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ABSTRACT
DOCTOTAL THESIS

THE IMPORTANCE OF RADIO-IMAGINING DIAGNOSIS IN THE PRE AND POST THERAPEUTIC EVALUATION OF ORTHODONTIC ANOMALIES WITH THE UNDERLINING VALUE OF THE CBCT IN THE MULTIPLANAR AND 3D QUANTIFICATION OF THE SKELETAL AND DENTO-MAXILLARY STRUCTURES

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I. GENERAL PART

1. Orthodontic mini-implants

1.1. Terminology

The terminology used for temporary anchorage devices is **mini-implant**. These devices do not osseo-integrate since they are only used for a short period of time before being removed. Mechanical retention is achieved by obtaining a wide contact area between the bone and the mini-implant. The **primary stability** of orthodontic mini-implants is determined by the interpenetration of it's active part with the surrounding bone, that is determined by a variety of factors including the insertion site, root proximity, mini-implant design, soft tissue thickness, insertion procedure, loading protocol, while cortical bone thickness playing a significant role. **Secondary stability** is determined by the bio-compatibility of the mini-implant with the surrounding bone. Secondary stability, not primary stability, is crucial for the mini-implant's long-term success rate. In order to achieve optimal secondary stability, the mini-implant must have adequate primary stability: if the mini-implant has mobility, it would be difficult to achieve optimal healing and an increased contact area between the bone and the mini-implant. Secondary stability is not granted by increased primary stability. From a clinical point of view, stability is defined as the sum of primary and secondary stability.

1.2. Concepts and controversies

1.2.1. Insertion method: self-tapping, pre-drilling or cortical perforation

The stability of mini-implants inserted using the self-tapping or pre-drilling method was evaluated, and both methods were found to be successful. Self-tapping systems, on the other hand, have a range of advantages, including reduced operating time, reduced bone debris, reduced heat release and minimal patient discomfort. Perforating the cortical bone is recommended in cases where it is dense and thick, especially in the posterior area in the mandible and the palate, to avoid the use of excessive torque values at the time of insertion and causing micro-fractures in the surrounding bone. This can be performed with superficial perforation within the cortical bone, and not with a burr exceeding 2 mm in depth.

1.2.2. Direct or indirect anchorage

Direct anchorage is obtained by pulling on the mini-implant head directly. This traction is typically provided by a chain or a nickel-titanium spring.

Indirect anchorage is obtained by using the mini-implant to increase the anchoring value of the teeth where the force is applied. Indirect anchorage has some advantages, focusing on anatomical factors, but it also comes with the risk of anchorage loss by bending of the intermediate arch, as well as a tilt or body translation of the mini-implant.

1.2.3. Loading protocol

The loading protocol should determine a favorable response of the adjacent bone. Caution is advised when inserting in the buccal side where there is a thin cortical bone, since they present higher risks due to poor primary stability. During the first three weeks there is a marked decrease in primary stability and an increase in secondary stability. This indicates that the mini-implants should be loaded immediately, particularly in adult patients. The primary stability index is used to determine the success rate after the mini-implant has been inserted. Loading, immediately after insertion, will accelerate osseo-integration because the bone in the compression zones mineralizes faster than the tension zones.

It is recommended to apply a low initial force, of less than 50 Ncm (50 gr), when loading immediately after insertion. A mini-implant can become loose due to loading using a high initial force, that exceeds the adaptive capacity of the bone, leading to micro-fractures in the thin cortical bone. The forces should be light, consistent and predictable.

1.3. Design and components

Mini-implants come in a wide range of sizes and shapes, each with its own set of characteristics. However, they all have three basic components: the head, neck and body. The most popular shape is one with a rectangular slot that allows the anchoring a spring and other auxiliary elements (elastics and ligatures). Depending on the thickness of the soft tissue, the neck may come in different sizes, thus preventing its hypertrophy. The average thickness of the soft tissue in the most common places for mini-implant insertion is 1-2 mm, so it is recommended to use mini-implants with a neck height of 2 mm, except for the palatal region where the thickness of the soft tissue can be 3-4 mm and a higher neck is recommended. The shape of the active part can be cylindrical or conical and from a biomechanical point of view, conical mini-implants increase the value of the insertion torque, especially in the coronal part, providing a larger contact surface with the surrounding bone. They are also easier to insert into the cortical bone provide a better mechanical connection between the active part and the bone. The progressive compression of the bone during insertion of the conical mini-implants leads to a greater stability compared to the cylindrical ones.

1.4. Indication/Contraindication

Indication: Retraction of the frontal group, distalizing/mezializing of the lateral area, molar uprighting, correcting rotations, intrusion/extrusion of the frontal area, intrusion/extrusion of the lateral area, maxillary skeletal expansion, correcting cross-bite/ scissor bite, pre-prosthetic treatment.

Contraindication

Contraindications to orthodontic treatment with mini-implants are those of implant treatment in general: systemic diseases associated with increased bone metabolism or bone loss (osteoporosis or uncontrolled diabetes). There are no specific contraindications to treatment with orthodontic mini-implants.

1.5. Risks/Complications

- **Damage to the roots or periodontal ligament**

The roots affected by the contact with the mini-implants regenerate within 12 weeks, given that there is no portal of infection.

- **Sinus or nasal perforation**

When inserting in the maxilla, there is the risk of oro-antral perforation (maxillary incisor area, posterior maxillary area, zygomatic process). These perforations are associated with a number of risks (sinusitis, mucocele and fistulas) and should be avoided. Perforations less than 2 mm are treated without complications and it is not necessary to remove the mini-implant.

- **Neuro-sensitive disorders**

The palate, the retro-molar region or the external oblique line are insertion sites where neuro-vascular structures are found. Minor neural effects without nerve sectioning resolve within 6 months.

- **Mini-implant fracture.**

It is quite rare, due to the adapted design and structure of the mini-implant to the optimal insertion torque values.

- **Pain**

Patients usually expect to feel intense pain, but most of the time they do not feel any discomfort either during or after the procedure. Most of the patients experience a feeling of pressure during insertion and up to 24 hours later and a low level of pain may occur.

Complication

1. **Soft-tissue**

The most common complication at the soft tissue level, is the inflammation around the mini-implant. This happens if the mini-implant is inserted in the mobile mucosa or if it exerts too much pressure on the fixed mucosa. If the inflammation does not resolve by improving the oral hygiene, or if it causes the patient discomfort, then it should be removed.

2. **Migration of the mini-implant**

1.6. Anatomical considerations

Factors to consider when inserting mini-implants

- Anatomical structures in the vicinity of the insertion site
- Bone quality
- Soft tissue thickness
- Patient comfort

1.7. Factors influencing the success rate of orthodontic mini-implants

1.3.1. Patient-dependent factors
1.3.2. Mini-implant-dependent factors
1.3.3. Surgical technique-dependent factors

2. Cone Beam Computed Tomography (CBCT)

1. SPECIAL PART

1. CORTICAL BONE THICKNESS EFFECTS ON THE SUCCESS RATE OF ORTHODONTIC MINI-IMPLANTS AND OTHER FACTORS ASSESSED BY CONE BEAM COMPUTED TOMOGRAPHY.

1.1. Context

Many variables that affect the stability of orthodontic mini-implants are still poorly understood. The purpose of this study was to determine the optimal sites for mini-implant placement in the maxilla and the mandible based on the thickness of the cortical bone and correlate it with other factors that influence the success rate of orthodontic mini-implants.

1.2. Material and methods

This research included a group of ten patients who were to receive orthodontic treatment. The following inclusion criteria were used: the presence of all dental units in the examined regions, the absence of apical pathology due to endodontic or periodontal causes, no medical history that can affect bone tissue (use of bisphosphonates), no severe facial or dental asymmetries and no vertical or horizontal bone loss.

Pretreatment cone beam computed tomography scans using Cranex Sordex 3D were taken and the scans were imported into 3-dimensional software for analysis as digital imaging. (OnDemand3App with the dental 3D). Cortical bone thickness was measured in 4 inter-radicular areas between: lateral incisor and canine, first and second premolars, second premolar and first molar and first and second molars.

The distance between the internal and external aspects of the cortex, in the middle of the inter-radicular distance between each two adjacent teeth was measured bucally and lingually/ palatally. The inter-radicular measurements were made 4 mm apical to the alveolar crest, which is approximately at the level of the mucogingival junction.

1.3. Results

The mandible provides more buccal cortical bone than the maxilla. The mandibular buccal region had the thickest cortical bone of all regions evaluated. The cortical bone in the mandibular buccal region was thicker than the cortical cone in the maxillary buccal and lingual regions: Cortical bone thickness in the mandibular buccal regions increases from anterior to posterior.

The highest buccal cortical thickness in the maxilla was between the first and second premolars (1.6 mm). The highest buccal cortical thickness in the mandible was between the first and second molars (2.5 mm).

1.4. Discussions

It is recommended to avoid inserting mini-implants in the anterior region (maxilla and mandible), given the insufficient thickness of the cortical bone, a low level of attached gingiva and often an insufficient inter-radicular distance. A CBCT scan of the patients provides information on the thickness of the cortical bone at the insertion site, anticipating the torque required to insert the mini-implant. The insertion technique (direct or indirect) is selected based on the thickness of the cortical bone and the torque value. If the thickness of the cortical bone is sufficient to provide an optimal torque, the insertion technique will be a direct one without requiring a preparation of the insertion site. If the thickness of the cortical bone is increased and the required torque will be excessive, pre-drilling of the cortical bone will be necessary before the insertion, so the torque value will decrease.

1.5. Conclusions

The optimal site for mini-implant placement in the anterior region is between the lateral incisor and the canine in the mandible. In the posterior region of both jaws the optimal sites are between the second premolar and first molar and between the first molar and second molar.

2. THE CORRELATION BETWEEN SOFT TISSUE BIOTYPE AND CORTICAL BONE THICKNESS AS SUCCESS FACTORS IN MINI-IMPLANT PLACEMENT – PILOT STUDY

2.1. Context

The cortical bone thickness is considered to be a decisive factor in the overall success/failure rate of the mini-implant. The increase in cortical bone thickness in the alveolar bone of maxilla and mandible has been shown to significantly increases the primary stability of the mini- implant. It is recommended that the mini-implant be placed in the attached gingiva, adjacent to the muco-gingival junction of the upper and lower arches. different areas of the buccal attached gingiva had different soft- tissue thicknesses. If orthodontic mini-implants with the same length are used in areas with different soft tissue thickness, the length of the implants inserted in the bone will be different. Therefore, soft tissue might be one of the key factors for successful implantation

This study aims to correlate two of the factors that influence the success rate of orthodontic mini-implants and establish the link between soft tissue biotype and the underlying cortical bone thickness.

2.2. Material and methods

Two different patients were chosen: one with a thick and one with a thin biotype, according to TRAN technique. If the outline of the underlying periodontal probe could be visualized through the gingival margin, it was classified as a thin biotype; if the outline of the underlying periodontal probe could not be visualized through the gingival margin, it would be classified as a thick biotype. The study area selected was the lateral maxillary region, on the buccal side, at the most common mini-implant site placement: first and second premolar, second premolar and first molar and between first and second molar.

Clinical measurements: the soft tissue thickness was evaluated, using a direct method with the periodontal probe and an endodontic stopper. After local anesthesia, the periodontal probe struck the soft tissue perpendicular to the cortical bone. The endodontic stopper is in contact with soft tissues. After removal of the periodontal probe, the thickness of the soft tissue shall be indicated by the stopper position. Measurement were made at the muco-gingival junction, being already stated that keratinized gingiva presents a lower risk of developing hypertrophic tissues and inflammation.

Radiological measurements: Cone Beam Computed Tomography scans using Cranex Sordex were carried out, in order to obtain radiographic measurements of the thickness of the cortical bone. CBCT scans have been imported into 3-dimensional analysis software as digital imaging. (On Demand 3D dental app). Cortical bone thickness was measured at the same spots like the soft tissues

2.3. Results and discussions

The thin biotype characterized by thin soft tissue was correlated with a thin cortical bone and the thick biotype, was correlated with a cortical bone. The thickness of soft tissue at the insertion site should be taken into account when selecting the appropriate length of mini-implants and consideration should be given to individual patient variations in soft tissue and cortical bone prior to insertion of any mini-implants.

The stability of the mini-implants depends on the quality and quantity of the cortical bone. The main objective of an orthodontic mini-implant is to achieve maximum stability by placing it in areas with a thick cortical bone (for mechanical retention) and a thin, keratinized soft tissue (to avoid inflammation). Before selecting the mini-implant, the soft tissue thickness at the insertion site should be measured and this procedure requires local anesthesia, delaying the selection until just before the mini-implant insertions procedure. The design of the mini-implants varies depending on the thickness of the soft tissue, therefore it implies for the orthodontist to have a wide range of mini-implants.

2.4. Conclusions

The correlation between gingival biotype and the cortical bone thickness would allow the clinician to select the optimal mini-implant design, to ensure a more predictable outcome.

3. ACCURATE DETERMINATION FOR ORTHODONTIC MINI-IMPLANT PLACEMENT USING ACRYLIC RESIN SURGICAL GUIDE AND CBCT

3.1. Context

Surgical guides are used for accurate and predictable insertion of orthodontic mini-implants. The insertion technique must be easy to perform and without risks for the surrounding anatomical structures. Depending on the insertion site, the risk level varies. One of the factors that influences the success rate of mini-implants is the correct positioning. Inserting mini-implants in the most predictable way ensures an increase in the success rate.

3.2. Objectives

The aim of this study is to compile data from the literature and highlight the latest methods for developing surgical guidelines based on design, materials and technique. A second aim is to illustrate the stages of development and clinical use of conventional versus digitally designed surgical guides.

3.3. Material and methods

An online search was performed in the PubMed electronic library using the following terms: surgical guides, orthodontic surgical guides, orthodontic surgical guides for mini-implants, orthodontic surgical guides for TADS (surgical guides for temporary anchorage devices). This search included studies from 1968 to 2016. Subsequently, a manual search was conducted in journals that address these topics: surgical guides and orthodontic mini-implants.

Inclusion and exclusion criteria

For the two variables studied (the material and the accuracy of inserting the mini-implants), in vitro, on cadaver or animal, as well as clinical studies were selected. Only studies that provided accurate informations on these parameters were selected.

3.4. Results

The initial search returned 414 results. The number of titles was reduced to 3- after they were evaluated. Of the 30 results, only 10 articles offered details on the two variables studied: material and accuracy.

Orthodontic surgical guides are made from a variety of materials depending on the complexity of the case. An analysis of the literature brought together various types of materials, from conventional to the latest discoveries in the field.

Depending on the design, the surgical guides are classified into three categories: with limiting design, with partially limiting design and with completely limiting design.

3.5. Discussion

Using a surgical guide is the safest way to insert mini-implants. There are clinical situations where classic surgical guides cannot be used, for example: rotated teeth, narrow jaw, where the access is difficult or where multiple mini-implants are needed. In these situations, it is recommended to use stereolithography guides.

3.6. Conclusions

Precise insertion reduces the risk of mini-implant failure and damage to the anatomical structures. It is also possible to insert several mini-implants using the same surgical guide.

4. A Custom-Made Orthodontic Mini-Implant-Effect of Insertion Angle and Cortical Bone Thickness on Stress Distribution with a Complex In Vitro and In Vivo Biosafety Profile

4.1. Introduction

The primary stability of mini-implants is considered the most important criterion to assess the success rate. It is defined as the result of the mechanical interlocking between the mini-implant with the surrounding bone, which is determined by several factors: cortical bone quality and quantity, operator technique and the diameter of the screw. Nevertheless, from a mechanical point of view, in order to achieve good primary stability, the goal of mini-implant placement is to obtain maximum inter-digitation between the bone tissue and the threads, while generating controlled compression forces in the bone. The optimal insertion angle of a mini-implant is important for cortical anchorage and there are different opinions regarding this aspect.

Besides the primary stability, the success rate of an orthodontic mini-implant is also related to the chemical composition of the metal alloy from which it is made and which must possess some essential features — in particular, biocompatibility/non-cytotoxicity—to be further approved for clinical use. Concerning this issue, it is of significant importance to assess the biocompatibility of the metal alloy proposed for the development of the custom-made mini-implant on buccal cells through basic cytotoxic methods, such as 3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bromide (MTT) assay and lactate dehydrogenase (LDH) release method, which are the most used in vitro colorimetric assays to evaluate the toxicity/cytocompatibility of a test sample. Moreover, to complete the safety profile of the designed mini-implant next to the in vitro models, in vivo protocols often can add features linked to the complexity of a biological system. For further prediction of the biocompatibility designed mini-implant, an in vivo evaluation can add relevant data to its safety profile. The hen's egg test on chorioallantoic membrane (HET-CAM) assay is a simple and versatile alternative to animal testing.

The aim of the present study is to evaluate the stability of a custom-made mini-implant using 3D finite element models and to validate its biosafety profile using primary human gingival fibroblasts (HGF cells) for further in vivo clinical application.

4.2 Materials and Methods

Three-dimensional finite element models of the maxilla were created after cone beam computed tomography scanning. Following the scanning, the morphological data was manually segmented using the InPrint software. Segmented models of the cortical and cancellous bone and the crowns of teeth 2.4, 2.5, 2.6 and 27 were imported into ANSYS Space Claim. A custom-made, self-drilling, tapered mini-implant was designed using FreeCad 0.18 software. The implant had a diameter of 1.7 mm, 8 mm in length, 0.8 mm pitch, 0.32 mm thread depth and the bracket-like head from Forestadent (Ortho Easy).

The implant was inserted into the most popular insertion site: the inter-dental space between the upper first molar and second premolar. Cortical bone was modeled with a 1 mm thickness for the first set of simulations, afterwards the thickness increased to 1.5 mm and 2 mm for the following simulations. Mini-implant insertion angles were: 30°, 60°, 90°, 120° and the pull-out test was simulated until the axial displacement of the implant was 0.01 mm. An experimental orthodontic traction force of 2 N was applied to the head of each implant both in the horizontal and in the vertical direction in order to simulate en-masse retraction and intrusion.

An amount of 24 simulations were performed, increasing CBT (1, 1.5 and 2 mm) and the angle of insertion (30°, 60°, 90°, 120°) and changing force orientation (horizontal and vertical). Each analysis was run and the peak von Misses (equivalent) stresses was extracted.

For the pull-out test, force reaction was determined varying the CBT and insertion angle. The pull-out test is the most commonly-used parameter for quantifying the stability of mini-implants, and a higher value suggests an increased stability. The Von Misses stress of the mini-implant and the bone surrounding it, was determined for the force analysis, by varying the CBT, insertion angle and force direction.

4.2.1. In vitro model

The cell line used in the current study consisted in primary human gingival fibroblast (HGF) monolayer, which were supplied by American Type Culture Collection (ATCC® PCS-201-018™), together with the culture medium - Fibroblast Basal Medium (ATCC® PCS-201-030™) and the required supplements - Fibroblast Growth Kit-Low serum (ATCC® PCS-201-041™) and 0.1% Penicillin-Streptomycin-Amphotericin B Solution (ATCC® PCS-999-002™). The cells were cultured under sterile conditions and humidified atmosphere, enriched with 5% CO_2 (Steri-Cycle i160 incubator; Thermo Fisher Scientific, USA). The method employed in the present study to assess the *in vitro* cytocompatibility profile of the custom-made orthodontic mini-implant was based on the extraction means, a technique suggested by ISO standard 10993-5:2009 for medical devices. Thus, the mini-implant was submerged into the culture medium and exposed to intermittent shaking for 24h. Afterwards, the mini-implant was removed and the resulting extraction medium was used to stimulate the HGF cells for different time intervals (24h, 48h, 72 h).

4.2.2. Cell morphology assessment

The possible morphological changes of HGF cells after exposure to the extraction medium was assessed by comparing photographs between control cells (un-stimulated cells) and treated cells.

4.2.3. *In vitro* colorimetric assays

In vitro colorimetric assays used the 3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bromide (MTT) assay and lactate dehydrogenase (LDH) release method. The protocol consists of culturing the cells to a density of 104 cells/well in 96-well plates and incubation overnight. In the following day, the cells were treated with the extraction medium of the custom-made mini-implant for different intervals of time (24h, 48h, 72h). At the end of each stimulation interval, the MTT/LDH protocol provided by the manufacture was employed. The optical density (O.D.) of each well was determined spectrophotometrically by means of a microplate reader (xMark™ Microplate; Bio-Rad Laboratories, Inc., Hercules, CA, USA).

4.2.4. *In vivo* biocompatibility assessment/vascular toxicity using the HET-CAM model

Extracted medium of mini-implants were evaluated using a slightly modified HET-CAM protocol. The fertilized eggs were incubated at 37 °C and 60% humidity, and were prepared according to the standard protocol. On day 9 of incubation, inside an opening performed on the eggs' shell, 200 μl of the extraction medium of the custom-made mini-implant was inoculated onto the displaying CAM vessels. The effect on the developing capillaries was assessed by monitoring the appearance of hemorrhage (H), lysis (L), or coagulation (C). Further an irritation score was calculated.

As controls, sodium laurylsulphate (SLS 0,5%) was used as irritative standard, while distilled water was used as the negative control. A follow-up of the tested specimens was also registered 24 and 48 hours after the inoculation.

4.3. Results

Insertion angle and CBT have significant impact on force reaction values ($p < 0.05$). When CBT increases (from 1 mm to 1.5 mm, 1 mm to 2 mm or 1.5 mm to 2 mm), force reaction increases as well.

The means plots and Scheffe's results, demonstrate that there is a significant change in force reaction when the insertion angle is changed. Force reaction values decreased gradually when increasing in the insertion angle (30° to 60° to 90°), and the value increased again in conjunction with increases in the insertion angle (90° to 120°).

Insertion angle, CBT and force direction have significant impact on the Von Mises stress level of the implant and the cancellous bone. Changing the direction of the force from horizontal to vertical leads to a decrease in the Von Mises stress level of the implant. There are statistically significant changes in stress levels in both implant and cancellous bone when the CBT is increased. The combined effects of force direction and insertion angle and of insertion angle and CBT are statistically significant in both implant and cancellous bone.

Based on Schefee's results and by inspecting the plots, when the insertion angle is changed from 30° to 60°, 90° or 120° degrees, all changes are statistically significant. Stress decreased at the mini-implant level when the insertion angle increased from 30°, 60° to 90° but it increased again at a 120° insertion angle, when the traction force was horizontal. Cortical bone stress had the lowest value with an insertion angle of 30° and the highest value when the implant was inserted at a 120° angle, while CBT was 1 mm. Cortical bone stress had the lowest value with an insertion angle of 90°and the highest value when the implant was inserted at a 30° angle, while CBT was 2 mm independent of the force direction

4.3.1. In vitro biological profile

HGF cells present a good viable population after exposure to the extraction medium of the test sample, the cells manifesting a time-dependent cell viability decrease as follows: cell viability above 98% after 24h post-stimulation, approximately 90% viable cells after an exposure time of 48h and a viable HGF population around 87% at 72h post-treatment. The LDH release method showed similar results (Figure 8B) with the ones obtained in the case of the MTT method. Accordingly, in terms of cytotoxicity, cell death also increased in a time-dependent manner, the cells expressing a cytotoxic rate of approximately 7% after 24h, which increased at 9.23% after 48h and finally reaching a cytotoxicity percentage of 10.61% after 72h post-exposure.

4.3.2. Vascular safety on the chorioallantoic membrane

Compared to the positive control, which induced severe alteration on blood vessel architecture and functionality, with a high irritation score, the tested mini-implant had a similar influence as the negative control, with no irritation at the vascular level of the developing CAM (IS=0). Furthermore, 24 and 48 hours after the sample application, there was no sign of toxicity and the embryos showed a high viability rate. The capillary bed was developing similar to normal conditions with no interventions and the angiogenic process was active.

4.4. Discussion

In this study, finite element models of the maxilla and the mini-implant were generated; orthodontic loading for en-masse retraction, intrusion and the pull-out test was simulated and the stress patterns generated by the implants were evaluated under different insertion angles and different CBT.

Regarding the clinical biosafety of our newly developed orthodontic mini-implant, basic cytotoxic assays were performed by employing an *in vitro* model based on primary human gingival fibroblasts (HGF cells). These cells were chosen due to their direct exposure to any possible ion release from the orthodontic mini-implant, but also due to the fact that the gingival fibroblasts are the principal cells involved in the generation of the soft tissue that surrounds the orthodontic mini-implant.

4.5. Conclusions

Present results revealed that oblique insertion provides adequate cortical bone engagement when the CBT is reduced. Stress distribution in the bone was high in the cortical, while very little stress was transmitted to the cancellous bone. In addition, it was significantly concentrated at the apex of the threads that were in contact with cortical bone.

When cortical bone thickness is reduced (1 mm), the 30°angle of insertion is recommended, to increase the contact area between the implant and the cortical bone. However, caution should be taken, as both the lever arm and the amount of threads exposed are increase as well. In this regard, future studies should asses the correlation between implant length, number of threads exposed and the insertion angle.

When cortical bone thickness is adequate (2 mm), an insertion angle of 90° is recommended; as the 30° insertion angle generates a great deal of stress that can cause micro-fractures and necrosis in the cortical bone, leading to mini-implant failure.

Regarding the biosafety profile of the mini-implant, the current *in vitro and in vivo* assessments endorse its use in further experimental clinical applications.

5. ORTHODONTIC MINI-IMPLANTS INSERTION PROTOCOL

1. Diagnosis, treatment plan and anchorage planning

2. Clinical and paraclinical investigations

   - Radiological examination (retro-alveolar, OPG, CBCT)
   - Determine the insertion site
   - Development of the surgical guide (where indicated)

3. Armanetarium
   - Selection of the mini-implant size
   - Screwdriver handle – straight head (short, medium, long)
   - Counter-angle piece (20:1) – counter-angle head (short, medium, long)
   - Burr for cortical perforation (where indicated)
   - Sterilization of the insertion kit

4. Mini-implant placement
   - Superficial anesthesia – mucosal ischemia
   - Checking the surgical guide
   - Determining and marking the insertion site
   - Cortical perforation- where indicated
   - Mini-implant insertion
   - Testing adjacent teeth to determine the proximity of the roots

5. After insertion
   - Post-operative instructions
   - It is recommended to apply a light force in the first weeks

6. Removing the mini-implant
   - Rotate counter-clockwise until completely removed

IV. FINAL CONCLUSIONS

The aim of this research was to evaluate anatomical factors, technique-related factors and structural factors that influence the success rate of orthodontic mini-implants, as well as to develop some basic protocols to integrate these medical devices into daily practice.

The fundamental anatomical factors that influence the selection of the mini-implant type and the surgical technique used are the cortical bone thickness, gingival biotype and the inter-radicular distance. Mini-implants should be inserted using a direct technique in areas with a minimum cortical bone thickness of 1 mm and a maximum of 2 mm, with an inter-radicular distance of 3 mm. The insertion sites that have these characteristics are: between the second premolar and the first molar in both jaws. When the cortical bone thickness is greater than 2 mm, it is recommended to use a drill to perforate the cortex thus reducing the risk of bone necrosis and overheating and therefore the risk of failure. To reduce the failure rate, it is recommended that the optimal insertion site to be chosen based on the criteria mentioned above and then the biomechanics to be built in that insertion site, not the other way around.

The correlation between cortical bone thickness and gingival biotype allows for a predictable outcome, thus measuring the cortical bone thickness, using CBCT investigations, data about the soft tissue thickness is obtained. This allows the choice of the type of mini-implant based on the thickness of the soft tissue without having to wait until the moment of the intervention, this clinical evaluation requiring anesthesia. To prevent inflammation, these devices should be inserted into keratinized soft tissue.

Traditional orthodontic techniques are simplified when new technology is used, and the use of a surgical guide is the safest and most predictable approach for placing mini-implants. A precise insertion decreases the risk of mini-implant failure as well as the impact on the surrounding anatomical structures. The use of digital models, orthodontic software, and 3-D printers in the digital orthodontic protocol allows for a more accurate and faster assessment. 3-D innovations are the future of orthodontics by reducing the risks, the chair-time and at the same time obtaining the ideal treatment plan for the patient. Surgical guides are recommended when there is the risk of affecting anatomical structures or when the inter-radicular space is decreased. When inserting mini-implants in the palate, as a component of appliances that perform disjunction, mesialization or distalization, it is recommended to position them parallel so that the device enters passively and without friction. In these cases, it is also recommended to use a guided technique.

Regarding the insertion technique, the findings of this study suggest an oblique insertion (30˚) when the cortical bone thickness is decreased (1mm) to increase the contact surface between the mini-implant and the cortical bone. To prevent necrosis and microfractures, a perpendicular insertion is advised when the cortical bone thickness is optimal (2mm). The cortical bone had the highest stress distribution, with a significant concentration of stress at the tip of the threads.

V. PERSONAL CONTRIBUTIONS

- Evaluation of the main anatomical factors that influence the success rate of orthodontic mini-implants: cortical bone thickness, gingival biotype and inter-radicular distance.
- Creating a custom-designed orthodontic mini-implant with ideal structural parameters and evaluation stress distribution at both the bone and the mini-implant.
- Validation of the biological profile for the custom-made mini-implant using the latest techniques: coriolantoid membrane method, LDH method, MTT
- Evaluation of the factors related to the insertion technique to reduce the failure rate: the insertion angle corelated with the cortical bone thickness and the use of surgical guides.
- A summary of mini-implant insertion procedure that uses both guided insertion techniques (presenting different types of surgical guides) and the direct insertion technique.