Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

5 year clinical evaluation of indirect full ceramic restorations(CEREC)

Protocol summary

Summary

Purpose: To evaluate the 5 year clinical performance of CEREC All ceramic indirect restorations, placed on tooth and implant abutments. Inclusion criteria: consisted of having received an indirect CAD/CAM all- ceramic restoration from the same private practice during the aforementioned time span Population and Sample size: 230 patients who had received CAD-CAM ceramic restorations (Cerec) between March 2009 to March 2010. Restorations consisted of veneers, inlay , onlay and crowns on natural tooth and implant abutments. Treatment was performed by one prosthodontist in a private clinic. Intervention and Time: The patients were recalled to be examined after 6 and 1224, 36, 48 and 60 months intervals. The follow-up examinations were performed by 2 prosthodontists other than the clinician who had placed restorations. For each patient, These data were collected: sex, age at crown delivery, tooth or implant position, luting agent, occluding teeth, endodontic treatment before delivery, post and core material, occlusal contacts, and periodontal parameters. CDA guidelines were used to evaluate the quality of restorations. Variables Alpha and Bravo (excellent and acceptable) were defined as successes, whereas variables Charlie and Delta (not acceptable) were defined as failures and remake of crown was necessary. The treatment was also considered a failure when the abutment tooth was extracted or implant failed following biologic complication. The patients were interviewed regarding their satisfaction using a visual analogue scale (VAS).

General information

Acronym

CAD/CAM

IRCT registration information

IRCT registration number: **IRCT2014083118981N1**
Registration date: **2014-10-24, 1393/08/02**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2014-10-24, 1393/08/02

Registrant information

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Omid Savabi
Name of organization / entity
Isfahan University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Isfahan university of medical science

Expected recruitment start date

2009-03-21, 1388/01/01

Expected recruitment end date

2010-03-20, 1388/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

5 year clinical evaluation of indirect full ceramic restorations(CEREC)

Public title

Survival and success rate of CAD/CAM All-ceramic crowns.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria Patients who referred to the clinic.;Patients which indirect CAD/CAM all- ceramic restoration has indication for their treatment.;Patients who needed single implant treatment. Exclusion criteria Patients who don't accept to enter the study.; Indirect all-ceramic restorations was contraindicated as a treatment option.

Age
From **18 years** old to **78 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **230**

Randomization (investigator's opinion)
N/A

Randomization description

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
Isfahan Regional Bioethics Committee

Street address
University of Medical Sciences

City
Isafahn

Postal code
8174673461

Approval date
2014-07-23, 1393/05/01

Ethics committee reference number
393400

Health conditions studied

1

Description of health condition studied
Other special examinations and investigations of persons without complaint or reported diagnosis

ICD-10 code
Z01.2

ICD-10 code description
Dental examination

Primary outcomes

1

Description
Survive or failure of treatment

Timepoint
6 ,12,24,36,48 and 60 months with calculation from the date of the insertion

Method of measurement
Clinical examination

Secondary outcomes

1

Description
Evaluation of technical and biological complications

Timepoint
6 ,12,24,36,48 and 60 months with calculation from the date of the insertion

Method of measurement
CDA guidelines for indirect restorations and periodontal parameters(Gingival Index, Plaque Index ,Probing pocket depth ,Bleeding on probing) for periodontal evaluations.

Intervention groups

1

Description
Intervention group 1: For tooth- supported crowns the abutment teeth were prepared with a circumstantially rounded shoulder (1.0 mm in width), an axial reduction of 1.5 mm, and an occlusal reduction of 1.5 to 2.0 mm with 6 to 7° taper. The preparation margins were located at the gingival level or not more than 1 mm subgingivally. Preparation protocol for inlays and onlays was as follows: 1.5-2.0 mm pulpal floor depth, 1.0-1.5 mm axial reduction, 2.0 mm isthmus width, 1.5-2.0 mm occlusal reduction with Rounded internal line angles. For veneers average labial reduction was 0.5 mm with a long chamfer margin. After preparation, the teeth were isolated by cotton roll and saliva ejector and were scanned with CEREC BlueCam (CEREC AC) from occlusal and buccul view and in occlusion. Restorations were designed with digital design software (CEREC 3D 3.85) and milled from Śirona glass ceramic blocks, Empress CAD, or emax CAD in a standard speed. After milling proximal contacts and static and dynamic occlusal contacts were checked and corrected with fine diamond burs and water cooling. Silicon disclosing medium (Fit Checker, GC Co) was used to check the fit of restorations. Resin cements were used for luting of the tooth-supported restorations. The patients were recalled to be examined after 6 and 12, 24, 36, 48 and 60 months intervals. The follow-up examinations were performed by 2 prosthodontists other than the clinician who had placed restorations. For each patient, These data were

collected: sex, age at crown delivery, tooth or implant position, luting agent, occluding teeth, endodontic treatment before delivery, post and core material, occlusal contacts, and periodontal parameters. CDA guidelines were used to evaluate the quality of restorations. Variables Alpha and Bravo (excellent and acceptable) were defined as successes, whereas variables Charlie and Delta (not acceptable) were defined as failures. The tooth extraction or loss of vitality or any condition result in remake of restoration were also consider as failure.

Category

Treatment - Other

2

Description

Intervention group 2; intervention1: For Implant-supported restorations, the implants were non-submerged (Soft tissue level, ITI Dental Implant System, Straumann AG, Basel, Switzerland). Conventional delayed loading protocol was followed after implant placement. All of the abutments were solid abutments. Abutments were scanned intraoraly with CEREC BlueCam (CEREC AC) from occlusal and buccul view and in occlusion. Restorations were designed with digital design software (CEREC 3D 3.85) and milled from emax CAD in a standard speed. Silicon disclosing medium (Fit Checker, GC Co) was used to check the fit of restorations. Resin cements were used for cementation of the Implant-supported restorations. The patients were recalled to be examined after 6 and 12, 24, 36, 48 and 60 months intervals. The follow-up examinations were performed by 2 prosthodontists other than the clinician who had placed restorations. For each patient, these data were collected: sex, age at crown delivery, implant position, luting agent, occluding teeth, occlusal contacts, and periodontal parameters. CDA guidelines were used to evaluate the quality of restorations. Variables Alpha and Bravo (excellent and acceptable) were defined as successes, whereas variables Charlie and Delta (not acceptable) were defined as failures and remake of crown was necessary. The treatment was also considered as a failure when implant failed following biologic complication. The patients were interviewed regarding their satisfaction using a visual analogue scale (VAS).

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Universuty of Medical Sciences

Full name of responsible person

Dr. Omid Savabi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Deputy of Research, Isfahan University of Medical Sciences

Full name of responsible person

Dr. Peyman Adibi

Street address

Hezar jarib St, Isfahan University of Medical Sciences, School of Dentistry

City

Isfahan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Research Deputy of Research, Isfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty