Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The comparison of Papilla preservation technique and pouch& tunnel with subepithelial connective tissue graft in dark triangle treatment

Protocol summary

Summary

One of the most important esthetics problems in periodontal plastic surgery is the ability to reconstruct papilla in anterior maxilla. Absence of papilla with dark spaces creates “Dark Triangle” which is an important aspect for the clinician to decide whether to treat or not .This problem will cause difficulties such as esthetics, food retention and phonetics. In most articles using sub-epithelial connective tissue with different incisions is recommended. Therefore in this research sub-epithelial connective tissue graft with papilla preservation technique and semilunar incision is used. Ten patients were chosen randomly according to inclusion criteria (above 18 years old; no systemic disease,..) and exclusion criteria (pregnancy; cigarette smoking,...). If there were more patients the number of samples would be increased in each group. Surgical sites are divided into two groups randomly (five patients in each group). Intervention group 1: primary incision is semilunar 3 mm below MGJ, secondary incision is sulcular. Full thickness flap is reflected in semilunar incision. Intervention group 2: papilla preservation technique is used .In cases of short papilla width for a better vascularization the horizontal incision is placed on labial portion. Before surgery the size of papilla is measured by Nordland and Tarnow index and is followed after 3 and 6 month .At the end the papilla is measured apicocoronally and mesiodistally .Wound repair Index and VAS esthetic index are analyzed as well.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201404071760N34**
Registration date: **2014-05-04, 1393/02/14**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2014-05-04, 1393/02/14

Registrant information

Name

Nargess Gholizadeh Pasha

Name of organization / entity

Fatemehzahra Infertility Reproductive Health Research Center, Babol University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology, Babol University of Medical Sciences

Expected recruitment start date

2014-03-11, 1392/12/20

Expected recruitment end date

2014-09-23, 1393/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of Papilla preservation technique and pouch& tunnel with subepithelial connective tissue graft in dark triangle treatment

Public title

The comparison of Papilla preservation technique and pouch& tunnel with subepithelial connective tissue graft in dark triangle treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: existence the dark triangle anterior max; Tarnow all black triangles classified under group I, II; the selected teeth vital and no bleeding after probing; people over 18 years old; ability to maintain good oral hygiene (Oleary plaque score <20%); without stretching the frenum Exclusion criteria: pregnancy; history of blood clotting problems, and hematologic; interfere with the healing agents (corticosteroids, anticancer); drugs interfering with platelet function (NSAIDS); smoking; any local or systemic disease with surgical procedures to prohibit administration; traumatic methods of brushing, toothbrush, toothpaste abrasives or harsh; long-term use of antibiotics in the previous quarter (more than 2 weeks); with known allergies to materials used in surgery; active infectious diseases (tuberculosis, hepatitis, HIV); use of drugs can lead to gingival enlargement.

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The ethics committee of Babol University of Medical sciences

Street address

Babol University of Medical sciences, Ganjafroz Avenue

City

Babol

Postal code

Approval date

2014-03-08, 1392/12/17

Ethics committee reference number

30/3810/پ

Health conditions studied

1

Description of health condition studied

Gingival recession

ICD-10 code

K06.0

ICD-10 code description

Gingival recession

Primary outcomes

1

Description

Treatment of dark Triangle

Timepoint

Before surgery and three and six months after surgery

Method of measurement

Indexed Nordland and Tarnow

Secondary outcomes

1

Description

APico - coronal Papilla dimension

Timepoint

Before surgery and three and six months after surgery

Method of measurement

Mm

2

Description

MOD Papilla dimension

Timepoint

Before surgery and three and six months after surgery

Method of measurement

Mm

3

Description

Healing

Timepoint

Before surgery and three and six months after surgery

Method of measurement

Healing index

4

Description

Beauty

Timepoint

Before surgery and three and six months after surgery

Method of measurement

Indexed beauty VAS

Intervention groups

1

Description

Intervention group 1: The first incision is semilunar 3 mm below MGJ .The second incision is sulcular .In semilunar incision flap is reflected full thickness .SCTG is taken from the palate in premolars site and is sutured with a 4-0 silk suture (Manufacturer: Ethicon, Iran) that has been previously passed from the papilla .Periodontal pack(non-eugenol, GC, USA) is placed both on donor and recipient site .For all patients CHX 0.12% is prescribed for two weeks twice a day for 30 seconds each time .Systemic antibiotics(Penicillin vk 500 mg qid) is prescribed for one week .Pack and suture are removed after two weeks.

Category

Treatment - Surgery

2

Description

Intervention group 2: Papilla preservation technique :papilla preservation incision is used and in cases where the width of papilla is short for better vascularization the horizontal incision is placed on labial .SCTG is taken from the palate in premolars site and is sutured in papilla with 4-0 silk suture(Ethicon, Iran)There after the horizontal incision is sutured with the same suture .Periodontal pack(Non-eugenol, GC, USA)is placed both in donor and recipient site .CHX 0.12 % is prescribed for all patients for two weeks twice per day for 30 seconds each time .Systemic antibiotics (Penicillin vk 500 mg qid) is prescribed for one week .Pack and suture are removed after two weeks.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental colleges of Babol, Babol University of Medical Sciences

Full name of responsible person

Dr. Morteza Rahimi Rad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology, Babol University of Medical Sciences

Full name of responsible person

Dr. Ali Bijani

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Vice Chancellor for Research and Technology, Babol University of Medical Sciences, Ganjafroz Avenue

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for Research and Technology, Babol University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Dental colleges of Babol

Full name of responsible person

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Position

Post graduate student of periodontology

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty