

**Accuracy, stability and safety of orthodontic mini-implant
template in the infrazygomatic crest zone**

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Chapter1

INTRODUCTION

1.1 Background of the study

Malocclusion is a term used in orthodontics to describe the improper alignment or positioning of the teeth and the jaws. It refers to any deviation from the ideal occlusion, which is the optimal alignment of the upper and lower teeth when the jaws are closed. Malocclusion can involve various dental and skeletal discrepancies, including crowding, spacing, misalignment, overbite, underbite, crossbite, open bite, and other irregularities in the dental arches. In simpler terms, malocclusion is a condition where the teeth and jaws do not fit together correctly, resulting in an abnormal bite. It can affect the appearance, function, and oral health of an individual. Orthodontic treatment aims to correct malocclusion and restore proper alignment, improving both the aesthetic appearance of the smile and the function of the teeth and jaws. The purpose of orthodontic treatment is to achieve a good functional bite and an aesthetic facial appearance. For orthodontists, a good facial profile is one of the most important parts of evaluating the effectiveness of orthodontic treatment. Orthodontic treatment has gradually become an important way to improve personal image and tends to be tailored, called personalized orthodontic treatment. With the continuous progress of industrial technology, the application of Computer-Aided Design/Computer-Aided Manufacturing (CAD/CAM) and Cone beam CT (CBCT) in orthodontics is becoming increasingly popular, providing hardware support for personalized and accurate orthodontic treatment. Various personalized

orthodontic devices have also emerged on this basis. Personalized orthodontic devices are personalized orthodontic treatment tools tailored to patients based on their individual tooth shape and arch characteristics, guided by the treatment target position, through personalized tooth arrangement experiments, and utilizing 3D digital design and printing technology. Microimplant or mini-screw, is a commonly used anchorage for orthodontists, has been widely used in clinical practice and plays an important role in solving difficult cases (Jones Jason P et al,2020) As a temporary bone anchorage, miniscrew is easy to implant and remove. However, the anatomical structure of the human body is complex, and the safety space is limited, so precise implantation of miniscrew is necessary.

Miniscrews are generally implanted between tooth roots, but the space between them is limited and there is a risk of injury to the roots (Kang Yoon-Goo et al,2009), so the orthodontist often choose to implant miniscrews at the zygomatic alveolar ridge.

The zygomatic alveolar ridge has sufficient bone mass, and the double-layer bone cortex of its buccal side and its top maxillary sinus can often be used to implant anchorage screws. Moreover, the zygomatic alveolar ridge is high, close to the center of resistance, and suitable for miniscrew implantation. However, bone mass and thickness of the buccal bone cortex must be taken into consideration when implanting miniscrews here to avoid damaging important structures such as the maxillary sinus and tooth root (Liou EJ et al,2007).

However, current study found that up to now, the design of miniscrew template is mainly applicable to tooth root (Kim SH et al,2007)and palate(Cassetta M et al,2018), and rarely applicable to zygomatic alveolar ridge.

Thus, the purpose of this study is to provide a digital orthodontic temporary anchorage devices (TADs) design and application of orthodontic miniscrew template by computer-aided design and manufacturing.

1.2 Temporary anchorage devices (TADS)

Ensuring anchorage control is essential for achieving successful orthodontic treatment. However, traditional methods of enhancing anchorage often present challenges such as large volume, complex structures, discomfort, and compromised oral hygiene for patients. Additionally, the extended wearing period of extraoral devices significantly impacts patients' quality of life. Therefore, the use of more advantageous temporary anchorage devices (TADS) in orthodontic treatment is becoming increasingly widespread. The clinical operation of implant nail implantation is mainly determined by the doctor by observing the radiation film to determine the implantation site, the position with the bilateral tooth roots, and the relationship with the maxillary sinus. Based on personal experience, the implant nail implantation operation is carried out. This clinical operation requires the surgeon to have a clear understanding of the anatomical structure of the surrounding tissues and extremely high experience requirements, otherwise it is very easy to cause damage to the tooth roots and surrounding tissues (Kuroda S et al,2007). In addition, the risk of implantation increases due to the number of tooth roots, the close distance between adjacent tooth roots, and the large variation of root branching, which leads to many young doctors being discouraged. Research has shown that the failure rate of implant implantation is still relatively high, mainly due to touching or damaging adjacent tooth roots during the implantation process (Lim G et al,2013). Kang et al. found

that when the implant nail damages adjacent tooth roots, it can reach up to 79.2% of implant screws become loose, while the loosening rate without contact with the tooth root is 8.3% indicates that the safety of planting nails is the key to success (Kang, et al, 2009). The high requirements of clinical operation, the high harm caused by improper operation, and the high failure rate seriously hinder the application of this technology in clinical practice and its popularization nationwide

1.3 Miniscrew template

Miniscrew templates have become a useful tool in orthodontic treatment, providing a guide for precise and accurate miniscrew placement. Research in this area has focused on developing new miniscrew templates to improve their design and efficacy.

One key research direction has been on investigating the impact of different template materials on their accuracy and stability. Studies have compared the accuracy of templates made from acrylic, resin, and metal, exploring how these materials influence stability and ensuring precise hole drilling for miniscrew placement.

Additionally, research has explored the use of computer-aided design (CAD) and computer-aided manufacturing (CAM) technologies to design and produce customized miniscrew templates. Studies have investigated the accuracy and efficacy of 3D-printed miniscrew templates, which allow for precise customization to a patient's specific anatomy and treatment needs.

Furthermore, researchers have explored the use of virtual planning software and surgical guides to further optimize miniscrew template design. Studies have

investigated the efficacy of using virtual surgical planning (VSP) software to plan miniscrew placement and create customized surgical guides, which provide a detailed guide for miniscrew insertion.

1.4 Cone-Beam computed tomography (CBCT)

Cone-beam computed tomography (CBCT) has been introduced for dental offices because of the reduced costs and size (Patel et al., 2009a; Patel et al., 2009b). The scans produced by a CBCT imaging system have a significantly reduced scan time, reduced cost for the patient, and use a lower radiation dose than medical CT (Ziegler et al., 2002; Scarfe et al., 2006). Different CBCT machines will have different radiation doses determined by the particular brand, settings, and the area of the mouth to be scanned. CBCT compensates for the disadvantage of the scanning method, which is that only the crown can be scanned. It also provides significant dose reductions of between 98.5% and 76.2% when compared to the patient dose reported for maxillofacial imaging by conventional CT (approximately 2000 mSv) (Scarfe WC, et al., 2008; Loubele M et al., 2009). Initial research on the accuracy of CBCT focused on the evaluation of linear (Goodarzi ,et al., 2015; Sherrard JF et al., 2010) or volumetric data, (Wang Y ,et al., 2011; Tayman MA et al., 2019) and was shown to be highly accurate with regard to alveolar bone defects and root length of varying voxel sizes (0.125–0.40 mm) (Damstra J ,et al., 2010; Lyu H et al., 2023).

1.5 Computer-Aided Design and Manufacturing(CAD/CAM)

The current status of “Dental CAD/CAM” (Computer-Aided Design/Computer-Aided Manufacturing) in the field of dentistry involves the application of advanced

computer technologies for designing and fabricating dental restorations and prosthetics with high precision and efficiency.

Dental CAD/CAM systems utilize specialized software and hardware to digitally create 3D models of dental structures, such as crowns, bridges, and dentures. These models are designed based on digital scans of patients' teeth or oral structures, obtained through intraoral scanners or cone beam computed tomography (CBCT).

Once the digital models are created, the CAD software allows dental professionals to design customized restorations with optimal fit, form, and function. They can manipulate the shape, size, and contours of the restorations, ensuring precise adaptation to the patient's dental anatomy. The software also enables the selection of appropriate materials and colors.

After the design phase, the CAM component of the system takes over. CAM software communicates with dental milling machines or 3D printers to accurately fabricate the designed restorations from various materials, such as ceramics, zirconia, or resin. The milling machines can precisely carve restorations from blocks of material, while 3D printers can produce intricate prosthetics using additive manufacturing techniques.

1.6 Miniscrew implantation

Orthodontic mini-implants have become an increasingly popular and effective option in providing orthodontic anchorage. Research in this area has focused on improving the accuracy and stability of mini-implant placement, as well as developing new designs and materials to optimize their function.

One major research focus has been on using imaging technology to improve implant placement accuracy. Advances in cone-beam computed tomography (CBCT) have allowed for more thorough and detailed 3D imaging of the patient's jaw structure, aiding in the identification of ideal placement sites. Additionally, computer-aided implant placement (CAIP) systems have been developed to guide the implantation process and improve accuracy.

Another research direction has been on improving the success rate and stability of mini-implants over time. Studies have explored the use of different implant designs and materials, such as tapered, self-tapping, and surface-treated implants, to enhance osseointegration and stability within the jawbone. Additionally, research has investigated the impact of implant diameter, length, and placement depth on the success of mini-implants.

Furthermore, researchers have examined the effect of implant placement on the surrounding teeth and tissues. Studies have investigated the impact of mini-implants on root resorption, periodontal health, and soft tissue irritation, and have suggested strategies to minimize these effects.

1.7 Digital model establishment

After the 1990s, the application of digital 3D modeling of teeth and jaws in dentistry has become increasingly widespread.

Researchers have developed three-dimensional (3D) scanning techniques to capture the geometry and texture of oral structures, including teeth, gums, and surrounding

tissues. These digital scans are then processed and converted into accurate and detailed virtual models, providing an alternative to traditional plaster models.

Digital oral models offer several advantages over traditional models. Firstly, they enable enhanced visualization and analysis of dental structures, allowing for improved treatment planning and evaluation. Dentists can manipulate the digital models, measure distances, angles, and volumes, and simulate treatment outcomes.

In addition, digital models facilitate communication and collaboration among dental professionals. They can be easily shared, stored, and accessed remotely, enabling interdisciplinary consultations and efficient treatment coordination.

Moreover, digital oral models serve as a valuable resource for dental research and education. Researchers can use these models to study various dental conditions, simulate treatment interventions, and investigate the efficacy of different procedures. Dental students can also enhance their learning experience by practicing virtual procedures on these models.

Despite these advancements, challenges remain in the adoption of digital oral models. Standardization, interoperability, and data security are areas that require further attention. Additionally, the cost of acquiring and maintaining the necessary technologies may limit widespread implementation.

1.8 Statement of problem

The use of mini-implant anchored orthodontic template is a relatively new technique in orthodontics that shows promise for improving treatment outcomes. However,

there is a lack of comprehensive research investigating the effectiveness and efficiency of this approach.

The problem statement for this research paper focuses on the need to evaluate the clinical outcomes, stability, patient comfort, and treatment duration associated with mini-implant anchored orthodontic guide. Additionally, it aims to address the limitations and challenges faced in the current available literature on this topic, including the lack of standardized protocols, inconsistent findings, and potential complications.

Moreover, considering the growing popularity of mini-implant anchored orthodontic template among orthodontists and patients, it is crucial to establish evidence-based guidelines and protocols to ensure the successful integration of this technique into orthodontic practice. Therefore, the problem statement seeks to explore the current gaps and limitations in the existing literature and provide valuable insights into the clinical benefits and drawbacks of utilizing mini-implant anchored orthodontic plates.

1.9 Justification of the study

The development of miniscrew template is of great significance in the field of orthodontic surgery. These devices provide a precise and efficient means of inserting screws into the bones of patients, especially in cases where the case is difficult. The use of miniscrew template greatly simplifies the surgical procedure, reducing both the risk of error and the overall time required for the operation.

Additionally, the use of miniscrew template has been shown to result in improved orthodontic outcomes, such as increased stability of the miniscrew. This can lead to reduce risk of complications such as implant migration.

Therefore, this study aims to provide a standardized protocol for designing and fabricating mini-implant anchored orthodontic plates, which can improve the overall clinical outcomes, patient comfort, and treatment efficiency. The findings of this study can also open new avenues for future research on advancing the miniscrew template design and fabrication techniques, leading to further innovation and improvement in orthodontic treatment modalities.

1.10 Novelty of the research:

The research on miniscrew template presents several novel aspects in the field of orthodontic surgery. Firstly, the development of this technology introduces a more precise and efficient method for inserting small diameter screws into bones. This represents a significant advancement compared to traditional methods, which often rely on freehand techniques and can be prone to errors. The introduction of miniscrew template provides surgeons with a standardized and reliable tool to achieve accurate screw placement.

Moreover, the use of miniscrew template allows for minimally invasive procedures, reducing the need for open surgery. This innovation not only enhances patient comfort but also minimizes the risk of complications associated with invasive surgical techniques. The ability to achieve comparable stability and outcomes through a less invasive approach is a noteworthy contribution to the field.

Finally, the production of guide plates is a fully digital design. The guide plate is suitable for the infrazygomatic crest zone, ensuring the accuracy of the implantation position and avoiding damage to important structures.

1.11 Aim and Objectives of the study

1.11.1 Aim of the study

This research aims to investigate the potential benefits of application new modified designed of orthodontic miniscrew template by computer-aided design and manufacturing in improving the accuracy and efficiency of panel installation in miniscrew application.

1.11.2 Objective

General objectives

The general objective of this research is to study the effect of utilizing modified miniscrew template as tools for the miniscrew placement.

Specific Objective

The specific objectives for this study will be:

1. To compare the accuracy of miniscrews implanted using modified template by computer-aided design and without template guide (conventional method).

2. To compare the stability of miniscrews implanted using modified template by computer-aided design and without template guide (conventional method).
3. To compare the safety of miniscrews implanted using modified template by computer-aided design and without template guide (conventional method).
4. To compare the accuracy of miniscrew implantation between using CBCT and digital model investigating.

1.11.3 Research questions

1. What is the effect of the accuracy of miniscrews implanted with and without guide?
2. What is the effect of the stability of miniscrews implanted with and without guide?
3. What is the effect of the safety of miniscrews implanted with and without guide?
4. What is the difference in accuracy of miniscrew implantation between using CBCT and digital model investigation?

1.11.4 Alternative hypotheses

1. There is a significant difference in the accuracy of miniscrews implanted with and without guide.
2. There is a significant difference in the stability of miniscrews implanted with and without guide.

3. There is a significant difference in the safety of miniscrews implanted with and without guide.
4. There is a significant difference in the accuracy of miniscrew implantation between using CBCT and digital model investigating.

Chapter 2

Literature review

2.1 Mini-implant

2.1.1 Definition of Mini-Implant

Orthodontic micro-implant nails (also known as orthodontic implants, orthodontic micro-implants, and temporary anchorage device) are small implants used in orthodontic treatment that are often used to provide additional support and anchorage to aid in tooth movement and the straightening process. These micro-implant nails are usually made of titanium alloy or other biocompatible materials, and their shapes and sizes are carefully designed to accommodate different treatment needs.

2.1.2 History of Mini-Implant

The concept of orthodontic micro-implant originally dates back to the 1980s, but it is only in recent years that they have come to receive widespread attention and research. With the advancement of medical technology and material science, the design and application of mini-implants have been continuously improved, bringing new possibilities to the field of orthodontics.

2.1.3 Types of Mini-Implant

According to their different designs and uses, orthodontic micro-implant nails can be divided into various types, micro-implant nails with different head designs, etc. Each of these mini-implant nails has its own characteristics. Each of these TADS has its own characteristics and can be selected and applied according to the patient's specific situation and treatment needs.

2.1.4 Uses of Mini-Implant

Orthodontic micro-implant nails play an important role in the clinic in the following ways:

1. Providing additional support and anchorage: TADS can provide additional support and anchorage points during tooth movement, helping to hold one or more teeth in place, preventing unwanted tooth movement and facilitating effective orthodontic treatment.

2. Expanding the scope and possibilities of orthodontic treatment: For some complex tooth movement and orthodontic cases, traditional orthodontic methods may have limitations. The introduction of micro-implant pegs can expand the scope of orthodontic treatment, providing more treatment options and possibilities, and making problems that would otherwise be difficult to solve possible.

3. Facilitating tooth movement and orthodontic results: The application of TADS can help improve tooth movement and facilitate the orthodontic process. They can be used in conjunction with traditional orthodontic treatments to achieve faster and more effective orthodontics, shortening the treatment cycle and improving the predictability and success rate of treatment.

4. Solving treatment challenges in complex cases: In some complex orthodontic cases, such as severe crowding and severe resorption of the alveolar bone, TADS can play an important role in helping doctors to solve the treatment challenges and improve the treatment effect and aesthetic results.

2.1.5 Current status of research on Mini-Implant

In recent years, a growing number of studies have been devoted to evaluating the effectiveness of orthodontic mini-Implant in different types of orthodontic cases, implantation stability, complication rates, and other factors. These studies have explored in depth the implantation technique, biological response and long-term results of micro-implant nails through clinical experiments, imaging evaluations and biomechanical analyses. As research continues, guidelines and best practices for the application of TADS are being refined and updated.

2.1.6 The success rate of miniscrew implantation

Alberto Conso laro believes that the shape of the alveolar ridge between teeth is flexible and variable(Voss PJ ,et al., 2014). Therefore, the reasons for the failure of orthodontic micro implants are often related to the structure of the alveolar bone, which can generally be attributed to the following reasons: the implant site is inclined towards the alveolar ridge of the upper and lower jaws. Miniscrew implantation is too close to the periodontal ligament, resulting in low bone density, low thickness, low alveolar bone volume, and low cortical bone thickness, which leads to poor fixation of the implant.Excessive pressure during implantation leads to slight fracture of the trabecular bone.. In addition to the alveolar bone structure, when implanting miniscrewss without considering the thickness of gingival tissue and the width of the attached gingiva, it may easily lead to periimplantitis, resulting in implant anchorage failure (Spinato S,et al., 2017). Other factors, including the

shape, length and diameter of the miniscrew, the immediate and early loading size of the implant, can also have a significant impact on the success rate of the implant.

Table 2.1. Miniscrew Implantation by guide between tooth roots

Author name	Imaging evaluation	Results
Ken Miyazawa et al (2010)	CBCT	No miniscrew was found to be in contact with a root either at insertion or before removal, both in the upper and in the lower arch.
Janghyun Paek, et al. (2014)	3D model scanner	The use of a custom-made, rigid guide when placing miniplates will minimize complications such as vertical mislocation or slippage of the miniplate during placement.
Matheus Melo Pithon et al (2010)	Periapical radiograph	The present surgical guide allows a controlled and accurate palatal miniscrew placement in three dimensions.
Eduardo Yugo Suzuki, et al (2008)	Periapical radiograph	The 3D surgical guide provides a precise method for miniscrew placement into the dentoalveolar bone.
Georgios Vasoglou, et al (2022)	CBCT and intraoral scanning	A 3D designed and manufactured surgical guide with information concerning CBCT and intraoral scanning ensures accuracy on mini-implant placement while design of

		the guide without the use of a CBCT is less accurate, especially on inclination of the implant.
Yu-Tzu Wang, et al (2017)	CBCT/laser scan image superposition	This study addressed integrating CBCT and laser scan image superposition; CAD and 3DP techniques can be applied to fabricate an accurate customized surgical template for dental orthodontic miniscrews.
Hong Liu, et al (2010)	CT	The proposed template has high accuracy and will be especially useful for patients who require precise miniscrew placement.

Table 2.2 Miniscrew Implantation in palate

Author name	Imaging evaluation	Results
Antonino Lo Giudice et al (2020)	CBCT	A case report about Maxillary Skeletal Expander (MSE)
Vincenzo Ronsivalle ¹ , et al (2023)	intra-oral scan (IOS) and CBCT scans of each guide was generated were imported into Blue Sky Plan* (USA)	A certain amount of clinical deviation can occur between planned and achieved position of orthodontic miniscrews in the anterior palate.
Giorgio Iodice et al (2010)	models were scanned using a 3D model scanner	Both direct and 3D-assisted TAD insertion methods are safe and accurate in the anterior palate. However, the use of insertion guides could facilitate TAD insertion, providing the opportunity to use palatal implants to the less-experienced clinicians.
Michele Cassetta et al. (2019)	CBCT and dental digital model images	Miniscrew-supported distal jet appliance can be used safely for first upper molar distalization.
Daniele Cantarella et al (2020)	the digital model of dental arches and cone-beam computed tomography (CBCT).	In the present case report, the digital planning was associated with a positive outcome of maxillary expansion and protraction in safety conditions

M. Cassetta, et al. (2018)	the fusion of cone-beam computed tomography (CBCT) and digital dental model images	The present surgical guide allows a controlled and accurate palatal miniscrew placement in three dimensions.
Diego Sánchez- Riofrío et al. (2020)	CBCT	Digital models, CBCT and CAD/CAM technology, are essential to accomplish the goals proposed in this article.
Kristian Kniha et al. (2021)	Preoperative lateral cephalograms; postoperative CBCT	The accuracy of an OMI position can be significantly increased by using a guide extension over the teeth. Vertical implant positions presented the lowest deviations. Postoperative oral scans and CBCTs represent diverging accuracy measure ments when compared with virtual planning
Jae-Jung Yua et al. (2012)	CBCT	The accuracy of an OMI position can be significantly increased by using a guide extension over the teeth. Vertical implant positions presented the lowest deviations. Postoperative oral scans and CBCTs represent diverging accuracy measurements when compared with

		virtual planning.
Maria R.et al. (2023)	CBCT and Intraoral scans images	The 3D-printed SGs did not reach the accuracy of the conventional SGs made of Pattern Resin but may provide sufficient accuracy for palatal OMI placement.
Silvia Izabella Pop.et al. (2022)	CBCT	<p>1. Disinfection with 4% Gigasept (Gigasept Instru AF; Schülke & Mayer GmbH, Norderstedt, Germany) is suitable both for SLA- and DLP-printed surgical guides.</p> <p>2. Heat sterilization at both 121 °C and 134 °C modifies the mechanical properties of the surgical guides and is not recommended as a sterilization method for surgical guides intended for mini-implant placement.</p>
Jian-Hong YU.et al. (2018)	CBCT	<p>Using FE analysis for biomechanical evaluation and combining with CT image, image superimposed method and CAD technique can fabricate accuracy/security customized surgical template for mini-screws with better primary</p>

		stability.
Lucia Pozzan .et al. (2022)	CBCT	<p>1. All operative steps contribute to a certain degree of deviations that lead to a cumulative effect.</p> <p>2. Te laboratory step has a smaller infuence on the angular deviations between planned and inserted miniscrews than the clinical steps.</p> <p>3. Cases with 2 TADs can be successfully performed with a 1-visit protocol must be approached with caution, given the lower degree of tolerance of the system.</p>

Table 2.3. Miniscrew Implantation in infrazygomatic crest zone

Author name	Imaging evaluation	Results
Li Su et al (2022)	the digital model of dental arches and cone-beam computed tomography (CBCT).	In the vertical direction, the accuracy of implantation with the template is higher than that of the traditional method without the template to avoid piercing the maxillary sinus mucosa in the infrazygomatic crest zone

2.2 Miniscrew guide

2.2.1 The advantage of Mini-implant guide

Mini-implant were placed more accurately when using surgical guides than when using a conventional method (Bae MJ et al.,2013). The accurate insertion of mini-implant using the guide allows doctors to precisely transfer the radiographic information from preoperative design to the surgical, thus minimizing the risks of root and injury (Suzuki EY et al.,2008). This novel approach is also leading to short orthodontic treatment time, minimal discomfort, and great patient acceptance.

2.2.2 The disadvantage of Miniscrew guide

The use of guide plates can easily lead to greater economic costs. It is always lead to the additional biological cost such as CBCT. We also need to consider the complications such as the breakage of the surgical guide itself during its use (Lo Giudice A et al.,2021)

2.2.3 The design of Miniscrew guide

The most common currently is the palatal mini-implant guide. As described in Figure 1,the surgical guide has designed some holes aimed at the correct positioning control(Cassetta M et al.,2013).As described in Figure 2,the surgical guide is made of archwire(Pithon MM et al.,2010).As described in Figure 3,the 3D surgical guide

can connect to any desired position by the archwire (Suzuki EY et al.,2008).As described in Figure 4,mini-screw spin-off slots were designed on the surgical template(Yu JH et al.,2018).As described in Figure 5,templates fabricated by SLA bonded with guided sleeves in the trajectory (Liu H et al,2010).

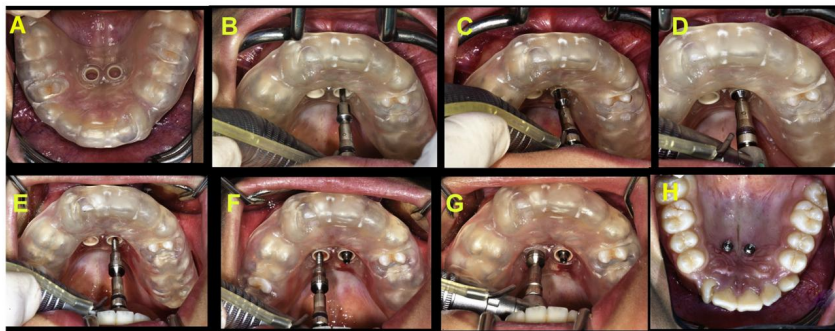


Figure 2.2.1 Palatal mini-implant guide



Figure 2.2.2 Guide made of archwire

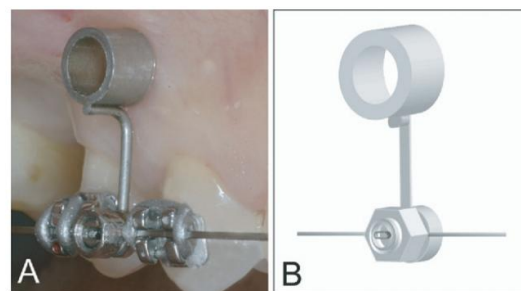


Figure 2.2.3 Guide made of archwire

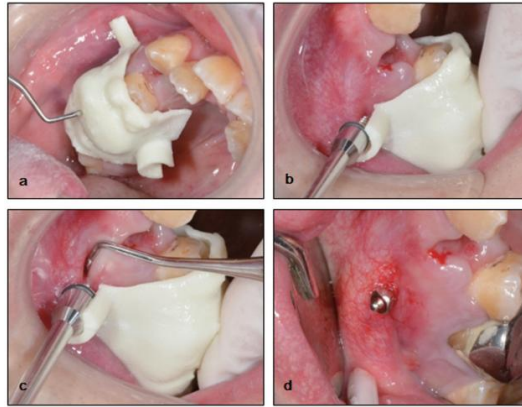


Figure 2.2.4 Guide with mini-screw spin-off slots

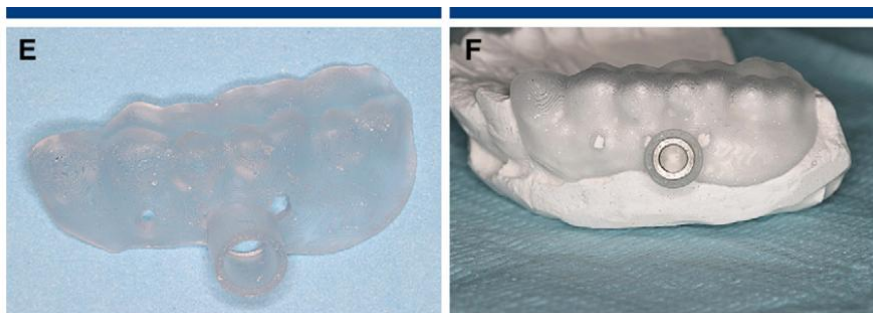


Figure 2.2.5 Guide with sleeves

2.3 Approaches to Improve the safety and stability of Miniscrew

2.3.1 Imaging technology

After the 1990s, the application of digital 3D modeling of teeth and jaws in dentistry has become increasingly widespread.

Researchers have developed three-dimensional (3D) scanning techniques to capture the geometry and texture of oral structures, including teeth, gums, and surrounding

tissues. These digital scans are then processed and converted into accurate and detailed virtual models, providing an alternative to traditional plaster models.

Digital oral models offer several advantages over traditional models. Firstly, they enable enhanced visualization and analysis of dental structures, allowing for improved treatment planning and evaluation. Dentists can manipulate the digital models, measure distances, angles, and volumes, and simulate treatment outcomes.

In addition, digital models facilitate communication and collaboration among dental professionals. They can be easily shared, stored, and accessed remotely, enabling interdisciplinary consultations and efficient treatment coordination.

Moreover, digital oral models serve as a valuable resource for dental research and education. Researchers can use these models to study various dental conditions, simulate treatment interventions, and investigate the efficacy of different procedures. Dental students can also enhance their learning experience by practicing virtual procedures on these models.

Despite these advancements, challenges remain in the adoption of digital oral models. Standardization, interoperability, and data security are areas that require further attention. Additionally, the cost of acquiring and maintaining the necessary technologies may limit widespread implementation.

2.3.2 Miniscrew guide

In recent years, with the rapid development of digitalization in oral applications, more accurate research methods have been provided for clinical doctors (Bae MJ et

al,2013). Qiu Lingling reconstructed teeth and jawbone models using CBCT, determined the three-dimensional spatial position of the tooth root using software such as Minics, designed the implantation position and angle, successfully printed resin guide plates, and implanted implant screws (Qiu L et al,2012) . Lo et al.used CBCT for digital design and printing of maxillary implant nail assisted arch expansion devices, and achieved good clinical treatment results(Lo et al,2020). This project successfully combines CBCT and 3Shape intraoral scanning data, uses software to establish an accurate three-dimensional integrated dental model, accurately evaluates the three-dimensional spatial position relationship of teeth, designs personalized micro implant guide plates based on patient treatment conditions, and finally produces personalized high-precision metal implant guide plates through CAD/CAM rapid printing, which are applied in clinical practice.

2.3.3 Miniscrew design

Miniscrews have become an important component in orthodontic treatment, providing a reliable source of anchorage for tooth movement. Research in this area has focused on developing new miniscrew designs to optimize their function and stability.

One research direction has been on investigating the effect of thread design on miniscrew stability. Studies have explored the impact of thread pitch, depth, and shape on the successful insertion and stability of miniscrews. Additionally, research has examined the use of self-drilling or self-tapping miniscrews, which eliminate the need for predrilling a pilot hole prior to insertion.

Another research focus has been on the use of surface treatments to improve miniscrew stability. Studies have investigated the impact of different surface treatments, such as acid etching, sandblasting, and anodizing, on the osseointegration and stability of miniscrews. Additionally, research has explored the use of biomaterial coatings, such as hydroxyapatite and titanium dioxide, to enhance the osseointegration of miniscrews.

Furthermore, researchers have explored the impact of miniscrew design on patient comfort and acceptance. Studies have investigated the use of miniscrews with different head designs, such as flat, square, or dome, to minimize tissue irritation and discomfort during treatment. Additionally, research has examined patient satisfaction with miniscrew design and ease of use.

2.4 Digital model

There is currently no consensus on which technology is most accurate for modeling (Akyalcin et al.,2013;Flügge TV et al.,2013).Different modeling methods have their own advantages and disadvantages. The most commonly used digital 3D modeling methods in clinical practice include laser 3D scanning technology, CT scanning technology, and direct intraoral scanning technology.Akyalcin et al. established three digitalization models for 30 orthodontic patients and found that the deviation of laser scanning is the smallest and its accuracy is better than CBCT(Akyalcin et al.,2013). Kim et al. established laser scanning digital models, physical models, and CBCT digital models for 60 orthodontic patients and measured their tooth width, arch length, and width. They found that the accuracy of laser scanning digital models was high(Kim et al .,2014). Kim et al. measured the anterior and full tooth bolton ratios

of 50 patients and found that laser scanning had higher accuracy compared to CBCT(Kim et al.,2016).

2.5Computer-Aided Design and Manufacturing(CAD/CAM)

Computer Aided Design (CAD) and Computer Aided Manufacturing (CAM) is becoming increasingly mature and plays a crucial role in stomatology.3D printing technology as a rapid prototyping technology that is a widely used technique in stomatology in the 20th century.The new industrial manufacturing technology developed in the late 1980s was initially used in industries such as aviation and aerospace.It refers to the use of materials such as photosensitive resins to layer computer-aided design models through design software.A technique of layer by layer stacking, editing and shaping contours to create a three-dimensional solid model. CAD/CAM technology is a means of transforming virtual designs into entities (Voss PJ ,et al., 2019).

Chapter 3

MATERIAL AND METHODS

3.1 Study design

This is a Randomised control trial.

3.2 Population and sample

3.2.1 References population

Orthodontics patients which is require to implant miniscrew as anchorage requirement at the Department of Stomatology, Xuanwu Hospital of Traditional Chinese Medicine.

3.3 Source of population

The samples will be recruited from the Dental Clinic, Beijing Xuanwu Traditional Chinese Medicine Hospital , Beijing Xuanwu TCM Hospital.

3.4 Ethical Considerations

Ethical approval has been obtained from Beijing Xuan Wu Hospital of Traditional Chinese . This study will apply for ethical approval from the Human Research Ethics Committee of USM.

This clinical trial will also planned to register in Clinical trial.gov.my.

Before collecting any personal data, ensure that all participants understand the purpose of data use and obtain their written consent.

All researchers will participate in data protection and privacy training to ensure they understand and comply with data protection policies. Establish a security incident reporting mechanism to ensure that any security incidents can be reported and handled in a timely manner.

3.5 Sample size calculation

Sample size were determined using power and sample size calculation software (version 3.1.9.7) (Dupont and Plummer 1990). Since the sample size calculated for other objectives gave less number of subjects in each group, therefore the sample size selected in this research is based on objective of miniscrew implantation. The given below are the categorization as per objective.

3.5.1 Objective 1

Sample size calculation based on the objective 1 related to the of guide on the miniscrew implantation. In a previous study the response within each subject group was normally distributed with standard deviation 1.82437mm(Su Li,Song Hui and Xiaofeng Huang,2022). If the true difference in the experimental and control means is 2.7403, the research will need to study 8 experimental subjects and 8 control subjects to be able to reject the null hypothesis that the population means of the experimental and control groups are equal with probability (power) 0.8. The Type I

error probability associated with this test of this null hypothesis is 0.05. The effective size is 1.5451013.

3.5.2 Objective 2

Sample size calculation based on the objective 1 related to the of guide on the miniscrew implantation. In a previous study the response within each subject group was normally distributed with success rate 86%, failure rate 2% (Lim H, et al., 2011). The research will need to study 8 experimental subjects and 8 control subjects to be able to reject the null hypothesis that the population means of the experimental and control groups are equal with probability (power) 0.8. The Type I error probability associated with this test of this null hypothesis is 0.05.

3.5.3 Objective 3

Sample size calculation based on the objective 1 related to the of guide on the miniscrew implantation. In a previous study the response within each subject group was normally distributed with standard deviation 0.12mm (Janson G, et al., 2013). If the true difference in the experimental and control means is 0.66, the research will need to study 10 experimental subjects and 10 control subjects to be able to reject the null hypothesis that the population means of the experimental and control groups are equal with probability (power) 0.8. The Type I error probability associated with this test of this null hypothesis is 0.05. The effective size is 1.3929508.

3.5.4 Objective 4

Sample size calculation based on the objective 1 related to the of guide on the miniscrew implantation. In a previous study the response within each subject group was normally distributed with standard deviation 0.02 um(Talaat S,, et al.,2017). If the true difference in the experimental and control means is 0.54, the research will need to study 6 experimental subjects and 6 control subjects to be able to reject the null hypothesis that the population means of the experimental and control groups are equal with probability (power) 0.8. The Type I error probability associated with this test of this null hypothesis is 0.05.The effective size is 1.799001.

Thus, a total sample size for this study will be 24 (12 for experimental and control group) after considering 20% drop-out.

3.6 Randomization of the subjects

The simple randomization method involves randomly assigning subjects to different groups. This means that each subject has an equal chance of being placed in any of the groups. The randomization process is typically done using a random number generator or a randomization table. This method helps ensure that the assignment of subjects to groups is unbiased and eliminates any potential selection bias. Therefore, it allows for a fair comparison between the groups and enhances the internal validity of the study.

Randomization:

In this study, participants will be randomly assigned to either the Intervention group or the control group using a computerized random number generator.

We will use simple randomization. Assuming 24 participants, we randomly assigned them to two groups (trial and control) of 12 participants each. The steps are as follows: generate 24 random numbers using a random number generator. Sort these random numbers. The first 12 were assigned to the intervention group and the last 12 to the control group. Ensure that participants are assigned to the corresponding group in this order.

Matching:

To control for potential confounding variables, participants will be matched based on key characteristics such as age, gender, and baseline health status. The study involves comparing treatment outcomes in two groups, participants will be paired so that each pair consists of individuals with similar baseline characteristics.

Blinding:

The study will employ a particular-blind design to minimize bias. The participants and the researchers administering the interventions will be aware of the group assignments. And the researchers who interact with participants and collect data will be unaware of group assignments. This blinding helps to prevent expectations or biases from influencing the outcomes and ensures that the study results are more reliable.

3.7 Sample frame

3.7.1 Inclusion criteria

(1) The orthodontic clinical design should include the use of miniscrews for anchorage requirements in maxillary arch.

(2) Age of 18-35 years old

(3) Patients must have no prior history of orthodontic treatment and must have a healthy periodontal condition or no history of trauma before the current orthodontic treatment.

3.7.2 Exclusion criteria

- (1) Patient with poor oral hygiene, history of systemic diseases and metal allergies;
- (2) Patients with osteoporosis and inability to retain the TAD;
- (3) Patients who require orthognathic surgery for severe skeletal malocclusion;
- (4) Smoking patients which will affect the success rate of the implant placement
- (5) Patients with incomplete medical records.

3.7.3 withdrawal criteria

(1)Patient's miniscrew implantation positiondevelops an infection

(2)Patient who produces persistent pain or discomfort that cannot be managed

(3)Significant bone resorption around the miniscrew site

(4.)The miniscrew becomes loose or shifts position,

(5)Patient who is allergicto the material of the miniscrew

Reference population: Orthodontic patient Chinese ethnic group



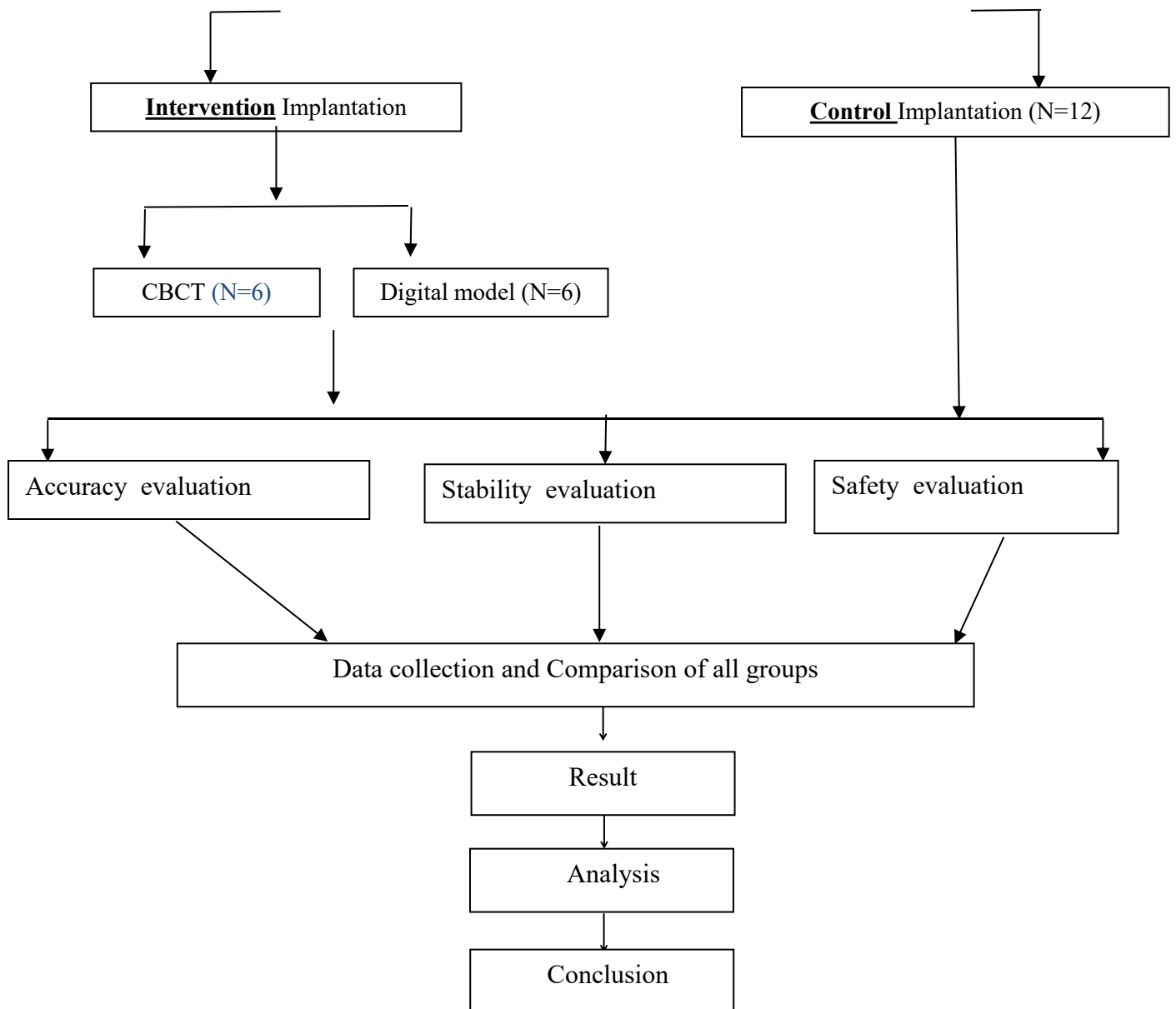
Source population: Orthodontic patient in Beijing TCM hospital



Inclusion criteria and exclusion criteria



Patients randomly divided into 2 groups with randomization



3.9 Variables and tools

3.9.1 Research tool

3.9.1.1 Routine orthodontics records before treatment

History and examination records

Digital model

CBCT

3.9.1.2 Routine orthodontics records after treatment

Digital model

Dental record models

CBCT

3.9.1.3 Special need to conduct the research

Ordinary gypsum (Hubei Jingmen Shishengtang Gypsum Industry .)

Dental alginate impression material (Beijing Hongye Dental Medical Equipment Factory)

Micro implant nail (Ningbo Cibe Medical Equipment)

Screwdriver (Ningbo Cibe Medical Equipment .)

Guide plate resin material (Beijing Xikema Medical Equipmen)

3D Metal Materials (Beijing Xikema Medical Equipment)

CBCT (5G, version FP; NewTom, Verona, Italy)

Software Segma Guide (Beijing Xikema Medical Equipment)

D700 scanner (3Shape, Denmark)

Itero scanner(invisalign,American)

3D printer (Beijing Xikema Medical Equipment)

3.9.2 Variables

3.9.2.1 Dependent variables

Clinical variables

-Looseness of mini-implant

-Shedding rate of mini-implant

-depth of exploration,

-gingival type

-gingival color and texture

-plaque index

-bleeding index

3.9.2.2 Variables for digital dental models acquisition

Distant of the root to the miniscrew tip

Distant between miniscrew tip to the maxillary sinus

3.9.2.3 Variables for CBCT acquisition

- the linear deviation of the tip and cap of the TADs in the mesio-distal, buccal-lingual, and vertical three-dimensional directions
- the angle deviation of the head and tail of the TADs in the mesio-distal, buccal-lingual, and vertical three-dimensional directions
- the distance between TADs and tooth root and maxillary sinus, and the distance between two tooth roots.
- The thickness of the inner and outer walls of the maxillary sinus
- the root resorption
- the thickness of the lingual bone of the TADs
- the thickness of the cancellous bone.

3.9.2.4 Independent variables

Gender

Age

3.10 Data collection and grouping

Twenty four (24) individuals who met the criteria will be randomly divided into 2 groups, 12 will be selected as the experimental group and mini-implants will be

implanted using guide plates, while others 12 participants will be selected as the control group and implanted mini-implants based on experience and no guide plates.

The recruitment will take about two months, using hospital bulletin boards and social media at Beijing Xuanwu TCM Hospital. All routine orthodontic diagnostic records will be collected. The patient was asked to sign an informed consent form before surgery, which took about 20 to 30 minutes. The doctor implanted the miniscrew, and the operation time was about half an hour. The study design will be used as assigning intervention and control group randomly. The postoperative clinical and imaging evaluation was about 6 months.

3.11 Stages of treatment

- 1) The patient undergoes routine pre-orthodontic examination, model analysis, cephalometric measurement, and develops an orthodontic treatment plan.
- 2) .The patient undergoes routine pre-orthodontic examination, model analysis, cephalometric measurement, and develops an orthodontic treatment plan.
- 3) The process of insertion of miniscrew will be depend on the group either **Intervention** Group or **Control** Group. The guide plate will be used for miniscrew insertion in **Intervention** Group and experience based on the patient's digital films for **Control** Group. The area of insertion of the miniscrew will be the upper alveolar ridge between premolars and molar tooth. The procedure will be performed under local injection anesthesia.
- 4) The process of implanting implant nails on **Intervention** Group is as follows: the material and model of the implanted micro implant nails are exactly the same as those of the traditional positioning set. The implant nail diameter is 2mm and the length is 10 mm. The implant surgery was performed by the same orthodontist in accordance with recommended operating procedures. Preoperative local anesthesia will be performed, and micro-implant nails will be implanted at the intended

implantation site under the guidance of the guide plate. The area of implantation is maxillary zygomatic alveolar ridge.

5) The process of implanting implant nails on the Control Group is as follows:

Similar to the intervention group, but the doctor implant the miniscrew based on experience with CBCT scans.

6) Collect data before and after implant nail implantation. The digital plaster models will be obtained by scanning with a D700 scanner (3shape, Denmark). Both digital models and CBCT scan data will be imported into Segma implant guide software (Beijing, China). The combination method is as follows: first, open the file in a way that only uses CBCT for implant design and adjust the density of anatomical landmarks such as the maxillary sinus, condylar foramen, or protrusions to an explicit level. Then, the teeth or jaw landmark points of the model and CBCT will be selected to reconstruct a 3D model.

4) The data collection will be performed by obtaining plaster model using intraoral scanner at T1(immediate post insertion) and T2 (6 months post insertion)

3.12 Design and fabrication of guide

The proposed structure will be made of three main components: a tooth guide part, a gingival guide part, and a steering part. The tooth guide and gingival guide parts are firmly connected by fracture lines. The mini-implant guide part is specifically designed to accommodate the angle and position required for miniscrew insertion. On the basis of the resin guide plate, add a guide hole structure and change it to a three-quarters circular shape.

During usage, the guide can be pre-designed in accordance with the desired planting

position and direction of the patient's mini-implant, enabling precise guidance during the implantation process. The designed guide's data is inputted into EnvisionTEC Vida 3D printer to create the mini-implant guide. Prior to the implantation of the mini-screw, patients will be informed about the potential risks and required to sign an informed consent form. The implantation procedure using the guide involved the insertion of a 2mm diameter and 13mm length mini-implant (Cibei, Ningbo, China) (Fig6) into the patient's maxillary zygomatic alveolar ridge. Upon completion of implantation, the guide will be removed.



Figure 3.12 A guide with a three-quarters circular hole

3.13 Analyses and measurements:

1. Main efficacy indicators.

A. CBCT analysis indicators: Based on the ideal position of the implant designed before surgery as the standard, the researcher will measure the linear deviation of the tip and cap of the TADs in the mesio-distal, buccal-lingual, and vertical three-dimensional directions, the angle deviation of the tip and cap of the TADs in the mesio-distal, buccal-lingual, and vertical three-dimensional directions, the distance between TADs and tooth root and maxillary sinus, and the distance between two tooth roots.

B. Clinical data analysis: The mobility of TADs. : The stability of a miniscrew can be evaluated through clinical examination by checking for mobility, and implant loosening and displacement.

2. Secondary efficacy indicators:

A. CBCT analysis indexes: The thickness of the inner and outer walls of the maxillary sinus, the root resorption, the thickness of the lingual bone of the TADs, the thickness of the cancellous bone, the position of the miniscrew, the surrounding bone density, and any signs of bone loss or inflammation around the screw.

B. Clinical data indicators: Implant diameter, length, gingival type, gingival color and texture, plaque index, depth of exploration, bleeding index, and symptoms.

Complications will be defined as obvious symptoms, swollen gums, mucous membranes, clinical mobility of TADs, root resorption, or obvious changes in normal anatomy around TADs, such as maxillary sinusitis.

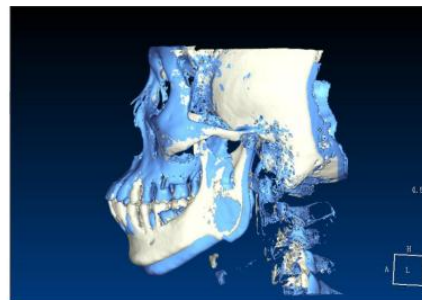
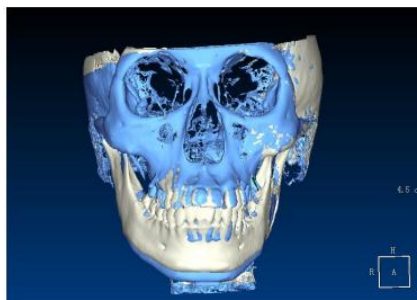


Figure 3.13 digital 3D model

3. Accuracy of miniscrews : **-the linear deviation of the tip and cap of the TADs in the mesio-distal, buccal-lingual, and vertical three-dimensional directions**

-the angle deviation of the head and tail of the TADs in the mesio-distal, buccal-lingual, and vertical three-dimensional directions

-the distance between TADs and tooth root and maxillary sinus, and the distance between two tooth roots.

-the thickness of cortical bone and cancellous bone

4. Stability of miniscrews : **-Looseness of mini-implant**

5. Safety of miniscrews : **Distant of the root to the miniscrew tip**

Distant between miniscrew tip to the maxillary sinus

-the distance between TADs and tooth root and maxillary sinus, and the distance between two tooth roots.

-the root resorption

3.14 Statistical analysis

Two doctors with more than 2 years of clinical CBCT image analysis experience performed image superimposition and measurement: everyone measured images once, with a 1-day interval, for a total of 3 measurements, and the average value was

taken. The linear deviation of the mini-implant tip and cap and the angular deviation of the long axis of the mini-implant in the bucco-palatal, mesio-distal and vertical directions were measured. The results were analysed by the SPSS statistical package version 19.0 (Chicago, USA). The Kruskal–Wallis H test of the multiple independent samples method was used to compare the three groups of mini-implant' deviation in the three directions. For the values that did not conform to a normal distribution, the Bonferroni method was used to correct the significance level for pairwise comparisons. One-way ANOVA was used for values that conformed to a normal distribution. P value less than 0.05 will be considered significant.

3.15 RISK

Compared to the traditional implantation method of implanting miniscrews in treatment, this experiment will produce 3D guide. Therefore, it is possible to increase the cost of planting nails

3.16 Sensitivity and interests of the community

Understand and respect the culture, values, and habits of the target community.

Ensure that the research design and implementation process respects these cultural characteristic

3. 17 Ethical review

3.18 Compensation

During the treatment process, complications may occur, such as infection at site of miniscrew insertion, miniscrew loose and dislodge, and also injury to the

tooth roots. If the above situation occurs, Department of Stomatology, Xuanwu Hospital of Traditional Chinese Medicine will bear all the treatment costs of the patient.

3.19 Possible benefit

This study will benefit individuals where the process of miniscrew implantation is likely to be safer if patients receive Intervention treatment during miniscrew implantation. Participants will have material fees waived as a reward.

Chapter 4

DUMMY TABLES

4.1 Annexure A

To compare the accuracy of TADs.

Name: _____ Ref. No. _____

The linear deviation of the TADs.

Miniscrew at BP		Miniscrew at MD		Miniscrew at VD	
Miniscrew	Miniscrew	Miniscrew	Miniscrew	Miniscrew	Miniscrew
Cap	Tip	Cap	Tip	Cap	Tip

BP, bucco-palatal direction; MD, mesio-distal direction; VD, vertical direction.

The angle deviation of the TADs.

Miniscrew at BP		Miniscrew at MD		Miniscrew at VD	
Right side	left side	right side	left side	right side	left side

4.2 Annexure B

To compare the safety of TADs.

Name: _____

Ref. No. _____

the distance between miniscrew and the tooth root

<u>Intervention / Control</u> groups		
Distance x axis	Distance Y axis	Distance Z axis

4.3 Annexure C

To compare the stability of TADs.

Name: _____

Ref. No. _____

Date: _____

Months	1	2	3	4	5	6	7
<u>Intervention group</u>							
<u>Control group</u>							

4.4 Gantt chart for research activities

Research Activities	2024		2025		2026	
	Jan – Jun	Jul – Dec	Jan- Jun	Jul- Dec	Jan- Jun	Jul- Dec
Ethical application and approval from USM						
Data collection						
Data analysis and interpretation						
Thesis write-up and submission						

4.5 Milestones and Dates

No.	Details	Estimated Date
1.	Ethical application and approval from USM	May 2024
2.	Data collection	January 2025
3.	Data analysis and interpretation	June 2025
4.	Thesis write-up and submission	January 2026

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5. APPENDICES