

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Clinical evaluation of the effectiveness of 3 laboratory fabrication methods on marginal adaptation of metal-ceramic single crowns, which are impressed digitally

Protocol summary

Study aim

Clinical evaluation of marginal adaptation of the metal-ceramic single crowns impressed digitally and fabricated by lost wax technique and CAD/CAM with new technology

Design

In this study, 60 abutment teeth in need of crown reconstruction that have inclusion criteria and come to Kermanshah dental college were randomly assigned to intervention groups.

Settings and conduct

Abutment teeth that require crown reconstruction randomly divide into 3 intervention groups. After impressing digitally and preparing tooth by the dentist specialist, the restoration of each group is made in the laboratory. These restorations are examined before and after vinylation with 3 techniques for marginal adaptation: 1-Parallel bite wing radiography 2-Touching the margins of crown using sonde 3-Silicone replica technique: In this technique, after molding the space between the crown and abutment tooth using silicone, the specimens are measured under a Stereomicroscope. In this triple blind study, patients and researchers and evaluator and laboratorist do not know the details of the study and the method of randomization.

Participants/Inclusion and exclusion criteria

INCLUSION: 1- Good general health 2- Periodontal health 3-No obvious sign or symptom of bruxism and/or clenching 4-Abutment requires reconstruction 5-Non-vital abutment teeth with positive long-term prognosis 6-Sufficient periodontal support for single crown restoration and minimum mobility 7-Sufficient tooth preparation length to ensure retention and resistance forms 8-Patients should be satisfied to join our study and sign the consent **EXCLUSION:** 1-Poor oral hygiene 2-Clinical sign and mobility (grade 2 and more) 3-Parafunctional habits 4-Periodontitis and severe gingivitis

Intervention groups

1-control group: casting crowns 2- CAD/Milling crowns 3- CAD/Ceramill Sintron crowns

Main outcome variables

Clinical adaptation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160213026538N4**

Registration date: **2019-09-06, 1398/06/15**

Registration timing: **prospective**

Last update: **2019-09-06, 1398/06/15**

Update count: **0**

Registration date

2019-09-06, 1398/06/15

Registrant information

Name

Hedaiat Moradpour

Name of organization / entity

Kermanshah University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2019-12-21, 1398/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical evaluation of the effectiveness of 3 laboratory fabrication methods on marginal adaptation of metal-ceramic single crowns, which are impressed digitally

Public title

Evaluation of single crowns marginal adaptation, fabricated in 3 different methods

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Good general health (No systemic disease affecting the clinical outcomes) Periodontal health (Plaque index and BOP should be under 20% before prosthodontic treatment) No obvious signs or symptoms of bruxism and/or clenching (Bruxism such as attrition and fractures on the patient's natural tooth or reconstructions, no pain on muscular palpation or tendomyopathy, no pain due to joints, no self reported bruxism or clenching) Abutment teeth requires reconstruction (abutment teeth with existing extensive cavities, fillings or crowns) Non-vital abutment teeth with positive long-term prognosis based on clinical and radiological assessment (No obvious peri-apical or periodontal lesions) Sufficient periodontal support for single crown restoration and minimum mobility Sufficient tooth preparation length to ensure retention and resistance forms Patients should be satisfied to join our study and sign the consent

Exclusion criteria:

Patients that are not willing or able to perform oral hygiene (Plaque index and BOP more than 20%) Abutment tooth with clinical signs Tooth with grade two or more mobility parafunctional habits Periodontitis, severe gingivitis, poor oral hygiene and high active caries

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample sizeTarget sample size: **60****Randomization (investigator's opinion)**

Randomized

Randomization description

Based on the random allocation rule, after determining

60 maxillary and mandibular first molars based on statistical calculations, 20 cards for the Casting group, 20 cards for the CAD/Milling group, and 20 cards for the CAD/Ceramill Sintron group will be placed in a draw glass, then the cards will be dropped out randomly and without replacement and resulting sequence will be recorded. Then, 60 envelopes are prepared and each random sequence created is recorded on a card and the cards are inserted into the envelope respectively. In order to maintain a random sequence, the envelopes are numbered to the same. In the end, the door covers are enclosed in boxes and placed in a box respectively. At the time of the start of the registration of the participants, according to the order of entry of qualified participants to study, one of the envelopes are opened in sequence and the participant's assigned group is revealed.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this clinical trial study, the main researchers involved in, the prosthodontic and student are blind to the assignment of each participant in each of the study groups. Participants in the study are blind toward their own group while they are aware of the similar costs and benefits of clinical treatments based on studies. Also the result analyst and the outcome evaluator, have no information about the data of each group. The Laboratorist is not also aware of each group assignment. Only a health care worker knows about the groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethic Committee of Kermanshah University of Medical Sciences

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Ethics Committee, Department of Research and Technology, Central Building, Shahid Beheshti Blvd.

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Approval date

2019-08-31, 1398/06/09

Ethics committee reference number

IR.KUMS.REC.1398.623

Health conditions studied

1

Description of health condition studied

Marginal adaptation of single unit restorations

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Marginal adaptation of restorations

Timepoint

Before and after veneering the restorations

Method of measurement

Adaptation is measured by using 3 methods: 1.Parallel bite wing radiography 2.Touching by a sonde 3. Silicone Replica technique

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Application of metal ceramic crowns fabricated by CAD/Milling technique

Category

Treatment - Devices

2

Description

Intervention group: Application of metal ceramic crowns fabricated by CAD/Ceramill Sintron

Category

Treatment - Devices

3

Description

Intervention group: Application of metal ceramic crowns fabricated by traditional and wax removal

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Kermanshah dental 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?

No

Title of funding source

Kermanshah Univeristy of Medical Sciences

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

Kermanshah University of Medical Sciences

Full name of responsible person

Hanieh Hamekhani

Position

Under graduated student of Dentistry

Latest degree

Medical doctor

Other areas of specialty/work

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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