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Design and fabrication of a non-invasive, wireless system for monitoring needle insertion during epidural puncture

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Abstract. Over the last decades epidural analgesia has gathered research interest and broad clinical acceptance. In this procedure, the detection of the epidural space is pivotal to avoid major complications. Although, some systems for supporting the anaesthetist in the epidural space detection are commercially available, this difficult procedure is often performed without any support. In previous articles, our research group described a new approach for a non-invasive detection of the epidural space; the assessment of the system was also performed both on a spinal column simulator and in *ex vivo* animal model (small pig). The mentioned system is based on a Force Sensing Resistor (FSR) that monitors the load exerted by the anaesthesiologist on the syringe plunger during the procedure. The resistance of the sensor is transduced into a voltage by means of a Wheatstone bridge (WB), then it is amplified, finally it is collected by a remote laptop. When the needle reaches the epidural space, the load applied by the anaesthesiologist decreases, so the consequent change of the system output may be used for the detection of the entrance within this space. The previous version of the system communicates to the laptop via USB. In this article, we described a new version of the system which communicates to the laptop via wireless. This solution aims at facilitating the use of the system in clinical settings. After the description of the measuring system, its preliminary assessment in patients undergoing epidural puncture will be reported.

1. Introduction

Epidural puncture has gathered interest in research and broad acceptance in clinical settings (e.g., during labour, and for relieving chronic back pain) [1],[2]. It has been shown that this procedure decreases patient morbidity after major surgery [2]. Although epidural analgesia is a very complex procedure with relevant risks of major complications (e.g., epidural haematoma, accidental dural puncture…) [3], it is usually performed without any technological support. During the procedure, the clinician pushes a syringe whose needle must reach the epidural space. This space is placed between the ligamentum flavum and the dura. The detection of the epidural space is usually performed by the

anaesthetist, who feels a decrement of pressure (called loss of resistance, LOR) because the epidural space is softer than the ligamentum flavum. Since the epidural space is thin and the procedure is performed without any technological support, the risk of accidental dural puncture is high. In order to minimize this risk, several systems have been proposed, most of them based on the LOR detection, showing promising results [4],[5],[6]. In previous studies we have described the working principle and the fabrication of a new system for epidural space detection; it was also assessed by simulators and in *ex vivo* animal model [7],[8],[9]. The proposed system does not require any changes to the standard procedure since the sensing part consists on a very thin force sensor placed on the syringe plunger. This thin sensing element has been used by our group also in other applications related to the anaesthesiology field for force or pressure monitoring [10],[11].

The previous version of the system communicates to the laptop by means of an acquisition board via USB. The aim of this study is twofold: *i)* to design and develop a new version of the system which communicates to the laptop via wireless (Bluetooth Low Energy) standard. This solution aims at facilitating the use of the system in clinical settings; *ii)* the preliminary assessment of the system on three patients undergoing epidural procedures. The article is structured as follows: in Section 2 the working principle of the system, its main components, and the new design are described; Section 3 focuses on the description of the preliminary experiments in clinical settings, and shortly describe the data analysis; in Section 4 the results collected during epidural puncture are illustrated; in Section 5 results, conclusions and future works are discussed.
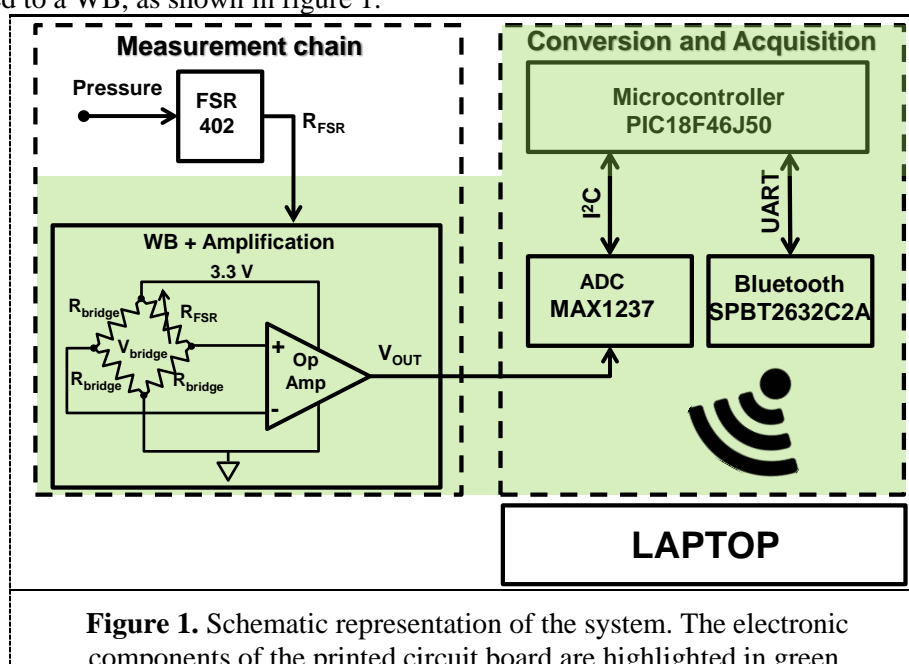
2. Working principle, design and fabrication of the system

2.1. Working principle

The measuring system here proposed consists of an FSR and a printed circuit board (PCB) to collect the analog output of the FSR, convert them into a digital signal and send data via Bluetooth connection (as show in figure 1).

The FSR (i.e., FSR 402, Interlink Electronics Inc., range of measurement from 0.2 N up to 20 N) is a polymer thick film that exhibits a decrease in resistance with increase in force applied to its active area. In this specific application, the FSR will be placed on the syringe plunger to sense the load exerted during the procedure by the operator.

The output of the FSR is an electrical resistance (R_{FSR}). For a force-to-voltage conversion, the FSR device is tied to a WB, as shown in figure 1.

Figure 1. Schematic representation of the system. The electronic components of the printed circuit board are highlighted in green.

In general, the relationship between the output of an FSR (R_{FSR}) and the force (F) that acts on the active area of the sensor can be expressed as in (1):

$$R_{FSR}(F) = 10^{a \cdot \boldsymbol{log_{10}}(F)+b} \tag{1}$$

where *a* and *b* are two constant values that can be calculated by data provided by the manufacturer. By considering the plot R_{FSR} *vs* F reported in the datasheet of FSR 402 [12], the coefficients a=-0.839 and b=4.2309 have to be used to obtain the best fitting curve of the expression (1).

The output of the WB (V_{bridge}) as a function of the R_{FSR} is described by the following equation:

$$V_{bridge} = V_{supply} \cdot \frac{R_{bridge} - R_{FSR}}{2 \cdot (R_{bridge} + R_{FSR})} \tag{2}$$

Being the V_{supply} the bridge voltage supply (i.e., 3.3 V) and the R_{bridge} the value of the three resistances positioned on the WB (see figure 1).

By placing (1) in (2) together with the *a* and *b* coefficient values, the V_{bridge} can be expressed as a function of F as in (3):

$$V_{bridge} = V_{supply} \cdot \frac{R_{bridge} - (10^{0.839 \cdot \boldsymbol{log_{10}}(F)+4.2309})}{2 \cdot (R_{bridge} + (10^{0.839 \cdot \boldsymbol{log_{10}}(F)+4.2309}))} \tag{3}$$

The value of V_{bridge} strictly depends on the R_{bridge}. As shown in figure 2, according to (3), the sensitivity of the system increases with the R_{bridge} (1 kΩ, 10 kΩ, 50 kΩ, 68 kΩ, and 100 kΩ in figure 2); on the other hand, the V_{bridge} saturates at lower values of F.
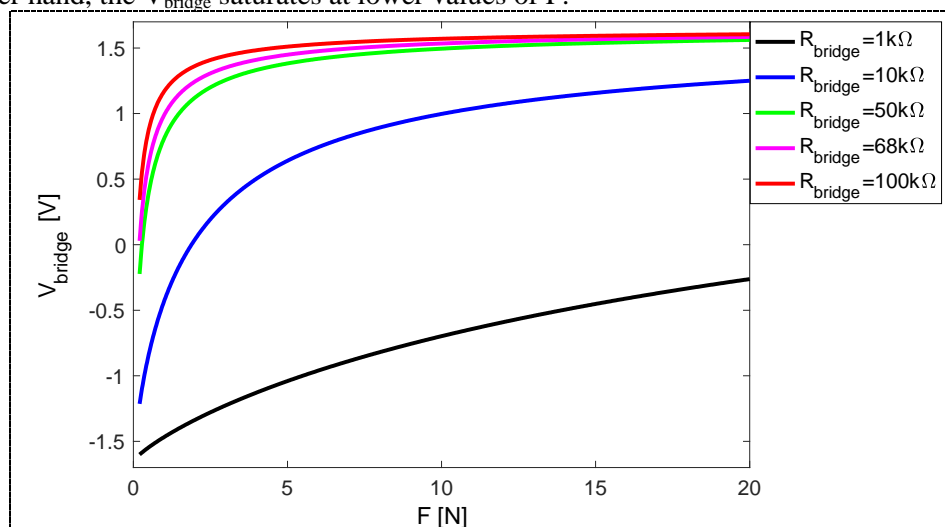

Figure 2. Output of the Wheatstone vs the force applied to the FSR using five different configurations.

In the specific application, the F can be considered uniformly applied on the syringe plunger: so, the pressure (P) exerted by the operator during the puncture may be expressed as the ratio between the F and the area in which F is applied. Since the epidural space can be detected by analyzing the passage from saturation to non-saturated condition of the system due to the LOR [7], [8], [9], and by considering the P values exerted during the passage through the ligamentum flavum and the epidural space, different values of R_{bridge} can be adopted. So, different configurations of the Wheatstone Bridges (in terms of R_{bridge} values) provides different sensitivities and measuring ranges to the LOR (see figure 2). In this study, we choose R_{bridge}= 10 kΩ: it allows collecting voltage changes from saturation (during the passage through the ligamentum flavum, F≥15 N [4]) to non-saturation (needle reaches the epidural space, F~2N).

2.2. Design and fabrication
The FSR used in this work was the FSR 402 (Interlink Electronics Inc). A custom PCB was designed in Eagle (Autodesk) and then manufactured in order to collect and transfer data to a laptop. The first stage of the PCB provides the physical connection to the FSR 402, the transduction of the R_{FSR} into a V_{bridge} by adopting one WB configuration (i.e., R_{bridge}= 10 kΩ) and the amplification of V_{bridge} to obtain a voltage output (V_{out}) with a differential amplifier. The second stage of the PCB allows the conversion and acquisition of the data: an analog-to-digital-converter (ADC) and a microcontroller are embedded into the PCB. In particular PCB includes: *i)* a 12-bit ADC unit (i.e., MAX1237, Maxim Integrated Inc.) with an integrated multiplexer, that converts the outputs of the WB; *ii)* a micro-controller (i.e., PIC18F46J50, Microchip Technology) that collects data from the ADC via an I2C digital bus, and sends the data through an UART port to a Bluetooth module (i.e., SPBT2632C2A, STMicroelectronics). This module provides the wireless communication to a remote laptop in MATLAB environment.

3. Preliminary experiments and data analysis
Preliminary experiments were performed using the proposed system with the configuration R_{Bridge}=10kΩ.This choice aims at figuring out the input-output relationship of this configuration which has intermediate metrological properties with respect to other analysed configurations (see figure 2): it has a sensitivity higher than the solution at 1 kΩ and lower than the one at 100 kΩ; while it has a measuring range lower than the solution at 1 kΩ, but bigger than the one at 100 kΩ. This preliminary analysis was performed on 3 patients undergoing epidural puncture, with age from 50 to 77 years. The enrollment started after the approval of the local medical ethics committee, and with written informed consent of the 3 patients. The 3 epidural punctures were performed by the same expert anaesthetist (M.C., with more than 5 years of experience), using the system by placing the FSR 402 on the syringe plunger. Figure 3 reports a picture of the typical scenario, where the positioning of the FSR on the syringe and the PCB, which embeds the Wheatstone bridge, the amplifier stage, the ADC unit, and the Bluetooth module are shown.
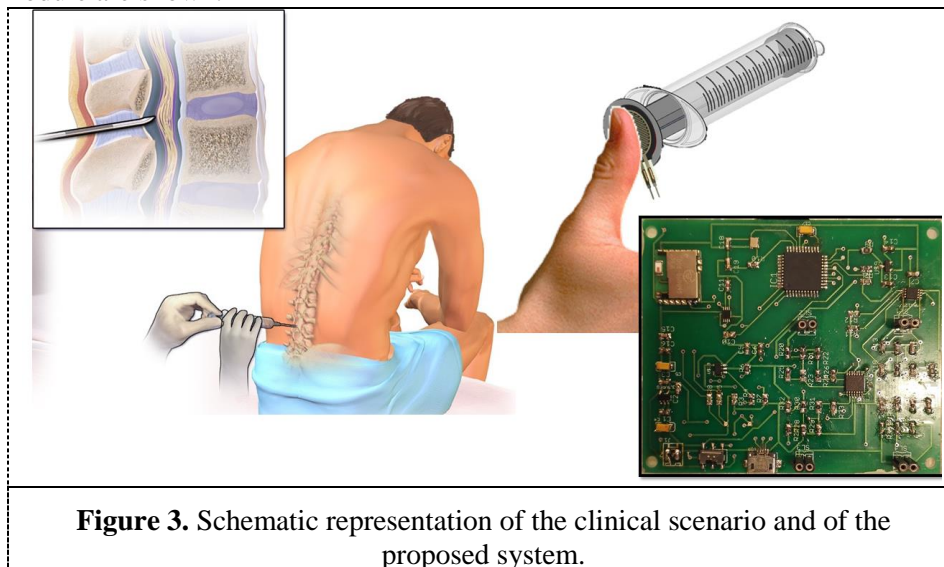

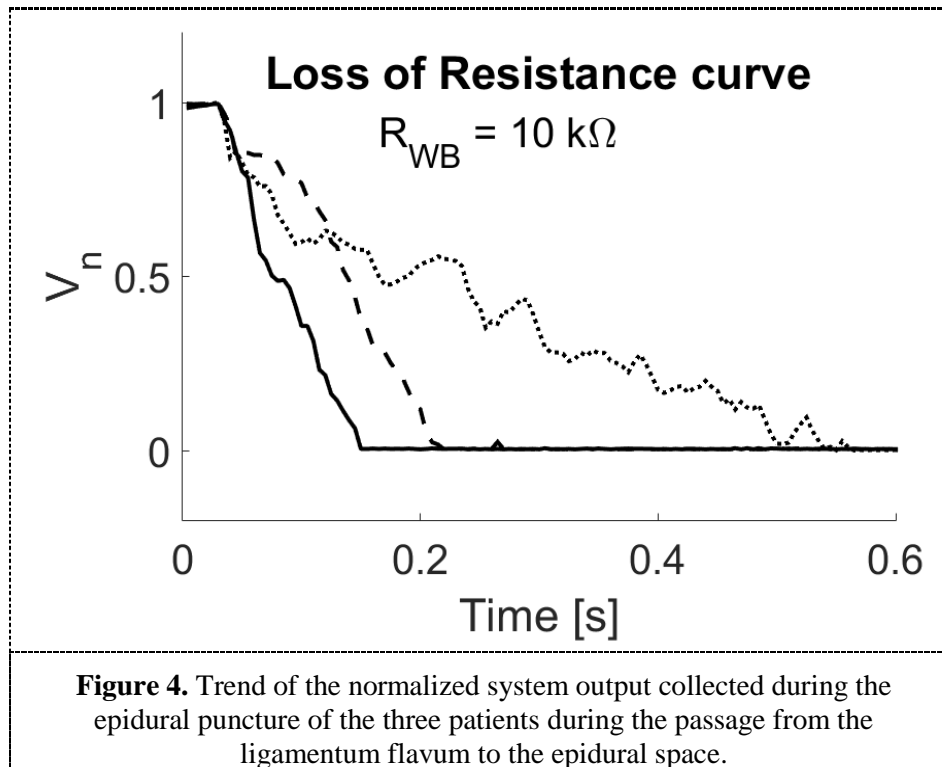**Figure 3.** Schematic representation of the clinical scenario and of the proposed system.

The output of the system (V_{out}) was recorded during the whole procedure starting from the skin perforation until the needle reached the epidural space. The detection of the epidural space was made by considering the feedback of the expert anaesthesiologist.

The data analysis is devoted to the extraction of the system response from the data collected during epidural puncture procedure. Basically, it can be schematically divided in two main steps: *i)* the V_{out} value was collected during the entire procedure and was normalized in order to have an output (V_n)

ranging from 0 to 1 in all the trials; *ii)* the V_n change due to the LOR was individuated; *iii)* the starting point of the LOR was manually selected. This curve represents the system output over the LOR; *iv)* the previous step was repeated for the three trials.

4. Results
Figure 4 shows the curves obtained during the epidural puncture of the three patients after the fourth step described in the previous section.

Figure 4. Trend of the normalized system output collected during the epidural puncture of the three patients during the passage from the ligamentum flavum to the epidural space.

The curve persists in saturation condition ($V_n=1$) up to the LOR, where the load exerted by the anaesthetist decreases. Related to this decrement there is a change of V_n up to a null value. This passage from $V_n=1$ to $V_n=0$ is the basis of the epidural space detection. In order to quantify this passage, the rise time, t_r, (defined as the time required for V_n to reach 0.10) was calculated for the three curves. It was 110 ms, 170 ms, and 450 ms. Since the anaesthetist pushes the syringe with a very low speed, a lag time shorter 500 ms (it fulfilled this requirement in all the three recorded procedures) is promising to consider the system available to support the clinician in the detection of the epidural space.

5. Discussion and conclusion
This article reports on design and assessment of non-invasive system for supporting the clinician in the detection of epidural puncture. Our group of research has already proposed new solutions for improving the management of critically ill patients [13],[14],[15] and has already assessed a previous version of the system on simulator and in *ex vivo* animal model [7],[8],[9]. In this article, we described a new version allowing the data collection via wireless communication to a remote laptop to facilitate the use of the system in clinical settings. The design of the system embeds four configurations by changing R_{bridge}, to adjust the system sensitivity and its measuring range. In this study, we have performed a preliminary assessment of the system on 3 patients using the configuration with $R_{bridge}=10k\Omega$. Considering the theoretical predictions shown in figure 2, R_{bridge} value strongly influences the system response: the system sensitivity increases with R_{bridge} and the measuring range

narrows with this parameter, the higher is the R_{bridge} value the shorter may be the t_r. Therefore, the use of a bigger value of R_{bridge} may improve the t_r value, but the risk is that the system will remain under saturation condition also after the LOR due to a narrower measuring range; on the other hand, the use of a smaller value of R_{bridge} may increase the t_r value, but will increase the measuring range. Future tests will focus on assessing the system on a bigger number of patients using different configurations to find the best trade-off between a shorter t_r and better static properties.

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