Influence of the Primary Stability and Temporary Prosthetics of a Placed Dental Implant on Implant Osseointegration and Further Function When Performing Immediate Implantation in the Posterior Tooth Regions.

2026.04.07

Ethical permission - Nr. 2026/4-1735-1199

Tooth extraction and subsequent implantation will be performed under local anesthesia. After tooth extraction, an osteotomy is performed in the tooth socket to create a bed for the implant. After that implant is placed. The patients will be divided into 3 groups, based on primary stability of the implant.

1. **If stability is low (5-10 Ncm):** Megagen BlueDiamond implants will be placed, and no temporary prosthesis will be applied; the implant will be submerged (sutured over).
2. **If stability is medium (15-35 Ncm):**Megagen BlueDiamond implants will be placed, and an individualized plastic healing abutment (gingival former) will be placed.
3. **If stability is high (40 Ncm and above):** Megagen BlueDiamond implants will be placed, and a temporary plastic tooth (temporary crown) will be placed.

After implant placement following parameters will be measured:

- Implant insertion depth and horizontal position with a periodontal probe, Implant Stability Quotient (ISQ), scanning of the implantation site with an intraoral scanner, and a 1-year follow-up examination.
- Torque (Ncm) will be measured with a standard implant insertion torque wrench.
- The Implant Stability Quotient (ISQ) will be measured non-contactually with the Ostell Mega ISQ II device. A magnetic component (SmartPeg) is screwed onto the implant. The Ostell Mega ISQ II device is held 3mm away from the component and sends magnetic impulses to the component. The component vibrates at its resonance frequency, which depends on the amount of bone-to-implant contact. The device records the frequency, converts it into the Implant Stability Quotient (ISQ), and displays a value from 1 to 100 on the screen.
- Periapical radiographs of the inserted implant will be taken using an X-ray machine.

After 8 weeks – group 1 and 2 groups are evaluated for implant integration. If implant is osseointegrated - the scan for implant prosthetics. Final ultra-polished Zr prosthesis is fabricated and delivered. Group 3 – after 4 months second stage surgery to expose the implant and evaluate for osseointegration. If implant is oseointegrated - the scan for implant prosthetics. Final ultra-polished Zr prosthesis is fabricated and delivered.

The following data will be collected during the one-year follow-up visit:

- Marginal bone level via radiological examination
- Determination of the Pink Esthetic Score (PES) index
- Determination of the Plaque Index (PI)
- Determination of the Probing Pocket Depth (PPD)
- Determination of the Bleeding on Probing (BOP) index
- Non-contact implant scanning with an intraoral scanner

Primary outcome measures:

1. Implant integration

Secondary outcome measures:

1. Implant insertion torque;
2. Implant insertion depth upon placement and after integration;
3. Marginal bone stability after prosthesis delivery and after one year;

4. Determination of the Pink Esthetic Score (PES) index after prosthesis delivery and after 1 year;
5. Determination of the Implant Stability Quotient (ISQ) value upon implant placement and after integration;
6. Determination of the Plaque Index (PI) after prosthesis delivery and after 1 year;
7. Determination of Probing Pocket Depth (PPD) after prosthesis delivery and after 1 year;
8. Determination of the Bleeding on Probing (BOP) index after prosthesis delivery and after 1 year.

PATIENT INFORMED CONSENT FORM

Approved by

Lithuanian Bioethics Committee

Biomedical Research Expert Group

Decision of 15 November 2016

AMENDED

Decision of the Lithuanian Bioethics Committee

Biomedical Research Expert Group

17 September 2024

Informed consent form, version No. 2, date: 02/10/2026

INFORMED CONSENT FORM

Title of the biomedical study: The effect of primary stability of an inserted dental implant and provisional prosthesis on implant osseointegration and subsequent function when performing immediate implantation in posterior teeth regions.

Protocol No.: 1

Sponsor: UAB "Vilniaus mokslo grupė"

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Email: juolekas@gmail.com

Sponsor's representative: Juozas Olekas

Principal investigator1: Tomas Linkevičius

Name of study center: UAB "Vilniaus mokslo grupė"

Address: Kęstučio 9-12, Vilnius

Tel. (principal investigator): +37068772840

Email (principal investigator): linktomo@gmail.com

1 Principal investigator — the investigator responsible for the specific patient who signs the Informed Consent Form during the study.

1. What is the purpose of this document?

This form provides you with information about the biomedical study, explains why the study is being done, the scientific procedures, benefits, risks, possible inconveniences and other important information. If you decide to participate, we will ask you to sign this consent form, by which you agree to follow the instructions of the treating investigator and the study team during the study. By signing this document, you agree to participate in the scientific study. Do not rush — read this document carefully. If you do not understand any word or statement, be sure to ask the study doctor or other study team members any questions you have. Before deciding, you may consult family members, friends or your physician.

2. Why are biomedical studies conducted?

It is important to understand that although health checks or medical procedures will be performed on you during a biomedical study, a biomedical study is fundamentally different

from routine (everyday) clinical practice. The aim of routine clinical practice is to treat you (i.e., a specific person, patient) and/or improve your health condition. The primary aim of a biomedical (scientific) study is to obtain new medical scientific knowledge that may help future patients with the same condition. In other words, the primary aim of this study is not direct benefit to your health.

3. Why is this study being done?

Tooth extraction and implantation are very common interventions. One treatment option is immediate placement of dental implants, when the implant is inserted immediately into the extracted tooth site during the same visit. After implantation, depending on the early primary stability obtained, different types of provisional prostheses may be attached to the implant. This allows faster treatment and better subsequent prosthetic results. Modern implants all show very good osseointegration and long-term function, but different implants may produce different early stability, which is important for further osseointegration. Currently there is no clear evidence about what early implant stability and what type of provisional prosthesis yield the best results. Therefore, this study aims to investigate how early implant stability and the type of provisional prosthesis influence implant osseointegration success.

4. Who is chosen to participate in this study?

We invite you to participate because you have posterior teeth in the upper or lower jaws that need extraction for various reasons and you meet the main inclusion criteria listed below. Main inclusion criteria for this study are: age ≥ 18 years; healthy patients without medical contraindications for dental implant surgery; posterior and premolar teeth to be extracted in both jaws; healthy soft tissues (bleeding on probing [BOP] < 20%, plaque index [PI] < 25%); signed informed consent and permission to use collected data for research purposes.

5. Who conducts / sponsors this biomedical study?

The sponsor of this biomedical study is UAB Vilniaus mokslo grupė. The needed funds for this study will be provided by UAB Vilniaus mokslo grupė; materials will be provided free of charge by the company Megagen Baltics.

6. Probability of being assigned to different study groups and characteristics of participation in those groups

Participants in this study will be divided into three groups and, depending on the primary implant stability, will receive one of three treatment options:

1. If stability is low (5–10 N/cm), Megagen BlueDiamond implants will be placed, no provisional prosthesis will be attached, and the implant site will be sutured with a non-resorbable membrane;

2. If stability is medium (15–35 N/cm), Megagen BlueDiamond implants will be placed and an individual plastic healing abutment (gum-forming healing cap) will be used;

3. If stability is high (40 N/cm and above), Megagen BlueDiamond implants will be placed and a temporary plastic tooth will be provided.

Group assignment primarily depends on the implant's early stability, which depends on your individual bone characteristics that become clear after tooth extraction.

7. How long will your participation in this study last?

Total study duration — 18 months.

Planned 5 visits to the study center:

- Tooth extraction, implantation, provisional prosthesis placement: 1 hr 15 min

- After 1 week — suture removal: 10 min

- After 2 months of healing — scanning for prosthesis fabrication, ISQ measurement: 45 min

- After 1 week — prosthesis delivery, soft tissue measurements: 45 min

- After 1 year — follow-up visit: 30 min

8. In which countries will this study be conducted?

The study will be conducted in one country — Lithuania.

9. How many subjects are expected to participate in this study?

It is expected that 90 people will participate in this study, for whom 90 teeth will be extracted and 90 dental implants placed immediately.

10. What will you need to do?

Your treatment will differ from routine care in that more measurements than usual will be taken and the overall treatment will be shorter than standard because you will receive immediate implant placement, which shortens the entire treatment by about 4–6 months.

We will ask your permission to non-invasively measure, for research purposes: implant insertion torque, implant stability quotient (ISQ), implant insertion depth and horizontal position; to examine the condition of soft tissues around the implants, implant osseointegration; to record the position of the tooth being implanted, the implant manufacturer, implant diameter and length; to scan the implant site; to record fixed gingiva measurements, implant prosthesis type and materials; peri-implant parameters of the prosthetically restored implant — bleeding on probing (BOP), probing pocket depth (PPD), plaque index (PI); and to take radiographs.

11. Will participation be beneficial to you? / What benefits can you expect from participating in this study?

Participants will receive modern, scientifically based treatment. An additional benefit is that you will receive immediate implantation so treatment will be completed earlier than standard delayed protocols. Immediate implantation (right after tooth extraction) is less common because it requires more knowledge and experience than delayed implantation (where after extraction one waits 4–6 months for soft tissue and bone healing before placing the implant). As a result, you will receive high-quality, faster treatment. There will be no financial benefit.

12. What risks and inconveniences are associated with participation in this study?

By participating you may experience inconveniences such as time spent traveling to the study site or completing study questionnaires. Study procedures may cause minor unpleasant sensations. Due to unforeseen circumstances, confidential information could become accessible to third parties without your consent.

Possible complications and inconveniences include:

- < 0 Ncm insertion torque — no fixation in bone. If a healing abutment is attached to such an implant and is disturbed by the tongue or chewing, the implant may be mobile during healing, increasing the risk of implant failure. When placing any dental implant there is always a possibility of weak fixation. With zero stability the implant will not be placed; the extraction socket will be left to heal and delayed implantation will be performed after 3 months.

- < 45 ISQ value after healing — indicates insufficient bone integration; clinically the implant would be either removed or left for longer healing depending on the situation.

- implant mobility at any stage — indicates poor bone healing; such an implant would be removed and re-implanted after 3 months of healing.

- infection at the implant site — the implant would be removed and the infection treated.

- postoperative pain, swelling, bleeding — common to all surgeries, usually controllable with analgesics and pressure dressings.

- injury to the inferior alveolar nerve from instruments or implant — to avoid this, cone beam CT is performed preoperatively and it is ensured that at least 2 mm safe distance to the nerve remains after implant placement. If nerve injury occurs the implant would be removed as soon as possible — full nerve recovery is expected in such cases.

- implant failure to osseointegrate — a rare complication.

- allergic reactions.

13. If something goes wrong? (Information about insurance)

You have the right to compensation for material and non-material damage to health suffered while participating in this study.

Interventional treatments used in this biomedical study may cause only minor temporary adverse effects on your health; therefore, if you suffer material or non-material damage to health as a result of participating, it will be compensated in accordance with the Law on Patients' Rights and Compensation for Damage to Health from funds accumulated in the account managed by the State Health Insurance Fund under the Ministry of Health, where health care institution contributions for compensation of patient health damage are collected.

You can review the insurance rules at the study site by asking the study doctor. If you believe you have suffered harm during the study, contact the study doctor.

14. What options do you have if you refuse to participate or withdraw consent?

Participation is voluntary; you have the right to refuse, and if you start you may withdraw at any time. Your decision to refuse or stop participating will not affect the routine health care you receive.

If you decide not to participate, the doctor will prescribe standard disease treatment, taking into account all relevant circumstances — your age, comorbidities, general health, etc.

All implants and surface combinations used in the study are used in routine practice. The investigator will discuss the benefits and risks of all available options with you.

15. Can you stop participating in the study?

If you decide to withdraw before the study ends, the investigator will provide and ask you to sign a free-form withdrawal request or fill in a withdrawal form. Before deciding to stop participating, please consult the investigator. You have the right to refuse further use of your health information collected for research purposes.

If you become unable to decide due to deteriorated health, your wish to withdraw will be respected, but legally this decision will be made by your spouse, or if none — one of your parents, adult children, guardian or custodian.

If you wish to continue treatment but not participate in the study, the necessary equivalent treatment procedures will be provided; implant treatment itself is standard. You will not incur additional financial consequences if you withdraw consent. After withdrawing and completing treatment under standard conditions, you are not required to continue care at the clinic where the clinical study was conducted.

16. Circumstances and criteria for termination of your participation

The study doctor or sponsor may stop the study or your participation at any time if you do not follow the investigator's instructions or if your health substantially worsens during participation. Complications may also cause inconveniences.

17. Will you incur any costs by participating in this study?

Participants are not paid for participation in biomedical studies. Study subjects will receive high-quality, scientifically based implant treatment.

18. Will your personal data be confidential?

Health information obtained during the biomedical study that can identify you is confidential and may be provided only in accordance with the General Data Protection Regulation, the Law on Patients' Rights and Compensation for Damage to Health of the Republic of Lithuania, and

other laws regulating personal data processing. The data controller is UAB Vilniaus mokslo grupė, company code: 300155110, address: Kęstučio 9-12, Vilnius.

To protect confidentiality you will be assigned a special code which will be used on all documents except the consent form. The list linking your name to the code will be kept in a safe to which only the principal investigator has access. Computers storing radiographs are password protected. Login codes are known only to investigators and are updated monthly.

The following categories of data will be collected (non-exhaustive list):

1. Identification data (name, surname, date of birth)

2. Contact details (address, phone, email)

3. Health data (position of the implanted tooth, implant manufacturer, implant diameter and length, insertion torque, ISQ values, fixed gingiva measurements, implant depth and horizontal position, implant prosthesis type and materials, peri-implant parameters PI, BOP, PPD indices)

4. Digital images (radiographs, scans of the implant site)

Identification and contact data will be collected from the outpatient medical record; health data — from study measurements; digital images — from radiographs and oral scans.

Health information obtained in this study is not considered confidential and may be published without your consent if you cannot be directly or indirectly identified from the published data.

19. Who and for what purpose will be able to access your personal data?

During the study we will process your personal data to evaluate the performance of the tested dental implant, ensure data reliability and participant safety. The sponsor must process your personal data for scientific research purposes; your consent is the lawful basis for processing. You may withdraw this consent at any time without giving reasons. After withdrawal your data will no longer be collected.

This study will collect and process your personal data, including health data. Types of personal data:

1) Identifying personal data — information allowing direct identification (e.g., name, birth date)

2) Pseudonymised data — identifying information replaced by a code (e.g., a number)

3) Anonymous data — information that no longer allows identification

By signing this form you agree that investigators and oversight institutions (e.g., State Medicines Control Agency, ethics committees) may access all information collected about you for the purposes of this study. Insurer representatives may also review your data if you apply for compensation for harm arising from study participation. All such persons must maintain full confidentiality.

Access to identifying personal data will be limited to investigators and other persons working at the study center or providing your health care. Sponsor-authorized representatives and competent authorities of Lithuania and/or foreign countries, and representatives of Lithuanian research ethics committees may inspect these data if necessary for study oversight. All persons with access must observe confidentiality under national data protection laws and the GDPR.

Other persons or companies will receive only coded health data that do not allow direct identification. “Coded” means documents will show a special number instead of your name; only the study doctor can link this number to you. The code list will always be kept at the study center so those who do not know the code cannot identify you.

Collected data will be used by study doctors only for this clinical trial.

You have the right to know what data were collected and to request correction of incorrect, incomplete or inaccurate personal data. If you withdraw from the study before its scheduled end, researchers will stop collecting new information about you and will destroy previously collected data.

Upon receiving a request to withdraw informed consent, the following steps are taken:

1. Verify requester identity and record request date

2. Initial assessment — determine which data the request covers (coded, anonymous, radiographs, etc.) and evaluate reasons if provided; the subject may decline to give reasons

3. Decision — the investigator immediately stops further data collection and study procedures for that person and informs the requester that accumulated data will be deleted

4. The person is informed when all data have been deleted

20. Will data be transferred outside the EU?

Data will not be transferred to third countries outside the EU.

21. How long will data collected during the study be kept and who is responsible?

All information will be recorded in electronic and paper documents created specifically for this clinical trial and stored at the study center for 15 years after study completion. This retention period is required by law to ensure data quality and control. Afterwards your personal data will be destroyed according to the study center's procedures. The principal investigator is responsible for document storage at the study center.

22. Who reviewed this biomedical/clinical study? / Whom to contact in case of questions?

For questions about your rights as a study participant you may contact the Vilnius Regional Biomedical Research Ethics Committee, M. K. Čiurlionio g. 21/27 (office 228), LT-03101 Vilnius, tel. (8-5) 2686998, email: rbtek@mf.vu.lt.

If you have questions about processing of your personal data, contact the investigator. The investigator may forward your query to the person responsible for data protection (data protection officer).

Data protection officers of institutions conducting this biomedical study:

Study center Data Protection Officer: Aivaras Gilys

Phone: +37061297926

Email: a.gilys@cortexlegal.lt

Workplace address: Konstitucijos per. 21A, LT-09306, Vilnius

You have the right to file a complaint about personal data processing with the State Data Protection Inspectorate. Complaints can be sent by mail (L. Sapiegos g. 17, 10312 Vilnius) or via the Inspectorate's electronic services: /go.php/lit/Prisijungti/37L. Inspectorate contact phone: (8-5) 212 7532, email: ada@ada.lt.

Other important information that may influence your decision to participate in the biomedical study

CONSENT TO PARTICIPATE IN THE BIOMEDICAL STUDY

I have read this Informed Consent Form and understood the information provided to me.

I was given the opportunity to ask questions and received satisfactory answers.

I understand that I can withdraw from the study at any time without giving reasons2.

I understand that to withdraw my consent to participate in the biomedical study I must inform the investigator/another authorized study person in writing.

I confirm that I had sufficient time to consider the information provided about the biomedical study.

I understand that participation in this study is voluntary.

I confirm that I give consent to participate in this biomedical study of my own free will.

I allow the use of my personal data to the extent and in the manner described in the Informed Consent Form.

I confirm that I received a copy of the Informed Consent Form signed by the investigator/another authorized study person.

If consent is given by the subject:

Subject

Name: _____ Surname: _____

Signature: _____ Date: _____ Time: _____

I confirm that the subject (or another person authorized to give consent) was given adequate time to decide on participation in the biomedical study, taking into account the nature of the study and other circumstances that could affect the decision. I encouraged the person (or other authorized person) to ask questions and answered them.

Investigator or other authorized study person

Name: _____ Surname: _____

Position in study: _____ Signature: _____

Date: _____ Time: _____

2 If the person gives consent themselves