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Studying patient outcomes after placing wide dental implants immediately in the first lower molar without surgery

Submission date 06/09/2025	**Recruitment status** Not yet recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 08/09/2025	**Overall study status** Ongoing	
Last Edited 09/09/2025	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims
This study aims to evaluate the outcomes of using ultra-wide dental implants placed immediately after tooth extraction in patients with a first lower molar that cannot be restored. The study will assess both clinical outcomes (such as implant success and survival) and patient-reported outcomes (such as pain, swelling, and daily activity).

Who can participate?
Adults aged 18 years or older who require the extraction of a first lower molar.

What does the study involve?
Participants will undergo a minimally invasive, flapless tooth extraction followed by immediate placement of an ultra-wide dental implant using a patient-specific surgical guide. Follow-up visits will include clinical and radiographic assessments, measurement of implant stability, and questionnaires about pain, swelling, daily activity, and satisfaction. The total follow-up period for each patient is 4 months.

What are the possible benefits and risks for participants?
Potential benefits include receiving advanced dental implant treatment and close monitoring by dental specialists. Risks may include postoperative pain, swelling, minor surgical complications, or implant failure, though all procedures are performed by experienced clinicians using standard safety protocols.

Where is the study run from?
The study is conducted at the Department of Oral and Maxillofacial Surgery, Faculty of Dentistry, University of Damascus, Syria.

When is the study starting and how long is it expected to run for?
July 2025 to May 2025. The first patient is expected to be enrolled in October 2025, and the last patient will be enrolled in December 2025. With a follow-up period of four months and additional time for data analysis, the study is expected to conclude by May 2026.

Who is funding the study?
The University of Damascus, Syria.

Who is the main contact?
Dr. Fouad Agha, aghafouad47@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
0992964458agha

Study information

Scientific Title
Patient reported and clinical outcomes following flapless, immediate placement of ultra wide implants in first lower molars

Study objectives
To evaluate the clinical and patient-reported outcomes of ultra-wide dental implants placed immediately after extraction in the first lower molar region.

Ethics approval required
Ethics approval required

Ethics approval(s)

Submitted 07/08/2025, Biomedical Research Ethics Committee of Damascus University (Almazzeh, Damascus, 00000, Syria; +963 (0)113341864; manager@hcsr.gov.sy), ref: DN-070825-318

Study design
Prospective open-label single-arm interventional clinical study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
University/medical school/dental school

Study type(s)
Quality of life, Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Immediate implant placement (IIP)

Interventions
All enrolled participants (singlearm cohort) will undergo atraumatic, flapless extraction of the designated unrestorable mandibular or maxillary molar using sectioning techniques to preserve all four socket walls. A patientspecific surgical guide (designed from preoperative CBCT and intraoral scan data) will be seated and verified for fit before osteotomy preparation. Implant osteotomies will be prepared according to the manufacturer's protocol for the ultra-wide dental implant, with sequential drilling under copious irrigation. The implant will be placed using a calibrated torque wrench.

Intervention Type
Procedure/Surgery

Primary outcome measure
Implant success rate measured by the dental researcher 4 months after the first surgical stage, according to the Pisa consensus criteria of the International Congress of Oral Implantologists (ICOI)

Secondary outcome measures
1. Implant survival rate measured by the dental researcher, defined as the proportion of implants remaining functional and in situ (not lost or failed), during the study period
2. Days of impaired daily activity, measured using self-reported in a diary as the number of days the patient was unable to fully or partially perform daily activities, during the first postoperative week
3. Postoperative pain was assessed by measuring daily pain levels using a Visual Analogue Scale (VAS), and self-reporting of the number of analgesic tablets consumed, during the first postoperative week
4. Postoperative swelling (edema) was measured using a 4-point scale (0: none, 1: mild, 2:

moderate, 3: severe) during the first postoperative week
5. Surgical and postoperative complications were assessed by measuring:
5.1. Intraoperative: bleeding, injury to adjacent structures, implant displacement, buccal plate integrity (yes/no, reported by clinician/patient).
5.2. Postoperative: early implant loss, bleeding, soft tissue dehiscence or infection at 1 week, 2 weeks, and 4 months
6. Marginal bone level (MBL): Measured mesially and distally using standardized digital radiographs (parallel technique with sensor holder), immediately after placement and after 4 months. Bone loss calculated with ImageJ software
7. Insertion torque: Maximum torque value recorded during implant placement (N·cm)
8. Implant stability (Resonance Frequency Analysis, RFA): Implant Stability Quotient (ISQ) values measured at 4 sites (mesial, distal, buccal, lingual) immediately after placement and at 4 months, averaged per implant
9. Osseointegration: measured using a reverse torque test (≤32 N·cm) after 4 months
10. Patient satisfaction: measured using a 5-point Likert scale (1: strongly agree, 5: strongly disagree) at 4 months post-surgery
11. Soft tissue biotype: Thin vs thick biotype assessed by probe transparency test at baseline and 4 months
12. Height of attached mucosa: Measured with periodontal probe at baseline, immediately post-surgery, and at 4 months
13. Mid-facial mucosal level: measured clinically relative to reference points (prosthesis margin or incisal edge) at baseline, immediately post-surgery, and after 4 months
14. Width of keratinized mucosa: measured distance from the gingival margin to the mucogingival junction, at baseline and after 4 months
15. Oral Health-Related Quality of Life: measured using the validated Arabic version of the Oral Health Impact Profile (OHIP-14) after 4 months

Overall study start date
27/07/2025

Completion date
10/05/2026

Eligibility

Key inclusion criteria
1. Presence of a permanent first mandibular molar indicated for extraction and immediate implant placement, with the extraction socket classified as Class I according to Elian et al. (2007)
2. Age ≥18 years
3. Presence of adjacent teeth to the tooth indicated for extraction.
4. Tooth indicated for extraction is free from acute infection (no periapical swelling or fistula)
5. Intact buccal plate at the extraction site, either before or after extraction
6. Absence of dehiscence or fenestration defects
7. Presence of ≥2 mm width of keratinized mucosa at the extraction/implant site
8. Good oral hygiene (plaque index ≤20% according to the O'Leary index)

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
45 Years

Sex
Both

Target number of participants
42

Key exclusion criteria
1. Systemic conditions: uncontrolled diabetes, bleeding or coagulation disorders, history of head and neck radiotherapy or chemotherapy within the last 6 months
2. Current use of medications affecting bone healing or oral surgery (e.g., corticosteroids, oral anticoagulants)
3. Patients who are smokers or alcohol-dependent
4. Pregnant or breastfeeding women

Date of first enrolment
01/10/2025

Date of final enrolment
18/12/2025

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University, Faculty of Dental Medicine
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Sponsor information

Organisation
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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

Intention to publish date
10/05/2027

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon reasonable request from the corresponding author after publication, Dr. Fouad Agha, aghafouad47@gmail.com

IPD sharing plan summary

Available on request