).

Important transducer parameters are: 1. Efficiency; must be high to minimize power consumption; 2. Dynamic range; from 1 to 10 mm; 3. Axial resolution; at least 0.5 mm.

### B. *Modeling of the Spinal Cord & Measurement Setup*

For laboratory experiments a model of the spinal cord in CSF, with realistic dimensions and acoustic impedance, was used. The dimensions were obtained from the MRI study [2]. Table 1 shows that the acoustic impedance of silicone rubber is close to the value of soft biological tissue. The spinal cord is modeled by a cylinder of silicone rubber with a diameter of 9.5 mm, immersed in water.

Table 1 Acoustic impedances of some materials and biological tissue.

| | **Acoustic impedance [MRyal]** |
|---|---|
| Water [5] | 1.52 |
| Soft tissue (except muscle) [5] | 1.35 - 1.68 |
| Perspex [5] | 3.2 |
| Sylgard silicone rubber [6] | 1.04 - 1.34 |
| Silicone rubber [7] | 1.91 |

The transducer is connected as shown in Fig. 4. The setup consists of a function generator (HP 33120A) and an oscilloscope (HP 54520A) connected to a PC by an IEEE-488 bus. The 1 ohm resistor is added to measure the current through the transducer. The spinal cord model is attached to a precision manipulator with a resolution of 1 μm. The manipulator is used to vary the distance between the transducer and the spinal cord model.

The piezoelectric transducer is a PXE-5 element with an area of 4×4 $\text{mm}^2$ and a thickness of 0.3 mm. The element is mounted with silver glue on printed circuit board and covered by a thin (≈ 40μm) epoxy (Hysol) layer. For all experiments a single sine wave with a period of 0.145 μs (6.9 MHz) and a peak-peak amplitude of 8 V is used as the excitation pulse.

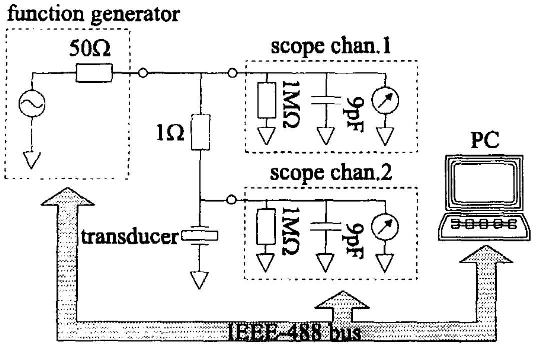

Fig. 4 Measurement setup for delay time versus distance measurements.

## III. RESULTS

### *A. Delay Time versus Distance Measurements*

Fig. 5 shows ringing of the transducer and the echo signal of the spinal cord model. The signal is averaged 32 times. The reflected signal is very small compared to the excitation signal. This is caused by the small reflection of the acoustic wave by the spinal cord model.

Ringing of the transducer lasts for about 7 µs, which corresponds to a distance of approximately 5 mm.

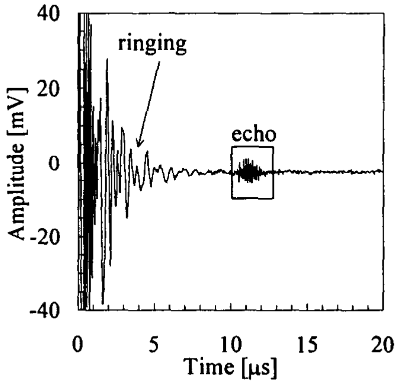

Fig. 5 Excitation signal (left) and echo signal (right).

The delay time of an echo is the interval between the time the excitation pulse is applied to the transducer and the time of arrival of the echo signal. The latter is indicated in Fig. 6 by the dashed line. The signal shown is the same as the echo shown in Fig. 5.

A series of delay time measurements was performed to measure the resolution and the dynamic range. Fig. 7 shows the results. The solid line represents a linear fit through the data points. From the figure it becomes clear that the resolution is better than 0.5 mm. The measured dynamic range varies from 4 mm to (at least) 12 mm, which is less than required.

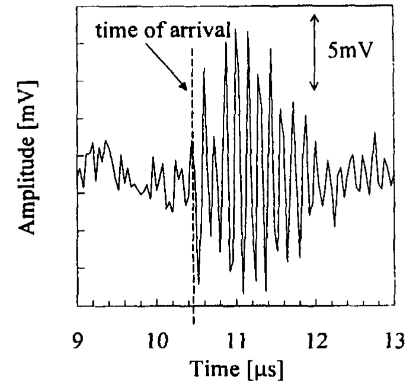

Fig. 6 Echo signal; enlargement of the echo signal of Fig. 5.

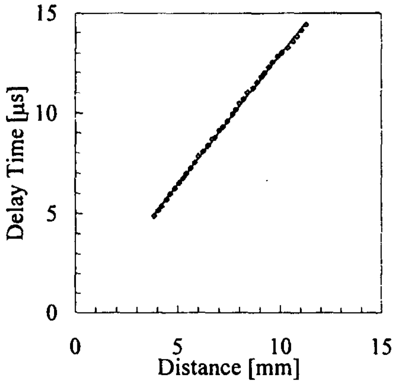

Fig. 7 Delay time versus distance.

Due to ringing of the transducer it was not possible to detect echo signals with a delay less than 5 µs. This delay corresponds to a distance of 3.8 mm. The shortest distance to be measured is 1 mm, which equals a delay time of 1.3 µs. To be able to detect the corresponding echo signal, ringing of the transducer must be reduced to less than 1.3 µs.

Ringing can be reduced by adding a lossy backing material with an acoustic impedance close to the value of the transducer. Unwanted frequency components (Fig. 5) can be removed by high pass filtering of the signal.

### *B. Power consumption*

The RMS current through the transducer can be calculated from:

$$i_{RMS} = B\sqrt{\frac{T_s}{2T}} \tag{2}$$

where $T_s$ is the period of the stimulation current, $T$ the interval between two successive excitation pulses, and $B$ the amplitude of the current.

The current was obtained from a 2048 times averaged voltage signal over the 1 ohm resistor, using channel 1 and 2 of the oscilloscope (Fig. 4). The peak-peak amplitude of the current through the transducer is 550 mA. The frequency of the pulse was 6.9 MHz. For an interval of 60 seconds between two excitation pulses, the RMS current is 9.6 µA.

The current consumption of SCS systems is approximately 50 µA. The current consumption of the used transducer will therefore reduce the battery lifetime by approximately 20 percent.

## IV. CONCLUSIONS

The proposed ultrasonic method can be used to determine the distance between the electrode and the spinal cord in order to control the stimulus amplitude for SCS, although some improvements have to be made.

Ringing of the transducer must be reduced to enable detection of the spinal cord at the minimum distance of 1 mm.

The axial resolution of the transducer is sufficient for this application.

The size of the transducer is within the maximum dimensions allowed.

## ACKNOWLEDGEMENTS

This investigation was supported in part by a grant from Medtronic Inc., Minneapolis, MN.

## REFERENCES

[1] G. Barolat, "Current Status of Epidural Spinal Cord Stimulation," *Neurosurgery Quaterly*, Vol. 5, pp. 98-124, 1995.

[2] J. Holsheimer, J.A. Den Boer, J.J. Struijk, and A.R. Rozeboom, "MR Assessment of the Normal Position of the Spinal Cord in the Spinal Canal", *American Journal of Neuroradiology*, Vol. 15, pp. 951-959, 1994.

[3] J. Holsheimer, J.J. Struijk, G. Barolat, and J. He, "Significance of the spinal cord position in spinal cord stimulation," *Acta Neurochir [Suppl]*, Vol. 64, pp. 119-124, 1995.

[4] E.A. Dijkstra, "Ultrasonic Distance Detection in an Epidural Spinal Cord Stimulation System," Master Thesis, University of Twente, 1995.

[5] P.N.T. Wells, "Ultrasonics in Clinical Diagnosis," second edition, ed. P.N.T. Wells, Churchill Livingstone, Edinburg, 1977.

[6] A.R. Selfridge, *"Approximate Material Properties in Isotropic Materials,"* IEEE Trans. Son. Ultrason., Vol. SU-32, pp. 381-394, 1985.

[7] G. L. Wojcik, D. K. Vaughan, V. Murray, and J. Mould, Jr. *"Time-domain modeling of composite arrays for underwater imaging,"* IEEE Ultrasonics Symposium Proceedings, pp. 1027-1032, 1994.