RESEARCH INFORMATION

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

Name of main and co-Researcher :

1.Su Li
2.Norma Binti Ab Rahman
3.Wang Jing

December 2024

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INTRODUCTION

You are invited to participate in a research project, the details as explained below. The information provided here is to help you to decide whether or not you would like to take part in the research.

The principal investigator in this project is Dr. Su Li who is a PhD student at the School of Dental Science, Universiti Sains Malaysia and Dr. Norma Ab. Rahman is a lecturer at the Orthodontics Unit, Universiti Sains Malaysia is her main supervisor.

Miniscrews are generally implanted between tooth roots, but the space between them is limited and there is a risk of injury to the roots, so the orthodontist often choose to insert miniscrews at the upper arch (maxillary) bone.

In this trial, 24 Orthodontics patients will be included who require to miniscrew as anchorage requirement at the Department of Stomatology, Xuanwu Hospital of Traditional Chinese Medicine. The patients will be divided randomly and equally into two groups, the Guide Group and the Conventional Control Group .Patients participating in this study will be given the same type of miniscrew.**The Guide Group will implant miniscrew in the guide of template and the Conventional Control Group will implant miniscrew by experience.**

The insertion of minisrew will be performed under local anesthesia (LA) and miniscrew will be implanted based on the guide template or experience based on the patient's digital films. Digital molds will be taken at 0, 6 months after the miniscrew insertion using oral scanning device.

PURPOSE OF THE STUDY

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

PARTICIPANTS CRITERIA

The research team members will discussed your eligibility to participate in this study. It is important that you are completely truthful with the staff including your health history.

This study will include individual who are:

(1) Require miniscrews for anchorage requirements in upper arch prior for braces treatment.
(2) Age of 18-35 years old
(3) Patients must have no prior history of braces treatment and must have a healthy periodontal condition or no history of trauma before.

STUDY PROCEDURES

1) The patient undergoes routine pre-orthodontic examination, model analysis, cephalometric measurement, and develops an orthodontic treatment plan.
2) The process of insertion of miniscrew will be depend on the group either Guide Group (GG) or Conventional Control Group (CG). The guide plate will be used for miniscrew insertion in GG and experience based on the patient's digital films for CG. The area of insertion of the miniscew will be the upper alveolar ridge between premolars and molar tooth. The procedure will be performed under local injection anesthesia.
3） The data collection will be performed by obtaining plaster model using intaoral scanner at T1(immediate post insertion) and T2 (6 months post insertion)

Expected duration of participation
6 months

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

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.

1. Research on compensation or treatment rights for related injuries

A.Medical compensation: If participants experience medical problems or injuries due to their participation in the study, the research institution typically provides necessary medical treatment or compensation. This typically includes treatment costs directly related to research, such as testing fees, medication fees, or other medical services.

B.Insurance arrangements: Many research projects provide insurance for participants to cover medical expenses incurred due to accidents or injuries during the research process. These insurances typically cover accidental injuries, illnesses, and other possible medical needs.

C.Medical tracking: During the research process, participants' health status is usually regularly monitored to ensure that any health-related issues related to the study are promptly addressed.

2. Compensation for disability or death caused by research related injuries

A.Disability compensation: If participants become disabled due to research related injuries, research institutions typically provide certain economic compensation or living support. This can include one-time compensation or long-term living allowances.

B.Death compensation: If a participant unfortunately passes away due to research related reasons, the research institution usually provides financial compensation to the participant's family or dependents. This compensation is aimed at reducing the economic burden caused by participating in the research.

C.Legal support: When dealing with injuries or deaths related to research, research institutions may provide legal support to assist participants and their families in handling relevant legal affairs and compensation claims.

REPORTING HEALTH EXPERIENCES.

Please contact, at any time, the following researcher if you experience any health problem either directly or indirectly related to this study.

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Department : School of Dental Science

(2）Dr. Norma Binti Ab Rahman

[MMC Registration No.3949]
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Email : drnorma@usm.my
Department : School of Dental Science

（3）Wang Jing
Phone No:+86 15901506308

Email : Kwwjjxa@163.com

Department : Department of Orthodontics ,School of Stomatological ,Beijing Stomatological Hospital Affiliated to Capital Medical University

PARTICIPATION IN THE STUDY

Your taking part in this study is entirely voluntary. You may refuse to take part in the study or you may stop your participation in the study at anytime, without any penalty or loss of benefits to which you are otherwise entitled. Your participation also may be stopped by the research team without your consent if in any form you have violated the study eligibility criteria. The research team member will discussed with you if the matter arises.**The investigator is serving as both investigator and the participant's service provider.Data measurements will be made by an experienced radiologist.**

POSSIBLE BENEFITS

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

Payment
Participants will not receive monetary compensation and will receive toothpaste as a reward.

Expense
Participants will receive free implantation of miniscrews, with surgical or material fees charged.

QUESTIONS

If you have any question about this study or your rights, please contact;

（1.）Su LI
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（3）Wang Jing
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I. C. No./Passport No.:E74204721

Email : Kwwjjxa@163.com

Department : Department of Orthodontics ,School of Stomatological ,Beijing Stomatological Hospital Affiliated to Capital Medical University

If you have any questions regarding the Ethical Approval or any issue / problem related to this study, please contact;

Mr. Mohd Bazlan Hafidz Mukrim
Secretary of Human Research Ethics Committee USM
Division of Research & Innovation (R&I)
USM Health Campus
Tel. No. : 09-767 2354 / 09-767 2362
Email : bazlan@usm.my

OR

Miss Nor Amira Khurshid Ahmed
Secretariat of Human Research Ethics Committee USM
Research Creativity & Management Office (RCMO)
USM Main Campus, Penang
Tel. No. : 04-6536537
Email : noramira@usm.my

CONFIDENTIALITY

Your information will be kept confidential by the researchers and will not be made publicly available unless disclosure is required by law._Participant's record such as digital mould data will be stored in the study model room at Department of Stomatology, Xuanwu Hospital of Traditional Chinese Medicine.

Data obtained from this study that does not identify you individually will be published for knowledge purposes.

Your original records may be reviewed by the researcher, the Ethical Review Board for this study, and regulatory authorities for the purpose of verifying the study procedures and/or data. Your information may be held and processed on a computer. Only research team members are authorized to access your information.

At the end of the study, the researchers will provide feedback on the results to each participant individually. Participants have the right to request access to the contents of their experimental records at any time. The participant has the right to refuse future storage and use of the collected information if the participant's data will be used in the future. Moreover, the experiment and the results will not be used for any commercial purposes or products, and the researchers and participants are not involved in any commercial interests.

By signing this consent form, you authorize the record review, information storage and data process described above.

Participant has right to refuse future storage and use of collected data. After the destruction of specimens and data, there will be records or reports confirming the completion of the destruction process. These records will be kept for 2 years for review and compliance checks.

For important findings related to the health of participants , we usually communicates directly with participants, providing detailed explanations and recommendations. This process may include face-to-face consultation, telephone communication, or written reports.

Fund

There is no fund support for this experiment.We are working hard to apply for funding for this project.

SIGNATURES

To be entered into the study, you or a legal representative must sign and data the signature page **[ATTACHMENT A or ATTACHMENT B (for genetic sample only) or ATTACHMENT C]**

Subject Information and Consent Form
(Signature Page)

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

Researcher's Name:

1.Su Li
2.Norma Binti Ab Rahman ***MDC 3949***
3.Wang Jing

To become a part this study, you or your legal representative must sign this page. By signing this page, I am confirming the following:

- I have read all of the information in this Patient Information and Consent Form **including any information regarding the risk in this study** and I have had time to think about it.
- All of my questions have been answered to my satisfaction.
- I voluntarily agree to be part of this research study, to follow the study procedures, and to provide necessary information to the doctor, nurses, or other staff members, as requested.
- I may freely choose to stop being a part of this study at anytime.
- I have received a copy of this Participant Information and Consent Form to keep for myself.

Participant Name

Participant I.C No

Signature of Participant or Legal Representative

Date (dd/MM/yy)

Name of Individual
Conducting Consent Discussion

Signature of Individual **Date**
(dd/MM/yy)
Conducting Consent Discussion

Name & Signature of Witness **Date**
(dd/MM/yy)

Note: i) All participants who are involved in this study will not be covered by insurance.

ATTACHMENT B

Subject Information and Consent Form
(Signature Page – Genetic Sample)

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

Researcher's Name: Su Li , Norma Binti Ab Rahman, Wang Jing

To become a part this study, you or your legal representative must sign this page. By signing this page, I am confirming the following:

- I have read all of the information in this Patient Information and Consent Form **including any information regarding the risk in this study** and I have had time to think about it.
- All of my questions have been answered to my satisfaction.
- I voluntarily agree to be part of this research study, to follow the study procedures, and to provide necessary information to the doctor, nurses, or other staff members, as requested.
- I may freely choose to stop being a part of this study at anytime.
- I have received a copy of this Participant Information and Consent Form to keep for myself.

_____

Participant Name

_____

Participant I.C No.

_____ _____

Signature of Participant or Legal Representative **Date** (dd/MM/yy)

_____

Name of Individual

conducting Consent Discussion

Signature of Individual **Date** (dd/MM/yy)
Conducting Consent Discussion

Name & Signature of Witness **Date** (dd/MM/yy)

Note: i) All participants who are involved in this study will not be covered by insurance.

ii) Excess samples from this research will not be used for other reasons and will be destroyed with the consent from the Human Research Ethics Committee, USM.

ATTACHMENTC

Participant's Material Publication Consent Form
Signature Page

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

Researcher's Name: ***Su Li , Norma Binti Ab Rahman, Wang Jing***

To become a part this study, you or your legal representative must sign this page.

By signing this page, I am confirming the following:

- I understood that my name will not appear on the materials published and there have been efforts to make sure that the privacy of my name is kept confidential although the confidentiality is not completely guaranteed due to unexpected circumstances.

- I have read the materials or general description of what the material contains and reviewed all photographs and figures in which I am included that could be published.

- I have been offered the opportunity to read the manuscript and to see all materials in which I am included, but have waived my right to do so.

- All the published materials will be shared among the medical practitioners, scientists and journalist world wide.

- The materials will also be used in local publications, book publications and accessed by many local and international doctors world wide.

- I hereby agree and allow the materials to be used in other publications required by other publishers with these conditions:

- The materials will not be used as advertisement purposes nor as packaging materials.

- The materials will not be used out of contex – i.e.: Sample pictures will not be used in an article which is unrelated subject to the picture.

Participant Name

Participant I.C No. **Participant's Signature** **Date** (dd/MM/yy)

Name and Signature of Individual **Date** (dd/MM/yy)
Conducting Consent Discussion

Note: i) All participants who are involved in this study will not be covered by insurance.