Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jun 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)

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+98 21 2200 7927

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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 Number 14 3rd floor

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

مرضیه علیخاصی

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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 scientific inquiries

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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