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Influence of bone union electrostimulation on corrosion of bone stabilizer in rabbits

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ABSTRACT

Purpose: The aim of the work was determination of influence of the selected methods and parameters of bone union electrostimulation on corrosion of stainless steel implants coated with passive and passive-carbon layer.

Design/methodology/approach: The semi-invasive and capacitively coupled electrical field methods of electrostimulation (without constant component) in rabbits were applied. The influence of electrostimulation on corrosion of implants was evaluated on the basis of the mass measurements and surface observations.

Findings: On the basis of the research no corrosion on the implants stabilizing the bone fracture was observed.

Research limitations/implications: Lack of visible and measurable corrosion requires the change of the methodology. Further research should be focused on the amount of metallic ions dissolved from the implants. Furthermore, it should be emphasized that the absence of corrosion of the electrostimulated implants is only one of many criteria describing the usefulness of electrostimulation parameters. The basic criterion is the biological effect obtained as the result of the electrostimulation.

Practical implications: The obtained results are the basis for selection of methods and current parameters of the bone union electrostimulation in further clinical research. In case of positive results, the bone union electrostimulation with the use of implants coated with the passive and passive-carbon layers would be valuable method in treatment of pathological bone fractures.

Originality/value: The paper is a continuation of the research on determining safe parameters of bone union electrostimulation of implants coated with the passive and passive-carbon layers.

Keywords: Metallic alloy; Biomaterials; Corrosion; Passive-carbon layer; Electrostimulation; Union bone

MATERIALS

1. Introduction

Stainless steel is a commonly used metallic biomaterial. A long-time research on usefulness of this material allowed to determine the requirements that have to be fulfilled to consider this material for short-time implants [1, 2].

Very advantagous feature of stainless steel is possibility of controlling mechanical properties in the wide range. It enables to change a biomechanical characteristics of a fixation not only by the changes of geometric features, but also by the change of mechanical properties. Nowadays, a great body of research is focused on the development of corrosion resistance, increasing a biocompatibility and limiting postoperative complications. This aim is reached by a surface treatment [3].

A passive, passive-carbon and carbon layers can be applied to increase the corrosion resistance of biomaterials. The passive layers are constituted in the two stage process, i.e. the electropolishing and chemical passivation. The carbon layer are deposited with the use of the RF PACVD process [4]. The passive-carbon layers of amorphous-crystalline structure are characterized by a good adhesion to metallic substrate and a deformability which is necessary for elastic osteosynthesis [5,6].

Furthermore, the layers are also characterized by good corrosion resistance (pitting, crevice, stress and fatigue) in body environment [7, 8, 9].

The external osteosynthesis is characterized by elasticity of fixation. Elastic fixation enables to use electromechanical effects that activate a bone union. The electromechanical effects are based on generation of electrical potentials as a result of loading, that enables a passage of action current through a fracture site. The passage of current causes the transportation of mineral matter that lead to the activation of the bone union. Electrical phenomena in bones (present during anatomical loading) allowed to use electrical current as the factor stimulating an osteogenesis [10]. The electrostimulation of bone union depends on the replacement of action currents with the currents generated by the electrostimulator. On the basis of many research was observed that the electrostimulation of bone union is advisable in pathological conditions like pseudarthrosis, delayed bone union, osteoporosis caused by underload and other [11, 12, 13]. However, the electrostimulation can lead to corrosion of implants [14, 15].

The aim of the work was influence of different methods of electrostimulation on the corrosion process of implants made of the stainless steel coated with the passive and the passive-carbon layer. “Safe” electrostimulation methods were applied. The “safe” methods and parameters should not initiate the corrosion of the stainless steel implants with the passive and the passive-carbon layers. This paper presents the preliminary experimental results in animals.

2. Methodology

The research on influence of the electrostimulation methods (and their parameters) of bone union on healing of bone fractures of rabbits was carried out in the Silesian Medical University in Katowice. Thirty nine chinchilla rabbits of 6-12 month age and within a weight range of 3,7-4,5 kg were used in the research. The animal tests were performed after approval by the ethical committee of the Silesian Medical University. All aspects of animal care complied with the appropriate regulations. The fractures were obtained by cutting the femurs with the use of the saw.

The fracture was stabilized with the use of the ZESPOL-micro system (Mikromed). The system consisted of self-threading screws, the self-clamping plate and nuts – fig. 1. The ZESPOL-micro stabilizer was made of stainless steel.

In order to isolate the soft tissues, a carbon layer was deposited (by means of the RF PCVD process) on the previously passivated surfaces [4]. The bone screws were fully coated with carbon layer or the 5 mm of the passive region was exposed - fig. 1. The passive region of the screw was implanted into the bone. This procedure was taken in order to ensure the passage of current through the fracture gap.

The B.Stim-1 i B.Stim-2 stimulators designed and produced by the Institute of Medical Devices and Technology in Zabrze were applied in the research.

The B.Stim-1 was designed for electrical stimulation of bone union as the invasive system, also popularly called “semiinvasive” –fig. 2.

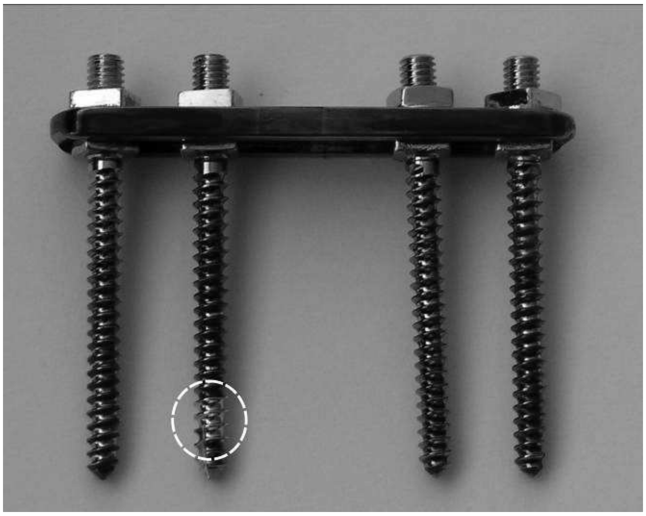

Fig. 1. The ZESPOL-micro stabilizer coated with the passive-carbon layer (the passive surface is marked)

In this method the cathode was the bone screw coated with the carbon layer with the uncoated passive region left. The remaining bone screws were fully coated with the passive-carbon layer. The stainless steel mesh implanted subcutaneously was considered as the anode - fig. 2. The subcutaneous position of the anode was applied in order to ensure good electric contact. The single-phase impulse current without constant component of the amplitude equal to 70 μA, the filling equal to 25 % and frequency of 1 Hz was applied in the research – fig. 3. The mean values of the amplitude and the current are equal to 17,5 μA and 0 μA respectively.

The B.Stim-2 stimulator was applied to stimulate the bone union by means of the capacitively coupled electrical field method.

Both the cathode and the anode are made of the stainless steel mesh. The electrodes were implanted subcutaneously in the fracture site- fig.5. The applied bone screws were fully coated with the passive-carbon layer.

The rectangular, symmetric, diphase current of the frequency equal to 60 kHz and the amplitude equal to 2,0 mA, modulated with the sinusoidal run of the frequency of 1 Hz was applied in the research – fig. 4. The mean value of the current is equal to 1,0 mA.

The rabbits were divided into several groups. The electrostimulation (semi-invasive or capacitive) period was equal to 1, 2, 4, 6 and 24 weeks. Each group consisted of the control group (the “non-stimulated” rabbits).

In order to evaluate the influence of the diverse electrostimulation methods on the corrosion resistance of implants, the following steps were taken before and after the research:

1. measurements of the bone screws mass (accuracy $5*10^{-5}$ g),
2. microscopic observations (with the use of the stereoscopic and the scanning electron microscope).

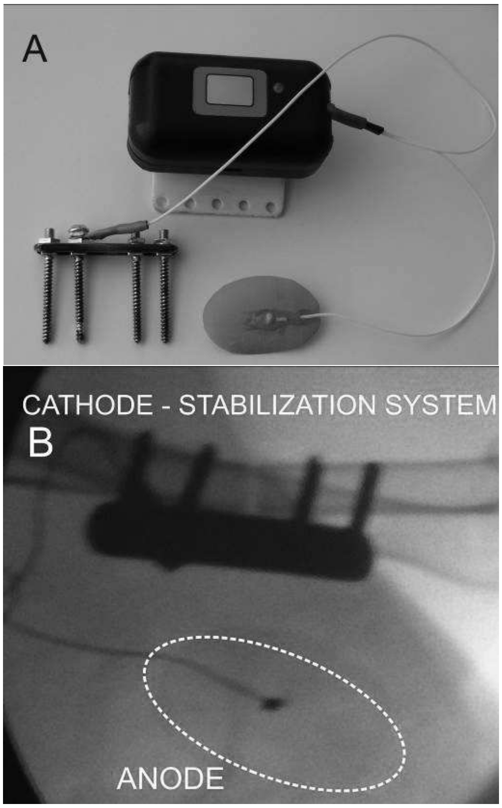

Fig. 2. Semi-invasive method of electrical stimulation of bone union: a) electrostimulator B.Stim-1 with electrodes, b) configuration of electrods – X-ray image

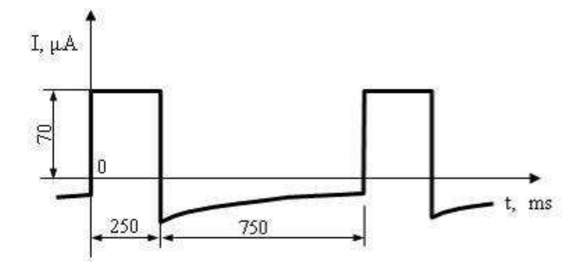

Fig. 3. Current characteristic used in semi-invasive electric stimulation method

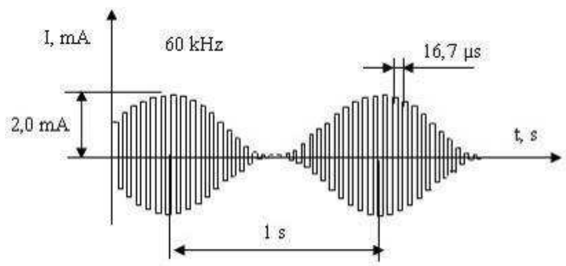

Fig. 4. Current characteristic used in capacitively coupled electrical field method

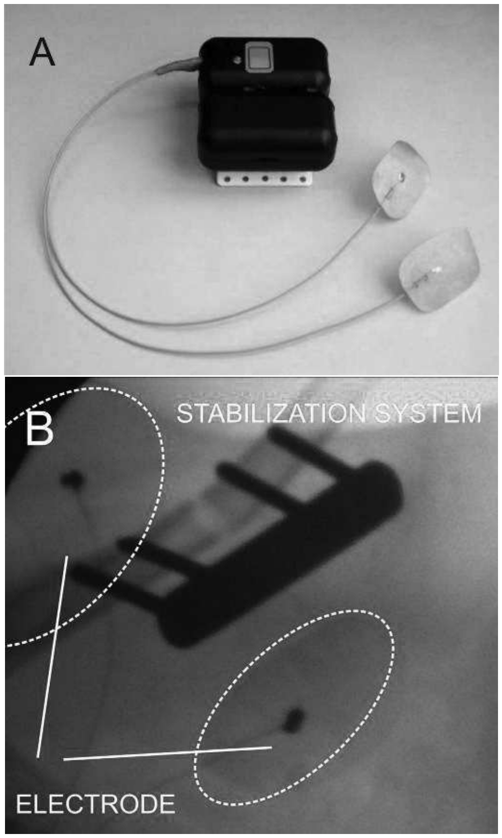

Fig. 5. Capacitively coupled electrical field method of electrical stimulation of bone union: a) electrostimulator B.Stim-2 with electrodes,b) configuration of electrods – X-ray image

3. Results

The mass measurements of the bone screws coated with the passive and passive-carbon layer (applied in the semi-invasive method) did not reveal any mass changes. The accuracy was equal to 5*10-5 g. Observations of the bone screws coated with the passive-carbon layer carried out in the scanning electron microscope did not reveal any corrosion damage (fig. 6). However, the bone screw with the passive layer applied as the cathode was locally etched. The etched regions were localized on the thread - fig 7. They were observed only on the bone screws used as the cathodes for 24 weeks.

The gravimetric measurements of the bone screws with the passive-carbon layer (used in the capacitively coupled electrical field method) did not reveal significant mass changes. Observations of the bone screws coated with the passive-carbon layer carried out in the scanning electron microscope did not reveal any corrosion damage.

The obtained results are compatible with the results obtained from the tests carried out in the Tyrode physiological solution.

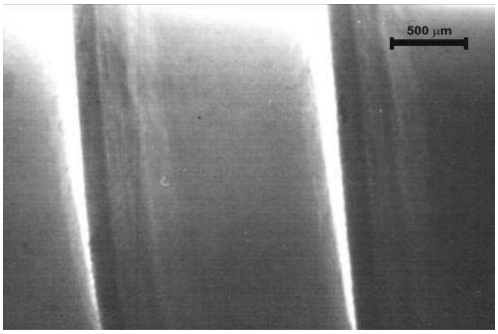

Fig. 6. Surface of bone screw with the passive-carbon layer after 24 weeks of electrostimulation, SEM

Fig. 7. Locally etched areas on the passivated surface of the electrodes (cathode) after 24 weeks of electrostimulation, SEM

4. Conclusions

On the basis of the results it can concluded that:

1. electrostimulation of bone union in rabbits with the use of the semi-invasive method (the pulse current without constant component) does not initiate corrosion of stainless steel implants coated with the passive and passive-carbon layer. Sparse etchings observed on the bone screw with the passive layer applied as the cathode in the semi-invasive method are local and do not cause the significant changes of mass.
2. electrostimulation of bone union in rabbits with the use of the capacitively coupled electrical field method (the rectangular, symmetric, diphase current of the frequency equal to 60 kHz and the amplitude equal to 2,0 mA, modulated with the sinusoidal run of the frequency of 1 Hz) does not initiate corrosion of the stainless steel implants coated with the passive-carbon layer.
3. the obtained results are compatible with the results obtained from the tests carried out in the Tyrode physiological solution [14, 15].

Acknowledgements

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