

# An alternative method to evaluate dental implant placement accuracy

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<b>Registration date</b> 07/06/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 18/10/2022	<b>Condition category</b> Oral Health	<input type="checkbox"/> 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?  
Jan van Hooft, Jan.cm.vanhooft@Radboudumc.nl

## Contact information

### Type(s)

Public

### Contact name

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## **Additional identifiers**

### **Clinical Trials Information System (CTIS)**

Nil known

### **Protocol serial number**

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

### **Study type(s)**

Other

### **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(s)**

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.

## **Key secondary outcome(s)**

There are no secondary outcome measures

## **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

### **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

Nijmegen

Netherlands

6525GA

## Sponsor information

### Organisation

Radboud Institute for Health Sciences

## Funder(s)

### Funder type

Other

### Funder Name

Investigator initiated and funded

## Results and Publications

### 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?
<a href="#">Results article</a>		05/10/2022	18/10/2022	Yes	No