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SpinalCOM: Ambulatory monitoring of the Spinal Cord

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Abstract

Little is known about the processes occurring after Spinal Cord (SC) damage. Whether permanent or recoverable, those processes have not been precisely characterized. Because usual imaging techniques (MRI, Echo-Doppler, ...) provide only limited information on this organ, there is an unmet need for methods to assess the functional consequences of the Spinal Cord Injuries (SCI) and the effect of therapeutic interventions. To meet this need, the SpinalCOM project aims to investigate a new imaging approach of the SC, through the realization of a multimodal communicating device for measuring the activity of the SC. A first proof of concept was validated with custom made prototypes through in vivo experiments on animals. This approach will establish locally and specifically the functional state of the SC, which will provide a breakthrough in the care and therapeutic trials in SCI.

1. Introduction

Trauma of the Spinal Cord (TSC) and pathologies of the spine are major causes of mortality and disability. Accounting thousands of new cases per year in Europe, vertebro-medullary injuries are common surgical procedure. After the acute phase, secondary mechanisms, including vascular, impact the functional prognosis. Traditional noninvasive imagery methods, such as Magnetic Resonance Imaging (MRI), do not provide functional information, which is crucial to judge the consequences of secondary injury mechanisms and the effectiveness of spontaneous recovery mechanisms or after therapeutic interventions.

Although interesting, functional MRI (fMRI) of the SC is a method under development and faces significant limitations. The temporal resolution is modest and the spatial resolution is limited by many artifacts [12]. Moreover, it does not provide continuous monitoring information. Finally, it imposes a total immobility of the patient. We are in remote conditions from everyday living conditions of the subject.

Also on the functional assessment plan, electrophysiological techniques, such as EEG (Electroencephalogram), SSEP (Somatosensory Evoked Potentials) or MEP (Motor Evoked Potentials), are useful for intraoperative monitoring. However, they show very limited contribution to the monitoring of TSC. Indeed, these weakly invasive techniques can't identify early metabolic dysfunction before neurological functions are permanently affected. Echo-Doppler is also an interesting non-invasive technique. However, the obtained data are rather qualitative: only plethysmograph on a large zone is obtained. Thus, there is an unmet need for methods to assess the functional consequences of TSC and, as part of clinical trials, the effect of surgical strategies, pharmacologic, or appropriate rehabilitation [7, 10, 12].

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2. Aim of the project

The SpinalCOM¹ project aims to establish the proof of concept of an innovative tool for the continuous ambulatory collection of electrophysiological and metabolic parameters simultaneously at the SC level in the big animal. The device employs the Diffuse Optical Imaging (DOI) principle and will make use of a PhotoDetector (PD) and a minimum of 2 pulsed light sources at different wavelengths, for acquisition of blood oxygen levels in real-time. This first embedded system is coupled with a tailor-made instrumentation to acquire bio-potentials, due to the SC electrical activity (ESG - ElectroSpinoGram). After processing, the obtained data will be transmitted by radiofrequency outwardly to be operated. The evaluation of metabolic activity is based on the neuro-hemodynamic coupling, an approach validated by brain imaging optic which is currently applied in humans. The SC is also studied by near infrared spectroscopy, typically, but with classical intraoperative monitoring equipment, which does not allow chronic measurement [4, 9]. In addition, in current experimental works [5, 11], it is the small animal which has been used as a model (mouse, cat). The relevance of measuring nerve activity by implanted electrodes (ESG)

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is, in turn, supported by numerous experimental studies [1, 8, 13].

To our knowledge, there is no system or project providing a device for continuously measuring both metabolic and electrophysiological parameters at the SC level. Moreover, the proposed project presents no equivalent measurement system for comparison/reference.

In fine, this project finds its clinical application in the field of TSC through the implementation of a multimodal device at the vertebra during orthopedic surgery, performed in the usual care of TME. This medical device is likely to produce a breakthrough, especially for monitoring patients during the surgical operation and also after and as part of the evaluation of new therapeutic approaches.

3. Scientific Results

This project, located at the intersection of engineering and medicine, builds on the significant results achieved by the various partners' projects, including a patent [6] and several articles in international journals and presentations at scientific conferences [2, 3, 5, 14–16]. Previously, in 2010, an elementary wired probe was developed and tested on 6 cats for about 10 hours [5]. This study has provided proof of concept for the visualization of neural processes by DOI in small animal. For 2 years, starting in September 2013, the Labex SMART has supported this project. Various experiments on big animals (closer to the human being) have been performed on FBM pig model in collaboration with veterinaries (subcontractor). With a spectrophotometer, the *in vivo* optical characterization of the SC was performed (see Fig. 1) and proof of feasibility of this type of measure has been made (see Fig. 2) and published [14–16]. Hard points have been identified and are actually addressed through prototyping.

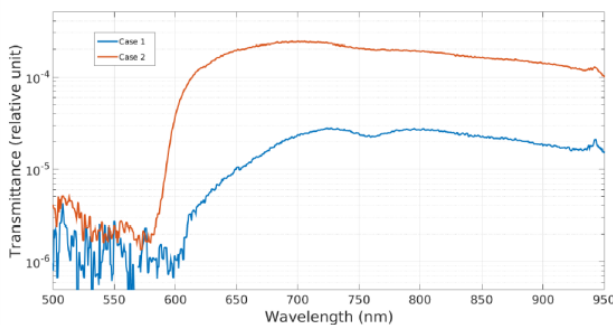


Figure 1. In vivo optical transmittance versus wavelength of the pig's SC before laminectomy (Case 1) and after (Case 2).

The measurements were performed with veterinaries of the XP-MED society, after obtaining permission from the local ethical committee of Cr2i (INRA, Jouy-en-Josas, France) under authorization number 03-1405.

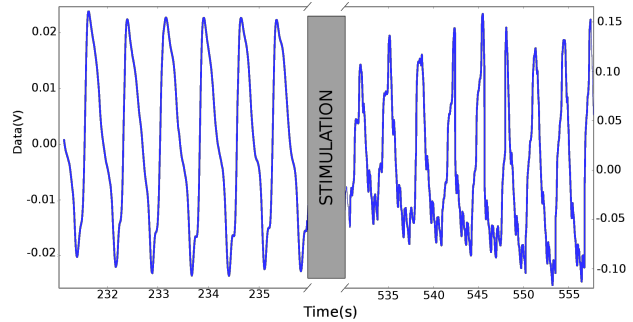


Figure 2. PPG of the SC with IR LED before and after chemical stimulation.

4. Futur works

The SpinalCOM project concerns the development of a new tool for doctors, which purpose is mainly to propose a new functional approach to exploration of the SC after TSC. At long term, the aim of this translational work is to develop a miniaturized device that can be implemented during decompressive surgery, carried out under the usual TSC in human being. At short term, we will focus on vertebrate animals in order to propose a tool for researchers and veterinaries. Then, the potential transfer to human being will be studied.

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