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A clinical study comparing two types of dental implant abutments used in fixed screw-retained prostheses

Submission date
14/10/2025

Recruitment status
No longer recruiting

Registration date
15/10/2025

Overall study status
Completed

Last Edited
15/10/2025

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study is exploring two different methods for fitting dental implants in people who need fixed replacement teeth. Both methods use the same type of implant, but differ in how the replacement teeth are attached. The goal is to find out which method offers better results in terms of comfort, durability, and long-term success.

Who can participate?
The study is open to adults who are in generally good health and missing one or more back teeth, and who need fixed, screw-retained dental implants. To take part, individuals must have enough healthy bone in the jaw to support the implants without needing extra bone grafting. They should also have healthy gums and no active infections in the mouth. The space between the upper and lower teeth must be suitable for the type of replacement being used. People who smoke heavily are not eligible, but non-smokers or light smokers (fewer than 10 cigarettes a day) may be considered. Participants must be motivated to keep their mouth clean and attend all follow-up visits for at least a year. Everyone must give written consent after the study has been fully explained.

What does the study involve?
Participants will be randomly placed into one of two groups. One group will receive implants with a special connector called a “multiunit abutment,” while the other group will receive implants with a standard prefabricated connector. Both groups will get fixed replacement teeth that are screwed into place. The procedure and follow-up care will be the same for everyone, and all parts will be fitted according to the manufacturer’s instructions.

What are the possible benefits and risks of participating?
Taking part may help improve dental treatment options in the future. Participants will receive high-quality dental care as part of the study. As with any dental procedure, there may be risks such as discomfort, infection, or complications with the implant, but these will be carefully managed by the clinical team.

Where is the study run from?
Department of Prosthodontics, Damascus University (Syria)

When is the study starting and how long is it expected to run for?
April 2024 to December 2024

Who is funding the study?
Department of Prosthodontics, Damascus University (Syria)

Who is the main contact?
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Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
UDDS-3062-01042024/SRC-1550

Study information

Scientific Title
Clinical evaluation of multiunit abutments versus prefabricated abutments in screw-retained implant-supported prostheses

Acronym
MuPFA Study

Study objectives
To clinically evaluate and compare the performance of multiunit abutments and prefabricated abutments used in screw-retained implant-supported prostheses, in terms of prosthetic adaptation (passive fit) between the abutment and the implant

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 01/04/2024, Biomedical Research Ethics Committee of Damascus University (University Presidency Building, University Campus, Baramkeh 23J89, Damascus, -, Syria; +963 1133923012; president@damasuniv.edu.sy), ref: 3062

Study design
Single-center interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment, Efficacy

Health condition(s) or problem(s) studied
Partial edentulism (missing posterior teeth) requiring implant-supported fixed prosthetic rehabilitation.

Interventions
Intervention 1 – Multiunit abutment group (test group):
Participants receive dental implants restored with multiunit abutments supporting screw-retained fixed prostheses.
• Implant system: MEGAGEN “Anyone” implants.
• Prosthetic workflow: conventional impression, fabricated screw-retained prosthesis fixed on multiunit abutments.
• Abutment and prosthesis screws torqued according to manufacturer’s specifications (≈25–35 N·cm).

Intervention 2 – Prefabricated abutment group (control):
Participants receive the same implant type restored with prefabricated abutments and a screw-retained fixed prosthesis.
Torque, Implant system and surgical protocol identical to the test group.

Randomisation will be performed with a 1:1 allocation ratio (Multiunit abutment: Prefabricated abutment). A computer-generated random sequence of permuted blocks (block size = 4) will be created by an independent statistician who is not involved in patient enrolment or outcome assessment. Allocation concealment will be ensured using sequentially numbered, opaque, sealed envelopes (SNOSE) prepared and signed by the independent statistician. Envelopes will be stored in a locked cabinet in the research office. After confirming eligibility and obtaining written informed consent, the enrolling clinician will open the next envelope in sequence to reveal the treatment allocation. The allocation will be recorded in the trial log and the participant’s case report form.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Accuracy of prosthetic adaptation (Passive fit) between implant and abutment components.
The passive fit of the screw-retained prosthesis on the implant-abutment complex will be evaluated using three validated methods applied sequentially:
1. Screw resistance (Ratchet torque) test (clinical method):

Gradual torque application (0–35 N·cm) using a manual torque wrench to detect any sudden increase in torque resistance or movement, indicating tension or misfit. Smooth, resistance-free tightening (Passive fit) denotes successful adaptation.
2. One-screw test (visual and tactile verification):
After securing one abutment screw, the seating of the opposing abutment is inspected visually and with an explorer for marginal gaps or vertical displacement. A stable, gap-free seating indicates passive fit.
3. Screw deformation analysis (mechanical evaluation):
The abutment screw used during the initial prosthesis fixation will be replaced with a new screw at follow-up. The removed screw will be cleaned ultrasonically and examined under an optical microscope to detect mechanical deformation, including:
o Thread flattening or wear
o Microcracks along threads
o Bending or surface irregularities
The presence of any deformation indicates internal stress due to misfit.
Timing of assessment:
• At prosthesis delivery (baseline)
• At follow-up (1 week post-loading)
Outcome classification:
Fit quality categorized as:
• Complete passive fit (no tension, no deformation)
• Partial fit with mild strain
• Non-passive fit / detectable misfit or screw deformation

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
15/12/2024

Eligibility

Key inclusion criteria
1. Good general health.
2. Presence of partial edentulism (missing one or more posterior teeth) requiring fixed, screw-retained, implant-supported prosthetic rehabilitation.
3. Adequate bone volume and bone quality type D2–D3, confirmed radiographically (CBCT).
4. Sufficient vertical bone height at the planned implant site to allow placement of standard-length implants without additional grafting.
5. Patients with healthy oral soft tissues and no active periodontal or mucosal infections.
6. Adequate inter-arch space and occlusal relationship to permit restoration with a screw-retained prosthesis.
7. Non-smokers or light smokers (<10 cigarettes/day).
8. Patients motivated to maintain oral hygiene and to attend all scheduled follow-up visits for at least 12 months.
9. Patients who have provided written informed consent to participate in the study after receiving full explanation of procedures and risks.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
20 years

Upper age limit
50 years

Sex
All

Total final enrolment
20

Key exclusion criteria
1. Systemic contraindications to oral surgery or implant placement (e.g., uncontrolled diabetes, hypertension, bleeding disorders, immunocompromised conditions).
2. History of bisphosphonate therapy or other antiresorptive or antiangiogenic medications affecting bone metabolism.
3. Smoking habit exceeding 10 cigarettes per day or use of smokeless tobacco.
4. Alcohol or drug abuse.
5. Pregnancy or lactation at the time of enrolment.
6. Untreated or active periodontal disease, mucosal lesions, or infection at the intended implant site.
7. Poor bone quality or quantity (types D1 or D4, insufficient vertical or buccolingual bone volume) precluding stable implant placement without grafting.
8. Previous bone augmentation or implant failure in the same site.
9. Parafunctional habits such as bruxism or clenching.
10. Malocclusion or unstable occlusal relationship preventing proper alignment of screw-retained restorations.
11. Patients on long-term corticosteroid therapy or radiotherapy to the head and neck region.
12. Allergy or hypersensitivity to titanium or any dental materials used in the study

Date of first enrolment
01/05/2024

Date of final enrolment
01/12/2024

Locations

Countries of recruitment
Syria

Study participating centre

Department of Prosthodontics, Damascus University
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Sponsor information

Organisation
Damascus University

ROR
https://ror.org/03m098d13

Funder(s)

Funder type
University/education

Funder Name
Damascus University

Alternative Name(s)
University of Damascus, , DU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Syria

Results and Publications

Individual participant data (IPD) sharing plan
Contact: Dr. Hasan Alzoubi, dr.hasan.alzoubi.93@gmail.com
Type of data shared: Individual participant data (IPD) including passive fit results.
Availability: Data will be available after publication of the primary results.
Access criteria: Data will be shared for academic, non-commercial research purposes following a formal request.

Consent and ethics: All participants provided informed consent/parental consent. Data will be anonymized before sharing.
Restrictions: No ethical or legal restrictions beyond participant confidentiality.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes