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DEVELOPMENT OF AN INSTRUMENTED IMPLANT COMPRISING CAPACITIVE SENSING TO MONITOR THE FRACTURE BONE HEALING

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1 Introduction

Bone fractures are a common health problem worldwide. The increasing number of people diagnosed with osteoporosis disease in active age groups highlights the crucial role that prevention and improved treatment play in reducing the consequences of disability, including productivity and quality of life [1]. Currently, the monitoring techniques rely on image analysis, which entails subjectivity, exposes patients to high rates of accumulated radiation, incurs high maintenance costs, lacks information about the biomechanical state of the fracture, and lacks continuous monitoring [2]. Therefore, it is mandatory to develop new methods capable of quantitatively assessing the bone healing process. This will enable the adoption of preventive protocols, such that the treatment time can be reduced or additional surgical interventions can be avoided. Therefore, it will support to decrease hospital costs and improve the patient's quality of life [3]. This work proposes a new bioelectronic osteosynthesis plate that includes capacitive sensors, capable of monitoring the bone fracture healing process. The monitoring ability relies on electrical capacitive changes in different bone tissues during the fracture healing process.

2 Materials and Methods

Computational models were developed to simulate variations in electrical capacitance during the healing process (Figure 1a). Four computational models of a bone fracture were developed using SolidWorks (v. 2022, Dassault Systemes) and COMSOL Multiphysics (v. 6.0, COMSOL), one for each healing stage: hematoma, soft callus, hard callus and bone remodeling. Capacitive variations along the bone fracture were simulated. For such purpose, new electronic plates were designed using the EAGLE (v. 9.6.2, Autodesk), comprising: (i) an analog-to-digital converter AD7745, for data acquisition of electric capacitive values; (ii) an ADG1606 multiplexer, to allow monitoring various capacitive sensors using a single converter AD7745; (iii) a RN4871 Bluetooth module, to provide data communication to extracorporeal computational platform; (iv) a PIC16LF1847 microcontroller, for data processing and control; and (v) a CR1216 3.3 V battery (Figure 1b). The sensor board incorporates a matrix network of striped capacitive sensors, according to a 2x7 sensing architecture. Structural simulations of the new developed plate, containing a volumetric region to incorporate the electronic system and a biocompatible polymer vulcanized to seal everything in the plate, were conducted to ensure similar mechanical characteristics in comparison with a plate currently used in clinical practice. For the *in vitro* tests,

the circuit was manufactured, porcine samples were collected, and each healing fracture stage was replicated: clotted blood to mimic the initial stage, crushed cartilage to mimic soft callus; crushed trabecular bone to mimic hard callus; and, finally, intact bone for the remodulation stage. These tests were conducted in a universal testing machine (Shimadzu AGS-X-10kN).

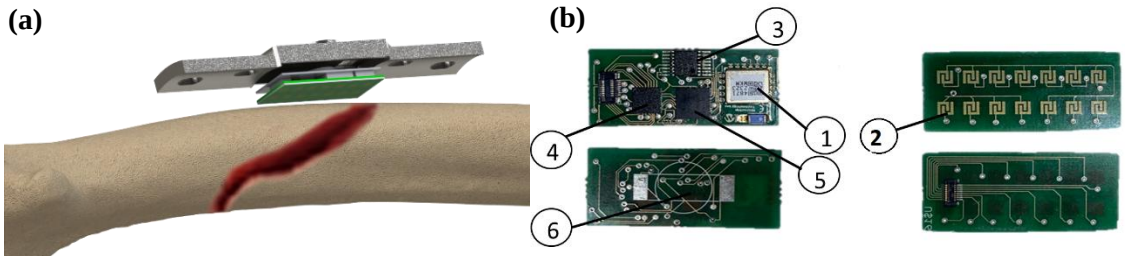

Figure 1- (a) Fractured bone with the new bioelectronic implant; (b) Electronic components: 1- Bluetooth module; 2- Capacitive matrix; 3-Analog-Digital convertor; 4-Multiplexer; 5- PIC16LF1847; 6- Battery.

3 Results and Discussion

Experimental results: A significant electric capacitance decrease was noticeable as the healing process progresses. These variations become increasingly lower as the bone recovers its intact-like characteristics similar to the original bone: in the first stage a variation of 0,494 pF was obtained; in the second, a variation of 0,163 pF; in the third stage, we obtained a variation of 0,090 pF; and, finally, in the fourth stage, small variations of 1,13 fF were observed. **Simulation results**: Prediction errors were found below 10%. Correlations of 92% for the inflammatory phase, 63% for the soft callus phase, and 99% for the hard callus phase, were obtained.

This work provides an impactful contribution and paves the way for the development of the new generation of bioelectronic fixation implants, holding great potential for translation into clinical practice.

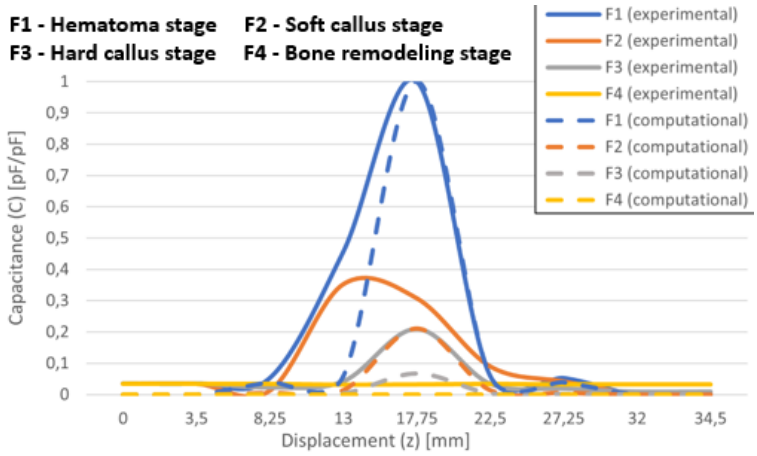

Figure 2 – Normalized capacitance variations from experimental and computational tests.

4 References

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