Comparison of Vertical Releasing Incisions and Horizontal Extending Incisions for Periodontal Accelerated Osteogenic Orthodontics in the Anterior Region: *A Randomized Controlled Trial with Surgical Time, Clinical and Radiographic Outcomes*

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Protocol and Statistical Analysis Plan

1. Background

In recent years, orthodontic treatment among adult patients has become increasingly prevalent in clinical practice, accompanied by a rise in orthodontic complications. Among these, labial bone plate resorption, gingival recession, and root exposure in the anterior region following orthodontic treatment are the most common complications and a frequent source of clinical disputes. In 2001, Wilcko et al. [1] introduced Periodontal Accelerated Osteogenic Orthodontics (PAOO). Initially developed to accelerate tooth movement during orthodontics [2], this technique has seen expanded indications and is now primarily utilized to increase alveolar bone volume and enhance labial bone thickness [3,4], thereby reducing the risk of post-orthodontic root exposure. The standard PAOO protocol involves: reflecting a flap, performing alveolar corticotomy, conducting particulate bone grafting, and subsequently closing the flap without excessive tension.[5] This technique combines corticotomy and bone grafting , not only accelerating orthodontic tooth movement but also augmenting periodontal hard tissue volume, expanding the range of labiolingual tooth displacement, and mitigating complications such as alveolar bone resorption, attachment loss, and root exposure.[6]

Due to inherent flap contraction and the increased volume from grafting materials, conventional PAOO requires periosteal releasing incisions at the flap base and additional vertical releasing incisions (VRIs) mesiodistally to reduce tension during flap repositioning.[6] Inadequate tension relief may lead to compromised healing, including interdental papilla necrosis, gingival recession, root exposure, or graft exposure with subsequent infection.[7] Beyond tension reduction, VRIs improve surgical access and simplify the procedure.However, in the esthetically sensitive anterior region, VRIs often result in visible scarring[8], frequently failing to meet patients' esthetic expectations. Consequently, some clinicians advocate avoiding VRIs in anterior periodontal surgeries.[8,9]

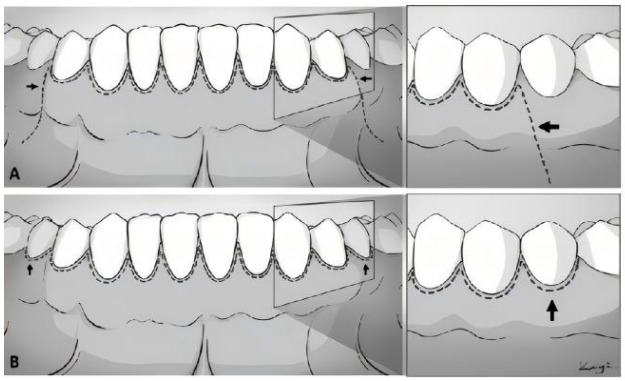


Figure 1. Schematic diagram of two different releasing incisions for periodontal accelerated osteogenesis orthodontics (PAOO) surgery: Vertical relaxation incisions (VRI) were made bilaterally on the distal side of the first premolar; Horizontal extension incisions (HEI) were added one more tooth on each side, extending to the distal of the second premolar.

Drawing from experience in traditional periodontal soft tissue grafting, we observed that adequate flap mobilization can be achieved without VRIs. Preliminary PAOO cases further demonstrated that horizontal extending incisions (HEIs) without VRIs provided sufficient space for graft placement and achieved favorable healing (Figures 1–2, spanning 1-2 teeth mesiodistally). Notably, during orthodontic movement, bone resorption predominantly occurs at the cervical region[10], where VRIs offer limited benefit as grafts tend to migrate apically[11].

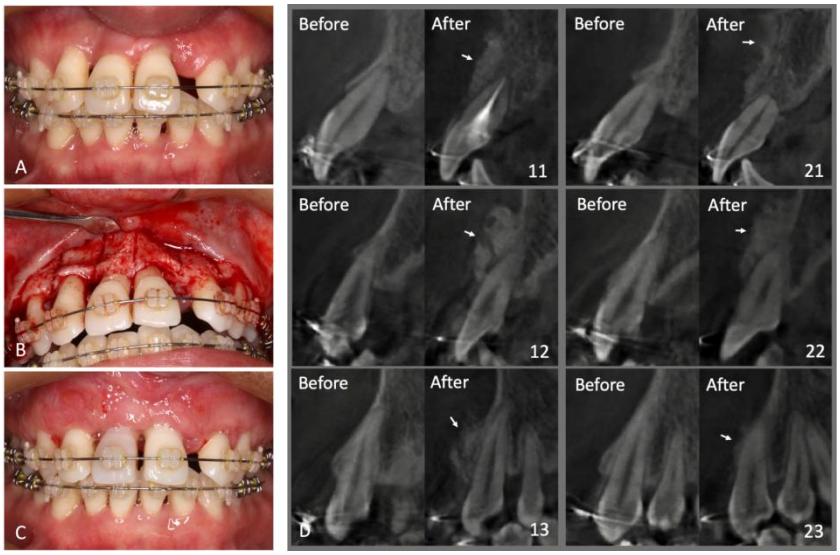


Figure 2. Preliminary Case: A: Intraoral photograph at baseline; B: Intraoperative view showing flap elevation with horizontally extended incisions (1–2 teeth mesiodistally); C: Excellent healing at 2 weeks postoperatively, with no wound dehiscence or graft exposure; D: CBCT comparison demonstrating significant labial bone augmentation post-treatment.

2. Aim

Currently, the comparative effects of VRIs versus HEIs on PAOO outcomes—including surgical efficiency, healing kinetics, adverse events, and bone augmentation efficacy—remain unclear, leaving the choice to individual operator preference. This randomized controlled trial evaluates both incision designs in anterior PAOO, comparing operative time, wound healing, complications, and bone gain to establish evidence-based surgical guidelines.

3. Study Design and Methods

This is a single-center, simply randomized, parallel-group clinical trial with 1:1 allocation ratio. The study will be conducted at the Department of Periodontology, Second Affiliated Hospital of Zhejiang University School of Medicine from ethics approval date 2022 through June 2024.

3.1 Inclusion Criteria:

(1) Patients aged 18-40 years without systemic diseases who are undergoing or planning orthodontic treatment

(2) Patients with thin alveolar bone and/or fenestration/dehiscence of labial bone plates in anterior teeth

(3) Patients whose anticipated orthodontic tooth movement will exceed the labial alveolar bone boundaries

3.2 Exclusion Criteria:

(1) Current smokers

(2) Pregnancy or lactation

(3) Untreated periodontitis

(4) Insufficient keratinized gingiva width (<2mm) or thin periodontal biotype (assessed by probing) [12]

(5) History of orthodontic and/or orthognathic treatment

(6) Systemic diseases contraindicating surgery (diabetes, hypertension, cardiac

diseases, malignancies, severe psychiatric disorders, etc.)

(7) Long-term use of immunosuppressants, bisphosphonates, or other relevant medications

(8) Poor compliance (unable to complete 1-year follow-up)

3.3 Withdrawal Criteria

(1) Development of exclusion criterion-related conditions requiring intervention

(2) Loss to follow-up during study period (excluding migration/death)

3.4 Ethical Considerations

This study will recruit orthodontic patients (either currently undergoing treatment or scheduled to begin treatment) from the Department of Orthodontics at the Second Affiliated Hospital of Zhejiang University School of Medicine. After being assessed by investigators and meeting the inclusion criteria, eligible participants will be referred to the Department of Periodontology where researchers will explain the clinical trial in detail and review the informed consent documents. All enrolled participants must provide written informed consent before participation. This study explicitly excludes vulnerable populations including individuals with mental disorders, critically ill patients, pregnant women, illiterate persons, minors (<18 years old), cognitively impaired individuals, students of principal investigators or research staff, subordinates of principal investigators or collaborating investigators, and employees of the research institution or study sponsor. The study protocol has been reviewed and approved by the Institutional Review Board/Ethics Committee of the Second Affiliated Hospital of Zhejiang University School of Medicine.

3.5 Preoperative Preparation:

Enrolled patients will complete cone beam computed tomography (CBCT) and routine tests (complete blood count, coagulation profile, and four infectious disease markers). Researchers will provide oral hygiene education and perform supragingival ultrasonic scaling before scheduling the surgery.

On the surgery day, Researcher J will conduct preoperative baseline measurements

including: probing depth (PD), clinical attachment level (CAL), keratinized gingival width (KGW), gingival recession depth (GRD), and gingival thickness. Preoperative CBCT measurements will include alveolar vertical height and alveolar ridge horizontal width (measured below the cemento-enamel junction at 2mm, 4mm and 6mm, recorded as BW2, BW4 and BW6 respectively). The bone graft material will be weighed with its container before surgery (recorded as W0+1) and the container will be weighed after surgery (W0). The net weight of graft material before surgery is recorded as W1 (W1=W0+1-W0). The remaining bone graft material will be collected after surgery, dried and weighed (recorded as W2). The actual amount of bone graft material used during surgery (Δ W) equals W1-W2. All measurements will be performed in duplicate and averaged. Prior to actual measurements, the researchers have passed consistency testing with Kappa value >0.4.

3.6 Surgical procedures:

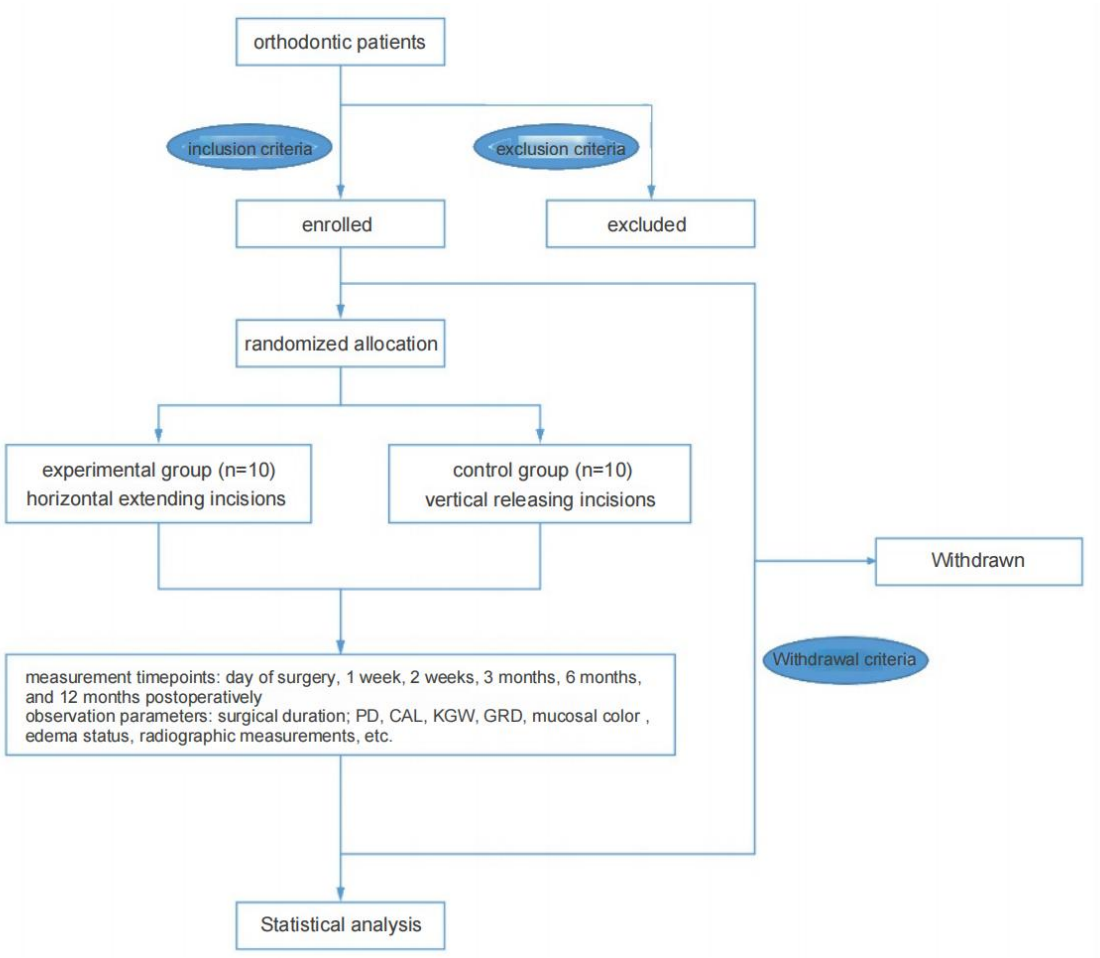
The surgical duration will be timed from initial gingival incision (post-anesthesia) to final suture placement, with measurements recorded by an external observer receiving signals from the circulating nurse.

A sulcular incision will be made on the labial aspect of anterior teeth. For the experimental group, horizontally extended incisions spanning 1-2 teeth will be added bilaterally to the sulcular incision, while the control group will receive vertical releasing incisions bilaterally. A full-thickness flap will be elevated extending 5mm beyond the root apex. Linear corticotomies parallel to the root axis will be created using piezoelectric surgery to access the medullary cavity. Geistlich Bio-Oss® (Switzerland) bone graft material will be placed on the alveolar bone surface and covered with a resorbable collagen membrane. A partial-thickness flap will be elevated at the apical region to achieve tension-free flap closure and suturing. Postoperative instructions will be provided by the researchers, along with follow-up appointment scheduling.

3.7 Postoperative Follow-up:

Weeks 1 and 2: Assess facial swelling, pain, mucosal color, edema, and membrane exposure. Sutures removed at 2 weeks.

Months 3, 6 and 12 (CBCT evaluations at 6 and 12 months): recording PD, CAL, KGW, GRD, scar formation, and alveolar dimensions.



3.8 Sample Size Calculation:

Based on the study by Zucchelli et al. [8], in the treatment of multiple-tooth gingival recession with coronally advanced flaps, the addition of vertical releasing incisions showed no significant effect on PD, CAL, GRD, or KTH changes at 12 months postoperatively. However, the group with vertical releasing incisions required significantly longer operative time (34.6 ± 3.9 min) compared to the group without (28.7 ± 2.2 min; $P < 0.01$). Using these data as reference, this study adopted an

independent samples t-test model with the following parameters: significance level (α) = 0.05 (two-tailed), power (1 - β) = 0.95, allocation ratio = 1:1. The required sample size was calculated using G*Power 3.1 software, yielding 9 patients per group. To account for a potential 20% dropout rate, the final sample size was adjusted to 11 patients per group (total N = 22).

3.9 Data Management and Confidentiality

A simple randomization method was employed: generated a list of 22 IDs (1-22) in Excel 2013, created a corresponding column of random numbers (0-1) and sorted IDs accordingly, first 11 IDs assigned to the test group (PAOO with horizontal extending incisions), remaining 11 IDs assigned to the control group (PAOO with vertical releasing incisions). Researcher A prepared sealed, opaque envelopes labeled with IDs 1-11, each containing a card specifying the assigned surgical approach. After sealing, Researcher A handed the envelopes to Researcher B and withdrew from further involvement. Researcher B enrolled participants based on inclusion criteria, assigned IDs sequentially by enrollment order, delivered sealed envelopes to the surgeon (W) intraoperatively, and conducted all postoperative measurements. All data underwent dual entry with third-party verification. Access required approval from the principal investigator. All identifiable records were kept confidential and disclosed only as legally permitted.

3.10 Statistical methods

Statistical analysis was performed using SPSS software (IBM Corp., Armonk, NY). Categorical variables were expressed as frequencies and percentages, with comparisons between groups using the Chi-square test or Fisher's exact test. Quantitative data including periodontal and radiographic measurements were expressed as mean, standard deviation (SD), median, and interquartile range (IQR). Intergroup comparisons utilized independent t-tests (normal distribution) or Mann-Whitney U tests (non-normal). The median differences and 95% confidence intervals (CIs) for the skewed data were estimated using the Hodges-Lehmann

method. Changes over time were evaluated using paired t-tests or Wilcoxon signed-rank tests. All tests were conducted with a two-tailed hypothesis, and statistical significance was set at set at $P < 0.05$. Measurement reliability was confirmed by intraclass correlation coefficient (ICC) from duplicate assessments (40 sites, 2-week interval) by a single examiner.

4. Informed Consent

This trial excluded vulnerable populations. Written informed consent was mandatory prior to study procedures, with details provided in the consent form. The consent process included: orthodontic patients at the study center were screened for PAOO eligibility by researchers; eligible candidates were referred to the Periodontology Department, where the study team explained the trial's risks/benefits in lay terms; after ensuring comprehension, participants voluntarily signed the consent form to proceed. Throughout the study (preoperative to follow-up), researchers addressed participant queries promptly.

5. Adverse Event Reporting

Participants in this study may face risks associated with periodontal surgery, with prevention, management and reporting procedures being identical to standard clinical protocols for periodontal surgical adverse events. Should any discomfort, new symptoms, or unexpected incidents occur during the study period - regardless of perceived relation to the research - the attending physician will evaluate and provide appropriate medical intervention. The following reporting protocols will be implemented for adverse events:

•All Adverse Events (AEs): Immediate management measures will be taken and properly documented in the case report forms.

•Serious Adverse Events (SAEs): In addition to immediate management and documentation in case report forms, the investigator will determine whether to discontinue or adjust treatment. SAEs must be immediately reported to:the Ethics Committee, Clinical Trial Institution, Study Sponsor and National and Provincial

Food and Drug Administration (within 24 hours). All SAEs must be additionally reported through the hospital's "Non-Punitive Internal Reporting System for Adverse Events and Near Misses".

References

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