

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**

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**B.D.S (2019)**

code

PROSTH

Date: 4/29/2025

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**Human Subjects Application Form**

**Kindly fulfill the following:**

***Research 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***

***Full name of the researcher(s): Heba Hossam Abd Elfattah Ahmed***

***Affiliation of the researcher(s): Prosthodontics department***

***Category of study: Master [✓] PHD/D [ ] Others [ ]***

***Type of study design: Randomized controlled clinical trial***

***Objective of the research: 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***

***Steps of the research in short, including the following:***

- *The inclusion and exclusion criteria for patient selection.*

**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

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- Heavy Smoking
  - Patients with anterior bone loss
  - Flabby tissues or sharp residual ridge.
  - Patients with neuromuscular disorders
- 
- *Mention the source of the patients enrolled in the research.*

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

- *Mention the settings with the place where the research will be conducted.*

*Faculty of Dentistry, Cairo University.  
Address: 11 Al Sarai Street, Al Manial, Cairo, Egypt*

- *In case of a patient below the age of 21 years old, a verbal assent from the participant and a written informed consent form will be signed from his/her parents/ guardian is required. (Not applicable)*
- *Description of the methodology:*

*The patients will be selected from the out-patient clinic of the Department of Prosthodontics, Faculty of Dentistry, Cairo University, Cairo, Egypt.*

*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.*

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*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 paralleling technique periapical digital x-ray. 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 measurements.*

*11b. Criteria for Discontinuing or Modifying Intervention:*

- Severe implant-related complications/ side effects (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 planning is done to motivate the patients.*

*12. Outcomes:*

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|                   | 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.*

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

- *Sample size calculation:* the estimated sample size: 48 implants with increasing the number by 15% to compensate for dropouts, so it becomes 56 implants.
- *Randomization in case of RCT:* 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.
- *Number of visits & follow up period:* Marginal bone level around the implants will be measured at 0,6,12 months using long paralleling technique periapical

**Direct benefit of the research to the human volunteer:** Replacement of the missing teeth with a fixed treatment option without need of teeth reduction.

**The scientific interest and the desired public benefit of the research:** Discover the best prosthetic option retained by implants in decreasing the amount of bone loss around the implant side.

**Side effects and the degree of risk and expected to occur and how to deal with them:**

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*Side effects related to implants e.g. Pain, infection and mobility leads to failure*

*Above minimal risk*

*Pain: Analgesics will be prescribed for the patient immediately after the surgery. Mainly related to the patient threshold but can be avoided by proper surgical procedures with continuous irrigation and pain control measures.*

*Infection: The infection can be avoided by prescribing antibiotics after the surgery and maintaining good oral hygiene measures ex using antibacterial mouthwash the day after surgery. If an infection is found, the investigator will irrigate the surgical site and follow-up will be required for 2 weeks, also curettage can be done. Post surgical Instructions should be maintained until complete healing occurs.*

*Implant mobility: If the implant is mobile due to high load from the opposing teeth causing implant failure, whether to remove the implant the waiting for healing and formation of new bone then reimplantation procedure can be done or consider the failing implant as a sleeping implant to avoid any unneeded surgical procedure. It can be avoided by proper case selection and treatment planning to avoid any heavy contact on the implant side.*

*Inflammation: Anti-inflammatory drugs prescribed for the patient with a cold compress for 15:20 mins on the outside near the implant site to reduce swelling. Avoid any irritants ex. Spicy food & smoking.*

*Bleeding: Can be avoided by proper case selection and medical history to avoid unusual bleeding. We can control it by Applying Pressure:*

*Use a Clean Cloth or Gauze: Place a clean cloth or gauze pad directly on the bleeding site & bite down gently but firmly for about 30 minutes to apply pressure and help stop the bleeding.*

*Do Not Rinse or Spit: Avoid rinsing your mouth or spitting, as this can dislodge the clot and worsen bleeding. Cold Compress: Apply an ice pack to the outside of your cheek near the implant site for 15-20 minutes to help constrict blood vessels and reduce swelling. Monitor the bleeding to check the severity: If the bleeding does not stop after 30 minutes of applying pressure or if it worsens, contact the investigator or go to the nearest emergency room.*

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*Oral Health Care Instructions After Dental Implant Surgery*

*Oral Hygiene:*

*Tooth Brushing: Use a soft-bristled toothbrush to clean your teeth twice a day. Be sure to gently clean around the implant area.*

*Dental Floss: Use dental floss regularly to remove food debris between teeth and implants.*

*Avoid Certain Foods:*

*Hard Foods: Avoid hard or sticky foods during the first few weeks after the implant.*

*Hot Foods: Stay away from very hot foods and beverages to prevent irritation.*

*Follow-Up:*

*Regular Appointments: Make sure to regularly monitor the condition of the implant.*

*-Report Any Issues: If the candidate experiences any pain or swelling, inform the investigator immediately.*

*Avoid Smoking*

*Quit Smoking: Smoking can negatively affect the healing process. Try to quit or reduce smoking.*

*Take Prescribed Medications:*

*Pain Relievers and Antibiotics: Follow doctor's instructions regarding the use of prescribed medications to reduce pain and prevent infection.*

*Rest and Recovery*

*Avoid Physical Strain: Try to rest and avoid strenuous physical activities during the recovery period.*

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*Use Mouthwash:*

*Antibacterial Mouthwash: Use an antibacterial mouthwash as recommended by your dentist to help maintain oral cleanliness.*

*Proper Nutrition:*

*Healthy Foods: Ensure you consume foods rich in vitamins and minerals to promote healing.*

*Monitor Symptoms:*

*Watch for Changes: Be aware of any changes in your condition, such as bleeding or swelling, and inform the investigator if anything unusual occurs.*

***Patient's full knowledge of the research steps: Reading [✓] Oral explanation [✓] Other [ ]***

1. I have carefully reviewed and understood the purpose of conducting the research and the nature of this study, and I understand what is necessary to accomplish these procedures.
2. The researcher has informed me of the possible therapeutic alternatives for this research.
3. The researcher has informed me of all the possible risks of this research and how to deal with it.
4. I agree to the imaging, recording, and all types of radiology to be performed in this study, on condition of anonymity.
5. I have made an accurate report on my health history and informed the doctor of all kinds of health reactions or unusual allergies to medicines, food, insect bites, anesthetics, dust or any reactions that have occurred to me from any other substances, abnormal bleeding or any other related conditions for my health.
6. I acknowledge that I am not involved in any other research from the beginning of this research until the end of this research and that I will inform the researcher if I enter any other research throughout the period of this research.
7. I undertake to return the medical devices (instruments) used in the research in case of discontinuation or when the research is completed.

***After knowing the available information related to the research, the volunteer or the person in charge will be able to choose freely whether or not to subscribe. In case of approval, kindly fill out the data shown. The volunteer has the right to withdraw from the research without giving reasons anytime.***

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*The researcher in charge of the research undertakes to keep the information of the volunteer person confidential by participating in the research, stating the methods used, such as replacing names with code numbers or hiding facial features when photographing (etc.).*

**Signature:**

**Date:**

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