

Marginal bone loss around the implant of screw-
retained implant restorations in the esthetic zone using
PEEK with composite veneering versus monolithic
zirconia restorations using a fully digital workflow: A
Randomized Controlled Clinical Trial

Protocol submitted to
Faculty of Dentistry, Cairo University
for partial fulfillment of the requirements for the master's
degree in Prosthodontics

By

Heba Hossam Abd El Fattah Ahmed

Faculty of Dentistry, MSA University in Egypt

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code

PROSTH

Supervisors' signature

Head of department's signature

Date:

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Name		Signature	Date	
1.				
2.				
<u>Research plan committee</u>				

Name	Signature	Date
1.		
2.		

I Administrative information:

1. Title:

Marginal bone loss around the implant of screw-retained implant restorations in the esthetic zone using PEEK with composite veneering versus monolithic zirconia restorations using a fully digital workflow: A Randomized Controlled Clinical Trial

2. Protocol Registration:

Study was registered on <https://clinicaltrials.gov/>

Unique Protocol ID:	
ClinicalTrials.gov ID	
Brief Title:	
Overall Status:	
Primary Completion Date:	
Verification Date:	

3. Protocol version:

First version.... protocol no.1

4. Funding:

This trial is self-funded by Heba Hossam Abd El Fattah (principal investigator).

5. Roles and responsibilities:

5.a Role of protocol contributors:

1. Dr. Azza Farahat. “Main Supervisor”.

Professor of Prosthodontics Faculty of Dentistry, Cairo University. Main Supervisor, outcome assessor, responsible for randomization process, sequence generation and allocation concealment, **analysis of the collected data**, data monitoring, reviewing the thesis and drawing conclusions

2. Dr. Mostafa Saeed “Assistant-Supervisor”

Lecturer of Prosthodontics, Faculty of dentistry- Cairo University. Co-supervisor, Guidance during the surgical part, **analysis of the collected data**, proofreading of the thesis and drawing conclusions.

3- Heba Hossam Abd El Fattah. “Principal Investigator”

Bachelor’s degree of Dentistry – MSA University in Egypt

Master’s degree student in Prosthodontics, Faculty of Dentistry, Cairo University. The main investigator will be responsible for funding the study, clinical part of the study, screening and recruitment of samples, follow up with the patients, writing the thesis, interpreting results and drawing conclusions.

5b. Trial Sponsor:

RCT Sponsor:

Faculty of Dentistry, Cairo University.

Address: 11 Al Sarai Street, Al Manial, Cairo, Egypt

Telephone: 23634965 - 23642938

Website address: www.dentistry.cu.edu.eg

5c. Role of study sponsors and funders:

The study will occur in the Department of Prosthodontics' digital laboratory, Faculty of Dentistry Cairo University, and is self-funded **with no external influence** on the study design or conduct, data collection, analysis or even data interpretation.

5d: Role of steering committee

- Department of Prosthodontics. Faculty of Dentistry. Cairo University is responsible for ensuring that the research idea follows the research plan of the department.

Prosthodontic research committee:

- Revising scientific data and approval of the protocol

Centre of evidence-based dentistry, Cairo university CEBD-CU committee/ Faculty of Dentistry, Cairo University

- Evidence- based committee / faculty of dentistry -Cairo university is responsible for protocol revision, reporting the methodology and the statistical method

Ethical committee - Faculty of dentistry - Cairo University:

- Responsible for approving that the research fulfills the required ethical criteria
- The Faculty and University Board approves the protocol once it is approved by the previously mentioned board and committees.

II. Introduction:

6. Background and rationale:

6a. Research question:

Is PEEK with composite veneer restoration superior to monolithic zirconia on decreasing the marginal bone loss around the implant site of screw retained implant restorations in the aesthetic zone?

Statement of the problem:

The dogma of the aesthetic effect of using different types of screw retained restorations supported on implants and how it affects the bony changes around implants and implants' survival rate in partially edentulous patients.

Rationale for conducting the research:

The research will be conducted to report the gold standard of which type of screw-retained fixed restorations on dental implants that can be successful and aids in decreasing the marginal bone loss around the implant sites and how it affects the bony changes around the implants installed in maxillary arches for partially edentulous patients in the aesthetic zone or whether there are specific precautions to be taken into consideration during implant planning concerned with the type of restorations to enhance the aesthetics and recommendations needed. Also, to recommend further research on this topic, more RCTs and the need to conduct a systematic review.

Review of literature:

- Partial edentulism (PE) is increasing among subjects worldwide, yet it is a multifactorial problem impairing speech, mastication and appearance affecting the patients' quality of life. This may affect patients' satisfaction and quality of life which made most of clinicians present different treatment modalities to decrease this phenomenon¹.
- Various prosthetic approaches have been introduced to enhance the quality of life for PE patients ranging from conventional Partial denture (PD) to Implant retained fixed restorations. Conventional

PDs have the advantage of being cheaper and easily constructed and maintained providing sufficient retention and stability³. However, biomechanics for a successful denture mainly depends on the conditions of abutments, favorable arch form, size and shape. Yet, the compressibility of the soft tissue and gingival biotype thickness can be an important factor offering a keratinized protection over the bone and reduces pain and discomfort for most patients. If the mentioned factors can be favorable, PDs can be considered a successful treatment modality and claimed to improve the quality of life¹.

- In the anterior region, especially in the maxilla, the use of dental implants can be a mechanical means for retaining PDs, improving the aesthetics and decreasing the bone loss over time beneath the prosthesis²
- . The use of implant- supported prosthesis (ISP) has had a great breakthrough in the last decades, retaining fixed restorations. However, still the patient's financial considerations are a major factor in selecting this prosthetic option and the choice of different types of restorations that aids in better aesthetics and decreased marginal bone loss around implants can be quite challenging. This has improved retention and stability of the prosthesis preserving the bone level and soft tissue. Osseointegration of dental implants is a significant key of success which resembles the direct structural and functional contact between bone and implant's surface by developing stable and asymptomatic fixation of an alloplastic material in the bone and maintaining such fixation during function².
- To improve such a process, especially in edentulous areas with high aesthetic concern, various modifications to restorations over dental implants have been innovated in the last few decades. It has been claimed that PEEK has an elastic modulus similar bone and is, thus, believed to avoid high-stress transfer at the bone-implant interface as well as reduce the stress shielding effect on the bone.
Thus, led to the proposition of using both PEEK and PEKK as an alternative for zirconia³.

- Various types of dental materials are used as fixed restorations including different types of ceramic restorations. Zirconia-based restorations have attained popularity because of their high aesthetic potential and great biocompatibility. Zirconium dioxide has been a satisfactory material for implant-supported restoration for the last 10 years, but the most common failure is chipping of veneering porcelain^{3,4}. One of the main advantages of using different types of fixed restorations over implants is the stress distributions in complex geometries such as implant-bone interfaces. Thus, the aim of the present study was to evaluate stress distribution at the peripheral bone (cortical and cancellous) and implant-abutment interface with different crown materials⁴.
- Several objective methods for the in-vivo assessment of bony changes around the implants are required at baseline of implant installation and after osseointegration especially at the crestal module of the implant bed. Radiographic assessment using long paralleling technique periapical x-ray, digital sensors can be a valid and reliable tool for bone assessment around the implants.

6b. Explanation for choice of comparators:

The comparator of this study will be the Monolithic Zirconia Restorations to be compared with the PEEK with composite- veneered restorations. This choice was based on the available articles and clinical trials made in the past few years concerned with bony changes around implants. Moreover, this is the most used by all the practitioners worldwide.

7. Objectives (Aim of the study):

The aim of the study is to evaluate the effect of changing the screw retained restorations with PEEK veneered by composite versus monolithic zirconia in bone changes and the survival rate of implant after placement procedure in the aesthetic zone.

The Null Hypothesis:

There is no difference between PEEK with composite veneer and monolithic zirconia in decreasing the marginal bone loss when the 2 are used as screw retained restorations over an implant that is placed in the aesthetic zone.

Primary Objective:

PICO:

- **Problem (P):** Partially edentulous patients with missing teeth in the maxillary aesthetic region.
- **Intervention (I):** Peek with composite-veneer (Visio.lign) screw retained restorations
- **Control Group (C):** Monolithic zirconia Screw retained restorations
- **Outcome (O):** Bony changes (Marginal bone loss)

Secondary objective:

-Evaluating the survival rate of different types of screw retained restorations over implants when using a peek with visiolign veneer versus monolithic zirconia restorations.

8. Trial design:

- Randomized Clinical Trial
- Two arms parallel groups
- Superiority trial
- 1: 1 Allocation ratio.

III. Methods:

A) Participants, interventions & outcomes

9. Study settings:

The patients will be selected from the outpatient clinic of the Department of Prosthodontics, Faculty of Dentistry, Cairo University, Cairo, Egypt.

10. Eligibility criteria:

Inclusion Criteria for participants:

- Partially Edentulous Patients with missing teeth in the maxillary aesthetic zone scheduled for screw retained restorations
- Age ranges between 20- 50 years.
- Free from any systemic disease that might compromise wound healing
- Angle's Class I skeletal maxillary-mandibular relationship
- Normal facial symmetry

Exclusion Criteria for participants:

- Patients with TMD problems
- Heavy Smoking
- Patients with anterior bone loss
- Flabby tissues or sharp residual ridge.
- Patients with neuromuscular disorders

11. Interventions

11a: Diagnosis:

-The diagnostic data will be collected by the principal investigator and confirmed for eligibility with the co- supervisor.

Patients of both groups will be subjected to:

1. Case history includes personal data, medical, dental and family history.
2. Clinical Examination.
3. Digital Intraoral Scans

Intervention:

Each participant will receive 2 implants installed in the aesthetic areas of maxillary arch prosthetically driven with the aid of digitally constructed surgical guides. Investigator and co- supervisor will load the provisional restorations after implant insertion and during the healing phase. Final restorations as a fixed partial denture will be inserted after 3 months

from the loading procedure. Marginal bone level around the implants will be measured at 0, 6, 12 months using long-cone paralleling technique using digital periapical radiographs. The periapical radiographs were obtained using parallel technique. A customized occlusal bite index will be fabricated by attaching an acrylic bite block made of hard acrylic to a film holder.

Standardized periapical radiographs will be taken preoperatively, immediately after placement of the implants and six months later during the second stage operation in both groups. The index will be saved for use at all visits to standardize film placement and cone angulation. A single examiner will perform radiographic interpretation and measurements⁷.

11b. Criteria for Discontinuing or Modifying Intervention:

- Severe implant-related complications (pain, infection, mobility, etc.)
- Patient death

11c. Strategies to improve adherence to intervention:

- Patients will be recalled 3,7 and 30 days after surgery to evaluate pain and healing process around
- Provide expensive treatment option (implants) to the patients for free
- Preoperative scaling and root planing is done to motivate the patients.

12. Outcomes:

	Outcome	Measuring device	Measuring unit
Primary outcome	Bone loss	Digital Subtraction Radiography (Parallel technique)	Numerical Scale
Secondary outcome	Survival Rate	Clinical examination	Binary (YES/NO)

Primary outcome:

Marginal Bone Loss

The Marginal Bone height level of both interventions and comparators will be radiographically assessed digitally by DIGORA (digital intraoral radiography systems that automatically adjust the gray levels of the image to enhance diagnostic quality), This offers consistent results and eliminates accidental over- or underexposures without having to change exposure settings for each patient. Using a long paralleling technique in millimeters, the marginal bone height level will be measured from two aspects of the implants mesial and distal areas of the marginal bone level. All data will be collected and sent to the statistician for the analysis required in mean difference and standard deviation.

13. Participant timeline

A schematic diagnostic chart for every patient showing demographic data, our justified treatment option and info concerned with the readings of the DIGORA imaging system device for every participant.

Time point	T ₀	T ₁ (Surgical phase)	T ₂ (one week after T ₁)	T ₃ (3 months after T ₁)	T ₄ (6 months after T ₁)	T ₅ (1year after T ₁)
Enrolment & Eligibility screen	✓					
Initial phase (Scans & allocation)	✓					
Surgical phase (implant placing)		✓				
Post operative care			✓			
Prosthetic phase				✓		
Outcome assessment					✓	✓

14. Sample size:

As reported in a previous publication, the estimated sample size: 48 implants with increasing the number by 15% to compensate for dropouts, so it becomes 56 implants.

15. Recruitment:

Patient seeking treatment in the Outpatient clinics of the Department of Prosthodontics, Faculty of Dentistry, Cairo University, Cairo, Egypt. Internship doctors from the diagnosis section will be notified to contact the principal investigator to collect the data concerned with the recruited patients in this study. Recruitment will be done by the principal investigator under the supervision of the main supervisor and co- supervisor.

B) Assignment of interventions:

16. Allocation:

16a. Sequence Generation:

- A random sequence will be generated by computer software (<http://www.random.org/>) in the Center of Evidence-Based Dentistry, Cairo University).
- Patients will be randomized into two groups with an allocation ratio of 1:1.

16b. Allocation concealment mechanism:

The randomization table will be kept with and only accessed by the main supervisor.

Numbered papers will be packed in opaque envelopes to be dragged by the patients.

16c. Implementation:

The randomization table will be kept with and only accessed by the main supervisor.

Numbered papers will be packed in opaque envelopes to be dragged by the patients.

17. Masking/blinding:

- This trial will be double blinded as the patients, and the outcome assessor will be blinded. The principal investigator and the co-supervisor cannot be blinded as the trial will include installation of two types of dental implants restorations with known surface texture.
- The final appearance of the restorations attached to implants will be the same according to the patients so that they will not be able to recognize which is the intervention and which is the comparator.

C) Data collection, management, and analysis:

18. Data collection:

- The phone numbers and address of the patient included in the study will be recorded from them or extracted from the patient's file.
- All records for the outcome measures for the records and follow-up assessment recordings will be collected and prepared in Excel spreadsheets by the principal investigator and saved on her personal laptop.

19. Data management:

- All data will be entered and saved electronically.
- Patient files are to be stored in numerical order and stored in secured files. Data will be encrypted using a password.
- All data will be maintained after completion of the study
- Reminding each participant for their follow-up periods and reaching them through their phone numbers.
- All data recordings will be sent to the statistician immediately at each interval of the follow-up which is immediately after implant placement, after 6 months, and 12 months.

20. Statistical methods:

- Numerical data will be described as mean and standard deviation or median and range. Data will be explored for normality using the Kolmogorov-Smirnov test and Shapiro-Wilk test.
- Comparisons between 2 groups of normally distributed numeric variables will be made using the independent T test and inside the 2 groups by paired t test while for non-normally distributed numeric variables will be done by Kruskal Wallis test.
- A p-value less than or equal to 0.05 will be considered statistically significant. All tests will be two tailed.

D) Data monitoring:

21. Monitoring

All data will be monitored by the data monitoring committee as mentioned and will be holding the duties for assessing the outcomes and trial discontinuation.

22. Harms

Harms expected would be loss of osseointegration and failure of implants. This complication will be addressed by making radiographic evaluation required at the follow-up intervals assessing the amount of bone around implants, signs of inflammation and any radiolucency reported around the implants. Failure of implants can be treated by mechanical debridement and irrigation by saline and citric acid for the implant bed and installing new implants.

23. Audit

Auditing will be done by the co supervisor and CEBD-CU committee.

IV. Ethics and dissemination:

24. Research ethics approval

This protocol and the template informed consent form will be reviewed by the Ethics Committee of Scientific Research -Faculty of dentistry Cairo University.

25. Protocol amendments

Any modifications to the protocol which may have an impact on the conduct of the study, potential benefit of the patient or may affect patient safety, including changes of study objectives, study design, sample sizes, study procedures, or significant administrative aspects will require a formal amendment to the protocol. Such an amendment will be agreed upon by the Council of Prosthodontics Department.

26. Informed consent

Researcher will introduce the trial to patients and provide a full explanation of its aim and benefits in plain language. Patients will then be able to have an informed discussion with the researcher. Researcher will obtain written consent from patients willing to participate in the trial. All consent forms have been translated into Arabic.

27. Confidentiality

All study-related information will be put in safekeeping. All participants' information will be stored in locked file cabinets. All records that contain names or other personal identifiers will be stored separately from study records identified by code number.

28. Declaration of interest

If there is any conflict of interest it will be declared.

29. Access to data

The principal investigator and the supervisors will be given access to the data sets. All data sets will be protected by passwords. To ensure confidentiality, data dispersed to project team members will be blinded to any identifying participant information. After completing the trial, it will be submitted to the Prosthodontics department at Cairo University for thesis discussion and publishing.

30. Post-trial care

All patients will be followed up for one year after the clinical trial is over. All Patients will be recalled at the time intervals for the follow up periods and instructed on regular maintenance for their prosthesis.

31. Dissemination policy:

This protocol will be revised by CEBD-CU then registered on clinicaltrials.gov. The trial will be described and written in a thesis form to be revised by the supervisors then submitted to the prosthodontic department to seek their approval. After the thesis's approval the trial will be ready to be published internationally.

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