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Clinical and radiographic evaluation of multi-unit abutments versus prefabricated abutments in screw-retained implant-supported prostheses

Submission date
04/11/2025

Recruitment status
No longer recruiting

Registration date
05/11/2025

Overall study status
Completed

Last Edited
05/11/2025

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 looking at two different types of small connectors used in dental implants. These connectors, called abutments, help attach artificial teeth (like crowns or bridges) to the implants placed in the jaw. The researchers want to find out which type of abutment works better when replacing missing back teeth. They are comparing multi-unit abutments (MUAs) and prefabricated abutments (PFAs) to see which one leads to better results over time.

Who can participate?
Healthy adults who are missing back teeth and need dental implants with fixed, screw-retained artificial teeth can take part. People won't be able to join if they have health problems that make oral surgery unsafe, smoke more than 10 cigarettes a day, have poor bone quality, or have active gum disease.

What does the study involve?
Everyone in the study will receive dental implants from the same brand. Half of the participants will get MUAs, and the other half will get PFAs. The surgical and dental procedures will be the same for both groups. After the implants are placed and the artificial teeth are fitted, participants will be followed for one year to check how well the treatment works.

What are the possible benefits and risks of participating?
Participants may benefit from receiving high-quality dental implants and close follow-up care. The study could also help improve future dental treatments. As with any dental surgery, there are some risks, such as discomfort, healing problems, or technical issues like loose screws. These will be carefully monitored.

Where is the study run from?
Damascus University (Syria)

When is the study starting and how long is it expected to run for?
January 2025 to April 2025

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
Professor Hasan Alzoubi, prof.hasan.alzoubi@damascusuniversity.edu.sy

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Scientific, Principal investigator

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Additional identifiers

Protocol serial number
DN-210125-391

Study information

Scientific Title
A randomized controlled clinical and radiographic trial to evaluate the performance of multi-unit abutments compared with prefabricated abutments in screw-retained implant-supported prostheses

Acronym
MUA-PFA Trial

Study objectives
1. To evaluate prosthetic technical complications (loosening, screw fracture, prosthesis movement).
2. To assess biological outcomes, such as marginal bone loss.
3. To measure patient satisfaction regarding comfort, function, and esthetics of the prostheses.
4. To determine whether multi-unit abutments provide superior clinical performance and biomechanical stability compared with prefabricated abutments over a 12-month follow-up period.

Ethics approval required
Ethics approval required

Ethics approval(s)

approved 21/01/2025, Biomedical Research Ethics Committee of Damascus University (University Presidency Building, University Campus, Baramkeh 23J89, Damascus, 00000, Syria; +963 1133923012; president@damasuniv.edu.sy), ref: 391

Study design
Single-center interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Efficacy, Treatment

Health condition(s) or problem(s) studied
Partial edentulism requiring fixed implant-supported prosthetic rehabilitation in posterior regions of the jaws.

Interventions
Participants will be randomly assigned to one of two groups in a 1:1 allocation ratio. In the test group, dental implants will be restored using multi-unit abutments supporting screw-retained fixed prostheses. The implant system used will be MEGAGEN “Anyone” implants. The prosthetic workflow will follow a conventional impression technique, with the prosthesis fabricated and fixed on the multi-unit abutments. Both abutment and prosthesis screws will be torqued according to the manufacturer’s recommendations (approximately 25–35 N·cm).
In the control group, participants will receive the same implant system restored with prefabricated abutments (PFAs) and screw-retained fixed prostheses, following an identical surgical protocol and torque specifications.
Randomisation will be performed using a computer-generated permuted block sequence (block size = 4) created by an independent statistician not involved in enrolment or assessment. Allocation concealment will be maintained through sequentially numbered, opaque, sealed envelopes (SNOSE) prepared and signed by the statistician, stored securely in the research office.
Following confirmation of eligibility and written informed consent, the enrolling clinician will open the next envelope in sequence to reveal the treatment allocation, which will be documented in both the trial log and the participant’s case report form.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Marginal bone level changes around implants supporting screw-retained prostheses with either multi-unit or prefabricated abutments measured using standardized periapical radiographs using a paralleling technique and digital image analysis software at baseline (prosthesis delivery), 3 months, 6 months, and 12 months post-loading

Key secondary outcome(s))
1. Technical and mechanical complications: Incidence of screw loosening, fracture, or prosthesis movement recorded throughout the 12-month follow-up period.
2. Patient satisfaction: Evaluated using a visual analogue scale (VAS, 0–10) assessing comfort, esthetics, and masticatory function at 6- and 12-month follow-ups.

Completion date
01/05/2026

Eligibility

Key inclusion criteria
1. Participants must be in overall good systemic health.
2. Individuals presenting with partial edentulism (missing one or more posterior teeth) who require fixed, screw-retained, implant-supported prosthetic rehabilitation.
3. Adequate alveolar bone volume and quality corresponding to types D2–D3, as confirmed by cone-beam computed tomography (CBCT).
4. Sufficient vertical bone height at the proposed implant site to allow placement of standard-length implants without the need for bone augmentation.
5. Healthy oral soft tissues, free from active periodontal or mucosal disease.
6. Proper inter-arch space and occlusal relationship adequate for fabrication of a screw-retained restoration.
7. Non-smokers or light smokers, defined as individuals consuming fewer than 10 cigarettes per day.
8. Motivated and compliant patients willing to maintain good oral hygiene and attend all scheduled follow-up appointments for a minimum of 12 months.
9. Participants who have provided written informed consent after receiving a detailed explanation of the study procedures, benefits, and potential 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
40

Key exclusion criteria
1. Systemic medical conditions that contraindicate oral surgery or implant placement, such as uncontrolled diabetes, hypertension, coagulation disorders, or immunodeficiency.
2. Current or previous use of bisphosphonates, antiresorptive, or antiangiogenic medications known to affect bone metabolism or healing.
3. Heavy smoking, defined as consumption of more than 10 cigarettes per day, or the use of

smokeless tobacco products.
4. History of alcohol dependence or substance abuse.
5. Pregnant or breastfeeding women at the time of recruitment.
6. Presence of untreated periodontal disease, oral mucosal lesions, or infection at or near the intended implant site.
7. Inadequate bone volume or poor bone density (types D1 or D4), or insufficient vertical or buccolingual dimensions preventing stable implant placement without bone grafting.
8. Previous bone grafting procedures or failed implants in the same anatomical site.
9. Parafunctional habits such as bruxism or clenching that may compromise implant stability or prosthesis integrity.
10. Malocclusion or unstable occlusion interfering with the proper alignment or function of screw-retained restorations.
11. Patients receiving long-term corticosteroid therapy or those with a history of head and neck radiotherapy.
12. Known allergy or hypersensitivity to titanium or any dental materials utilized in the study.

Date of first enrolment
22/01/2025

Date of final enrolment
25/04/2025

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 bone loss, complications, and satisfaction 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