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EVALUATION OF THE EFFECT OF ACRYLIC REMOVABLE DENTURES ON THE IMMUNOMETABOLIC PROFILE AND QUALITY OF LIFE OF PATIENTS

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The purpose of our study was to assess the removable orthopedic constructions impact, made by different methods, on the immunometabolic profile and quality of life of patients in the clinic of orthopedic dentistry. The problem of reducing residual monomers in orthopedic structures has been innovatively solved by developing the technology of their vacuuming using a system of technical means. We included in the study an indicator for assessing the quality of life of patients at all stages of orthopaedic treatment and taking into account the specifics of experiments and the use of questionnaires. Concerning statistically significant changes among patients who used removable orthopedic constructions, the worst results of quality of life before and after treatment were detected in $^{2}N_{2}$, using removable dentures which were manufactured by without vacuum method 32.4±0.47 and 92.8±0.35 points, respectively. Despite the fact that the indicators changed 1.27 times in the direction of increase, the final level of quality of life, reflected in the IV stage of orthopedic treatment (6 months after treatment), remained the worst among these patients. Prospects for further research on the use of acrylic base plastics in the treatment of removable dentures are related to the study: the impact of material on the adaptation of the prosthetic area, the impact of structural dental material on the quality of life of patients before treatment with removable orthopedic structures.

Key words: removable orthopedic constructions, treatment methods, residual monomer, immunometabolic profile, vacuum method, quality of life.

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ОЦІНКА ВПЛИВУ АКРИЛОВИХ ЗУБНИХ КОНСТРУКЦІЙ НА ІМУНОМЕТАБОЛІЧНИЙ ПРОФІЛЬ ТА ЯКІСТЬ ЖИТТЯ ПАЦІЄНТІВ

Мета дослідження полягала в оцінці впливу конструкцій знімних зубних протезів, виготовлених за різними методиками, на імунометаболічний профіль та показники якості життя пацієнтів в клініці ортопедичної стоматології. Була інноваційно вирішена проблема зменшення залишкового мономеру у ортопедичних конструкціях за рахунок розробки технології їх вакуумування з використанням системи технічних засобів. Нами був включений у дослідження показник оцінки якості життя пацієнтів на всіх етапах ортопедичного лікування та з урахуванням специфіки проведення експериментів та використанням анкети-опитувальника. Розглядаючи статистично значущі зміни серед пацієнтів, що використовували знімні ортопедичні конструкції, найгірший рівень якості життя до та після лікування виявлено в $^{2}N_{2}$, користуючись знімним протезами без вакуумування 32,4±0,47 та 92,8±0,35 балів відповідно. Незважаючи на те, що показники змінилися в 1,27 рази в бік підвищення, кінцевий рівень якості життя, відображений на IV етапі проведення ортопедичного лікування (через 6 місяців після лікування), залишився серед цих пацієнтів найгіршим. Перспективи подальших досліджень з питань застосування акрилових базисних пластмас на етапах лікування знімними конструкціями зубних протезів пов'язані з вивченням: впливу матеріалу знімних ортопедичних конструкцій на адаптацію протезного ложа, впливу конструкційного зубо-технічного матеріалу на якість життя пацієнтів до закінчення лікування знімними ортопедичними конструкціями.

Ключові слова: знімні конструкції, методика лікування, залишковий мономер, імунометаболічний профіль, вакуумний метод, якість життя.

The study is a fragment of the research project "Restoration of the quality of life of patients with major dental diseases of the organs and tissues of the maxillofacial area with the help of orthopedic treatment and rehabilitation", state registration No. 0122U000350.

During treatment of patients by removable orthopedic constructions of dentures (ROCs) is noted the importance of using acrylic plastics to adapt the prosthetic area, restore masticatory function and improve quality of life at the stages of patient's treatment [1]. In addition, it should be said that taking into account these groups of materials for ROCs could also adversely affect the condition of the oral mucosa (OM) and the process of adaptation to ROCs [4]. It is mentioned that the level of residual monomer (RM) is urgent because of the cytotoxic substance of methyl methacrylate (MMA), as is shown of different international investigations [5, 9]; and normal level of RM is determined by the corresponding ISO, the influence of MMA on the functional state of OM epithelium based on immunometabolic parameters.

We have innovatively solved the problem of reducing residual monomer in ROC by developing technology for their vacuuming, in order to improve the manufacturing technology and treatment of patients by partial and complete removable dentures [11]. One of the purposes in the context of solving our problem was to reduce the residual monomer –its extraction by placing the structure in an aqueous substance for a certain time period.

To reduce time and increase the efficiency of monomer extraction from acrylic material, ROCs were placed in an aqueous medium with a temperature of 60-85 ^{0}C under a controlled vacuum sphere. An important aspect was the creation of a vacuum as an additional factor in intensifying the process.

To ensure the vacuuming of removable dentures, a set of equipment and tools were developed, using of which involves working with a special vacuum chamber and device to create a vacuum to our certain technology [9].

To assess the effectiveness of the applied schemes and technologies of orthopedic treatment there was a very good solution to include an indicator of the quality of life (QL) at all stages of orthopedic treatment and taking into account the specifics of the experiments [7]. Forming information and results occurred with a help of unified examination and registration of epidemiological material using our questionnaire "Quality of life questionnaire of patients with complete or partial absence of teeth in the manufacture of complete and partial removable dentures" [8].

The purpose of the study was to assess the ROCs impact, of made by different methods, on the immunometabolic profile and quality of life of patients in the clinic of orthopedic dentistry.

Materials and methods. The study was conducted at the Department of Orthopedic Dentistry on the base of the University Dental Center in Kharkiv National Medical University.

Deontological aspects are resolved taking into account the legislation in Ukraine, the Law of Ukraine "About 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.

The study was performed with the minimal psychological loss for patients. Patients were fully informed about the purpose and methods of the study, the potential benefits 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. The work was reviewed and approved by the Bioethics Commission of the KNMU of the Ministry of Health of Ukraine. The total number of investigated patients was among 151 patients (76 – without vacuum method in ROC and 75 – with evacuation).

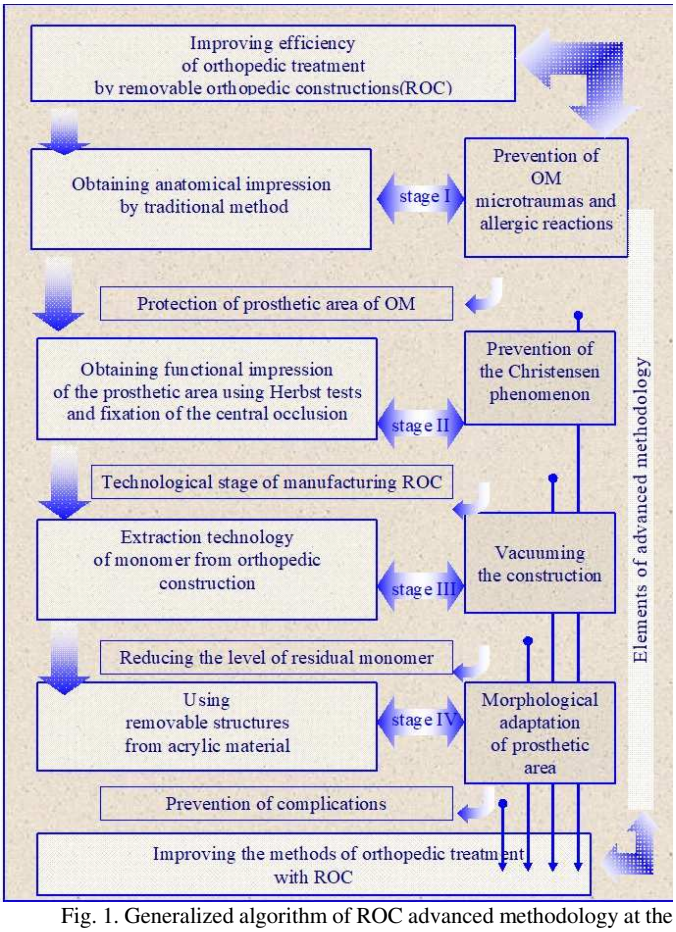

Fig. 1. Generalized algorithm of ROC advanced methodology at the stages of clinical monitoring preparation of the alveolar process by surgery and, if necessary, removal of exostoses.

Mostly, to see indicators of the manufactured method, attention was based on the content of secretory immunoglobulin (sIgA) and indicators of oxidative homeostasis such as: reduced glutathione (RG), superoxide dismutase (SOD), catalase (CAT) was performed the biological substrate was the saliva of patients, which was removed before treatment (stage I), 4–6 days after the establishment of the structure (stage II), 17–21 days after placing ROCs (stage III) and in a remote period of orthopedic treatment (stage IV) after 6 months. The content (sIgA) was determined by an immunoenzymometric analysis. Dates of RG, SOD, CAT was studied in biochemical reactions, in accordance with the recommendations and existing methods [4, 9].

Performing experiments, the following methods were used: variation statistics [3], analysis of probability distribution of traits with an assessment of the reliability of the obtained results: average indicators (Mn), their average error ($\pm$ m_n), coefficient of variation (C_v, %) were calculated, which is the ratio of the standard deviation of a random variable to its expected value, represented by the formula: $C_{v=} \sigma / \hat{k}$.

σ – is the standard deviation of a random variable;

$\hat{k}$ – is the expected (average) value of a random variable.

The degree of reliability of the difference between the average comparison groups was evaluated using a Student's criterion, according to the formulas: $t = |X1-X2| / \sqrt{m\,2 + m2}$. The difference between

the indicators of the groups was considered significant at t≥1.96, which corresponds to a high level of reliability and accuracy for clinical trials – 95.0 % and a level of reliability – p<0.05.

Results of the study and their discussion. The improvement of treatment was based on the physical, technological and clinical protection of the prosthetic area to prevent complications and increase the patient's psychological adaptability same as morphological on the prosthetic area.

An improved method of manufacturing ROC using the traditional method, the essence of which is to perform the following sequence (fig. 1):

– to obtain a complete anatomical impression, alginate impression material is used (impression material "Stomalgin-05", JSC "STOMA", Ukraine), standard impression tray and standard technology of obtaining the impression are used. Received a full anatomical impression of the jaw with the above alginate impression material;

– gypsum models for the manufacture of individual impression trays performed according to standard methods, according to the requirements for ROC, using auxiliary dental materials to reduce trauma to the periodontal tissues of the gums (according to the program of the first stage of monitoring);

– fitting of individual impression trays was performed according to the standard method of Hebst functional tests;

– functional impressions were obtained with the help of polyvenylsalkasan impression material ("Cielast K Extra" JSC "STOMA", Ukraine) [9];

– to reduce possible complications and to restore the adapted prosthetic plane in the formation of occlusal patterns was used a facial arch ("Artex Facebow", AmannGirrbach, Austria);

– amannGirrbach articulator was used to reproduce the artificial oral cavity, artificial teeth Yamahachi (Dental MFG., Co, Japan) of the appropriate size, color and type were chosen;

– plastered the wax structure in the polymerization cuvette according to the traditional methodic by the reverse method, using the proposed legation packaging material;

– replacement of wax reproduction of a ROC was performed on a water bath;

– mixing of the plastic was carried out in a glass vessel, which is appropriate for acrylic plastics, namely – in the pre-poured monomer (liquid) was added powder (polymer), mixed tightly to evenly wet the powder with liquid to obtain a homogeneous mass and doughy stage;

– in the dough-like stage, the plastic was placed in the shape of the prosthetic area (pre-covered with insulate varnish), and then placed the cuvette under pressure;

– polymerization was performed according to the manufacturer's instructions, after complete polymerization, ROC was separated from legation packaging material, the quality of polymerized plastic was evaluated, its preliminary and final machining was performed;

– in case of clinical compliance of the ROC, it was polished, then to reduce the level of RM, placed the structure in the vacuum chamber VK-01 and, after extraction in vacuum, performed the final stage - applying ROC on the prosthetic area, checking its fixation and stabilization.

After manufacturing of ROC and its position to the patient according standard method, degree of adaptation was assessed after 17-21 days (according to the program of the third stage of clinical monitoring).

We included an indicator of quality of life (QL) at all stages of orthopedic treatment and taking into account the specifics of the experiments to assess the effectiveness of the applied schemes and technologies of orthopedic treatment. The questionnaire consists of 22 questions and includes 3 information blocks that are important in the analysis of the dynamics of the QL criteria during all stages of orthopedic treatment.

The Social block, which includes 4 points, is to take revenge on the main information, linking with general position and condition of human. The Common block has 6 points, where respondent more precisely pays attention to adventages and disadvantages of proposed to him prosthetic treatment. Last, Special block, can be powered in 13 points which shows the specific input of ROCs on the immunometabolic profile of the patients.

Answers, according to the list of, were subjected to the scaling process, turning into points to simplify statistical analysis. Each question was transferred with goals from 1 to 5 as the following: excellent score – 100–110 points (for one poll); good score – 88–99 points (for one poll); satisfactory result – 66–87 points (for one poll); unsatisfactory result – 44–65 points (for one poll); poor result – 22–43 points (for one poll).

We monitored immunometabolic parameters at the stages of orthopedic treatment (see table 1). Level of sIgA before orthopedic treatment (stage I) varied from 0.682±0.036 mg/ml up 0.705±0.039 mg/ml and did not differ significantly in patient groups (p>0.05).But an increasing of sIgA was registered in the second stage – 4–7 days after the installation of the removable denture (p<0.05).

It should be noted that after the establishment of ROCs (stage III) in all groups of patients there was an increase in the level of sIgA, but the most pronounced changes took place in patients with ROCs, made by traditional methods. At the same time, in patients who were at the second stage of orthopedic treatment and were selected ROCs with the method of vacuum, sIgA changes were the lowest.

RG in saliva also changed significantly depending on the stage of orthopedic treatment. Among patients with one removable denture per one patient, the level of RG varied (respectively 23.3±1.3 c.u./min, 29.2±0.6 c.u/min and 27.9±0.4 c.u./min, which can be explained by decreasing in the toxic effects of RM from ROCs of the patient (table 1).

In groups $^1N_2$ and $^2N_2$, at the second stage of prosthetics, the level of RG was higher than in groups $^1N_3$ and $^2N_3$ 29.2±0.6 c.u./min and 26.1±0.3 c.u./min.

Table 1

Patients' immunometabolic profile depended on stages of orthopedic treatment, amount of ROCs and method of reducing the RM

Indices and stages of treatment	Clinical groups of patients					
	Total N_1=151		without vacuum method N_2=76		with vacuum method N_3=75	
	S $^1N_1$=78	T $^2N_1$=73	S $^1N_2$=39	T $^2N_2$=37	S $^1N_3$=39	T $^2N_3$=36
sIgA, mg/ml						
stage I	0.682±0.036	0.705±0.039	0.667±0.022	0.702±0.038	0.701±0.031	0.707±0.019
stage II	0.751±0.013	0.798±0.012	0.784±0.019	0.851±0.026	0.721±0.027	0.728±0.031
stage III	0.789±0.028	0.884±0.039	0.847±0.035	0.964±0.031	0.728±0.041	0.792±0.035
Glutathione restored, c.u./min						
stage I	23.4±0.7	24.3±0.8	23.3±1.3	24.1±1.2	23.9±1.4	24.2±0.8
stage II	28.5±0.5	27.9±0.4	29.2±0.6	28.7±0.8	26.1±0.3	28.2±0.7
stage III	28.7±0.4	30.3±1.3	27.5±0.9	33.5±1.3	26.8±0.6	27.4±0.5
Superoxide desmutase, c.u./min						
stage I	1435.0±28.0	1482.0±45.0	1478.0±55.0	1394.0±54.0	1473.0±46.0	1450.0±38.0
stage II	1456.0±24.0	1583.0±43.0	1472.0±43.0	1581.0±62.0	1456.0±34.0	1519.0±32.0
stage III	1556.0±31.0	1645.0±24.0	1583.0±56.0	1696.0±39.0	1555.0±34.0	1572.0±44.0
Catalase,c.u./min						
stage I	4.36±0.17	4.26±0.27	4.09±0.29	4.21±0.16	4.28±0.32	4.12±0.31
stage II	5.74±0.15	7.18±0.25	6.16±0.36	8.35±0.27	5.09±0.46	5.65±0.33
stage III	5.28±0.23	6.79±0.29	5.69±0.31	6.91±0.36	4.89±0.37	6.45±0.38

O – patients with one ROC; T– patients with two ROCs; stage I – before orthopedic treatment; stage II – 4– 7 days after setting denture; stage III – 17– 21 days after setting denture; stage IV – 6 months after setting denture.

A similar relationship was found in stage III in patients with two ROCs (with vacuum 27.4±0.5 c.u./min, without vacuum – 33.5±1.3 c.u./min, $p<0.05$). It is clear that during the second stage of orthopedic treatment by ROC with their preliminary evacuation it is possible to avoid tension at the level of functioning of the enzymatic chain of oxidative homeostasis (OH). During our investigation results of the level of SOD were analyzed. It was revealed that the value was reliably developed in the form of the manufacturing method ROC and prosthetics between them, 1478.0±55.0 c.u./min up to 1696.0±39.0 c.u./min. The results directly indicated that there was a positive injection of a well-developed method and the reduction of metabolic change of maladjustment on the level of OH and explain the changes of RM with vacuuming.

Results of data with CAT in the saliva ranged from 4.09±0.29 c.u/min to 8.35±0.27 c.u/min and removed depending on the method of manufacturing. Stage I reflects a significant difference between the comparison groups ($p>0.05$), while in stage II, if we were talking about groups $^2N_1$, there is a significant ($p<0.05$) increase in the level of CAT in patients treated in $^2N_2$ 8.35±0.27 c.u/min and 5.65±0.33 c.u/min ($p<0.05$). More pronounced differences were found in the case of ROCs with the number of two, $p<0.001$. The findings indicate a maximum increase in the level of CAT in patients of all groups after the establishment of ROC, which allows us to identify this enzyme as the most informative indicator of the response of oral mucosa to the level of RM.

Regarding an evaluation of results based on the quality of life with patients, depending on which ROCs were restored dentition defects, their number in the oral cavity of the patient, different ways to reduce the effect of residual monomer on OM and immunometabolic profile in each of the 4 stages, the quality of life levels were different, the data of which are shown in table 2.

Table 2

Evaluation of life quality indicators of patients at the stages of orthopedic treatment depending amount of ROCs and method of reducing the RM

Indexes and stages treatment	Clinical groups of patients					
	total N_1=151		without vacuum method N_2=76		with vacuum method N_3=75	
	Conclusions S $^1N_1$=78	T $^2N_1$=73	S $^1N_2$=39	T $^2N_2$=37	S $^1N_3$=39	T $^2N_3$=36
stage I (points)	48.45±0.02	34.65±0.06	47.35±0.31	32.4±0.47	49.55±0.67	36.9±0.15
stage II (points)	69.78±0.04	62.55±0.05	66.15±0.25	57.8±0.27	73.4±0.5	67.3±0.32
stage III (points)	92.29±0.03	89.9±0.03	89.78±0.45	88.2±0.63	94.8±0.17	91.6±0.2
stage IV (points)	96.85±0.06	93.7±0.04	95.5±0.7	92.8±0.35	98.2±0.14	94.6±0.2

***:** the result of each survey is displayed as the arithmetic mean of one patient from a similar clinical group: O – patients with one ROC; T – patients with two ROCs; stage I – before orthopedic treatment; stage II – 4–7 days after setting denture; stage III - 17-21 days after setting denture; stage IV – 6 months after setting denture.

Thus, considering statistically significant changes among patients who used ROC, the worst QL before and after treatment was detected in $^2N_2$, who were using removable dentures, which was manufactured without vacuum method 32.4±0.47 and 92.8±0.35 points, respectively. Despite the fact that the indicators changed into 1.27 times in the direction of increase, the final level of QL, reflected in the IV stage of orthopedic treatment (6 months after treatment), remained the worst among these patients.

The structured analysis of immunometabolic profile of our investigated patients during proposed stages of orthopedic treatment revealed that in comparison with the initial values at the II stage there was an increasing in almost all indicators characterizing the activation of the enzyme chain of oral mucosa, this suggests to reflection of the reduction of the impact of RM in patients due to the evacuation of ROC.

A straight index, which we can highlight is the growth of CAT's relative content as a view of functional rearrangement and activation of the enzymatic chain, this permits to judge that to draw a conclusion about the direct expediency of using the modified vacuum method as its effect on the indicators of the immunometabolic profile of the patient.

These changes are multidirectional and, in general, can be assessed as a satisfactory adaptation of the oral cavity to the orthopedic structure, as the growth of catalase and peroxidase reflects the physiological nature of the reaction [6, 10].

This is due to the restructuring of relationships in the system of both antioxidant and local immune defenses. Therefore, we studied the systemic relationships between the enzymatic chain of antioxidant protection and sIgA and found that in the process of adaptation of the oral cavity to the temporary orthopedic structure, all studied indicators are correlated with the level of residual monomer [2, 3]. In particular, a direct correlation with sIgA 0.923 and medium strength with the level of glutathione peroxidase 0.682, as well as an inverse relationship with the level of reduced glutathione 0.961 was found between the level of MR and superoxide desmutase 0.789 during our investigations [9]. In our study groups, without evacuation with the number of two removable orthopedic structures, the compensatory reaction is combined with an increase in sIgA levels, which indicates deeper immunometabolic changes and may determine the need for antioxidants.

According to the results of all the questions of the questionnaire on the quality of life of patients who were treated with ZOK during the study, it is possible to indicate the importance and feasibility of using the vacuum method [6, 11].

Conclusion

It can be concluded that the functional state of OM is characterized by a compensatory reaction of OH, which is manifested by the restructuring of the functional state of the enzymatic chain at the stages of ROC. Therefore, it is advisable to use this technology at the stages of orthopedic treatment with removable orthopedic structures of dentures to improve the quality of life of patients.

The studied patients of groups $^1N_3$ and $^2N_3$ had a QL level higher than in $^1N_2$ and $^2N_2$, the generalized average value of which was in stage I 49.55±0.67 and 36.9±0.15 and in stage IV 98.2±0.14 and 94.6±0.2 points, which permits to create a conclusion about the direct effect and improvement of the immunometabolic profile of patients (values of secretory immunoglobulin sIgA, reduced glutathione, superoxide dismutase and catalase) by creating a vacuum and modifying the determined technologies of vacuuming of orthopedic constructions. Based on the results obtained on all questions of our specific QL questionnaire of patients who were treated by ROC during our scientific

researching, it is possible to indicate the importance and expediency of using the vacuum method in the clinic of orthopedic dentistry.

Prospects for further research on the using of acrylic base plastics in the treatment by ROC are related with different investigations of influence the material into ROC as on the adaptation of the prosthetic area, and the impact of material on the quality of patient's life during all time of orthopedic treatment by ROC.

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