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Evaluation of cortical bone thickness and spongy bone density in non-dental maxillary and mandibular regions for orthodontic mini-implant placement

Submission date 22/02/2024	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 08/05/2024	**Overall study status** Completed	
Last Edited 29/05/2024	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims
This study uses a special type of X-ray called cone beam computed tomography (CBCT) to look at the amount and quality of bone in two specific areas of the jaw: the infrazygomatic crest (IZC) and the mandibular buccal shelf (MBS). These areas are often used to place small devices called temporary anchorage devices (TADs) in orthodontics. We want to see if the bone in these areas is thick and dense enough to hold these devices securely. We believe that if the bone is at least 1 mm thick, it will be stable enough. We will also check how dense the bone is, as denser bone can help keep the TADs in place better. The results of this study will help us understand if these areas are good for placing TADs and could improve how orthodontic treatments are done.

Who can participate?
Participants must have undergone CBCT scans for orthodontic, prosthetic planning, or orthognathic surgery purposes. They should also be in good health.

What does the study involve?
All participants' CBCT scans will be analyzed using specialized software. The study will measure the bone thickness and density in the infrazygomatic crest (IZC) and mandibular buccal shelf (MBS) regions. Overall bone widths will also be recorded. This data will help to determine the suitability of these sites for temporary anchorage device (TAD) placement in orthodontic treatments.

What are the possible benefits and risks of participating?
Since this is a retrospective study using previously acquired CBCT scans, there are no direct benefits or risks for participants

Where is the study run from?
The study is being conducted at the Dental Clinic of the University of L'Aquila in Italy.

When is the study starting and how long is it expected to run for?
The study protocol was developed on December 1, 2022. Data collection will begin after approval from the regional ethics committee. The measurement phase will be completed by December 1, 2024, and the study is expected to conclude by February 2025.

Who is funding the study?
The University of L'Aquila in Italy. There is no external funding for this study.

Who is the main contact?
The main contact person for this study is Dr Simone Ettore Salvati, reachable at simoneettore.salvati@graduate.univaq.it

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
PROTO-2022-12 Rev.8

Study information

Scientific Title
Non-alveolar vestibular bone sites for temporary anchorage devices in orthodontics: a quantitative and qualitative analysis

Acronym

NAVBS-TAD-O-QQAD

Study objectives
Current study hypothesis as of 29/05/2024:
The primary hypothesis of this study is that cortical bone thicknesses in the infrazygomatic crest (IZC) and mandibular buccal shelf (MBS) regions are sufficient to ensure primary stability for temporary anchorage devices (TADs), specifically above a cut-off value of 1 mm. The null hypothesis (H0) posits that cortical bone thicknesses in these regions are not sufficient to ensure this stability, while the alternative hypothesis (HA) suggests that they are sufficient.

Additionally, the secondary hypotheses include the assessment of cancellous bone density and total bone thickness. The null hypothesis for cancellous bone density (H0) states that it is not high enough in the IZC and MBS regions to contribute to enhanced primary stability of TADs, whereas the alternative hypothesis (HA) asserts that it is high enough. For total bone thickness, the null hypothesis (H0) claims that the bone thickness in these regions is not wide enough to accommodate most TADs available in the market, while the alternative hypothesis (HA) contends that the bone thickness is adequate for this purpose.

Previous study hypothesis:
The rationale for conducting this study lies in the need to comprehensively evaluate the bone quantity and quality in the alveolar bone regions where temporary anchorage devices (TADs) are commonly applied in orthodontic treatment. By utilizing cone beam computed tomography (CBCT) scanning, this research aims to investigate cortical bone thickness and cancellous bone density in the interradicular zones (IZC) and mandibular buccal shelf (MBS) across individuals with diverse demographic and craniofacial characteristics. The primary hypothesis is that cortical bone thickness exceeding 1 mm in the IZC and MBS regions will be adequate to ensure optimal primary stability for TAD placement. Additionally, it is hypothesized that higher cancellous bone density in these regions will further enhance the stability of TADs. Furthermore, this study intends to document overall bone widths to provide insights into the selection of appropriate TAD lengths for different anatomical sites. Overall, this investigation aims to contribute valuable data to the understanding of bone dynamics relevant to orthodontic treatment planning and TAD utilization.

Ethics approval required
Ethics approval required

Ethics approval(s)
notYetSubmitted 22/02/2024, Territorial Ethics Committee Abruzzo Region (C.Et.R.A.) (Not provided, L'Aquila, 67100, Italy; Not provided; cer@regione.abruzzo.it), ref: Not provided

Study design
Single-centre retrospective cross-sectional study

Primary study design
Observational

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Evaluation of bone characteristics for orthodontic mini-implant placement in select patients

Interventions

Current interventions as of 29/05/2024:
All CBCT records will be processed and analyzed using the open-source medical image processing platform, 3D Slicer v 5.4.0. Since prior studies have demonstrated no significant differences between linear distances and angles assessed with reconstructed lateral cephalogram (RLC) obtained from a CBCT scan and lateral skull teleradiography, 2D images will be derived from each CBCT scan through lateral radiographic projection. The RLCs will be analyzed using the web-based digital cephalometric analysis program, WebCeph version 1.5.0, to define craniofacial patterns, with a focus on the Facial Height Ratio (FHR) or Jarabak's quotient.

To ensure accurate measurements, the DICOM dataset will undergo a re-slicing process to visualize sections more consistent with anatomical symmetry. This involves reorienting the axial, sagittal, and coronal planes using the Transforms module, followed by resampling and realigning the region of interest with the Resample Scalar Volume and Crop modules within the 3D Slicer platform. Measurements will be standardized and oriented using the Transforms Reformat Widget Module.

For the MBS region, spatial reference planes will be positioned to ensure repeatability. The axial plane will be positioned tangent to the furcations of the first and second mandibular molars, the sagittal plane at the center of the dentoalveolar process, and the coronal plane perpendicular to the other two planes. Measurements will be conducted on four coronal slices, two passing through the centers of the mesial and distal roots of the second mandibular molar and two tangential to the proximal surfaces.

For the IZC region, spatial reference planes will also be arranged to ensure consistency. The axial plane will be positioned tangentially at the furcation of the first mandibular molar, the sagittal plane will pass through the furcations of the first and second mandibular molars, and the coronal plane will be perpendicular to the other two planes. Measurements will be taken on five coronal slices, four passing through the mesiobuccal and distobuccal roots of the first and second maxillary molars and one tangential to the point of proximal contact.

Bone thickness and density will be assessed according to established classification systems. The thickness of the cortical bone and the total bone thickness will be measured using the Markups module, while the cancellous bone density will be classified based on grayscale values obtained from the Segment Statistics module within the 3D Slicer platform.

Previous interventions:
Cone beam computed tomography (CBCT) scanning records will be processed and analyzed using the open-source medical image processing platform, 3D Slicer v 5.4.0. To ensure compatibility with lateral skull teleradiography, 2D images will be derived from each CBCT scan through lateral radiographic projection. The resulting reconstructed lateral cephalograms (RLCs) will be assessed using the web-based digital cephalometric analysis program, WebCeph version 1.5.0, to define craniofacial patterns, with a focus on Facial Height Ratio (FHR) or Jarabak's quotient. Reslicing the DICOM dataset will be performed to enhance anatomical symmetry and reliability of measurements. This will involve reorientation of the axial, sagittal, and coronal planes using the Transforms module, followed by resampling and realignment of the region of interest using the Resample Scalar Volume and Crop modules within the 3D Slicer platform, respectively. Measurements will be standardized and oriented using the Transforms Reformat Widget Module. Spatial reference planes will be positioned in the mandibular buccal segment (MBS) and the interradicular zone (IZC) to ensure repeatability and reliability. Linear measurements of bone thickness will be conducted using the Markups module. For MBS,

measurements will be taken on four coronal slices passing through the mesial and distal roots of the second mandibular molar and tangential to the proximal surfaces. Similarly, in the IZC region, measurements will be taken on five coronal slices passing through the mesiobuccal and distobuccal roots of the first and second maxillary molars and tangential to the proximal surfaces. Bone thickness and density will be assessed according to established classification systems. The cancellous bone density will be classified based on grayscale values obtained from the Segment Statistics module within the 3D Slicer platform.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Cortical bone thickness in the infrazygomatic crest (IZC) and mandibular buccal shelf (MBS) regions measured using cone beam computed tomography (CBCT) scanning at a single timepoint post-scan acquisition

Key secondary outcome(s))
1. Cancellous bone density in the infrazygomatic crest (IZC) and mandibular buccal shelf (MBS) regions measured using cone beam computed tomography (CBCT) scanning at a single timepoint post-scan acquisition
2. Overall bone widths (cortical and cancellous) in the IZC and MBS regions measured using CBCT scanning at a single timepoint post-scan acquisition

Completion date
01/12/2024

Eligibility

Key inclusion criteria
Current inclusion criteria as of 29/05/2024:
1. Radiographic examinations (CBCT) performed for orthodontic purposes, prosthetic planning, or orthognathic surgery
2. Patients in good health

Previous inclusion criteria:
1. Radiographic examinations (CBCT) performed for orthodontic purposes
2. Patients between 18 and 50 years of age
3. Patients in good health

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Current exclusion criteria as of 29/05/2024:
1. Radiographic examinations (CBCT) of patients with congenital craniofacial abnormalities (e.g. micrognathia, cleft lip or palate, etc) or syndromes
2. CBCT images with motion artifacts in the region of interest due to patient movement during the scanning process
3. CBCT images with metal artifacts in the region of interest due to the presence of dental implants, amalgam filling, etc.
4. Patients previously undergoing oral rehabilitation with zygomatic implants
5. Patients with a history of fractures in the region of interest
6. Patients with systemic or local pathologies that have an effect on bone metabolism
7. Patients under bisphosphonate therapy

Previous exclusion criteria:
1. Radiographic examinations (CBCT) performed for prosthetic planning or orthognathic surgery
2. CBCT images with motion artefacts due to patient movement during the scanning process
3. CBCT images with metal artefacts due to the presence of dental implants, amalgam filling, etc
4. Patients aged under 18 or over 50
5. Patients previously undergoing oral rehabilitation with zygomatic implants
6. Patients with a history of fractures in the region of interest
7. Patients with congenital craniofacial abnormalities (e.g. micrognathia, cleft lip or palate, etc)
8. Patients with systemic or local pathologies that affect bone metabolism
9. Patients under bisphosphonate therapy

Date of first enrolment
01/06/2024

Date of final enrolment
30/09/2024

Locations

Countries of recruitment
Italy

Study participating centre
Dental Clinic - University of L'Aquila
Via G. Petrini, Building “Rita Levi Montalcini”
L'Aquila
Italy
67100

Sponsor information

Organisation
University of L'Aquila

ROR
https://ror.org/01j9p1r26

Funder(s)

Funder type
University/education

Funder Name
Università degli Studi dell'Aquila

Alternative Name(s)
University of L'Aquila

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Italy

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study will be stored in a publicly available repository. The repository can be accessed via the following link: https://docs.google.com/spreadsheets/d/1DlTQWyGkKMkS6kyR1YVb0Lu4QLAe44F9/edit?usp=sharing&ouid=107268639835396758852&rtpof=true&sd=true

Type of Data Shared:
Raw data obtained from measurements.

Availability of Data:
The data will be available immediately. As measurements are conducted, they will be added to the case report form. At the conclusion of the study, the data will remain available indefinitely.

Access Criteria:
The data will be accessible for evaluation, analysis, or comparison purposes. There are no specific access criteria; the data will be openly accessible to anyone interested.

Purpose of Data Sharing:
The data will be shared for the purpose of evaluation, analysis, or comparison.

Consent from Participants:
Participants have consented to the sharing of their anonymized data for research purposes.

Data Anonymization:
All data shared will be anonymized to protect the privacy and confidentiality of participants.

Ethical or Legal Restrictions:
There are no ethical or legal restrictions on the sharing of this data.

Other Comments:
The repository will facilitate transparency and reproducibility in research by providing access to the raw data obtained from measurements conducted during the study.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			23/02/2024	No	Yes
Protocol file		13/02/2024	23/02/2024	No	No
Protocol file		25/05/2024	28/05/2024	No	No