

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effectiveness of hyaluronic acid application in coronally advanced flap(CAF) technique in root coverage

Protocol summary

Study aim

Determining the effect of using hyaluronic acid (HA) gel with Coronally Advanced Flap (CAF) technique on root cover of patients referred to the School of Dentistry of Islamic Azad University of Medical Sciences

Design

According to the results of the study of Radhika Kumar et al. (34) for PPD variable using Advanced Repeated Measure ANOVA Power Analysis option of PASS 11 software, considering $\alpha = 0.05$ and $\beta = 0.2$, the mean standard deviation of the effect on the two time variables The measurement was equal to 0.25 with 4 replications and the type of intervention was equal to 0.11 with 2 repetitions. The minimum sample size required for 13 pairs of samples (13 controls and 13 items) was calculated. The value was calculated.

Settings and conduct

This study is a split-mouth randomized double-blind clinical trial on patients with bilateral Miller's cl 1 gingival recession and referred to the Department of Periodontics, School of Dentistry, Tehran Azad University of Medical Sciences

Participants/Inclusion and exclusion criteria

Patients over 18 years of age. Patients with O'LEARY Index (plaque control index) less than 20%. (58 Presence of at least two buccal gingival analyzes (depth of analysis ≥ 2 mm) and no loss of interproximal joints (Miller class 1) in the anterior regions of the maxilla and mandible (central, lateral, canine, first and second premolars) that have bilateral Cosmetic problems or dental allergies. The presence of CEJ is clear and recognizable. Has sufficient gingival thickness. (thick biotype)

Intervention groups

For the case group after performing CAF technique from Crossed linked-hyaluronic acid (Hyaluronic acid, Hyadent BG, Bioscience, Germany

Main outcome variables

Probe depth / Analysis depth / Analysis width /

Keratinized gingival width / Mean root cover / Miselin
Complete root cover Clinical adhesion surface

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211106052978N1**

Registration date: **2021-12-02, 1400/09/11**

Registration timing: **registered_while_recruiting**

Last update: **2021-12-02, 1400/09/11**

Update count: **0**

Registration date

2021-12-02, 1400/09/11

Registrant information

Name

Fatemeh Zolfaghari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-18, 1400/08/27

Expected recruitment end date

2022-05-17, 1401/02/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of hyaluronic acid application in coronally advanced flap(CAF) technique in root coverage

Public title

Effectiveness of hyaluronic acid in coronally advanced flap(CAF)

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients over 18 years of age. Patients with O'LEARY Index (plaque control index) less than 20%. Presence of at least two buccal gingival analyzes (depth of analysis $\geq$ 2mm) and no loss of interproximal joints (Miller class در) in the anterior regions of the maxilla and mandible (central, lateral, canine, first and second premolars) that have bilateral Cosmetic problems or dental allergies. The presence of CEJ is clear and recognizable. Has sufficient gingival thickness. (thick biotype) Minimum keratinized gingival width (at least 1 mm for shallow lesions and 2 mm for $\geq$ 5 mm lesions) Controls and cases patients in similar areas (type of jaw, type of tooth

Exclusion criteria:

Systemic disease pregnancy Active periodontal disease in the desired area. (Probe depth more than 4mm and BOP) Presence of veneer or restoration with edge on CEJ. History of periodontal surgery in the desired areas in the last 6 months. Smoking Long-term use of antibiotics in the last 6 months. Use of steroids and drugs affecting periodontal tissues

Age

From 18 years old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: 13

More than 1 sample in each individual

Number of samples in each individual: 2

Presence of at least two buccal gingival analyzes (depth of analysis $\geq$ 2mm) and no loss of interproximal joints (Miller class در) in the anterior regions of the maxilla and mandible (central, lateral, canine, first and second premolars) that have bilateral Cosmetic problems or dental allergies.

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, during surgery, using the coin toss method, it is determined which side of the case group and which side of the control group. In this way, the side of the control heads and the side of the case tails were

considered, and after dropping the coin on the case side of hyaluronic acid gel, and on the control side, surgery without hyaluronic acid gel was performed.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, an examiner who measures clinical parameters and reviews and interprets the results, and participants are unaware of which side is the control and which side is the case. Participants (patients) did not know which side of the surgical site used the hyaluronic acid gel.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of the School of Dentistry, Tehran Azad University of Medical Sciences

Street address

9th neyestan pasdaran

City

tehran

Province

Tehran

Postal code

19585175

Approval date

2020-05-26, 1399/03/06

Ethics committee reference number

IR.IAU.DENTAL.REC.1399.045

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**

Probe depth

Timepoint

base line / 6 weeks later / 3 months later / 6 months later

Method of measurement

Probing Pocket Depth (PPD): Measured in the midfacial area from the gingival margin to the end of the pocket by a periodontal probe.

2

Description

recession depth

Timepoint

base line / 2 weeks later / 6 weeks later / 3 months later / 6 months later

Method of measurement

Recession Depth (RD): In the midfacial area from the CEJ to the most apical margin of the gingival margin

3

Description

recession width

Timepoint

base line / 2 weeks later / 6 weeks later / 3 months later / 6 months later

Method of measurement

Recession Width (RW): The width of the gingival resorption is measured at the CEJ.

4

Description

width of keratinized tissue

Timepoint

base line / 2 weeks later / 6 weeks later / 3 months later / 6 months later

Method of measurement

. The width of keratinized tissue, measured from the gingival margin to the MGJ, is measured in the medial region.

5

Description

Mean root coverage

Timepoint

base line / 6 weeks later / 3 months later / 6 months later

Method of measurement

Mean Root Coverage (MRC): The average percentage of root surface previously it was exposed but is now covered. Based on this formula, it is calculated: $(\text{Depth of initial analysis} - \text{RD}_i \text{ and depth of analysis day} - \text{RD}_p) / (\text{RD}_i - \text{RD}_p) \times 100$

6

Description

Complete root coverage

Timepoint

base line / 6 weeks later / 3 months later / 6 months later

Method of measurement

Complete Root Coverage (CRC): Percentage of patients whose root surface is completely covered. And is calculated based on this formula: $(\text{number of specimens that received full root cover} / \text{NCRC and total number of}$

specimens $\square$ NT) $\text{NCRC} / \text{NT} \times 100$

7

Description

Clinical attachment level

Timepoint

base line / 6 weeks later / 3 months later / 6 months later

Method of measurement

Clinical Attachment Level (CAL): In the midfacial areas of RD + PPD

Secondary outcomes

empty

Intervention groups

1

Description

For this research, the trapezoidal CAF technique based on Zucchelli method will be used. (60) After local anesthesia with a Persocaine-E 2% cartridge (lidocaine hydrochloride 20 mg, epinephrine 12.5 micrograms, Darupakhsh Co., Iran) first the root coverage line (CEJ) is determined and then the amount of flap coronation (Y) will be calculated using the opposite formula: $Y = \text{RD} \square 1\text{mm}$ (this 1mm is used to compensate for contraction after surgery.) Then this distance from the tip of the anatomical papilla to the apical is marked. The location of the horizontal incision will be epicoronally. The horizontal incisions will extend mesiodistally from the margin of gingival resorption to 3 mm and at the end of each of them will be a vertical incision that is about 3-4 mm inwards. The alveolar mucosa expands. After determining the boundaries of the incisions, the flap is lifted as described below. , Get up. The apical margin of the gingival resorption is then lifted full-thickness by a narrow alveolus up to 3 mm more apical than the bone crest (to provide sufficient volume of tissue to cover the root). And the rest of the areas that are apical to the bone area are split-ticked to allow the flap to coronalize. Doing this requires two different cuts, which include: 1. Deep incision: to separate the muscle connections from the periosteum (with a razor parallel to the bone surface) 2. Superficial incision: To separate the muscle connections from the alveolar mucosa (by a razor parallel to the mucosal surface), the anatomical papillae are then de-epithelialized, followed by a gentle root planning with a gracy court (# 5-6, hu-friedy) is performed in the area of the area that was previously the root of the exposure, and after determining which side of the case and which side is the control; Crossed linked-hyaluronic acid (Hyaluronic acid, Hyadent BG, Bioscience, Germany) was used for the case group after CAF technique to cover the root surface before suturing. HA as a cartridge It is disposable and is inserted into the syringe, completely covering the root surface according to the factory instructions, and finally the flap becomes coronal at 1mm beyond the CEJ. The stitches are then sewn with a 50 nylon thread as described. After coronalizing the flap, the first suture is sutured at the

apical end of the vertical mesial incision as a simple discontinuous periosteal suture in the coronal direction. The second suture is inserted at the end of the distal vertical incision in the same manner as described (these two sutures hold the flap in the desired coronal area). The vertical incisions are then made one by one with intermittent sutures from the apical to the coronal. Finally, the coronal part of the flap is closed with a sling suture so that first the needle takes the base of the mesial surgical papilla from the outside and after piercing the de-epithelialized anatomical papilla, it comes out from the palatal side, bypassing the tooth and It passes under the distal point of contact and again on the buccal side from the outside, it takes the base of the distal surgical papilla and after piercing the distal de-epithelialized anatomical papilla, it goes around the tooth again and passes under the mesial point of contact; Finally, it is tied at its entrance in Mesial.

Category

Treatment - Surgery

2

Description

Control group: For this research, the trapezoidal CAF technique based on Zucchelli method will be used. (60) After local anesthesia with a Persocaine-E 2% cartridge (lidocaine hydrochloride 20 mg, epinephrine 12.5 micrograms, Darupakhsh Co., Iran) first the root coverage line (CEJ) is determined and then the amount of flap coronation (Y) will be calculated using the opposite formula: $Y = RD - 1\text{mm}$ (this 1mm is used to compensate for contraction after surgery.) Then this distance from the tip of the anatomical papilla to the apical is marked. The location of the horizontal incision will be epicoronally. The horizontal incisions will extend mesiodistally from the margin of gingival resorption to 3 mm and at the end of each of them will be a vertical incision that is about 3-4 mm inwards. The alveolar mucosa expands. After determining the boundaries of the incisions, the flap is lifted as described below. , Get up. The apical margin margin of the gingival resorption is then lifted full-thickness by a narrow alveolus up to 3 mm more apical than the bone crest (to provide sufficient volume of tissue to cover the root). And the rest of the areas that are apical to the bone area are split-ticked to allow the flap to coronalize. Doing this requires two different cuts, which include: 1. Deep incision: to separate the muscle connections from the periosteum (with a razor parallel to the bone surface) 2. Superficial incision: To separate the muscle connections from the alveolar mucosa (by a razor parallel to the mucosal surface), the anatomical papillae are then de-epithelialized, followed by a gentle root planning with a gracy court (# 5-6, hu-friedy) is performed in the area of the area that was previously the root of the exposure, and finally the flap becomes coronal at 1mm beyond the CEJ. The stitches are then sewn with a 50 nylon thread as described. After coronalizing the flap, the first suture is sutured at the apical end of the vertical mesial incision as a simple discontinuous periosteal suture in the coronal direction. The second suture is inserted at the end of the distal vertical incision in the same manner as described

(these two sutures hold the flap in the desired coronal area). The vertical incisions are then made one by one with intermittent sutures from the apical to the coronal. Finally, the coronal part of the flap is closed with a sling suture so that first the needle takes the base of the mesial surgical papilla from the outside and after piercing the de-epithelialized anatomical papilla, it comes out from the palatal side, bypassing the tooth and It passes under the distal point of contact and again on the buccal side from the outside, it takes the base of the distal surgical papilla and after piercing the distal de-epithelialized anatomical papilla, it goes around the tooth again and passes under the mesial point of contact; Finally, it is tied at its entrance in Mesial.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Dentistry of Islamic Azad University of Tehran

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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
Islamic Azad University

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Dr Saeed Sadatmansouri

Position
Associate professor

Latest degree
Specialist

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Sharing plan

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

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

Data Dictionary

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