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"PEEK versus Titanium Customized Healing Abutments: Evaluation of Peri-implant Soft Tissues and Sulcus Fluid Bacterial Load"

(A randomized Controlled clinical study)

Thesis Protocol
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By

Samar Fawki Fakhr El Din El Desouki

Master's degree student in the Department of Oral Medicine, Periodontology & Oral Diagnosis, Faculty of Dentistry, Ain Shams University.

BDS 2017

(Faculty of Dentistry, MSA University)

SamarFakhrEldin@dent.asu.edu.eg

Under the Supervision of:

Associate Prof. Dr. Ahmed El Sayed Hamed Amr

Associate Professor of Oral Medicine, Periodontology and Oral diagnosis Faculty of Dentistry, Ain-Shams University

Dr. Hadeel Gamal Salem Al Malahy

Lecturer of Oral Medicine, Periodontology and Oral Diagnosis Faculty of Dentistry, Ain Shams University Faculty of Dentistry

Associate Prof. Dr.Nashwa El-Khazragy

Assistant professor of clinical pathology/Hematology Faculty of Medicine, Ain Shams University

Ain Shams University
Faculty of Dentistry
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I-Abstract

Statement of problem: Polyetheretherketone (PEEK) is a polymer that has many potential uses in dentistry because of esthetic and biologic reasons for maintaining the health of peri-implant soft tissues during healing. Polyetheretherketone (PEEK) healing abutments have superior properties such as biocompatibility, inert chemical properties, white color, and decreased liability for biofilm accumulation.

Aim of the study: This study will be carried out to compare two different materials, Polyetheretherketone (PEEK) vs Titanium (Ti) used to fabricate customized healing abutments placed simultaneously with a guided delayed dental implant.

Materials and Methods: This will involve a clinical assessment of peri-implant soft tissue changes. Moreover, peri-implant sulcus fluid (PISF) will be measured for total bacterial load.

II. Background

Successful aesthetic implant therapy has several sequential goals, such as prosthetically driven 3D implant placement. Implant placement must be done in the ideal position to support the restoration and the surrounding soft and hard tissues. The placement of a definitive restoration should also be in harmony with the adjacent natural teeth and surrounding soft tissue.***(Funato et al., 2007)***.

Guided implant surgery can provide precise, predictable, and safe implant placement**.** Computer-generated surgical guides vary in design according to the dental condition (edentulous or partially edentulous), type of support (tooth, mucosa, or bone), and degree of limitation (non-limiting, partially limiting, or completely limiting) ***(Vercruyssen et al., 2014; Pyo et al., 2019)***.

The use of healing abutments has the function of enabling adequate healing of peri-implant soft tissue and promoting a good profile of peri-implant mucosa that allows an adequate emergence profile of the prostheses supported by the implant. They are available in different lengths and project through the soft tissue into the oral cavity. Janakievski stated that prefabricated healing abutments are unable to support the supracrestal soft tissues because of their circular profile. Therefore, a custom healing abutment is preferred because it provides a replica of the definitive restoration to the patient's gingival architecture. ***(Molina et al., 2017; Susin et al., 2019)***.

An evaluation of the use of customized healing abutments has been performed, aiming to assess the possible advantages associated with this treatment modality. This procedure allows for the peri implant tissue and improve aesthetics until crown delivery. CAD/CAM allows the fabrication of high-quality implant abutments from solid blocks of different materials. ***(Joda et al., 2016; Finelle et al., 2017; Ruales-Carrera et al., 2019)***.

The contours of the healing abutment are based on the contours of a provisionally designed definitive prosthesis. The healing abutment promotes tissue healing and obtains contours that are well matched with the contours of the definitive prosthesis**.** ***(Berberi et al., 2014; Mehra et al., 2016; Yunus et al., 2016)***.

Currently, healing abutments made of polymers such as polyetheretherketone (PEEK), which have been used in orthopedic surgery, are used in dentistry, because of esthetic and biologic reasons for maintaining the health of peri-implant soft tissues during healing**.** ***(Volpe et al., 2008)***.

Polyetheretherketone (PEEK) healing abutments can be chosen instead of titanium healing abutments because of their superior properties, such as biocompatibility, inert chemical properties, white color, and decreased liability for biofilm accumulation. ***(Rea et al., 2017)***.

II-Research Question

"Do PEEK healing abutment may have a favorable effect on peri implant soft tissue that may be related to the superior biological properties of PEEK regarding both decreased biofilm accumulation and healing stimulation?"

PICOTS Elements:

Patient/Problem	Patients that are eligible for implant placement within inclusion criteria.
Intervention	PEEK customized healing abutment.
Comparator	Titanium customized healing abutment.
Outcome	Clinical evaluation of peri-implant soft tissue changes.
Time	1 month after implantation. 4 months after implantation (just before prosthetic procedures)
Setting	Faculty of Dentistry, Ain Shams University.

IV.Aim of the study

This study will be carried out to compare two different materials Polyetheretherketone (PEEK) vs Titanium (Ti) used to fabricate customized healing abutments placed simultaneously with guided delayed dental implant.

Primary outcome:

Clinical evaluation of peri-implant soft tissue changes the Probing Depth (PD), Plaque Index (PI) score and Width of keratinized tissue (WKT).

Secondary outcome:

Biochemical evaluation of peri-implant sulcus fluid (PISF) total bacterial load.

Clinical Relevance:

The result will affect the gold standard in choosing the healing abutment for implant patients, regarding which one offers less biofilm accumulation& healing stimulation.

- **Hypothesis:**

Our study suggests that if we used customized healing abutment synthesized from PEEK, this may have a favorable effect on peri implant soft tissues regarding decreased plaque accumulation and healing stimulation in compared to the customized conventional titanium healing abutments.

VI.Ethical consideration

•**Risk and discomfort of patients**: This research will be conducted with consideration of patient safety and with attempts to reduce any discomfort to patient, risks include postoperative pain, edema that can be controlled with medication.

•**Minimization of the risk:** Patient baseline vitals will be taken before any medical procedure to ensure patients safety. Moreover, all medical operation will be conduct under standardized infection control procedure.

•**Criteria for Discontinuation of Study/patient:** patient will be allowed to leave study if developed any complications either related to the study intervention or related to the general condition of the patient. The patient will have the right to withdraw from the study at any time.

•**Benefits to the Patients and to the Community**: patients will receive an aesthetically and functionally implant with no cost. The community will benefit from this study by having a wider range of healing abutments to choose from.

•**Privacy:** All patients identification including patient data and pictures will be locked and not shared.

•**Confidentiality:** patient's data will be treated with utmost confidentiality. In which no personal other than the researchers will be able to view the patient's data.

•**Data Management:** All patient's data will be saved on researcher's personal laptop that are not connected to any intranet connections and no copies will be made in any kind of database.

•**Consent Procedures if Applicable**: any medical procedures and photographs will have a printed written consent form.

•**Patient Informed Consent Form:** a proper consent form will be formulated &signed by the patient before starting any procedure.

VII. Study Design:

Randomized, controlled, parallel design, two arms clinical trial.

VII. Materials and Methods:

- **Study Setting:** Faculty of Dentistry, Ain Shams University.

- **Sample Size Calculation:** A power analysis was designed to have adequate power to apply a two-sided statistical test of the null hypothesis that there is no difference would be found between different groups. By adopting an alpha level of (0.05), a beta of (0.2) (i.e., power=80%) and an effect size (d) of (1.32) calculated based on the results of a previous study, the predicted sample size (n) was a total of (22) cases (i.e., 11 cases per group). Two patients will be added to each group to compensate for any loss. Sample size calculation was performed using G*Power version 3.1.9.7

- **Eligibility criteria:**

Inclusion Criteria:

1.Patients should be systematically free from any disease as according to Cornell Medical Index-Health Questionnaire (Pendleton et al., 2004).
2.Both genders.
3.Age from 20-50 years.
4.Missing tooth in esthetic zone (Anterior/Premolar) to be restored with standard implant, with no need for additional bone and soft tissue augmentation procedures. (Beretta et al., 2019)
5.Implants primary stability ISQ ≥ 70 unites using the Osstell Mentor (Baltayan et al., 2016).
6.BuccoLingual bone width ≥ 6 mm.
7. Mesio distal space ≥ 7 mm (Jensen, 1989)
8.Sound Mesial and distal neighboring teeth.
9.At least 6 natural teeth remaining in the same arch .

10.Mouth opening ≥ 30mm.
11.Enough keratinized mucosa.
12.Thick phenotype.

Exclusion Criteria:

1) Poor oral hygiene condition.

2)Pregnant and lactating females.

3)Smokers.

Justification for Exclusions:

To reduce any confounding factors and bias that may affect the results of this study.

Study procedures:

1- **Randomization and allocation concealment technique**: Patients will be randomly allocated according to predetermined computer-generated randomization using www.Randomizer.org

2- **Details of the interventions, testing and follow up:**

- Group I (Customized PEEK Healing Abutment):
  13 patients will receive guided delayed implant and a customized PEEK healing abutment placed simultaneously with implant surgery.
- Group II (Customized Titanium Healing Abutment):
  13 patients will receive guided delayed implant and a customized titanium healing abutment placed simultaneously with implant surgery.

Study protocol and surgical steps

A) Presurgical procedures:

1)Detailed clinical examination, full history, and radiographic examination (CBCT) will be performed initially to aid in patients' selection.

2)After enrollment, all participants will sign the informed consent.

3)All participants will be subjected to periodontal phase I treatment including periodontal supra- and sub-gingival debridement and oral hygiene instructions.

4)Preliminary impression for upper arch and cast fabrication will be made.

5)Pre-operative virtual planning for implant placement in ideal 3D position by appropriate software and preparation of digital surgical guide.

6)According to virtual implant future position healing abutment will be fabricated by milling machine.

B) Surgical procedures:

1)After local anesthesia administration, flapless fully guided osteotomy site preparation and implant will be place through the guide (Fully digital)

2)Check the ISQ to exceed or equal 70 unit.

3)A customized PEEK or Titanium healing abutment will be placed.

Assessment:

- Clinical assessment.
- Biochemical assessment.

The following clinical parameters will be recorded for the individuals on the following 1,4 months post implantation (Rüdin et al., 1970)

Clinical Parameters Included:

Probing Depth (PD): (Caton, 1980)
Will be measured from the gingival margin to the depth of the pocket at four points (mesio-facial, mid-facial, disto-facial and mid-lingual) to the nearest millimeter using UNC periodontal probe The average of the three facial points will be recorded as the facial probing depth (FPD), while the mid-lingual point will be recorded as the lingual probing depth.

Plaque Index (PI) score: (Mombelli et al., 1987)
0 = No detection of plaque
1= Plaque only recognized by running a probe across the smooth marginal surface of the implant.
2 =Plaque can be seen by the naked accumulation eye greater than 25%
3 Abundance of soft matter

Gingival Index (GI)score: (Lobene et al.,1986)
0= Normal.
1=Mild inflammation, slight change in color, little change in texture of any portion of gingival unit.
2=Mild inflammation for entire gingival unit.
3= Moderate inflammation of gingival unit.
4= Sever inflammation of gingival unit.

Gingival Bleeding Time Index (GBTI): (Muhlemann &Son, 1971)
Locate areas of gingival sulcus bleeding upon gentle probing and recognize
presence of early gingival inflammation
1 = healthy looking papillary and marginal gingiva, bleeding on probing
2 = bleeding on probing and color change in gingiva

3 = bleeding on probing, color change, slight edema
4 = bleeding on probing, color change, obvious edema
5 = spontaneous bleeding, color change, marked edema or ulceration.

Width of keratinized tissue (WKT): (Newman et al., 2012)
The distance between the gingival margin and mucogingival junction at the mid-buccal area, which was measured by a UNC periodontal probe with 1 mm accuracy.

PISF samples:
PISF sampling will be performed at the dental implant sites. Using standardized paper strips Periopaper. Paper strips will be placed at the entrance of the peri-implant sulcus and will be inserted to a standardized depth of 1 mm at each site regardless of the PD. In order not to affect the actual fluid volume, sampling time will also standardize as 30 s. Samples with evidence of gingival bleeding were not included. The PISF samples will then be placed in sterile, wrapped Eppendorf tubes and stored until the day of laboratory analysis (Tözüm et al., 2007).

3- **Blinding techniques:** single blinding

IX. Statistical Analysis

The obtained results will be collected, tabulated, and subjected to appropriate statistical analysis.

X. Funding of the Study

This study will be personally funded by the researcher.

XI. References

Baltayan S, Pi-Anfruns J, Aghaloo T, Moy PK. The Predictive Value of Resonance Frequency Analysis Measurements in the Surgical Placement and Loading of Endosseous Implants. J Oral Maxillofac Surg. 2016 Jun;74(6):1145-52. doi: 10.1016/j.joms.2016.01.048. Epub 2016 Feb 1. PMID: 26917203.

Berberi AN, Noujeim ZN, Kanj WH, Mearawi RJ, Salameh ZA. Immediate placement and loading of maxillary single-tooth implants: a 3-year prospective study of marginal bone level. J Contemp Dent Pract 2014; 15:202-8.

Beretta, Mario, et al. "Peri-implant soft tissue conditioning by means of customized healing abutment: a randomized controlled clinical trial." Materials 12.18 (2019): 3041.

Cakan U, Delilbasi C, Er S, Kivanc M (2015) Is it safe to reuse dental implant healing abutments sterilized and serviced by dealers of dental implant manufacturers? An in vitro sterility analysis. Implant Dent 24:174–179.

Chen ST, Buser D. Clinical and esthetic outcomes of implants placed in postextraction sites. Int J of Oral Maxillofac Implants. 2009;24:186-217.

Chen ST, Buser D. Esthetic outcomes following immediate and early implant placement in the anterior maxilla – a systematic review. Int J of Oral Maxillofac Implants. 2014;29:186-21

Chew M, Tompkins G, Tawse-Smith A, Waddell J, Ma S (2018) Reusing titanium healing abutments: comparison of twodecontamination methods. Int J Prosthodont 31:613–618.

Cochran DL, Nummikoski PV, Schoolfield JD, Jones AA, Oates TW. A prospective multicenter 5-year radiographic evaluation of crestal bone levels over time in 596 dental implants placed in 192 patients. J Periodontol 2009;80(5):725–33.

De Almeida EO, Pellizzer EP, Goiatto MC, Margonar R, Rocha EP, Freitas Jr , et al. Computer-guided surgery in implantology: review of basic concepts. J Craniofac Surg 2010;21(6):1917–21.

Faul, Franz, et al. "G* Power 3: A flexible statistical power analysis program for the social, behavioral, and biomedical sciences." Behavior research methods 39.2 (2007): 175-191.

Finelle G, Lee SJ. Guided immediate implant placement with wound closure by computer-aided design/computer-assisted manufacture sealing socket abutment: case report. Int J Oral Maxillofac Implants. 2017;32(2):e63-e67.

Jemt T. Measurements of tooth movements in relation to single-implant restorations during 16 years: a case report. Clin Implant Dent Relat Res 2005;7:200-8.

Joda T, Ferrari M, Braegger U. A digital approach for one-step formation of the supra-implant emergence profile with an individualized CAD/CAM healing abutment. J Prosthodont Res. 2016;60(3):220-223.

Lang LA, Sierraalta M, Hoffensperger M, Wang RF. Evaluation of the precision of fit between the Procera custom abutment and various implant systems. Int J Oral Maxillofac Implants 2003;18:652-8.

Margonar R, Queiroz TP, Luvizuto ER, Betoni-Junior W, Zocal EA. Mandibularrehabilitation using immediate implant loading after computer-guided surgery. J Craniofac Surg 2012;23(2):e129–32.

McGlumphy, EA. Implant-supported fixed prostheses. In:Rosenstiel SF, Land MF, Fujimoto J, eds. Contemporary Fixed Prosthodontics. 4th ed. St Louis, Mo: Elsevier; 2006:466–504

Mehra M, Somohano T, Choi M. Mandibular fibular graft reconstruction with CAD/CAM technology: A clinical report and literature review. J Prosthet Dent 2016;115:123-8.

Molina A, Sanz-Sánchez I, Martín C, Blanco J, Sanz M. The effect of one-time abutment placement on interproximal bone levels and periimplant soft tissues: a prospective randomized clinical trial. Clin Oral Implants Res. 2017;28(4):443-52

Mücahide Akoğlan , Ufuk Tatli , Cem Kurtoğlu , Fariz Salimov , Mehmet Kürkçü Effects of different loading protocols on the secondary stability and peri-implant bone density of the single implants in the posterior maxilla Clin Implant Dent Relat Res 2017 Aug;19(4):624-631.

Newman MG, Takei H, Klokkevold PR, Carranza FA. Carranza's clinical periodontology. Elsevier health sciences, 11th edition: 2012. P. 460-1, 452-60.

Pow EH, McMillan AS. A modified implant healing abutment to optimize soft tissue contours: A case report. Implant Dent 2004; 13:297-300.

Priest G. Virtual-designed and computer-milled implant abutments. J Oral Maxillofac Surg 2005;63:22-32.

Proussaefs P. Immediate provisionalization with a CAD/CAM interim abutment and crown: a guided soft tissue healing technique. J Prosthet Dent2015;113:91-5.

Pyo SW, Lim YJ, Koo KT, Lee J. Methods used to assess the 3D accuracy of dental implant positions in computer-guided implant placement: a review. J Clin Med 2019;8(1).

Rea M, Ricci S, Ghensi P, Lang NP, Botticelli D, Soldini C. Marginal healing using polyetheretherketone as healing abutments: an experi-

Susin C, Finger Stadler A, Fiorini T, de Sousa Rabelo M, Ramos UD, Schüpbach P. Safety and efficacy of a novel anodized abutment on soft tissue healing in Yucatan mini-pigs. Clin Implant Dent Relat Res. 2019;21(Suppl 1):34-43.

Volpe S, Verrocchi D, Anderson P, Gottlow 1, Sennerby L. Comparion of early bacterial colonization of PEEK and titanium healing abutments using real-time PC. Appl Osseointegration Res. 2008;6:54-56.

Wadhwani C, Schonnenbaum TR, Audia F, Chung KH (2016) Invitro study of the contamination remaining on used healing abutments after cleaning and sterilizing in dental practice. Clin Implant Dent Relat Res 18:1069–1074.

Yunus N, Masood M, Saub R, Al-Hashedi AA, Taiyeb Ali TB, Thomason JM. Impact of mandibular implant prostheses on the oral health-related quality of life in partially and completely edentulous patients. Clin Oral Implants Res 2016; 27:904-9.