THE JUSTIFICATION FOR A RATIONAL DESIGN OF A DENTAL IMPLANT WITH A LOCKABLE MOUNT - ATTACHMENT.

Odilkhon Salimov, *Tashkent state dental institute, e-mail: Doc.salimov@mail.ru;*
Avzal Akbarov, *Tashkent state dental institute, e-mail: Avzal@rambler.ru*
Nigman Khabilov, *Tashkent state dental institute, e-mail: nigman.khabilov@tdsi.uz;*
Barno Pulatova, *Tashkent state dental institute, e-mail:wonderland8540@gmail.com*

Abstract: At present, the implants are performed in the form of one screw element, in which the intraosseous and extraosseous parts are parts of the whole screw, as well as two parts in the way of separate screw elements connected, one of which acts as the intraosseous part and the extraosseous part [4,5,9,11,12,17,27]. The team of the Department of Hospital and Faculty Orthopedic Dentistry created a domestic dental implant, made in the form of a screw contains the intracostal part in the form of a rod with a thread and a section with a smooth surface, the extraostal part for the crown in the form of a rectangular parallelepiped, which is connected to the screw with a ball head. The intracostal and extraostal parts are made as one whole.

Keywords: domestic dental implant; lock fixation; attachments; prosthetics on implants; toxicity.

Introduction: Partial loss of teeth is the largest percentage of the pathology of the dental system, which requires orthopedic treatment [2, 6,8,15]. In a number of cases, there are conditions under which it is impossible to apply traditional methods of prosthetics, a way out of such situations with the effective restoration of chewing function, aesthetic appearance and psycho-emotional completeness in patients may be the use of various options of dental implantation [1,3,7,10,13].

The majority of implant systems are performed with a fixed attachment (ball head), which becomes a serious problem in case of abrasion or deformation of the attachment in the process of operation, there are not uncommon cases of mineral deposits on the working surface of the attachment, which speeds up their wear even more. Our challenge was to develop a dental implant with a removable ball head that is easy to perform, easy to use, and to expand the range of dental implant products.

The aim of the research was the development of a new design of a domestic dental implant with a lock fixation-attachment.

Materials and methods of research: To solve the tasks, we used engineering and design, experimental, medical and biological, toxicological, biochemical, microbiological, statistical methods.

Results and discussions: Technical results of the proposed design include the possibility of replacing a worn ball head with a new one without the need to remove the implant or perform restoration work on the ball head.

The set task is solved by the fact that in a dental implant with an attachment made in the form of a screw, containing the intraosseous part in the form of a threaded rod with a smooth surface and an extraosseous part for the crown with a smooth surface of the intraosseous part, In this case, the intracostal and extraostal parts are made in one piece, the extraostal part is made in the form of a rectangular parallelepiped, which is connected to the screw with a ball head, which is an element of the attachment.

In order to improve the design of the partial detachable prosthesis with lock fixation we offer our own design of the dental implant (a patent of the Republic of Uzbekistan for utility model FAP No 01100).

The ball head of the implant and the latch form the attachment, while the latch is made in the form of a cylindrical cap, inside which there is a rubber element with a slot providing the possibility of fixation of the ball head. This design feature allows fixation of the implant without dental cement and provides convenience for the specialist and the patient when using removable dentures.

Besides, if the rubber element or ball head wears out, they can be replaced with new ones.

The implant is made in monolithic, with the intraosseous (apical) part and the extraosseous part for the crown (abutment) representing the individual parts of a solid screw fitted with a removable ball screw. This implant is used for single-stage implantation.

Combination of two functions (plug and gingival shaper) in one extra skeletal part of the mentioned implant simplifies and speeds up the treatment process, as there is no need to perform the second surgical intervention to remove the plug and shaper installation, which leads to the treatment cost reduction. Making the ball head removable allows its replacement in case of wear or damage.

Fig.1 shows the general view of the implant with a smooth surface in the form of a cylinder and with a segment-shaped end.

1 - intracostal part,

3 - threaded rod section,

4 - section in the form of a cylinder,

2 - extra skeletal part,

5 - section in the form of a rectangular parallelepiped,

6 - ball screw 7,

7 - ball head, which is an element of the attachment,

8 - end as a segment.

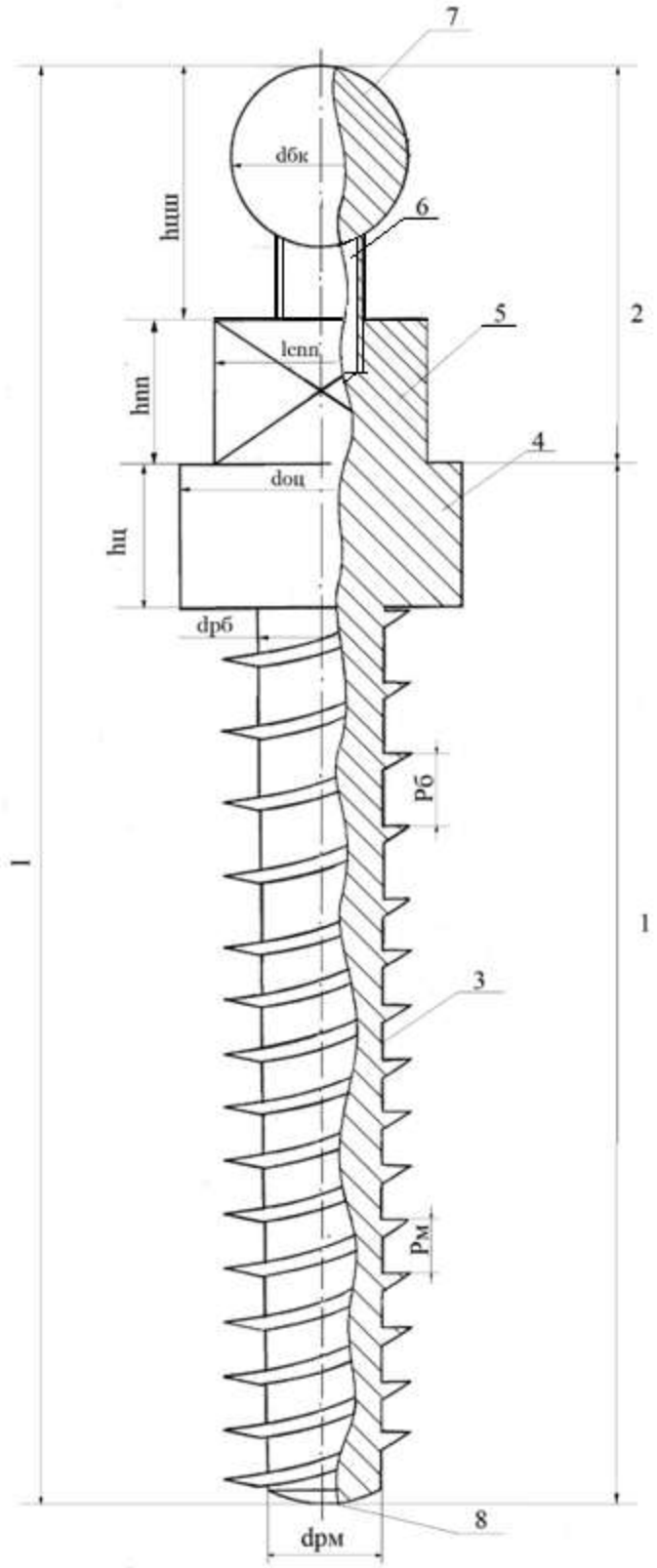
Fig. 2 - shows the type of fixture (the second element of the attachment) in the section. 10 - cylindrical cap, 11 - rubber element, 12 - slit.

The dental implant consists of the intraosseous (apical) part 1 with the stem section 3 with the thread and the section with the smooth surface and the extraosseous part 2 in the form of

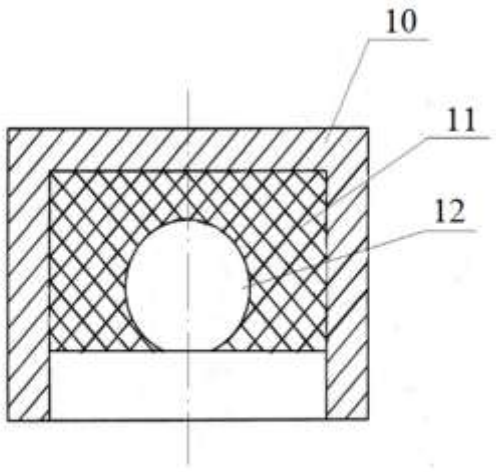
the crown head on the side of the section with the smooth surface of the intraosseous part 1. The extracortical part 2 for the crown (abutment) is designed as a rectangular parallelepiped 5, which is connected to the screw 6 with the ball head 7, which is an element of the attachment. The end of the stem section 8 with thread is either segmented or conical.

The latch (Fig. 2) is the second element of the attachment and is used for attaching a denture. The latch is made in the form of a cylindrical cap 10, inside which there is a rubber element 11 with a slit 12, which is made in a form that provides the possibility of fixation of the ball head 7.

The proposed dental implants have the level of consumer properties and can be used for fixation of both fixed and removable dentures and in various clinical situations.



Фиг. 1



Фиг. 6

Study of the irritant effect of the implant on the oral mucous membrane of the Syrian hamster. The possible irritating effect of the implant extraction on the oral mucous membrane of experimental animals was studied in accordance with ISO-10993-10 after obtaining the extraction in accordance with ISO-10993-12. Acclimatization and maintenance of animals was performed according to ISO-10993-2 [18]. Hamsters with weight of 100-120 g of both sexes were used in the experiment. In the experiment 12 animals were used, divided into 2 groups of 6 heads each. In the control group of animals 0.9 % sodium chloride solution was used. The experimental group of animals had a tooth implant extraction. The tested solutions were used by wetting cotton balls not exceeding 5 mm in diameter. The exposition of the contact of the cotton balls in the cheek-bag cavity was 5 minutes hourly during 4 hours of the experiment, i.e. the contact was exposed to the tested solutions four times.

Macroscopic comparative examination of the test animals' cheek-bag mucosa state with the control group's cheek-bag mucosa found no difference in the action of extracting fluid (0.9% sodium chloride solution) with the action of extraction obtained from a dental implant. According to the assessment of the irritation index, the obtained data should be regarded as "minimal" and similar effect indicates the absence of irritant effect of the dental implant on the oral mucosa of the hamster.

Thus, the extracts from the domestic dental implant from the VT-1.00 alloy have no toxic and irritating effect and are safe.

The results of the study of chronic toxicity. In the study of chronic toxicity, it was found that the domestic dental implant did not cause any changes in the general state and behavior of experimental animals: they remained active, eaten completely, drank as needed, responded normally to touch, pain and light irritations. No changes in pupil size, coordination of movements, lacrimaciation and salivation were observed. The appearance of hair and skin remained unchanged during the experiment.

Hematological parameters of peripheral blood were studied in animals before the operation, 1 and 3 months after the operation.

As we can see from Table 1. and Fig.1, the number of erythrocytes remained unchanged. In the control group the index was 5.5±0.5 x 1012l, in the main group of animals before the operation it was 5.8±1.2 x 1012/l, in 1 month 5.9±0.8 x 1012/l and in 3 months 5.7±0.6 x 1012l, respectively. In the control group the number of leukocytes made up 7.8±2.9 x 109l, in the main group of animals before the implant installation the number of leukocytes made up 8.8±1.9 x 109l, in 1 month after the domestic titanium dental implant installation - 8.8±2.1 x 109l, in 3 months - 8.7±2.0 x 109l. No changes were observed in animals in the experiment on the part of SEA.

Table 1: Hematological parameters of peripheral blood in experimental animals at installation of a domestic dental implant.

Indicators	Control group	Observation period		
		Before surgery	1 month	3 months
Erythrocytes x $10^{12/л}$	5,5±0,5	5,8±1,2	5,9±0,8	5,7±0,6
Leukocytes x $10^{9/л}$	7,8±2,9	8,8±1,9	8,8±2,1	8,7±2,0
ESR	2	2	3	2,5

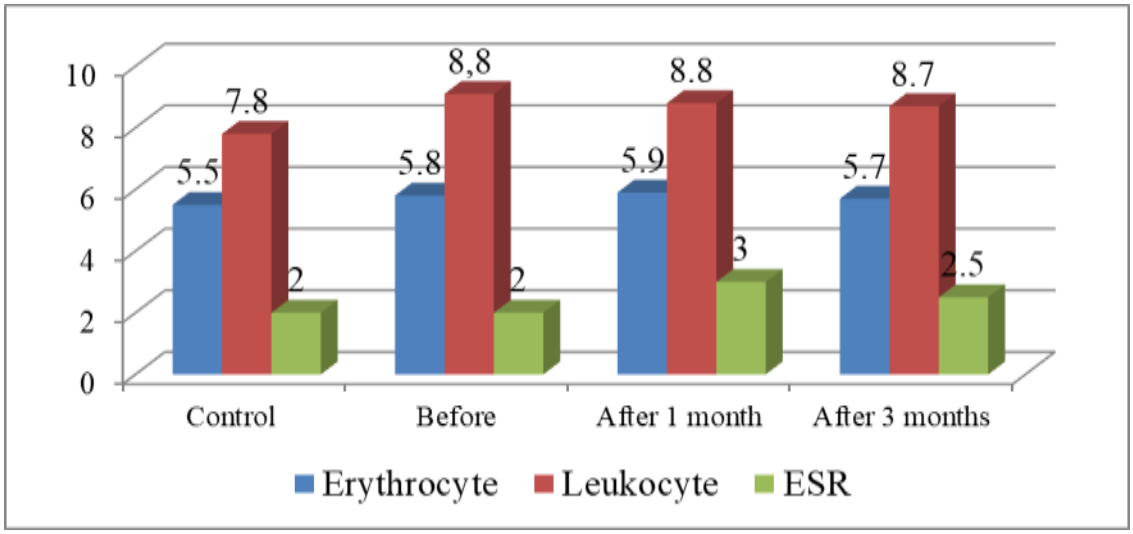


Fig.1. Blood dynamics indices in experimental animals with the domestic dental implant installation

The study of **blood biochemical indices** of experimental animals before the operation and in different terms after installation of domestic titanium dental implant showed (Fig.4.2.) that ALT, AST and bilirubin indices do not change reliably. ALT activity was 33.3 mmol/l before

surgery, 30.7 mmol/l 1 month after surgery and 31.6 mmol/l 3 months after surgery, respectively. AST was 17.6 mmol/l before surgery, 1 month after surgery 15.3 mmol/l and 3 months after surgery 16.2 mmol/l, respectively. Total bilirubin before the operation was 8.71 mmol/l, 1 month after the operation 8.35 mmol/l and 3 months later 8.5 mmol/l, respectively.

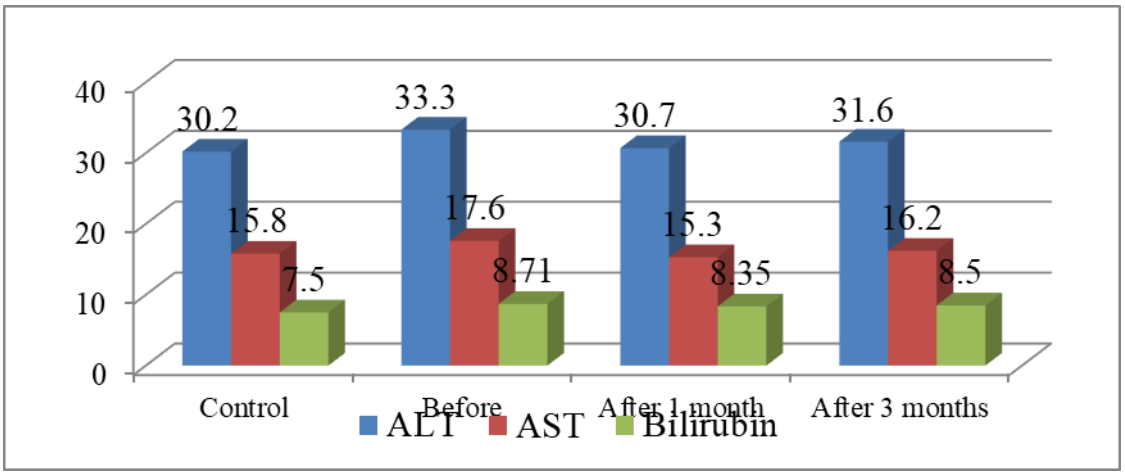


Fig.2. Biochemical parameters of the blood dynamics in experimental animals at the domestic dental implant installation

In 3 months after the operation all parameters are similar to those of the control group. The results of experimental studies show that the implantation of domestic dental implant from titanium in experimental animals is not accompanied by changes in red and white blood and biochemical indicators.

The immunological researches of blood in the main group of animals (Tab.2.) on the 7th day showed statistically reliable increase of IgA 1,37±0,32 g/l, (0,66±0,29 g/l in the control group animals). Starting from the 14th day and in the following terms of the study (on the 28th day, 3 months after the operation) no reliable changes in blood immunoglobulins were observed, except for IgE (on the 14th, 28th day and 3 months after the operation) (Fig.3).

Besides, the blood parameters of the osteoporosis program in experimental animals with dental implant placement were studied.

As can be seen from Fig.3.Osteocalcin increases after 3 months with pre-treatment rates of 57%, TP1NP remains unchanged, the amount of calcium in the blood increases by 9%, phosphorus decreases by 22% and vitamin D3 does not change.

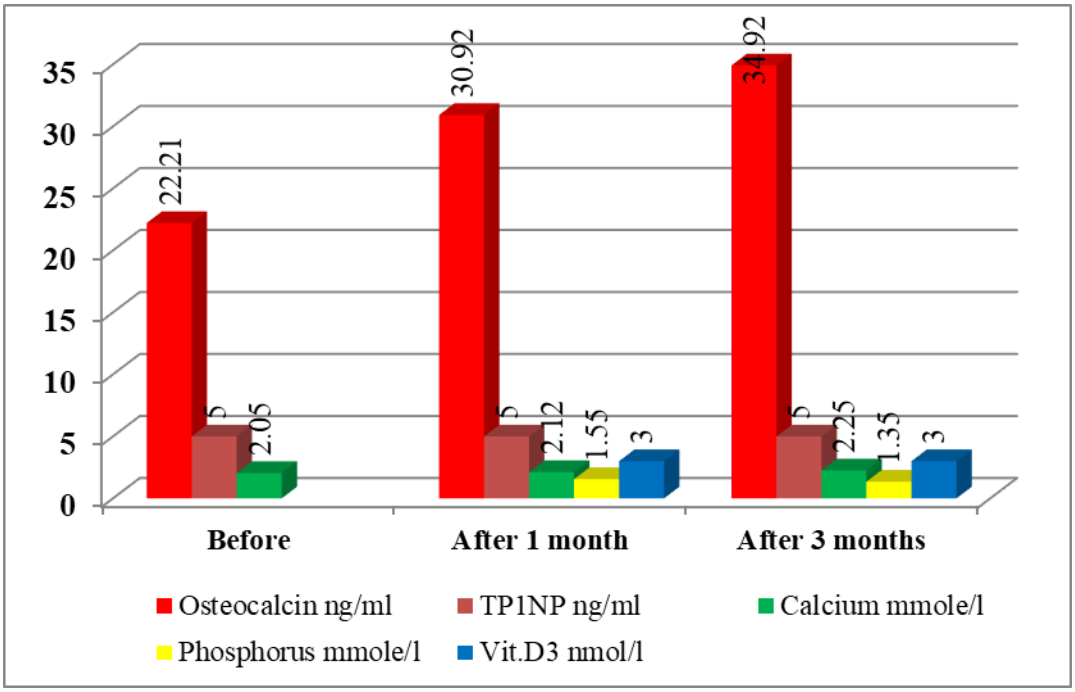

35
30
25
20
15
10
5
0
22.21
5
2.05
30.92
5
2.12
1.55
3
34.92
5
2.25
1.35
3
Before
After 1 month
After 3 months
Osteocalcin ng/ml
TP1NP ng/ml
Calcium mmole/l
Phosphorus mmole/l
Vit.D3 nmol/l

Table 2.:Immunological parameters of blood in experimental animals in dynamics at installation domestic dental implant

Показатели	Контрольная группа	После операции			
		на 7-е сутки	на 14-е сутки	на 28- е сутки	через 3 месяца
Ig A, г/л	0,66 ± 0,29	1,37±0,32*	0,62±0,47	0,4±0,31	0,65±0,05
Ig M, г/л	0,33±0.06	1,36±0,45*	0,47±0.02	0,4+0,14	0,41±0,16
Ig G, г/л	4,05±1,83	5,74±0,33	3,35±2,15	3,1±1,8	5,32±0,42
Ig E, г/л	24,6±5Д	7,17±0,12*	11,5±4,8*	34,3±12,8*	16,5±7,5*

Note: * - the difference is valid in comparison with the control group at P<0.05.

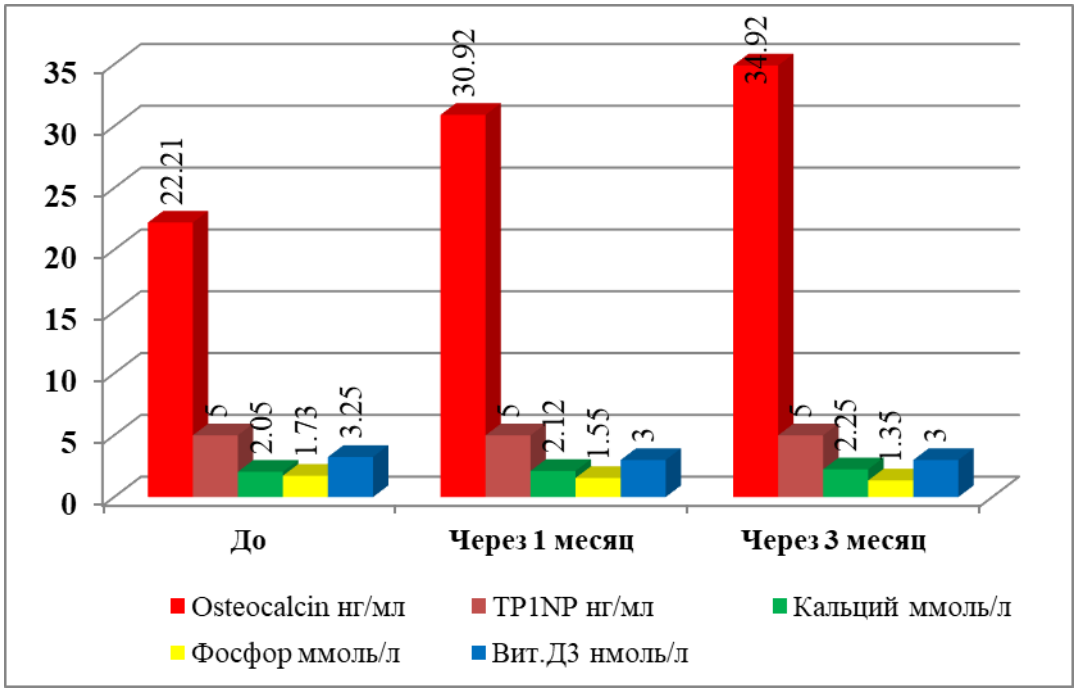


Fig. 3. Blood indices according to the program for osteoporosis in experimental animals with domestic dental implant installation

Thus, after the installation of the dental implant in experimental animals within 30 days after the operation, some deviations of the studied parameters of peripheral blood from the original were observed. In 3 months after the operation all parameters are similar to those of the control group of animals.

Immunological parameters of blood in experimental animals in dynamics at installation of a domestic dental implant

Indicators	Control Group	After surgery			
		on the 7th day	on the 14th day	on the 28th day	через 3 месяца
Ig A, g/l	0,66 ± 0,29	1,37±0,32*	0,62±0,47	0,4±0,31	0,65±0,05
Ig M, g/l	0,33±0.06	1,36±0,45*	0,47±0.02	0,4+0,14	0,41±0,16
Ig G, g/l	4,05±1,83	5,74±0,33	3,35±2,15	3,1±1,8	5,32±0,42
Ig E, g/l	24,6±5Д	7,17±0,12*	11,5±4,8*	34,3±12,8*	16,5±7,5*

Note: * - the difference is valid in comparison with the control group at P<0.05.

The results of experimental studies show that the implantation of domestic dental implant from titanium in experimental animals is not accompanied by changes in red and white blood, biochemical indicators.

The results of studying the tightness of the domestic implant construction under the influence of aggressive media in vitro. The components of the dental implant and accessories for its assembly were sterilized by autoclaving at the temperature of 1500C within 30 minutes. The implant parts were assembled in a sterile box. The implant as assembled was placed in 3 tubes with the nutrient medium: 1 tube with St.aureus, 2 tubes with Str.pyogenes, 3 tubes with St.aureus and Str.pyogenes microbial suspension. After 3-day incubation in the thermostat at 37^0 C, the broth implant was placed for 45 minutes in 6% hydrogen peroxide solution for decontamination, then was washed with physiological solution. After washing the implant was disassembled into sterile broth and incubated in the thermostat at 370 C for 48 hours. At the end of incubation period sowing from sugar broth on blood agar was carried out. The cups were incubated at 370C for 72 hours. At the end of incubation period microorganism growth was recorded. The components of the domestic dental implant construction made of titanium after contamination with staphylococcus, streptococcus and mixed culture of these bacteria turned out to be sterile that indicates the implant construction tightness.

Consequently, the absence of growth of test strains of St.aureus, Str.pyogenes and suspension of these microorganisms testifies to the tightness of the structure of the domestic titanium dental implant.

Table 3.: Test results of the tightness of the domestic implant construction in case of the exogenous infection in vitro

Research Series	Exposure factors (exposure time 48 hours)				
	St.aureus	Str.pyogenes	Suspended germs	6% hydrogen peroxide	Brothy culture
№1	 No height.				 No height.

After implantation of the developed dental implant by an experimental animal, the operating wound healed with primary tension, without signs of inflammation. The animals remained active, food was eaten completely, drank as needed, reacted normally to touch, pain and light irritations. No changes in pupil size, coordination of movements, lacrimation or salivation were observed. In peripheral blood there was a slight increase in lymphocytes during the first month after surgery. No changes in the number of immunoglobulins A, M, G were observed in the postoperative period, except for IgE. The above mentioned changes in peripheral blood in the postoperative period are the natural reaction of the organism to the operational trauma.

The study of blood biochemical indices of experimental animals before the operation and in terms of 1, 3 months after the implant placement showed that ALT, AST and bilirubin indices don't change significantly that testifies to the absence of toxic effect.

The research on the tightness of the domestic implant structure in case of exogenous infection in vitro by St.aureus, Str.pyogenes test strains and weight of these microbes during 3 days incubation in the thermostat at 37^0 C didn't reveal the growth of test strains. The absence of microbial growth testifies to the tightness of the domestic implant design.

Conclusions:

Thus, the data obtained allow us to conclude:

1.The developed dental implant implanted in the jaw bones of experimental animals did not cause morphological changes in their bodies, which allows recommending it for clinical studies;

2.Experimentally proved medical and biological safety of the domestic dental implant application allows recommending this development for mass production;

3.The proposed domestic innovative technology reduces expenses 2-2.5 times per 1 implant that allows to state high economic efficiency of the final research product;

4.The conducted researches allow recommending introduction of the developed domestic dental implant in practice of surgical and orthopedic dentistry.

References

[1] Abdullayev, S.Yu.; Aripova, M.H. Use of the new biologically compatible materials at replacement of the jaw defects (in Russian) // Dentistry. M., - 1999.- №3.- P.37-38.
[2] Alyoshina O.A. Clinical and expert estimation of errors and complications in orthopedic dentistry at prosthetics by fixed dentures. / Abstract of Cand. of Medical Sciences. - Nizhni Novgorod. - 2011, 157 p.
[3] Bulanova, I.M.; Volozhin, A.I.; Malginov, N.N. Microfocus roentgenography and X-ray computer tomography at estimation of a reparative regeneration of a bone tissue (in Russian) // Innovative approaches in radial diagnostics: Materials of scientific - practical conf. - 18-19 August 2008. - p. 25.
[4] Valiyev, R.Z. Creation of the nanostructured metals and alloys with the unique properties using the intensive plastic deformations (in Russian) // Russian Nanotechnology. pp.208-216.
[5] Iordanishvili, A.; Abramov, D. Dental structural materials: pathophysiological substantiation for optimal use at dental implantation and prosthetics (in Russian) // Russian nanotechnology. - 3733 c.
[6] Kazachkova, M.A.; Turkbaev, A.; Zhivushkin, A. A. Research of the properties of the cobalt and nickel alloys used in dentistry (in Russian) // Dental technician .-2005. Pp. 18−20.
[7] Kulakov, A.A. Dental surgery and maxillofacial surgery. National Handbooks.- GOTAR-Media.- 2010.- 928 p.

[8] Kulakov A.A., Grigoryan A.S., Filonov M.R. Influence of different in chemical composition coatings of intraossal titanium implants on their integration into bone // Russian Bulletin of Dental Implantology. 2007.- № 2.- P.132-138.
[9] Lomakin M. V., Filatova A. S., Soloshchansky I. I. Directed bone regeneration in the reconstruction of the alveolar bone volume in the field of dental implantation. // Journsl: Russian Dentistry. - 2011.-4(5).- pp. 15-18.
[10] Malginov N.N., Volozhin A.I., Lebedenko I.Yu., Vasiliev A.Yu., Chernyaev S.E., Kiseleva E.V., Serova N.S., Petrovskaya V.V., Perova N.G. Experimental substantiation of the application of mesenchymal stem cells and advanced titanium implants to accelerate osteo-integration // Russian Dental Journal. - – 2011. - № 2. - pp. 13-15.
[11] Mirgazizov M.Z., Mslikyan M. Features of Tissue Integration of Porous and Non-Porous Implants Based on Titanium and its Alloys with Form Memory // Problems of Dentistry and Neurostomatology. -1999.- №2.- pp.41-43
[12] Mitroshin, A.N. Comparative estimation of the osseointegration of the screw conical and cylindrical titanium implants processed by the micro-arc oxidation method (in Russian) // Fundamental investigations. - − 2011. - − №9. - pp. 447-451.
[13] Moseiko A.A. Application of zirconium in dental implantology // Dental Implantology Newsletter. -2007.- ¹4.- P.98-100.
[14] Muslov S.A., Shumilina O.A. Medical nitinol: friend or foe? Again about biocompatibility of titanium nickelide // Fundamental researches. - – 2007. - – № 10. - pp. 87-89.
[15] Nikolskiy, V.D.; Zhuruli, G.N. Tsalikov, N.A. Prosthetic design choice at prosthetics on the dental implants at full adentia (in Russian) // Eurasian Union of Scientists. Medical Sciences. - 2015. - № 7 (16). - P.78-80.
[16] Paraskevich, V.L. Basic structures of the dental prostheses on implants // Dentist. 2002. - № 5. - pp. 8-12.
[17] Paraskevich, V.L. Dental implantology. Basics of theory and practice: Scientific and practical manual. Minsk. 2002. - pp. 240-275.
[18] Razdorsky V.V. Evaluation of biocompatibility of implants made of titanium nickelide in experiment on animals // Dentistry. -2008. -№6.- pp.9-13.
[19] Devil, S.A.; Stoikov, S.V. Overview of the properties of the materials used in manufacture of the dental implants (in Russian) // Ukrainian Dental Almanac. - 2013.- № 4.- C. 101-104.
[20] Barone A., Toti P., Marconcini S., Derchi G., Saverio M., Covani U.Esthetic outcome of implants placed in fresh extraction sockets by clinicians with or without experience: a medium-term retrospective evaluation //The International Journal of Oral & Maxillofacial Implants.-2016.-vol. 31.-№ 6.-P. 1397–1406.
[21] Balevi B. Do preoperative antibiotics prevent dental implant complication // Evid Based Dent 9 (4). - 2008. - P. 51-52.
[22] Cicciu M, Bramanti E, Matacena G, Guglielmino E, Risitano G. FEM evaluation of cemented-retained versus screw-retained dental implant single-tooth crown prosthesis. IntJClinExpMed 2014;7:817-25.
[23] Chrcanovic B. R., Albrektsson T., Wennerberg A. Dental implants inserted in fresh extraction sockets versus healed sites: a systematic review and meta-analysis //J. of Dentistry.- 2015.- vol. 43.-№ 1.P. 16–41.

[24] Chrcanovic B. R., Albrektsson T., Wennerberg A. Immediately loaded non-submerged versus delayed loaded submerged dental implants: a meta-analysis // International Journal of Oral and Maxillofacial Surgery.-2015.-vol. 44.- № 4.-P.493–506,

[25] Han C.-H., Mangano F., Mortellaro C., Park K.-B. Immediate loading of tapered implants placed in postextraction sockets and healed sites //J. of Craniofacial Surgery.-2016.- vol. 27.-№5.-P.1220–1227.

[26] Hua Xi Kou Qiang Yi Xue Za Zhi. 2017 Feb 1;35(1):18-28. doi: 10.7518/hxkq.2017.01.003. Current dental implant design and its clinical importance

[27] Mangano F. G., Mastrangelo P., Luongo F., Blay A., Tunchel S., Mangano C. Aesthetic outcome of immediately restored single implants placed in extraction sockets and healed sites of the anterior maxilla: a retrospective study on 103 patients with 3 years of follow-up // Clinical Oral Implants Research.- 2016.

[28] Ranjan Gupta; Kurt K. Weber. StatPearls Publishing; . 2017 Dec 18. Dental, Implants

[29] Smeets R., Stadlinger B., Schwarz F. et al. Impact of dental implant surface modifications on osseointegration // BioMed Research International.- 2016.- vol. Article ID 6285620.- 16 p.

[30] Shemtov-Yona K, Rittel D. An overview of the mechanical integrity of dental implants. Biomed Res Int. 2015; 2015: 73-84. doi: 10.1155/2015/547384.

[31] World Health Organization.Adentia: fact sheet no.18. World Health Organization website. 2016. http://www.who.int/mediacentre/factsheets/fs42/eng, accessed March 12.