

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

References: 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.