Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparing proximal contact of direct and in-direct restorations for reconstruction of endodontically treated teeth: Randomized Clinical Trial

Protocol summary

Study aim

The aim of the present study is to record the proximal contact tightness (PCT) created in the process of clinical restoration of the crowns of root canal treated teeth (RCT) and to compare them in two groups of direct and indirect restorations.

Design

The clinical trial has two intervention groups without control and blinding, block randomization with parallel groups. Numbered envelopes are used for randomization.

Settings and conduct

Patients referred to Shahed dental clinic with one RCT. In one group, after receiving the root treatment, they will undergo complete crown restoration by composite in one session and the PCT with the adjacent teeth will be measured by a specially designed dynamometer device and it will be reported numerically. PCT is also measured by a dentist with dental floss and a score between 0 and 10 is assigned to it. In the second group, after core buildup and preparing the tooth for receiving crown, it is scanned by a dental scanner, and after manufacturing and delivering the Zirconia crown PCT will be measured.

Participants/Inclusion and exclusion criteria

Patients between the ages of 12 and 70 years old with a RCT. Half of the crown should remain after removing the weak or decayed structures, but one of the mesial or distal contacts with the adjacent teeth should be opened. Adjacent teeth should be available to make contact and both teeth should have no obvious clinical mobility. The patient has signed a written consent form. Patients who are Pregnant, lactating, or have severe systemic disorders will be excluded from the study.

Intervention groups

One group will receive direct restoration (composite restoration in one session) and the other group will receive indirect restoration (tooth preparation to receive full zirconia crown).

Main outcome variables

PCT (dynamometer test); type of restoration; PCT (VAS test)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230311057684N1**
Registration date: **2023-03-15, 1401/12/24**
Registration timing: **prospective**

Last update: **2023-03-15, 1401/12/24**
Update count: **0**

Registration date

2023-03-15, 1401/12/24

Registrant information

Name

Sepideh Behzadi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-20, 1402/01/31

Expected recruitment end date

2023-06-21, 1402/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparing proximal contact of direct and in-direct restorations for reconstruction of endodontically treated teeth: Randomized Clinical Trial

Public title
Comparing proximal contact of direct and in-direct restorations for reconstruction of endodontically treated teeth: Randomized Clinical Trial

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients between the ages of 12 and 70 years Patients with permanent dentition A patient with good oral health Patients with normal occlusion The patient has at least one root-treated tooth (first or second molar, first or second premolar of the maxilla or mandible) in need of crown restoration. At least one of the mesial or distal surfaces of the tooth is completely missing and the contact with the adjacent tooth is completely open The adjacent tooth should be available for gaining proximal contact In the root treated tooth, at least two healthy tooth walls are left after removing the weak or decayed tooth structure Have received good quality root canal treatment The patient has signed the written consent form

Exclusion criteria:
Having any severe systemic disease or allergy or intraoral lesions A patient who has periodontal diseases and has lost a lot of periodontal structure (more than 40%) A patient with parafunction or bruxism A patient who has uncontrollable gum bleeding after probing Treated tooth or the tooth adjacent to it has a pathological mobility (grade ≥ 1) The patient is a pregnant or a lactating woman The patient has a mental or physical disability The patient has untreated disorders of the jaw joint

Age
From **12 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, the random allocation rule is used. In this way, according to the two main treatment approaches including direct and indirect restoration, 40 cards are prepared. On 20 of them, code A (corresponding to direct restorative treatment) and on the other 20 cards the code B (related to indirect restorative treatment) is written. Then the cards are placed in opaque envelopes and thrown into a container. Then, the previous dentist From the beginning of the treatment of each tooth, an envelope will be randomly selected and according to the corresponding code, direct or indirect treatment will be performed. The selection of envelopes is without replacement and the selected envelopes will be discarded after registering the type of treatment.

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 Shahed university

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No 39, Italy St, Vesal Shirazi St, Keshavarz Blvd

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Tehran

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Postal code
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Approval date
2023-02-26, 1401/12/07

Ethics committee reference number
IR.SHAHED.REC.1401.171

Health conditions studied

1

Description of health condition studied
Carious teeth in need of root treatment and crown restoration

ICD-10 code
K03.9

ICD-10 code description
Disease of hard tissues of teeth, unspecified

Primary outcomes

1

Description
Proximal contact tightness between the tooth receiving the restoration and the adjacent teeth

Timepoint
Immediately after completing the dental crown restoration

Method of measurement

In order to evaluate the proximal contact, three dentists involved in this study were fully trained and their opinion compliance with the preliminary study (Pilot Study) was checked. (kappa coefficient equal to 0.86 is considered based on statistical test). In order to evaluate the PCT with the adjacent tooth in this study, we will first place the patient's chair (dental unit) in a position where his head is at an angle of 45 degrees with the horizon and he is asked to rest his head completely on the chair. Then the following two methods are used for this evaluation: 1. VAS test (Visual Analogue Scale): For this purpose, dental floss with handles (Ever clean dental floss picks, Iran) will be used and after the floss passes through from Occlusal to gingival, PCT will be recorded as a number from 0 to 10 in VAS format. It should be noted that VAS is a standard visual ruler that can be used in various stuations to rank many variables that cannot be reported numerically and especially in cases that depend on the feelings of the person testing or being tested. 2. Dynamometer test: In order to quantify the PCT, a dynamometer device is used on the order of researchers and made by mechanical science experts. This force measuring device has a sensor sensitive to the application of force (Force sensing resistor, Tekscan co.) with an accuracy of one hundredth of a newton, and a piece designed and connected to the head probe in such a way that a dental floss with a handle can be fixed in this piece. At the same time as the thread passes from the occlusal to the gingival side of the proximal contact area, the force graph is drawn according to time (coded using Arduino micro controller) and the maximum force will be recorded as the force necessary to pass the floss from the proximal contact. In other words, this force represents the intensity of proximal contact. For each examined area, a dental floss is placed in this device and the process of force recording will be repeated three times for each area. Then, the average of these three numbers will be recorded as the proximal contact intensity.

Secondary outcomes

1

Description

Restoration contour in a way that it does not cause gingivitis

Timepoint

After receiving direct or indirect restoration

Method of measurement

Checking the contour via parallel radiography

Intervention groups

1

Description

Intervention group: Performing direct restoration: one week after the root treatment, the patient will return for restoration. First, the fragile and unsupported structure of the tooth is removed and the weak cusps of the tooth are shortened (the cusps whose isthmus is more than half the distance between the peaks of the cusps or the adjacent marginal ridge is missing). Then, the metal matrix strip, which is shaped by a suitable burnisher and has a suitable convexity in the occluso-gingival direction, is placed using a Tofflemire holder and a suitable wedge is placed beside it. It will be done in a way that does not interfere with the proximal contact site. After making sure that the proper isolation is established, the direct repair of the composite will be done according to the existing standards as follows. After ensuring proper isolation, the remaining tooth enamel is etched with 37% phosphoric acid (Ultraetch 35%, U.S.A.) for 20 seconds, then rinsed for 20 seconds and gently dried so that that the dentin remains semi-moist (glistening appearance). Eighth generation bonding agent (Ambar Universal APS, FGM, Joinville, SC, Brazil) is applied according to the manufacturer's instructions and cured by a light curing unit (LED Lightcuring Unit, Kerr, U.S.A.) for 30 seconds. It should be noted that the radiation level of the device is evaluated by a radiometer at the beginning of each session. The restoration is done with the help of Vittra APS composite (FGM, Joinville, SC, Brazil) by incremental method. In the incremental layering technique, the first layer with a thickness of 1 mm is placed on the gingival floor and cured. Then the next layers with a thickness of less than 2 mm will be placed diagonally (so that each layer is in contact with one of the two lingual or buccal walls) and will be cured. It should be mentioned that in order to cure the layers of composite that are in the vicinity of the matrix strip, with a suitable instrument (Contact Pro contact forming instrument, CEJ Dental Inc), first the matrix strip will be pushed towards the adjacent tooth with the maximum force of the dentist's hand and At the same time, the light cure device will turn on for 10 seconds. Then, to complete the polymerization, the dentist will remove the instrument and exposure will be done again for another 40 seconds. After the build-up is completed, the occlusion will be corrected and finishing and polishing will be completed. For this purpose, first, red banded burs (Drendel+Zweiling Diamant GmbH, Kalletal, Germany), needle and taper are used for proximal surfaces and egg shaped burs for occlusal surfaces. After shaping the restoration, in the first stage of polishing, a yellow banded bur (D+Z) with needle, taper, or egg shapes is used. After that, the polishing process is completed using cup and cone polishing rubbers (Kenda polishers) in pink, green, and then white colors respectively.

Category

Treatment - Other

2

Description

Indirect restoration: First, the fragile and unsupported structure of the tooth is removed, and after the core buildup, indirect restoration will be done for monolithic zirconia crown. Fiber post is used in the largest canal of each tooth for core reconstruction. References for the amount for emptying the canal will include the height of the clinical crown, a minimum of 5 mm of gutta-percha remaining at the end of the canal, or the first curve in the canal, whichever is greater. After cementing the fiber

post with self-adhesive dual-cure resin cement (Panavia F2.0, Kuraray, Tokyo, Japan), the rest of the tooth will be reconstructed according to the steps mentioned in the direct restoration section by composite. After the restoration of the teeth, it will be prepared. The minimum occlusal and axial reduction for this restoration is 1 mm. For scanning the tooth, the gingiva is first moved with a 00 subgingival thread (Ultrapak; Ultradent, South Jordan, UT, USA). Then the tooth will be scanned by a scanner (Iaton). In order to eliminate the possible error caused by the influence of a third party in the laboratory (laboratory technician), the indirect restoration design will be done by the dentist involved in the study (who also performs direct restorations) with Exocad software. Then the crown is made with a CAM machine using a zirconia block. Then the crown is ready for sintering and glazing in the corresponding furnace. Since the crown manufacturing process takes one to two weeks, in order to protect the patient's teeth during this interval, a temporary crown is made with acrylic (Acropars TR2, Marlic Medical Inc., Eshtehard, Iran) and is cemented with temporary resin cement (E.T.C, Parkell, Edgewood, NY, USA). The prepared crown is tried and adjusted in the patient's mouth. To try the crown, first the proximal contacts and then the internal fit of the crown will be checked using a silicone material (Fit-Checker, GC America Inc., Alsip, IL, USA). After cleaning the inner surface of the crown with alcohol and drying it, special zirconia primer (Z-Prime Plus, Bisco Inc.) will be applied to the surface. Finally, Self-adhesive resin cement (Panavia F2.0, Kuraray, Tokyo, Japan) will be used to bond the ceramic restoration according to the factory instructions.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Dental clinic of Shahed University
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
Shahed 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
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Shahed University
Full name of responsible person
Sepideh Behzadi
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Resident
Latest degree
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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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Part of the data is accessible. including proximal contact tightness (dynamometer), proximal contact tightness (VAS) and the type of restoration performed for each patient.

When the data will become available and for how long
The beginning of the access period in 2023

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
If researchers need our available data to conduct similar research.

From where data/document is obtainable
Sepideh Behzadi, 00989127380806, behzadisepide@yahoo.com

What processes are involved for a request to access data/document
After completing the data collection, by sending an email to the provided email and explaining the reason for the need to access the data.

Comments