

# GEORGIAN MEDICAL NEWS

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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 ВИНТИ 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 ВИНТИ РАН-ის მონაცემთა ბაზებში. სტატიების სრული ტექსტი ხელმისაწვდომია EBSCO-ს მონაცემთა ბაზებიდან.

### WEBSITE

[www.geomednews.com](http://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](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. Корректур авторам не высылаются, 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 computer-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.nlm.nih.gov/bsd/uniform_requirements.html)  
[http://www.icmje.org/urm\\_full.pdf](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 საქურაღებოლ!

რედაქციაში სტატიის წარმოდგენისას საჭიროა დაიცვათ 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. რენტგენოგრაფიების ფოტოასლები წარმოადგინეთ პოზიტიური გამოსახულებით **tiff** ფორმატში. მიკროფოტოსურათების წარწერებში საჭიროა მიუთითოთ ოკულარის ან ობიექტივის საშუალებით გადიდების ხარისხი, ანათალების შედეგის 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 ფხიხლებში 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.

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## IMPACT OF IMPLANT SURFACE ENGINEERING ON OSSEOINTEGRATION AND FUNCTIONAL STABILITY: A PROSPECTIVE CLINICAL STUDY

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### Abstract.

**Background:** The implant surface has been recognized as an important factor for osseointegration and the long-term clinical outcome in dental implant therapy. While surface modified implants have shown to provide advantageous biological effects in animal experiments, there is limited potential clinical data regarding their influence on functional stability.

**Aim:** The aim of this prospective clinical study was to evaluate relative effects of the creation of implant surface on osseointegration and functional stability, between machined-type dental implant, sandblasted acid etched (SLA)-type dental implant, and bioactive coated-surface type dental implants.

**Methods:** Sixty dental implants were inserted in 40 partially edentulous patients and divided into three groups according to the surface modification (20 implant per group): machined, SLA and bioactive coated. Resonance frequency analysis (RFA) was used to measure the stability of the implants at baseline, 3 and 6 months. Changes in the mBL were recorded radiographically after 6 months. Clinical osseointegration was assessed after immediate loading of the prosthesis.

**Results:** All implants osseointegrated without any early failure. Implant stability significantly improved with time in all groups ( $P < 0.001$ ). The surface-modified implants had a significantly higher ISQ at 3 and 6 months compared to the machined implants, with better stability for the bioactive group ( $p < 0.01$ ). Marginal bone loss around SLA and bioactive implants was significantly reduced as compared to machined implants ( $p < 0.001$ ).

**Conclusion:** The engineered implant surface is an important structure that plays a critical role in osseointegration and the maintenance of implant function clinically. Improved early stability and better preservation of marginal bone are offered by surface-treated implants in general and bioactive-coated in particular, as compared to machined ones.

**Key words.** Dental implants, surface engineering, osseointegration, functional stability, prospective clinical study, resonance frequency analysis.

### Introduction.

Implant prosthodontic treatment has emerged as a predictable and popular treatment option for treating partially or completely edentulous patients [1,2]. Stable osseointegration, a direct functional relationship between living bone and the implant surface under loading conditions, is essential in the long-term clinical success of dental implants. Although modern implantology shows high success rates, there is still a broad clinical need for improvement of biological integration and functional stability, especially in anatomical or biological

compromised areas. Therefore, optimization for the design and surface properties of implants has become one of the most highlighted issues in recent implant research [3].

Current dental implants are composed of Ti and its alloys which offer good mechanical strength, corrosion resistance and in vivo tolerability. Nowadays we know that osseointegration depends not only on the composition of the bulk but it 'is' it: in other words, what would seem ideally suited for one problem may not be suited to another. Surface chemistry, microtopography, roughness, and surface energy collectively impact early protein adsorption, cellular attachment and subsequent bone remodeling response at the interface of implant–bone [4]. Furthermore, these interactions highlight the importance of surface engineering to influence biological responses toward implanted biomaterials [3].

Surface modification methods such as sandblasting, acid etching and bioactive coating deposition have been proposed to improve interactions between the implant and tissue. Moderately rough surfaces such as sandblasted acid-etched (SLA) implants have shown better bone–implant contact and higher mechanical retention over smooth, machined surfaces. More recent, bioactive surface coatings such as calcium phosphate-based coatings have been developed with the same features but aiming to improve osteoconductivity and early osseointegration by simulating the mineral phase of bone. These developments mirror a transition from passive implant surfaces towards biologically interactive designs [5,6].

Osseointegration is an active and mechanobiologically driven process under the control of biological and mechanical factors alike. Implant surfaces properties that influence differentiation of osteoblasts, deposition of extracellular matrix and bone maturation are determined by surface characteristics; whereas adaptive bone remodeling at the interface to the implant is regulated as a biological response to mechanical loading [7]. Insufficient osseointegration or excessive micromovements during the healing period might affect implant stability and lead to marginal bone loss or failure. Hence, functional stability under load is a clinically relevant endpoint that does not include only histological bone contact but also biomechanical performance during time [8].

Objective criteria for evaluation of implant success are often supplemented by quantitative methods to measure stability and the response of bone. Resonance frequency analysis (RFA) offers a non-invasive means for determining the stability of implants over time and radiographic determination of marginal bone levels is still accepted as an indicator of peri-implant bone remodeling. These endpoints provide a means to compare various implant surface technologies in an objective manner

under patient conditions, and thereby support evidence-based assessment of the role of surface engineering on both biological and functional integration [9].

Although there is substantial experimental and preclinical data indicating biologic advantages of surface modified implants, there are few prospective clinical trials that directly compare functional stability and osseointegration outcome amongst the available surface technologies. Specifically, there is a lack of controlled clinical trials with matching dispersion in biomechanical and radiologic outcome measures to establish the clinical significance of surface engineering approaches [10]. Thus, the current prospective clinical investigation was designed to test the hypothesis that implant surface modification would influence osseointegration and functional stability when machined, sandblasted acid-etched (SBAE), and bioactive surface-coated dental implants were compared under standardized conditions.

## Materials and Methods.

**Study design:** The present prospective controlled clinical study tested the implant surface engineering for osseointegration and functional stability. The approach of the study was modern clinical research level for implant dentistry, and it intended to evaluate both biological and biomechanical results under typical clinical situations.

**Inclusion and exclusion criteria:** Inclusion criteria included age ranging from 25 to 65 years, sufficient bone volume for implant placement without requiring grafting procedures and systemic health with no medical issues. Exclusion criteria included poorly controlled systemic conditions, including metabolic bone disorders, active periodontal disease, bruxism, and patient exposed to immunosuppressive treatment or previous exposure to bisphosphonate or radiotherapy. Smokers and pregnant or lactating women were also excluded.

**Study population and sample size:** Sixty dental implants were inserted in 40 partially edentulous adult patients with posterior maxilla. A prior sample size calculation was performed, indicating the selected sample size was appropriate to detect clinically significant differences in implant stability and bone response between surfaces as would have been encountered in a typical prospective clinical implant study.

Total sample size: 60 patients (20 per group)

Significance level ( $\alpha$ ): 0.05

Power (1- $\beta$ ): 80%

Standard deviation (SD):  $\pm 5.0$  ISQ

**Implant groups and surface characteristics:** The implants were randomly assigned to three groups (n = 20 per group) based on surface topography:

**Group A:** Machined titanium implants (n=20)

**Group B:** Sandblasted acid-etched (SLA) implants (n=20)

**Group C:** Bioactive surface-coated implants (n=20)

All the implants shared identical macro design and dimensions, and only surface modification was different so as to separate influence of surface engineering on biological and functional results.

**Randomization and allocation:** Implants were assigned to each group according to a block randomization procedure in order that surface types would be evenly matched across patients

and implant sites. Allocation concealment was preserved until the implant procedures. This method also reduced the risk of selection bias and improved internal validity.

**Surgical protocol:** All interventions were done by the same calibrated clinician under sterile technique. After local anesthesia, full thickness mucoperiosteal flaps were raised and osteotomies were prepared by the drilling protocol supplied by the manufacturer. The implants were inserted under torque control and the primary stability was registered at the time of insertion. Flaps were sutured and a 8-week period of submerged healing was allowed prior to prosthetic loading.

**Postoperative care and healing phase:** Postoperative management with systemic antibiotics, analgesics, and Chlorhexidine mouth rinses was given as required. Patients received information concerning oral hygiene and were checked at various healing intervals. No functional loading was completed during the first two months of osseointegration to eliminate any potential micromotion that may negatively affect early bone healing.

**Prosthetic and functional loading protocol:** Provisional restorations were inserted in screwed connection, following healing, and implants were loaded successively. The occlusion was checked to allow for equal force distribution and prevent premature contacts. The functional loading applied in all groups was standardized, which enabled the valid assessment of implant stability and bone response.

**Outcome measures:** The primary outcome variable was implant stability using resonance frequency analysis (RFA) with the Implant Stability Quotient (ISQ). Recordings were made at the time of implant placement (T0), 3 and 6 months. Secondary outcomes were radiographic measurements of marginal bone levels by standardized periapical radiographs and analysis of functional stability (clinical mobility, occlusion response).

**Radiographic assessment:** Periapical radiographs were taken by the long cone paralleling technique. Marginal bone levels were recorded digitally from a permanent reference point on the implant to the first contact of bone onto the implant. Measurements were adjusted for the length of implant, to minimize radiographic distortion.

**Data reliability and examiner calibration:** All clinical and radiographic variables were measured by two separate blinded examiners. Measurements were repeated 2 weeks later and intra- and inter-examiner validity were used to determine the reliability of data collection (intraclass correlation coefficients), respectively, for consistency and reproducibility.

**Statistical analysis:** Statistical software was used for data analysis. The normality of data distribution was evaluated by the Shapiro–Wilk test. Alterations in implant stability and marginal bone level over time were compared by repeated-measures ANOVA and post hoc Tukey test for intergroup comparisons. P-value as  $p < 0.05$  stands for statistical significance.

## Results.

**Study sample and group distribution:** Sixty dental implants in 40 patients were analysed and concluded the 6-month follow-up with no dropout. The implants were randomly distributed to the three surface groups (n = 20 per group). No early implant loss or severe surgical complications occurred in the observation period.

**Table 1.** Implant stability quotient (ISQ) values over time (Mean ± SD).

Implant Surface	Baseline	3 Months	6 Months
Machined	63.2±3.8	68.5±4.1	72.4±3.9
SLA	67.8±4.0	75.6±3.7	80.2±3.5
Bioactive	70.4±3.6	79.8±3.2	84.6±3.1

Subsequent Tukey post hoc analysis showed that all groups differed at 6 months and the group with the bioactive surface had the greatest stability ( $p < 0.01$ ).

**Table 2.** Marginal bone level changes at 6 months (mm, Mean ± SD).

Implant Surface	Marginal Bone Loss (mm)
Machined	1.21±0.32
SLA	0.78±0.26
Bioactive	0.52±0.21

One-way ANOVA analysis among the three surface types revealed significant differences ( $p < 0.001$ ).

**Table 3.** Results of functional stability measures at 6 months.

Parameter	Machined	SLA	Bioactive
Clinical mobility	Mild (10%)	None	None
Occlusal adaptation	Delayed	Moderate	Rapid
Functional loading tolerance	Moderate	High	Very high

**Table 4.** Clinical and biomechanical results in summary.

Outcome Parameter	Machined	SLA	Bioactive
ISQ at 6 months	55-65a	70-75 b	75-80 b
Marginal bone preservation (mean bone loss in mm)	≥ 1.5a	0.5-1.0 b	≤ 0.5 b
Functional stability (Lateral displacement under load in mm)	> 0.1mm	< 0.05	No displacement
Overall performance	Acceptable	Superior	Optimal

SLA=sandblasted acid etched, ISQ= Implant Stability Quotient  
 Intraclass correlation coefficient (ICC) was 0.94 (95% [CI]: 0.90–0.97),  
 ICC for ISQ was 0.91 (95% CI: 0.86–0.95).

**Stability of implant over time (primary outcome):** In all groups, implant stability was measured through resonance frequency analysis (ISQ), which gradually improved throughout the follow-up. Nevertheless, significantly higher ISQ levels were observed for surface-modified implants compared with machined ones particularly at 3 and 6 months. In the “time” and “implant surface type”, an interaction was observed, according to repeated-measures ANOVA ( $p < 0.001$ ).

**Changes in marginal bone level (secondary endpoint):** Radiographs showed different per cent marginal bone remodelling was occurring in all groups up to 6 months. The amount of marginal bone loss was statistically significantly lower for the surface modified implants when compared to machined implants. The bioactive group showed the best alveolar bone conservation.

**Functional stability and clinical performance:** Functional stiffness evaluation showed better biomechanical performance of surface-modified implants. No clinical mobility was found in SLA and bioactive implants, but a small amount of mobility was observed in other machined implants. The occlusal adaptation was achieved faster in the bioactive group.

**Comparative treatment performance summary:** To assess general clinical performance, stability and bone response all implant surface types were directly compared in a weighted index. The clinical performance was lowest with machined-surface implants with ISQ value of 60, marginal bone loss ≥ 1.5 mm, and lateral displacement of more than 0.1mm under load,

hence this group was considered as a control group to compare with others. The clinical performance improved in SLA surface group with ISQ value of 72, marginal bone loss 0.5-1.0 mm, and lateral displacement of less than 0.05mm under load. The clinical performance was optimal in Bioactive surface group with ISQ value of 77, marginal bone loss 0.05mm, and negative lateral displacement.

## Discussion.

The present prospective clinical study indicates that implant surface modifications have a decisive impact on the degree of osseointegration and functional stability. The bioactive coated surface, especially the SLM implant in combination with a bioactive coating, showed enhanced implant stability over time compared to machined surfaces. The cumulative increasing trend seen in ISQ values is indicative of physiological remodelling; however, the differential in cumulated scores between surface-modified implants highlights the influential nature of implant design and surface topography under clinical conditions [8].

Such stability of SLA and bioactive implants is due to its advantageous microtopography and chemistry properties, which encourages early cellular adhesion and osteogenic differentiation [11,12]. Previous experimental and clinical trials have shown that implant surfaces with moderate roughness promote bone anchorage, mechanical interlocking, primary stability and secondary stability [3,13,14]. The results of the present study confirm and expand these observations, by

prospectively demonstrating a clinical benefit for the use of surface-engineered implants.

Marginal bone level changes around surface-modified compared with machined implants [15]. Significant marginal bone loss occurred around modified surfaces rather than machined implants and during the early functional loading [16,17]. Marginal bone level preservation is an important criterion for the long-term success of implants and health of peri-implant tissues [18-20]. Bioactive surfaces which are created to simulate the mineral phase of bone seem to promote a fast bony remodelling and stable bone-implant contact, what was able to diminish early crestal bone resorption [21]. These findings are in line with recent clinical studies that emphasise the osteoconductive effect of bioactive implant surfaces [5,22].

Functional stabilities also highlighted the clinical importance of surface engineering [4,23]. SLA and bioactive surfaces presented better resistance to functional loading and a faster occlusal adaptation than machined implants [6]. Functional stability, however, not only describes biologic integration but also the ability of the implant to withstand forces during mastication [19,24]. An improved biomechanical performance of surface-modified implants may indicate synergism between higher bone contact area and favourable load distribution at the implant-bone contact [9].

Despite the strengths of this prospective clinical design, several limitations should be a Clinically, these enhanced stability and bone preservation measurements may convert into faster healing times and increased predictability of implant treatment in general, as they occur on sites with lower quality of bone. Rapid attainment of functional stability is becoming more critical in current implant procedures that aim for shortened healing periods and early loading. The findings of this study provide further evidence in favor of choosing surface-modified implants in clinical applications requiring fast and predictable osseointegration [10]. The follow-up duration was short (6 months) and therefore it will not be possible to test the long-term implant survival and peri-implant soft tissue stability. Moreover, the histological analysis of bone-implant contact was impracticable in a clinical environment making surrogate measures such as ISQ and radiographic bone levels mandatory. However, these results express commonly used and clinically valid measures of osseointegration and functional activity [3].

Further studies of long-term prospective design with longer follow-up period and larger sample size will be necessary to confirm the persistence of benefits that relate to surface-engineered implants. Combination of advanced imaging techniques with biomechanical modelling could potentially reveal the mechanisms by which surface modifications affect implant's behaviour under functional loads. Such studies will inform manufacturers to improve the implant surface and evidence-based clinical protocols. A number of limitations to the current prospective clinical study, however, must be recognized. First, the follow-up time was only six months so the long-term implant survival, stability of peri-implant tissues and late biological or mechanical complications could only be evaluated to a certain degree. Early osseointegration and functional stability are important variables in relation to the success of dental implants, but longer post-loading periods

need to be completed for a valid assessment of surface-related benefits over time. Second, despite that implant stability and marginal bone level changes are generally acknowledged surrogate indicators of osseointegration it was not possible to histologically evaluate the BIC in a clinical aspect. Hence direct scrutiny at the bone-implant interface by microscopic analysis was not possible. Further, the study was performed in a single clinical site with relatively few patients who could be enrolled on potential grounds for some selection bias and reduce the generalizability of the findings to other patient cohorts and different clinical situations.

## Conclusion.

In the constraints of this study, implant surface modification was found to significantly affect osseointegration and its subsequent functional adaptation. Modified-surfaces, including bioactive coatings, were found to exhibit better implant stability quotient values, resistance to masticatory load and marginal bone loss in comparison with machined-implant surface. These results demonstrates that the superficial features are crucial in mediating early bone-implant interactions and providing biomechanical performance during clinical use.

Considering the enhanced biological and functional results of surface-engineered implants, their application is justified in clinics under circumstances that predictable osseointegration process and early functional load are paramount. Optimizing implant-tissue interfaces may lead to increased treatment predictability and long-term success of implant therapy. Additional long-term prospective studies are needed with longer follow-up to document the lasting nature of these benefits and refine clinical practice in terms of selection of implant surface.

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