RESEARCH PROJECT

PROJECT OVERVIEW

1. Project title

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

2. Investigators

Simone Ettore Salvati DDS, Ph.D – *Principal investigator*
Postdoctoral Student, Postgraduate School of Orthodontics, Department of Life, Health & Environmental Sciences, University of L'Aquila, Italy

Giorgio Iodice DDS, MSc, Ph.D – *Principal investigator*
Adjunct Clinical Professor, University of Naples Federico II, Italy

Giuseppe Marzo MD – *Project coordinator*
Full Professor, Postgraduate School of Orthodontics, Department of Life, Health & Environmental Sciences, University of L'Aquila, Italy

Vincenzo Quinzi DDS, MSc, Ph.D – *Research associate*
Researcher, Postgraduate School of Orthodontics, Department of Life, Health & Environmental Sciences, University of L'Aquila, Italy

Daniele Parrello DDS, MSc – *Research associate*
Private Practice, Legnano, Italy

Mauro Farella DDS, MSc, Ph.D – *Research director, Statistician*
Full Professor, Postgraduate Programme in Orthodontics, Faculty of Dentistry, University of Otago, New Zealand

3. Background

In the past two decades, the use of temporary anchorage devices (TADs) has revolutionized orthodontic treatment.[1] TADs have led to a paradigm shift in terms of patient compliance, preservation of anchorage, and the simplification of treatment for various difficult malocclusions. TADs can be inserted into different areas based on therapeutic procedures and bone supply available, such as sections of the edentulous maxilla, the interradicular septum of the dentulous alveolar process, the infra-apical and supra-apical areas, the palate (median or paramedian), the retromolar area, the zygomatic bone, and the basal mandibular body.[2,3]

While the interradicular area is an excellent site for TADs insertion, it limits the versatility of these devices, for example, when the alveolar ridge represents the pathway in which the tooth moves.[4] Additionally, there is a risk of damaging tooth roots when placing TADs in the interradicular area.[5,6] The introduction of palatal TADs has significantly revolutionized the concept of skeletal anchorage in orthodontics. Palatal TADs provide a larger area of cortical bone, allowing for the development of more versatile devices and reducing the risk of root damage compared to interradicular TADs.[7–9] However, their cost is often considerably higher due to patented device planning techniques offered by various companies in the industry.

The constant search for new areas in which to apply TADs has led to the adoption of the infrazygomatic crest (IZC) and mandibular buccal shelf (MBS) as new sites of choice.[10] Biomechanical advantages related to the simplification of techniques normally used to perform complex movements are the main reasons for this adoption.[11] TADs on the IZC are advantageous in hyperdivergent subjects where intrusion of the upper posterior teeth is desired,[12] as well as in cases of class II distalization, which are often associated with molar mesiorotation.[13] The force vector that can be expressed by using TADs on the IZC is more favourable for these types of correction. Further advantages can be provided by TADs applied in the mandibular buccal shelf region, for example, in cases of molar uprighting movements or distalization of the entire lower arch for class III correction.[14]

Recent literature has investigated the bone characteristics of IZC and MBS in relation to sex, age, and different skeletal patterns with the aim of defining the quantity of bone at these sites.[15,16] According to Laursen et al., we know that these characteristics are crucial to obtain the primary stability of skeletal anchorage.[17] The authors have reported that the cortical bone should have a thickness of more than 1 mm in order to achieve a stable TAD placement. On the other hand, at the time of writing, only one author has delved into the qualitative aspects of these sites by investigating bone density.[18] This is surprising, especially considering that, as in implant surgery, in the context of skeletal anchorage in orthodontics, the prior assessment of bone quality at the chosen site, along with other treatment planning parameters, constitutes a crucial factor in achieving good primary stability.[19–21]

4. Aims

This study aims to utilize cone beam computed tomography (CBCT) scanning to assess both bone quantity and quality in the IZC and MBS regions across individuals with varying age, sex, and craniofacial patterns. By analyzing the regions typically used for the application of TADs, our research question posits the hypothesis that cortical bone thicknesses in IZC and MBS are sufficient to ensure primary stability, specifically above a cut-off value of 1 mm.

Simultaneously, the authors intend to evaluate the cancellous bone density in the same IZC and MBS regions, recognizing that higher density contributes to the enhanced primary stability of these devices.
During the execution of linear measurements, we also aim to record overall bone widths (cortical and cancellous) as typical paths for the insertion of TADs. This additional data will provide readers with information on the average lengths of TADs to be selected for different sites.

5. Participating sites

Dental Clinic - University of L'Aquila
Via G. Petrini, Building "Rita Levi Montalcini"
67100 L'Aquila Italy

6. Study design

- **Type of study:** Retrospective cross-sectional study
- **Data sources:** 3D image set from CBCT scans of patients who were referred to a private practice in the city of Legnano, Italy. CBCT scans were obtained using an i-CAT scanner (Imaging Sciences International, Hatfield, PA, USA) with the following acquisition parameters: 120 kVp, 37 mA, 1 mm slice thickness, 40 seconds acquisition time, 0.3 mm voxel size, and a 23x17 cm field of view.
- **Population/Sample size:** The population size is of 84 subjects. The sample size calculation was done with G power analysis software (G*Power Version 3.1.9.6, Kiel University, Germany) by taking the mean and standard deviation values of bone thickness from Murugesan and Jain,[22] and Aleluia et al.[23] studies. The required sample size with a margin of error of 5% and 95% confidence level was estimated at 54 subjects.
- **Expected duration of study:** 6-8 months

7. Eligibility criteria

Inclusion criteria
Radiographic examinations (CBCT) performed for orthodontic purposes;
Patients between 18 and 50 years of age;

Patients in good health

Exclusion criteria

Radiographic examinations (CBCT) performed for prosthetic planning or orthognathic surgery;
CBCT images with motion artifacts due to patient movement during the scanning process;
CBCT images with metal artifacts due to the presence of dental implants, amalgam filling, etc
Patients aged under 18 or over 50;
Patients previously undergoing oral rehabilitation with zygomatic implants;
Patients with a history of fractures in the region of interest;
Patients with congenital craniofacial abnormalities (e.g. micrognathia, cleft lip or palate, etc);
Patients with systemic or local pathologies that have an effect on bone metabolism;
Patients under bisphosphonate therapy

8. Study procedures

All CBCT records will be processed and analyzed using a freely available open-source medical image processing platform (3D Slicer v 5.4.0; link: https://slicer.org).[24] Since Kumar et al.[25] demonstrated no significant differences between linear distances and angles assessed with reconstructed lateral cephalogram (RLC) obtained from a CBCT scan and lateral skull teleradiography, we have chosen to obtain 2D images from each CBCT scan through lateral radiographic projection of the entire volume. The RLCs will be analyzed using a web-based digital cephalometric analysis program (WebCeph version 1.5.0, AssembleCircle Corp., Pangyoyeok-ro, Bundang-gu, Seongnam-si, Gyeonggi-do, Republic of Korea) to define their craniofacial pattern. The Facial Height Ratio (FHR) or Jarabak's quotient will be considered and measured for this purpose.[26] This approach determines the facial type by establishing a correlation between the posterior facial height, which is divided by the anterior facial height and then multiplied by 100. The results are presented as percentages with values below 59% classified as hyperdivergence, values between 59% and 63% falling within the neutral range (normodivergence), and values above 63% indicating hypodivergence.

Due to non-standardized head positions during the acquisition of 3D scans, we may end up with images that are suboptimally oriented or off-axis. This can lead to variations in measurements, making them less reliable compared to reality.[27] To address this issue, it is advisable to subject the DICOM data set to a re-slicing process to visualize sections that are more consistent with the anatomical symmetry of both sides. For this purpose, we will first use the Transforms module, available within the 3D Slicer platform. In the frontal view, the coronal plane will be rotated around the sagittal axis until the most internal points of the right and left frontozygomatic sutures at the margin of the orbital rim (anatomical reference points ZR and ZL used in posteroanterior cephalometry) are simultaneously positioned on the axial plane. In the lateral view, the sagittal plane will be rotated around the transverse axis until the Frankfurt plane (defined by anatomical reference points Porion and Orbitale on the right side) is parallel to the axial plane. In the axial view, the transverse plane will be rotated around the vertical axis until the mid-sagittal line (the line passing through the center of the foramen magnum and the crista galli) is perpendicular to the coronal plane. At the end of the reorientation process of the sections, the volume will then be resampled using the Resample Scalar Volume module, which is also part of the 3D Slicer platform. Subsequently, the Crop module will be applied to realign the region of interest (ROI) box with the new spatial coordinates of the resampled volume.

To standardise measurements on CBCT images and minimise errors, all images will be oriented before the measurement step. For this purpose, the Transforms Reformat Widget Module, available within the 3D Slicer platform, will be used.
For the MBS region, spatial reference planes will be positioned following a specific procedure to ensure repeatability for all subjects and thus make all subsequent measurements reliable. The axial plane (transverse) will initially be positioned so that it is tangent to the furcations of the first and second mandibular molars. The sagittal plane (anteroposterior) will be placed at the center of the dentoalveolar process, passing through the axes of the mesial root of the first mandibular molar and the distal root of the second mandibular molar. At this point, by establishing an origin point along the intersection between the two planes described above and halfway between the two furcations, the axial plane will be rotated along the sagittal axis until it is perpendicular to the sagittal plane. Finally, the coronal plane (vertical) will be oriented so that it is perpendicular to the two above planes and can be slid along the intersection direction to bring it, in the subsequent measurement phase, to the level of the respective long axes of the mesial and distal root of the second mandibular molar.
For the IZC region, spatial reference planes will be arranged using another specific procedure, again in order to ensure consistency across all subjects, thereby enhancing the reliability of subsequent measurements. The axial plane (transverse) will be positioned tangentially at the furcation of the first mandibular molar. The sagittal plane (anteroposterior) will be placed to pass through the furcations of the first and second mandibular molars. These two planes will already be perpendicular to each other. Subsequently, the coronal plane (vertical) will be oriented to be perpendicular to the aforementioned planes. It can then be slid along the intersection direction to align it, in the subsequent measurement phase, with the respective long axes of the mesiobuccal and distobuccal roots of the first and second maxillary molars.

The measurement phase of bone thicknesses will then be conducted using the Markups module available within the 3D Slicer platform.
As defined by the studies of Chang and subsequently confirmed by Ghosh, the preferred site for the application of TADs in the MBS is the buccal region adjacent to the roots of the second mandibular molar.[28–30] Measurements in the MBS region will then be taken using four coronal slices. Two of these slices (LMR7 and LDR7) will pass through the centers of the mesial and distal roots of the second molar. The additional two slices (LMPR7 and LDPR7) will be

tangential to the proximal surfaces, both mesial and distal, of the same second molar, thus also providing assessment of the proximal regions.

Several studies have measured the apicocoronal depth (bone height) of the MBS by tracing vertical lines at distances of 4, 5, and 6 mm buccally from the cementoenamel junction (CEJ), intersecting the outer cortical bone of the mandible at two points.[31–34] This type of measurement seems appropriate, considering that Ghosh defines the initial insertion point of TADs in the MBS to be located 2 mm below the mucogingival junction in the alveolar mucosa.[30] Additionally, Chang states that MBS bone screws should be positioned with an axial inclination as parallel as possible to the roots of the first and second mandibular molars.[35]

Some studies have also focused on the position of the Inferior Alveolar Nerve Canal (IANC) or its distance from the site of TADs insertion.[33,36] This also appears to be a valid observation, given that the variability of the nerve pathway in the MBS area poses a tangible risk of injury during the insertion of these devices. Measurements on each coronal radiographic slice will therefore be conducted, simulating the trajectory of TADs in the MBS according to the aforementioned characteristics. The measurement steps will be as follows:

- The sagittal plane and the axial plane will first be taken as the reference lines, and for this purpose, they will both be positioned at the CEJ of the second molar. At this point, on each radiographic slice, starting from where the axial plane and the sagittal plane intersect, three vertical lines will be drawn buccally respectively at 4, 5, and 6 mm from the intersection. These lines, thanks to the previous image orientation phase, will be parallel to the roots of the first and second mandibular molars;
- The thickness of the cortical bone will be measured on these lines, and it will be classified according to the new jawbone classification system recently introduced by Wang et al.[37] into three levels: A, B, and C, with classification intervals of A: > 1.1 mm, B: 0.7-1.1 mm, and C: < 0.7 mm;
- Finally, the bone height (apicocoronal depth) will be measured within the segments between the points of intersection of the vertical lines with the outer cortical bone of the MBS. In the context of this last step, the position of the IANC relative to the measured segment will be observed: a minimum distance of 2 mm will be the limit parameter considered to exclude the risk of nerve damage. In cases of IANC interference, for distances less than 2 mm, the bone height will be measured from the coronal point of intersection with the outer cortical bone, along the vertical line, up to the point of first interference with the IANC. This measurement will then be indicated with a distinctive mark.

Since bone thickness is typically symmetrical on both sides of the mandible in patients with a symmetrical structure, the above measurements will only be carried out on the left side.[38]

The preferred site for placing TADs in the IZC has been defined by Liou as the buccal area adjacent to the roots of the first maxillary molar; subsequently, Lin advocated for a more posterior position, buccal to the roots of the second maxillary molar.[39–41] Measurements in the IZC region will then be taken using five coronal slices. Four slices (UMBR6 and UDBR6, as well as UMBR7 and UDBR7) will pass through the centers of the mesiobuccal and distobuccal roots of the first and second molars. The last slice (UPR67) will be tangential to the point of proximal contact between the first and second molars, thus also providing assessment of the proximal region.

Vargas et al. conducted a study on the bone thickness of the IZC, using as the upper limit for their measurements the highest apex between the distobuccal root of the first maxillary molar and the mesiobuccal root of the second maxillary molar.[31] This precaution seems to be appropriate since, according to the indications of Liou and Lin, the initial insertion of TADs in this area should be performed perpendicular to the buccal plate or the tooth axis.[39,40] Establishing this upper limit therefore helps reduce the risk of root damage during TADs placement. It should also be added that Liou and Lin themselves agree that, once the screw tip has penetrated the cortical bone, the TADs must be gradually angled 55-70° relative to the occlusal plane to reach their final position. Based on the aforementioned characteristics, simulating the trajectory of TADs in the IZC, the measurement phase will be carried out on each individual coronal radiographic slice. This will involve the following steps:

- The axial plane will first be taken as the reference line, and for this purpose, it will be positioned at the highest apex between the mesiobuccal and distobuccal roots of the first and second molars. At this point, on each radiographic slice, starting from where the axial plane intersects the buccal cortical bone of the maxilla, lines will be drawn at 55, 60, 65, and 70 degrees of angulation relative to the axial plane line;
- The thickness of the cortical bone will be measured on these lines, and it will be classified according to the new jawbone classification system recently introduced by Wang et al.[37] into three levels: A, B, and C, with classification intervals of A: > 1.1 mm, B: 0.7-1.1 mm, and C: < 0.7 mm;
- Finally, the total bone thickness will be measured within the segments between the points of intersection of the lines previously drawn with the outer surfaces (buccal and sinus) of the cortical bones of the IZC.

In this case as well, we will consider symmetric bone thickness on both sides of the maxilla, with our assessment focused on the left side.

Finally, within the 3D Slicer platform, the analysis phase of cancellous bone density in the areas previously subjected to linear measurements will be conducted. The literature on maxillary bone quality has long described and distinguished various types, also defining their predominance in terms of distribution in the four maxillary regions: anterior and posterior maxilla, and anterior and posterior mandible.[42,43] Therefore, we believe that the density of cancellous bone is likely to be the same throughout the MBS or IZC region. For this reason, the density assessment will be performed only once within the MBS and IZC of each patient. On the selected radiographic slice for assessing cancellous bone density, proceeding along the direction of one of the linear measurements described above, an area 2 mm wide will be delimited using the Segment Editor module, with a length sufficient to ensure that no portions of cortical bone are included. The 2 mm width was chosen based on the diameter of TADs typically used for the MBS and IZC regions.[30,35] Finally, the Segment Statistics module will determine the level of cancellous bone density as a mean value in grayscale (GV). The cancellous bone density will then be classified according to the new mandibular bone classification system recently introduced by Wang et al.[37] into three levels: 1, 2, and 3, with a classification range of 1: > 600 GV (=420g/cm³), 2: 300-600 GV (=160 g/cm³-420 g/cm³), and 3: < 300 GV (=160 g/cm³).

9. Statistical considerations and data analysis

To be determined (Prof. Mauro Farella)

10. Ethical considerations

Pending assessment and approval by the Territorial Ethics Committee Abruzzo Region (C.Et.R.A.)

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