Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

Comprative study the clinical outcomes of the Endocrowns and Conventional crowns fabricated by Computer Aided Design/Computer Aided Manufacturing (CAD/CAM): A Randomized clinical trial

Protocol summary

Study aim

Comprative study the clinical outcomes of the Endocrowns and Conventional crowns fabricated by CAD/CAM

Design

In this Randomized Triple blinded Clinical trial study, 44 maxillary and mandibular teeth in need of crown reconstruction that have inclusion criteria and visit the prosthodontist's clinic in kermanshah are randomly assigned to intervention groups

Settings and conduct

Teeth in need of crown reconstruction are randomly divided into 2 intervention groups.clinical treatment is done by a prosthodontist with 10 years of work experience in a dental clinic.in each group the restorations are made of Lithium disilicate glass-ceramic and fabricated by CAD/CAM and inserted after the tooth preparation.then,teeth are followed for 6 months by another prosthodontist and a calibrated examiner based on CDA(California Dental Association) criteria.in this triple blinded study,only the prosthodontist who insert the restorations knows about the groups and participants,outcome evaluators and result analyst are blinded.

Participants/Inclusion and exclusion criteria

INCLUSION:1. Have the opposite teeth in functional occlusion and at least one proximal contact. 2. Acceptable oral hygiene and periodontally healthy. 3. Good general health. 4. No obvious signs or symptoms of bruxing and/or clenching. 5. The patient is ready to take part in the study and sign the testimonial. EXCLUSION:1. Presence of para-functional habits. 2. Presence of periodontal problems and dental or medical history that can complicate the preparation of the restoration. 3. The lack of cooperation of the patients to observe oral hygiene.

Intervention groups

1-control group:conventional crowns fabricated by CAD/CAM. 2-Endocrowns fabricated by CAD/CAM

Main outcome variables

shade match,surface texture,marginal integrity,fracture,recurrent caries,retention,Wear,Antagonist Wear,Mobility,Pocket depth,Bleeding on probing,Gingival index,Plaque index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160213026538N5**
Registration date: **2020-05-17, 1399/02/28**
Registration timing: **prospective**

Last update: **2020-05-17, 1399/02/28**
Update count: **0**

Registration date

2020-05-17, 1399/02/28

Registrant information

Name

Hedaiat Moradpoor

Name of organization / entity

Kermanshah University of Medical Siences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-21, 1399/03/01

Expected recruitment end date

2020-08-22, 1399/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comprative study the clinical outcomes of the Endocrowns and Conventional crowns fabricated by Computer Aided Design/Computer Aided Manufacturing (CAD/CAM): A Randomized clinical trial

Public title

Comprative study the clinical outcomes of the Endocrowns and Conventional crowns

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who need their maxillary or mandibular teeth to be restored and have the opposite teeth in functional occlusion and at least one proximal contact with the adjacent teeth Acceptable oral hygiene and periodontally healthy(plaque index and bleeding on probing had to be below 20% previously to the prosthodontic treatment) Good general health(no systemic disease that should negatively influence the clinical outcome) No obvious signs or symptoms of bruxing and/or clenching (bruxism such as attritions and existing fractures on the patients natural teeth or reconstructions, no pain on muscular palpation or tendomyopathies, No pain causing joint sound, no selfreported bruxing or clenching) The patient is ready to take part in the study and sign the testimonial

Exclusion criteria:

Presence of para-functional habits including clenching,bruxism or grinding Presence of periodontal problems and dental or medical history that can complicate the preparation of the restoration The lack of cooperation of the patients to observe oral hygiene(Plaque index and BOP should be below 20%)

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Based on the random allocation law, after determining 44 maxillary and mandibular molars based on statistical calculations, 22 cards for the Endocrown group and 22 cards for the Conventional crown 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,44 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, only the prosthodontist who insert the crowns and endocrowns knows about the groups and the outcome evaluators(other prosthodontist and the calibrated examiner) 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, have no information about the data of each group.It should be mentioned as the restorations have no differences in appearance after insertion,triple blinding is available.

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

Province

Kermanshah

Postal code

6715847141

Approval date

2020-01-14, 1398/10/24

Ethics committee reference number

IR.KUMS.REC.1399.127

Health conditions studied

1

Description of health condition studied
Shade match of Endocrown Compared to Conventional Crown
ICD-10 code
ICD-10 code description

2

Description of health condition studied
Fracture of Endocrown Compared to Conventional Crown
ICD-10 code
ICD-10 code description

3

Description of health condition studied
Surface texture of Endocrown Compared to Conventional Crown
ICD-10 code
ICD-10 code description

4

Description of health condition studied
Marginal integrity of Endocrown Compared to Conventional Crown
ICD-10 code
ICD-10 code description

5

Description of health condition studied
Retention of Endocrown Compared to Conventional Crown
ICD-10 code
ICD-10 code description

6

Description of health condition studied
Recurrent caries in Endocrown Compared to Conventional Crown
ICD-10 code
ICD-10 code description

7

Description of health condition studied
Wear of Endocrown Compared to Conventional Crown
ICD-10 code
ICD-10 code description

8

Description of health condition studied
Antagonist Wear in Endocrown Compared to Conventional Crown
ICD-10 code
ICD-10 code description

9

Description of health condition studied
Periodontal health in Endocrown Compared to Conventional Crown
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Shade match of Endocrown and Conventional Crown
Timepoint
At the time of the restoration insertion,1 week later,3 and 6 months later
Method of measurement
California Dental Association(CDA) Follow up evaluation criteria

2

Description
Surface texture of Endocrown and Conventional Crown
Timepoint
At the time of the restoration insertion,1 week later,3 and 6 months later
Method of measurement
California Dental Association(CDA) Follow up evaluation criteria

3

Description
Marginal integrity of Endocrown and Conventional Crown
Timepoint
At the time of the restoration insertion,1 week later,3 and 6 months later
Method of measurement
California Dental Association(CDA) Follow up evaluation criteria

4

Description
Fracture of Endocrown and Conventional Crown
Timepoint
At the time of the restoration insertion,1 week later,3 and 6 months later
Method of measurement
California Dental Association(CDA) Follow up evaluation criteria

5

Description
Recurrent Caries in Endocrown and Conventional Crown
Timepoint
At the time of the restoration insertion,1 week later,3 and 6 months later
Method of measurement
California Dental Association(CDA) Follow up evaluation

criteria

6

Description
Retention in Endocrown and Conventional Crown
Timepoint
At the time of the restoration insertion,1 week later,3 and 6 months later
Method of measurement
California Dental Association(CDA) Follow up evaluation criteria

7

Description
Mobility of the tooth in Endocrown and Conventional Crown
Timepoint
At the time of the restoration insertion,1 week later,3 and 6 months later
Method of measurement
By a dental mirror

8

Description
Wear of Endocrown and Conventional Crown
Timepoint
At the time of the restoration insertion,1 week later,3 and 6 months later
Method of measurement
California Dental Association(CDA) Follow up evaluation criteria

9

Description
Antagonist Wear in Endocrown and Conventional Crown
Timepoint
At the time of the restoration insertion,1 week later,3 and 6 months later
Method of measurement
California Dental Association(CDA) Follow up evaluation criteria

10

Description
Pocket depth in Endocrown and Conventional Crown
Timepoint
At the time of the restoration insertion,1 week later,3 and 6 months later
Method of measurement
Dental probe

11

Description
Bleeding on probing in Endocrown and Conventional Crown
Timepoint
At the time of the restoration insertion,1 week later,3 and 6 months later
Method of measurement
Dental probe

12

Description
Gingival index in Endocrown and Conventional Crown
Timepoint
At the time of the restoration insertion,1 week later,3 and 6 months later
Method of measurement
Gingival index

13

Description
Plaque index in Endocrown and Conventional Crown
Timepoint
At the time of the restoration insertion,1 week later,3 and 6 months later
Method of measurement
Plaque index

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Conventional crowns made from Litium disilicate glass-ceramics and fabricated by CAD/CAM
Category
Treatment - Other

2

Description
Intervention group: Endocrowns made from Litium disilicate glass-ceramics and fabricated by CAD/CAM
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr Moradpour Dental clinic
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
Farid Najafi
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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
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Position
Under graduated student of Dentistry
Latest degree
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Person responsible for updating data

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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