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Retention of complete dentures made from traditional and digital impressions

Submission date	Recruitment status	[_] Prospectively registered
21/07/2025	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/08/2025	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
19/08/2025	Oral Health	[X] Record updated in last year

Plain English summary of protocol
Background and study aims
This study aims to assess whether intra-oral scanners can provide a good fit and retention for complete dentures when used for final impression taking.

Who can participate?
Patients who have had missing upper teeth for more than 6 months

What does the study involve?
Participants underwent two types of impressions: conventional impressions involved using custom trays with impression compound and zinc oxide eugenol, and digital impressions using an intra-oral scanner. The conventional impressions were digitised using a laboratory scanner and then both impressions were compared. Two complete denture bases were printed out of both impressions and were assessed by two specialists.

Where is the study run from?
Faculty of Dentistry, Damascus University (Syria)

When is the study starting and how long is it expected to run for?
January 2024 to June 2025

Who is funding the study?
The study is self-funded as part of a postgraduate academic project and is supported by Damascus University (Syria)

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Fit and retention of complete denture bases fabricated from conventional and digital impressions, modified in the post dam. A comparative in-vivo study

Study objectives
The use of intra-oral scanner for taking complete denture's impressions has comparable results of adaption and retention as using conventional impressions

Ethics approval required
Ethics approval not required

Ethics approval(s)

Study design
Single-centre interventional double-blinded non-randomized controlled trial

Primary study design
Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied
Fit and retention of complete denture bases

Interventions
This is a single-centre interventional non-randomised clinical study conducted to assess the effect of intra-oral scanners on the fit and retention of complete denture bases.

The intervention involves using the intra-oral scanner to take a final impression of edentulous arches for complete denture fabrication and then printing denture bases.

The control group involves taking zinc oxide eugenol impressions of the same edentulous patient.

The differences between the control group and the test group will be measured by overlapping both impressions using Geomagic Control X.

Retention will be assessed by two specialists after printing denture bases from both impressions.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Fit of complete denture bases measured by both conventional and digital impressions will undergo a 3D analysis after converting them to STL files to determine how close the digital impression is to the conventional impression, considering the conventional one as a reference while creating a colour map to showcase the difference, immediately after taking both impressions via Geomagic X.

Key secondary outcome(s))
Retention of complete denture bases. Two resin bases will be printed from both impressions, then assessed by two specialists at the department of removable prosthodontics in Damascus University after printing the resin complete denture bases.

Completion date
17/06/2025

Eligibility

Key inclusion criteria
1. Edentulous patients in the maxillary region for no less than 6 months
2. Residual ridges are rounded and U-shaped
3. No signs of inflammation on the mucosa and soft tissues

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
All

Total final enrolment
20

Key exclusion criteria
1. Severe absorption of the residual ridges
2. Flabby tissues
3. Non collaborative patients

Date of first enrolment
25/03/2024

Date of final enrolment
15/02/2025

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University
Faculty of Dentistry
Mazzeh Highway
Damascus
Syria
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Sponsor information

Organisation
Damascus University

ROR
https://ror.org/03m098d13

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
Available upon request from morhafmbn@gmail.com

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes