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Dynamic navigation guided surgery accuracy to place dental implants

Submission date	**Recruitment status**	[X] Prospectively registered
03/10/2021	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
25/03/2022	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
25/03/2022	Oral Health	[ ] 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

Protocol serial number
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

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Itesi srl

Funder Name
XNav Technologies

Results and Publications

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).

IPD sharing plan summary
Available on request