Measurement of Displacement of Percutaneous Lead for Spinal Cord Stimulation

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Abstract: A Medtronic implantable neurostimulation system is indicated for spinal cord stimulation (SCS) as an aid in the management of chronic, intractable pain of the trunk and limbs. The method of anchors fixing may have a significant influence on the elimination or reduction of the SCS lead displacement. The aim of the research was an experimental examination and comparison of electrodes displacement for three different ways of fixing of the lead using anchor. The displacements were measured on pigs using optical methods. The displacement of the electrode depends greatly on the number of anchors and on the manner the lead is fixed. The fixing the lead using two anchors with a loop between them significantly reduces the total displacement of the electrode.

Keywords: measurement of displacement, digital image stereo-correlation method; image processing.

1 Introduction

The spinal cord stimulation electrodes used in the clinic are either minimally invasive cylindrical electrodes to be implanted percutaneously. The lead migration is the most common complication encountered with SCS systems. Strategies have been identified to reduce the occurrence of lead migration for SCS implantation [1, 2]. The fixing electrodes at points of their exit from the spinal space is performed using of anchors which are securely fixed to the lead and sutured with two stitches to the fascia, Fig. 1.

The aim of the research was an experimental examination and comparison of electrodes displacement for three different ways of the fixing of the lead. Three electrodes were gradually implemented into the epidural space of the pig and fixed in three different ways:

- using one anchor (Fig.1),
- using two anchors,
- using two anchors, with loop.

The set of measurements was carried out for each of fixing way. The method of fixing may have a significant influence on the elimination or reduction of the electrode feed.

Fig. 1: The electrode fixed using one anchor.

The experimental measurements were carried out in the Laboratory of electrophysiology of the 1st Faculty of Medicine, Charles University in Prague on pigs under standard laboratory conditions. Measurements were scanned in a state without breathing.

2 Measurement of Lead Displacement

The electrode of stimulator with the connecting cable were threaded through the epidural space and led out to the surface of the body of the pig. The lead was fixed in the incision before entering into the pig‘s spine using one of the methods listed above. The second end of the lead was tunneled to the side of the pig and the extension of the lead connected to a rope. The rope passed over a pulley and it was loaded by a weight which caused the electrode to move. The load grew slowly from 0 to 10 N for 15 seconds. The displacement of the electrode was measured and evaluated using two different optical methods:

- Digital image stereo-correlation method,
- Digital image processing method.

2.1 Digital Image Stereo-correlation Method

The measurement and evaluation were carried out using the optical correlation device ISTRA4 Dantec Dynamics which allows for non-contact measurement of three-dimensional displacements of points on the surface of a body. One white target with a random speckle pattern of black dots was attached to the electrode and a second one was attached to the skin of pig (Fig. 2). The targets moved slowly during the loading of extension lead. The images of the two moving targets were recorded simultaneously using two cameras with a sampling frequency of 17 frames per second (Fig. 3). The recorded images were then processed in the ISTRA4 software and the 3D coordinates (x, y, z) of the target points were determined. The three components of displacement Δx, Δy a Δz are calculated as the difference coordinates of the points on the actual image and the reference image. The example of total displacement evaluation is in Fig. 4. The electrode target lies freely on the dorsal part of the pig and therefore the movement of the target is a *general spatial motion* whose approximate evaluation is only qualitative. The total displacement d of the tip of the electrode was chosen for comparison of the electrode movement in the three different ways of fixing the lead:

$$d = \sqrt{(\Delta x)^2 + (\Delta y)^2 + (\Delta z)^2} \quad (1)$$

The influence of the different ways of fixing the lead is apparent from Fig. 5 where the graphs of total displacement d during the loading are displayed. The displacement of the electrode depends greatly on the number of anchors and on the manner the lead is fixed. It is evident that fixing the lead using two anchors with a loop between them significantly reduces the total displacement of the electrode.

Fig. 2: Targets with random speckle pattern.

Fig. 3: Photogrammetric system with two cameras.

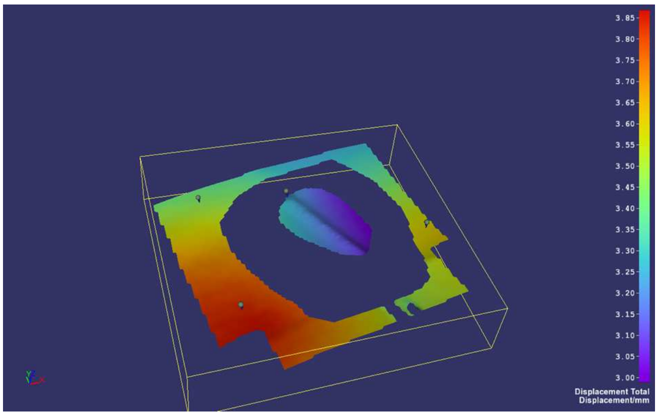

Fig. 4: The example of total displacement evaluation.

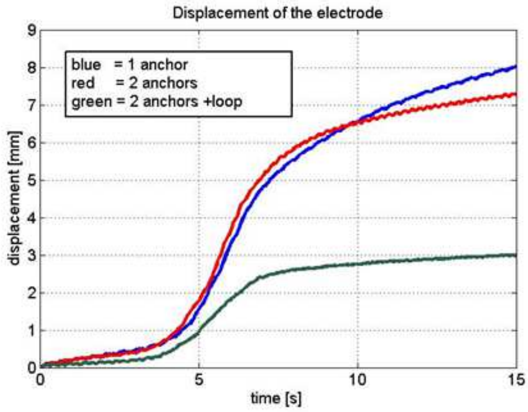

Fig. 5: Total displacement of the end the electrode during 15 seconds of loading.

2.2 Measurement of Electrode Displacement by Means of Digital Image Processing

The aim of the measurement was to precisely determine the displacement of the electrode in the longitudinal direction of the spine. A small glass tube with an internal diameter of 3 mm was sewn onto the skin of the dorsal part of the pig parallel to the spine, using two stitches. The lead was threaded through the epidural space, brought to the surface and inserted into the tube, see Fig. 6. Two targets were glued onto the surface of the tube with a distance of 100 mm between them ensuring a fixed benchmark for every photographic image. The electrode could move freely in the tube axis direction while its movement in the transverse direction was limited by the tube wall. The extension of the lead was loaded the same way as in the previous cases. In every experiment two digital images of the electrode position were recorded with a resolution of 4608 x 3456 pixels. The first image was recorded before load application when the electrode was in the starting position and the second one was recorded in steady state at the end of loading.

The pixel coordinates of both targets and of the tip of the electrode were determined in every image in Matlab Image Processing Toolbox. The coordinates correspond to places with maximum correlation coefficient between matrix *A* and matrix B. The matrix A contains the grayscale intensities of rectangular area around the targets or around the electrode tip. The matrix B of the same size picked from every image using detailed scanning. The correlation coefficient *r* is defined by

$$r = \frac{\sum_m \sum_n \left(A_{mn} - \bar{A}\right)\left(B_{mn} - \bar{B}\right)}{\sqrt{\left(\sum_m \sum_n \left(A_{mn} - \bar{A}\right)^2\right)\left(\sum_m \sum_n \left(B_{mn} - \bar{B}\right)^2\right)}}, \tag{2}$$

where $\bar{A}$ and $\bar{B}$ are the means of values in matrices *A* and *B*. The distance of targets in units of pixels in every image was used for conversion between pixels and millimetres. The targets distance was 100 mm, or about 2811 pixels, respectively, and therefore the accuracy of the measurement of the position of the electrode is higher than 0.1 mm.

The position of the electrode tip was determined in every image and the displacement of the electrode was calculated as the difference between its positions before and after loading. The results of the three sets of measurements are in Fig. 7 and in Table 1. It is evident that the way the supply lead is fixed is crucial in avoiding the displacement of the electrode due to a sudden movement of the patient.

The exploratory data analysis (EDA) was conducted within the framework of statistical analysis of the results and the parametricity was verified by Shapiro-Wilk test. Subsequently, the analysis of variance (ANOVA) was used to assess the significant differences between electrode displacements measured for three ways of fixing the electrode. It was established that the results are significantly different on the significance level α = 0.001.

Tab. 1: Displacement of electrode for different fixation arrangements.

fixation arrangement	1 anchor	2 anchors	2 anchors and loop
number of measurements [-]	12	12	11
average displacement [mm]	15.41	9.35	0.92
standard deviation [mm]	1.41	0.46	0.48

Fig. 6: Experimental setup of the measurement of electrode displacement.

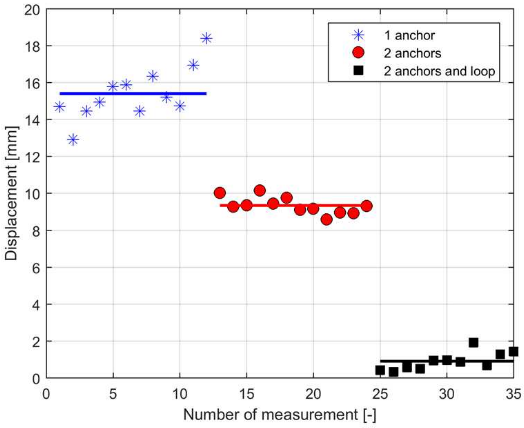

Fig. 7: Displacement of electrode for different fixation arrangements.

3 Conclusion

The results obtained by both measuring methods show the difference between the tested types of fixation. Fixing an electrode with two anchors already considerably reduced the displacement of the electrode, and when it was fixed using two anchors and a loop the electrode barely moves as the average displacement was less than 1 mm.

Based on the statistical evaluation, it is possible to state that the differences between experimental results obtained for the three different types of fixing the lead are statistically significant.

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