MODEL FOR ASSESSING THE SAFETY INDEX OF CONSTRUCTIONS BASED ON HYDROXYAPATITE

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Synthetic hydroxyapatite is used in biomedical engineering for its desirable mechanical properties. But not all scaffolds are biocompatible in use. The safety of implants depends on the competence of medical personnel, manufacturing technology, as well as biological, mechanical and other properties. Although there are regulatory standards for the safety of biomaterials, the assessment of their biocompatibility is a difficult task, which is associated with the properties of spacesuits, the duration of contact with tissues. The article proposes a method for assessing the safety of implants depending on various factors that form their biocompatibility.

KEYWORDS

hydroxyapatite, biocompatibility, scaffold, risk assessment, grading system, management of risks

1. INTRODUCTION

Today, health care is based on technology, and biomedical engineering is the driving force behind this development. Development of new biomaterials, including implants with desired mechanical properties - an achievement of biomedical engineering [Macala 2009, Tan 2020]. Synthetic hydroxyapatite nanoparticles are used in tissue replacement due to the similarity in composition with natural tissues [Panda 2013 and 2016, Sukhodub 2018, Keltoum 2021]. Achieving the best compromise between the mechanical and biological parameters of such materials is not always a simple procedure, although this is one of the important conditions for their use as scaffolds in tissue engineering [Rimar 2016, Valicek 2016]. The scaffolds are not permanent implants, but they must be biodegradable to allow the cells to produce their own extracellular matrix [Macala 2017, Dolcimascolo 2019]. Not all biomaterials are equally useful when used as directed. Because of this, there are risks of biocompatibility when using spacesuits from different biomaterials [Valicek 2017, Labun 2020, Chernobrovchenko 2021]. The safety of implants is influenced by biological, physical-mechanical and other properties [Panda 2014, Pandova 2018, Eltom 2019, Zeynep 2019, Wang 2020].

Assessing the best options among new technologies is complicated by trade-offs between benefits and risks, which are difficult to quantify due to the limited and fragmented information available [Duplakova 2018, Chernobrovchenko 2021]. Although there is a highly regulated environment, assessing the biological suitability of suits is a complex task associated with various factors, including mainly the chemical nature and physical properties of the material, the contact tissue and the duration of contact. International standards such as ISO 10993-1 are used to demonstrate compliance with regulatory requirements, but they may not provide sufficient guidance or hazard control capabilities [Zaborowski 2007, Mrkvica 2012, Michalik 2014, Baron 2016, Murcinkova 2017, Olejarova 2017, Bernard 2018, Chaus 2018, Straka 2018a,b, Modrak 2019, Panda 2019, Bozek 2021, Dyadyura 2021, Vagaska 2017 and 2021].

Therefore, the aim of the work is to create an integrated system for assessing and managing risks associated with the development, production and intended use of space suits from different biomaterials.

2. MATERIALS AND METHODS

Factors affecting the safety of space suits include: biological properties, physico-chemical-mechanical factors, patient characteristics, scientific research results, preclinical test results, manufacturing technology, and the competence of medical personnel (Fig. 1).

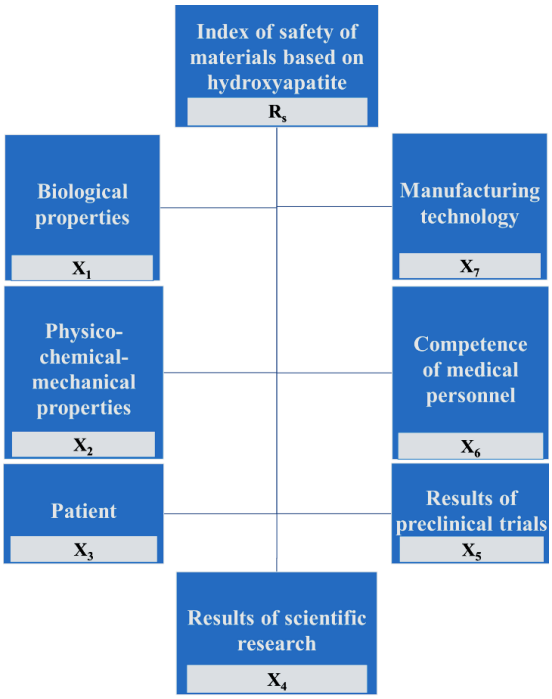

Figure 1. Factors affecting the safety of scaffolds

Each factor is made up of sub-factors. Biological properties are determined by osteoinduction, osteoconduction, osseointegration, and solubility of ingredients (Fig. 2).

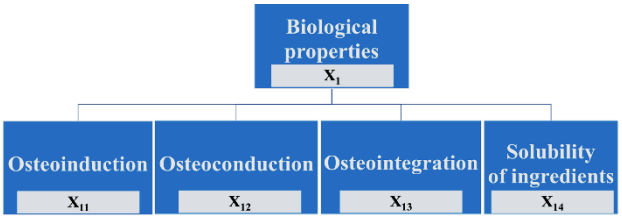

Figure 2. Biological properties of scaffolds

Physico-chemical-mechanical properties are determined by: porosity, mechanical strength, (ISO 13175-3:2012 Implants for surgery — Calcium phosphates — Part 3: Hydroxyapatite and beta-tricalcium phosphate bone substitutes (IDT)), grain size (ISO 13383-1:2012. Fine ceramics (advanced ceramics, advanced

technical ceramics) — Microstructural characterization — Part 1: Determination of grain size and size distribution) (Fig. 3).

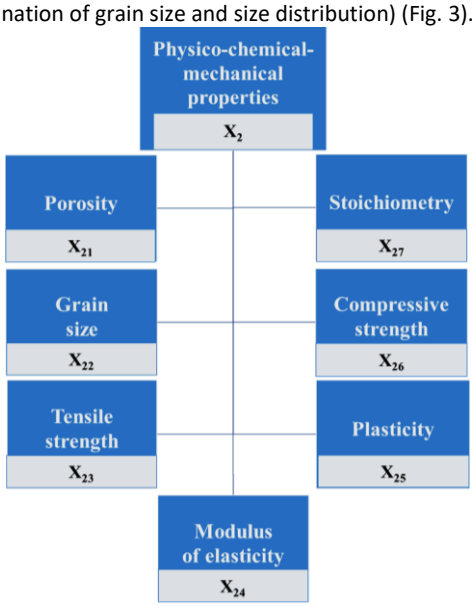

Figure 3. Physico-chemical-mechanical properties

The characteristics of the patient include trauma and body characteristics (Fig. 4).

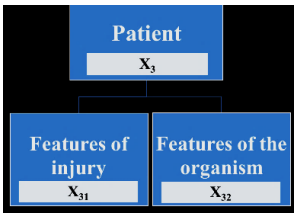

Figure 4. Patient features

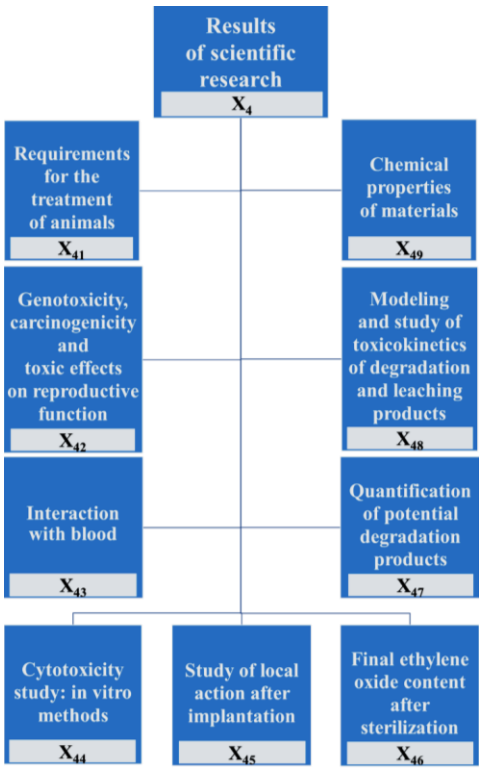

Figure 5. Results of scientific research

The results of scientific research (Fig. 5) are determined by: requirements for the treatment of animals (ISO 10993-2:2006 "Biological evaluation of medical devices - Part 2: Animal welfare requirements"); genotoxicity, carcinogenicity and toxic effects on reproductive function (ISO 10993-3:2014 Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity, IDT); interaction with blood (ISO 10993-4:2017 Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood, IDT); cytotoxicity (ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for *in vitro* cytotoxicity); local action after implantation (ISO 10993-6:2016 Biological evaluation of medical devices - Part 6: Tests for local effects after implantation); final action of ethylene oxide after sterilization (ISO 10993-7:2008/Cor.1:2009 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals", IDT); quantification of potential degradation products (ISO 10993-9:2019 "Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products"); modeling and study of toxicokinetics of degradation and leaching products (ISO 10993-16:2017 Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables); chemical properties (ISO 10993-18:2020 Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within s risk management process); general toxic effect (ISO 10993-11:2017 "Biological evaluation of medical devices - Part 11: Tests for systemic toxicity); physicochemical, morphological and topographic properties of materials (ISO/TS 10993-19:2020 Biological evaluation of medical devices - Part 19: Physico-chemical, morphological and topographical characterization of materials); immunotoxic effect of medical devices (ISO/TS 10993-20:2006 Biological evaluation of medical devices - Part 20: Principles and methods for immunotoxicology testing of medical devices. Preclinical studies include ex vivo, in vivo studies (Fig. 6).

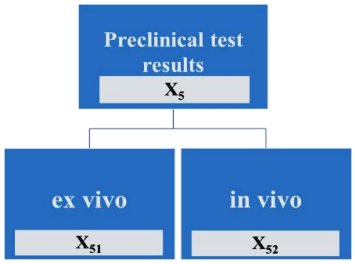

Figure 6. Preclinical test results

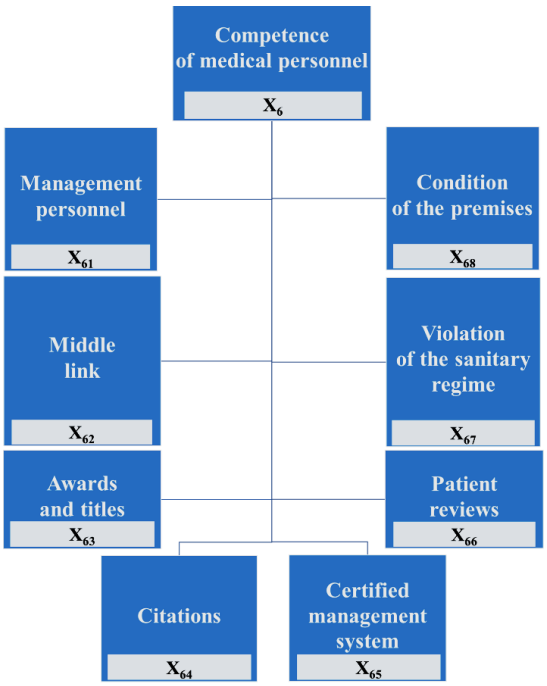

Figure 7. Competence of medical personnel

The competence of medical personnel is determined by: managerial personnel, middle management, awards and titles, citation, certified management system, customer reviews, violation of the sanitary regime, the condition of the premises (Fig. 7).

Factors of manufacturing technology include the condition of the equipment, the pH of the medium, the temperature regime, time, pressure, and the chemical composition of the medium (Fig. 8).

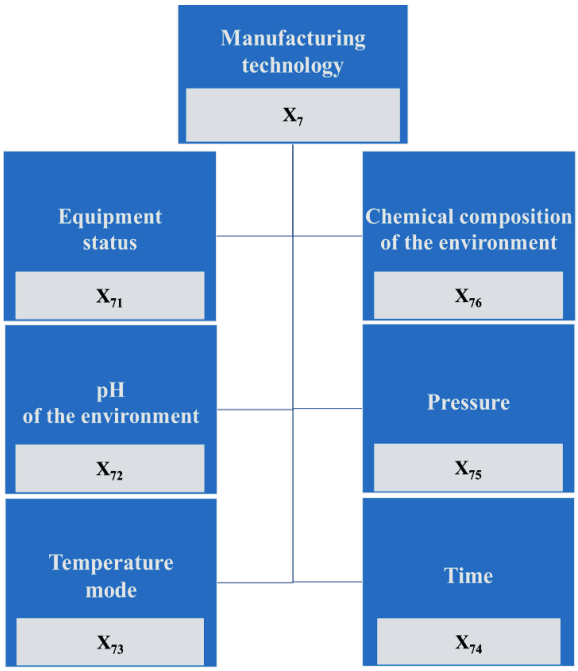

Figure 8. Manufacturing technology

3. ASSESSMENT OF BIOCOMPATIBILITY BY AN EXPERT METHOD

3.1 In the factorial model, the assessment of the biocompatibility of hydroxyapatite-based scaffolds is expressed by the R_s index, which is determined by the formula:

$$R_s = (d_1x_1 + d_2x_2 + d_3x_3 \dots + d_nx_n), \quad (1)$$

where, d_1, d_2, d_3, … dn - weights of factors determined by the results of studies for which the following d_1, + d_2, + d_3, … + d_n = 1. The biocompatibility index R_s is determined expertly so that when $x_1 = x_2 = x_3 \dots = x_n = 100$ the maximum value of the index R_s=100

x_1 - factor "Biological properties", which characterizes the interaction of the material with the tissues of the host;

x_2 - factor "Physico-chemical-mechanical properties", which characterizes the properties of bone substitute;

x_3 - factor "Patient", which characterizes the state of health of the patient;

x_4 - factor "Results of scientific research", characterizing the results of studies of biological factors on the body;

x_5 - factor "Results of preclinical trials" characterizing the results of preclinical studies;

x_6 - factor "Competence of medical personnel" characterizing the experience of medical personnel;

x_7 - factor "Manufacturing technology", which characterizes the results of preclinical studies.

In turn, the factors $x_1 – x_7$ are determined by subfactors that can be calculated using the information provided by the applicant.

3.2 Factor "Biological properties" is determined by the formula:

$$R_s = d_{11}x_{11} + d_{12}x_{12} + d_{13}x_{13} + d_{14}x_{14} + \dots + d_{1\alpha}x_{1\alpha}, \quad (2)$$

where, d_{11}, d_{12}, d_{13}, d_{14}, $d_{1\alpha}$ - weighting factors, $d_{11} + d_{12} + d_{13} + d_{14} + \dots + d_{1\alpha} = 1$ i $\alpha = 5, 6, \dots, n$;

x_{11} - subfactor "osteoinduction";

x_{12} - subfactor "osteoconduction";

x_{13} - subfactor "osteointegration";

x_{14} - subfactor "solubility of ingredients";

$x_{1\alpha}$ - subfactor - a set of subfactors included in the standards for assessing the biocompatibility of hydroxyapatite-based scaffolds.

3.3 Factor "Physico-chemical-mechanical properties" is determined by the formula:

$$R_s = d_{21}x_{21} + d_{22}x_{22} + d_{23}x_{23} + d_{24}x_{24} + d_{25}x_{25}, + d_{26}x_{26}, d_{27}x_{27} \dots + d_{2\alpha}x_{2\alpha}, \quad (3)$$

where, d_{21}, d_{22}, d_{23}, d_{24}, d_{25}, d_{26}, d_{27}, $d_{2\alpha}$ - weighting factors, $d_{21} + d_{22} + d_{23} + d_{24} + d_{25}$, d_{26}, $d_{27} + \dots + d_{2\alpha} = 1$ i $\alpha = 8, 9, \dots, n$;

x_{21} - subfactor "porosity";

x_{22} - subfactor "grain size";

x_{23} - subfactor "tensile strength";

x_{24} - subfactor "modulus of elasticity";

x_{25} - subfactor "plasticity";

x_{26} - subfactor "compressive strength";

x_{27} - subfactor "stoichiometry";

$x_{2\alpha}$ - subfactor - a set of subfactors included in the standards for assessing the biocompatibility of hydroxyapatite-based scaffolds.

3.4 The "Patient" factor is determined by the formula:

$$R_s = d_{31}x_{31} + d_{32}x_{32} + \dots + d_{3\alpha}x_{3\alpha}, \quad (4)$$

where, d_{31}, d_{32}, $d_{3\alpha}$ - weighting factors, $d_{31} + d_{32} + \dots + d_{3\alpha} = 1$ i $\alpha = 3, 4, \dots, n$;

x_{31} - subfactor "features of injury";

x_{32} - subfactor "features of the organism";

$x_{3\alpha}$ - subfactor - a set of subfactors included in the standards for assessing the biocompatibility of hydroxyapatite-based scaffolds.

3.5 The factor "Results of scientific research" is determined by the formula:

$$R_s = d_{41}x_{41} + d_{42}x_{42} + d_{43}x_{43} + d_{44}x_{44} + d_{45}x_{45}, d_{46}x_{46}, d_{47}x_{47}, d_{48}x_{48}, d_{49}x_{49} \dots + d_{4\alpha}x_{4\alpha}, \quad (5)$$

where, d_{41}, d_{42}, d_{43}, d_{44}, d_{45}, d_{46}, d_{47}, d_{48}, d_{49}, $d_{4\alpha}$ - weighting factors, $d_{41} + d_{42} + d_{43} + d_{44} + d_{45}$, + $d_{46} + d_{47} + d_{48} + d_{49}$... + $d_{4\alpha} = 1$ i $\alpha = 10, 11, \dots, n$;
x_{41} - subfactor "requirements for the treatment of animals";
x_{42} - subfactor "genotoxicity, carcinogenicity and toxic effects on reproductive function";
x_{43} - subfactor "interaction with blood";
x_{44} - subfactor "cytotoxicity study: in vitro methods";
x_{45} - subfactor "study of local action after implantation";
x_{46} - subfactor "final ethylene oxide content after sterilization";
x_{47} - subfactor "quantification of potential degradation products";
x_{48} - subfactor "modeling and study of toxicokinetics of degradation and leaching products";
x_{49} - subfactor "chemical properties of materials";
$x_{4\alpha}$ - subfactor - a set of subfactors included in the standards for assessing the biocompatibility of hydroxyapatite-based scaffolds.

3.6 Factor "Preclinical test results" is determined by the formula:

$$R_s = d_{51}x_{51} + d_{52}x_{52} + \dots + d_{5\alpha}x_{5\alpha}, \quad (6)$$

where, d_{51}, d_{52}, $d_{5\alpha}$ - weighting factors, $d_{51} + d_{52} + \dots + d_{5\alpha} = 1$ i $\alpha = 3, 4, \dots, n$;
x_{51} - subfactor "ex vivo";
x_{52} - subfactor "in vivo";
$x_{5\alpha}$ - subfactor - a set of subfactors included in the standards for assessing the biocompatibility of hydroxyapatite-based scaffolds.

3.7 The factor "Competence of medical personnel" is determined by the formula:

$$R = d_{61}x_{61} + d_{62}x_{62} + d_{63}x_{63} + d_{64}x_{64} + d_{65}x_{65} + d_{66}x_{66} + d_{67}x_{67} + d_{68}x_{68}\dots + d_{6\alpha}x_{6\alpha} \quad (7)$$

where, d_{61}, d_{62}, d_{63}, d_{64}, d_{65}, d_{66}, d_{67}, d_{68}, $d6_{\alpha}$ - weighting factors, $d_{61} + d_{62} + d_{63} + d_{64} + d_{65} + d_{66} + d_{67} + d_{68}\dots + d_{6\alpha} = 1$ i $\alpha = 9, 10, \dots, n$;
x_{61} - subfactor "management personnel";
x_{62} - subfactor "middle link";
x_{63} - subfactor "awards and titles";
x_{64} - subfactor "citations";
x_{65} - subfactor "certified management system";
x_{66} - subfactor "patient reviews";
x_{67} - subfactor "violation of the sanitary regime"
x_{68} - subfactor "condition of the premises"
$x_{1\alpha}$ - subfactor - a set of subfactors included in the standards for assessing the biocompatibility of hydroxyapatite-based scaffolds.

3.8 Factor "Manufacturing technology" is determined by the formula:

$$R_s = d_{71}x_{71} + d_{72}x_{72} + d_{73}x_{73} + d_{74}x_{74} + d_{75}x_{75} + d_{76}x_{76} + \dots + d_{7\alpha}x_{7\alpha}, \quad (8)$$

where, d_{71}, d_{72}, d_{73}, d_{74}, d_{75}, d_{76}, $d_{7\alpha}$ - weighting factors, $d_{71} + d_{72} + d_{73} + d_{74} + d_{75}$, + $d_{76} + \dots + d_{7\alpha} = 1$ i $\alpha = 7, 8, \dots, n$;
x_{71} - subfactor "equipment status";
x_{72} - subfactor "pH of the environment";
x_{73} - subfactor "temperature mode";
x_{74} - subfactor "time";
x_{75} - subfactor "pressure";
x_{76} - subfactor "chemical composition of the environment";
$x_{7\alpha}$ - subfactor - a set of subfactors included in the standards for assessing the biocompatibility of hydroxyapatite-based scaffolds.

4. RESULTS

The weight of subfactors is determined by the expert method and according to the results of the research [Murcinkova 2013, Zizovic 2020, Trishch 2021, Panda 2021].

Table 1. Used for evaluation purposes the values of the coefficients of the significance of factors d_i and subfactors d_i

№	d_1	d_{11}	d_{12}	d_{13}	d_{14}					
1	0.01	0.25	0.25	0.25	0.25					
	d_2	d_{21}	d_{22}	d_{23}	d_{24}	d_{25}	d_{26}	d_{27}		
2	0.001	0.14	0.14	0.14	0.14	0.14	0.14	0.16		
	d_3	d_{31}	d_{32}							
3	0.1	0.5	0.5							
	d_4	d_{41}	d_{42}	d_{43}	d_{44}	d_{45}	d_{46}	d_{47}	d_{48}	d_{49}
4	0.8	0.111	0.111	0.111	0.111	0.111	0.111	0.111	0.111	0.112
	d_5	d_{51}	d_{52}							
5	0.044	0.05	0.05							
	d_6	d_{61}	d_{62}	d_{63}	d_{64}	d_{65}	d_{66}	d_{67}	d_{68}	
6	0.0297	0.1121	0.1121	0.1121	0.1122	0.1147	0.1122	0.2046	0.2046	
	d_7	d_{71}	d_{72}	d_{73}	d_{73}	d_{75}	d_{76}			
7	0.0148	0.1166	0.1166	0.1166	0.1166	0.1166	0.1166			

Subfactor x_{61} "Management personnel" is determined by the formula:

$$x_{61} = 0{,}5(x_{61}^1 + x_{61}^2) \quad (9)$$

x_{61}^1 – characterizes the level of personnel, determined according to table 2.

$$Z_1 = \frac{1}{N} Z_i \quad (10)$$

N – number of senior executives, $Z_i = 1$ – if the manager has a higher education; 0,5 – if secondary specialized education, 0 - if there is no special education.

Table 2. Staff level

Z_1	Up									
	to 0.1	0.1-0.2	0.2-0.3	0.3-0.4	0.4-0.5	0.5-0.6	0.6-0.7	0.7-0.8	0.8-0.9	More than 0.9
x_{61}^1	0	12	23	34	45	56	67	78	89	100

x_{61}^2 – characterizes the length of service in the field of medicine of personnel, determined according to Table 3, depending on the average length of service of managers in the industry.

$$Z_2 = \frac{1}{N} \sum_{i=1}^{N} Z_{2i} \quad (11)$$

Z_{2i} = work experience of the i-th manager in years.

Table 3. Staff work experience

Z_2	Up									
	to 0.1	1.2-2.3	2.3-3.4	3.4-4.5	4.5-5.6	5.6-6.7	6.7-7.8	7.8-8.9	8.9-10	More than 10
x_{61}^2	0	12	23	34	45	56	67	78	89	100

Subfactor x_{62} "Middle link" is determined by the formula:

$$x_{62} = 0{,}5\ (x_{62}^1 + x_{62}^2) \quad (12)$$

x_{62}^1 – determined according to table 4 depending on the average length of service of employees of the organization y.

$$Z_1 = \frac{1}{L}\Sigma y_i \quad (13)$$

L – the number of employees, y_i – work experience of the i-th employee in years.

Table 4. Average seniority of employees

y	Up									
	to 1.2	1.2-2.3	2.3-3.4	3.4-4.5	4.5-5.6	5.6-6.7	6.7-7.8	7.8-8.9	8.9-10	More than 10
x_{62}^1	0	12	23	34	45	56	67	78	89	100

x_{62}^2 – determined according to table 5, depending on the proportion of employees with higher and secondary specialized education in the field of medicine α.

$$\alpha = \frac{1}{L}\sum_{i=1}^{L}\alpha_i \quad (14)$$

where α_i = 1 – if the i-th employee has a higher specialized education; 0,5 – if higher non-profile or secondary profile education, 0 - if no education.

The subfactor x_{63} "Awards and titles" is determined by the formula:

x_{63} = 100 - the presence of employees (at least one) with a scientific degree and the title of "Honorary Medic" or analogs; 50 - the presence of one employee with a scientific degree and the title of "Honorary Medic" or analogs; 0 – in the absence of employees with an academic degree and title.

Table 5. The value of x_{62}^2, depenfing on the part of employees who have higher and secondary specialozed education

α	Up									
	to 0.1	0.1-0.2	0.2-0.3	0.3-0.4	0.4-0.5	0.5-0.6	0.6-0.7	0.7-0.8	0.8-0.9	More than 0.9
x_{62}^2	0	12	23	34	45	56	67	78	89	100

The subfactor x_{64} "Citation rate" is determined according to Table 6, depending on the presence of positive notifications about the organization in the media for the entire time of its presence on the market.

Table 6. The value of the "Citation" subfactor

β	Up									
	to 6	6-9	9-12	12-15	15-18	18-21	21-24	24-27	27-30	More than 30
x_{64}	0	12	23	34	45	56	67	78	89	100

Subfactor x_{65} "Certified Management System" is determined by the expression:

x_{65} = 100 - availability of certificates for the quality management system, ecology and labor protection, 50 - availability of a certificate only for the quality management system; 0 – in the absence of certificates for the quality management system.

Subfactor x_{66} "Patient reviews" is determined by the expression:

x_{66} = 100 – if there are more than three positive patient reviews, 50 - the presence of one to three positive reviews; 0 – in the absence of positive feedback.

Subfactor x_{67} "Violation of the sanitary regime"" is determined by the expression:

x_{67} = 100 – in the absence of violations, 50 - minor violation; 0 – gross violation

Subfactor x_{68} "Condition of the premises " is determined by the expression:

x_{68} = 100 – satisfactory condition, 50 - minor violation; 0 – gross violation.

5. CONCLUSIONS

The result of this work is a method for determining the safety of frameworks. To develop the methodology, an analysis of the factors affecting the biocompatibility of implants was carried out, weight coefficients for each factor were determined by an expert method. It has been established that the most significant factor is the results of scientific research, the least significant is the manufacturing technology.

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