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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	[_] Prospectively registered [X] Protocol
Registration date 10/06/2025	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 10/06/2025	**Condition category** Oral Health	[_] Individual participant data [_] 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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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.

Primary study design
Interventional

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

Study type(s)
Treatment

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

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Complete removable denture

Primary outcome(s)
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

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
30 Years

Upper age limit
90 Years

Sex
All

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
Mazzeh Highway
Damascus
Syria
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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
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