Assessment of the Effect of the Tongue in Groove Technique in Nasolabial Angle and Nasal Tip Projection Changes

Protocol summary

Study aim
Assessment of the Effect of the Tongue in Groove Technique in Nasolabial Angle and Nasal Tip Projection Changes

Design
Clinical trial with before and after comparison

Settings and conduct
Patients which refer to oral and Maxillofacial department of Buali hospital and private office. The study is a randomized clinical trial before and after assessments and follow up for 6 months.

Participants/Inclusion and exclusion criteria
Exclusion criteria consist of the history of previous septo rhinoplastic surgery; trauma to the nose; normal range of nasolabial angle (90-110) and normal tip projection according to good method assessment (55-60 %). Also any jaws deformity requiring orthognathic surgery and any craniomaxillofacial syndrome causing nose deformation, was excluded. Inclusion criteria consist of an abnormal range of naso labial angle and nasal tip projection which should be out of the normal range of 90-110 degree and 55-60%, a patient with a clear history of cranio facial syndrome; trauma to the nose, rhinoplasty surgery; jaw deformities and also a surgery done just based on TIG technique without any other methods contribution which affecting on tip and radix area.

Intervention groups
Tongue in groove surgical technique by definition involves a method by which the medial crura is pulled posteriorly over the caudal part of the nasal septum, in fact this is a type of intervention on the treated specimens. Some angles, such as nasolabial angle or nasal projection, are within the normal range, by using this method. This technique also has effects such as correction of septal deviation or columellar overexpression, which were not examined in this study. Non-use of cartilage, this technique is more and more popular today.

Main outcome variables
Nasolabial Angle; Nasal Tip Projection

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: IRCT20180102038189N1
Registration date: 2019-12-31, 1398/10/10
Registration timing: retrospective

Registrant information
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Dental branch of azad university
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-01-31, 1396/11/11
Expected recruitment end date
2019-06-22, 1398/04/01
Actual recruitment start date
2018-03-01, 1396/12/10
Actual recruitment end date
Trial completion date
2019-11-07, 1398/08/16

Scientific title
Assessment of the Effect of the Tongue in Groove Technique in Nasolabial Angle and Nasal Tip Projection Changes

Public title
The Effect of the Tongue in Groove Technique in Nasal Tip Changes

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
The limit of the Nasolabial Angle should not be in normal range of 90-110 degree
The limit of the Nasal Tip Projection should not be in normal range of 55-60 percentages
The patient should not have a past rhinoplasty surgery
The patient should not have a Craniomaxillofacial syndrome
The patient should not have a Maxillofacial skeletal deformity
The patient should not have a history of trauma to the nose
The surgery should be done based on TIG technique and other methods effecting on nasal tip and nasal radix should not be done

Exclusion criteria:
The limit of the Nasolabial Angle is in the normal range of 90-110 degree
The limit of the Nasal Tip Projection is in the normal range of 55-60 percentages
The patient had a past rhinoplasty surgery
The patient has a Craniomaxillofacial syndrome
The patient has a Maxillofacial skeletal deformity
The patient has a history of trauma to the nose
The surgery should be done in association with other methods effecting on nasal tip and nasal radix

Age
From 18 years old to 55 years old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 20
Actual sample size reached: 20

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Islamic Azad University, Dental branch

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Pasdaran Ave., 9th Neiestan

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Postal code
1946853314

Approval date
2018-05-27, 1397/03/06

Ethics committee reference number
IR.IAU.DENTAL.REC.1397.022

Health conditions studied

1

Description of health condition studied
Changes in Nasolabial Angle and Nasal Tip Projection

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
The measure of Nasolabial Angle

Timepoint
Pre operative measuring, immediate post operative measuring, 6 months after the surgery

Method of measurement
Measuring by Using Standard Photography with Golden Ratio Software

2

Description
The Measure of Nasal Tip Projection

Timepoint
Pre operative measuring, immediate post operative measuring, 6 months after the surgery

Method of measurement
Measuring by Using Standard Photography with Goode technique

Secondary outcomes
empty
Intervention groups

1
Description
Tongue in groove surgical technique by definition involves a method by which the medial crura is pulled posteriorly over the caudal part of the nasal septum, in fact this is a type of intervention on the treated specimens. Some angles, such as nasolabial angle or nasal projection, are within the normal range, by using this method. This technique also has effects such as correction of septal deviation or colomellar overexpression, which were not examined in this study. Non-use of cartilage, this technique is more and more popular today. The study is a comparative study; before and after using the technique. The groups undergoing surgical intervention using the above technique will be measured after angular and projection correction. It is technically sensitive and has very stable results, technically most surgeons refuse to do it and prefer simple techniques with poor results, but in aesthetic practice long-term survival is the principle.

Category
Treatment - Surgery

Recruitment centers

1
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Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable