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# Efficacy of periodontal soft tissue augmentation prior to orthodontic treatment on preventing gingival recession: study protocol for a randomised controlled trial

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## ABSTRACT

**Introduction** In adult patients with thin phenotype, gingival recession is obvious in the mandibular incisors after a large amount of lingual tooth movement. A systematic review indicated that soft tissue augmentation before orthodontic treatment might yield satisfactory results with respect to the progression of gingival recession. However, the studies included had a low-to-moderate level of evidence. This study was designed to investigate the efficacy of soft tissue augmentation prior to orthodontic treatment on the prevention of gingival recession.

**Method and analysis** This is a single-centre, single-blind, randomised controlled, double-armed parallel group comparison trial. This study was initiated in December 2021 and end in December 2025 (anticipated). Patients with mild crowding in the lower arch and a thin gingival type was enrolled and randomly assigned in a 1:1 ratio to either group A (having soft tissue augmentation prior to orthodontic treatment) or group B (having orthodontic treatment only). The planned number of enrolled patients was 48 (24 patients × 2 groups). The primary endpoint was the mean change in recession of the gingival margin. Secondary endpoints included the probing depth, gingival phenotype, frequency of complete root coverage, gingival thickness, width of the keratinised gingiva, clinical attachment level, gingival recession class, full-mouth plaque score, alveolar bone thickness in the faciolingual dimension of the lower anterior teeth and lower incisor inclination.

**Ethics and dissemination** The study protocol was approved by the Ethical Committee of the Shanghai Stomatological Hospital (certificate number (2021)016). The study was conducted in accordance with the Declaration of Helsinki, the Clinical Trials Act and other current legal regulations in China. Written informed consent was obtained from all the participants. The results of this study will be reported in journal publications.

**Trial registration number** ChiCTR2100050892.

## STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This was the first randomised controlled trial to evaluate the efficacy of soft tissue augmentation in preventing gingival recession prior to orthodontic treatment of patients with a thin gingival type in the lower incisors.
⇒ The timepoint of follow-up was arranged according to the time of orthodontic visit to avoid the loss to follow-up.
⇒ The test performer and participants cannot be blinded to the intervention; this represented a limitation.
⇒ The follow-up in the trial lasted for more than 36 months.
⇒ The major limitation was the generalisability since this study was conducted in China and only in Chinese patients.

## INTRODUCTION

Gingival recession is defined as apical dislocation of the gingival margin to the cementoenamel junction. This results in root exposure, which may lead to tooth hypersensitivity, increase susceptibility to root caries and cause aesthetic problems. Gingival recession occurs due to several factors, such as oral hygiene status, congenital phenotype, alveolar bone characteristics and orthodontic tooth movement. Patients who have a thin biotype have been suggested more susceptible to gingival recession.[1 2] Alveolar bone deficiency around the teeth is another factor that contributes to gingival recession.[3] Bone dehiscence and fenestration are more commonly found in patients with a thin alveolar bone plate. Therefore, a thin alveolar bone plate is suggested to be associated with alveolar bone resorption as well as subsequent gingival recession.[4] Another possible aetiological factor for gingival recession is orthodontic tooth movement. It was considered that the thickness of alveolar bone around the teeth with movement should be at least 1 mm,[5] which would ensure that teeth are moved orthodontically in

the supporting alveolar bone envelope. The study revealed that excessive incisor proclination moved the teeth out of the alveolar bone housing; these teeth may then develop partial alveolar bone dehiscence and experience subsequent gingival recession.[6] In particular, mandibular incisors are prone to exhibit recession. The main reason is that the alveolar plate around the mandibular incisors is thinner, and the thickness of keratinised gingiva is more inadequate than that of other areas.

Currently, an increasing number of patients require orthodontic treatment for lip protrusion. The treatment plan usually includes tooth extraction and lingual movement of the incisors to obtain a good profile. Most of these patients have narrow alveolar bone plates and thin phenotype in the lower anterior area. An obvious gingival recession was observed in this area when teeth had a large amount of lingual movement with the thin phenotype, especially in adults. Tipping movement is more likely to occur than bodily movement in the anterior teeth when they move lingually in the inadequate alveoli. The excessive inclination of the anterior teeth leads to bone dehiscence or fenestration on the labial side of their root and subsequent gingival recession. Compared with adolescents, adults have a lower rate of bone and gingival remodelling. For adult patients with thin phenotype, new bone and gingiva may not be formed on the labial side of the teeth in time following the lingual movement of the teeth.

Autogenous soft tissue grafts are considered the gold standard for the prevention or treatment of gingival recession.[7] The tunnel technique (TUN) allows flap elevation with no detachment of the papillary tissues and no vertical releasing incisions.[8] It was demonstrated that the TUN was equally successful to the coronally advanced flap (CAF) method in covering gingival recessions of Miller classes I and II with high aesthetic results.[9 10] Our clinical experience indicates that soft tissue augmentation in the mandibular anterior labial area prior to orthodontic treatment may be a viable alternative for patients with thin biotypes. Pertinently, a systematic review indicated that soft tissue augmentation before orthodontic treatment might yield satisfactory results with respect to the progression of gingival recession.[11] However, the studies included had a low-to-moderate level of evidence. Randomised controlled trials (RCTs) are needed to clarify the timing for soft tissue augmentation. Recently, an animal experiment was conducted to evaluate the efficacy of prophylactic gingival grafting on the prevention of gingival recession induced by orthodontic treatment. It was found that the autogenous connective tissue graft group showed enhanced gingival thickness compared with that of the controls.[12]

Therefore, the present RCT aimed to determine the preventive efficacy against gingival recession by soft tissue augmentation prior to orthodontic treatment. The results of the study could provide useful information on the indication and timing of soft tissue augmentation for orthodontic patients.

## METHODS AND ANALYSIS

### Study design and setting

This study aimed to determine the efficacy of periodontal soft tissue augmentation prior to orthodontic treatment on preventing gingival recession for patients with mild crowding in the lower arch and thin gingival type. This single-centre, single-blind, randomised controlled, double-armed parallel group comparison trial' was initiated in December 2021, following the approval by the Ethical Committee of the Shanghai Stomatological Hospital in August 2021 and the registration/publication at Chinese Registry of Clinical Trials (ChiCTR) (registration number: ChiCTR2100050892) in September 2021. This study was scheduled to end in December 2025 (anticipated). Candidates was recruited at the Department of Orthodontics, Shanghai Stomatological Hospital from December 2021 to June 2022 (anticipated). Notification of patient recruitment wwas published in the hospital and on its official websites. As shown in figure 1, patients was asked to participate in this study, and informed consent was obtained prior to the eligibility assessment. Then, the eligible patients was enrolled and randomised. The protocol version is V.4.0.

### Sample size calculation

Our hypothesis was that the intervention might decrease participants' height of the gingival margin (HGM). In the pilot study, the HGM score decreased by 0.48±0.33 mm in patients who had undergone orthodontic treatment. It was assumed that the mean HGM of the lower anterior teeth was 0.28 mm in the patients with soft tissue augmentation prior to orthodontic treatment. The sample size was calculated with an assumed power of 90% to detect a minimum clinically significant difference in the HGM of 0.2 mm (using α=0.05). The sample size calculation was based on a two-sided hypothesis. In consideration of a potential dropout rate of approximately 20%, a total sample size of 48 patients was required in this study. The sample size was calculated according to the following formula:

$$n_A = Kn_B \text{ and } n_B = \left(1 + \frac{1}{K}\right)\left(\sigma \frac{z_{1-\alpha/2} + z_{1-\beta}}{\mu_{A-\mu B}}\right)^2.$$

### Consent

Informed consent documents was provided to the candidates. Written consent was obtained from the candidates and/or their guardians after they receive a full explanation of this study. After obtaining informed consent, the candidates was assessed for eligibility and then be enrolled in this study.

### Eligibility criteria

Patients with mild crowding in the lower arch and a thin gingival type was included in this study. Mild crowding is defined as the difference of 0–4 mm between the required space and the available space. The thin gingival type is defined as a gingiva through which the outline of the underlying probe is visible. The detailed inclusion

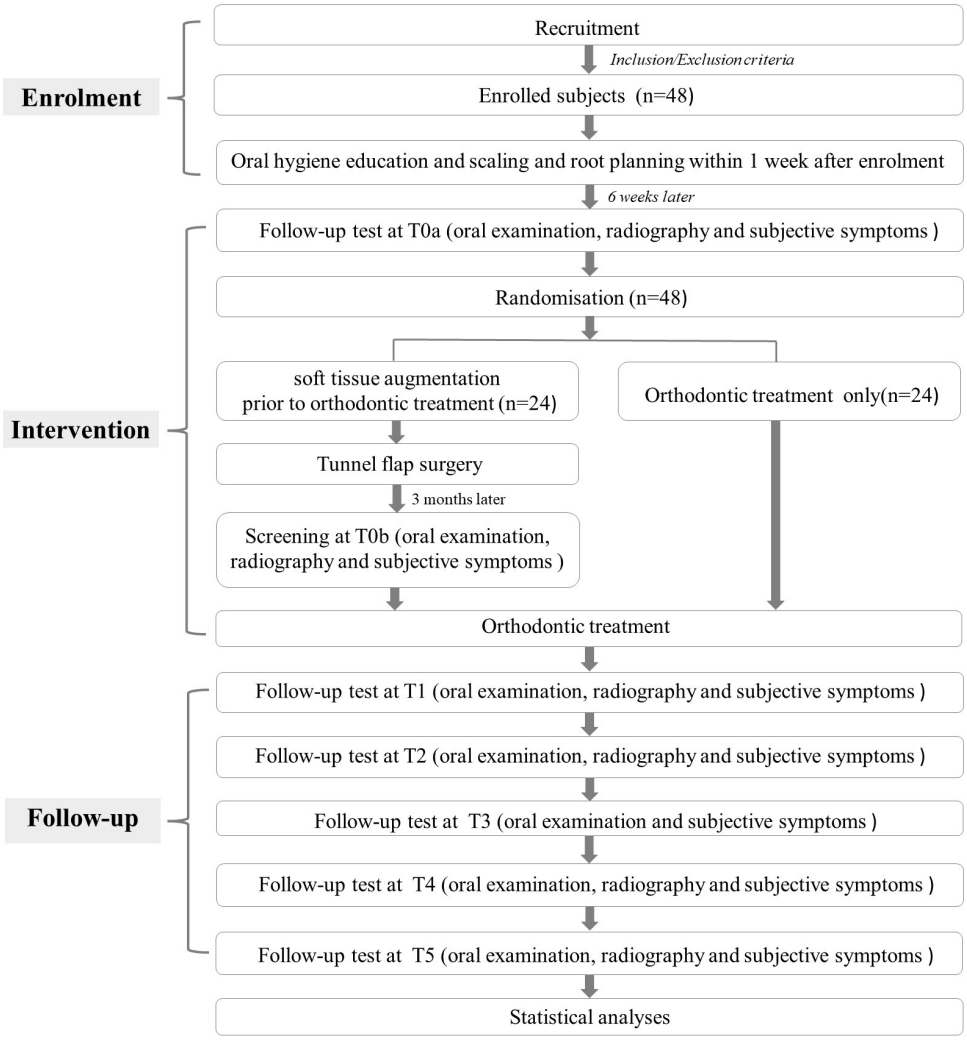


**Figure 1** Flow chart of study design.

criteria were as follows: (1) 22–35 years old, (2) mild crowding in the lower arch, (3) Spee curve within 2 mm, (4) orthodontic patients with two mandibular premolars extracted, (5) thin gingival type and (6) patients who agree to enter this trial and sign the informed consent form. The exclusion criteria were as follows: (1) a history of orthodontic treatment; (2) RT2 or 3 gingival recession in the lower anterior teeth; (3) a width of the attached gingiva less than 2 mm; (4) a history of periodontal surgery in the lower anterior teeth; (5) aggressive tooth brusher and high frenal attachment; (6) usage of drugs that may affect gingival conditions (eg, hyperplasia) and periodontal tissue; (7) pregnancy and nursing women, or women who planned to be pregnant during orthodontic treatment; (8) the presence of systemic diseases (such as hyperthyroidism, diabetes, primary and secondary immunodeficiency diseases, serious infectious diseases, etc) or long-term medical history that may affect the treatment outcome and (9) a history of smoking.

## Random allocation

After obtaining consent, eligible patients was randomly assigned to group A or group B. The allocation sequence was generated by computer software (SAS 9.4). Wei Zhang had generated the allocation sequence. To reduce the predictability of the random sequence, details of any planned restriction were provided in a separate document that is unavailable to those who enrolled the participants and assigned the interventions. To conceal assignment, opaque, sealed envelopes were made that will contain ID numbers and groups of patients to be randomised. These envelopes were assigned to Yichen Xu and opened immediately before intervention. Yichen Xu did not attend the enrolment of the participants, assignment of the interventions or assessment of the outcome. Jing Chen enrolled participants, and Qiang Li assigned participants to interventions.

## Blinding

The random number sequence was retained by the group divider and the study leader. The group divider grouped the participants according to the sequence. The outcome indicators were assessed using a single-blind method. The data collectors and outcome evaluators did not know the group information during the whole research process.

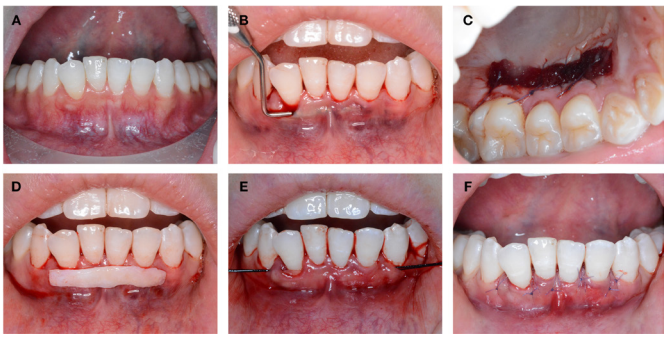


**Figure 2** The procedure of soft tissue augmentation by tunnel flap surgery. (A) Preoperative photos, (B) preparation of the recipient area, (C) preparation of subepithelial connective tissue flap, (D) the amount of connective tissue required in the recipient area, (E) the connective tissue flap was placed in the envelope and (F) suture.

### Study intervention and observation

Full-mouth scaling and root planing was performed 6 weeks before soft tissue augmentation for the group A and 6 weeks before orthodontics treatment for the group B, respectively. Patients assigned to group A received soft tissue augmentation by the same periodontist (JL), who is a periodontist with more than 5 years of working experience. Then, patients in group A underwent subsequent orthodontic treatment 3 months after surgery. The periodontal health was examined at the time of surgery following the latest classification of periodontal diseases and conditions. Briefly, the procedure of tunnel flap surgery was performed according to Zuhr *et al*[13] (figure 2). The autogenous connective tissue graft was harvested from the palate. It was trimmed to an adequate size with a thickness of 1.0–1.5 mm and a width of 5.0–6.0 mm. Afterwards, the flap was inserted into the TUN and only cover the lower incisor sites. The flap was laterally extended to the adjacent papillae and extend beyond the mucogingival junction until it could be moved coronally. Suspension suture of gingival papilla was applied. After the operation, the participants were instructed to take analgesics and use antimicrobial rinses for plaque control. Sutures were removed 14 days later, and follow-up was conducted 3 months after surgery. Then, the patients received subsequent orthodontic treatment 3 months after soft tissue augmentation. Two mandibular premolars (one on each side) were extracted during orthodontic treatment. The appliance was self-ligating metal brackets (Damon Q, Ormco, USA). Patients assigned to group B only received orthodontic treatments without tunnel flap surgery. They received orthodontic treatment as the above. The orthodontic treatment was performed by three orthodontics with more than 3 years experience. During the treatment, they provided some charts of oral hygiene instructions and sent reminders to the patients to ensure their compliance.

Table 1 shows the schedule of assessments performed at each observation point. Inspections of patients' characteristics (age, sex, height, weight and oral hygiene habits), periodontal condition (HGM, probing depth, phenotype, gingival thickness, width of keratinised gingiva, clinical attachment level, gingival recession class and full-mouth plaque score (FMPS)), alveolar bone thickness on the faciolingual dimension of the lower anterior teeth, lower incisor inclination and subjective symptoms were conducted by general inspection and interview. Endpoint measurements were performed before the treatment (baseline survey; T0a), 3 months after tunnel flap surgery (T0b), when teeth alignment is completed (T1), when the extraction space is closed (T2), 3 months (T3), 12 months (T4) and 36 months (T5) after the extraction space is closed. During the observation period, the patients did not be allowed to use any agents that affected gingival conditions (eg, hyperplasia), such as phenytoin. They did also not be allowed to have other types of periodontal surgery or participate in other clinical trials that involve periodontal treatment. The periodontal examination was made by two periodontists with more than 5 years of working experience. They had passed the conformance test, and the Kappa value is 0.89. Two doctors performed the examination of the same patient at the timepoint independently, and the average value of the measurements was calculated as the result.

### Outcomes

The experimental teeth lower anterior teeth (31, 32, 41 and 42).

#### Primary endpoint

The primary endpoint of the trial was the mean change in HGM in millimetre from baseline (T0a) to the primary timepoint (T2). The HGM is defined as the distance between the gingival margin and incisal edge at the mid-buccal aspect of the experimental tooth. Digital scans were taken at different time points, and the gingival recession changes were measured with stereolithography (STL) superimpositions.

#### Secondary endpoints

Probing depth (in mm), the distance from the gingival margin to the bottom of the sulcus at mid-buccal aspect of the experiment tooth.

a. Gingival phenotype, measured using coloured tip periodontal probe by the probe transparency method.
b. Gingival thickness (in mm), digital scans were taken at different time points, and the gingival thickness changes were assessed with STL superimpositions.
c. Width of keratinised gingiva (in mm), the distance from the most apical point of the gingival margin to the mucogingival junction at the mid-buccal aspect.
d. Clinical attachment level (in mm), measured at mid-buccal aspect from the enamel-cemental junction (CEJ) to the bottom of the sulcus.
e. Gingival recession class, according to the classification of Cairo (RT1, 2 nd 3).[14]
f. Frequency of complete root coverage (in %).[15]

Table 1 The schedule of enrolment, interventions and assessments

| | Study period | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Enrolment | Allocation | | Postallocation | | | | Close-out |
| Timepoint | $-T_1$ | $T_{0a}$ | $T_{0b}$ | $T_1$ | $T_2$ | $T_3$ | $T_4$ | $T_5$ |
| Enrolment: | | | | | | | | |
| Eligibility screen | | √ | | | | | | |
| Informed consent | | √ | | | | | | |
| Allocation | | √ | | | | | | |
| Interventions: | | | | | | | | |
| Tunnel technique | | √/× | | | | | | |
| Orthodontics | | | √ | √ | √ | √ | √ | √ |
| Assessments: | | | | | | | | |
| Patients' characteristics | | √ | | | | | | |
| Height of the gingival margin | | √ | √ | √ | √ | √ | √ | √ |
| Probing depth | | √ | √ | √ | √ | √ | √ | √ |
| Gingival phenotype | | √ | √ | √ | √ | √ | √ | √ |
| Gingival thickness | | √ | | √ | √ | | √ | √ |
| Clinical attachment level | | √ | √ | √ | √ | √ | √ | √ |
| Width of keratinised gingiva | | √ | √ | √ | √ | √ | √ | √ |
| Gingival recession class | | √ | √ | √ | √ | √ | √ | √ |
| Frequency of complete root coverage | | √ | √ | √ | √ | √ | √ | √ |
| Full-mouth plaque score | | √ | √ | √ | √ | √ | √ | √ |
| Alveolar bone thickness | | √ | | √ | √ | | √ | √ |
| Lower incisor inclination | | √ | | √ | √ | | √ | √ |
| Subjective symptoms | | √ | √ | √ | √ | √ | √ | √ |

g. Oral hygiene status measured using the FMPS.[16]
h. Alveolar bone thickness on the faciolingual dimension of the teeth (in mm), measured according to the study.[17] Radiographs were generated from cone beam computed tomography (CBCT) and then carried out directly on sagittal sections by the software Dolphin Imaging. According to the study,[17] a line was defined to pass by the middle of the root canal and extend from the middle of the incisal edge to the apical root. This line determineed the long axis of each lower incisors, as a reference plane. Three points were marked on the reference plane in the cervical (2 mm from the CEJ), middle and apical parts of the root. Then three perpendiculars were drawn from the three points on the reference plane, respectively. The length of the perpendiculars represented the thickness of alveolar bone at these levels.
i. Lower incisor inclination, the angular indicator to assess the protrusion of the teeth. Lateral cephalometric radiographs obtained from CBCT were traced through the Dolphin Imaging software. The incisor mandibular plane angle is the angle between the long axis of lower incisor and the mandibular plane.

### Subjective symptoms

Subjective symptoms, including gingival aesthetics, gingival sensitivity, pain and swelling, were assessed according to the Visual Analogue Scale. The patient-reported outcome measures were used to measure the health status and functional status of the patients.

## Data collection, data management and monitoring

A case report form was used for data collection. The participants were identified by central registration numbers for anonymisation. Data collection and management was carried out by the data collectors and outcome evaluators who did not know the group information to avoid bias. The electronic data collection tool was EpiData. The monitoring team confirmed every 3 months whether the trial was following the protocol and the provisions of good clinical practice. The datasets used and/or analysed during the current study were available from the corresponding author on reasonable request. The publication of the trail data will be completed by a person appointed by the principal investigators.

## Safety evaluation

During the study, the investigators constantly monitored patients for any adverse events (AEs) through regular

medical checkups. All related AEs, not only side effects of TUN surgery or orthodontic treatment but also any untoward medical occurrences, were reported and recorded. The side effects of TUN surgery included temporary or permanent numbness, injury to the temporomandibular joint, associated muscle paralysis, postoperative bleeding and flap necrosis. Root resorption and severe gingival regression was considered side effects of orthodontic treatment. The observation time for AE reports was from T0 to T5. The researcher would take corresponding measures if necessary. AEs was followed up until recovery to a normal level or a non-AE level was reached.

### Statistical analysis

All statistical analyses were based on the intention to treat principle and performed with SAS software (V.9.4 or above), and tests were performed at the 0.05 significance level unless otherwise noted. Continuous data was presented as the mean ± SD, while categorical data was presented as numbers (percentages). For the primary endpoint and all continuous secondary endpoints, the difference between the two groups was compared by a mixed-effect model including baseline level as a covariate. The statistical test on categorical secondary endpoints the $\chi^2$ test, Fisher exact test or Cochran-Mantel-Haenszel test.

### Patient and public involvement

Written informed consent were obtained from all the participants after they received a comprehensive explanation of this study

### Ethics and dissemination

This study and its protocol were approved by the Ethical Committee of the Shanghai Stomatological Hospital (certificate number (2021)016). The study was conducted in accordance with the Declaration of Helsinki, the Clinical Trials Act and other current legal regulations in China. Written informed consent were obtained from all the participants after they received a comprehensive explanation of this study. Data from the present research was registered with the International Clinical Trials Registry Platform. Additionally, the results will be disseminated at medical conferences and through journal publications.

## DISCUSSION

Adult patients who have convex profiles usually require lip retrusion. These patients need to undergo tooth extraction and lingual movement of incisors. Most of these patients generate insufficient alveolar bone plates and thin phenotype in the mandibular anterior area. For these patients, gingival recession was obvious in the mandibular incisors after a large amount of lingual tooth movement occurred. At present, soft tissue augmentation is commonly applied after gingival recession to increase the thickness and height of the gingiva. However, this approach is often less effective, especially in the lower anterior areas. The reasons for the noted lack of effectiveness may be that the alveolar bone in the mandibular incisor area is too thin to support the grafted gingival flap and that the gingival here is too thin to provide sufficient nutrition for the transplanted gingival flap. Prophylactic soft tissue augmentation prior to orthodontic tooth movement seems to be an alternative. The original narrow alveolar bone plate and gingiva may provide some support for the growth of the gingival flap if transplantation is performed before orthodontic treatment. Thick transplanted gingival tissue, which contains extracellular matrix and a larger amount of collagen fibres, can enhance the resistance of collapse and contraction. The present study was designed as an RCT to determine whether gingival grafting prior to orthodontic treatment can prevent gingival recession induced by tooth movement.

This study protocol still had several challenges and limitations. The first was the challenge of patients' compliance. The development of gingival recession was a lengthy process, and the study included a long observation time. The last endpoint measurements in the present study would be performed 36 months after the extraction space was closed (T5). Additional services, including periodontal examination and maintenance, were provided for patients quarterly to enhance their adherence to the process. The time point of follow-up was arranged according to the time of orthodontic visit, and the clinical research coordinator reminded the patients of the scheduled assessment. The second challenge was that the follow-up period from the beginning to the time when the extraction space was closed (the primary endpoint) might be insufficient to induce gingival recession. One of the reasons was that gingival recession occured slowly after orthodontic treatment was completed. Obvious gingival recession induced by tooth movement might not be found when the mandibular extraction space was closed. Thus, a longer follow-up period was needed to observe the changes in the gingiva. The other reason was that the gingiva might be swollen when the treatment was completed due to poor oral hygiene during orthodontic therapy. Regular periodontal examination and maintenance was provided for the participants to reduce the possibility of gingival swelling. The third limitation was the consistency of orthodontic treatment. The standard operating procedure for tooth movement was sent to orthodontic doctors before the study began. All orthodontic doctors received specific training to ensure consistency.

The results of this study could provide valuable evidence for the indication and timing of soft tissue augmentation for orthodontic patients. It could contribute to the prevention of gingival recession of the labial gingiva in the lower incisors after orthodontic treatment for patients with thin biotypes.

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**Contributors** QL conceived the study and led the proposal and protocol development. JC contributed to study design and to development of the proposal. JL, FZ, WZ, YW, YX and YP provided intellectual input to improve the study design and revise the protocol. WZ supervised the conception and design of this study. QL, JC and WZ drafted the protocol. All the authors read and approved the final manuscript.

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**Competing interests** None declared.

**Patient and public involvement** Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

**Patient consent for publication** Not applicable.

**Provenance and peer review** Not commissioned; externally peer reviewed.

**Data availability statement** Deidentified participant data will be available from the corresponding author on reasonable request. The email address of the corresponding author is lqq401@sina.com. Please provide a detailed protocol for the proposed study, and to supply information about the funding and resources of the study. Reuse will be permitted if all the materials are reasonable. Both the protocols and statistical analysis plans will be available.



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