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Can 3D scanning and digital production techniques improve the fit of a dental crown and reduce the time taken in patients who have a dental implant to replace an extracted molar or premolar?

Submission date 19/01/2020	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 25/01/2020	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 27/01/2020	**Condition category** Oral Health	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol

Background and study aims

In dental practice, dental impressions should be taken for most cases to manufacture implant-supported crowns. With the development of digital technologies in dentistry, the conventional workflow could be gradually replaced by more accurate and comfortable technology. A digital impression is a three-dimensional replica of dentation captured by intra-oral scanning. With this digital impression, a virtual crown could be designed on computer software and then milled by CAD/CAM milling machine. Good accuracy of this digital workflow was proven in experimental studies. However, clinical studies are still lacking. This study is to compare crown accuracy and time efficiency of posterior single implant treatment between digital workflow and conventional workflow.

Who can participate?

Adults over the age of 17 who missed single posterior premolar or first molar for at least three months

What does the study involve?

Participants are asked to join this study after they are evaluated to be a good candidate for single implant treatment in the posterior area. Participants are randomly allocated to one of two groups. Those in the first group receive implant surgery and Intra-oral scanning at first appointment and get crown delivery four months later. Those in the second group receive implant surgery at first appointment, conventional impression three months later at a second appointment and crown delivery one month later at third appointment. Chair-side operation time was recorded and crown morphology was scanned before and after crown adjustment for data analysis. The study lasts one year in total.

What are the possible benefits and risks of participating?
There will be no immediate direct benefit to those taking part. But there should be benefits to future patients who receive implant treatment because digital workflow might greatly shorten treatment time and increase crown accuracy. The main risk of digital workflow is crown inaccuracy and the possibility of re-manufacture in the test group. In that case, the conventional workflow will be applied and participants will have to come one more appointment to get crown delivery.

Where is the study run from?
Peking University School and Hospital of Stomatology, China

When is the study starting and how long is it expected to run for?
September 2018 to October 2019

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Crown accuracy and time efficiency in posterior single implant treatment using immediate digital impression and split-file workflow: a randomized control trial

Study objectives
Posterior single implant treatment using immediate digital impression and split-file workflow is as accurate and time efficient as workflow using conventional impression after implant healing.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/09/2019, Institutional Review Board of Peking University School and Hospital of Stomatology
(22 Zhongguancun South Avenue, Haidian District, Beijing 100081, China; +86-10-82195759; keyanchuethics@163.com), ref: PKUSSIRB-201840188

Study design
Single center interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Comparison of 3D scanning and conventional impressions for crown production in people receiving a dental implant to replace an extracted molar

Interventions
Half of the patients are randomized into test group that receives Intra-oral scanning (IOS) immediately after implant placement and crown delivery four months later, while the other half are included into control group that will have a conventional impression three months after implant placement and crown delivery one month later. A non-subject-related researcher will perform the random allocation sequences by using computer-generated random numbers.

Data collection: All crowns were scanned with the same intraoral scanning (3 shape TRIOS Color, 3shape, Denmark) chairside before any clinical adjustment was made. STL files were generated and marked as PRE files. After crown adjustment, post adjustment crowns were scanned by the same scanner to generate a new STL file, POST file. PRE and POST files were both exported to the analysis software (Geomagic Control 2014, Geomagic, USA) for pre and post crown adjustment evaluation. After proper trimming, post file was superimposed on pre file by employing algorithm of best fit alignment. Mesial and distal interproximal surfaces were then trimmed off and grouped as INTERPROXIMAL both in pre and post files. The remaining files

were grouped as OCCLUSION. 3D deviation analysis between pre and post files were conducted both in INTERPROXIMAL and OCCLUSION. Average distance in 3D deviation analysis was recorded to represent the amount of crown adjustment.
Chair-side time was recorded in minutes by an independent investigator for both workflows. In test group, times of operation and IOS for first visit and crown delivery (crown adjustment of occlusion and interproximal contact) for second visit were recorded. In control group, times of operation for first visit, conventional impression for second visit and crown delivery for third visit were recorded. Total chair-side time for each workflow was calculated by adding times of several visits.

Duration of follow-up: Patients were followed-up until the end of crown delivery.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Intra-oral scanner: 3Shape Trios Color, 3Shape, Denmark Computer-aided design (CAD) software: 3Shape Designer, 3Shape, Copenhagen, Denmark 5-axis milling machine : Organical Multi 5X, R+K CAD/CAM Technology, Germany

Primary outcome(s)
3D deviation analysis between pre and post files

Key secondary outcome(s))
Total chair-side time for each workflow was recorded in minutes by an independent investigator for both workflows

Completion date
01/10/2019

Eligibility

Key inclusion criteria
1. Aged ≥18 years.
2. Missing single posterior premolar or first molar for at least 3 months.
3. Sufficient bone height and width at implant site (vertical bone height ≥10 mm, buccal-lingual bone width ≥6 mm)
4. Sufficient prosthetic space (Vertical height ≥5 mm, mesial-distal distance ≥6 mm)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
32

Key exclusion criteria
1. Local or systemic contraindication for implant therapy
2. Adjacent teeth or antagonistic teeth with mobility of Class II or Class III

Date of first enrolment
01/09/2018

Date of final enrolment
01/09/2018

Locations

Countries of recruitment
China

Study participating centre
Peking University School and Hospital of Stomatology
Department of Oral Implantology
No 22, Zhongguancun South Street
Haidian District
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100081

Sponsor information

Organisation
Peking University Stomatological Hospital

ROR
https://ror.org/00s2xkh70

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes