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An alternative method to evaluate dental implant placement accuracy

Submission date
24/05/2022

Recruitment status
No longer recruiting

Registration date
07/06/2022

Overall study status
Completed

Last Edited
18/10/2022

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Normally, to evaluate how accurately oral implants are placed in patients, after placing the implant, a second X-ray scan (cone-beam computed tomography [CBCT]) is obtained and this second scan is compared with the first preoperative scan to determine how accurately the implant is placed. This means a patient is exposed to radiation two times, once before and once after implant placement. The aim of this study is to determine if an intraoral scan (IOS) is also valid to evaluate oral implant placement accuracy. This would mean that a second X-ray can be avoided, lowering the radiation dosage for those patients.

Who can participate?
Patients who need to have a tooth/teeth replaced using oral implants

What does the study involve?
Patients do not need to undergo additional steps, since both preoperative scans are needed anyway to plan the ideal implant location, the postoperative CBCT is normally used to evaluate the implant location and the postoperative IOS is needed to manufacture the prosthetic device which is later placed on top of the implant (e.g. a dental crown or bridge).

What are the possible benefits and risks of participating?
The benefit of this study is that, if the intraoral scan is a valid alternative, there is no need to obtain a second, postoperative CBCT to evaluate the accuracy of implant placement. This results in halving (since a preoperative CBCT is necessary for treatment) the patient's radiation load. There are no risks involved in this study since the postoperative CBCT is a standard procedure to evaluate implant placement accuracy and the postoperative intraoral scan also needs to be obtained to manufacture the prosthetic device on the dental implant.

Where is the study run from?
The department of Oral and Maxillofacial Surgery at Radboudumc Nijmegen (The Netherlands)

When is the study starting and how long is it expected to run for?
May 2019 to December 2020

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Intraoral scanning as an alternative to cone-beam computed tomographies to evaluate the accuracy of dental implant placement: a prospective clinical trial

Study objectives
Intraoral scans are a valid alternative to cone-beam computed tomographies to evaluate the accuracy of oral implant placement

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/05/2019, METC Oost-Nederland (6500 HB Nijmegen, the Netherlands; +31 (0)24 361 3154; metcoost-en-cmo@radboudumc.nl) ref: 2020-6449

Study design
Prospective clinical trial

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Replacement of missing teeth using oral implant

Interventions
All patients underwent the same treatment; a 3D X-ray (cone-beam computed tomography [CBCT]) and intraoral scan (IOS) were obtained both before and after implantation of the oral implants. These steps are part of the regular treatment protocol and as such, did not differ from patients that underwent the same treatment but were not participating in the study. After these steps, the researchers compared those scans and so no follow-up is necessary, since the researchers only needed the data from the pre- and post-operative scans. The scans are matched using the 3DMedX software, manufactured by the Radboudumc 3D lab. This matching procedure is automated. No randomisation took place.

Intervention Type
Other

Primary outcome measure
The discrepancy between planned and placed implant: The matched preoperative IOS and CBCT including the planned implant is matched automatically with either the postoperative CBCT or IOS, in which the actual implant location is visible. The 3DMedX software produces a set of XYZ coordinates for both the planned and placed implant and the discrepancy between the location of the planned and the actually placed implant are calculated in millimeters.

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
07/05/2019

Completion date
01/12/2020

Eligibility

Key inclusion criteria
Partially dentate patients referred to the department of Oral and Maxillofacial Surgery at Radboudumc Nijmegen tot install at least one dental implant.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
22

Total final enrolment
16

Key exclusion criteria
1. Severe periodontal disease
2. Severe bruxism
3. Usage of intravenous bisphosphonates

Date of first enrolment
01/03/2020

Date of final enrolment
01/10/2020

Locations

Countries of recruitment
Netherlands

Study participating centre
Radboudumc
Geert Grooteplein Zuid 10
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Sponsor information

Organisation
Radboud Institute for Health Sciences

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Sponsor type
Research organisation

Website
https://www.radboudumc.nl/en/radboud-institute-for-health-sciences/organization

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/11/2022

Individual participant data (IPD) sharing plan
The plan is to share the IPD in the DANS Easy repository after publishing of the study results

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		05/10/2022	18/10/2022	Yes	No