Intelligent Technologies as Assistive Tools during Pelvic Intraoperative Neuromonitoring

Tomasz Moszkowski, Fraunhofer Institut für Biomedizinische Technik, Germany, AGH-University of Science & Technology, Poland
Joanna Marszałek, Wrocław University of Technology, Poland
Steven Shepard, Stanford University, the USA
Roman Ruff, Fraunhofer Institut für Biomedizinische Technik, Germany
Thilo Krüger, inomed Medizintechnik GmbH, Germany
Werner Kneist, Universitätsmedizinklinik der Universität Mainz, Germany
Klaus-Peter Hoffmann, Fraunhofer Institut für Biomedizinische Technik, Germany

Abstract

Surgical intervention within the pelvic region can lead to postoperative deficits of urinary, fecal, and sexual function. Intraoperative neuromonitoring in the pelvic region (pIONM) may dramatically improve the quality of living of patients after colorectal cancer surgery. Minimizing the invasiveness of the method is a top priority for intelligent assistive technologies. Following several computing and phantom simulations, we developed a system for continuous minimally invasive pIONM that allows for surface stimulation of the sacral area within the pelvic region, acquisition of spontaneous activity within the anal canal, and control of the quality of the tissue-electrode contact via a self-developed impedance measurement system.

1. Introduction

Cancer treatment in the form of surgical procedures, e.g. the colorectal cancer excision, due to patient diversity can lead to postoperative deficits of urinary, fecal, and sexual function [1-3]. This has a dramatic effect on the quality of life of the patients. The main reasons for deficits of the autonomic innervation within the pelvic region are pulling, pressure, thermal stress, severance, or knotting of the nerves. Any irritation to the nerves could lead to a deficit of physiological nerve function along the neural pathways of the autonomic nervous system and cause aberrant behavior in the innervated organs – the bladder, the internal anal sphincter (IAS), and sexual organs.

Pelvic intraoperative neuromonitoring (pIONM) performed meanwhile surgery provides an assistive tool in the nerve-sparing surgery [4]. The surgeon electrically stimulates the autonomous nerves in the designated region and observes the neuromodulatory change as the response of the IAS and the bladder [6]. Moreover, research has been conducted in order to provide the surgeon with means of continuous monitoring during surgery. Current pIONM procedure utilizes direct stimulation of the autonomous nerves using intraoperative stimulation probes. In order to elicit the desired tissue, the surgeon needs to extend the operative field by removing the tissues surrounding the nerves of interest. Minimizing the invasiveness of the method requires the development of intelligent assistive technologies.

This paper describes first results and progress in autoPIN, a German research project that aims at an innovative assistance pIONM system intended to prevent nerve damage during pelvic surgeries. The highly automated and navigated assistance system shall provide the user with precise and safe information during surgery.

2. Methods

This section contains a description of the main methods employed in developing a system for navigated stimulation and minimally invasive signal acquisition during intraoperative neuromonitoring. In our approach, modelling of electrical phenomena accompanying transcutaneous stimulation is followed by an evaluation of the method in a phantom and swine animal model.

2.1 Equipment

For surface stimulation and signal acquisition, we used dry Polydimethylsiloxane (PDMS) based electrodes, whose development process and suitability for recording of biopotentials have been already firmly established [7]. An intelligent four-channel electrode was developed to be inserted into the anal canal (see Figure 1 a). The electrode allows for active monopolar and bipolar signal acquisition. For stimulation purposes, circular PDMS-based electrodes (3cm and 2cm of diameter) were fixed onto a flexible printed circuit board using a conductive silicon adhesive (see Figure 1 b). A multi-channel stimulation setup included a neurostimulator, biopotential amplifier, demultiplexer (supplied by inomed GmbH), a National Instruments USB-6225 DAQ card, and a PC workstation. National Instruments LabVIEW 8.5 programming environment served to develop the control software for the system designed to perform an impedance measurement of the stimulation electrodes, sweep through a range of parameters used for electric stimulation (amplitude, width and frequency of a pulse signal of cathodic current), and allow to simultaneously stimulate the nerve tissue and acquire signals at 20 kHz sampling frequency from the bladder and IAS (Figure 2 shows the entire setup).

a) b)

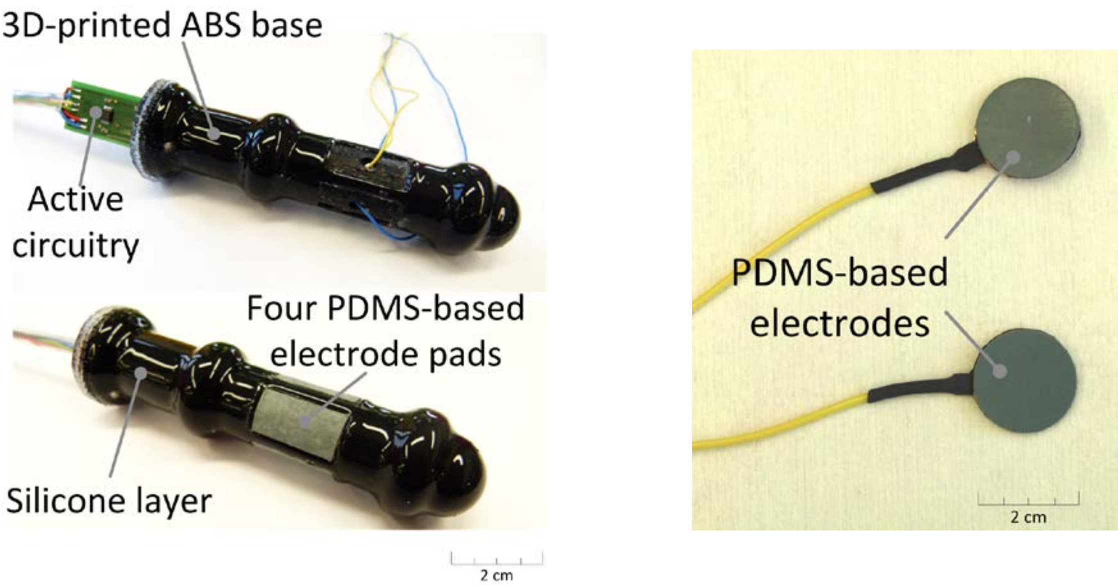

Figure 1: The PDMS-based electrodes used in the study: a) acquisition of the electrical activity within the anal canal, b) surface stimulation of the sacral area

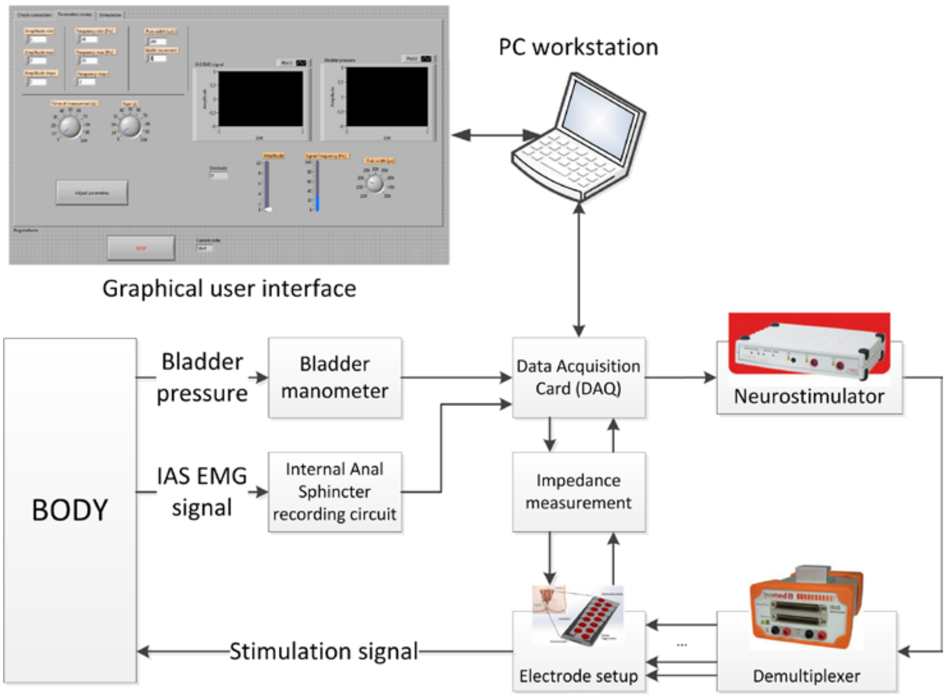

Figure 2: The system for minimally invasive intraoperative neuromonitoring in the pelvic region

2.2 Modelling

A 2-dimensional model helped to model the electrical phenomena within tissues using the finite element method (Figure 3). The used electrodes and the setup were preliminarily tested on a phantom agarose model and on a male swine animal model. The agarose model consisted of a solution of agarose and sodium chloride in deionized water (17.5 g Agarose, 1.4 g NaCl, 800 ml DI water). The impedance measurement system and stimulation electrodes were tested in the agarose model. The electrodes' suitability for signal acquisition in the anal canal was confirmed via an impedance measurement using an Otto Bock EIMS impedance measurement system in a preliminary animal study.

3. Results

The absolute impedances – measured within the swine anal canal – of the four channels of the recording electrode remained below 1 kOhm for frequencies exceeding 110 Hz (Figure 4 a). Spontaneous electrical activity within the anal canal could be recorded using both the monopolar and the bipolar setting (Figure 4 b). In the agarose phantom model, the stimulation electrodes exhibited low impedance of less than 500 Ohm for frequencies exceeding 300 Hz (Figure 5 a).

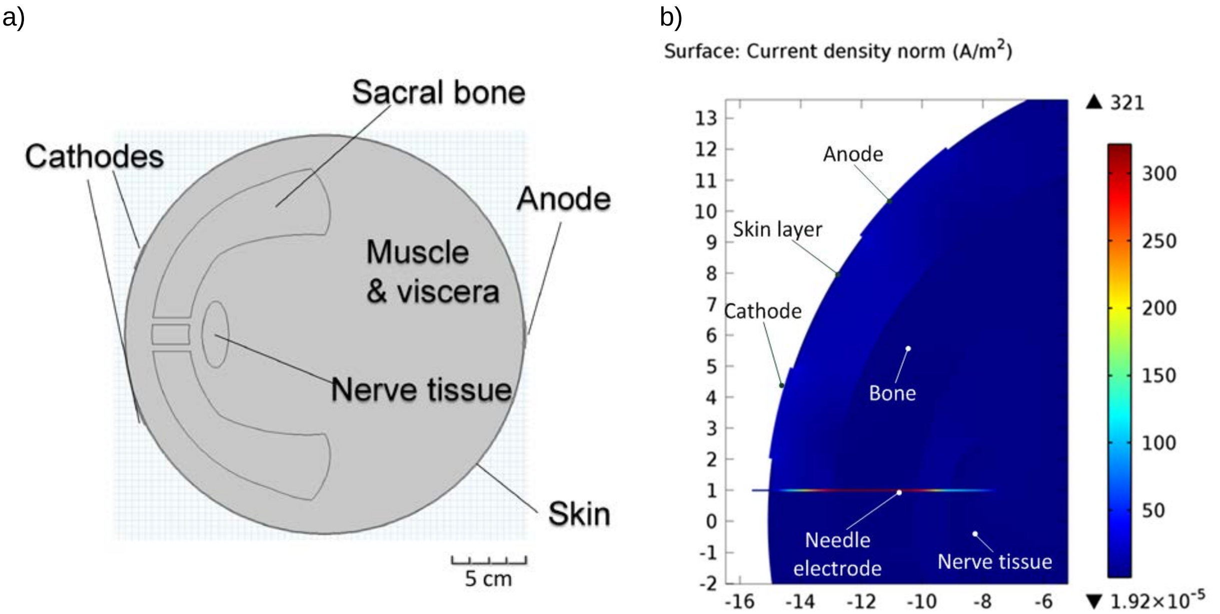

Figure 3: The results of modelling using a 2-dimensional finite element method model: a) a geometry modelling the transversal cross-section of the sacral area, b) current density norm during surface stimulation: constant 15 mA current

The tested setup could perform a highly repeatable impedance measurement with a standard deviation of below 10 Ohm for frequencies above 20 Hz (Figure 5b). The stimulation protocol could produce a cathodic pulse current of up to 130 mA pulse amplitude, up to 450 Hz pulse frequency, and up to 500 µs pulse width. Figure 5 c depicts a pulse generated by the setup during cathodic stimulation of the agarose phantom using two PDMS-based dry stimulation electrodes.

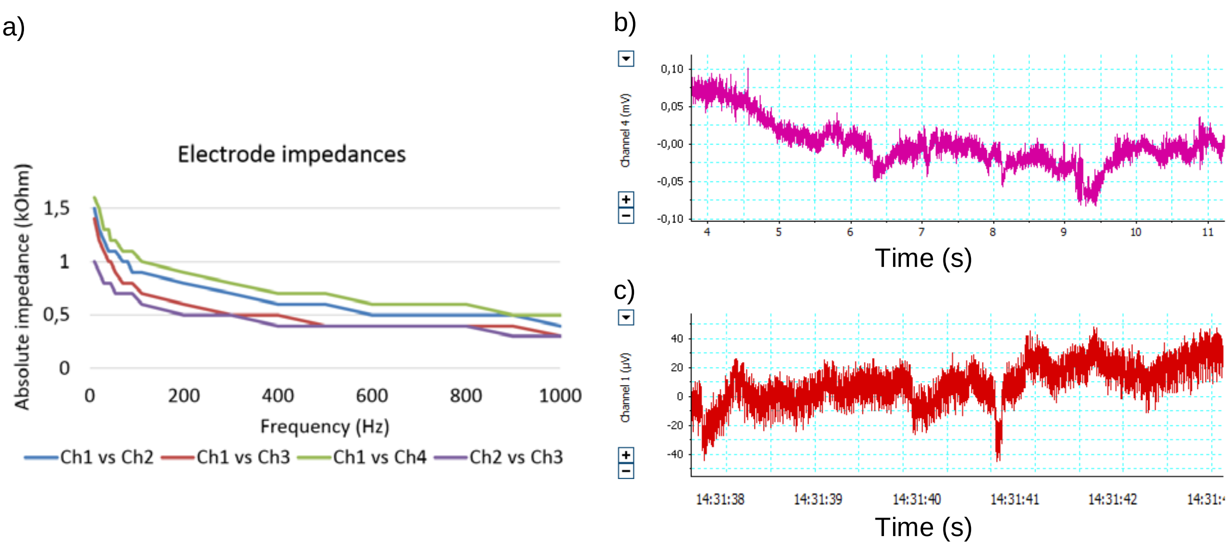

Figure 4: The impedance measurement of all channels on the electrode placed in the anal canal remains below 1 kOhm for signal frequencies exceeding 110 Hz: a) results of the impedance measurement (EIMS Otto Bock impedance measurement system). Unfiltered spontaneous electrical activity within the anal canal acquired using the designed acquisition electrode: b) unipolar recording (channel 4), c) bipolar recording (channel 2 vs. channel 1)

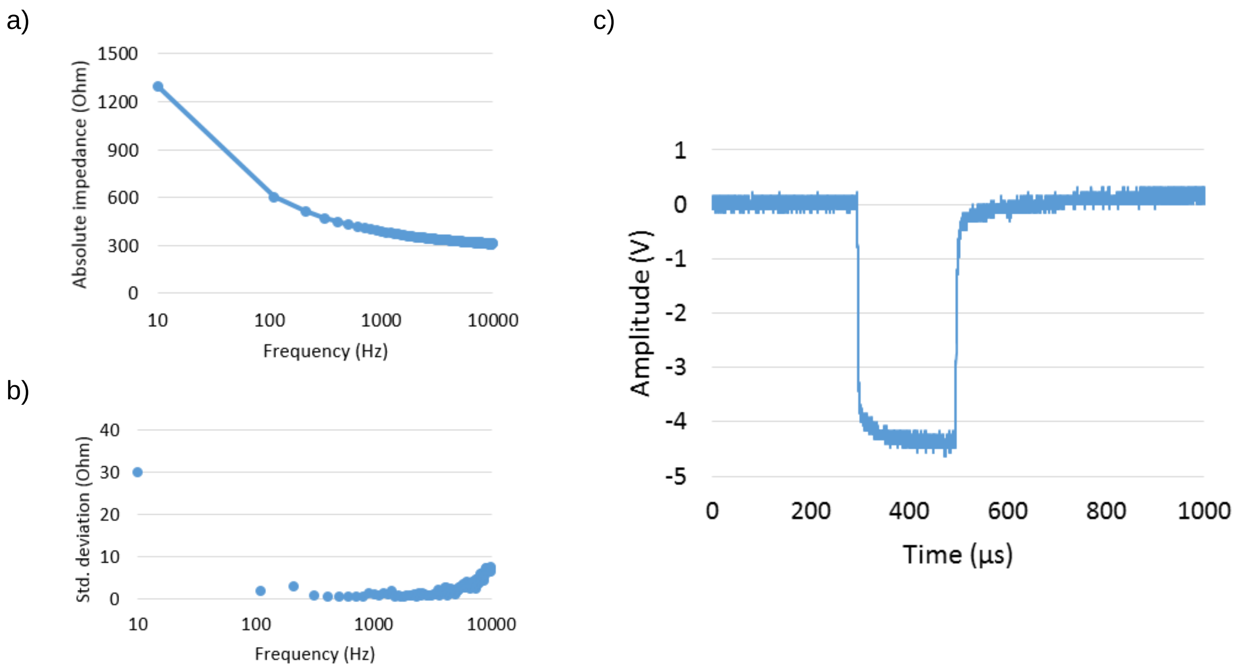

Figure 5: The results of evaluation of the stimulation electrodes (2 cm of diameter, 10 cm of inter-electrode distance) on an agarose phantom: a) the mean absolute impedance (10 samples) measured using the designed setup, b) the corresponding standard deviation of the impedance measurement, c) an example of a voltage drop under current-controlled stimulation (10 mA, 200 µs pulse width, 30 Hz pulse frequency)

4. Conclusions and perspectives

The developed system can produce a cathodic stimulus suitable for surface stimulation, acquire the spontaneous electrical activity of the anal canal, and perform repeatable impedance measurement. As a part of animal and clinical evaluation, the next steps are the identification of IAS activity due to neurostimulation in the acquired signal; identification of stimulation parameter ranges evoking the organ response; optimization of the electrode placement to yield the best stimulation outcome; development of an algorithm for automatic detection of the organ answer based on the organ activity; and development of a machine-learning protocol to determine which of the parameter sets provided the best setting for intraoperative neuromonitoring.

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Contact: Tomasz Moszkowski, tomasz.moszkowski@ibmt.fraunhofer.de, +49 6894 980 305