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

Clinical Trial Protocol

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