

Studying jaw joint problems in completely edentulous Syrian patients before and after receiving new full dentures

Submission date 09/06/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 10/06/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 10/06/2025	Condition category Oral Health	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

This study aims to examine problems in the jaw joint (called the temporomandibular joint, or TMJ) in patients who have lost all their teeth (edentulous). Many completely edentulous patients wear old or poorly fitting dentures, which may lead to pain, joint sounds, or difficulty moving the jaw. The study aims to assess whether providing a new complete denture improves these symptoms.

Who can participate?

Completely edentulous patients aged 30 to 90 years who were already wearing old complete dentures and had symptoms related to the TMJ.

What does the study involve?

Participants underwent a clinical examination to assess pain, joint sounds, and jaw movement before and 6 months after receiving a new complete denture. The dentures were made according to proper dental standards. No medications or surgical treatments were involved.

What are the possible benefits and risks of participating?

Participants may experience relief from jaw pain, improved chewing function, and better denture comfort. There are no known medical risks, as the intervention is non-invasive and follows standard dental procedures.

Where is the study run from?

The study was conducted at the Faculty of Dentistry, Damascus University, Syria.

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

January 2021 to May 2024

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?

Dr. Yusra Abdulaziz Al-Kurdi, Faculty of Dentistry, Damascus University, yusraalkurdy9@gmail.com

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

Evaluation of the prevalence of temporomandibular disorders in completely edentulous Syrian patients before and after the delivery of new complete dentures: a clinical study

Study objectives

The study hypothesizes that the insertion of a new, properly constructed complete denture will significantly reduce temporomandibular joint (TMJ) symptoms, including joint pain, joint sounds, and restricted mandibular movement, in completely edentulous Syrian patients.

Ethics approval required

Ethics approval not required

Ethics approval(s)

This is a retrospectively registered, observational study. No clinical intervention was performed. Accordingly, no formal ethics committee approval was required by the institution. However, all participants signed written informed consent forms before being included in the study.

Study design

Single-centre non-randomized unblinded uncontrolled interventional pre–post study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital, University/medical school/dental school

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Temporomandibular disorders (TMD) in completely edentulous patients requiring new complete dentures

Interventions

This is a retrospectively registered, single-centre interventional pre–post clinical study conducted to assess the impact of new complete denture insertion on temporomandibular joint (TMJ) symptoms in completely edentulous Syrian patients.

The intervention involves delivering a new, complete, and removable denture to completely edentulous Syrian patients. The dentures are fabricated according to prosthodontic standards to ensure proper fit, retention, occlusion, vertical dimension, and centric relation. There is no control group, no randomization, and no blinding. All participants will be examined before and after the intervention. The follow-up period is six months, during which TMJ symptoms will be clinically evaluated.

Intervention Type

Device

Pharmaceutical study type(s)

Not Applicable

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Complete removable denture

Primary outcome measure

Temporomandibular joint symptoms (pain, joint sounds, movement limitation) measured using clinical examination based on RDC/TMD Axis I at baseline and after 6 months of new denture use

Secondary outcome measures

The following Secondary outcome measures are assessed at baseline and after 6 months:

1. Pain severity measured using the Visual Analog Scale (VAS)
2. Range of mandibular movement measured using a millimeter ruler
3. Muscle tenderness measured using digital palpation, according to RDC/TMD Axis I criteria

Overall study start date

01/01/2021

Completion date

30/11/2024

Eligibility

Key inclusion criteria

1. Completely edentulous patients (both maxilla and mandible)
2. Aged between 30 and 90 years
3. Wearing old, removable complete dentures
4. Complaining of temporomandibular joint symptoms (pain, sounds, movement limitation)
5. Willing and able to participate in clinical examination and follow-up

Participant type(s)

Patient

Age group

Mixed

Lower age limit

30 Years

Upper age limit

90 Years

Sex

Both

Target number of participants

103

Total final enrolment

103

Key exclusion criteria

1. Patients with a history of TMJ trauma or surgery
2. Patients with systemic joint diseases
3. Patients with incomplete records or who missed follow-up visits
4. Patients with psychological or neuromuscular disorders affecting TMJ assessment

Date of first enrolment

10/09/2021

Date of final enrolment

30/05/2024

Locations

Countries of recruitment

Syria

Study participating centre

Faculty of Dentistry – Damascus University

Mazzeah 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

<https://www.damascusuniversity.edu.sy/>

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

Publication and dissemination plan

Planned publication in a peer-reviewed journal and possible presentation in scientific conferences.

Intention to publish date

12/12/2024

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Dr. Yusra Abdulaziz Al-Kurdi (yusraalkurdy9@gmail.com). Data will be anonymised and shared with qualified researchers upon reasonable request for academic purposes only. Participant consent was obtained, and ethical approval was granted for data use in this context.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			10/06/2025	No	No