

Study Protocol

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

NCT Number: Not yet assigned

Document Date: February 20, 2024

Study Type:
Interventional (Clinical Trial)

Study Design:

- Allocation: Randomized
- Intervention Model: Parallel Assignment
- Masking: None (Open Label)
- Primary Purpose: Treatment

Study Population:

- Total Sample Size: 12 patients
- Age Range: 40–60 years
- Inclusion Criteria:
 - Completely edentulous mandibular arch
 - Adequate bone quantity and quality for implant placement
 - Class I maxilla-mandibular relationship
 - Sufficient inter-arch space (≥ 25 mm)
 - Good oral hygiene
- Exclusion Criteria:
 - Systemic diseases affecting tissue healing
 - History of radiation therapy in head/neck region
 - Neurological or psychological disorders affecting oral hygiene
 - Parafunctional habits
 - Heavy smoking, alcoholism, or drug abuse

Study Groups / Interventions:

- Group I (Control): CAD/CAM Titanium bar attachment mandibular overdenture (6 patients)
- Group II (Study): CAD/CAM PEEK bar attachment mandibular overdenture (6 patients)

Outcome Measures:

Primary Outcome:

- Retention force of mandibular overdenture measured in Newtons using a digital force meter at insertion, 6 months, and 1 year

Secondary Outcomes:

- Marginal bone loss around implants measured via digital periapical X-rays at insertion, 6 months, and 1 year
- Bar deviation assessed digitally by STL file superimposition at 6 months and 1 year

Study Setting:

Prosthodontics Department, Faculty of Dentistry, Tanta University, and CAD/CAM

laboratory

Ethical Consideration:

Informed consent will be obtained from all participants according to the guidelines of the Research Ethics Committee, Faculty of Dentistry, Tanta University

Key References (Optional):

1. Resnik RR. Misch's Contemporary Implant Dentistry. 4th ed. Elsevier; 2020.
2. Abdullah A, Muhammed F, Zheng B, Liu Y. An Overview of CAD/CAM in Restorative Dentistry. Dent Mater J. 2018;7:1-10.
3. Elkady DM, El-Sherbini NN. Footprint of Different Bar Materials on Complete Overdenture Retention. ADJC. 2023;5:397-404.