ISRCTN97129635 https://doi.org/10.1186/ISRCTN97129635

A comparison between traditional surgical technology and implant technology manufactured through 3D printing for nasal repair in patients with cleft lip

Submission date
16/06/2024

Recruitment status
No longer recruiting

Registration date
21/06/2024

Overall study status
Completed

Last Edited
21/06/2024

Condition category
Genetic Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
A cleft lip is one of the most common congenital clefts in the facial area. The nasal deformity following bilateral lip clefts has a severe and direct impact on the patient's appearance and psychological health. Many severe deformities may hinder the patient's breathing and speech, and many post-cleft nasal repair surgeries have chosen to cut cartilage grafts from the ribs (costal cartilaginous graft) because it has proven effective in obtaining excellent surgical results. In this study, the researchers attempt to avoid the disadvantages of traditional open-technique surgery in nasal repair by shortening the time and avoiding a second surgery for the donor area by using 3D printing and designing customized biocompatible silicone implants. This study will be the world's first controlled, randomized, two-group study that will compare the traditional surgical approach (rhinoplasty) with costal cartilaginous grafts and implants manufactured for nasal repair in patients with cleft lip.

Who can participate?
Patients aged 18 years and over undergoing cleft lip closure and needing nasal repair

What does the study involve?
Participants are randomly allocated to one of two groups. Patients in the control group will undergo rhinoplasty and receive a costal cartilaginous graft. Patients in the experimental group will undergo rhinoplasty and receive 3D-printed biocompatible silicone implants.

What are the possible benefits and risks of participating?
Possible benefits are restoring aesthetic, speech and breathing function for patients. Possible risks are on the same level as any surgical operation or procedure.

Where is the study run from?
Al-Assad Hospital (Syria)

When is the study starting and how long is it expected to run for?
January 2024 to April 2025

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
1. Dr Fatima Elmi, fatimaelmi14@gmail.com
2. Prof. Dr Bassel Brad, bassel.brad@damascusuniversity.edu.sy
3. PD Dr Dr Lie Li

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Fatima Elmi

ORCID ID
https://orcid.org/0000-0002-3528-2779

Contact details
Mazzeh Highway
Damascus University
Damascus
Syria
0000
+963 (0)937371462
fatimaelmi14@gmail.com

Type(s)
Scientific

Contact name
Prof Bassel Brad

ORCID ID
https://orcid.org/0000-0002-2428-5499

Contact details
Mezzeh Highway
Damascus
Syria
0000
+963 (0)955873388
bassel.brad@damascusuniversity.edu.sy

Additional identifiers

Protocol serial number
0000

Study information

Scientific Title
Comparison between the conventional surgical technique and implants manufactured by 3D printing regarding cleft lip rhinoplasty patients

Study objectives
Null hypothesis:
The studied groups are equal, and there is no significant difference in nasal repair between the traditional surgical technique and implants manufactured by 3D printing in the research variables studied among cleft lip patients.

Alternative hypothesis:
The groups studied are not equal, and there is a significant difference in nasal repair between the traditional surgical technique and implants manufactured by 3D printing in the research variables studied among cleft lip patients.

Ethics approval required
Ethics approval not required

Ethics approval(s)
Approved 14/05/2024, the medical research committee at Damascus University faculty of dental medicine, +963 (0)944703131, +963 (0)940404840, +963 (0)966195484; abeer79.aljoujou@damascusuniversity.edu.sy, Mohammad.hajeer@damascusuniversity.edu.dy, khaldoun.darwich@damascusuniversity.edu.sy), ref: DN-290424-232

Primary study design
Interventional

Study design
Multicenter interventional randomized clinical trial

Study type(s)
Other, Quality of life, Treatment, Safety

Health condition(s) or problem(s) studied
Cleft lip

Interventions
Following sample enrollment and recruitment, the sample is randomly divided into two groups for this investigation via https://randomizer.org/. Patients in the control group will undergo rhinoplasty (open technique) and receive a costal cartilaginous graft.
Patients in the experimental group will undergo rhinoplasty (open technique) and receive 3D-printed biocompatible silicone implants.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Symmetry measured using geometric morphometrics-based Holistic Facial Asymmetry Score (HFAS)
at baseline, preoperative, 1 week and 4 months postoperatively
2. Pain following surgical intervention is measured using the visual analogue score (VAS) at baseline, 24, 48 and 72 hours

Key secondary outcome(s)
1. Surgical operation time: the duration of each surgery will be calculated in minutes by subtracting the time of leaving the OR from the time of entering the OR. Based on the scheduled duration, the calculated durations were categorized as either overestimation or underestimation. Finally, each independent variable was categorized and coded for analysis (one timepoint - intraoperative).
2. Patient satisfaction measured using the Revised American Pain Society Patient Outcome Questionnaire (APS-POQ-R) at three timepoints: baseline, 24 and 72 hours
3. Bioreceptivity – bioacceptance measured by examining the following:
3.1. Implant's biological function: by accurately assessing the implant's biological function, one can determine how well the implant interacts with the surrounding tissue. Measured at 1 week, 1 month and 3 months postoperatively.
3.2. Biodegradation analysis: entails assessing how a biological system interacts with the body by examining the processes of biodegradation and tissue integration. Measured at 1 week, 1 month and 3 months postoperatively.
3.3. Evaluation of swelling and inflammation: the degree of swelling and inflammation can be quantified as a measure of implant acceptability. Measured at 1 week, 1 month and 3 months postoperatively.
3.4. Cell distribution study: the distribution and kinds of cells surrounding and inside the implant can be examined to determine its biological acceptability. Measured at 1 week, 1 month and 3 months postoperatively.

Completion date
14/04/2025

Eligibility

Key inclusion criteria
1. Older than 17 years old
2. The patient must not have a history of syndrome or any atrophy in the middle third of the face affecting the nasal structures
4. The patient must not have had a previous nose repair operation
5. The lip closure process should be performed using similar techniques
6. There is no case of pregnancy if the patient is female
7. There is no maxillofacial pain in the target area
8. There is no compensation or metal instrument in the body that may interfere with the resonator's magnetic field

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
45 Years

Sex
Male

Total final enrolment
20

Key exclusion criteria
1. Younger than 18 years old
2. The patient has a history of syndrome
3. There is atrophy in the middle third of the face, which affects the nasal structures
4. There is any compensator or metal instrument in the body that may interfere with the field of the PCI magnet resonator

Date of first enrolment
20/05/2024

Date of final enrolment
20/02/2025

Locations

Countries of recruitment
Syria

Study participating centre
Assad University Hospital
Mazzeh Highway
Damascus
Syria
000

Sponsor information

Organisation
Damascus University

ROR
https://ror.org/03m098d13

Organisation
University Hospital Oldenburg

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date