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STUDY OF THE INFLUENCE OF BIOCOMPATIBLE CONSTRUCTION MATERIALS ON INDICATORS OF ORAL FLUID OF PATIENTS WITH AN ALLERGIC STATUS DURING ORTHOPEDIC TREATMENT WITH REMOVABLE PROSTHESES

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An analysis of the results of clinical studies showed that from 15 % to 43 % of people who are forced to use orthopedic constructions have “intolerance” of certain materials of crowns and dental prostheses. The obtained data prove the effect of structural materials on the parameters of the oral fluid of patients with an allergic status – a significant deterioration of the quality of the oral fluid was recorded due to a decrease in pH, an increase in galvanic currents and electrical conductivity already 1 day after the application of arc prostheses. The conducted research made it possible to improve the quality of orthopedic treatment of patients with an allergic status by using alternative biocompatible materials in the manufacture of removable structures of dental prostheses.

Key words: orthopedic treatment, intolerance, allergic status, brace prostheses, glass ceramics, oral fluid.

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ДОСЛІДЖЕННЯ ВПЛИВУ БІОСУМІСНИХ КОНСТРУКЦІЙНИХ МАТЕРІАЛІВ НА ПОКАЗНИКИ РОТОВОЇ РІДИНИ ПАЦІЄНТІВ ІЗ АЛЕРГОЛОГІЧНИМ СТАТУСОМ ПРИ ОРТОПЕДИЧНОМУ ЛІКУВАННІ ЗНІМНИМИ ПРОТЕЗАМИ

Аналіз результатів клінічних досліджень показав, що від 15 % до 43 % людей, які вимушено користуються ортопедичними конструкціями, мають «непереносимість» певних матеріалів коронок і зубних протезів. Отримані у дослідженні дані доводять вплив конструкційних матеріалів на показники ротової рідини пацієнтів із алергологічним статусом – зафіксовано достовірне погіршення якостей ротової рідини за рахунок зниження pH, збільшення гальванічних струмів і електропровідності уже через 1 день після накладення бюгельних протезів. Проведене дослідження дало змогу підвищити якість ортопедичного лікування пацієнтів із алергологічним статусом шляхом застосування альтернативних біосумісних матеріалів при виготовленні знімних конструкцій зубних протезів.

Ключові слова: ортопедичне лікування, непереносимість, алергологічний статус, бюгельні протези, склокераміка, ротова рідина.

The study is a fragment of the research project “Optimization of methods for diagnosis and treatment of basic dental diseases”, state registration No. 0119U002899.

Modern orthopedic dentistry is concerned about the increase in the number of cases of diseases caused by the patient's “individual intolerance” of the materials from which the prostheses used by him are made. Analysis of the results of clinical studies showed that from 15 % to 43 % of people who are forced to use orthopedic constructions have an "intolerance" of certain materials of crowns and dental prostheses [1, 4]. It is believed that the basis of this phenomenon lies in the corrosion processes of metals of orthopedic

constructions in the oral cavity, which lead to the appearance of galvanic currents and sensitization of the body to them with the development of allergic diseases [14].

Given that the prevalence of allergic diseases has increased dramatically over the past 50 years [1, 9], it can be expected that the frequency of intolerance to metal orthopedic materials will increase. Today, this is 20–25 % of cases in the system of non-infectious pathology of the oral cavity [3, 11, 15]. According to N.V. Timofeeva-Kiltseva and F.A. Polivoda (2016), in 91.7 % of cases, patients associate the onset of symptoms with the intolerance syndrome with the start of using a new orthopedic construction.

The use of different metals and alloys in orthopedic treatment creates conditions for the occurrence of a galvanic element and can lead to the appearance of microcurrents in the oral cavity. Saliva is the electrolyte, and the metal parts are the electrodes [3]. Galvanic currents can occur not only in the presence of prostheses made of dissimilar alloys, but even when the prostheses are made only of stainless steel, due to the complexity of its alloy and the unequal dose of constituent components in different serial releases. Therefore, a potential difference occurs between prostheses in the oral cavity and galvanic currents are formed. The strength of the current is affected by various factors: the size of the prosthesis, the presence of adhesions between its parts, the composition and structure of stainless steel, mechanical and thermal treatment of the prosthesis, the quality of its polishing and the place of placement in the mouth [5, 8, 11].

Long-term results of the impact of metal orthopedic structural materials on oral fluid in patients with gastrointestinal tract pathology are observed. Such patients were categorically advised not to use metal orthopedic structures made of stainless steel, since, along with the subjective sensations of the taste of metal and acid that arise, a significant increase in the amount of mixed oral fluid and a decrease in pH were noted [12, 14]. Examination of the oral cavity revealed slight redness of the mucous membrane of the oral cavity in the area of metal orthopedic structures, changes characteristic of lichen planus and leukoplakia appeared.

When studying the function of the salivary glands in patients with metal inclusions in the oral cavity, their influence on the quantitative and qualitative composition of saliva was revealed. This was especially true of chromium-nickel alloy and stainless steel, which, according to the authors, reduce the activity of salivary transaminases and lactate dehydrogenases [7, 10].

The purpose of the study was to establish the impact of dental materials on oral fluid parameters and to improve the quality of orthopedic treatment of patients with allergic status by using alternative biocompatible materials in the manufacture of removable structures of dental prostheses.

Materials and methods. The study was performed at the Department of Orthopedic Dentistry, University Dental Center, Kharkiv National Medical University.

Deontological aspects are resolved within the framework of the legislation in force in Ukraine, the Law of Ukraine “On Medicines”, 1996, Art. 7, 8, 12, principles of ICH GCP (2008), order of the Ministry of Health of Ukraine No. 690 of 23.09.2009 “On approval of the Rules for clinical trials and expertise of materials of clinical trials and model regulations on the ethics commission”, as amended; World Health Association Declaration of Helsinki. Patients were fully informed about the purpose and methods of the study, the potential gains and risks, and the possible discomfort with the diagnosis and treatment. All ethical requirements for maintaining the confidentiality of the information received during the study are fulfilled.

To achieve the goal, 263 patients with defects of the dentition of the upper and lower jaws and a history of allergic status, aged from 35 to 62 years old, were examined, orthopedic treatment and oral fluid research was carried out, of which 142 were men, 121 were women, who were made arc prostheses with a cobalt-chromium alloy frame. Oral fluid was studied at the following stages: I – before prosthetics; II – 1 day after applying prostheses. 1 month after prosthetics, 53 patients (35 men and 18 women aged 41 to 62 years) were singled out, who complained of a burning sensation in the oral cavity, dryness, soreness of the mucous membrane, a metallic taste, a change in taste sensitivity, and a headache. These patients were divided into two groups (group 1 – only a arc prosthesis was made, 21 patients, of which 13 men, 8 women; group 2 – with metal fixed structures and an arc prosthesis was made, 32 patients, of which 22 men and 10 women) and continued the research at the following stages: III – 1 month after prosthetics; IV – 1 week after removal of prostheses from the oral cavity; V – after the application of metal parts of prostheses with coating by glass ceramics; VI – 1 month after covering the metal parts of the arc prostheses with glass ceramics.

Oral fluid pH and electrical conductivity were determined using a laboratory professional pH/ORP/EC/Temp meter ADWA AD8000 (Hungary). Oral fluid was collected in the morning on an empty stomach in a special sterile test tube and immediately measured.

A PASCO PS-2160 galvanometer was used to determine the strength of galvanic currents in the oral cavity. Each patient underwent a series of measurements of the potential difference between the metal

parts of the brace prostheses using two electrodes that were placed on the metal elements of the structures. From a series of several indicators, we fixed the highest indicator obtained in the patient.

The database was created based on the results of randomized controlled trials using Microsoft Excel, 2007. Statistical processing of the research results was performed using Statistica v. 8.0. The test of the hypothesis about the equality of general averages in the two groups being compared was carried out using the non-parametric Mann-Whitney test for independent and Wilcoxon tests for dependent samples, percentage ratios – using the χ-square test [2].

Results of the study and their discussion. The main physical parameters of the oral fluid of patients who were found to be intolerant to metal structures are presented in table 1. The study showed that in the first two stages, the pH of the oral fluid in both groups was within the physiological norm (from 6.73±0.42 to 6.98±0.23) and no significant difference ($p>0.05$) was found between the indicators. We saw the first clear reliable ($p<0.01$) differences in pH values when comparing the results of group 2 at stages II and III – 6.73±0.42 and 5.09±0.31, respectively, after 1 month of use made prostheses. At the same stage, the results of pH values of group 1 were also compared – 6.91±0.29 and 6.02±0.3 – the differences are significant, but at the lowest level ($p<0.05$).

Determination of galvanic currents showed a significant ($p<0.001$) difference between groups 1 and already at stage 1 – 1.05±0.21 mA and 14.38±0.62 mA, respectively. 1 day after applying the arc prostheses, we recorded a significant ($p<0.001$) difference between the first and second stages in both groups: 1 group – 1.05±0.21 mA and 5.13±0.18 mA; group 2 – 14.38±0.62 mA and 18.53±1.12 mA. Repeated measurement of galvanic currents after 1 month of using arc prostheses revealed a significant ($p<0.001$) increase in indicators in group 1 to 23.4±1.92 mA and in group 2 to 38.4±2.56 mA at stage III of the study (Table 1).

Table 1

The leading physical indicators of the oral fluid of patients who were found to be intolerant to metal structures

Index / Stage	pH of oral fluid, (unit)		Galvanic currents, (mA)		Conductivity, (mS/cm)	
	group 1 n=21	group 2 n=32	group 1 n=21	group 2 n=32	group 1 n=21	group 2 n=32
stage I	6.98±0.23	6.93±0.35^{d}	1.05±0.21^{ce}	14.38±0.62^{cf}	2.15±0.03^{g}	3.09±0.02^{h}
stage II	6.91±0.29^{a}	6.73±0.42^{bd}	5.13±0.18^{e}	18.53±1.12^{f}	2.98±0.05^{g}	3.56±0.1^{h}
stage III	6.02±0.3^{a}	5.09±0.31^{ab}	23.4±1.92^{e}	38.4±2.56^{f}	4.05±0.48^{bg}	5.54±0.54^{ah}
stage IV	6.84±0.24^{a}	6.53±0.19^{a}	7.22±0.35^{c}	19.31±1.1^{c}	2.53±0.28^{b}	3.72±0.46^{a}
stage V	7.03±0.24^{d}	6.99±0.39^{d}	0.95±0.12^{i}	13.85±0.98^{k}	2.52±0.12^{l}	3.12±0.28^{l}
stage VI	7.03±0.09^{d}	7.02±0.16^{d}	0.91±0.09^{i}	13.91±0.83^{k}	2.26±0.05^{l}	2.98±0.11^{l}

Notes: stage I – before prosthetics; stage II – in 1 day after applying prostheses; stage III – 1 month after prosthetics; stage IV – 1 week after removal of prostheses from the oral cavity; stage V – after the application of metal parts of prostheses with coating by glass ceramics; stage VI – 1 month after covering the metal parts of the arc prostheses with glass ceramics. a – reliable differences in level $p<0.05$; b – reliable differences in level $p<0.01$; cefgh – reliable differences in level $p<0.001$; dikl – differences are not reliable, $p>0.05$

When determining the electrical conductivity of the oral fluid, a significant ($p<0.001$) difference was recorded between stages I and II in group 1 – 2.15±0.03 mS/cm and 2.98±0.05 mS/cm, respectively , as well as in group 2 – 3.09±0.02 mS/cm and 3.56±0.1 mS/cm. The study of this indicator at the next stage III again showed a highly reliable ($p<0.001$) increase in values to 4.05±0.48 mS/cm in group 1 and to 5.54±0.54 mS/cm in group 2.

The obtained data indicate obvious changes in the properties of oral fluid due to the presence of metal orthopedic structures in the oral cavity, in addition, a significant difference ($p<0.05$) in pH values between group 1 6.02±0.3 and group 2 5.09±0.31 by groups at stage III of the study, a significant difference at the level of $p<0.001$ at stages I, II and III between the values of galvanic currents and also a significant ($p<0.001$) difference of electrical conductivity indicators at stages I and II of both groups, which again confirms the significance of the amount of metal elements in the oral cavity and their influence on the main physical parameters of the oral fluid.

At stage IV of the study, 1 week after the removal of the arc prostheses from the oral cavity of the patients, the restoration of the pH of the oral fluid was recorded in both groups – 6.84±0.24 in group 1 and 6.53±0.19 in group 2 to the physiological norm, which is a significant ($p<0.05$) difference compared to the previous stage.

The measurement of galvanic currents at the fourth stage revealed a significant ($p<0.001$) difference with the previous results in both groups and a significant improvement in the condition of the

patients. Thus, 7.22±0.35 mA was recorded in group 1 (for comparison – at the previous stage 23.4±1.92 mA) and 19.31±1.1 mA in group 2 (a step earlier – 38.4±2.56 mA). In addition, there is an obvious reliable difference (99.9 %) between the indicators of groups 1 and 2.

The study of electrical conductivity 1 week after the removal of arc prostheses in patients also showed positive dynamics – pH and electrical conductivity indicators in both groups at this stage do not differ significantly ($p>0.05$) from the results of the first stage. In the first group, the values decreased from 4.05±0.48 mS/cm to 2.53±0.28 mS/cm (compared to stage III), which is significantly significant at the $p<0.01$ level. As for group 2, the difference in indicators is also significant, $p<0.05$, they are 5.54±0.54 mS/cm and 3.72±0.46 mS/cm between the previous and current stages, respectively. The difference between the indicators of both groups at the fourth stage is significant at the $p<0.05$ level.

At stages V and VI, the study was conducted immediately after the application and after 1 month of using arc prostheses with metal parts coated with glass ceramics, respectively. According to the pH indicator of the oral fluid, the results of both groups are within the range from 6.99±0.39 to 7.03±0.09, which corresponds to normal physiological indicators and is not significantly different ($p>0.05$) from indicators of the first stage, which indicates full adaptation to prosthetics.

A similar result was obtained when determining the galvanic currents – from 0.95±0.12 mA at stage V to 0.91±0.09 mA at stage VI in group 1 (there is no significant difference ($p>0.05$) both between the last stages and between VI and I, $p>0.05$). In group 2 – 13.85±0.98 mA and 13.91±0.83 mA, respectively, at stages V and VI, $p>0.05$, and also between VI and I – $p>0.05$.

The electrical conductivity indices also returned to the level of the I stage and lie in the range from 2.26±0.05 mS/cm to 3.12±0.28 mS/cm, which in both groups does not reliably differ between stages V and VI ($p>0.05$), nor between VI and I ($p>0.05$).

Thus, the obtained results prove that the use of glass ceramics as a covering material for the metal parts of the brace prosthesis has a positive effect and prevents the appearance of symptoms of intolerance to metal structures. This was especially clearly expressed in the patients of the first group, since clinical symptoms in them were caused only by the use of a arc prosthesis. As for the second group, due to the presence of other metal structures in the oral cavity of the patients, the values of the indicators of galvanic currents and electrical conductivity are slightly higher than in the first group, but even so, the patients did not complain about their well-being after the examination at the sixth stage.

The risks of "individual intolerance" by patients of metal prostheses are becoming an increasingly important topic today. Some studies have demonstrated the potential toxicity of dental metal alloys. For example, Kim et al. [10] noticed that the cobalt-chromium alloy exhibits cytotoxic and inflammatory effects. In particular, they found it to be cytotoxic to human gingival fibroblasts and osteoblasts. In addition, it significantly affects the production and increase of the level of inflammatory mediators. However, there is insufficient evidence to state that cobalt-chromium alloys are cytotoxic for every patient, as most in vitro studies have shown no toxicity. Rusu et al. [13] reported the absence of cytotoxicity in cobalt-chromium alloys. Forster et al. [6] found that cobalt-chromium alloys show good cell proliferation, although Gălă¸teanu et al. [7] observed a decrease in cellular toxicity with exposure time. Of course, other metal alloys can be used. For example, titanium alloy is usually considered an effective substitute for cobalt-chromium. If symptoms of intolerance are detected, the manufacture of a new prosthesis from another alloy will successfully reduce the negative effects. For this reason, dental applications of titanium alloys may be prescribed to patients who typically experience allergic reactions to exposure to the metal. However, our proposed use of alternative biocompatible materials in the manufacture of removable structures of dental prostheses proves that it is possible to eliminate the negative effects of metal on the state of the oral cavity (for example, which appeared for the first time after prosthetics) without making a new denture, but only by covering it with glass ceramics.

Conclusion

The impact of dental construction materials on the parameters of the oral fluid of patients with an allergic status was revealed – a significant ($p<0.001$) deterioration of the quality of the oral fluid was recorded due to a decrease in pH, an increase in galvanic currents and electrical conductivity already 1 day after the application of arc prostheses. Research has confirmed the possibility of symptoms of intolerance to metal orthopedic materials, even if one structure is used. The dependence of the main physical indicators of oral fluid on the number of metal elements of orthopedic structures in the oral cavity has been proven.

In general, the conducted research made it possible to improve the quality of orthopedic treatment of patients with an allergic status by using alternative biocompatible materials to manufacture removable structures of dental prostheses. Therefore, further research will be directed at using glass-ceramics to manufacture non-removable orthopedic structures to improve the quality of life of this category of patients.

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