ISRCTN96988513 https://doi.org/10.1186/ISRCTN96988513

New surgical technique for facial dimple creation

Submission date 08/10/2024	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 09/10/2024	**Overall study status** Completed	
Last Edited 09/10/2024	**Condition category** Surgery	

Plain English summary of protocol
Background and study aims
Surgical creation of facial dimples (dimpleplasty) was first introduced by Boo-Chai in 1962. Despite advancements in surgical approaches made in recent years, there remains a need for a reliable, minimally invasive method that ensures consistent results and high patient satisfaction. This study aims to evaluate a newly proposed surgical technique for facial dimpleplasty, focusing on patient satisfaction, and early recovery symptoms and complications.

Who can participate?
Patients aged between 18 and 30 years who requested dimpleplasty

What does the study involve?
Patients were randomly assigned to either the control group, who received the original dimpleplasty technique, or the test group, who underwent a new surgical technique. Patient-reported outcomes, such as the patient's satisfaction with their decision, outcome and face appearance, and complications were assessed.

What are the possible benefits and risks of participating?
This study will determine the effectiveness of a newly developed surgical procedure for dimpleplasty compared to the conventional method. There is a risk of not achieving optimal results in some cases but the study team can manage these cases with other methods.

Where is the study run from?
Damascus University (Syria)

When is the study starting and how long is it expected to run for?
May 2022 to May 2024

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
Dr Omar Hamdan, omarhamdancedr@gmail.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Dr Omar Hamdan

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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Study information

Scientific Title
A new proposed surgical technique for dimpleplasty

Study objectives
Does the newly proposed surgical technique for dimpleplasty perform better than the conventional technique in terms of patient satisfaction, early recovery symptoms, and complications.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 10/06/2022, Damascus University ethics committee (Damascus, Damascus, 0000, Syria; +963 (0)992964458; manager@hcsr.gov.sy), ref: 22918

Study design
Comparative interventional randomized controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

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

Study type(s)
Quality of life, Efficacy

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
Artificial facial dimpleplasty

Interventions
The first group received dimpleplasty following the technique described by Bao et al. (2007) (control group), while the second group underwent dimpleplasty using a new surgical technique proposed by the authors of this study (test group).

Randomization method: sealed envelope method

Control group:
All surgical procedures were performed under local anesthesia. The ideal location of the facial dimple was determined. The location of the dimple placement was marked on the cheek skin. The buccal mucosa was incised using a no.15 blade, with the incision measuring 2 to 3 mm in length and positioned below the papilla of the Stensen's duct. A syringe needle is then punctured through the cheek from the marked skin and pulled through the buccal mucosa incision. A 3-0 monofilament nylon suture is threaded into the pinhole of the syringe needle and drawn through using a vacuum extractor. Once the suture is pulled through, the needle is gradually withdrawn to the dermis. The needle's direction is then adjusted, puncturing through the dermis and muscle, and pulled through the buccal mucosa incision again. The suture was drawn through the pinhole of the syringe needle, which was then removed from the skin. This process sutures the active facial muscles and dermis together. The knot is tied, forming the dimple.

Test group:
All surgical procedures were performed under local anesthesia. The ideal location of the facial dimple was determined. The location of the dimple placement was marked on the cheek skin. A syringe needle was punctured through the cheek from the marked skin and pulled through the buccal mucosa incision. The buccal mucosa was incised using a no.15 blade, with the incision measuring 4 to 6 mm in length. Dissection of the mucosa was performed to reveal the underlying buccinator muscle. A rectangular portion of the muscle (6 × 4 mm) was excised using fine tissue scissors. The remaining muscle parts and the dermis were then connected using an

absorbable 3-0 Vicryl thread. A knot was made between the muscle and the dermis at the upper part of the incision, and another knot was made at the lower part of the incision. The buccal mucosa was closed with a 5-0 monofilament nylon suture.

Follow-up duration: 2 weeks

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Patient’s satisfaction with decision assessed using the FACE-Q instrument 1 week after the procedure
2. Patient’s satisfaction with outcome assessed using the FACE-Q instrument 4 weeks after the procedure
3. Patient’s satisfaction with overall face appearance assessed using the FACE-Q instrument at baseline and 2 weeks after

Secondary outcome measures
Post-operative complications evaluated using a four-point scale questionnaire 1 week after the procedure

Overall study start date
09/05/2022

Completion date
19/05/2024

Eligibility

Key inclusion criteria
1. Aged between 18 and 30 years
2. Capable of understanding the study procedures and committed to follow-up
3. Maintaining good oral hygiene

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
30 Years

Sex
Female

Target number of participants

20

Total final enrolment
20

Key exclusion criteria
1. Presence of any facial deformities
2. Previous dimpleplasty procedures
3. Suffering from systemic diseases
4. Undergoing radiation therapy in the head and neck region within the last 6 months
5. Smoking

Date of first enrolment
22/11/2022

Date of final enrolment
22/03/2023

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University
Damascus
Syria
0000

Sponsor information

Organisation
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Sponsor details
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Sponsor type
University/education

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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 high-impact peer-reviewed journal

Intention to publish date
19/05/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available on request from Dr Omar Hamdan (omarhamdancedr@gmail.com) and in the publication related to it after the end of the research. Type of data that will be shared: demographic information (age, gender), location of the dimpleplasty, clinical measurements, and the photos of the clinical procedure.

IPD sharing plan summary
Available on request