

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Clinical evaluation of primary molars crown reconstruction with stainless steel crown and direct composite crown

Protocol summary

Study aim

Determining the success, durability and parents' satisfaction of direct composite crown and stainless steel crown in primary molars in pediatric department of Islamic Azad University of Medical Sciences, Dental school; 2020

Design

Randomized clinical trial, including control group and parallel groups, performed on 33 patients. Randomization is achieved through dice tossing and opening sealed envelopes.

Settings and conduct

After pulp treatment, 2mm of Zonalin is applied over the orifices as the deepest layer of the filling, followed by a 1mm layer of lining glass ionomer. Then the cavity is filled with dual cure core build up composite. SSC preparation is performed and after choosing the right size, a putty and wash impression is taken from the tooth covered by the SSC. After removing the SSC, 1mm reduction with fissure bur is performed on healthy walls. After isolation, the core build up material is injected inside the impression, at the location of the prepared tooth, the tray is placed inside the mouth at the exact place. Tray is held with minimum pressure over the tooth for 5 minutes,, then the tray is removed and the composite is light cured for 120 seconds. On the next session the contralateral tooth is restored with SSC. The research is performed in Tehran pedodontics department of Islamic Azad University of Iran.

Participants/Inclusion and exclusion criteria

Cooperative patients; in the range of 4-8 years old; acceptable oral hygiene. at least two intact buccal and lingual walls supported by healthy dentin . no root caries and no root resorption . Children should not have traumatic occlusion.

Intervention groups

In intervention group, the teeth are restored with direct composite crown; in control group the teeth are restored with stainless steel crown.

Main outcome variables

The main outcome is achieving a colored crown with appropriate cost without laboratory procedures.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200601047626N1**
Registration date: **2020-07-20, 1399/04/30**
Registration timing: **prospective**

Last update: **2020-07-20, 1399/04/30**

Update count: **0**

Registration date

2020-07-20, 1399/04/30

Registrant information

Name

Parisa Aref

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2268 6004

Email address

p_aref@dentaliau.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical evaluation of primary molars crown reconstruction with stainless steel crown and direct composite crown

Public title

Primary molar reconstruction with direct composite crown

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Both first primary molars of one of the dental archs require crown coverage after pulp treatment Each tooth has at least two intact buccal and lingual walls Proxogingival floor is supragingival and caries free Remaining walls should be supported by intact dentin and have the width of at least 2mm Patients should be cooperative Patients should be 4-8 years old

Exclusion criteria:

Existing traumatic occlusion Teeth with pathological root resorption Teeth with root caries Teeth with hypoplastic lesions Patients with low oral hygiene based on OHI-S criteria

Age

From **4 years** old to **8 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **33**

More than 1 sample in each individual

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

33 patients whose first primary molars of a jaw require complete cusp coverage because of pulp treatment. teeth should at least have to intact buccal and lingual walls. Therefore cases include pulpotomized teeth with MO, DO, MOD cavities. Proximogingival floor should be supragingival and cries free. Remaining walls should be supported by intact dentin and have at least 2mm thickness. Patients should be cooperative and 4-8 years old.

Randomization (investigator's opinion)

Randomized

Randomization description

In each patients, teeth are selected for coverage with SSC or composite crown randomly. The first side to be treated is selected by coin tossing and the type of the crown is selected by opening the envelopes.

Blinding (investigator's opinion)

Not blinded

Blinding description**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

Street address

No.9, Neyestan 9th Alley, Pasdaran Ave., Tehran.

City

Tehran

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Tehran

Postal code

1946853314

Approval date

2020-05-31, 1399/03/11

Ethics committee reference number

IR.IAU.DENTAL.REC.1399.035

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

Primary teeth caries

ICD-10 code

-

ICD-10 code description

-

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

Marginal adaptation

Timepoint

3-6 months

Method of measurement

Examination with dental explorer

2**Description**

Gingival health

Timepoint

3-6 months

Method of measurement

Probing

3

Description

Secondary caries

Timepoint

3-6 months

Method of measurement

Bitewing radiography

4

Description

Marginal discoloration

Timepoint

3-6 months

Method of measurement

Direct observation

5

Description

Integrity

Timepoint

3-6 months

Method of measurement

Examination with dental explorer and light

6

Description

Parents' satisfaction with restoration's appearance

Timepoint

3-6 months

Method of measurement

Questioning

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After pulp treatment, 2mm of zonalin (Golchay, Iran) is applied over the orifices as the deepest layer of the filling, then it is covered by a 1mm layer of lining glass ionomer (Willman and Peinn, Germany) in order to avoid the detrimental effect of zonalin on composite material. The interior walls are cleaned so that healthy dentinal walls were observed. A metal matrix band is applied and then retained with wedge. The interior walls and proximal box are etched with 37% phosphoric acid for 30 seconds and care is taken in order not to etch the lining glass ionomer. The etchant is rinsed with water for 20 seconds and then air dried. Dental bonding single bond (3M ESPE USA) is applied, air dried for 10 seconds and light cured for 20 seconds. The dual cure core build up material is injected into the tooth until the occlusal surface. After the chemical curing is finished, the tooth is light cured for 2 minutes (40 seconds from each side). The rubber dam, matrix and

wedge are removed and the SSC preparation is performed. 1,5 mm space between occluding teeth and 1mm space between adjacent teeth are achieved. After selection of the appropriate SSC and adjusting it on the tooth, a putty and wash impression is taken from the tooth covered by the SSC. This would give us the exact anatomy of the SSC for the later composite crown, so that the restoration could be an aesthetic replica of the SSC. The SSC is then removed and in order to achieve sufficient composite thickness around the tooth, outer supragingival walls are reduced 1mm with a fissure bur. Gingival bleeding is arrested by injection of access edge material (Centrix, USA) around the tooth. After injecting, the cotton role which is provided by the manufacturer is applied over the tooth, and the patient bites it for 2 minutes. Then the paste is washed out from the sulcus. If bleeding could not be stopped, the rest of the treatment is postponed to another session. In the next step the tooth is isolated with cotton roles and gingival cord and polytetrafluoroethylene (PTFE) tapes are used to cover the adjacent teeth. Etching and bonding is performed as earlier mentioned. The core build up material is injected inside the impression, at the location of the prepared tooth. Cotton roles are removed and the tray is placed inside the mouth at the exact place. Tray is held with minimum pressure over the tooth for 5 minutes, so the chemical curing is assured to be completed, then the tray is removed and the composite is light cured for 40 seconds from buccal, lingual and occlusal separately. Restoration margins are checked and excess materials are removed if any present. Occlusion is checked and final finishing and polishing is done. The final step is to apply a thin layer of Biscover polishing liquid Biscover LV (Bisco, Schaumburg, IL, USA), over the restoration, to do that; first the composite is etched for 15 seconds and rinsed with water, then a thin layer of the liquid is applied is awaited to be there for 15 seconds and finally cured for 30 seconds. for final assessment of the restoration a bitewing radiography is achieved.

Category

Treatment - Other

2

Description

Control group: teeth in the control group are restored with SSC.

Category

Treatment - Other

Recruitment centers

1

Recruitment center**Name of recruitment center**

pedodontics department of Islamic Azad University of Medical Sciences, Tehran Branch

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research Department pf Islamic Azad University of
Tehrran, DEntal Branh

Full name of responsible person
Arash Azizi

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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

Research Department pf Islamic Azad University of
Tehrran, DEntal Branh

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

Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Parisa Aref

Position
Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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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

variants of 1st specific goal: 4-8 year old patient; cooperative patient (Frankel 1-2); both first primary molars of one jaw needs pulp treatment and crown restoration at least two healthy buccal and lingual walls be present which are supported by intact dentin with 2mm thickness absence of subgingival caries variants of 2nd specific goal: bleeding on probing; presence or absence of caries in bitewing radiography; catching with explorer; presence of fractures on enamel or dentin; mobile restoration; restoration's fracture or loss; marginal discoloration; crack or fracture on restoration variants of 3rd specific goal: parents' satisfaction by the appearance of the restoration all the potential data can be shared after unrecognition of the patients

When the data will become available and for how long

access is opened 6 months after publication of results

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

parisa aref through email p_aref@dentaliau.ac.ir

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

through email

Comments