The Preliminary Application of Socket-shield Technique in Orthodontic Extraction and Fixed Orthodontic Treatment

NCT06510621

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Dear Patient,

We sincerely invite you to participate in a study titled, " The Preliminary Application of Socket-shield Technique in Orthodontic Extraction and Fixed Orthodontic Treatment." This study is conducted at the Guangzhou Medical University First Affiliated Hospital. The study protocol has been discussed and approved by an expert committee and has passed the review by the Ethics Committee of Guangzhou Medical University First Affiliated Hospital. This study will strictly adhere to the Declaration of Helsinki and relevant laws and regulations of China.

Before deciding whether to participate in this clinical trial, please read the following information carefully. It will help you understand the purpose of this study, its procedures and duration, as well as the potential benefits, risks, and discomforts of participation. You are encouraged to discuss this information with your relatives or friends, or consult with the study doctor, who will answer any questions you may have to assist in making an informed decision.

1. Background and Objective of the Study

In orthodontic treatment, tooth extraction is often necessary for cases involving crowding or protrusion. The process from extraction, alignment, leveling, to space closure may take six months to a year or longer. Following extraction, significant physiological alveolar bone resorption often occurs. This results in a decrease in alveolar bone height and a narrowing of the buccolingual width at the extraction site, leading to a buccal depression and difficulty in moving orthodontic teeth into the extraction area. Forced movement of teeth into such an area can lead to bone fracture, fenestration, and complications such as root resorption, periodontal and pulpal symptoms, or gingival recession.

In 2000, Hurzeler introduced the use of a healthy labial root fragment during immediate anterior tooth implantation to retain the periodontal ligament, avoiding labial bone plate resorption due to reduced blood supply. This approach, known as the socket-shield technique (SST), demonstrated that labial bone plates retained with the labial root fragment did not undergo bone remodeling or resorption. Haseeb et al. studied SST and a modified version (retaining the buccal root fragment without implant insertion), finding that both techniques effectively prevented buccal bone plate resorption after extraction, enhancing the long-term aesthetics of bridge restoration.

This study applies the shield technique in patients undergoing orthodontic extraction of premolars, with the root fragment removed at an appropriate time. Using cone-beam computerized tomography (CBCT), we will measure changes in alveolar bone height, width, and extraction space closure speed before and after extraction.

The objective is to explore the effect of the shield technique on premolar site preservation and clinical efficacy in orthodontic extraction treatment, providing a foundation for its application in clinical orthodontics.

2. Participation Process and Requirements

If you agree to participate in this study, each participant will be assigned a code, and a medical record file will be created. During the study, we will perform the shield technique on one side of the premolars, executed by a physician trained and skilled in this technique. CBCT imaging will be conducted before and after extraction (a total of four times within one year). Postoperative follow-up will monitor your wound healing and oral condition, with CBCT data used for study purposes. Once you choose to participate, we hope you will attend follow-up visits, examinations, and adhere to the study schedule.

3. Potential Benefits of the Study

If the extraction technique proves effective, it may slow alveolar bone resorption, preserve bone volume at the extraction site, facilitate smoother orthodontic treatment, and reduce risks of bone fracture or fenestration. However, these benefits cannot be guaranteed. We hope the information obtained from your participation will help guide future patients with similar conditions. We appreciate your involvement.

4. Potential Risks and Compensation

This study will not harm your physical, psychological, or social relationships, nor will it negatively impact your disease diagnosis or treatment. During the study, you may not experience any adverse reactions or may experience varying levels of adverse reactions. Regardless of the severity of any adverse events, please report them to your study physician with as many details as possible so that appropriate treatment or management can be provided. If any of the following adverse events occur, please contact your study physician immediately.

The shield technique is well established in implantology, demonstrating efficacy in preserving the labial bone plate. Its application in orthodontics is more limited; potential issues with the shield technique include the loosening of root fragments, increased bleeding during surgery, postoperative wound infection, bleeding, wound pain, or secondary loosening of root fragments. For those who agree to participate and undergo the shield technique, the study will cover the cost of the shield and extraction

procedures. Additionally, participants will receive free CBCT imaging at each scheduled follow-up and a payment of 200 RMB for each visit (including transportation and lost work expenses). Free medical services will be provided during each follow-up visit.

5. Privacy and Confidentiality

If you decide to participate in this study, your participation and personal data will remain confidential. Medical records will be kept at the hospital. When necessary, government agencies or members of the ethics review committee may review your personal data at the study site to ensure that the study complies with regulations. Any public reports of the study results will not disclose your identity. Every effort will be made to protect the privacy of your medical records within the limits of the law. You may access and, if necessary, modify your personal information at any time.

By signing this informed consent form, you agree that your personal and medical information may be used as described above. Your records will be stored in the archives of Tianjin Medical University Cancer Hospital and will only be accessible to the research team.

When the results of this study are published, your personal medical information will remain confidential.

6. Your Rights

Your participation in the trial is entirely voluntary, and you may withdraw from the trial at any time without reason. This will not affect your relationship with the medical staff or your future diagnosis and treatment. All your personal data and observation records will be kept confidential and used solely for this study. During the trial, you can access relevant information at any time. If you encounter any problems or need consultation, please contact the supervising physician.

7. Contact Information for the Ethics Committee

If you have questions related to participant rights or wish to provide comments and suggestions regarding this study, please contact the Ethics Committee of the Guangzhou Medical University First Affiliated Hospital at 020-83062938.

Informed Consent Signature Page

I have carefully read the above informed consent form and understand the purpose, potential benefits, and risks of the study. The investigator has explained the medical terms in plain language. I have had the opportunity to ask questions, and all of them have been answered in an understandable way. I am free to choose not to participate or to withdraw from the study at any time by notifying the responsible doctor, without affecting my medical treatment or rights.

I have received a copy of this informed consent form, and my doctor has provided a thorough explanation. I voluntarily consent to participate in this clinical trial. I agree that the relevant parties may verify my original medical records to cross-check the collected study data.

Participant's Signature (Print):
Participant's Phone:
Participant's ID Number:
Date: ____ Year ____ Month ____ Day

Legal Representative's Signature (Print):
Legal Representative's Phone:
Legal Representative's ID Number:
Date: ____ Year ____ Month ____ Day

(Note: If the participant cannot sign in person, a legal representative's signature is required.)

I confirm that I have explained the clinical trial details to the patient, including potential benefits and risks.

Investigator's Signature (Print):
Contact Phone:
Date: ____ Year ____ Month ____ Day