

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of Placement Accuracy (Precision & Trueness) In Digitally-guided Implants and Prefabricated Provisional Single-unit Restorations: A Clinical Trial Study

Protocol summary

Study aim

Evaluating the accuracy of digitally-guided implant placement and single-unit prefabricated temporary restorations

Design

This study has only one intervention group and no control group. The sample size was calculated based on the Valente 2009 study and the two main variables of Lateral Apical Deviation and Angular Deviation. 14 implant units will be included.

Settings and conduct

All patients are examined and treated in the faculty of dentistry at Tehran University of Medical Sciences. Surgical guides, customized abutments, and temporary crowns are designed in the virtual environment using CBCT records and intraoral scans. Surgical guides, customized abutments, and temporary crowns are manufactured. After performing a flapless implant surgery using the surgical guide and installing the customized abutment, a post-surgical CBCT radiography will be taken. Another intraoral scan is taken after cementing the temporary crown. Implant and crown locations are compared with their designed position using 3shape software.

Participants/Inclusion and exclusion criteria

Patients who need single-implant crowns are included (there might be multiple sites in the mouth that needs implants, but no one receives adjacent implants). Cases that require graft or sinus lift surgery before implant placement were excluded.

Intervention groups

Patients needing single-unit implant restorations will be included in the only intervention group. These patients will receive digitally-guided implants, customized abutments, and temporary crowns.

Main outcome variables

Implant angular deviation : Implant lateral apical

deviation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211208053334N1**

Registration date: **2022-08-06, 1401/05/15**

Registration timing: **prospective**

Last update: **2022-08-06, 1401/05/15**

Update count: **0**

Registration date

2022-08-06, 1401/05/15

Registrant information

Name

Parsa Pirooz

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2200 7927

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p-pirooz@student.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-11, 1401/05/20

Expected recruitment end date

2022-09-11, 1401/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Placement Accuracy (Precision & Trueness)
In Digitally-guided Implants and Prefabricated Provisional
Single-unit Restorations: A Clinical Trial Study

Public title

Evaluation of Implant Placement by digital method

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

at least two months after tooth extraction acceptable
occlusion

Exclusion criteria:

presence of a systemic disease smoking contraindication
for surgical procedures presence of parafunctional habits
presence of TMJ complications need for graft or sinus lift
surgery

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **14**

Randomization (investigator's opinion)

N/A

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features

this study includes only one group of patients. the aim of
this study is to compare the position of implant and its
temporary restoration with its digitally designed
counterpart. As a result, there is no blinding or
randomization in this study.

Secondary Ids

empty

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

Ethics committee of Tehran University of Medical
Sciences

Street address

Hassanabad - Zargandeh ghadir alley omidvar alley

Number 14 3rd floor, Tehran, 1916994696, Iran

City

Tehran

Province

Tehran

Postal code

1916994696

Approval date

2021-12-19, 1400/09/28

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.1101

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

Partial loss of teeth, unspecified cause

ICD-10 code

K08.40

ICD-10 code description

Partial loss of teeth, unspecified cause

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

the difference in implant angulation of designed and
actual implants

Timepoint

immediately after surgery

Method of measurement

post-surgical CBCT

2**Description**

the difference in apex location of designed and actual
implants

Timepoint

immediately after surgery

Method of measurement

post-surgical CBCT

Secondary outcomes**1****Description**

the difference in placement angle of designed and actual
crowns

Timepoint

two weeks after surgery and placement of the temporary
restoration

Method of measurement

post-operative intraoral scanning

2**Description**

the difference in crown depth of designed and actual

crowns
Timepoint
two weeks after surgery and placement of the temporary restoration
Method of measurement
post-operative intraoral scanning

3
Description
Early Implant Failure
Timepoint
up to three months after surgery
Method of measurement
clinical and radiographic examination

4
Description
Bleeding on Probing
Timepoint
3 months after surgery
Method of measurement
periodontal probing

5
Description
peri-implant probing depth
Timepoint
3 months after surgery
Method of measurement
periodontal probing

Intervention groups

1
Description
Intervention group: single-unit implant placement in partially edentulous patients with the aid of surgical guides, which are designed (3shape dental system©) and printed after obtaining intraoral scan and CBCT radiographic records. Each patient undergoes a single-session surgery. Implant fixtures (DIO Implant©) are placed without incisions (flapless surgery) and according to the drilling protocols related to the fixture size. Customized healing abutments are inserted immediately after fixture placement. A post-surgical CBCT radiography will be taken after the surgery. Temporary crowns will be cemented (Hoffman zinc phosphate cement©) two weeks after the surgery, and a subsequent intraoral scan will be recorded. The actual fixture and crown position will be compared using post-surgical records. Patients will be set to come back after three months to assess the clinical success of the implants (early implant failure, bleeding on probing, and peri-implant probing depth).
Category
Treatment - Surgery

Recruitment centers

1
Recruitment center
Name of recruitment center
Dentistry Faculty - Tehran University of Medical Sciences
Full name of responsible person
parsa pirooz
Street address
Hassanabad - Zargandeh ghadir alley omidvar alley
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Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
مرضيه عليخاى
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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
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
parsa pirooz
Position
student
Latest degree
A Level or less
Other areas of specialty/work
Dentistry
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Person responsible for updating data

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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

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Radiographic records, intraoral scans, and virtual designs for surgical guides, customized abutments, and temporary crowns will be available. These records don't allow patient recognition; each will be merely made related to an intraoral scan.

When the data will become available and for how long

Study documents will be available to applicants three months after the article's publication.

To whom data/document is available

Researchers in possession of a study proposal related to our study topic are eligible to receive the records.

Under which criteria data/document could be used

Using study records for further investigations and analysis as well as combining these records with other studies to reach more comprehensive results are suitable.

From where data/document is obtainable

records can be requested by contacting
parsa.pirooz78@gmail.com

What processes are involved for a request to access

data/document

The request will be assessed based on the study proposal and the researchers' intent to use the records.

The records will be immediately provided after it is established that there is no possibility of misuse.

Comments