

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Clinical evaluation of marginal fit of monolithic zirconia FDP, using scan able and conventional polyvinyl siloxane impression materials

Protocol summary

Study aim

Determining the most accurate molding method for use in prosthetic work

Design

clinical trial, control group, parallel groups

Settings and conduct

Among the patients referred to the dentures department of Shiraz Dental School, 10 people will be selected for lateral tooth replacement.

Participants/Inclusion and exclusion criteria

Patients who have lost their lateral teeth The patient should not be a deep bite The patient should have sufficient crown length

Intervention groups

Because the type of molding impressions and the method used in making prostheses and its marginal accuracy are of great importance, the purpose of this in-vivo study is to evaluate the marginal fit using conventional and scanable poly-vinyl siloxane impression materials, Then the accuracy of these two impression materials in recording the margin area will compare.

Main outcome variables

clinical evaluation of marginal fit

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201011048994N1**

Registration date: **2021-01-26, 1399/11/07**

Registration timing: **registered_while_recruiting**

Last update: **2021-01-26, 1399/11/07**

Update count: **0**

Registration date

2021-01-26, 1399/11/07

Registrant information

Name

benika abbasi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3625 2335

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-18, 1399/07/27

Expected recruitment end date

2021-03-10, 1399/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical evaluation of marginal fit of monolithic zirconia FDP, using scan able and conventional polyvinyl siloxane impression materials

Public title

marginal fit of monolithic zirconia FPD

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

All people who need a 3-unit bridge to replace a lateral tooth

Exclusion criteria:

All people who do not have lateral teeth The abutments have sufficient crown length

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample sizeTarget sample size: **10**

More than 1 sample in each individual

Number of samples in each individual: **2**

From the prepared teeth of every 10 people take impression as the first group by the one-step putty-wash technique, which according to the manufacturer's instructions, first mixes two putty poly-vinyl siloxane scan capable pastes and puts them inside. Then light material is injected by guns on it and a tray is placed in the mouth and sufficient pressure is applied until the final set and the resulting molds are scanned by a scanner (3ShapeD810; 3Shape) SD laser scanned. Due to the properties of the molding material, there is no need to use spray when scanning. For the second group, again out of every 10 people in the same session, a mold is taken with putty poly-vinyl siloxane conventional material and then light material is taken on it with the same steps as with added silicone material (Panasil putty soft and initial contact light, Kettenbach, Eschenburg, Germany) is used. And then its gypsum cast is poured by Stone Dye Type IV gypsum. (GC Fujirock, GC corporation, leuven, Belgium). In the molds of the second group, in order for the surfaces of these dies to be able to be scanned, they are sprayed with a scan. These dies are also scanned by (3ShapeD810; 3Shape) SD laser scanned. The data obtained from both groups is converted to CAD data (3Shape CAD Design software; 3Shape).

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

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

Ethics committee of Shiraz University of Medical Sciences

Street address

Shiraz, Qasrdasht St., Corner of Mehr St., Shiraz

Dental School, First floor, Fixed Prosthesis Ward

City

Shiraz

Province

Fars

Postal code

۷۵۸۷۸- ۷۱۹۵۶

Approval date

2020-12-27, 1399/10/07

Ethics committee reference number

IR.SUMS.DENTAL.REC.1399.174

Health conditions studied**1****Description of health condition studied**

clinical evaluation of marginal fit

ICD-10 code

-

ICD-10 code description

-

Primary outcomes**1****Description**

Percentage of molding material error

Timepoint

End of treatment when prosthesis is delivered

Method of measurement

The replica is made and then the thickness of the silicon outer layer is measured with a microscope at 230X magnification (AM413FIT Dino-Lite Pro; Dino-Lite Electronic Corp. and image analysis software (DinoCapture 2.0; AnMo Electronics Corp.). Shows the marginal fit.

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: From 10 prepared teeth, a mold is prepared by a one-step putty-wash technique. According to the manufacturer's instructions, first two putty poly-vinyl siloxane scan capable pastes are mixed and placed inside, and then the light material by The gun is injected into it and a tray is placed in the mouth and sufficient pressure is applied until the final set and the resulting molds are scanned by a scanner (3ShapeD810; 3Shape) SD laser scanned. Control group: For every 10 people in the same session, a mold is taken with putty poly-vinyl siloxane conventional material and then light material is taken on it with the same steps as with added silicone material (Panasil putty soft and initial contact light,

Kettenbach, Eschenburg, Germany) Is used. And then its gypsum cast is poured by Stone Dye Type IV gypsum. (GC Fujirock, GC corporation, leuven, Belgium). In the molds of the second group, in order for the surfaces of these dies to be able to be scanned, they are sprayed by scanning spray

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Prosthodontics, Shiraz Dental School

Full name of responsible person

mohammad hasan kalantari

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Email

kalantarim@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Hasan Kalantari

Street address

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dental@sums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Hasan Kalantari

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Mohammad Hasan Kalantari

Position

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Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
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Position
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Latest degree
Medical doctor

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data is potentially shareable after unidentified individuals

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

There are no special conditions

From where data/document is obtainable

abbasi_b@sums.ac.ir

What processes are involved for a request to access data/document

After reviewing the application and the reasons provided by the applicant, the data files will be sent as a PDF file via email.

Comments