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ЕЖЕМЕСЯЧНЫЙ НАУЧНЫЙ ЖУРНАЛ

Медицинские новости Грузии

საქართველოს სამედიცინო სიახლენი

GEORGIAN MEDICAL NEWS

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GMN: Georgian Medical News is peer-reviewed, published monthly journal committed to promoting the science and art of medicine and the betterment of public health, published by the GMN Editorial Board since 1994. GMN carries original scientific articles on medicine, biology and pharmacy, which are of experimental, theoretical and practical character; publishes original research, reviews, commentaries, editorials, essays, medical news, and correspondence in English and Russian.

GMN is indexed in MEDLINE, SCOPUS, PubMed and VINITI Russian Academy of Sciences. The full text content is available through EBSCO databases.

GMN: Медицинские новости Грузии - ежемесячный рецензируемый научный журнал, издаётся Редакционной коллегией с 1994 года на русском и английском языках в целях поддержки медицинской науки и улучшения здравоохранения. В журнале публикуются оригинальные научные статьи в области медицины, биологии и фармации, статьи обзорного характера, научные сообщения, новости медицины и здравоохранения. Журнал индексируется в MEDLINE, отражён в базе данных SCOPUS, PubMed и ВИНИТИ РАН. Полнотекстовые статьи журнала доступны через БД EBSCO.

GMN: Georgian Medical News – საქართველოს სამედიცინო სიახლენი – არის ყოველთვიური სამეცნიერო სამედიცინო რეცენზირებადი ჟურნალი, გამოიცემა 1994 წლიდან, წარმოადგენს სარედაქციო კოლეგიისა და აშშ-ის მეცნიერების, განათლების, ინდუსტრიის, ხელოვნებისა და ბუნებისმეტყველების საერთაშორისო აკადემიის ერთობლივ გამოცემას. GMN-ში რუსულ და ინგლისურ ენებზე ქვეყნდება ექსპერიმენტული, თეორიული და პრაქტიკული ხასიათის ორიგინალური სამეცნიერო სტატიები მედიცინის, ბიოლოგიისა და ფარმაციის სფეროში, მიმოხილვითი ხასიათის სტატიები.

ჟურნალი ინდექსირებულია MEDLINE-ის საერთაშორისო სისტემაში, ასახულია SCOPUS-ის, PubMed-ის და ВИНИТИ РАН-ის მონაცემთა ბაზებში. სტატიების სრული ტექსტი ხელმისაწვდომია EBSCO-ს მონაცემთა ბაზებიდან.

WEBSITE

www.geomednews.com

К СВЕДЕНИЮ АВТОРОВ!

При направлении статьи в редакцию необходимо соблюдать следующие правила:

1. Статья должна быть представлена в двух экземплярах, на русском или английском языках, напечатанная через **полтора интервала на одной стороне стандартного листа с шириной левого поля в три сантиметра**. Используемый компьютерный шрифт для текста на русском и английском языках - **Times New Roman** (**Кириллица**), для текста на грузинском языке следует использовать **AcadNusx.** Размер шрифта - **12**. К рукописи, напечатанной на компьютере, должен быть приложен CD со статьей.

2. Размер статьи должен быть не менее десяти и не более двадцати страниц машинописи, включая указатель литературы и резюме на английском, русском и грузинском языках.

3. В статье должны быть освещены актуальность данного материала, методы и результаты исследования и их обсуждение.

При представлении в печать научных экспериментальных работ авторы должны указывать вид и количество экспериментальных животных, применявшиеся методы обезболивания и усыпления (в ходе острых опытов).

4. К статье должны быть приложены краткое (на полстраницы) резюме на английском, русском и грузинском языках (включающее следующие разделы: цель исследования, материал и методы, результаты и заключение) и список ключевых слов (key words).

5. Таблицы необходимо представлять в печатной форме. Фотокопии не принимаются. **Все цифровые, итоговые и процентные данные в таблицах должны соответствовать таковым в тексте статьи**. Таблицы и графики должны быть озаглавлены.

6. Фотографии должны быть контрастными, фотокопии с рентгенограмм - в позитивном изображении. Рисунки, чертежи и диаграммы следует озаглавить, пронумеровать и вставить в соответствующее место текста **в tiff формате**.

В подписях к микрофотографиям следует указывать степень увеличения через окуляр или объектив и метод окраски или импрегнации срезов.

7. Фамилии отечественных авторов приводятся в оригинальной транскрипции.

8. При оформлении и направлении статей в журнал МНГ просим авторов соблюдать правила, изложенные в «Единых требованиях к рукописям, представляемым в биомедицинские журналы», принятых Международным комитетом редакторов медицинских журналов - http://www.spinesurgery.ru/files/publish.pdf и http://www.nlm.nih.gov/bsd/uniform_requirements.html
В конце каждой оригинальной статьи приводится библиографический список. В список литературы включаются все материалы, на которые имеются ссылки в тексте. Список составляется в алфавитном порядке и нумеруется. Литературный источник приводится на языке оригинала. В списке литературы сначала приводятся работы, написанные знаками грузинского алфавита, затем кириллицей и латиницей. Ссылки на цитируемые работы в тексте статьи даются в квадратных скобках в виде номера, соответствующего номеру данной работы в списке литературы. Большинство цитированных источников должны быть за последние 5-7 лет.

9. Для получения права на публикацию статья должна иметь от руководителя работы или учреждения визу и сопроводительное отношение, написанные или напечатанные на бланке и заверенные подписью и печатью.

10. В конце статьи должны быть подписи всех авторов, полностью приведены их фамилии, имена и отчества, указаны служебный и домашний номера телефонов и адреса или иные координаты. Количество авторов (соавторов) не должно превышать пяти человек.

11. Редакция оставляет за собой право сокращать и исправлять статьи. Корректура авторам не высылается, вся работа и сверка проводится по авторскому оригиналу.

12. Недопустимо направление в редакцию работ, представленных к печати в иных издательствах или опубликованных в других изданиях.

При нарушении указанных правил статьи не рассматриваются.

REQUIREMENTS

Please note, materials submitted to the Editorial Office Staff are supposed to meet the following requirements:

1. Articles must be provided with a double copy, in English or Russian languages and typed or compu-ter-printed on a single side of standard typing paper, with the left margin of **3** centimeters width, and **1.5** spacing between the lines, typeface - **Times New Roman** (**Cyrillic**), print size - **12** (referring to Georgian and Russian materials). With computer-printed texts please enclose a CD carrying the same file titled with Latin symbols.

2. Size of the article, including index and resume in English, Russian and Georgian languages must be at least 10 pages and not exceed the limit of 20 pages of typed or computer-printed text.

3. Submitted material must include a coverage of a topical subject, research methods, results, and review.

Authors of the scientific-research works must indicate the number of experimental biological species drawn in, list the employed methods of anesthetization and soporific means used during acute tests.

4. Articles must have a short (half page) abstract in English, Russian and Georgian (including the following sections: aim of study, material and methods, results and conclusions) and a list of key words.

5. Tables must be presented in an original typed or computer-printed form, instead of a photocopied version. **Numbers, totals, percentile data on the tables must coincide with those in the texts of the articles.** Tables and graphs must be headed.

6. Photographs are required to be contrasted and must be submitted with doubles. Please number each photograph with a pencil on its back, indicate author's name, title of the article (short version), and mark out its top and bottom parts. Drawings must be accurate, drafts and diagrams drawn in Indian ink (or black ink). Photocopies of the X-ray photographs must be presented in a positive image in **tiff format**.

Accurately numbered subtitles for each illustration must be listed on a separate sheet of paper. In the subtitles for the microphotographs please indicate the ocular and objective lens magnification power, method of coloring or impregnation of the microscopic sections (preparations).

7. Please indicate last names, first and middle initials of the native authors, present names and initials of the foreign authors in the transcription of the original language, enclose in parenthesis corresponding number under which the author is listed in the reference materials.

8. Please follow guidance offered to authors by The International Committee of Medical Journal Editors guidance in its Uniform Requirements for Manuscripts Submitted to Biomedical Journals publication available online at: http://www.nlm.nih.gov/bsd/uniform_requirements.html
http://www.icmje.org/urm_full.pdf
In GMN style for each work cited in the text, a bibliographic reference is given, and this is located at the end of the article under the title "References". All references cited in the text must be listed. The list of references should be arranged alphabetically and then numbered. References are numbered in the text [numbers in square brackets] and in the reference list and numbers are repeated throughout the text as needed. The bibliographic description is given in the language of publication (citations in Georgian script are followed by Cyrillic and Latin).

9. To obtain the rights of publication articles must be accompanied by a visa from the project instructor or the establishment, where the work has been performed, and a reference letter, both written or typed on a special signed form, certified by a stamp or a seal.

10. Articles must be signed by all of the authors at the end, and they must be provided with a list of full names, office and home phone numbers and addresses or other non-office locations where the authors could be reached. The number of the authors (co-authors) must not exceed the limit of 5 people.

11. Editorial Staff reserves the rights to cut down in size and correct the articles. Proof-sheets are not sent out to the authors. The entire editorial and collation work is performed according to the author's original text.

12. Sending in the works that have already been assigned to the press by other Editorial Staffs or have been printed by other publishers is not permissible.

Articles that Fail to Meet the Aforementioned Requirements are not Assigned to be Reviewed.

ავტორთა საყურადღებოდ!

რედაქციაში სტატიის წარმოდგენისას საჭიროა დავიცვათ შემდეგი წესები:

1. სტატია უნდა წარმოადგინოთ 2 ცალად, რუსულ ან ინგლისურ ენებზე,დაბეჭდილი სტანდარტული ფურცლის 1 გვერდზე, 3 სმ სიგანის მარცხენა ველისა და სტრიქონებს შორის 1,5 ინტერვალის დაცვით. გამოყენებული კომპიუტერული შრიფტი რუსულ და ინგლისურენოვან ტექსტებში - **Times New Roman (Кириллица)**, ხოლო ქართულენოვან ტექსტში საჭიროა გამოვიყენოთ **AcadNusx.** შრიფტის ზომა – 12. სტატიას თან უნდა ახლდეს CD სტატიით.

2. სტატიის მოცულობა არ უნდა შეადგენდეს 10 გვერდზე ნაკლებს და 20 გვერდზე მეტს ლიტერატურის სიის და რეზიუმეების (ინგლისურ, რუსულ და ქართულ ენებზე) ჩათვლით.

3. სტატიაში საჭიროა გაშუქდეს: საკითხის აქტუალობა; კვლევის მიზანი; საკვლევი მასალა და გამოყენებული მეთოდები; მიღებული შედეგები და მათი განსჯა. ექსპერიმენტული ხასიათის სტატიების წარმოდგენისას ავტორებმა უნდა მიუთითონ საექსპერიმენტო ცხოველების სახეობა და რაოდენობა; გაუტკივარებისა და დაძინების მეთოდები (მწვავე ცდების პირობებში).

4. სტატიას თან უნდა ახლდეს რეზიუმე ინგლისურ, რუსულ და ქართულ ენებზე არანაკლებ ნახევარი გვერდის მოცულობისა (სათაურის, ავტორების, დაწესებულების მითითებით და უნდა შეიცავდეს შემდეგ განყოფილებებს: მიზანი, მასალა და მეთოდები, შედეგები და დასკვნები; ტექსტუალური ნაწილი არ უნდა იყოს 15 სტრიქონზე ნაკლები) და საკვანძო სიტყვების ჩამონათვალი (key words).

5. ცხრილები საჭიროა წარმოადგინოთ ნაბეჭდი სახით. ყველა ციფრული, შემაჯამებელი და პროცენტული მონაცემები უნდა შეესაბამებოდეს ტექსტში მოყვანილს.

6. ფოტოსურათები უნდა იყოს კონტრასტული; სურათები, ნახაზები, დიაგრამები - დასათაურებული, დანომრილი და სათანადო ადგილას ჩასმული. რენტგენოგრამების ფოტოასლები წარმოადგინეთ პოზიტიური გამოსახულებით **tiff** ფორმატში. მიკროფოტოსურათების წარწერებში საჭიროა მიუთითოთ ოკულარის ან ობიექტივის საშუალებით გადიდების ხარისხი, ანათალების შეღებვის ან იმპრეგნაციის მეთოდი და აღნიშნოთ სურათის ზედა და ქვედა ნაწილები.

7. სამამულო ავტორების გვარები სტატიაში აღინიშნება ინიციალების თანდართვით, უცხოურისა – უცხოური ტრანსკრიპციით.

8. სტატიას თან უნდა ახლდეს ავტორის მიერ გამოყენებული სამამულო და უცხოური შრომების ბიბლიოგრაფიული სია (ბოლო 5-8 წლის სიღრმით). ანბანური წყობით წარმოდგენილ ბიბლიოგრაფიულ სიაში მიუთითეთ ჯერ სამამულო, შემდეგ უცხოელი ავტორები (გვარი, ინიციალები, სტატიის სათაური, ჟურნალის დასახელება, გამოცემის ადგილი, წელი, ჟურნალის №, პირველი და ბოლო გვერდები). მონოგრაფიის შემთხვევაში მიუთითეთ გამოცემის წელი, ადგილი და გვერდების საერთო რაოდენობა. ტექსტში კვადრატულ ფჩხილებში უნდა მიუთითოთ ავტორის შესაბამისი N ლიტერატურის სიის მიხედვით. მიზანშეწონილია, რომ ციტირებული წყაროების უმეტესი ნაწილი იყოს 5-6 წლის სიღრმის.

9. სტატიას თან უნდა ახლდეს: ა) დაწესებულების ან სამეცნიერო ხელმძღვანელის წარდგინება, დამოწმებული ხელმოწერითა და ბეჭდით; ბ) დარგის სპეციალისტის დამოწმებული რეცენზია, რომელშიც მითითებული იქნება საკითხის აქტუალობა, მასალის საკმაობა, მეთოდის სანდოობა, შედეგების სამეცნიერო-პრაქტიკული მნიშვნელობა.

10. სტატიის ბოლოს საჭიროა ყველა ავტორის ხელმოწერა, რომელთა რაოდენობა არ უნდა აღემატებოდეს 5-ს.

11. რედაქცია იტოვებს უფლებას შეასწოროს სტატია. ტექსტზე მუშაობა და შეჯერება ხდება საავტორო ორიგინალის მიხედვით.

12. დაუშვებელია რედაქციაში ისეთი სტატიის წარდგენა, რომელიც დასაბეჭდად წარდგენილი იყო სხვა რედაქციაში ან გამოქვეყნებული იყო სხვა გამოცემებში.

აღნიშნული წესების დარღვევის შემთხვევაში სტატიები არ განიხილება.

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CLINICAL-MORPHOLOGICAL SUBSTANTIATION OF THE FIBROUS MATRIX WITH BIOGEL CENO BONE™ APPLICATION FOR PRESERVATION OF THE ALVEOLAR PROCESS OF THE JAWS AFTER THE TEETH REMOVAL

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Introduction.

The success of the dental implantation procedure depends on a number of clinical conditions and operating factors, among which an important place is occupied by the qualitative and quantitative parameters of the alveolar process in the area of the extracted tooth [1,2]. Sufficient supply and appropriate density of bone tissue contribute to the achievement of sufficient mechanical and then also biological stability of the intraosseous titanium support, the implementation of osseointegration, and the predictable functioning of the orthopedic structure based on the intraosseous element [1-4]. However, the loss of a unit of dentition provokes the development of interrelated changes in the structure of the bone tissue of the extraction site with a reduction in the parameters of the width and height of the alveolar process [5-7].

Hansson S. and Halldin A. (2012) substantiate the resorption of the alveolar process after the tooth extraction from the point of view of the fundamental principles of bone tissue physiology and the Wolff's law to the mechanostat, according to which the bone tissue in its mass and structure adapts to the mechanical forces acting on it [5]. The authors summarize that the loss of a tooth provokes a critical decrease in stresses and stretching's in the bone structure, almost to the complete leveling of the physiological deformity necessary to maintain its appropriate anatomical level. The absence of appropriate active stimuli in the structure of the bone tissue in the area of extraction, in turn, causes a reduction in its buccal-lingual and apico-coronal geometric parameters [5].

A systematic examination performed by Van der Weijden F. (2009) showed that the reduction in the width of the alveolar process in the area of extraction reaches 3.87 mm, the clinical average loss of the height of the vestibular plate is 1.67 mm, and the average radiological loss of the height of the process is also 1.67 mm [6]. At the same time, the analysis of weighed averages made it possible to state the fact that the clinical loss of parameters of the width of the alveolar process exceeds similar indices of height loss for the same monitoring period. Similar results were represented by Tan W. and colleagues (2012), who also confirmed the predominant loss of horizontal parameters of the alveolar process (at 29-63 %) compared with the loss of vertical components (11-22 %) during the six-month monitoring period after extraction [8].

Thus, the reduction of the geometric parameters of the alveolar process after the removal of problematic teeth limits the possibilities for predictable implantation manipulation, which, in turn, may negatively affect the level of success of the achieved rehabilitation results in the future. The preservation of the initial geometrical parameters of the alveolar process of the jaws after the tooth extraction procedure contributes to the formation of conditions for the next delayed implantation in clinical situations with limited opportunities for the implementation of the protocol for the immediate installation of intraosseous titanium supports. The use of mineralized bone, as a passive frame for the preservation of the hole, leads to compaction of the bone in the area of bone grafting, which is undesirable for implantation. Instead, demineralized allogeneic bone, such as CenoBone™ biogel, lacks the mineral component, and a biogel base containing the bone morphogenetic proteins required for bone formation, serves as a framework. Reinforcement with polymer fibers of the fluid consistency of the biogel base can stabilize this hybrid matrix.

The questions of scientific-practical discussion include the effectiveness of approaches to the preservation of sockets of extracted teeth, which would maximally contribute to the retention of the corresponding indices of the width and height of the bone in the area of interest, recorded at the time of extraction, and compensate for the effect of resorption due to the absence of appropriate mechanical stimuli in the area of the socket.

The aim of the study – was to evaluate the possibility and effectiveness of a fibrous matrix in combination with CenoBone™ biogel use in order to preserve the initial geometric parameters of the alveolar process in the area of the extracted teeth sockets.

Materials and methods.

Fabrication and preparation for research of fibrous biopolymer non-woven matrix. The formation of the polymer fibrous non-woven matrix based on poly (L-lactide) (PLLA) was carried out according to the method developed by us, which is confirmed by the patent for the invention of Ukraine (№ 119958). The preparation of microfibers took place in a sterile, dust-free environment. After washing out the sucrose, the fibers were dried in a thermostat at a temperature of 35°C for 10-20 minutes, after which they were hermetically packed into the double "Medicom" bags 0.6 mm thick (according to EN 868-5, ISO 11140-1, ISO 11607- 1). For the purpose of sterilization, the irradiation of microfiber matrices was performed using "Elektronika ELU-4" linear accelerator. Fibrous biopolymer matrices received a total dose of electron irradiation (30+0.3) kGy, which provided a surgical level of sterilization (10^{-6}).

Experimental research methods. In order to achieve the goals, set before the clinical stage, an experimental study was performed using laboratory animals (adult sexually mature male rabbits weighing 1100-1400 g), which were in vivarium on a normal diet. The keeping of animals and manipulations were carried out in accordance with the provisions of the European Convention for the Protection of Vertebrate Animals Used for

Experimental and Other Scientific Purposes (Strasbourg, 1985), "the General Ethical Principles for Experiments on Animals", adopted by the First National Congress on Bioethics (Kyiv, 2001), Law of Ukraine "On the Protection of Animals from Ill-Treatment" (2006).

The test animals were divided into 2 groups. The main group I – included 30 animals, which were implanted a polymer fibrous non-woven matrix based on poly (L-lactide) (PLLA) into the bone tissue.

The comparison group II included 30 animals, which were surgically formed a defect in the bone tissue, followed by suturing. All animals were operated on under general anesthesia. For this, there was performed an intravenous premedication with a solution of atropine sulfate 0.1 % – 0.22-0.27 mg/kg; diphenhydramine 1 % – 4.6-5.2 mg/kg; droperidol 0.25 % – 1.25 mg; ketorolac trimetamine 1 % – 0.1 ml. Propofol 1 % – 15 mg/kg intravenously was used as an induction of anesthesia. Propofol 1 % – 25-30 mg/kg/h intravenously was also used to maintain anesthesia. A skin incision was made on the left in the middle and slightly below the knee joint, soft tissues were separated to the periosteum, and the proximal tibial condyle was skeletonized on the anteromedial side (Figure 1).

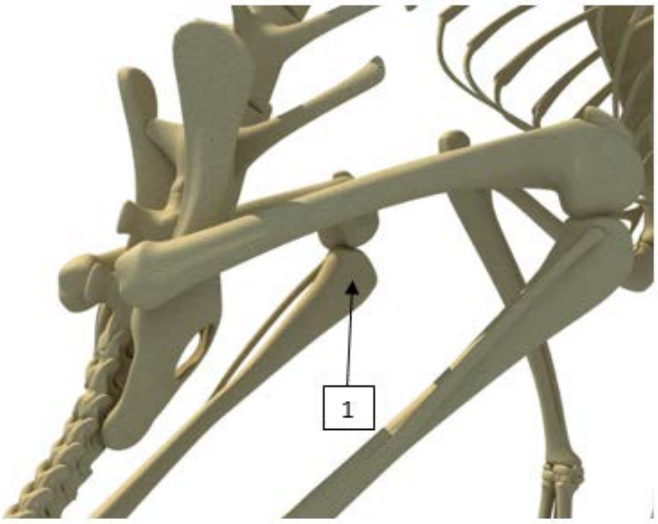

Figure.1. *Scheme of the rabbit skeleton: 1 – the area of defect formation (proximal process of the thibia).*

Using a drill, a defect in the bone tissue with a diameter of up to 5 mm was formed with a bone cutter, into which a polymer fibrous non-woven matrix was placed. The wound was sutured in layers. Material was taken from bone tissue in both groups at the 1st, 2nd, 3rd, 4th and 5th months. When taking the material, the experiment was completed by an overdose of 2% sodium thiopental solution 1.5 ml intravenously.

To perform a general histological study, special histological studies, bone tissue fragments were fixed in a 10 % solution of neutral formalin (pH-7.0). Histological sections of bone tissue were stained with hematoxylin and eosin according to Masson.

Clinical research methods. At the clinical stage, the formation of the studied population of patients was carried out in accordance with the following inclusion criteria: 1) the age of patients ranged 18-45 years; 2) the presence of a problem tooth with an extensive carious lesion, endodontic pathology, periodontal or traumatic lesions that are not amenable to therapeutic treatment and are characterized by the presence of indications for extraction; 3) the written consent of the patient to conduct a complex of diagnostic and surgical procedures in order to ensure rehabilitation through a single implantation in the area of the extracted tooth; 4) the presence of clinically pronounced inflammatory changes in the area of problem teeth, arguing the expediency of implementing a specifically delayed implantation protocol; 5) the possibility of conducting a minimally invasive procedure for extracting a problematic unit of the dentition; 6) registration of the state of the socket of the extracted tooth, belonging to the II or III classes of post-extraction defects according to the classification offered by Caplanis-Lozada-Kan [9].

The following were used as exclusion criteria: 1) the age of patients less than 18 or more than 45 years; 2) the presence of systemic general somatic pathologies that could potentially affect the result of extraction or implantation; 3) the fact of smoking patient; 4) the presence of the fact of osteonecrosis or the intake of bisphosphonates in the anamnesis; 5) the state of pregnancy; 6) long-term use (more than 20 days) of non-steroidal anti-inflammatory medicines or other drugs that affect the process of bone tissue remodeling; 7) the ratio of the post-extraction defect to I or IV class in accordance with the offered classification of Caplanis-Lozada-Kan.

Thus, a total study sample of patients was formed in the amount of 72 people who were recommended the removal of one problematic tooth with the possibility of implementing a delayed implantation protocol (4 months after extraction). Randomizer specialized software (https://www.randomizer.at/) was used for randomized allocation of patients to the study group and the control group. As a result, the study group was represented by 35 patients (24 males and 11 females), and the control group – by 37 patients (18 males and 19 females).

Surgical intervention was performed in the same way both among the patients of the study group and among the patients of the control group, and included the implementation of the following stages: 1) performing infiltration and conduction anesthesia; 2) conducting angular or trapezoidal incisions with their minimum expansion to ensure better tissue mobilization; 3) extraction of teeth using forceps, elevators and piezotome in cases of root breaking with maximum preservation of surrounding tissues; 5) curettage and revision of the post-extraction socket condition; 4) in a significant initial deficiency of the surrounding bone tissue, the flap was mobilized in order to improve the visualization of the intervention area.

Subsequently, the patients of the study group were performed the filling of the post-extraction socket with a fibrous matrix developed by the authors of the article in combination with CenoBone™ biogel. In order to do this, after preparing the holes, a sterile bag with fibers was unpacked, and CenoBone™ biogel was added to the fibers, after which they were mixed with a spatula and introduced into the defect (Figure 2).

Patients of the control group were not filled or covered the sockets of the extracted teeth. Immediately after the operation, all patients were performed a procedure of cone beam computed

tomography to record the initial levels of bone tissue in the intervention area using the appropriate reference points to measure geometric parameters. Patients of both groups were performed suturing of the sockets with the removal of sutures on the 10th day after the operation. Repeated computed tomography examination of patients was carried out 4 months after the primary surgical intervention using the same reference points to record the necessary geometric parameters. The analysis of bone tissue parameters in the area of the sockets of the extracted teeth 4 months after extraction was carried out on the basis of the results obtained of a tomographic study in the ImageJ software (Wayne Rasband (NIH)) using a specialized BoneJ plugin [10].

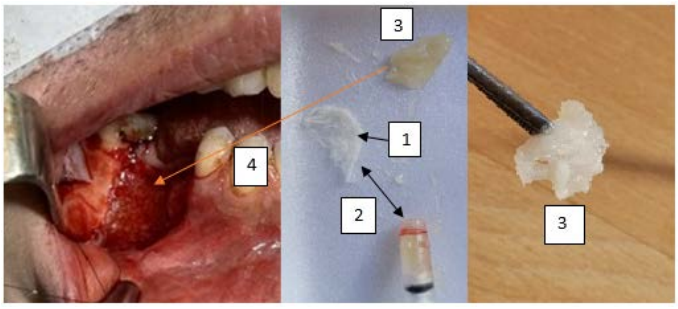

Figure.2. *Scheme of bone grafting: 1 – biopolymer fibrous non-woven matrix, 2 – mixing of fibrous matrix with CenoBone™ biogel material, 3 – ready mixed with CenoBone™ biogel fibers, 4 – introduction of material into the bone defect.*

Statistical research methods. Statistical analysis of numerical data was carried out using Microsoft Excel 2019 software (Microsoft Office 2019 (Microsoft). All the quantitative data obtained in the study corresponded to the normal type of distribution according to the Shapiro-Wilk's W test, and therefore the interval (M±m) was used to represent their central tendency: arithmetic mean (Mean) ± Standard error. To assess the reliability of the differences in the results obtained in comparison with the control group, the parametric t-test (Student's test) was used. Hypotheses about the relationship between the studied parameters were tested by calculating the Pearson correlation coefficient. The reliability of the difference in qualitative data between the comparison groups was determined according to the results of calculating the Chi-squared test with Yates's correction for continuity. A value of $p<0.05$ was considered probable.

Results and discussion.

Results of experimental studies. Histological examination of the bone tissue 1 month after the implantation of the polymer matrix showed the growth of connective tissue with a loose arrangement of connective tissue fibers mainly in the central and peripheral parts of the defect. There were also noted the multiple foci of osteoid – 18.96 % per 1 μm^2 with close contact with the fibrous non-woven polymer matrix, which indicated the beginning of bone mineralization and regeneration processes in the area of the defect (Figure 3).

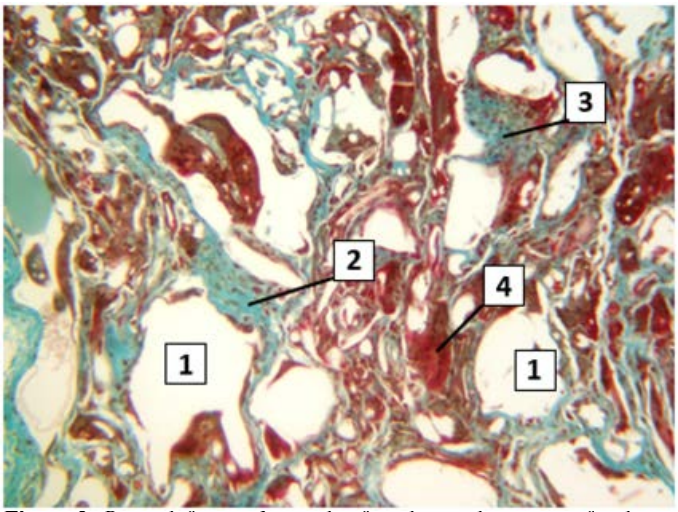

Figure.3. *Bone defect in 1 month after the implantation of polymer matrix in the proximal condyle of the tibia of the hind limb of the rabbit. 1 – location of polymer implant fibers, 2 – connective tissue fibers, stained blue, 3 – cellular elements of the connective tissue, 4 – osteoid, stained red. Staining according to Mason. Magnification: ocular lens 10, field lens 40.*

In 2 months after implantation, the process of osseointegration of the matrix and bone tissue increased, which is confirmed by increased growth of circularly located tightly adjacent collagen fibers to the polymer matrix and an increase in osteoid up to 34.38 % ($p<0.05$), which significantly differed from the previous period.

At the end of 3-4 months, mineralized lamellar bone tissue was already noted in the area of the bone defect. The presence of numerous osteocytes, in our opinion, indicated the completion of the process of osteogenesis and the presence of already formed bone. The proportion of non-mineralized bone plates was only 8.91 % ($p<0.05$), which was significantly lower than the corresponding index at the end of the 2nd month of the experiment and reflected the process of active mineralization and compaction of bone tissue (Figure 4).

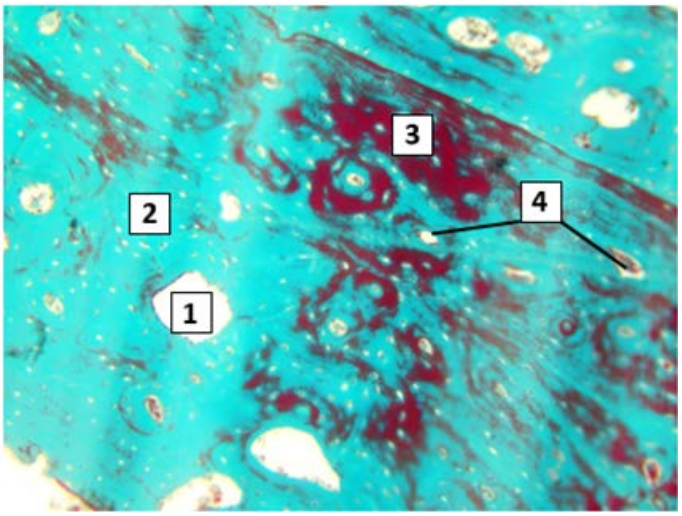

Figure.4. *Bone defect for a period of 3 months after implantation of the polymer matrix in the proximal condyle of the tibia of the hind limb of the rabbit. 1 – locations of polymer implant fibers, 2 – mineralized*

bone matrix, 3 – osteoid, 4 – central channels of osteons. Staining according to Mason. Magnification: ocular lens 10, field lens 20.

At the 5th month of the experiment, there was noted the presence of a full-fledged mineralized bone tissue with lysis of the fibers of the non-woven polymer matrix and the presence of microosteoid foci in the defect zone, the proportion of which was 0.13 % ($p<0.05$), which is almost 25-fold lower than the previous experimental group and at 86 % less than the control group index (the proportion of osteoid in the control group is 0.94 %).

As shown by the results of histological studies, the active formation of the connective tissue matrix in the area of bone defect was noted already in the early stages of the experiment and was replaced by osteoid, followed by the organization of a well-formed and organized bone structure in three mutually perpendicular directions. The percentage of osteoid in the experimental group, compared with the control values, testified to the pronounced skeletal effect of the implanted microfibrous polymer matrix. This matrix effect was also noted in the compact and circular arrangement of most collagen fibers around groups of polymeric microfibers. That is, a group of polymer fibers created a kind of substrate for building bone tissue on it.

Results of clinical studies. Taking into account the variability of the initial levels of the height of the bone walls of the sockets of the extracted teeth among the patients of the study group and the control group, the systematization of their actual reduction was carried out according to the tomographic examination data after 4 months of the primary surgical intervention. Thus, in the study group, the average level of resorption of the medial bone wall of the socket was 0.6±0.4 mm (indices range – 0.3-0.8 mm), the distal bone wall – 0.4±0.3 mm (indices range – 0.2-0.6 mm), buccal bone wall – 1.4±0.7 mm (range of indices – 0.9-2.0 mm), lingual bone wall – 1.2±0.7 mm (range of indices – 0.8-1.9 mm). In the control group, the average level of bone tissue resorption reached 1.4±0.5 mm on the medial side (indices range – 0.8-1.7 mm), on the distal side – 0.9±0.6 mm (indices range – 0.7-1.5 mm), on the vestibular side – 2.2±0.4 mm (range of indices – 1.5-2.6 mm), on the oral side – 2.1±0.6 mm (range indices – 1.3-2.4 mm). Analyzing the results of both groups, a statistical difference was noted between the change in the vertical parameters of the alveolar process from the medial/distal sides and the buccal/lingual sides ($p<0.05$). The difference between the comparison and control groups was also statistically significant in terms of changes in vertical parameters on the medial ($p<0.05$), buccal ($p<0.05$) and lingual ($p<0.05$) sides of the sockets. In the study group, in which the filling of the sockets was performed using a fibrous matrix in combination with CenoBone™ biogel, the change in the horizontal parameters of the socket (mean reduction index) 4 months after extraction was 1.8±0.5 mm (value range – 1.3 -2.4 mm), and in the control group – 3.2±0.9 mm (value range – 2.1-3.5 mm), while the difference between the groups was statistically significant ($p<0.05$) (Figure 5 and Figure 6).

The results obtained indicate that the use of a fibrous matrix contributes to a more pronounced effect of preserving the bone parameters of the socket of the extracted tooth in comparison with the changes that were recorded during the physiological healing of the socket without the use of any additional materials.

Analysis of computed tomography data in patients of both groups after 4 months showed the presence of bone tissue in the area of the extracted teeth sockets. As a detailed analysis of axial sections of bone tissue showed, all patients had a decrease in the size of the defect due to the restoration of bone tissue from the periphery to the center (Figure 7).

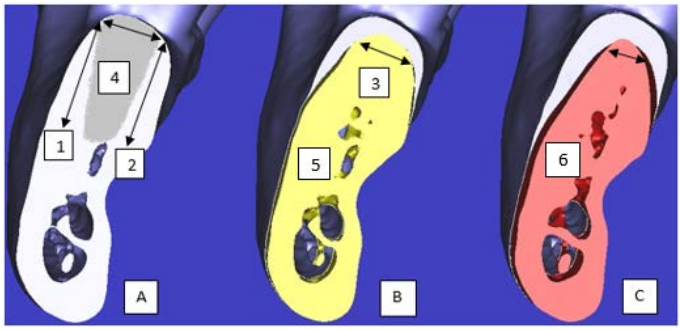

Figure.5. *Cross-section of the alveolar part of the lower jaw. Schematic representation of the degree of atrophy of the hole in patients of two clinical groups. A - condition after bone plastic surgery (1 - vertical parameters buccal side, 2 - vertical parameters lingual/palatal side, 4 - CenoBone™ and fibrous matrix); B – comparison of the condition after plastic surgery with the study group 5 (3 - horizontal parameters); C – comparison of the state after plastic surgery with the control group 6.*

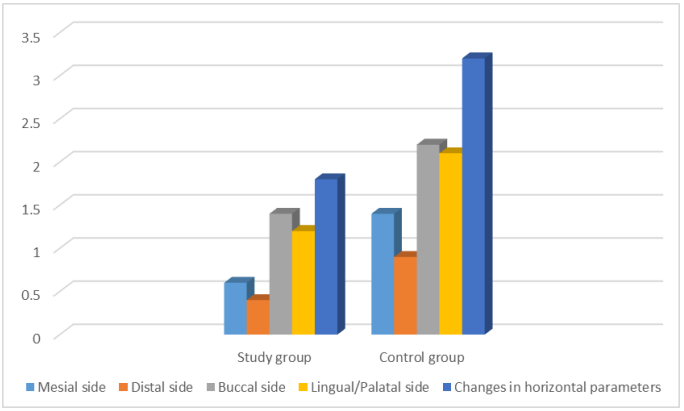

Figure.6. *Comparison of changes in the geometric parameters of bone tissue in the area of the sockets of extracted teeth in the study group and the control group.*

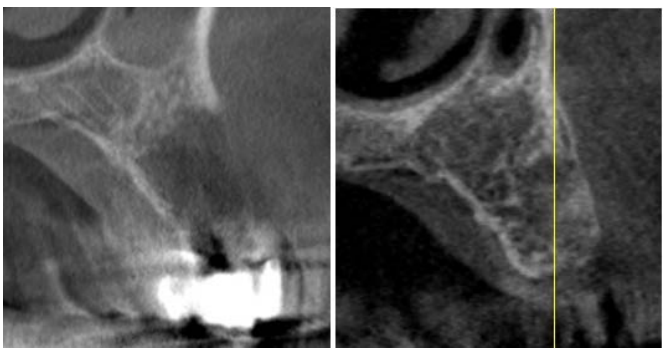

Figure.7. *Computed tomography data, cross-section of the alveolar process of the upper jaw. Patient M., 4 months after tooth extraction and microfiber bone grafting in combination with CenoBone™ biogel. A – the state of the socket of the extracted tooth before the operation, B – restoration of bone tissue 5 months after the operation.*

Analysis of the parameters of bone tissue in the area of the sockets of the extracted teeth 4 months after extraction based on the results of a tomographic study, using a specialized plugin BoneJ, revealed the following indices: the level of anisotropy of the filled defect area in the study group and the comparison group was 0.567-0.819 and 0.619-0.956, respectively (statistical difference between the indices of the two groups could not be identified – $p>0.05$). The level of association between the anisotropy indices and the difference in relative density in the comparison group was represented by the value of the correlation coefficient $r=0.31$, and in the study group – $r=0.39$. The data obtained indirectly indicate that the use of a fibrous matrix in combination with CenoBone™ biogel does not affect the quality of the newly formed bone tissue. This is indicated by the results of the tomography, namely the fact of the absence of encapsulation of the material, since the materials used by us in the research are not radiopaque, and therefore the trabecular structure visualized in the images, refers to the bone one.

During implantation, the necessity for additional augmentation was noted in 5 patients (14.28 %) in the study group, and in 19 patients (51.35 %) in the control group.

The range of results obtained in reducing the level of bone tissue in the area of the sockets of extracted teeth is similar to that described in previously published studies. So, Schropp L. and colleagues drew attention to the fact that the most progressive loss of bone tissue in the area of preliminary performed extraction occurs during the first 12 weeks, during which the reduction in the width of the crest reaches 28.4 % and increases up to 50 % during a 1-year observation (with a range of absolute indices from 2.7 to 12.2 mm) [7]. At the same time, the indices of such a reduction are always more pronounced in the horizontal plane than in the vertical one. Although some authors have also summarized that the level of the height of the alveolar process in the area of the extracted tooth also almost never reaches the vertical indicators of the bone in the area of its contact with the existing tooth [5,6].

A number of studies have described similar methods for preserving the original geometric parameters of the bone tissue, which also made it possible to achieve an acceptable clinical result. Thus, a systematic review performed by Orgeas G. et al. (2013) found that sufficient preservation of the parameters of the height and width of the residual process in the area of the socket of the extracted tooth can be achieved using only insulating membranes [11]. Matiolla A. et al. (2018) described a new method of bone preservation by filling the socket of an extracted tooth with a resorbable polylactic membrane, which was covered with a collagen matrix. Such additional overlap contributes not only to the protected stabilization of the clot in the socket, but also to better healing of the surrounding soft tissues [12]. The authors managed to achieve the conditions for the subsequent placement of dental implants in all tooth sockets filled with polylactic membranes. Lemke M. and colleagues (2014) using a small study sample, have determined that the use of polylactic acid membranes helps to minimize the effect of bone resorption in the area of the socket of the extracted tooth and even its growth up to an average of 0.29±1.79 mm during 4 months' observation period, while among patients in the control group (for whom no methods of preserving the socket were used), the loss of bone tissue level averaged 1.06±0.51 mm during the same observation period. The positive effect of the polylactic acid membrane on the stability of the level of the surrounding soft tissues was also proved by the authors in their study (minimization of changes in the level of the gums up to 0.10±1.39 mm) [13].

The consensus decision of the DGI Consensus Conference indicates the positive effect of the preservation procedure of tooth socket and process on the whole, on the preservation of the vertical and horizontal parameters of the jawbone tissue: in such a way it is possible to reduce horizontal bone loss at 59 % and vertical bone loss at 109 % [14]. In the absence of the implementation of techniques for the preservation of the extracted socket, the necessity for additional augmentation of the implantation area 5-fold increased. Although, Weng D. et al. (2011) also noted that at the moment there are no specific recommendations regarding specific techniques for performing the socket preservation procedure, as well as the use of various types of materials for this purpose, taking into account the heterogeneity of clinical data given in previously published studies, cannot be formulated [14]. Although, a study by Chan H.-L. and colleagues (2013) confirmed the hypothesis regarding the difference in bone quality index when filling the socket with different types of bone substitutes. The results of preliminary performed studies indicate that the average amount of vital bone in the natural healing of the socket is up to 38.5 %±13.4 %, and connective tissue – up to 58.3 %±10.6 % [15]. The limited evidence obtained indicates that the use of demineralized allografts and autografts contributes to an increase in the proportion of the vital bone fraction up to 6.2–23.5 %, and, accordingly, the percentage of the connective tissue fraction decreases [15]. In the above study, it was not possible to identify signs of the influence of the fibrous matrix on the quality of the new bone tissue formed in the area of the extracted tooth socket. This is evidenced by the data of tomographic studies, which show the formed spongy structure of the bone, which practically does not differ from the intact bone. In turn, the preservation of the geometric parameters of the process can be due, on the one hand, to the presence of a porous fibrous matrix, which in combination with the biogel and fibrin framework formed in the wound, forms a kind of bridge for tissue construction, and on the other hand – due to the morphogenetic proteins contained in the demineralized alomatrix. The specified matrix effect of fibers is also confirmed by the results of the above-described histological studies of the structure of bone tissue.

The framework and hydrophilic effect of the biopolymer fibrous matrix developed by us, can also be used as a local system for the delivery of various substances into the wound, such as antibiotics, growth factors or cell culture, etc.

Conclusions.

As a result of the performed study, it was possible to determine that the use of a fibrous matrix in combination with CenoBone™ biogel contributes to the preservation of the geometric parameters of the alveolar process in the area of the extracted teeth sockets during a 4-month observation period. The results obtained

indicate a more pronounced effect of a socket preservation with the use of a fibrous matrix in combination with CenoBone™ biogel compared to conventional healing of the tooth extraction area, which was confirmed by the results of a tomographic study. Thus, this approach could be recommended for the implementation in practice, in order to optimize the conditions for delayed implantation in the area of teeth removed due to endodontic, periodontal, traumatic lesions or extensive carious pathology with inflammatory changes that were pronounced at the time of intervention.

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SUMMARY

CLINICAL-MORPHOLOGICAL SUBSTANTIATION OF THE FIBROUS MATRIX WITH BIOGEL CENO BONETM APPLICATION FOR PRESERVATION OF THE ALVEOLAR PROCESS OF THE JAWS AFTER THE TEETH REMOVAL

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The aim of the study was to evaluate the possibility and effectiveness of fiber matrix use in order to maintain the original geometric parameters of the bony crest in the area of removed teeth.

The experimental study was performed on laboratory animals (rabbits). 30 animals of the main group were implanted with a polymer matrix in the area of bone defect, 30 animals of the control group were formed bone defect. Patients in the study group were performed with filling-out of a post-extraction socket by fiber matrix developed by the authors of the article (patent for invention of Ukraine № 119958) in combination with biogel CenoBonetм. For patients in the control group filling or overlapping of the post-extraction socket were not conducted. Computed tomography was performed at the period of 4 months after the initial surgical intervention. Analysis of the parameters of bone tissue in the area of the removed teeth 4 months after extraction was performed on the basis of the tomography-results in the ImageJ software (Wayne Rasband (NIH)) using the specialized BoneJ plugin.

The results of experimental studies confirmed that percentage of osteoid in the main group, compared with the control indicators, showed a pronounced framework effect of the implanted microfiber polymer matrix. This fact was confirmed by the presence of complete mineralized bone tissue in the defect zone with lysis of the fibers of the non-woven polymer matrix and the presence of microosteoid foci, the proportion of which was 0.13% ($p<0,05$), which is 86% less than in the control group.

The analysis of clinical studies showed that average level of resorption of the medial bone wall of the post-extraction socket was 0,6±0,4 mm (range of indicators – 0,3-0,8 mm), distal bone wall – 0,4±0,3 mm (range of indicators – 0,2-0,6 mm), vestibular bone wall – 1,4±0,7 mm (range of indicators – 0,9-

2,0 mm), lingual bone wall – 1,2±0,7 mm (range of indicators – 0,8-1,9 mm). In the control group, the average level of bone resorption reached from the medial side 1,4±0,5 mm (range of indicators – 0,8-1,7 mm), from the distal side – 0,9±0,6 mm (range of indicators – 0,7-1,5 mm), from the vestibular side – 2,2±0,4 mm (range of indicators – 1,5-2,6 mm), from the oral side – 2,1±0,6 mm (range of indicators – 1,3-2,4 mm). In both groups the statistical difference between the change in the vertical parameters of the residual crest from the medial/distal sides and the vestibular/oral sides was noted ($p<0,05$).

Obtained results indicate a more pronounced preservation effect of the using fiber matrix compared with the usual healing of the tooth extraction region, which was confirmed by the results of the tomography study. Thus, this approach can be recommended for implementation in practice to optimize the conditions for delayed implantation in the area of the teeth removed due to endodontic, periodontal, traumatic lesions or extensive caries pathology with the expression of inflammatory changes at the time of intervention.

Keywords. Microfiber biopolymer matrix, biogel CenoBone™, histological analysis, computed tomography, bone tissue

РЕЗЮМЕ

КЛИНИКО-МОРФОЛОГИЧЕСКОЕ ОБОСНОВАНИЕ ПРИМЕНЕНИЯ ВОЛОКНИСТОГО МАТРИКСА С БИОГЕЛЕМ CENO BONE™ ДЛЯ СОХРАНЕНИЯ АЛЬВЕОЛЯРНОГО ОТРОСТКА ЧЕЛЮСТЕЙ ПОСЛЕ УДАЛЕНИЯ ЗУБОВ

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Цель исследования – оценить возможность и эффективность использования волокнистого матрикса с целью сохранения исходных геометрических параметров альвеолярного отростка в области лунок удаленных зубов.

Эксперимент проводился на лабораторных животных (кролях). 30 животным основной группы имплантировали полимерный матрикс в зону костного дефекта, 30 животным контрольной группы формировали костный дефект. Пациентам группы наблюдения проводили заполнение постэкстракционной лунки разработанным авторами статьи волокнистым матриксом (патент на изобретение Украины № 119958) в сочетании с биогелем CenoBone™. Пациентам группы контроля заполнение или перекрытие лунок удаленных зубов не проводилось. Анализ параметров костной ткани в области лунок удаленных зубов через 4 месяца после экстракции проводился на основе полученных результатов томографического исследования в программном обеспечении ImageJ (Wayne Rasband (NIH)) с использованием специализированного плагина BoneJ.

Результаты экспериментальных исследований подтвердили, что процентная доля остеоида в основной группе, по сравнению с контрольными показателями, свидетельствовала о выраженном каркасном эффекте имплантированного микроволокнистого полимерного матрикса. Этот факт подтверждался наличием в зоне дефекта полноценной минерализованной костной ткани с лизисом волокон нетканого полимерного матрикса и присутствием микроостеоидных ячеек, доля которых составляла 0,13 % ($p<0,05$), что на 86 % меньше показателя контрольной группы.

Анализ клинических исследований показал, что средний уровень резорбции медиальной костной стенки лунки составлял 0,6±0,4 мм (диапазон показателей – 0,3-0,8 мм), дистальной костной стенки – 0,4±0,3 мм (диапазон показателей – 0,2-0,6 мм), щечной костной стенки – 1,4±0,7 мм (диапазон показателей – 0,9-2,0 мм), языковой костной стенки – 1,2±0,7 мм (диапазон показателей – 0,8-1,9 мм), а в группе контроля: с медиальной стороны 1,4±0,5 мм (диапазон показателей – 0,8-1,7 мм), с дистальной стороны – 0,9±0,6 мм (диапазон показателей – 0,7-1,5 мм), с вестибулярной стороны – 2,2±0,4 мм (диапазон показателей – 1,5-2,6 мм), с оральной стороны – 2,1±0,6 мм (диапазон показателей – 1,3-2,4 мм). В обеих группах была статистическая разница между изменением вертикальных параметров альвеолярного отростка с медиальной/дистальной сторон и щечной/языковой сторон ($p<0,05$).

Полученные результаты свидетельствуют о более выраженном эффекте презервации лунки с применением волокнистого матрикса по сравнению с обычным заживлением области удаления зуба, что было подтверждено результатами томографического исследования. Таким образом, данный подход может быть рекомендован для внедрения в практику с целью оптимизации условий для проведения отсроченной имплантации в области зубов, удаленных по причине эндодонтических, пародонтальных, травматических поражений, или обширной кариозной патологии с выраженными на момент вмешательства воспалительными изменениями.