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
	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

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Non randomised study

Study setting(s)

University/medical school/dental school

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet

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 measure

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.

Secondary outcome measures

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.

Overall study start date

05/01/2024

Completion date

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

Age group

Not Specified

Sex

Both

Target number of participants

20

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

Ѕугіа

Study participating centre

Damascus University

Faculty of Dentistry Mazzeh Highway Damascus Syria

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Sponsor information

Organisation

Damascus University

Sponsor details

Mazzah Damascus Syria

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Sponsor type

University/education

Website

http://www.damascusuniversity.edu.sy

ROR

https://ror.org/03m098d13

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal

Intention to publish date

15/09/2025

Individual participant data (IPD) sharing plan

Available upon request from morhafmbn@gmail.com

IPD sharing plan summary

Available on request