

# Method for Determining the Electromagnetic Compatibility of Biomaterials

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## Abstract

Biocompatibility of implant materials is one of the decisive factors in the effectiveness of reconstructive surgery. The criteria for biocompatibility cover several factors, but they do not include electromagnetic compatibility (EMC), which can affect the success of surgical operations in the long term. The authors of the article present a method for studying and determining the EMC of biomaterials, which contributes to their objective choice. The electromagnetic processes that may occur at the interface of contact between the implant and biotissue and characterize their interaction are considered. An assessment of the level of microwave signals at the temperature of the human body has been carried out, and the possibility of generating positive and negative energy fluxes has been shown. The electromagnetic properties of a number of implantable biomaterials have been studied and their comparative analysis has been carried out. Prognostic recommendations have been developed for the experimentally studied materials in order to ensure an increase in the efficiency of surgical interventions.

## Keywords 1

Biomaterials, electromagnetic compatibility, microwave radiation, positive and negative fluxes.

## 1. Introduction

A wide range of materials of natural and synthetic origin are used in modern medicine, in particular, bioceramics, bioglass, polymers, metals, as well as composite materials that use organic and inorganic fillers [1]. Recently, combined biomimetic scaffold (Tour G., 2012) have been used according to the tissue engineering, the inner base of which are the metal, ceramic or polymeric framework and the outer coating is dielectric, including the use of nanomaterials and powder fillers to eliminate bone defects and regenerate soft tissues [2-4].

The compatibility of biomaterials in contact with human body tissues is determined by many criteria, in particular resistance to biocorrosion, chemical stability, biological tolerance, biodegradation, etc. It is usually evaluated in a short period of time when the implant is placed, which can stay and have a prolonged effect on the human body. Such medical objects, which include implant materials and implants for prolonged use, are classified by the American FDA as class 111 materials, with a high probability of risk. Therefore, rather strict conditions of compatibility are imposed for the purpose of use in the patient's body.

All manifestations of compatibility or incompatibility, as well as complex biological, chemical and physical processes take place in the contact area between the biomaterial and the living biotissue.

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Unfortunately, the study of these processes is complicated by the physical (closed) location of the implants and requires more detailed research at the microscopic (cellular, molecular) level, in the implant-biotissue area [5].

In the process of designing ideal implants for tissue engineering, the graft-tissue contact area is a very important part that needs to be improved, since most of the interactions between grafts and surrounding tissues occur exactly in this zone.

Unresolved and unstudied problems include the presence of a weak electromagnetic field (radiation) in the contact area of the biomaterial, which is inherent to both living tissue and biomaterial (implant), which interact due to the introduction of the implant into the human body and its heating to the standard human body temperature of 36,6° C. This statement is true for dielectric materials, as there is no radiation of metallic materials due to the skin effect at this temperature.

The authors of many publications, studying the influence of weak electromagnetic fields (EMF) and radiation (EMR) of the technogenic nature radio range, point to their mainly negative impact on biological objects, humans and the environment, especially with prolonged exposure [6,7].

The available authors studies [8] reflect the impact of a weak EMF of a computer during its prolonged (more than 6 hours) use on dental tissues. Using the method of laboratory analysis, the authors confirm the change in the chemical state and the harmful effect of computer EMR on cellular level.

However, it is known that short-term, dosed exposure to microwave signals can be effectively used in microwave therapy in many diseases [9].

It is important to conduct in-depth studies of the effects of weak EMF, in order to better understand the levels of compatibility of biological objects and the human body, by frequency and energy range.

However, numerous theoretical and experimental studies have been conducted on the effect of weak electromagnetic fields and radiation on the surface layers of biotissues, the criterion of electromagnetic compatibility (EMC) of biomaterials for internal application has not yet been applied.

At the same time, dielectric and combined materials used as intratissue implants and have/form/change their own EMF at human body temperature, which interacts with EMF and human body structures, at least in the area of their introduction. This interaction can be defined as a new criterion for the interaction of the human body and the implant, which characterizes their electromagnetic compatibility in general and can be manifested at the local or general level of the organism. These issues partially considered by the authors [10].

Radiating (electromagnetic) characteristics of implants can differ significantly from similar characteristics of living tissues and, in the long-term variant of their use, are able to disrupt the electromagnetic state (homeostasis) of surrounding cells.

In work [11] a method of formation and evaluation of EMR in optical range is proposed. In this case, depending on the temperature of the optical radiation source, positive and negative fluxes of EMR can be created, implemented by heating or cooling of the optical radiation source. This paper considers features and physical processes of appearance of positive and negative fluxes of optical range under the influence of temperature gradients without analyzing the processes of the physiological impact of such EMR fluxes on living tissues.

Using a highly sensitive radiometric system, the authors of [12] registered the presence of positive and negative EMR fluxes in the microwave range and conducted clinic and laboratory studies of their effect on biological objects and the human body. According to the results of the studies, a method of treatment based on the formation, evaluation and use of positive and negative fluxes of EMR of the microwave range for surface irradiation of human skin was proposed.

In addition, a number of laboratory experiments were carried out, and the reaction of some surface biological tissues to the EMR was determined. As a result of laboratory studies, it was revealed that surface irradiation of a cancerous tumor with positive EMR fluxes accelerates its growth, and with negative ones it slows it down. The general disadvantage of the studies under consideration is the lack of connection with the human's internal EMR, which is important for the implants installed in the human's body.

Thus, the performed analysis shows that EMR have an impact on biological objects and human body, therefore preliminary research of electromagnetic compatibility of implantable biomaterials for medical purposes made of them is an urgent task.

## 2. Description of the method for assessing the electromagnetic compatibility of biomaterials

The authors of the article proposed a new method for assessing the EMC of implantable biomaterials before their incorporation into the human body, which consists in the following. First, the average temperature and EMR are determined at several points of the human (patient) body. Then the biomaterial under study is heated to the set (average) temperature of the human body and its emissivity is measured, and the level of deviation of the biomaterial EMR  $R$  from the human body radiation is calculated according to the formula:

$$R = P_M / P_H \quad (1)$$

where  $P_M$  - radiation level of biomaterial;  $P_H$  - the average level of radiation of the human body.

The implementation of the algorithm for measuring and converting signals proposed by the authors makes it possible to make a more objective assessment of the EMC of biomaterials with biological tissues of the human body.

## 3. The physical essence of the method for evaluating EMC biomaterials

Electromagnetic properties of biomaterials are still insufficiently studied, although they can significantly influence the processes of their interaction with living tissues at human body temperature. It can be explained by a very low signal level of the microwave range, which is within  $10^{-13} \dots 10^{-14}$  W at the indicated temperature. At the same time the emissivity of the implant and the nearby biotissues may differ from each other, that will cause the appearance of difference EMR fluxes.

At a standard temperature, a heated implant and nearby cells form a noise signal, the integral level of which can be determined using the Nyquist formula:

$$P = S(f, T) \Delta f = kT \Delta f \quad (2)$$

where  $S(f, T)$  - spectral density of the noise EMR of the object under study;  $k$  - Boltzmann's constant ( $1,38 \cdot 10^{-23}$  J/K);  $T$  - thermodynamic temperature of the object (K);  $\Delta f$  - frequency band in which the measurement is made. For a real radiometric system, the average value is  $\Delta f = 1,35 \cdot 10^8$  Hz. At a human body temperature of  $36,6^0$  C, the integral power calculated by the formula (2) in the analysis frequency band is  $P_H = 5,77 \cdot 10^{-13}$  W.

When the emissivity of the human body  $P_H$  and biomaterial  $P_M$  differ, electromagnetic incompatibility arises, and positive or negative EMR fluxes are formed. The energy of the biotissue adjacent to the implant may increase or decrease, which is equivalent to the effect of increasing or decreasing its temperature gradient.

From the above, the constant effect of the difference in EMR fluxes in the contact area of the implantable material can positively or negatively affect the processes of reparative tissue regeneration and decrease or increase the risks of postoperative complications.

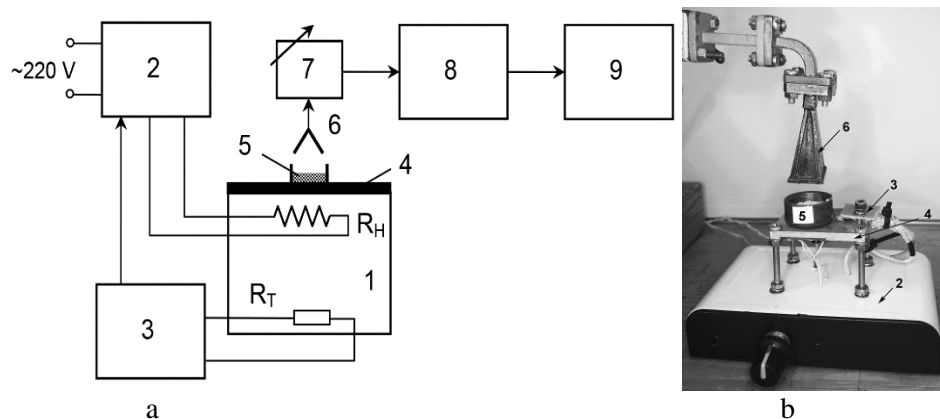
Implementation of the method of formation and evaluation of EMR of biomaterials is carried out at three stages. At the first stage in several points the exact measurement of human body temperature is made, and high-sensitivity radiometer measures the level of EMR and determines the average value of parameters  $T_H, P_H$ . At the second stage, the biomaterial or implant is heated to a certain temperature  $T_H$  and the radiation of the biomaterial  $P_M$  is measured. At the third stage, the level of electromagnetic compatibility of the biomaterial with the human body is calculated using the formula (1).

## 4. Results of experimental studies

### 4.1. Description of technical support

Fig.1a shows a schematic diagram of the installation for measurements. Measurements were made on a certified high-sensitivity radiometric system in the laboratory of National Technical University of

Ukraine “Igor Sikorsky Kyiv Polytechnic Institute”. The sensitivity of the system is  $1 \cdot 10^{-14}$  W, the operating range is 37...53 GHz. The study was conducted at a frequency of 52 GHz.



**Figure 1:** Structural setup for measuring the microwave emissivity of materials (a) Structural setup for measuring the microwave emissivity of materials (b).

The diagram shows: 1 - thermostat; 2 - power supply; 3 - temperature controller; 4 - temperature-controlled plate for heating; 5 - test material; 6 - receiving antenna; 7 - input attenuator; 8 - radiometric measuring system; 9 – indicator.

#### 4.2. Description of research materials

The following biomaterials, which are used in maxillofacial reconstructive surgery were provided by Oral and Maxillofacial Surgery Department O.Bogomolets National Medical University:

1. Osteoplast-T is a biomaterial of demineralized and non-demineralized bone collagen in combination with sulfated glycosaminoglycans.

2. Polyhemostat – the drug belongs to the pharmacological group of local hemostatic agents. Active ingredients are: aminocaproic acid, dry extract of Hypericum herb, liquid extract of Yarrow herb, dry extract of Horsetail herb, dense extract of Nettle leaves, dry extract of Oak bark, 0.05% Chlorhexidine solution; auxiliary substance – Calcium alginate.

3. Powder of calcium salt of orthophosphoric acid is a natural mineral compound that is found in minerals: phosphorite, apatite, hydroxyapatite.

4. Synthekost – bioactive glass (300-500 microns), used to fill bone defects, as well as for the induction of subsequent osteogenesis.

5, 6. Bone defect fillers – preparations Biomin GT 500, Biomin GT 700 - two-phase ceramics based on hydroxyapatite and tricalcium phosphate with particles of different sizes.

Samples of biological materials 1, 2 are made from natural living components, and those marked with positions 3-6 are of mineral synthetic origin. Results of experimental researches of EMR of given biomaterials and estimation of their relative radiating ability of human body are given in table 1.

**Table 1**

Results of experimental studies of EMF of biomaterials and assessment of their relative radiation capacity of the human body

	Test samples	Power, $10^{-13}$ W/cm <sup>2</sup>	$P_M / P_H$
H	Human	5.76	1
1	Osteoplast T	5.35	0.92
2	Polyhemostat	5.20	0.90
3	Ca <sub>2</sub> (PO <sub>4</sub> ) – calcium salt	0.80	0.14
4	Bioactive glass (300-500 mkm)	0.76	0.13
5	Biomin GT -700	0.04	< 0.01
6	Biomin GT -500	0.02	< 0.01

As noted in Table. 1, the materials most similar in terms of emissivity are Osteoplast-T and Polygemostat, which have deviations in the EMR level of 7,1 and 9,7%, respectively.

Using formula (2) and the results of experimental measurements, the authors calculated the equivalent temperature for the most matching materials  $T = P / k\Delta f$ , for Osteoplast-T it is 287 K, and for polyhemostat it is 279,5 K

The above samples of biomaterials 1 and 2 from table 1 have an emissivity that matches the human body; materials 3 and 4 are 6-8 times less, and materials 5, 6 are two orders of magnitude less.

Materials of synthetic origin have a significant deviation from the EMR level of the human body and correspondingly increased level of negative flux, therefore, preference should be given to materials with electromagnetic characteristics close to the human body.

## 5. Conclusions

1. The use of the suggested method makes it possible to simplify the signal conversion algorithm, its technical implementation and the possibility of evaluating the EMC of implantable materials with living tissues, in particular, of the human body.

2. The conducted research is promising for evaluation of electromagnetic properties and biological compatibility of implantable biomaterials, in particular those created using modern technologies.

3. The use of microwave electromagnetic radiation-compatible implantable materials with the human body will not change or disrupt the tissues energy homeostasis of the recipient area and the course of biological processes in them, including reparative ones.

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