

# Dynamic navigation guided surgery accuracy to place dental implants

<b>Submission date</b> 03/10/2021	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 25/03/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 25/03/2022	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

An implant-supported fixed dental prosthesis (FDP) can be used to replace both teeth and gum tissue. The consequences of incorrect implant position may become evident in the short and long term and are not correctable without the removal of the implant in many instances. The use of computed tomography (CT), including low radiation dosage cone beam computed tomography (CBCT), and CAD/CAM (computer-aided design/computer-assisted manufacturing) technology have created the possibility for preoperative implant planning and proper communication with the patient, surgeon and the prosthodontist. Dynamic navigation is real-time coordination of the surgeon's hands and eyes by 3D visualization of the implant site preparation with high magnification achieved through dedicated hardware and software consistently tracking and matching the real patient with the virtual patient during the surgery. Dynamic guided surgery or navigation allows the surgeon a real-time visualization of the implant site while the drills are in function without any template hiding the surgical field. Full guidance is possible, deviations from the predetermined plan can be assessed in "real time" and the related adjustments of position can be made at any time during the surgery in case any event occurs. The aim of this study is to evaluate deviations from pre-operative digital planning between implants placed by a dynamic navigation system.

### Who can participate?

Patients aged 18 years or older who need an implant-supported fixed dental prosthesis (FDP) in the anterior and premolar area of the upper and lower jaw

### What does the study involve?

Dental implants are positioned by means of a dynamic navigation system and immediate post-operative CBCTs are performed in order to assess the accuracy of implant placement.

### What are the possible benefits and risks of participating?

Not provided

### Where is the study run from?

Policlinico Tor Vergata (Italy)

When is the study starting and how long is it expected to run for?  
October 2020 to December 2022

Who is funding the study?  
1. Itesi srl (Italy)  
2. XNav Technologies (USA)

Who is the main contact?  
Dr Paolo Carosi  
paolo.carosi@alumni.uniroma2.eu

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Paolo Carosi

**ORCID ID**  
<https://orcid.org/0000-0002-2442-1091>

**Contact details**  
Viale Montpellier 1  
Rome  
Italy  
00033  
+39 (0)3277998699  
paolo.carosi@alumni.uniroma2.eu

## Additional identifiers

**EudraCT/CTIS number**  
Nil known

**IRAS number**

**ClinicalTrials.gov number**  
Nil known

**Secondary identifying numbers**  
205.20

## Study information

**Scientific Title**  
Accuracy of implants positioned by means of a dynamic navigation system

**Study objectives**

To evaluate linear and angular deviations from pre-operative digital planning between implants placed via a dynamic navigation system.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 28/10/2020, the Ethical Committee of Policlinico Tor Vergata (Viale Oxford, 81 - 00133, Rome, Italy; +39 (0)6 2090 1; info@ptvonline.it), ref: 205.20

**Study design**

Single-center observational single-cohort study

**Primary study design**

Observational

**Secondary study design**

Cohort study

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet

**Health condition(s) or problem(s) studied**

Dental implants

**Interventions**

Dental implants are positioned by means of a dynamic navigation system (XGUIDE, XNAV Technologies) and immediate post-operative CBCTs are performed in order to assess the accuracy of implant placement.

**Intervention Type**

Device

**Phase**

Not Applicable

**Primary outcome measure**

Linear and angular deviations from pre-op digital planning between implants placed via dynamic navigation surgery measured using postoperative CBCT on the day of implant placement at the end of the surgery

**Secondary outcome measures**

Effect of mouth opening (mm) and the right or the left side of the mouth on the accuracy of the implant positioning measured using postoperative CBCT on the day of implant placement at the end of the surgery

**Overall study start date**

28/10/2020

**Completion date**

31/12/2022

## Eligibility

**Key inclusion criteria**

1. Patients of both sexes aged 18 years or older
2. Requiring a single-tooth implant-supported fixed dental prosthesis (FDP) in the upper and lower jaw
3. Healthy patients
4. Full mouth bleeding and full mouth plaque index lower than or equal to 25%
5. Bone height for at least 10-mm long implants
6. Bone width of at least 5 mm and 6 mm for narrow (NP 3.75 mm) and regular (RP 4.3 mm) implants, respectively
7. Fresh extraction sockets with an intact buccal wall
8. At least 4 and 5 mm of bone beyond the root apex in the mandible and maxilla

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

40

**Key exclusion criteria**

1. General medical (American Society of Anesthesiologists, ASA, class III or IV) and/or psychiatric contraindications
2. Pregnancy or nursing
3. Any interfering medication such as steroid therapy or bisphosphonate therapy; alcohol or drug abuse
4. Heavy smoking (>10 cigarettes/day)
5. Radiation therapy to head or neck region within 5 years
6. Untreated periodontitis
7. Acute and chronic infections of the adjacent tissues or natural dentition

- 8. Severe maxillomandibular skeletal discrepancy
- 9. High and moderate parafunctional activity
- 10. Absence of opposite teeth

**Date of first enrolment**

01/04/2022

**Date of final enrolment**

31/08/2022

## **Locations**

**Countries of recruitment**

Italy

**Study participating centre**

**Policlinico Tor Vergata**

Viale Oxford, 81

Rome

Italy

00133

## **Sponsor information**

**Organisation**

Itesi srl

**Sponsor details**

Viale Liegi 44

Rome

Italy

00033

+39 (0)684242567

studiopozzi@me.it

**Sponsor type**

Hospital/treatment centre

## **Funder(s)**

**Funder type**

Hospital/treatment centre

**Funder Name**

Itesi srl

**Funder Name**

XNav Technologies

## **Results and Publications**

**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal.

**Intention to publish date**

31/03/2023

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Paolo Carosi ([paolo.carosi@alumni.uniroma2.eu](mailto:paolo.carosi@alumni.uniroma2.eu)).

**IPD sharing plan summary**

Available on request