

A Microcontroller-based Instrument for Prostheses Osseointegration Measurement by Electrochemical Impedance Spectroscopy

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Abstract- A method based on Electrochemical Impedance Spectroscopy (EIS) for the diagnosis of prosthesis osseointegration was proposed by the Authors in previous works [1]-[2]. In this paper, the design, the implementation, and the metrological characterization of a microcontroller-based prototype conceived as a stand alone instrument to be used for *in-vivo* clinical applications are presented. The preliminary experimental results of laboratory evaluation are presented.

I. Introduction

The functionality of an osseointegrated implant depends strongly on the lack of mobility and on the quality of the deep contact surface between metallic fixture and bone [3]-[5]. In percutaneous implants (as acoustic aids BAHA® and dental implants), usually, the osseointegration process is evaluated by verifying the mechanical stability of the fixture. In particular, specific attention has to be paid to tests after 1-3 months from the implant placement, before to be loaded with the actual prosthesis, and in general, during the entire life as clinical follow up. Main traditional clinical methods for the evaluation of osseointegration process exploit X-rays. However, X-rays are invasive and incapable of detecting information about soft tissues and implant contact layer. Other, instrumental, methods exploit special characteristics of the implant, such as the mechanical resonance for dentistry prosthesis [6].

In a previous work [1], the authors proposed a low-invasive measurement method based on EIS to analyze the interface between the bone and the metallic implant. Positive indications about the method effectiveness were gathered from experimental *in vitro* investigations on emulation of transcutaneous metallic implants. Afterwards, a suitable *in vivo* test procedure, and a corresponding measurement layout, for gathering information about osseointegration of metallic prosthesis by measuring electrical impedance over a suitable frequency spectrum were investigated [2]. Preliminary clinical experimental results showed EIS a valid alternative, no-destructive and low-invasive technique, to the diagnosis of the osseointegration level [2]. However, to be transferred in practical use, the proposed measurement method has to be implemented in an easily to handle instrument.

In this paper, after a brief recall of the proposed method, the design details of a microcontroller-based instrument prototype for EIS measurements to evaluate the osseointegration level are illustrated. Furthermore, the results of preliminary laboratory tests are presented.

II. The proposal

In the following, the basic ideas underlying: (i) *the measurement method*, and (ii) *the micro-instrument design* are shown.

A. Measurement Method

The electrochemical impedance spectroscopy is exploited to characterize the tissue prosthesis interface. The method has been validated *in vitro* and *in vivo* on percutaneous prostheses by PC-based proof demonstrators [1]-[2]. In percutaneous prostheses, the measurement electrodes can be connected directly to the metallic implant, by avoiding the insertion of further tissue layers in the measurement circuit.

The impedance measurement of the proposed EIS device, is based on the *Direct Measurement* method: a sinusoidal current stimulus is injected through the metallic implant and the surrounding tissues by

means of the A+/A- electrodes and acquired, the relative voltage drop is acquired by means of the V+/V- electrodes. Thus, the magnitude $|Z_x|$ of the tissue impedance can be evaluated by the ratio of the peak amplitudes of the voltage and current signals, while the phase θ of the impedance can be evaluated as the phase difference between the acquired sinusoidal voltage and current signals:

$$Z_x = \frac{|V|}{|I|} e^{j(\theta_v - \theta_i)} \quad (1)$$

B. Micro-instrument Design

In the following, details about the design of the proposed instrument are provided at *hardware* and *firmware* levels.

Hardware

The hardware design of the proposed micro-instrument prototype is mainly based on (Fig.1): (i) a microcontroller (MCU) board by IAR Systems, containing a 32-bit floating-point MCU (TMS470R1A256 of Texas Instruments, ARM7 core) with a 16-channels 10-bits ADC and a serial port (RS-232) used for PC data transfer, (ii) an analog interface circuit, and (iii) a 16-bits digital to analog converter (DAC) by Linear Technologies (LTC1657L).

The DAC, driven by the MCU with a 16-bits parallel port, is used to obtain an analog sinusoidal stimulus through A+/A- electrodes to the system under measurement. The amplitude and the *dc* component of the stimulus are selected by a suitable firmware through the communication port.

The analog interface design (Fig. 2) was aimed specifically at handling low-amplitude signals, thus, differential amplifiers were used to guarantee high noise immunity and common-mode rejection, necessary in low-frequency measurements on living biological systems [5]. Its main tasks are: (i) preconditioning the voltage stimulus signal, (ii) gathering and amplifying the voltage and current signals from the system under measurement, and (iii) adapting the sinusoidal signals for the ADC input specifications.

The voltage drop is gathered by means of the V+/V- electrodes, while, the current flowing between the A+/A- electrodes is converted into a voltage by means of an automatically selected and known reference resistor R_p .

The voltage section (Fig. 2) includes mainly stages devoted to signal conditioning, dc offset regulation, voltage clamping, and output coupling.

The current section (Fig. 2) includes mainly blocks devoted to signal conditioning stage, common mode noise rejection, clamping, and output coupling.

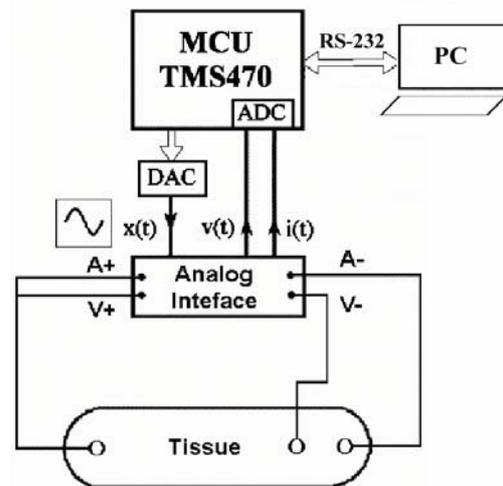


Fig. 1 Block diagram of the proposed micro-instrument.

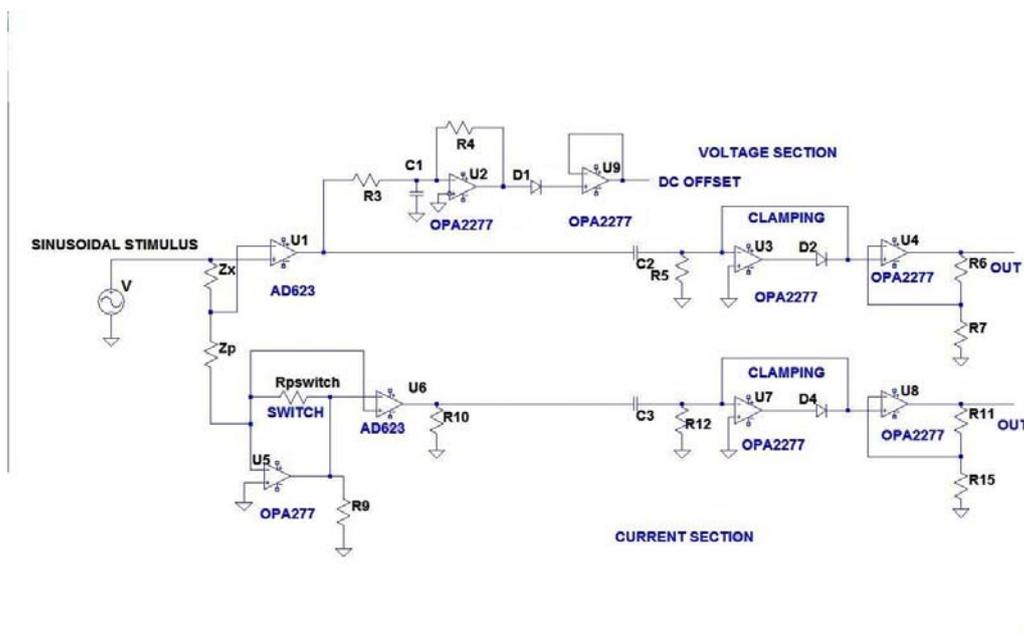


Figure 2. Schematic of the custom interface for analog signal conditioning.

Firmware

Main issue of firmware is ADC management. In particular, the ADC acquires an integer number of sinusoidal periods, that is relatively prime to the number of total samples record. This guarantees that the recorded samples are uniformly distributed in phase from 0 to 2π [7]. In particular, the number of total sample was setted to 100, while the number of acquired period to 13, giving a sampling rate of less than 8 times the measurement frequency.

The sine waves reconstruction is performed according to a 7-parameters sine-fitting algorithm [8], a non-linear iterative least-square method for the measurement of amplitudes and phase difference between two records of digitized sine waves with the same frequency.

The application firmware performs (Fig. 3):

- (i) the initialization of the instrument hardware and firmware,
- (ii) the generation of the test signal by driving suitably the DAC;
- (iii) the setting of the ac and dc components of the voltage signal between the V+/V- electrodes, realizing a software potentiostat function by means of a loop procedure,
- (iv) the automatic choice of the best value of the reference resistor R_p ,
- (v) (iii) the sine waves reconstruction according to the abovementioned 7-parameter algorithm,
- (vi) the impedance evaluation according to eq. (1);
- (vii) the communication via the serial port to receive commands and send results, status, and fault codes.

III. Preliminary experimental results

The prototype of the proposed micro-instrument is shown in Fig. 4.

The micro-controller device is linked with a RS-232 port to a PC, in order to communicate with a user interface implemented in LabVIEW®. The PC is only a terminal, without any computational functionality.

The software allows:

- (i) to set up and send the measurement parameters (dc and amplitude of the stimulus, as well as sweep frequency range) to the prototype,
- (ii) and receive the measurement results and store in an ASCII file.

The performance of the micro-instrument prototype were assessed in laboratory preliminary tests by means of two electrical test circuits. The circuit topology is shown in Fig. 5, where:

- R_a and R_b were decade reference resistors with an uncertainty of $\pm 0.15\%$ in 1 Ω step, and $\pm 0.05\%$ in 10 Ω –10 k Ω step,
- and C was a decade reference capacitor with an uncertainty of $\pm 0.25\%$ in 100 pF step and $\pm 0.1\%$ in 1 nF–100 nF step at 1 kHz.

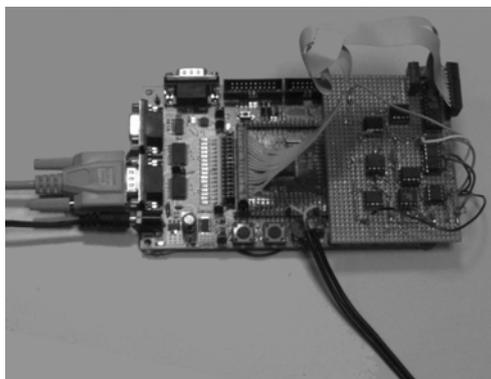


Figure 4. - The micro-instrument prototype.

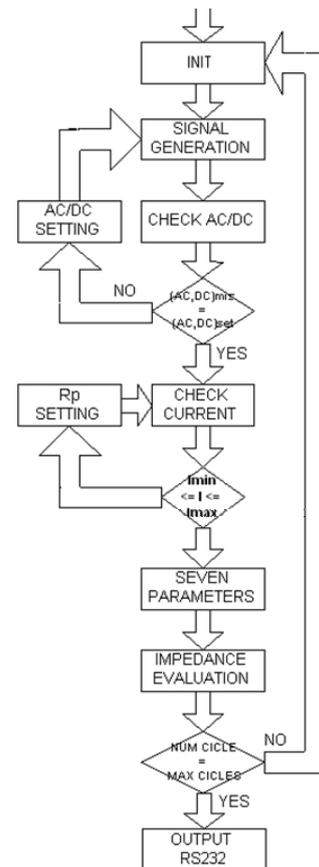


Figure 3. - Firmware flow chart.

The nominal values of R_a , R_b and C, for each electrical circuit used in the test, are listed in Tab. 1. The circuits have different characteristics, and emulate typical prosthesis bone interface tissues [2]. Measurements were carried out in the frequency range (50 Hz, 1 kHz), and the amplitude of the voltage sinusoidal stimulus was fixed at 40 mV without polarization (0 mV *dc* component).

The sample number, acquired within logarithmic frequency scale, was 20. Results shown in Fig. 5, for module and phases of both the two circuits highlights a very satisfying agreement between measured and reference values.

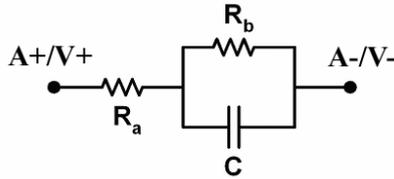


Figure 5. - Topology of the electrical circuit used in the test.

Tab. I: Nominal values of the components in test electrical circuit.

	R_a [Ω]	R_b [Ω]	C [μF]
Z_1	100.0	1000.0	1.0
Z_2	1000.0	1200.0	0.90

IV. Conclusions

The design of a low-cost microcontroller-based instrument for prosthesis osseointegration assessment is proposed. The osseointegration level evaluation method is based on the electrochemical impedance spectroscopy. However, the proposed instrument can be used also for other EIS-based measurement applications, such as electrochemical corrosion assessment of metallic structures.

The preliminary characterization results of laboratory tests show a predominance of correctable deterministic error. Further work will be devoted to a comprehensive calibration in the operating range, as well as to in-vivo on field testing.

Acknowledgments

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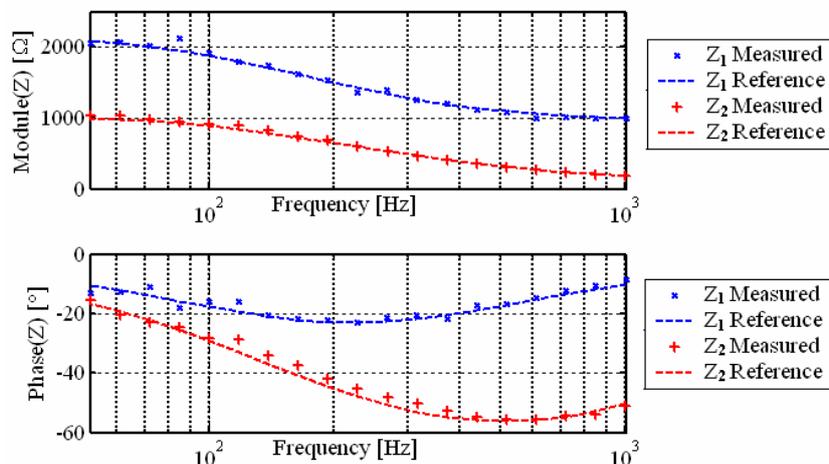


Figure 6. - Measurements result on two electrical circuits test.

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