

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Comparison of clinical efficacy of primary anterior restoration with two different types of post systems with reconstruction of severely damaged teeth in 3-5 years old children

Protocol summary

Study aim

Specifying the clinical success of anterior deciduous repairing through two systems of customized glass fiber post and composite post postal systems in dental restoration with extensive destruction in patients referred to the specialist Pediatric Clinic of the Faculty of Dentistry Islamic Azad University of Medical Sciences, Tehran in 2020.

Design

This was a clinical trial study with a parallel, double-blind group, randomized for 32 patients with 64 samples, which used coins in order to determine care quadrants and the opening envelopes for treating each tooth.

Settings and conduct

Samples will be selected from 3-5-year-old children who go to the Pediatric Clinic of the School of Dentistry of the Islamic Azad University of Medical Sciences in Tehran

Participants/Inclusion and exclusion criteria

Inclusion criteria: Cooperator on the basis Frankel I and II Mentally and physically healthy children The maxillary anterior deciduous tooth in which its pulp was involved and had similar caries on both sides and more than two-thirds of its root length remained without analysis. At least 1 mm of the supragingival structure without caries
Exclusion criteria: Children with mental and physical disorders History of trauma Existence of destructive oral habits Teeth with hypoplasia poor oral hygiene

Intervention groups

The first group made use of customized glass fiber post as a post so that 3 mm of it remained inside the canal, and the remaining was placed out of the canal as the core. The second group used composite as a post. After applying bonding in this group, one layer of flow composite was placed inside the canal. Then the micro-hybrid composite was condensed inside the canal and consequently placed as a layer up to a height of 3 mm.

Main outcome variables

surface texture ; marginal integrity; marginal discoloration ; secondary caries; restoration failure ; retention; gingival health

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200531047611N1**

Registration date: **2020-07-06, 1399/04/16**

Registration timing: **prospective**

Last update: **2020-07-06, 1399/04/16**

Update count: **0**

Registration date

2020-07-06, 1399/04/16

Registrant information

Name

Faezeh Abedi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2020-10-21, 1399/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of clinical efficacy of primary anterior restoration with two different types of post systems with reconstruction of severely damaged teeth in 3-5 years old children

Public title

Comparison of clinical efficacy of primary anterior restoration with two different types of post systems in severely damaged teeth

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Cooperator on the basis Frankel I and II Mentally and physically healthy children who were not involved in systemic disease The maxillary anterior deciduous tooth which its pulp was involved The maxillary anterior deciduous tooth with similar caries on both sides A tooth with more than two-thirds of its root length without physiological or pathological analysis (internal and external) At least 1 mm of the supragingival structure without caries

Exclusion criteria:

History of trauma Existence of destructive oral habits Teeth with hypoplasia Children involved in poor oral hygiene

Age

From **3 years** old to **5 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **32**

More than 1 sample in each individual

Number of samples in each individual: **2**

-

Randomization (investigator's opinion)

Randomized

Randomization description

The teeth of each patient were randomly selected to be repaired through a composite post or customized glass fiber post. The randomization method was that the side that started first was determined by a coin, and then it was decided on the treatment when opening a closed envelope.

Blinding (investigator's opinion)

Double blinded

Blinding description

The consequence assessors were different from the therapist, and the assessor was not aware of the information of patients and the type of treatment taken

on the teeth. The patient was not also informed of the type of treatment on the teeth.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Islamic Azad university of medical sciences, dental school

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No.9, Neyestan 9th alley, Pasdaran Ave.

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Approval date

2020-05-27, 1399/03/07

Ethics committee reference number

IR.IAU.DENTAL.REC.1399.031

Health conditions studied**1****Description of health condition studied**

Primary dental caries

ICD-10 code

K02.63

ICD-10 code description

Dental caries on smooth surface penetrating into pulp

Primary outcomes**1****Description**

Surface texture

Timepoint

3,6 months after treatment

Method of measurement

Observation

2**Description**

Marginal integrity

Timepoint

3,6 months after treatment

Method of measurement

Examination with dental explorer

3

Description

Marginal discoloration

Timepoint

3,6 months after treatment

Method of measurement

Observation

4

Description

Secondary caries

Timepoint

3,6 months after treatment

Method of measurement

Radiography

5

Description

Restoration failure

Timepoint

3,6 months after treatment

Method of measurement

Observation

6

Description

Retention

Timepoint

3,6 months after treatment

Method of measurement

Observation

7

Description

Gingival health

Timepoint

3,6 months after treatment

Method of measurement

Probing

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: All treatments (pulpectomy and repair) were carried out by a therapist. In the first session of treatment, adequate anesthesia was imposed on teeth. Mechanical and chemical measures were prepared by rotary files (easyinsmile international cord-NITI Engine File, USA) (usually up to file number 30) and solutions such as normal saline. In the following, the

canals were dried by paper points. Root canals would be filled by metapex paste (Metapex, META, Korea). In the second session, from the beginning of the canal, it was emptied by a fissure bar connected to angle number 008 (Tizkavan Company, Tehran, Iran) to create a post space of 4 mm. After cleaning and drying the layer post space, a 1 mm thick layer of optical glass ionomer cement (Willmann & Pein- Glass liner, Germany) was replaced (on metapex). Then 3 mm post space was standardized for all samples. After cleaning and rinsing 3 mm at the beginning of the canal, 1-2 second pure air was applied to dry the canal, and then bonding was carried out through the method of self-etching according to the factory instructions. 1-2 bonding drop (Bisco-ALL-BOND UNIVERSAL, USA) was rubbed in the canal in the form of two separate layers, and its additions were removed by pure air. Then, customized strip-shaped fibers (Angelus, Brazil) of customized glass fiber post was applied in accordance with factory instructions. 1-2 bonding drop (Bisco-ALL-BOND UNIVERSAL, USA) was rubbed in the canal in the form of two separate layers, and its additions were removed by pure air. Then, customized strip-shaped fibers (Angelus, Brazil) of customized glass fiber post was used in accordance with factory instructions. So that, 3 mm of it remained inside the canal, and the remaining (2mm) was placed outside of the canal as a core. Some 5 mm strip-shaped fibers were packed inside the canal along with a thin layer of resinous cement (Bisco-DOU-LINK UNIVERSAL, USA), until the space inside the channel was completely filled. After that, it was cured for 20 seconds by a dental light curing device with a power of 800 mw / cm². To rebuild the crown, the enamel was etched for 15 seconds by 35% phosphoric acid (Scotchbond™ Etchant, 3M ESPE, MN, USA). Bonding was applied in the same way as addressed above and after 10 seconds of curing, and the crown was restored by microhybrid composite (Bisco-AELITE ALL / PURPOSE BODY, USA) and the method of incremental.

Category

Treatment - Other

2

Description

Control group: All treatments (pulpectomy and repair) were carried out by a therapist. In the first session of treatment, adequate anesthesia was imposed on teeth. Mechanical and chemical measures were prepared by rotary files (easyinsmile international cord-NITI Engine File, USA) (usually up to file number 30) and solutions such as normal saline. In the following, the canals were dried by paper points. Root canals would be filled by metapex paste (Metapex, META, Korea). In the second session, from the beginning of the canal, it was emptied by a fissure bar connected to angle number 008 (Tizkavan Company, Tehran, Iran) to create a post space of 4 mm. After cleaning and drying the layer post space, a 1 mm thick layer of optical glass ionomer cement (Willmann & Pein- Glass liner, Germany) was replaced (on metapex). Then 3 mm post space was standardized for all samples. After cleaning and rinsing 3 mm at the beginning of the canal, 1-2 second pure air was applied

to dry the canal, and then bonding was carried out through the method of self-etching according to the factory instructions. 1-2 bonding drop (Bisco-ALL-BOND UNIVERSAL, USA) was rubbed in the canal in the form of two separate layers, and its additions were removed by pure air. Then, customized strip-shaped fibers (Angelus,Brazil) of customized glass fiber post was applied in accordance with factory instructions. 1-2 bonding drop (Bisco-ALL-BOND UNIVERSAL, USA) was rubbed in the canal in the form of two separate layers, and its additions were removed by pure air. In the following, bonding was applied by the self-etching method based on the factory instructions. 1-2 bonding drop (Bisco-ALL-BOND UNIVERSAL, USA) was rubbed in the canal in the form of two separate layers, and its additions were removed by pure air. The composite was then utilized as a post (as a control group). In this group, after applying the bonding in the same mentioned method and its curing for 20-30 seconds (based on factory instructions), one layer of flow composites (Bisco-AELITEFLO /AELITEFLO LV,USA) was placed inside the canal and was layered up to a height of 3 mm. The crown rebuild was performed by microhybrid composite

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Pediatric dentistry department of Islamic Azad university of medical sciences, Tehran branch

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

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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

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Faezeh Abedi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

information form No.1 & 2 potential data can be shared after being unrecognizable

When the data will become available and for how long

access is opened 6 months after publication

To whom data/document is available

researchers occupied in scientific and higher education facilities

Under which criteria data/document could be used

for systematic review with permission of the researcher

From where data/document is obtainable

Faezeh Abedi 09132040583 faezehabedi72@yahoo.com

What processes are involved for a request to access data/document

through E-mail

Comments