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Electromagnetic Compatibility of Implantable Biomaterials for Reconstructive and Restorative Surgery of Facial Bones

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The critically important part for reconstructive and restorative surgical interventions in facial bones results is the interface of implant-tissue surfaces. The importance of taking into account the processes occurring at the border of the distribution of the implant and living tissue is due to many factors. Among them are well-known ones, such as biological compatibility, consistency of physicochemical parameters, etc. But, at the same time, the issues of electromagnetic interaction between implant materials and biological tissues remain unresolved. So, it's actual to investigate the interaction of implanted materials and tissues they are in contact. The authors considered the sources of formation of low-intensity microwave signals generated by the implant and living tissue. In this article, the authors demonstrate that microwave electromagnetic radiation is an important indicator and a new criterion for the physical compatibility of dielectric implantation biomaterials. It is proposed to use the term "electromagnetic compatibility" for the possibility of evaluating implant materials. This makes it possible to quantify the materials that come into contact with the human body during implantation. It should be noted that it is extremely difficult to measure the microwave radiation of the implant and biological tissue with existing technical means. This is due to the extremely low power of the emitted signals. The authors created a radiometric system with a sensitivity of 10^{-14} W. Using a highly sensitive radiometric system, a study of the radiation capacity of a number of implantable biomaterials was conducted. The possibility of forming positive and negative flows of microwave radiation, which can occur between adjacent tissues and implants, is shown. Violations of electromagnetic compatibility and, accordingly, the energy state of the surrounding biotissues, can qualitatively and quantitatively affect the reparative processes in the area of interventions, prolong the recovery period of adjacent tissues. So, it must be taken into account when choosing dielectric implant biomaterials.

Keywords: implant biomaterials; microwave radiation; electromagnetic homeostasis; bone regeneration

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Introduction

Facial bone defects resulting from injuries, wounds, inflammatory processes, tumors, etc. require complex reconstructive and restorative operations with extended rehabilitation periods. The use of implantable biomaterials compatible by many criteria, including physical compatibility, creates conditions for reducing postoperative complications, reducing rehabilitation time, and improving the patient's life [1, 2].

Based on modern achievements of tissue bioengineering, existing surgical methods of directed bone and soft tissue restoration widely use biomimetic scaffold systems, both of synthetic and natural origin or their combination. The inner base of such systems is a metal, ceramic or polymer frame, and the outer coating is dielectric (Tour G., 2012) [1–5].

The use of implantable biomaterials for the purpose of eliminating facial bone defects involves their long-term stay in the human body under the influence of cyclic biomechanical loads in contact with bone and soft tissues, including the mucous membrane [1, 5].

It is expected that the implant materials will contribute to the processes of healing and tissue regeneration, which are inevitably associated with inflammatory reactions. However, at the same time, other reactions can also occur (bone resorption and desorption (the substance is released from the surface or through it), blood clotting, suppuration, fibrous encapsulation, etc.), depending on the state of the implantation bed, chemical and physical properties of the materials, their destruction and/or biodegradation.

Problems constantly arise because "normal biology" becomes "abnormal" in direct contact with foreign materials transplanted in vivo. The so-called "intelligent surface" of implants seems quite static compared to the dynamic biology of a living organism.

Biophysical properties of implant materials occupy an important place among the requirements for its installation and control of functioning, such as: high X-ray contrast; low magnetic susceptibility; strength (similar or greater than that of biotissue); plasticity; surface structure; close coefficients of electrical conductivity and thermal conductivity; close levels of electromagnetic activity (emission and absorption of electromagnetic waves of a certain range).

At the same time, the level of electromagnetic radiation, its impact on organs, tissues and cells in the area of their contact with implantable biomaterials remains the least studied criterion of their biophysical compatibility.

1 Features of the electromagnetic interaction of implants with biotissue

Research in recent years on the regulatory and adaptive processes of biological systems note that an integral part of the functioning of the human body and its intercellular interaction is the presence of biochemical reactions accompanied by the formation and emission of electromagnetic fields (EMF). Endogenous constant and variable electric fields, magnetic fields generated by the heart, brain, muscles, bone tissue and all living cells are defined.

Liquid crystal collagen is considered an important element of intercellular interaction at the molecular level, EMF reception and conduction. Forming cluster systems with water molecules, collagen gives the connective tissue liquid crystalline properties, which facilitates the passage of EMF energy and can act as a communication system.

The presence of nerve endings, hormones and biologically active substances, as well as cells of the immune system, provides connective tissue with integrative and regulatory functions of body systems. The transmission of signals in this tissue can affect (or be affected by) physiological or pathological processes, changing the state of health and the course of the disease and forming a unique system – electromagnetic homeostasis of the human body [6, 7].

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

Dielectric and combined materials used as intratissue implants and at the temperature of the human body can form and/or change their own EMF, which interacts with the EMF of the human body in the area of their introduction. The specified energy processes that occur during the electromagnetic interaction of the human body with biomaterial can be manifested at the local or general level of the organism and reflect the presence and functioning of the electromagnetic homeostasis system. This is confirmed by a number of experimental studies conducted by the authors [8, 9], using highly sensitive radiometric equipment.

The body's temperature stability and electromagnetic homeostasis is also maintained in the event of changes in environmental factors: temperature, pressure, man-made radiation or cosmic magnetic and microwave fields [10]. The formation of an internal (endogenous) microwave field around a dielectric implant biomaterial poses the task of studying their radiative properties, with the aim of determining electromagnetic compatibility with the human body.

The authors [8, 9] conducted studies of some dielectric biomaterials for medical purposes. As a result, the emissivity was determined and the presence of positive and negative microwave electromagnetic flows that can occur between the implant and living tissue was determined, a significant influence of microwave flows was established, both on certain types of cells (oncological) at the local level, and on the human body in as a whole.

Currently, a significant number of implantation methods and materials with both negative and positive properties have been developed and studied [11]. Most materials are characterized by: lack of a structure similar to bone tissue, the ability to resist significant biomechanical loads, different levels of biophysical compatibility [12].

Therefore, there is a need to study the electromagnetic properties of bone substitute implantation biomaterials before their use.

Figure 1 shows three possible options for the interaction of the implant (implantation material) with the adjacent tissues of the human body.

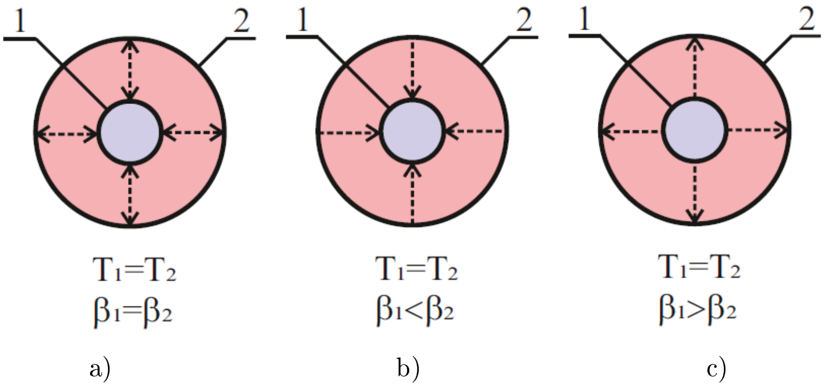

Fig. 1. Scheme of interaction of microwave flows of the implant with adjacent tissues of the human body

Designation in the figure: 1 – implant; 2 – adjacent tissues; T_1, T_2 – temperature of the implant and adjacent tissues; β_1, β_2 – coefficient of radiation capacity of the implant and adjacent biotissue.

Dielectric implant 1 of natural or synthetic origin is surrounded by adjacent biotissues 2. The thermal field of the human body uniformly heats both the implant and the adjacent biotissues, forming microwave fields that interact with each other. At the same temperature of these two objects, the electromagnetic interaction is determined by the emissivity of the implant β_1 and biotissue β_2. At the same time, there are three options for the formation of such interaction indicated in Fig. 1. In the first option (Fig. 1a), at the same temperature of the implant and biotissue ($T_1 = T_2$), as well as equal coefficients of radiation capacity ($\beta_1 = \beta_2$), an equilibrium interaction is established between them and this option is characterized by their complete electromagnetic compatibility. In the second option (Fig. 1b), at the same temperature ($T_1 = T_2$), the radiation capacity of the implant is lower than that of the adjacent tissues ($\beta_1 < \beta_2$). The gradient of the distribution of the electromagnetic field is directed from the biotissue to the implant, characterized by the selection of energy and the formation of a negative flow in relation to the adjacent biotissue. The third option is possible (Fig. 1c), when($T_1 = T_2$) but the radiation capacity of the implant is greater than that of biotissues ($\beta_1 > \beta_2$). The direction of the EMF flow is directed from the implant to the biotissue, characterized by the addition of energy and the formation of a positive flow. It should be noted that energy exchange in the form of microwave negative and positive flows between the implant and adjacent biotissues in the long term can change the course of reparative processes in the body, affect the effectiveness of clinical intervention. The power of the electromagnetic flux emitted by a physical body is determined by its temperature, and the level, in general, is described by the well-known law and Planck's formula. It should be noted that a low-intensity signal is formed at a human body temperature of 310 K, so its measurement is carried out using special highly sensitive equipment – a radiometric system (RS).

The integral power P_Σ for a microwave signal can be determined (calculated) by the Rayleigh-Jeans formula or the simpler Nyquist formula, as the product of the emissivity β by the temperature T and k the Boltzmann constant. If it is necessary to obtain a result with the use of hardware, the frequency band of the analysis Δf_{RS} of the measuring RS must also be taken into account. At the same time, the calculation formula takes the form:

$$P_{\sum} = kT\Delta f_{RS}. \quad (1)$$

For a completely black body (CBB) $\beta_{CBB} = 1$, at a temperature equivalent to the human body of 310 K and a bandwidth of the radiometric system on which experimental studies were carried out $\Delta f_{RS} = 10^8$ Hz, the value of the integral power calculated by formula (1) is $P_{\sum CBB} = 4,2 \cdot 10^{-13}$ W. Since the emissivity Δf_{RS} of the human body and implant materials is lower than CBB, the radiated power level will also be lower and needs experimental evaluation. The relationship between the emissivity of the research object and its integral power is described by the well-known Kirchhoff formula, and taking into account our notations, we obtain the calculation expression

$$P_{\sum} = \beta_o P_{\sum CBB}, \quad (2)$$

where $\beta_o = \beta_1; \beta_2$ are the coefficients of the radiation capacity of the implant and the human body. From formula (2), we get the expression for calculating the coefficients of the emissivity of the research objects

$$\beta_o = \beta_1; \;\; \beta_2 = P_{(1;2)\sum} / P_{\sum CBB}\,. \quad (3)$$

Thus, as follows from formula (3), in order to determine the coefficients of the emissivity of the implant and the human body, it is necessary to measure the integral power of these research objects and make the appropriate calculations

2 Technical support and research technology

The level of body radiation, at a human temperature of 310 K in the microwave range, is extremely low. The authors of this study developed and certified a non-standardized radiometric system for the frequency range of 37…53 GHz by the State Standard of Ukraine. The measurement band of the integral power, which is determined by the radiometric channel, is $\Delta f_d = 10^8$ Hz.

The sensitivity approved by the RS certification is at the level of $3 \cdot 10^{-14}$ W, which allows you to reliably measure the radiation of the human body, which is within the range of $(2,5\ldots4,0)\cdot10^{-13}$. Experimental stand for measuring the radiation capacity of the human body and of implantation materials is located on the basis of the department of applied radioelectronics of National Technical University of Ukraine “Igor Sikorsky Kyiv Polytechnic Institute”. The stand includes a highly sensitive NU-2 radiometric system and a standard TS-80M-2 thermostat for heating materials up to human body temperature of 310 K. Research was conducted at a frequency of 51 GHz. The general method of conducting experimental studies and a detailed description of the procedure for measuring the emissivity of various biomaterials, in order to determine their compatibility, were carried out by the authors in [9]. To compare the radiation of implant materials, at the beginning of each study, the average level of microwave radiation power (flow) of three respondents was evaluated.

3 Description of research objects and their radiation level

As part of the agreement on scientific and technical cooperation between the National Technical University of Ukraine “Igor Sikorsky Kyiv Polytechnic Institute” (Department of applied radioelectronics) and the Bogomolets National Medical University (Department of Surgical Stomatology and Maxillofacial Surgery), implant materials used (as implants) for reconstructive and restorative surgery of facial bones were investigated.

The researchable biomaterials were divided according to their origin on the two main groups.

Natural origin:

1. Human body – measurement from the middle of the inner side of the palm;
2. Solid vertebral bone (VB) – whole tubular bone of animal origin;
3. Milled vertebral bone (BP) – the tubular bone of animal origin;
4. Cerabone, BotissDental – bone substitute material of animal origin (granules 0,5…1,0 mm), which has spatial stability, hydrophilicity of the surface of its particles, which retains similarity with human bone (surface, porosity, chemical composition). Its resorption time is 6…9 months;
5. Parasorb (Resorba) – collagen cones made of native horse collagen fibers, which provide fast and reliable hemostasis, blood clot stabilization in bone defects and subsequent tissue regeneration during – 2…4 weeks;
6. Gelatamp (Roeko) – porous hemostatic sponge, which consists of hardened gelatin – 9,5 mg and colloidal silver – 0,5 mg, with a resorption time of up to 4 weeks.

Synthetic origin:

7. Medical glue with folic acid (MG+FA);
8. Medical glue without folic acid (MG-FA) – the long-acting biocomposite based on reticulated polyurethane, which has the ability to polymerize in the bone cavity, to be used as a barrier membrane, and to gradually dissolve within 9…12 months [12];
9. Hydroxyapatite powder (HA) – the material is synthesized from an aqueous solution of calcium and phosphorus salts, which can be used in combination with other components of multiphase ceramics or cover the surface of implants;
10. Synthekist – glass-ceramic powder (300…500 microns), used to fill bone defects, as well as for the influence to the process of reparative osteogenesis;
11. Biomin GT-700 - a two-phase preparation, ceramics based on hydroxyapatite and tricalcium phosphate with particles 700…800 microns in size;
12. Biomin GT-500 – a two-phase preparation, ceramics based on hydroxyapatite and tricalcium phosphate with particles 400…600 microns in size.

A complete list of research objects according to their origin is given in Table 1.

Tabl. 1 Research objects

Object number	**Natural origin**	**Object number**	**Synthetic origin**
1	Human palm (average radiation)	7	MG+FA
2	Solid vertebral bone	8	MG-FA
3	Milled vertebral bone	9	Hydroxyapatite (powder)
4	Cerabone (granules)	10	Synthekist (powder)
5	Collagen sponge	11	Biomin GT-700 (powder)
6	Gelatin sponge	12	Biomin GT-500 (powder)

The results of experimental measurements of the integral power and calculation of the radiative capacity coefficients of the research objects are shown in Table 2.

Table 2 covers (by columns) the numbering of the implant materials, the radiometric system measured integral power, with an analysis band of 100 MHz at 51 GHz, the value of the emissivity coefficient of each material and the percentage ratio of the integral power of the material to the integral power of the human body.

The analysis of the results of experimental studies of the radiative capacity of implant materials given in Table 2 indicates a significant spread of data, both in terms of the level of radiative power and its coefficient. It should be noted that the coefficient β_1 of implantation materials of natural origin (position 2-4) is close to the radiative capacity of the human body β_2 and has a difference (smaller) of 1,3. . . 5 times. The use of these materials creates weak negative EMF currents, so they can be considered electromagnetically compatible with the human body. Some of the materials (position 7-9) have up to 15 times lower emissivity coefficient β_1, and accordingly form a significant negative EMF flux, so they can be classified as insufficiently compatible. The last group (positions 5, 6, 10-12) is characterized by a significantly reduced level of radiation (by 15. . . 25 times), the formation of negative EMF fluxes from the tissues in the direction of these materials. These materials are considered energetically incompatible and unfavorable for long-term contact with the tissues of a living organism especially when used in large quantities.

Tabl. 2 Results of experimental research

Research objects	**Power** P_Σ, $\cdot 10^{-13}$ **W**	**Coefficient** β_1 ($\beta_1 = P_\sum / P_{CBB}$)	**% from** β_2
1	2,3	0,54	100
2	1,8	0,42	77
3	1,1	0,26	47
4	0,6	0,14	26
5	0,2	0,05	8
6	0,2	0,05	8
7	0,6	0,14	24
8	0,4	0,09	18
9	0,2	0,05	8
10	0,1	0,02	4
11	0,1	0,02	4
12	0,1	0,02	4

Figure 2 shows a conditional division of experimentally tested implant materials regarding their electromagnetic compatibility with the human body.

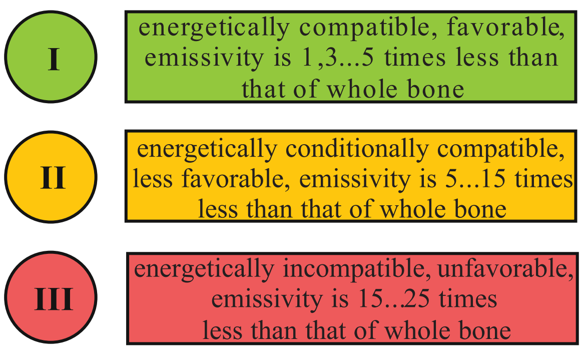

Fig. 2. Groups of the research's objects according to the electromagnetic compatibility with human body

4 Predictive analysis of research results

Microwave electromagnetic radiation of a dielectric implantation material or an implant made of it is a constant value depending on its composition and the ambient temperature, which for the human body is 310 K. The difference in the emissivity coefficients of the tissue of the human body and the implanted biomaterial, despite the constancy of the temperature in the place of contact, can lead to the emergence of positive or negative flows of electromagnetic energy and the appearance of electromagnetic incompatibility. With large gradients (differences) of EMF flows (more than 50%) and their long-term effect, during the use of the implant, the prolonged effect of the difference of these flows affects the processes of tissue regeneration and increases the risks of postoperative complications, especially with significant volumes of the implantable substance. Taking into account the results of experimental studies of radiation ability, it is advisable to divide implant materials into several groups according to electromagnetic compatibility for reconstructive and restorative surgery of the bones of the facial joint. More favorable are materials made from substances of organic origin and less favorable materials of synthetic origin are made from mineral inorganic substances.

Conclusions

1. The data presented in the Tables 1, 2 show that the radiation intensity levels of the research objects differ significantly from each other.

2. If the energy level of the bone is lower than the energy level of the implanted material, the energy flow relative to the bone will be positive, and if it is higher, it will be negative.

3. Materials of the II and III groups (Fig. 2), under the condition of prolonged contact, can contribute to the deterioration of the process of reparative regeneration of tissues due to their energy suppression or exhaustion.

4. The use of materials compatible with microwave electromagnetic radiation for the regeneration of bone tissue will maintain the optimal level of reparative processes, contribute to the physiological or improved efficiency and predictability of the results of surgical interventions, shorten the healing period and will better restore the structural and functional state of tissues.

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Електромагнітна сумісність імплантованих біоматеріалів для реконструктивно-відновної хірургії кісток обличчя

Яненко О. П., Перегудов С. М., Шевченко К. Л., Маланчук В. О., Швидченко В. С., Головчанська О. Д.

Критично важливою частиною для результатів реконструктивно-відновлювальних хірургічних втручань на кістках обличчя є межа поверхонь імплант-тканина. Важливість врахування процесів, що відбуваються на межі розподілу імпланту та живої тканини, обумовлена багатьма факторами. Серед них є загально відомі, такі як біологічна сумісність, узгодженість фізико-хімічних параметрів та ін. Але, разом з цим, залишаються неврахованими питання електромагнітної взаємодії матеріалів для імплантації та біологічних тканин. Отже, актуальним є дослідження взаємодії імплантованих матеріалів і тканин, з якими вони контактують. Авторами розглянуто джерела формування низькоінтенсивних мікрохвильових сигналів, які утворюються імплантом та живою тканиною. У цій статті автори демонструють, що мікрохвильове електромагнітне випромінювання є важливим показником і новим критерієм фізичної сумісності біоматеріалів діелектричної імплантації. Для можливості оцінювання матеріалів-імплантів пропонується використовувати термін «електромагнітна сумісність». Це дає можливість кількісної оцінки матеріалів, що при імплантації контактують з тілом людини. Слід зазначити, що вимірювати мікрохвильове випромінення імпланту та біологічної тканини існуючими технічними засобами вкрай складно. Це обумовлено наднизькою потужністю випромінюваних сигналів. Авторами створено радіометричну систему з чутливістю на рівні 10^{-14} Вт. За допомогою високочутливої радіометричної системи проведено дослідження радіаційної здатності ряду імплантованих біоматеріалів. Показана можливість формування позитивних і негативних потоків мікрохвильового випромінювання, які можуть виникати між суміжними тканинами та імплантатами. Порушення електромагнітної сумісності і, відповідно, енергетичного стану оточуючих біотканин, можуть якісно і кількісно впливати на репаративні процеси в зоні втручання, подовжувати період відновлення прилеглих тканин. Тому це необхідно враховувати при виборі діелектричних біоматеріалів для імплантатів.

Ключові слова: імплантаційні біоматеріали; мікрохвильове випромінення; електромагнітний гомеостаз; регенерація кістки