Trials

STUDY PROTOCOL

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Evaluation of maxillary miniscrew-anchored molar distalization appliance versus clear aligners in adult with Class II malocclusion: study protocol for a randomized controlled trial

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Abstract

Background Angle Class II malocclusion typically presents with overbite, distal molar relationship, and crowding of the upper anterior teeth. The distal movement of the maxillary molars is considered an optimal treatment strategy, as it can circumvent the need for orthodontic extraction. Clear aligners are currently used for molar distalization. However, this approach is not without its limitations, including the loss of anterior tooth anchorage and an extended treatment duration. To address these issues, this study introduces a novel molar distalization appliance. A clinical randomized controlled trial will compare the efficacy of this appliance with clear aligners, specifically assessing differences in the rate of tooth movement.

Methods This study will recruit 30 patients aged 18–35 with Angle Class II malocclusion, characterized by distal molar relationship, mild to moderate crowding, or protrusion of anterior teeth. Patients will be randomly divided into two groups: the experimental group using a novel molar distalization appliance, and the control group using clear aligners for molar distalization. Both groups will use orthodontic miniscrews as an anchorage, with elastic traction for molar distalization. Cone-beam CT and digital dental models will be collected before orthodontic intervention and after molar distalization for all samples. This study will register pre- and post-treatment images using maxillary bone structures and then analyze three-dimensional tooth movement. The study will further calculate the distance of molar distal movement per unit time as the tooth movement rate and compare whether there is a difference between the experimental and control groups.

Discussion This randomized controlled trial will serve as evidence that the novel molar distalization device, compared to clear aligners, whether offers advantages such as shorter treatment duration and superior control of tooth movement. It can provide a novel method for orthodontic clinical treatment of patients with Angle Class II malocclusion.

Trial registration ClinicalTrials.gov ChiCTR2300069122. Registered on 7 March 2023.

Keywords Angle Class II malocclusion, Molar distalization, Mini-screws anchorage, Clear aligners

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Administrative information

Note: the numbers in curly brackets in this protocol refer to SPIRIT checklist item numbers. The order of the items has been modified to group similar items (see http://www.equator-network.org/reporting-guidelines/spirit-2013-statement-defining-standard-protocol-items-for-clinical-trials/).

Title {1}	Evaluation of miniscrew-anchored molar distalization appliance versus clear aligners in adult with Class II malocclusion: study protocol for a randomized controlled trial
Trial registration {2a and 2b}.	Registry name: Therapeutic effect of a new patent appliance combined with micro-implant anchorage on the overall distalization of molars Trial identifier: ChiCTR2300069122
Protocol version {3}	Version 1.1 Issue date: 1 May 2024
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Name and contact information for the trial sponsor {5b}	Shanghai Stomatological Hospital. Address: No.356 Beijing East Road, Shanghai, China
Role of sponsor {5c}	This funding source had no role in the design of this study and will not have any role during its execution, analyses, interpretation of the data, or decision to submit results.

Introduction

Background and rationale {6a}

Maxillary molar distalization has become an effective method for treating mild to moderate crowding or protrusion of the upper teeth in Angle Class II patients [1, 2]. The headgear, an extraoral appliance, is an effective device for molar distalization, but it requires high patient compliance, so its practicality is not good [3]. Another type of intraoral devices, such as the pendulum appliances and distal jet appliances, can also achieve molar distalization, but they are prone to cause distal tipping of the maxillary molars [4], and may also lead to problems such as anchorage loss of the anterior teeth [5].

In recent years, the distalization of maxillary molars with clear aligners (CAs) has been proven to be a reliable clinical technique and is recommended by guidelines [6]. Current research shows that CAs can achieve bodily distal movement of the maxillary molars, with no significant distal tipping or vertical movements [7, 8]. The latest study shows that compared to fixed appliances, CAs seemed to have better control of distal tipping of molars in patients treated with miniscrew-assisted molar distalization [9].

The limitation of distalizing maxillary molars with CAs is the low rate of tooth movement. The conventional treatment plan for molar distalization with CAs is sequential movement, that is, first moving the maxillary second molar, and when it has moved 50%, the maxillary first molar is moved, followed by the maxillary premolars. This plan can protect the anterior anchorage, but the efficiency of tooth movement is low. Literature shows that the time required for distalizing maxillary molars with CAs can be as long as 40–50 weeks [10]. To shorten the treatment time, some scholars have proposed using methods such as corticotomy [11] or photobiomodulators [10] to accelerate tooth movement, but these methods have not yet been widely used.

Another limitation of clear aligners is the potential loss of anterior anchorage [12]. Research shows that during the process of distalizing maxillary molars with CAs, the distance of molar distalization is directly proportional to the loss of anterior anchorage [13]. Finite element studies show that the use of orthodontic miniscrews can reduce the loss of anterior anchorage during molar distalization with CAs [14]. However, theoretically, it is impossible to completely avoid the loss of anterior anchorage [15].

This study proposes a miniscrew-anchored molar distalization appliance (MAMD) (Fig. 1). The main advantage of this device is that it can simultaneously move all the teeth from the maxillary canines to the second molars, theoretically having a higher efficiency of tooth movement. The device includes cast bands on the bilateral canines and first molars, with a stainless-steel rod welded to the molar and canine bands on one side. A traction hook is designed at the canine for orthodontic elastics to achieve distal movement of the maxillary molars. If the canines' position is unfavorable, consider placing the bands on the first premolars. At the same time, this device uses a Nance button to connect the bilateral maxillary first molars, making the bilateral posterior dental arch a whole. This can maintain the width and height stability of the molars and reduce the distal tipping and rotation that occur when the tooth is subjected to force alone. Therefore, it has an advantage in controlling tooth movement.

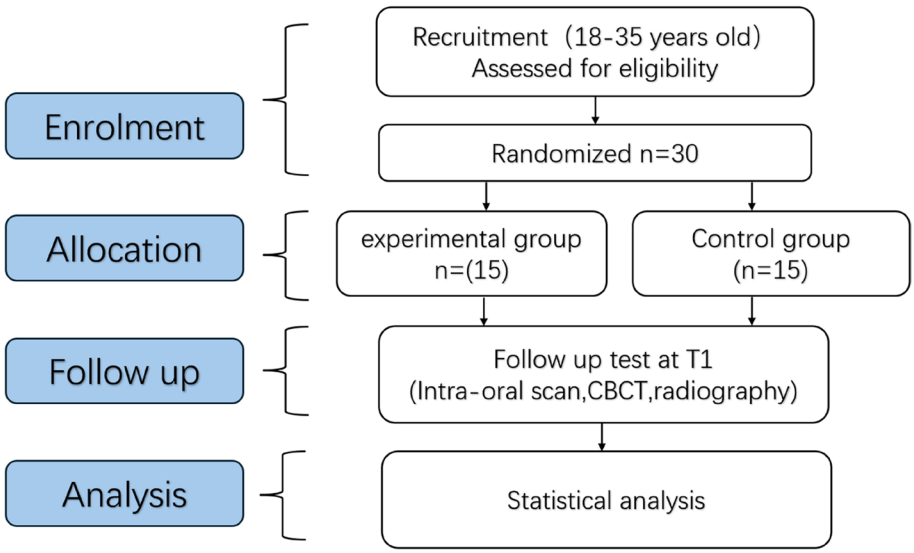

Fig. 1 Flow chart of the trial design

Current methods for measuring tooth movement include cephalometric analysis [9], Cone-beam computed tomography(CBCT) [16], and digital dental models [17], each with its own limitations. Cephalometric analysis offers valuable insights into dental structures, yet it is limited to providing two-dimensional perspectives, unable to assess horizontal tooth movement or rotation. Conversely, Cone Beam Computed Tomography (CBCT) imaging allows for the observation of both crown and root movement. However, during CBCT imaging, the dental arches are typically in occlusion, posing challenges in locating crown landmarks accurately. In recent years, digital dental models have garnered significant attention from scholars due to their radiation-free nature and high image precision. While literature demonstrates the efficacy of digital dental models in three-dimensional tooth movement measurement with commendable accuracy, they often lack root information. To address this gap, our study integrates CBCT imaging with digital dental models to enable comprehensive three-dimensional tooth movement measurement, facilitating simultaneous assessment of crown and root positions.

Objectives {7}

The objective of this study is to utilize CBCT and digital dental models to assess and contrast the rate of tooth movement between the miniscrew-anchored molar distalization appliance (MAMD) and clear aligners (CAs) via the registration of the maxillary bone structure. Additionally, our aim is to investigate potential differences in molar movement control and anterior anchorage loss between the two appliances.

Trial design {8}

This study is a single-center, superiority randomized controlled trial (Fig. 1), designed to evaluate whether the miniscrew-anchored molar distalization appliance (MAMD) is superior to clear aligners (CAs) in terms of tooth movement efficiency and control. The trial follows the CONSORT guidelines. Participants will be recruited from the Shanghai Stomatological Hospital. Clinical research coordinators will undergo comprehensive training on the design, methods, clinical interventions, and retention of trial documents for this study. Subsequently, they will elucidate the study's purpose and arrangements to the patients. The subjects enrolled in the study will be randomly allocated into the experimental and control groups at a ratio of 1:1. The experimental group will receive treatment with MAMD, while the control group will undergo treatment with CAs. Both groups of patients will undergo CBCT and oral scanning before clinical intervention (T0) and after the completion of molar distalization (T1). Ultimately, tooth movement and other relevant indicators will be evaluated between the groups.

Methods: participants, interventions, and outcomes

Study setting {9}

All participants in this study were recruited at the Shanghai Stomatological Hospital, Fudan University. The clinical intervention and oral scanning procedures will be conducted in the Department of Orthodontics, while CBCT images will be obtained in the Department

of Radiology. Information regarding subject recruitment can be accessed on the hospital's official website.

Eligibility criteria {10}

All participants in this study will undergo evaluation by two orthodontic specialists possessing over 15 years of clinical experience in orthodontics.

The inclusion criteria for this study are as follows:

1. The patient is aged 18–35 years old, regardless of gender.
2. Permanent dentition, with fully erupted second molars, complete dentition without missing or supernumerary teeth.
3. Angle Class II, bilateral Class II molar relationship, with mild to moderate crowding and/or overjet.
4. The clinical plan is designed to maxillary molars distalization, with no tooth extraction plan except for maxillary third molars.
5. Missing or designed extraction of maxillary third molars.

The exclusion criteria for this study are as follows:

1. Serious tooth defects or dental morphology anomalies.
2. History of orthodontic treatment, dental trauma, or temporomandibular joint disorder.
3. Poor oral hygiene or history of periodontal disease.
4. Combined systemic diseases include cardiovascular disease, liver, and kidney disease, etc.
5. Individuals with abnormal bone metabolism (including those taking anti-bone resorption drugs, hormone drugs, immunosuppressants)

Informed consent? {26a}

After the clinical research assistant provides a comprehensive explanation of the study to the subjects, written informed consent will be obtained from the participants.

Additional consent provisions for collection and use of participant data and biological specimens {26b}

The consent form will explicitly request participants' agreement regarding the utilization of their personal data. Additionally, participants will be asked to authorize the research team to share pertinent data with ethics committees or regulatory bodies involved in the study. Notably, the trial does not entail the collection of biological specimens for storage.

Interventions

Explanation for the choice of comparators {6b}

Clear aligners (CAs) have demonstrated efficacy in addressing mild to moderate upper dental crowding or overbite through maxillary molar distalization. Unlike traditional headgear or pendulum appliances, CAs facilitate bodily movement of molars without tilting. They have gained widespread acceptance for treating Angle Class II malocclusion. However, the conventional sequential tooth movement design needs step-by-step adjustments, potentially prolonging treatment duration and risking anterior anchorage loss. Extended treatment periods require heightened patient compliance and oral hygiene maintenance.

Hence, in this study, we have opted to utilize proven-effective CAs as the control group, contrasting them with the MAMD in terms of treatment duration, tooth movement control, and preservation of anterior anchorage.

Intervention description {11a}

All eligible participants will be randomly assigned in a 1:1 ratio subsequent to signing an informed consent form. The two groups consist of the control group (CAs) and the experimental group (MAMD). Preceding intervention, all participants will undergo oral scanning and CBCT (T0). Following this, distinct intervention measures will be implemented for each group. Upon the completion of molar distalization, oral scanning, and CBCT will be conducted once more for all enrolled patients.

In the experimental group, MAMD will be utilized. Initially, glass ionomer cement will be used to bond the orthodontic appliance. Concurrently, miniscrews (Ormco™, VectorTAS, 8 mm*1.4 mm) will be implanted in the buccal interradicular area between the maxillary first and second molars. If space is inadequate, miniscrews will instead be implanted between the maxillary first molars and second premolars. Subsequent to this, elastics (Ormco™, 1/4 in., 6 oz) will be applied between the miniscrews and canines to achieve distal movement of the maxillary molars and premolars. Patients will be responsible for replacing the elastics by themselves every 24 h. Throughout the intervention period, orthodontic experts will conduct monthly follow-up assessments. Completion of molar distalization (T1) will be determined once the molar relationship reaches Angle Class I, and sufficient anterior space has been created to address crowding or incisor protrusion. The appliance utilized by the experimental group is illustrated in Fig. 2.

In the control group, clear aligners (Align Technology Inc., Santa Clara, CA, USA) will be employed, following a sequential movement strategy known as the V-shaped plan. Initially, the upper second molar will be

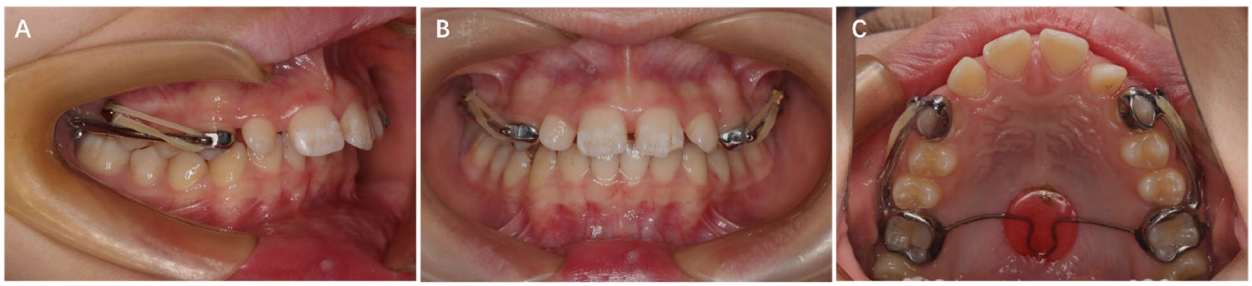

Fig. 2 Miniscrew-anchored molar distalization appliance (MAMD). **A** Sagittal view; **B** frontal view; **C** occlusal view

moved, and once it has shifted by 50%, the upper first molar will then be moved. This sequential process will be repeated until the movement of the premolars is completed. Completion of molar distalization (T1) will be considered once the first premolars have reached the expected position. The treatment plan will be executed following a review by orthodontic experts. To preserve anterior anchorage, a miniscrew (Ormco™, VectorTAS, 8 mm*1.4 mm) will also be implanted in the same position. Elastics (Ormco™, 1/4 in., 6 oz) extending from precision cuts on the canines to the miniscrews will be utilized, to be replaced by the patient every 24 h. Each aligner requires to be worn at least 22 h per day, and for 10 days before the next pair can be replaced. The clear aligners utilized by the control group are depicted in Fig. 3.

Criteria for discontinuing or modifying allocated interventions {11b}

Participants retain the autonomy to decide whether to withdraw from the study at any point. In instances where adverse events arise, adversely affecting the participant's health, or in cases of poor patient compliance impacting study outcomes, the participant's involvement in the study will be promptly terminated. Those who choose to leave the study will receive continued follow-up care until their condition stabilizes.

Strategies to improve adherence to interventions {11c}

This study will offer consultation services for participants via WeChat and telephone to address unforeseen events and coordinate treatment schedules, thereby enhancing treatment compliance. Additionally, the wearing conditions of elastics and the status of miniscrews will be collected through regular inquiries.

Relevant concomitant care permitted or prohibited during the trial {11d}

The use of non-steroidal anti-inflammatory drugs (NSAIDs) is prohibited during this study due to their potential impact on bone remodeling and tooth movement rate. However, alternative pain management strategies will be provided to ensure patient comfort. Patients experiencing discomfort will be advised to use cold compresses and orthodontic wax to alleviate irritation, and if necessary, topical anesthetic gels may be recommended for localized relief.

Provisions for post-trial care {30}

Participants have the right to decide to withdraw from the study. This study has been reviewed and approved by the Ethics Committee of Shanghai Stomatological Hospital, ensuring that all participant rights are protected. In the event that a participant experiences an adverse reaction or requires additional medical care due to the study intervention, the hospital will cover the related

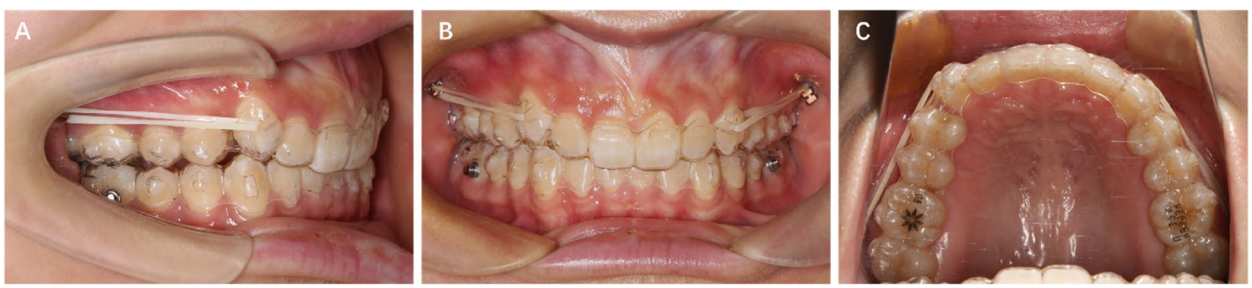

Fig. 3 Clear aligners (CAs). **A** Sagittal view; **B** frontal view; **C** occlusal view

medical expenses or provide appropriate compensation in accordance with institutional policies. Participants will be informed of these protections before enrolling in the trial.

Outcomes {12}

This study will collect CBCT and digital dental models of the subjects before treatment and after the completion of molar distalization. All data will be anonymized and coded by the clinical research coordinator, and then processed by the researchers to reduce potential bias in the data analysis process.

Participants will take CBCT (Marita, Tokyo) before and after treatment and save it in.dicom format. The CBCT images will be taken with 0.3 mm^3 voxel size,160 mm × 160 mm field of view, 90 kV tube voltage, 6 mA tube current, and 3.0 s scan time. These data will be exported into Dolphin11.95 (Dolphin Imaging & Management Solutions, Chatsworth, CA, USA) software, and the three-dimensional coordinate system of the image will be adjusted. The registration function will be used to achieve voxel-based registration on the maxillary bone structure (Fig. 4). After the registration is completed, the CBCT images before and after treatment will be unified into the same coordinate system and exported.

This study will use the iTero Intra-oral Scanner (iTero, Align Technology, San Jose, CA) to collect digital dental models and save the data in.stl format. The CBCT images and corresponding dental models will be imported into 3DmeStudio (https://studio.3dme.ai), and alignment function will be used to align the model with the CBCT image (Fig. 5). The dental model will be adjusted to the same coordinate system as the CBCT image and then exported. The same steps will be used to images before and after treatment to achieve the registration of the dental models based on the maxillary bone structure.

Primary outcome

Molar distal movement rate: In 3Dslicer, the mesiobuccal cusp points of the maxillary first molar before and after treatment will be positioned separately to obtain three-dimensional coordinates (Fig. 6). The difference in the sagittal coordinates is the distance of molar distal movement. By calculating the distance of molar distal movement per unit time, the rate of maxillary molar distal movement can be obtained. Further comparisons will be made between the experimental group and the control group to see if there are any differences.

Secondary outcomes

Three-dimensional tooth movement: In 3Dslicer, the crown landmarks of the maxillary molars and premolars will be positioned separately (Fig. 6). The difference in three-dimensional coordinates can be used to obtain the movement distance of the crown in three dimensions. By measuring the difference in the angle of the line connecting the mesiobuccal and distobuccal cusp of the maxillary first molar before and after treatment on the horizontal plane and sagittal plane, the rotation and angulation can be obtained respectively [17]. In Dolphin 11.95, the root apex of the tooth root will be positioned, and the difference in three-dimensional coordinates can be used to obtain the movement of the root.

Anterior anchorage loss: By calculating the difference in three-dimensional coordinates of the crown and root landmarks of anterior teeth before and after treatment, the position changes of the upper anterior

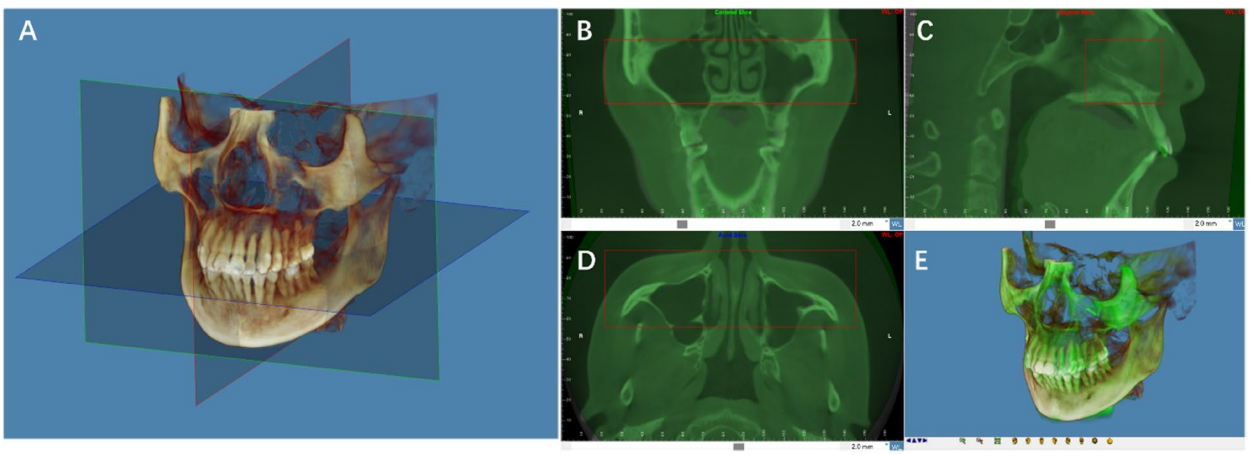

Fig. 4 Voxel-based registration of CBCT based on the maxillary region. **A** Three-dimensional coordinate system of CBCT; **B** coronal view of registration areas(red box); **C** sagittal view; **D** axial view; **E** 3D view

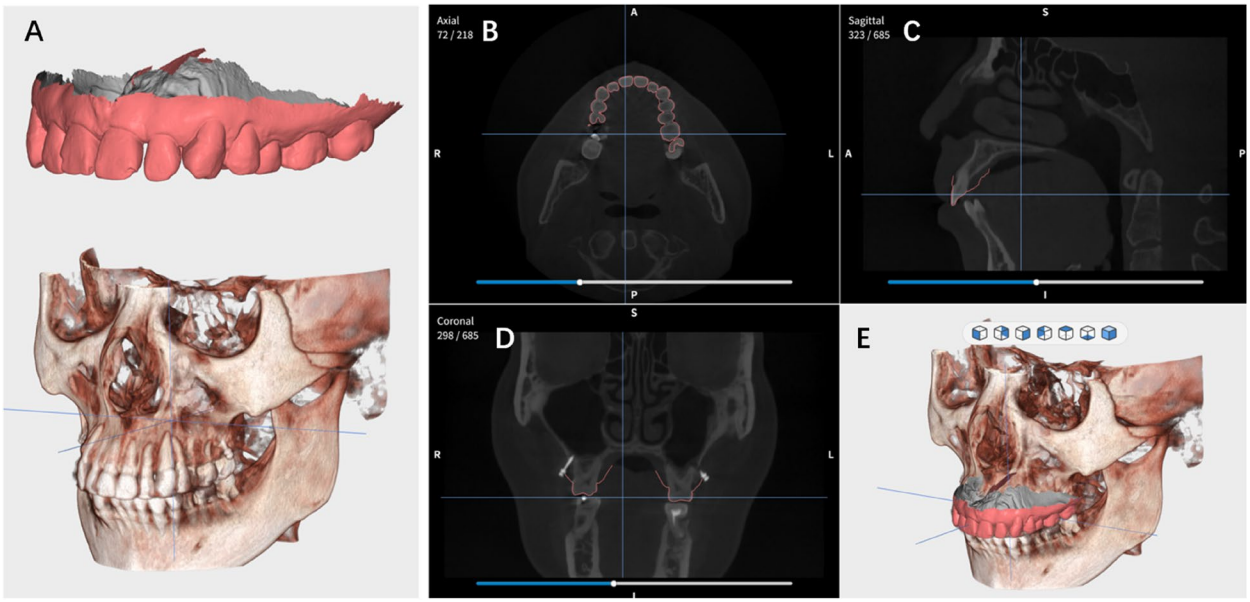

Fig. 5 Alignment of the dental model based on CBCT. **A** Dental model and CBCT image at the same time; **B** axial view of alignment; **C** sagittal view; **D** coronal view; **E** 3D view of alignment

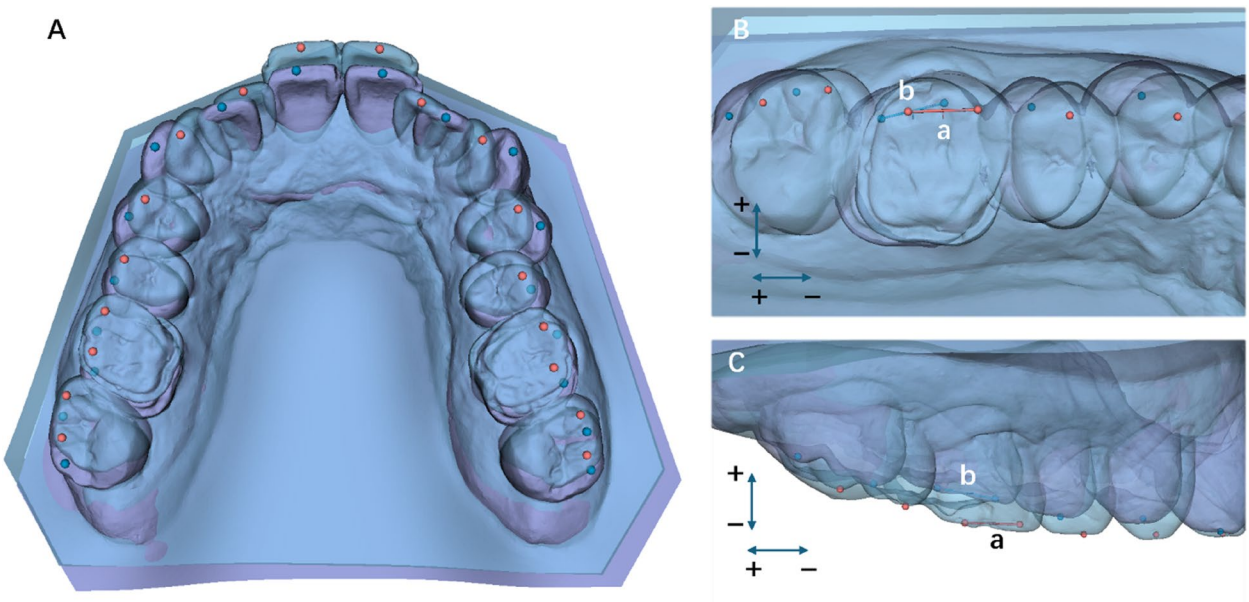

Fig. 6 Measurements of digital dental model. **A** Landmarks before treatment (red points), after distalization (blue points); **B** occlusal view, molar rotation was calculated by the angle between line a and b in the transverse plane; **C** sagittal view, molar distal tipping was calculated by the angle formed between line a and b in the sagittal plane

teeth during treatment can be obtained, and then analyze the loss of anchorage.

Cephalometric analysis: Dolphin 11.95 software will be used to take cephalometric measurements.

Participant timeline {13}

The clinical trial schedule and patient's timeline (Figs. 7 and 8) outline the sequence of events. Upon enrollment in the study, patients will undergo CBCT, oral scans,

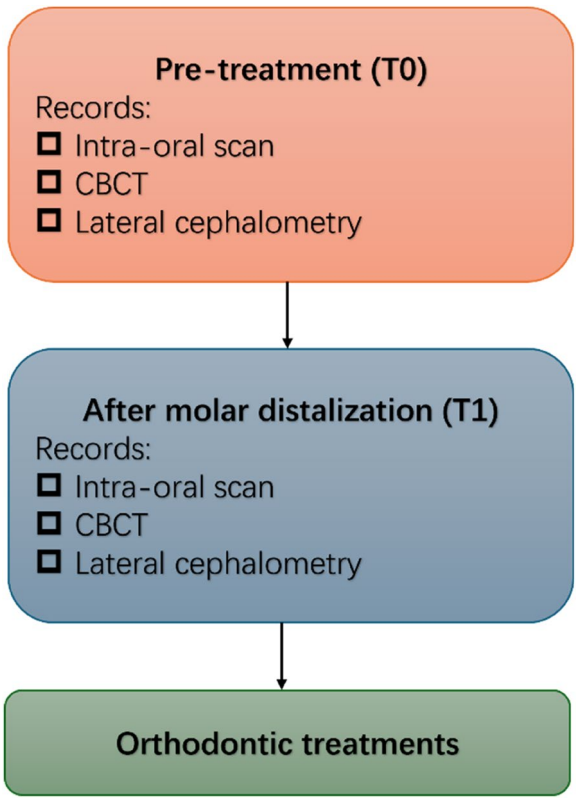

Fig. 7 The clinical trial schedule

and lateral cephalometric radiographs before orthodontic intervention (T0). Subsequently, following the completion of molar distalization (T1), patients will undergo the same imaging procedures. Throughout these phases, patients will routinely capture intraoral photos to monitor tooth movement. Upon concluding molar distalization, patients will proceed with subsequent orthodontic treatment.

Sample size {14}

The sample size for this study was determined using G*Power 3.1.9.6 (University Dusseldorf, Germany). Drawing from existing literature and preliminary experimental findings, it was estimated that clear aligners typically require approximately 8 ± 2 months to complete molar distalization, while MAMD achieves a similar outcome in about 5 ± 2 months. With a significance level (α) set at 0.05, power (1-β) at 0.90, and employing a two-sided test, it was computed that both the control and experimental groups necessitate a minimum of 11 cases each. To mitigate the potential loss to follow-up, the study will enroll 15 patients in each group, resulting in a total of 30 patients.

Recruitment {15}

Recruitment is slated to commence in June 2024 at the Shanghai Stomatological Hospital, which boasts all the requisite departments for this investigation. The recruitment announcement for potential participants will be displayed on the hospital's official website. Prospective participants will be afforded a two-week window to deliberate on their participation in the study.

Assignment of interventions: allocation

Sequence generation {16a}

This study employs a block randomization approach, wherein all samples will be segmented into 5 groups, each comprising 6 subjects. Random numbers will be generated by the clinical research coordinator utilizing SAS 9.4 (SAS Institute Inc., Cary, NC, USA). Subsequently, each group will be divided into experimental and control subgroups at a 1:1 ratio.

Concealment mechanism {16b}

In this study, the sealed envelope method is employed to conceal the randomization scheme.

Implementation {16c}

The clinical research coordinator initiates the process by generating a random number table using SAS software, subsequently completing the randomization scheme based on the generated results. The grouping outcomes are then placed in sequentially numbered opaque sealed envelopes in accordance with the scheme. Subsequently, the clinical researcher evaluates whether the patient meets the predefined inclusion criteria. Upon the patient's decision to participate and subsequent signing of the informed consent form, they are assigned a numerical identifier based on their enrollment time. The clinical researcher selects the envelope corresponding to the patient's assigned number, and after the patient signs on the envelope, they unveil it to determine their grouping assignment. Following this, the respective intervention measures are implemented accordingly.

Assignment of interventions: blinding

Who will be blinded {17a}

Given the utilization of two distinct orthodontic appliances in this study, implementing blinding for both participants and researchers is impractical. However, to uphold the integrity of the analysis, the analyst will remain blinded to patients' information throughout the measurement process.

	STUDY PERIOD			
	Enrolment	Allocation	Post-allocation	Close-out
TIMEPOINT	$-t_1$	t_0	t_1	t_x
ENROLMENT:				
Eligibility screen	X			
Informed consent	X			
Recruitment	X			
Allocation		X		
INTERVENTIONS:				
MAMD*			X	
CAs*			X	
ASSESSMENTS:				
Molar distal movement rate				X
Three-dimensional tooth movement				X
Anterior anchorage loss				X
Cephalometric analysis				X

Fig. 8 Patient's timeline. * Miniscrew-anchored molar distalization appliance. ** Clear aligners

Procedure for unblinding if needed {17b}

The item is not applicable. The analysts are not allowed to be unblinded under any circumstances.

Data collection and management

Plans for assessment and collection of outcomes {18a}

Case Report Forms (CRFs), meticulously crafted by specialists, serve as the principal documentation tool for this study. Prior to commencement, researchers will undergo comprehensive training covering recruitment, screening, randomization, evaluation, and instructions for accurately completing the CRF. It is mandatory for investigators to record each subject's data in the CRF. All entries in the CRF must be presented in a clear and legible manner. Any revisions to the CRF should be executed by drawing a single line through the erroneous data, ensuring both the incorrect entry and the corrections remain legible. The researcher must then provide their signature alongside the date of correction adjacent to the amended data. Subsequently, the original CRFs will be returned to the sponsoring center at the Shanghai Stomatological Hospital.

Plans to promote participant retention and complete follow-up {18b}

The clinical research coordinator will oversee follow-up tracking and offer consultation services to each enrolled patient, aiming to optimize participant compliance throughout the study period.

Data management {19}

Image data from all patients will be methodically gathered and regularly verified. To maintain analyst blinding, primary data will be encoded. Upon conclusion of the trial, the encoded data will be exported into SPSS 29.0 (Chicago, USA) for subsequent analysis.

Confidentiality {27}

Participants will be informed that their data will be stored and analyzed on a computer, with access restricted solely to members of the research team

handling individual participant information. Additionally, participants will be made aware that their clinical records may undergo review by representatives of the sponsor and/or regulatory authorities. All undisclosed information, encompassing patent applications, production processes, and fundamental data, will be upheld as confidential. Any public dissemination of study results will safeguard the personal identities of participants. Trial data will be accessible for inquiry and sharing, with restrictions confined to web-based electronic databases to prevent any inadvertent disclosure of personal privacy information.

Statistical methods

Statistical methods for primary and secondary outcomes {20a}

The primary research outcome is the rate of distal movement of the molars. This study is designed as a superiority trial, with the primary hypothesis defined as follows:

Null hypothesis (H_0): There is no significant difference in molar distal movement rate between MAMD and clear aligners.

Alternative hypothesis (H_1): MAMD achieves a significantly higher molar distal movement rate than clear aligners.

To test for superiority, a two-sided independent sample *t*-test will be conducted if the data follow a normal distribution (Shapiro–Wilk test, $p > 0.05$). If normality is not met, a Mann–Whitney U test will be used instead. The significance level (α) is set at 0.05.

Similarly, the secondary research outcome of this study pertains to the three-dimensional movement distance of the crown and root landmarks. Comparable statistical methodologies are employed to analyze potential differences in data between the experimental and control groups. All statistical analyses are conducted utilizing SPSS 29.0.

Methods for additional analyses {20b}

Descriptive statistical analysis will be used for the measurements of lateral cephalometric.

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data {20c}

This study will use an intention-to-treat (ITT) analysis, including all randomized participants in their originally assigned groups, regardless of protocol adherence. Missing data will be handled using the last-observation-carried-forward (LOCF) method to ensure data integrity and minimize bias.

Plans to give access to the full protocol, participant-level data, and statistical code {31c}

The datasets analyzed during the current study will be available from the corresponding author on reasonable request.

Oversight and monitoring

Composition of the coordinating center and trial steering committee {5d}

A supervisory committee comprising three seasoned doctors will be formed to oversee and manage adverse events throughout the study. This committee convenes every four weeks to assess the research's progression. Given the single-center nature of this clinical study, a coordination committee is deemed unnecessary. The data processing team for this study comprises two orthodontists and a statistical expert.

Composition of the data monitoring committee, its role and reporting structure {21a}

Given that the intervention methods in this study are conventional treatment approaches with minimal safety concerns, a data monitoring committee is deemed unnecessary.

Adverse event reporting and harms {22}

Researchers are mandated to promptly record and report any adverse events within a 24-h timeframe. Serious adverse events will be expeditiously reported to the ethics committee.

Frequency and plans for auditing trial conduct {23}

A supervisory group comprising three seasoned orthodontists will conduct monthly visits to ensure adherence to the research plan and compliance with Good Clinical Practice (GCP) guidelines. During these monitoring visits, the monitor will meticulously review the Case Report Forms (CRFs) of participating trial subjects to verify the completion of all items and ascertain data collection adherence to the research protocol. Furthermore, the monitor will cross-reference the CRF data with clinical records or original data to confirm consistency.

Plans for communicating important protocol amendments to relevant parties (e.g. trial participants, ethical committees) {25}

Throughout the study, procedural adjustments may arise that could impact the research or patient safety. Any proposed modifications must be mutually agreed upon by the sponsor/researcher and the ethics committee before implementation. Following approval, the informed

consent form will be revised in accordance with the modified research protocol and subsequently re-signed by the participants.

Dissemination plans {31a}

The final research results will be published in a medical journal by the principal clinical researchers.

Discussion

Distal movement of the maxillary molars is an effective method for correcting Angle Class II malocclusion, but the conventional methods for molar distalization all have limitations. Extraoral arch orthodontic appliances require patients to have good compliance. Pendulum appliances can only achieve distal tilting movement of the molars. CAs have limitations such as low efficiency of tooth movement, loss of anterior tooth anchorage, and dental arch width increasing [18]. Fixed appliances assisted by miniscrews allow for group distal movement of teeth and reduce treatment time [19], but it has limitations in esthetics and distal molar tipping [9]. So we proposed MAMD which is expected to achieve high-efficiency bodily distal movement.

Previous studies often use the distal movement of the maxillary first molar into position as the endpoint of the study, which overlooks the impact of the subsequent movement of the other teeth on the maxillary molars. Therefore, this study chooses the movement of the maxillary first premolars into position as the endpoint of the study. At this time, the distal movement of the maxillary premolars and molars has been completed. It is more accurate and reliable to evaluate the three-dimensional movement of the posterior teeth and the loss of anterior tooth anchorage.

Lateral cephalometric radiographs are the conventional method for evaluating the clinical effect of distal movement of maxillary molars. This method has limitations as it can only obtain information about the sagittal movement of the teeth and cannot evaluate the horizontal movement and rotation of the teeth. Scholars use digital dental models or CBCT images to perform three-dimensional evaluations of tooth movement, both of which have their own limitations. Therefore we combine dental models and CBCT images to achieve three-dimensional measurement of tooth movement and this method has the advantages of good accuracy and reliability [20].

Trial status

The study has been ongoing since May 2023. Recruitment is expected to begin in June 2024 and be complete by the end of 31 December 2025. The protocol version is 1.1 (issue date 1 May 2024).

Abbreviations

MAMD	Miniscrew-anchored molar distalization appliance
CAs	Clear aligners
CBCT	Cone-beam computed tomography
CRF	Case report forms

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Not applicable.

Authors' contributions {31b}

Dr. Hao Liu and Dr. Cui Ye wrote this manuscript and Dr. Haimiao Wu approved the final version for publication. Dr. Hao Liu and Ziyan Tang will lead the data collection. Dr. Haimiao Wu and Dr. Zhicheng Gong led the conception and design of the study. All authors have reviewed drafts of the manuscript and given final approval.

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Declarations

Ethics approval and consent to participate {24}

This study was approved by the Ethical Committee of the Shanghai Stomatological Hospital on 8 December 2022 (certificate number 2022–017) , and amendment review passed expedited ethical review on 6 June 21, 2024. Informed consent will be obtained from all participants. The results of the trial will be published in peer-reviewed journals and presented at national and international conferences.

Consent for publication {32}

These are available from the corresponding author on request.

Competing interests {28}

The authors declare that they have no competing interests.

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