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

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Name of organization / entity

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-07-22, 1399/05/01

Expected recruitment end date
2020-09-22, 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.
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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 damn, 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 polytetrafluroethylene (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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1

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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
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Parisa Aref
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Latest degree
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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 unrecognization 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