

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

clinical evaluation of the marginal adaptation of metal ceramic single unit crowns fabricated by lost wax technique and new Computer Aided Design/Computer Aided Manufacturing technologies

Protocol summary

Study aim

clinical determining of marginal adaptation of metal ceramic single unit restorations 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 in need of crown reconstruction are randomly divided into 3 intervention groups. After the teeth are prepared by the dentist specialist, the restoration of each group is made in the laboratory. This restoration is examined for the time before and after vinylation with 3 techniques for marginal adaptation: 1- 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 double blind study, patients and researchers do not know the details of the study and the method of randomization.

Participants/Inclusion and exclusion criteria

INCLUSION: 1- good general health 2- periodontally healthy 3- no obvious signs or symptoms of bruxing and/or clenching 4- abutment teeth in need of reconstruction 5- non-vital abutment teeth with positive long-term prognosis upon clinical and radiological assessment 6- the tooth should have enough periodontal support for single unit restoration and also minimal mobility 7- the tooth should have enough preparation length to ensure the retention and resistance forms 8- the patient is ready to take part in the study and sign the testimonial
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: casing 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: **IRCT20160213026538N3**

Registration date: **2018-11-18, 1397/08/27**

Registration timing: **registered_while_recruiting**

Last update: **2018-11-18, 1397/08/27**

Update count: **0**

Registration date

2018-11-18, 1397/08/27

Registrant information

Name

Hedaiat Moradpour

Name of organization / entity

Kermanshah University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2018-11-22, 1397/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
clinical evaluation of the marginal adaptation of metal ceramic single unit crowns fabricated by lost wax technique and new Computer Aided Design/Computer Aided Manufacturing technologies

Public title
evaluation of the marginal adaptation of single unit crowns

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 good general health(no systemic disease that should negatively influence the clinical outcome) periodontally healthy(plaque index and bleeding on probing had to be below 20% previously to the prosthodontic treatment) no obvious signs or symptoms of bruxing and/or clenching((bruxismsuch as attritions and existing fractures on the patientsnatural teeth or reconstructions, no pain on muscular palpationor tendomyopathies, no pain causing joint sound, no selfreportedbruxing or clenching) abutment teeth in need of reconstruction (abutment teeth withexisting extensive cavities, fillings or crowns) non-vital abutment teeth with positive long-term prognosis uponclinical and radiological assessment (no peri-apical or apparentperiodontal lesions) the tooth should have enough periodontal support for single unit restoration an also minimal mobility the tooth should have enough preparation length to ensure the retention and resistance forms the patient is ready to take part in the study and sign the testimonial
Exclusion criteria:
 The patient is not willing or able to observe oral hygiene (Plaque index and BOP should be below 20%). The abutment tooth has clinical sign. The tooth has grade two or more mobility. parafunctional habits Periodontitis, severe gingivitis, poor oral hygiene and high caries activity

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Based on the random allocation law, 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 the 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)
Double blinded

Blinding description
in this clinical trial study, the main researchers involved in the prostodontics and students are blind to the assignment of each participant in each of the study groups. Participants in the study are blind toward their own group when 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. 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
 Ethics Committee of Kermanshah University of Medical Sciences
Street address
 Ethics Committee, Department of Research and Technology, Central Building, Shahid Beheshti Boulevard, Kermanshah
City
 kermanshah
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 Kermanshah
Postal code
 6715847141
Approval date
 2018-01-03, 1396/10/13
Ethics committee reference number

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 of restorations

Method of measurement

adaptation is measured using 3 methods:1-parallal bite wing radiography2-touch using a sonde3-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

Control group: application of metal ceramic crowns fabricated by traditional wax removal

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

kermanshah dental university

Full name of responsible person

Hedaiat Moradpour

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Shariati Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

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

Kermanshah University 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

Mahsa Samavati

Position

Under graduated Student of Dentistry

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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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