Official Title: Evaluation of PEEK Versus Titanium Bar Attachments with Implant Assisted Mandibular Complete Overdenture Fabricated by CAD/CAM Technology

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Evaluation of PEEK versus Titanium Bar Attachments with Implant Assisted Mandibular Complete Overdenture fabricated by CAD/CAM Technology

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Introduction

Edentulism is considered a poor health outcome and may compromise the quality of life. According to the (World Health Organization) WHO, complete edentulism is affected by several factors including access to care, attitude towards dental hygiene, dentist/population ratios, oral health knowledge, education level, socioeconomic status, and lifestyle. The prosthetic management of the edentulous patient has been a major challenge for dentistry.[1]

The classical treatment plan for the edentulous patient is the conventional complete denture, this treatment has several complications that occur frequently due to several factors as an atrophic alveolar ridge, thin mucosa covering it, reduced bony support, muscular factors, age of the patient, and its influence on adaptation.[2] Wearing mandibular complete dentures (CD) is usually more problematic than maxillary CD because of the inherent displacing movement of the tongue and muscular borders, and decreased surface area. These problems direct the researchers to focus more on the lower jaw. Therefore, the problem of stability and retention of a complete denture is partially solved with the use of an overdenture.[3]

Implant dentistry has given hope to edentulous patients in obtaining a prosthesis which is adequately retained, stable and comfortable as well. Insertion of implants creates a more favorable environment for restoration in such patients. Implant assisted prostheses options for edentulous arch include implant supported fixed prosthesis and implant supported removable prosthesis. While the first offers many advantages like being esthetically pleasing and feels like a natural dentition, they are very expensive and not indicated in many conditions. Due to the severe loss of mandibular alveolar

ridge, provision of fixed prosthesis would be inadequate to compensate for the loss of both soft and hard tissue, thus compromising the facial aesthetics.[4,5]

With time, mandibular implant assisted complete overdenture IACO treatment has gained considerable acceptance. It is an attractive treatment option because of its relative simplicity, minimal invasiveness, and affordability. The prosthesis is supported by both implant and mucosa and generally requires fewer implants when compared with the totally implant-supported prosthesis design. Fewer implants and a removable prosthesis offer a less complex and less expensive option for an edentulous patient and more hygienic.[6]

The most common protocol used in IACO treatment is the placement of two implants in the anterior area of the mandible. This can be carried out in 2 ways. It can be splinted implants by bar attachments or un splinted implants by stud type attachments[7]. Many factors affect attachment selection, such as jaw morphology, inter arch distance, the desired retention, prosthesis type, inclination and number of implants, financial options, and the availability for maintenance visits[3]. Bar attachment increases overdenture retention and is used to splint implants with the lowest complications in the prosthetic superstructure and maximum patient satisfaction. It offers stress-breaking action and cross-arch involvement, which allows occlusal forces to be shared between the abutments.[9]

Three root form implants are placed in the A, C, and E positions for the second overdenture treatment option (OD-2). The advantages of splinting A, C, and E implants compared with implants in the B and D positions are many. The additional implant provides a sixfold reduction in superstructure flexure and limits the consequences previously discussed. In addition, screw

loosening occurs less frequently because three coping screws retain the superstructure rather than two. Implant reaction forces are reduced with a third implant compared with two implants.[9]

The introduction and evolution of computer-aided designing and computer-aided manufacturing (CAD\CAM) technology in dentistry have greatly revolutionized treatment concepts and prostheses fabrication. Full digitalization leads to favorable clinical outcomes, better retention, fewer patient visits, potentially enhanced material properties and biocompatibility, advances in standardization of both clinical results and research, simplified identification of anatomical landmarks on digitized casts reproducible and less time-consuming tooth arrangements, easy data storage, and production of duplicate dentures[10-12.]

In the prosthetic field, the digital revolution has a strong impact because the dentist can capture optical impressions with IOS these impressions are used by the dental technician for the planning and hence the production of a whole series of prosthetic restorations Patients favors optical impressions, which have eliminated the need for conventional analog impressions with trays and materials. The optical impressions also eliminate the discomfort linked to the conventional analog impressions; they are easy to capture for the clinician. They can be sent directly to the dental laboratory by e-mail, at no cost. The dental technician can view the impressions and immediately give feedback to the clinician, while the patient sits comfortably in the dental chair with no time wasting.[13-15.]

During the manufacturing of a conventional cast-bar attachment, dimensional changes can occur, associated with the impression-making and fabrication of an accurate dental cast, as well as the lost-wax casting protocol.

These dimensional changes (if poorly controlled) risk causing distortion.[16] Using CAD/CAM technology in overdenture prosthesis provides a computerized virtual bar design and modification, eliminating the laboratory steps such as casting and modelling. A good passive fit, lower distortion ratio and long-term success are observed in bar-retained overdentures produced with this technique.[17]

Various metals and alloys are commonly used in the fabrication of bar attachments. In the past, gold alloys were preferred but, due to their expensiveness and flexibility, this material is no longer preferred. Alternative materials for the fabrication of metal bar frameworks are: cobalt-chromium (Co-Cr), silver-palladium (Ag-Pd) alloys and titanium (Ti) and non-metallic restorations are used with metal allergy patients., Polyetheretherketone (PEEK) can be used as an alternative for a non-metallic framework.[17]

PEEK was first developed in 1978 as a thermoplastic, polycyclic, semi-crystalline polymer obtained by binding ketone and ether functional groups with aryl rings. It has superior mechanical properties, resistance to hydrolysis, chemical wear, and high temperatures with its low-weight advantage. The modulus of elasticity is close to alveolar bone and additional advantages are shock-absorbing. It is a biologically inert material with no evidence of cyto-toxicity or immunogenicity. It also offers corrosion resistance, low plaque affinity, and minimal creep. Several studies reported that using PEEK as a bar attachment material has better resuts.[17-20.]

Retention is the first factor responsible for patient satisfaction with the prosthesis, and it is defined as that quality inherent in the dental prosthesis acting to resist the forces of dislodgment along the path of placement. (33%) of prosthodontic complications are related to loss of retention. The rate of

attachment wear is related to its material of construction, which should be wear-resistant to maintain a stable retention force over-time. It was concluded that the least accepted retention force gained by different attachment systems in implant-retained overdenture was between 5 and 8 N in the long-term function.[2,20,21.]

Research on OD3 is very rare. So the first null hypothesis of this study is that there is no significant difference in retention , the second null hypothesis is there is no significant difference in bone lose around implant and the third null hypothesis there is no significant difference in bar diviation between Titanium and PEEK bars fabricated by CAD/ CAM technology used with implant assisted mandibular complete overdenture.

Aim of the work

Evaluation of OD retention, bone level around implant and bar deviation of PEEK versus Titanium Bar Attachments with Implant Assisted Mandibular Complete Overdenture fabricated by CAD/CAM Technology.

Materials and Methods

Study design

This study will be conducted as a clinical trial.

Study setting

This clinical study will be carried out at the Prosthodontic Department, Faculty of Dentistry, Tanta University and CAD-CAM laboratory.

Patient selection:

The patients will be selected from those attending the outpatient clinic of the Prosthodontic Department , Faculty of Dentistry, Tanta University

on the following criteria:

Inclusion criteria

- Completely edentulous patients free from systemic diseases that may affect soft or hard tissue healing.
- Patient's age ranges from 40 to 60 years old.
- The bone quality and quantity of the mandibular alveolar ridge must fulfill the criteria for implant placement.
- They have normal class I maxilla-mandibular relationship and sufficient inter-arch space with at least 25mm for bar attachment.
- They have good oral hygiene.

Exclusion criteria

- Systemic disorders that may influence soft or hard tissue healing as oral diseases.
- Patients with history of radiation therapy in the head and neck region.
- Patients with neurological or psychological problems that may impair good oral hygiene.

- Patients with parafunctional habits.
- Patients with heavy smoking, alcoholism, and drug abuse.

Ethical consideration

The purpose of the present study will be explained to the patients and informed consents will be obtained according to the guidelines on human research adopted by the Research Ethics Committee, Faculty of Dentistry, Tanta University.

Patient number selection (power analysis)

The total number of sample sizes for this study is 12 samples. The significance level was 0.05 and the power sample size was more than 80% for this study and the confidence interval 95 % and the actual power is 95.79%. The sample size is calculated based on a previous study [21]; the calculations are done using a computer program G power version 3.

The formula of sample size

$$sample\ size = \frac{({\sigma_1}^2 + {\sigma_2}^2)\left(Z_\alpha + Z_\beta\right)^2}{(\Delta - \Delta_0)^2}$$

Where:

Z = Z value (1.96 for 95% confidence level)

α= alpha level (The significance level was 0.05)

β= beta level.

Δ= difference under the null hypothesis

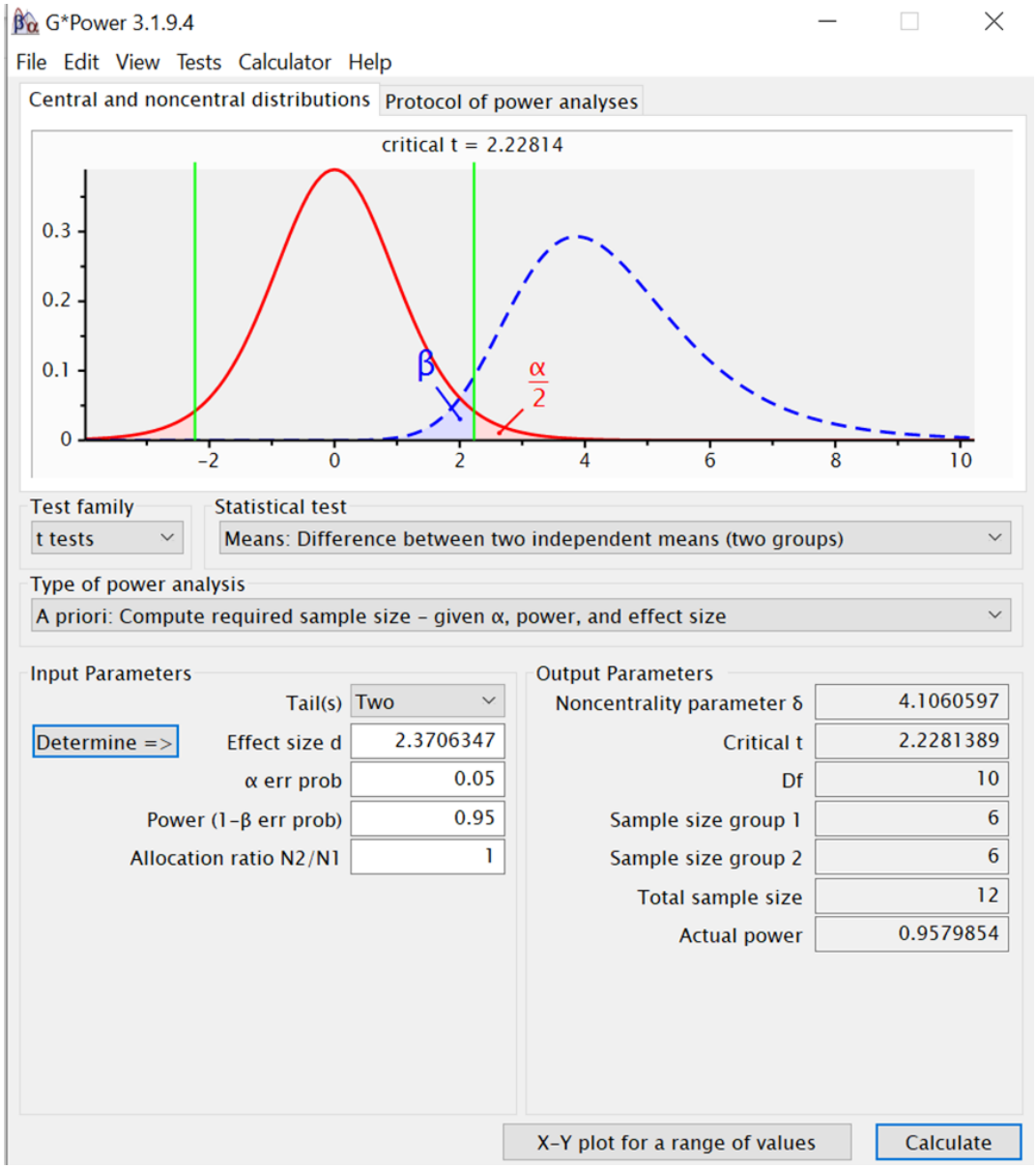

Fig1. Print screen of G power 3 software* showing samples size analysis

* G Power Analysis software, Heinrich Heine University Düsseldorf . Germany

Prosthetic procedures

1. Accurate oral examination**.**
2. Conventional CD will be fabricated that will be needed for digital implant planning and surgical guide designing and fabrication.
3. Three relevant implants will be installed in ACE position in the mandible fig (2).

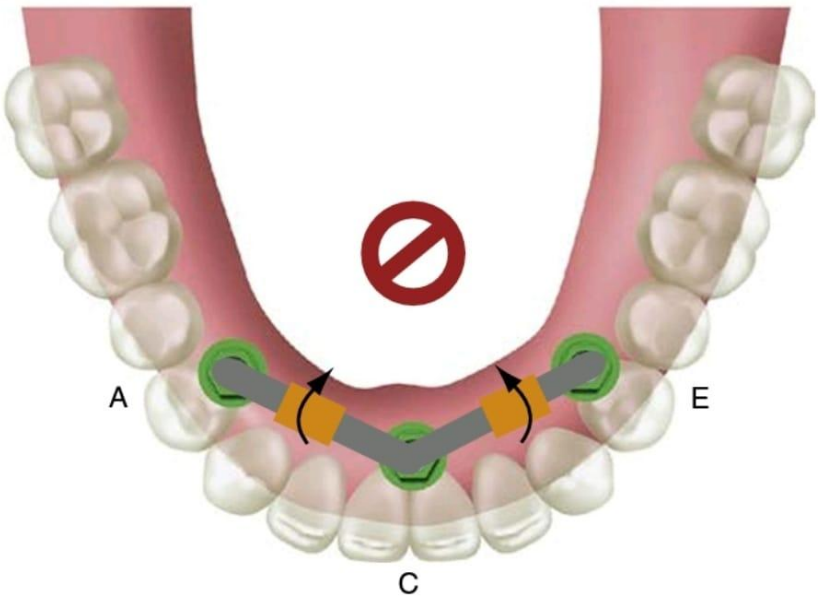

Fig (2) showing OD option 3 corresponds to implant in A, C,E positions are connected by bar.[9]

4. After 3 months healing and osseointegration. Intra oral scanning will be carried out using an intra oral scan body to transport the correct implant position to the designing software.
5. Hader bar will be designed.
6. 3d printed model will be fabricated and digital analogs will be cemented.
7. Verification jig will be fabricated and tried in the patient mouth.
8. After verification, the designed bar will be milled.

9. A complete overdenture will be designed on the virtual model with the virtual bar.
10. Conventional jaw relation will be performed and scanned by extra oral scan and the STL files will be stored in the software for virtual setting.
11. Digital try in will be printed and tried in the patient mouth.
12. The digitally designed complete overdenture will be completed digitally.
13. Finally, the milled bar will be tightened in the patient mouth and the female housing (clips) will be direct picked up.

Study groups.

Group I (control group):

Six patients will receive digital mandibular implant overdenture assisted by CAD/CAM Titanium bar attachment.

Group II (study group):

Six patients will receive digital mandibular implant overdenture assisted by CAD/CAM PEEK bar attachment.

Methods of evaluation

All patients will be evaluated radiographically, clinically, and digitally.

- **Radiographic evaluation**

Digital periapical X ray films will be carried out to measure marginal bone loss around implants at time of insertion of the prosthesis, after 6 months then after 1 year. [22, 23]

- **Clinical evaluation**

Retention of the complete overdenture will be evaluated clinically at insertion time, after 6 months and after one year of insertion. Retention force will be measure in Newton's using a digital retention testing device (Digital

force meter) *which has wide range of force measurement (0-5000) gm, connect to a wire loop on the lower denture and pulled vertically. [21]

- Digital evaluation

The deviation of the bar attachments will be evaluated digitally by superimposition the STL files recorded by scanning the bar during follow up after six months then after 1year over the reference data recorded at the time of insertion.[24]

Statistical analysis:

Statistical analyses will be performed using Statistical Package for Social Sciences (SPSS version 26). Numerical variables will be expressed by descriptive statistics as mean, standard deviation, and range, nominal data will be represented by frequency, percent and median. P value <0.05(*) was considered significant difference & P-value <0.001(**) was considered highly significant difference.

*47544Lanetech Instrument, cooperation, Beijing

References

1. Gulnar A, Altintas S, Yilmaz O, Ates G. Rehabilitation of the completely edentulous young patient with the “Malo Bridge”: A case report. Niger J Clin Pract. 2020; 23: 13-18.

2. Darvell BW, Clark RK. The physical mechanisms of complete denture retention. Br. Dent J. 2000; 189: 248-252.

3. Ikbal M, Mude AH, Dammar I, Launardo V, Sudarman I A. Locator or Ball Attachment Systems for Mandibular Implant Overdentures: A Systematic Review. Sys Rev Pharm. 2020; 11: 15-19.

4. Rodrigues RC, Faria AC, Macedo AP, Sartori IA, Mattos Mda G, Ribeiro RF. An in vitro study of non-axial forces upon the retention of an O-ring attachment. Clin Oral Implants Res 2009; 20: 4-9.

5. Dixit S, Acharya S. Benefits of overdentures. J. Nepal Dent. Assoc, 2010;11 :97-100.

6. Ekelund JA, Lindquist LW, Carlsson GE, Jemt T. Implant treatment in the edentulous mandible: a prospective study on Brånemark system implants over more than 20 years. Int J Prosthodont. 2003;16: 602-608.

7. British Society for the Study of Prosthetic Dentistry. The York consensus statement on implant-supported overdentures. Eur J Prosthodont Restor Dent. 2009; 17: 164-165.

8. Trakas T, Michalakis K, Kang K, Hirayama H. Attachment systems for implant retained overdentures: a literature review. Implant Dent. 2006; 15: 24-34.

9. Randolph R. Resnik. MISCH'S CONTEMPORARY IMPLANT DENTISTRY.4th ed. Saint Louis: Elsevier; 2020; P 575.

10. Abdullah A, Muhammed F, Zheng B, Liu Y. An Overview of Computer Aided Design/Computer Aided Manufacturing (CAD/CAM) in Restorative Dentistry. Dent Mater J. 2018; 7: 1-10.

11. Wang C, Shi YF, Xie PJ, Wu JH. Accuracy of digital complete dentures: A systematic review of in vitro studies. J Prosthet Dent. 2020; 1 :1-8.

12. Villias A, Papadopoulos T, Polychronakis N, Karkazis H, Polyzois G. Effect of digital workflow on the marginal fit of long-span implant-supported bars for Kennedy II class removable prostheses in vitro. Stoma Edu J. 2021;8(1):33-44.

13. Mangano, F., Mangano, C., Margiani, B., & Admakin, O. Combining intraoral and face scans for the design and fabrication of computer-assisted design/computer-assisted manufacturing (CAD/CAM) polyether-ether-ketone (PEEK) implant-supported bars for maxillary overdentures. Scanning. Volume 2019, Article ID 4274715, 14 pages .

14. AlRumaih, H. S. Clinical applications of intraoral scanning in removable prosthodontics: a literature review. J. Prosthodont., 2021; 30: 747-762.

15. Tasopoulos, T., Kouveliotis, G., Karoussis, I., Rfa Silva, N., & Zoidis, P. A full digital workflow for the duplication of an existing implant retained overdenture prosthesis: a novel approach. J. Prosthodont.,2021; 30:555-560.

16. Alsayed, H. D. Integrating Analog and Digital Workflow to Fabricate Implant Mandibular Complete Overdenture with a Milled Titanium Bar: A Clinical Report. Int J Periodontics Restorative Dent., 2023;2: 111-115.

17. Kumbulo glu, O. Koyuncu, B. Yerlio glu, G. Al-Haj Husain, N. Ozcan, M. Stress Distribution on Various Implant-Retained Bar Overdentures. Materials 2022, Article ID 5093248, 15 pages.

18. Elkady, D. M., & El-Sherbini, N. N. Footprint of Different Bar Materials on Complete Overdenture Retention. ADJC. 2023 ;5: 397-404.

19. Mohammed, S. L. Effect of Two Different Digitally Constructed Bar Materials on The Supporting Structures of Implant-Retained Mandibular Overdenture (In-Vitro Study). ASDJ. 2022; 29:15-22.

20. Nassar, H. I., Abdelaziz, M. S. Retention of bar clip attachment for mandibular implant overdenture. BMC Oral Health. 2022; 1:222- 227

21. EL-Shorbagy, Z. A., El-sheikh, M. M., Ali, N. S. Retention Assessment of PEEK Telescopic Attachment with Two Different Matrix Materials for Implant Retained Over Dentures (Randomized Clinical Trial) Eur. Chem. Bull. 2023; 12:3251-3257.

22. Eskandarloo A, Arabi R,Bidgoli M, Yousefi F, Poorolajal J. Association between marginal bone loss and bone quality at dental implant sites based on evidence from cone beam computed tomography and periapical radiographs. Contemp Clin Dent 2019; 10:36-41.

23. Sapkota B, Upadhyaya C, Rimal U, Mahanta S. Evaluation of marginal bone level after implant placement and before loading, by digital radiography. J Kathmandu Med Coll. 2022; 11:48-51.