Maxillary molar distalization using clear aligners and temporary anchorage devices (TADs)

2024 Research Aid Awards (RAA)

Dr Christie Shen

chrishen@upenn.edu
O: 626-298-9187

FollowUp Form

Award Information

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Title of Project:*
Maxillary molar distalization using clear aligners and temporary anchorage devices (TADs)

Award Type
Research Aid Award (RAA)

Period of AAOF Support
July 1, 2024 through June 30, 2025

Institution
The Trustees of the University of Pennsylvania

Names of principal advisor(s) / mentor(s), co-investigator(s) and consultant(s)
Dr. Chenshuang Li (mentor), Dr. Chun-Hsi Chung (mentor)

Amount of Funding
$6,000.00

Abstract
(add specific directions for each type here)

Please see the attached document.

Respond to the following questions:

Detailed results and inferences:*
If the work has been published, please attach a pdf of manuscript below by clicking "Upload a file".
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Were the original, specific aims of the proposal realized?*
The original aim of the proposal was to perform a detailed evaluation of the molar distalization efficacy of clear aligners in combination with temporary anchorage devices (TADs). This goal was successfully achieved through CBCT and digital model analysis and assessment of treatment outcomes. While the CAT+TADs system did not significantly improve the amount of maxillary molar distalization compared to previous clear aligner studies, it did result in increased bodily movement and molar intrusion. These findings contribute meaningful insights to the clinical understanding of molar distalization with clear aligners and TADs. Although the study did not yield a definitive clinical guideline, it laid important groundwork and identified the need for future comparative studies.

Were the results published?*
No

Have the results of this proposal been presented?*
Yes

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AAOF funding has been instrumental in supporting my research. I have used the funding to purchase essential research software necessary for the completion of my projects. Additionally, the funding has supported travel and registration costs for national and international conferences, where I have presented my research. It has also covered poster printing expenses, allowing me to present my findings to peers and leaders in the field. These opportunities have enhanced my research dissemination, broadened my professional network, and contributed directly to my growth as a clinician and researcher.

Accounting: Were there any leftover funds?

$844.69

Not Published

Are there plans to publish? If not, why not?*

Yes, the research is currently under review by a journal for publication.

Presented

Please list titles, author or co-authors of these presentation/s, year and locations:*

Maxillary Molar Distalization with Clear Aligner Therapy And Temporary Anchorage Devices. Christie Shen, Shaonan Zhou, Qianqian Wang, Jay Bowman, Chun-Hsi Chung, Chenshuang Li. 2025. American Association of Orthodontists Annual Session 2025 for the William R. Proffit Resident Scholar Award Program. Philadelphia, PA.

Maxillary Molar Distalization with Clear Aligner Therapy And Temporary Anchorage Devices. Christie Shen, Shaonan Zhou, Qianqian Wang, Jay Bowman, Chun-Hsi Chung, Chenshuang Li. 2025. International Association for Dental, Oral, and Craniofacial Research General Session & Exhibition 2025. Barcelona, Spain.

Was AAOF support acknowledged?

If so, please describe:

Yes, AAOF support was acknowledged on both posters presented.

Internal Review

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Maxillary Molar Distalization with Clear Aligner Therapy and Infrazygomatic Temporary Anchorage Devices System

Christie Shen, DDS

THESIS

April 14th, 2025

School of Dental Medicine

Presented to the Faculty of the University of Pennsylvania
in Fulfillment of the Requirements for the Degree of Master of Science in Oral Biology

Chenshuang Li, DDS, PhD, DMD – Thesis Supervisor

Assistant Professor, Department of Orthodontics

Clinical Director of Orthodontic Clinic   _____

Chun-Hsi Chung, DMD, MS – Thesis Supervisor

Professor, Department of Orthodontics
Chauncey M. F. Egel Endowed Chair
Director of Postdoctoral Orthodontics Program   _____

Wenjing Yu, DDS, PhD- Thesis Committee Chair

Instructor, Department of Orthodontics

Associated Predoctoral Director of Orthodontics   _____

Adeyinka Dayo, BDS, MS- Thesis Committee Member

Clinical Assistant Professor, Department of Oral Medicine   _____

Myra F. Laird, PhD- Thesis Committee Member

Assistant Professor, Department of Basic and Translational Science   _____

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Abstract

Chapter 1: Molar Distalization by Clear Aligners with Sequential Distalization Protocol

Introduction: With the popularity of clear aligners, the sequential distalization protocol has been more commonly used for molar distalization. However, the amount of molar distalization that can be achieved, as well as the accompanying side effects on the sagittal dimension, are unclear.

Methods: Registered with PROSPERO (CRD42023447211), relevant original studies were screened from seven databases (MEDLINE [PubMed], EBSCOhost, Web of Science, Elsevier [SCOPUS], Cochrane, LILACS [Latin American and Caribbean Health Sciences Literature], and Google Scholar) supplemented by a manual search of the references of the full-reading manuscripts by two investigators independently. A risk of bias assessment was conducted, relevant data were extracted, and meta-analysis was performed using RStudio.

Results: After the screening, 13 articles (11 involving maxillary distalization, two involving mandibular distalization) met the inclusion criteria. All studies had a high or medium risk of bias. The meta-analysis revealed that the maxillary first molar (U6) mesiobuccal cusp was distalized 2.07 mm [1.38 mm, 2.77 mm] based on the post-distalization dental model superimposition, and the U6 crown was distalized 2.00 mm [0.77 mm, 3.24 mm] based on the post-treatment lateral cephalometric evaluation. However, the U6 mesiobuccal root showed less distalization of 1.13 mm [−1.34 mm, 3.60 mm], indicating crown distal tipping, which was validated by meta-analysis (U6-PP angle: 2.19° [1.06°, 3.33°]). In addition, intra-arch anchorage loss was observed at the post-distalization time point (U1 protrusion: 0.39 mm [0.27 mm, 0.51 mm]), which was corrected at the post-treatment time point (incisal edge-PTV distance: −1.50 mm [−2.61 mm, −0.39 mm]).

Conclusion: About 2 mm maxillary molar distalization can be achieved with the sequential distalization protocol, accompanied by slight molar crown distal tipping. Additional studies on this topic are needed due to the high risk of bias in currently available studies.

Chapter 2: Vertical Control in Molar Distalization by Clear Aligners

Background: Molar distalization is used to correct molar relationships or to create space for mild anterior crowding. However, whether clear aligners can provide proper vertical control with the sequential distalization strategy has been highly debated. Thus, the current study aimed to systematically review the amount of dentoskeletal changes in the vertical dimension that results from sequential molar distalization in clear aligner therapy without temporary anchorage devices (TADs).

Methods: Registered with PROSPERO (CRD42023447211), relevant original studies were screened from seven databases and supplemented by a manual search by two investigators independently. Articles were screened against inclusion and exclusion criteria, and a risk of bias assessment was conducted for each included article. Relevant data were extracted from the included articles and meta-analysis was performed using RStudio.

Results: Eleven articles (nine for maxillary distalization and two for mandibular distalization) were selected for the final review. All studies have a high or medium risk of bias. For maxillary molar distalization, the meta-analysis revealed 0.26 mm [0.23 mm, 0.29 mm] of maxillary first molar intrusion based on post-distalization dental model analysis, as well as 0.50 mm [−0.78 mm, 1.78 mm] of maxillary first molar intrusion and 0.60 mm [−0.42 mm, 1.62 mm] of maxillary second

molar intrusion based on post-treatment lateral cephalometric analysis. Skeletally, there was a −0.33° [−0.67°, 0.02°] change in the SN-GoGn angle, −0.23° [−0.30°, 0.75°] change in the SN-MP angle, and 0.09° [−0.83°, 1.01°] change in the PP-GoGn angle based on post-treatment lateral cephalometric analysis. There was insufficient data for meta-analysis for mandibular molar distalization.

Conclusions: No significant changes in vertical dimension were observed, both dentally and skeletally, after maxillary molar distalization with a sequential distalization strategy. However, further studies on this topic are needed due to the high risk of bias in the currently available studies.

Chapter 3: Maxillary Molar Distalization with Clear Aligner Therapy and Infrazygomatic Temporary Anchorage Devices System

Introduction: Based on systematic reviews and meta- analyses, approximately 2 mm of maxillary molar distalization can be achieved with sequential molar distalization with clear aligner therapy (CAT) without skeletal anchorage. Distalization is accompanied by significant distal crown tipping and insignificant changes in the vertical dimension. Thus, combining CAT with temporary anchorage devices (TADs) has been proposed, but a detailed evaluation is lacking.

Methods: This retrospective study evaluated pre-treatment (T1) and post-anterior retraction (T2) cone beam computed tomography (CBCT) images and digital models of adult patients treated with CAT + infrazygomatic TADs with at least 1 mm of programed maxillary first molar distalization. Achieved tooth movement shown on the CBCT and intraoral scan was compared to prescribed ClinCheck tooth movement.

Results: The present study included 38 sides from 21 patients (17 females, 4 males; 28.71±4.16 years old at T1). At the crown level, about 1 mm of molar distalization was achieved (first molar (U6): 1.05 mm [-0.8, 3.6] based on digital models, 0.80 mm [-1.1, 3.4] based on CBCTs; second molar (U7): 0.95 mm [-1.8, 4.4] based on digital models, 1.25 mm [-1.9, 3.7] based on CBCTs), which is significantly lower than the prescribed ClinCheck movement (U6: 3.05 mm [1.0, 5.6]; U7: 3.05 mm [0.9, 6.1]). We observed limited crown distal tipping and mesial-out rotation but significant buccal expansion and intrusion of the maxillary molars. In addition, a negative correlation was detected between the amount of prescribed molar distal movement and the distalization efficacy. Measurements based on the CBCT and digital models were comparable for maxillary molar, rotation and tipping, as well as maxillary central incisor retraction and buccal crown torque. However, CBCT and digital model measurements showed discrepancies in vertical measurements.

Conclusion: The CAT+TADs system did not significantly improve the efficacy of maxillary molar distalization when compared to existing clear aligner studies but provided more bodily movement and intrusion of the molars. As all patients in this study were treated with TADs, further studies with comparative designs are needed to isolate and evaluate the contribution of TADs to molar distalization.

Table of Contents

Summary of Chapters

Chapter		Summary
Literature Review	1. Molar Distalization by Clear Aligners with Sequential Distalization Protocol	• Systematic review and meta-analysis • Aim: to assess the amount of distalization achieved with clear aligner therapy (CAT) without temporary anchorage devices (TADs) and the accompanying effects of rotation and tipping of molars as well as anterior anchorage loss • 13 articles were included for final analysis • Approximately 2 mm of maxillary molar distalization can be achieved with the sequential distalization protocol, accompanied by slight molar crown distal tipping • Intra-arch anchorage loss was observed at the post-distalization time point, which was corrected at the post- treatment time point • Additional studies on this topic are needed due to the high risk of bias in currently available studies
	2. Vertical Control in Molar Distalization by Clear Aligners	• Systematic review and meta-analysis • Aim: to systematically review the amount of dentoskeletal changes in the vertical dimension that results from sequential molar distalization in CAT without TADs • Eleven articles were selected for the final review • No significant changes in vertical dimension were observed, both dentally and skeletally, after maxillary molar distalization with a sequential distalization strategy • Further studies on this topic are needed due to the high risk of bias in the currently available studies
Manuscript	3. Maxillary Molar Distalization with Clear Aligner Therapy and Infrazygomatic Temporary Anchorage Devices System	• Retrospective CBCT and digital model superimposition study • A limited amount of maxillary molar distalization can be achieved with sequential molar distalization with CAT • Combining CAT with TADs has been proposed, but a detailed evaluation is lacking • Records were evaluated pre-treatment (T1) and post-anterior retraction (T2) on cone beam computed tomography (CBCT) images and intraoral scans of adult patients treated with CAT + infrazygomatic TADs with at least 1 mm of programed maxillary first molar distalization • 38 sides from 21 patients (17 females, 4 males; 28.71±4.16 years old at T1 • At the crown level of the first molar (U6), about 1 mm of molar distalization was achieved based on digital model superimpositions and 0.80 mm was achieved based on CBCT superimpositions • At the crown level of the second molar (U7) about 0.95 mm of molar distalization was achieved based on digital model superimpositions and 1.25 mm was achieved based on CBCT superimpositions • Distalization achieved was significantly lower than the prescribed movement (U6: 3.05 mm [1.0, 5.6]; U7: 3.05 mm [0.9, 6.1]). • Limited crown distal tipping and mesial-out rotation significant buccal expansion and intrusion of the maxillary molars were observed • A negative correlation was detected between the amount of prescribed molar distal movement and the distalization efficacy • TADs did not significantly improve the efficacy of maxillary molar distalization with CAT but provided more bodily movement and intrusion of the molars

Chapter 1: Molar Distalization by Clear Aligners with Sequential Distalization Protocol: A Systematic Review and Meta-Analysis

1. Introduction

Achieving effective and efficient molar distalization to correct molar relationships and create space for crowding relief has been a long-lasting subject of debate in orthodontics. Historically, some of the most commonly used maxillary molar distalization strategies include inter-arch appliances such as class II elastics,[1] Carriere 3D Motion appliance,[2] Forsus fatigue resistant device,[3] mandibular anterior repositioning appliance (MARA),[4] Herbst appliance,[5] SAIF-springs,[6] as well as intra-arch appliances such as the Pendulum,[7] Jones jig,[8] First Class Appliance,[9] and Distal Jet.[10] Other distalization strategies include extraoral appliances such as headgear.[11] For many of the appliances mentioned above, there are concerns about patients' acceptance.[12] For instance, several patients have reported difficulty in eating soon after delivery of these fixed appliances.[13] Other side effects reported by patients include toothaches, limited maximum opening, aching jaws, difficulty in the upkeep of oral hygiene, and soreness on the lip/cheek due to abrasion from appliances.[12,14]

In the past two decades, clear aligners have become popular as a more esthetic, less invasive, and more hygienic option for patients seeking orthodontic treatment.[15] To achieve molar distalization with clear aligners, the sequential distalization protocol was introduced.[16] The sequential distalization protocol is designed to start with moving the second molar distally. When the second molar reaches 50% of the total movement, the first molar starts moving distally, and so on up to the canine, and lastly, en masse incisor retraction is initiated. During the whole protocol, inter-arch elastics are often used to utilize the opposing arch as the anchorage. However, whether this protocol is a viable option for a significant amount of molar distalization is still questionable.[17,18] When evaluated on the crown level on dental models, some articles reported up to 2.68 ± 0.50 mm distalization of the mesial buccal cusp of the maxillary first molar, [19-23] while other articles reported unsatisfactory amounts of distalization were achieved.[24,25] Patterson et al. found that anterior–posterior correction achieved at the end of clear aligner therapy for class II patients is only 6.8% of the predicted amount (0.23 mm achieved of the 3.29 mm predicted amount),[24] and both Patterson et al.[24] and Taffarel et al.[25] concluded that treatment of Class II malocclusions with clear aligners would not meet the standards of the American Board of Orthodontics (ABO) Model Grading System.

It is worth noting that while bodily distalization is a more desirable treatment outcome for molar distalization, several molar distalization strategies report crown distal tipping and mesial out–distal in rotation of molars,[19,20] which are unwanted side effects that easily cause relapse to the original tooth position.[26] The previous literature indicates that pure crown tipping is the most predictable movement of clear aligners,[17] and the movement involving any amount of root control has poor predictability, especially for the posterior teeth.[17,27] Thus, whether the sequential distalization protocol in clear aligner therapy can achieve bodily distalization of the molars needs to be further evaluated.

In addition, with inter-arch elastic usage as an integral part of the sequential distalization protocol, anchorage loss in opposing arches has been reported in conjunction with molar distalization.[28] Excessive incisor proclination or protrusion can result in undesirable side effects such as alveolar bone loss and gingival recession.[29] These concerns suggest the need to evaluate the amount of anchorage loss created by molar distalization.

Considering all the clinical questions mentioned above, a systematic review was conducted in the current study to examine the current evidence on the amount of molar distalization achievable with the sequential distalization protocol of clear aligner therapy. Moreover, this review aims to assess the accompanying effects of rotation and tipping of molars as well as anterior anchorage loss, ultimately providing clinical insight into the effectiveness and limitations of clear aligner therapy.

2. Materials and Methods

This study was registered with PROSPERO (registration number: CRD42023447211) on 1 August 2023, and is compliant with the 2020 Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guideline.[30] All original articles were accessed through a search from the following electronic databases: MEDLINE (PubMed), EBSCOhost, Web of Science, Elsevier (SCOPUS), Cochrane, LILACS (Latin American and Caribbean Health Sciences Literature), and Google Scholar, with an initial search finish date of 13 February 2024.

2.1. Study Selection Criteria

Based on the framework of population, interventions, comparison, and outcomes (PICOs), we conducted a systematic literature review on the sequential distalization protocol of clear aligner therapy for molar distalization (**Table 1**). The inclusion criteria comprised (1) longitudinal studies (both prospective and retrospective) comparing pre- and post-distalization/treatment records, (2) participants with permanent dentition, and (3) molar distalization achieved by sequential distalization protocol. The exclusion criteria were (1) participants with congenital abnormalities or systemic pathologies, (2) case reports, (3) conference abstracts, (4) opinions, editorials, guidelines, or letters to the editors, (5) systematic reviews, (6) utilization of TADs or other auxiliaries during molar distalization, (7) molar distalization protocol not described, and (8) inconsistent data within the article and did not receive responses from the corresponding author(s). No language or date restrictions were imposed. The PRISMA flow diagram illustrating the process of obtaining the final included articles is presented in **Figure 1**.

Table 1. The PICO questions of this study.

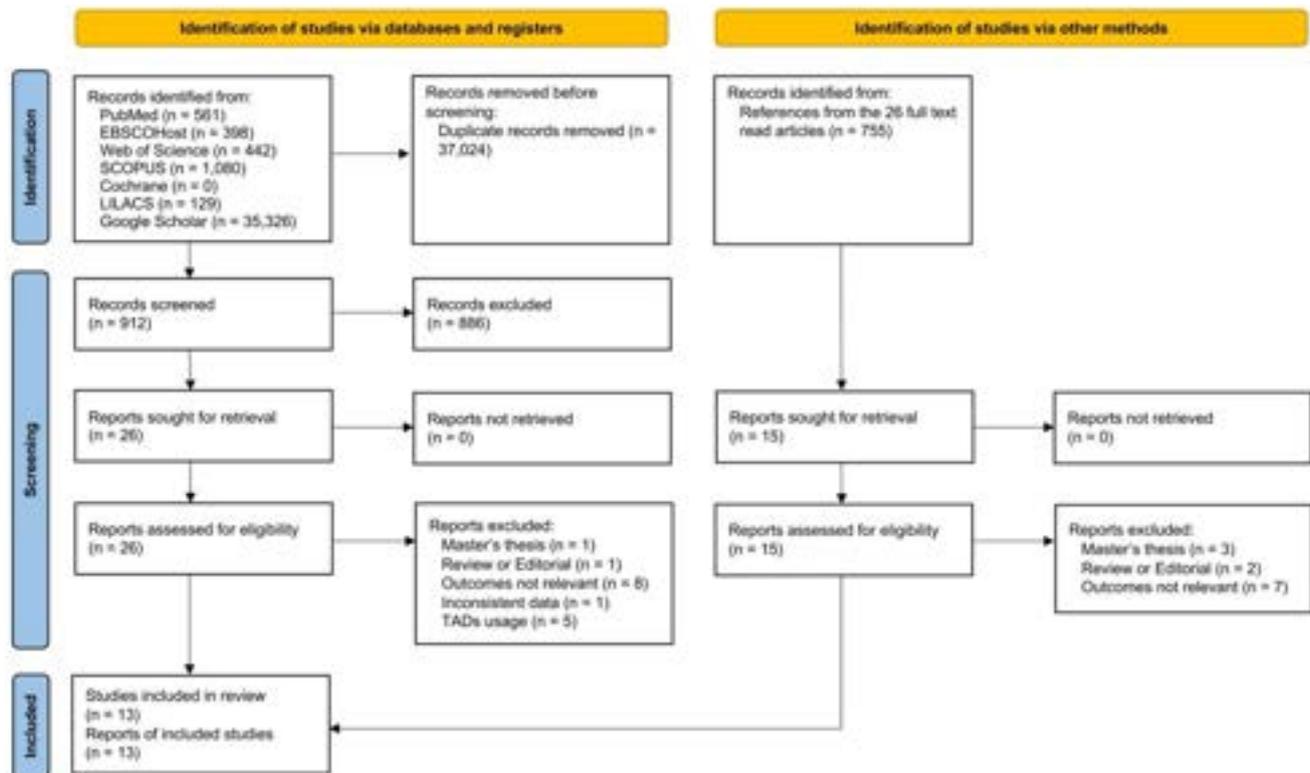| Criteria	Description
Population	Patients undergoing orthodontic treatment with clear aligners requiring molar distalization
Intervention	Molar distalization with sequential distalization protocol of clear aligner therapy
Comparisons	The control is pre-treatment models and radiographs
Outcome	The amount of molar distalization, molar rotation, molar tipping, and anterior anchorage loss achieved during molar distalization with clear aligners

Figure 1. The PRISMA flow diagram demonstrating the study identification and screening.

2.2. Search Strategy

Our search strategy in all included databases is as follows: ("aligners" AND "molar distalization"), ("aligner" AND "molar distalization"), ("clear aligners" AND "molar distalization"), ("clear aligner" AND "molar distalization"), ("sequential distalization"), ("class II" AND "aligners"), ("class II" AND "aligner"), ("class II" AND "clear aligner"), ("class II" AND "clear aligners"), ("class III" AND "aligners"), ("class III" AND "aligner"), ("class III" AND "clear aligner"), ("class III" AND "clear aligners"), and ("invisible removable thermoplastic appliance"). In addition to the initial search, we manually reviewed the references cited in the articles identified for full-text reading. The full texts of these articles were thoroughly examined and evaluated against the predetermined inclusion and exclusion criteria. Two authors (C.S. and T.H.P.) independently carried out the literature search and screening to ensure the reliability and comprehensiveness of the results. In cases of discrepancies between the two authors, a third author (C.L.) was consulted for further discussion.

2.3. Data Extraction and Analysis

For all the articles included for further data analysis, relevant information was extracted from each article, including study type, arch treated, sample size, gender, age, clear aligner brand, type of records, timing of treatment records, as well as parameters evaluating molar distalization, molar rotation, molar tipping, and maxillary and mandibular anterior anchorage loss reported by dental model superimposition or by radiographic analysis.

2.4. Risk of Bias/Quality Assessment

Due to the heterozygosity of the study types of the included studies, the risk of bias protocol was modeled after one established in a previous publication,[31] which is similar in design to our study. A total of 17 biases were evaluated in four categories: study design, study measurements, statistical analysis, and others (**Table 2**), which were scored by two authors (C.S. and T.H.P.) individually. In cases of disagreement, a third author (C.L.) provided input. Each article's

score was calculated by dividing the number of met criteria by the total number of criteria. The risk of bias—low, medium, or high—was determined based on factors such as intra-rater reliability, interrater reliability, and blinding of the examiner and/ or statistician. A low risk of bias was assigned if both reliability and randomization criteria were met. A high risk of bias was indicated if inter-rater reliability was not assessed and if randomization was not conducted. All other studies were categorized as having a medium risk of bias (**Table 2**).

2.5. Statistical Analysis

The outcomes of this study were as follows: (1) the amount of molar distalization achieved during distalization with clear aligners, as well as the amount of concurrent (2) molar rotation, (3) molar tipping, and (4) anterior anchorage loss. A meta-analysis utilizing the data extracted from the included articles was conducted using RStudio (version 2023.09.1+494, Posit Software, PBC).[32,33] In cases where articles only provided the mean difference along with upper and lower 95% confidence intervals, the standard deviation was computed using the conventional definition $SD = \sqrt{N} \times (\text{upper limit} - \text{lower limit})/3.92$, regardless of the normal distribution within the sample population.[34] The meta-analysis was carried out employing a random effects model, and heterogeneity was evaluated for variance among studies using the Tau2 method (τ^2). The results were presented as mean and 95% confidence interval [CI]. Sensitivity analysis and selective reporting within studies were not evaluated due to the limited number of studies included per analyzed variable.

3. Results

3.1. Literature Searching and Study Selections

Through the initial search with seven electronic databases, 37,936 potential articles (561 from PubMed, 398 from EBSCOHost, 442 from Web of Science, 1080 from SCOPUS, 0 from Cochrane, 129 from LILACS, and 35,326 from Google Scholar) were identified (**Figure 1**). A total of 912 articles remained for abstract screening following duplicate removal. A total of 26 articles were retrieved for full-text reading. A total of 755 records were also manually retrieved from the references of the full-text reading articles and 15 additional articles were retrieved for full-text reading. A total of 28 of the retrieved articles were excluded because they were master's theses,[35-38] reviews or editorials,[39-41] inconsistent data,[42] utilized TADs,[43-47] or the outcomes were not relevant.[18,25,27,48-59] Therefore, after adhering to the guidelines presented by the PRISMA, 13 articles were included for final analysis.[19-23,60-67]

3.2. Risk of Bias

The strength of evidence was evaluated by conducting a methodological risk of bias assessment on the 13 studies included (**Table 2**). Among these, only one study[60] reported both random sampling and random allocation of treatment. The remaining studies did not provide information on randomization. Four studies[60,61,63,67] mentioned blinding conducted by the examiner, but only one[60] of them extended blinding to the statistician. Other studies did not incorporate blinding measures. Intra-rater reliability was addressed in 7 of the 13 studies,[19,21,22,60,61,63,65] while one article's reporting on intra-rater reliability was unclear.[23] Three articles reported inter-rater reliability.[19,22,61] Based on criteria on randomization and reliability testing, none of the studies scored low for risk of bias. Five studies were categorized as having a medium risk of bias,[19,20,22,60,61] while the remaining eight were deemed to have a high overall risk of bias.[21,23,62-67]

Table 2. Risk of bias assessment of the thirteen included studies. ⊕: Low risk of bias; ?: medium risk of bias; ⊖: high risk of bias.

		Maxillary											Mandibular	
		Garino et al. (2016)[60]	Ravera et al. (2016)[61]	Chen et al. (2017)[20]	Zhang et al. (2017)[23]	Li et al. (2018)[62]	Caruso et al. (2019)[63]	Cui et al. (2022)[64]	Saif et al. (2022)[22]	D'Anto et al. (2023)[19]	Lin et al. (2023)[65]	Loberto et al. (2023)[21]	Wu et al. (2021)[66]	Rota et al. (2022)[67]
1. Study Design (6)	A. Objective: objective clearly formulated	⊕	⊕	⊕	⊕	⊕	⊕	⊕	⊕	⊕	⊕	⊕	⊕	⊕
	B. Sample size: considered adequate and estimated before collection of data	⊕	⊕	?	⊖	?	?	?	⊕	?	⊖	⊕	?	⊕
	C. Baseline characteristics: similar baseline characteristics	⊕	⊕	?	?	⊕	?	⊕	⊕	⊕	⊕	⊕	⊕	⊕
	D. Co-interventions	⊕	⊕	⊕	⊕	⊕	⊕	⊕	?	⊕	⊕	⊕	⊕	⊕
	E. Randomization													
	Random sampling	⊕	⊖	⊖	⊖	⊖	⊖	⊖	⊖	⊖	⊖	⊖	⊖	⊖
	Random allocation of treatment	⊕	⊖	⊖	⊖	⊖	⊖	⊖	⊖	⊖	⊖	⊖	⊖	⊖
2. Study Measurements (5)	F. Measurement method: appropriate to the objective	⊕	⊕	⊕	⊕	?	⊕	⊕	⊕	⊕	⊕	⊕	⊕	⊕
	G. Blind measurement: blinding													
	Blinding (examiner)	⊕	⊕	⊖	⊖	⊖	⊕	⊖	⊖	⊖	⊖	⊖	⊖	⊕
	Blinding (statistician)	⊕	⊖	⊖	⊖	⊖	⊖	⊖	⊖	⊖	⊖	⊖	⊖	⊖
	H. Reliability													
	Reliability described? (intra-rater reliability)	⊕	⊕	⊖	?	⊖	⊕	⊖	⊕	⊕	⊕	⊕	⊖	⊖
	Adequate level of agreement? (inter-rater reliability)	⊖	⊕	⊖	⊖	⊖	⊖	⊖	⊕	⊕	⊖	⊖	⊖	⊖
3. Statistical Analysis (5)	I. Statistical analysis													
	Appropriate for data	⊕	⊕	⊕	⊖	⊖	⊕	⊕	⊕	⊕	⊕	⊕	⊖	⊕
	Combined subgroup analysis	⊕	⊕	⊕	⊖	⊖	⊕	⊕	⊕	⊕	⊕	⊕	⊖	⊕
	J. Cofounders (co-interventions): confounders included in the analysis	⊕	⊕	⊖	⊖	⊖	⊕	⊕	?	⊕	⊕	⊕	⊖	⊕
	K. Statistical significance level													
	p-value stated?	⊕	⊕	⊕	⊖	⊕	⊕	⊕	⊕	⊕	⊕	⊕	⊕	⊕
	Confidence intervals stated?	⊖	⊕	⊖	⊖	⊖	⊖	⊖	⊖	⊕	⊖	⊕	⊖	⊕
4. Other	L. Clinical significance	⊕	⊕	⊕	?	⊕	⊕	⊕	⊕	⊕	⊕	⊕	⊕	⊕
	Total score	15	14	7	3	5	10	9	10	12	10	12	6	12
	Percentage of the total	88.24	82.35	41.18	17.65	29.41	58.82	52.94	58.82	70.59	58.82	70.59	35.29	70.59
Risk of bias		MED	MED	MED	HIGH	HIGH	HIGH	HIGH	MED	MED	HIGH	HIGH	HIGH	HIGH

3.3. Demographic Data

The main characteristics of the included studies are summarized in **Table 3**. Five [19,21,22,60,66] of the studies were prospective, five [61,63-65,67] were retrospective, and three [20,23,62] had an unclear study type. A total of 11 studies evaluated maxillary molar distalization.[19-23,60-65] Wu et al.[66] and Rota et al.[67] were the only studies that evaluated mandibular molar distalization. Most of the studies utilized Invisalign as their choice of clear aligner, but an article by Zhang et al.[23] used Angel Aligner and an article by D'Anto et al.[19] used Ordoline aligners. Articles by Li et al.[62] and Cui et al.[64] did not identify what clear aligner brands were used.

Table 3. Characteristics of the thirteen included studies. F: female, M: male, CBCT: cone–beam computed tomography, Y: yes, N: no.

Study	Study Type	Maxillary or Mandibular	Patient Age (Years)	Sample Size (F/M)	Clear Aligner Brand	Post-Distalization Records			Post-Treatment Records		
						Digital Model	Lateral Ceph	CBCT	Digital Model	Lateral Ceph	CBCT
Garino et al. (2016)[60]	Prospective	Maxillary	30.5	30 (18F/12M)	Invisalign	-	-	-	N	Y	N
Ravera et al. (2016)[61]	Retrospective	Maxillary	29.73 ± 6.89	20 (11F/8M)	Invisalign	-	-	-	N	Y	N
Chen et al. (2017)[20]	Unclear	Maxillary	25.3 (14–43)	15	Invisalign	Y	N	N	-	-	-
Zhang et al. (2017)[23]	Unclear	Maxillary	14.0 ± 3.1	7 (5F/2M)	Angel Aligner	Y	N	N	-	-	-
Li et al. (2018)[62]	Unclear	Maxillary	25.3 (21–34)	11 (7F/4M)	Unclear	-	-	-	Y	Y	N
Caruso et al. (2019)[63]	Retrospective	Maxillary	22.7 ± 5.3	10 (8F/2M)	Invisalign	-	-	-	N	Y	N
Cui et al. (2022)[64]	Retrospective	Maxillary	27.8 ± 5.38 (18–38)	18	Unclear	-	-	-	N	N	Y
Saif et al. (2022)[22]	Prospective	Maxillary	25.4 (17–39)	38 (34F/4M)	Invisalign	Y	N	N	-	-	-
D'Anto et al. (2023)[19]	Prospective	Maxillary	25.7 ± 8.8 (18–45.5)	16 (12F/4M)	Ordoline aligner	Y	N	N	-	-	-
Lin et al. (2023)[65]	Retrospective	Maxillary	26.64 ± 3.02 (23.1–31.5)	7	Invisalign	-	-	-	Y	N	Y
Loberto et al. (2023)[21]	Prospective	Maxillary	14.9 ± 6	49 (27F/22M)	Invisalign	Y	N	N	-	-	-
Wu et al. (2021)[66]	Prospective	Mandibular	>18	20 (12F/8M)	Invisalign	N	N	Y	-	-	-
Rota et al. (2022)[67]	Retrospective	Mandibular	25.6 ± 4.5	16 (8F/8M)	Invisalign	-	-	-	N	Y	N

In terms of the type and timing of treatment records, six studies (five for maxillary molar distalization[19-23] and one for mandibular molar distalization[66]) evaluated post-distalization records, and seven studies (six for maxillary molar distalization[60-65,68] and one for mandibular molar distalization[67]) evaluated post-treatment

records. Within each time point, a mixture of dental model, lateral cephalometric analysis, and CBCT analysis were presented among the studies. Thus, the data collection and analysis were sub-grouped based on the arch in which distalization was performed as well as the timing and type of records provided in each included article.

3.4. Maxillary Molar Distalization

The amount of maxillary molar distalization was evaluated on post-treatment and post-distalization dental models (**Table 4**) and post-treatment radiographs (**Table 5**). Distalization was measured based on varying parameters.

Table 4. The amount of maxillary molar distalization in millimeters (mm) evaluated on the dental model. The data are reported as mean ± standard deviation.

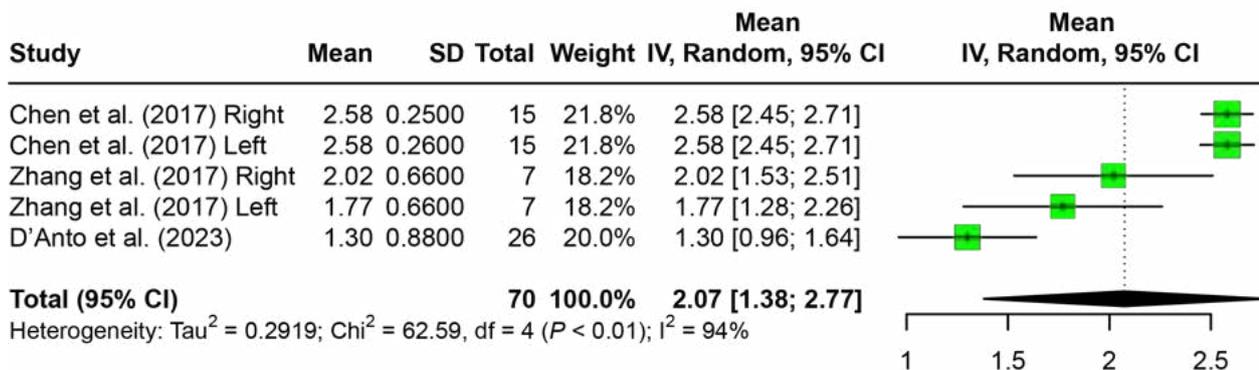| Time Points	Tooth	Parameters	References	Amount of Distalization
Post-distalization	U6	MB cusp (mm)	Chen et al. (2017) Right[20]	2.58 ± 0.25
			Chen et al. (2017) Left[20]	2.58 ± 0.26
			Zhang et al. (2017) Right[23]	2.02 ± 0.66 *
			Zhang et al. (2017) Left[23]	1.77 ± 0.66 *
			D'Anto et al. (2023)[19]	1.30 ± 0.88
			Loberto et al. (2023) Right[21]	2.4
			Loberto et al. (2023) Left[21]	2.4
		DB cusp (mm)	D'Anto et al. (2023)[19]	1.42 ± 0.94
			Loberto et al. (2023) Right[21]	3.0
			Loberto et al. (2023) Left[21]	2.2
		CC [5] (mm)	Saif et al. (2022)[22]	1.81 ± 0.84
	U7	MB cusp (mm)	Chen et al. (2017) Right[20]	2.68 ± 0.50
			Chen et al. (2017) Left[20]	2.57 ± 0.26
			D'Anto et al. (2023)[19]	1.76 ± 1.14
		DB cusp (mm)	D'Anto et al. (2023)[19]	1.54 ± 1.13
		CC (mm)	Saif et al. (2022)[22]	1.85 ± 0.88
Post-treatment	U6	Molar sagittal distance (mm)	Li et al. (2018)[62]	2.12 ± 1.09
		MB cusp (mm)	Lin et al. (2023)[65]	0.67 ± 0.50 $
		DB cusp (mm)	Lin et al. (2023)[65]	0.84 ± 0.60 $
		MP cusp [6] (mm)	Lin et al. (2023)[65]	0.36 ± 0.40 $

U6: maxillary first molar; U7: maxillary second molar; MB: mesiobuccal; DB: distobuccal; CC: center of crown; MP: mesiopalatal; *: average and standard deviation calculated based on data provided on the distalization of maxillary molars obtained from seven patients; $: data from a dental model incorporated into CBCT

Meta-analyses (**Figure 2**) were performed on the amount of maxillary first and second molar mesiobuccal cusp distalization evaluated on post-distalization dental models. The maxillary first and second molars showed significant distalization of 2.07 mm [1.38 mm, 2.77 mm] and 2.38 mm [1.19 mm, 3.57 mm], respectively.

Meta-analyses were also performed on the amount of maxillary first (U6, **Figure 3**) and second molar (U7, **Figure 4**) distalization evaluated on radiographic images. A random effects model was used for meta-analysis for the parameters U6 and U7 PtV-CC (distance between the pterygoid vertical plane and the center of the crown of the maxillary molar), PtV-MC (distance between the pterygoid vertical plane and the mesial cusp of maxillary molar), PtV-PRA (distance between the pterygoid vertical plane and the palatal root apex of the maxillary molar), and PtV-VMRA (distance between the pterygoid vertical plane and the vestibulomesial root apex of maxillary molar). Of the four parameters analyzed for the U6 distalization evaluated on radiographic images, both parameters at the crown level showed a significant amount of distalization, while both parameters at the root level showed non-significant distalization (**Figure 3**). Of the four parameters analyzed for U7

distalization evaluated on radiographic images, parameters at the crown level as well as at the palatal root apex showed a significant amount of distalization, while the mesial buccal root apex did not (**Figure 4**).

A. Amount of maxillary first molar mesiobuccal cusp distalization evaluated on post-distalization dental model

Study	Mean	SD	Total	Weight	Mean IV, Random, 95% CI
Chen et al. (2017) Right	2.58	0.2500	15	21.8%	2.58 [2.45; 2.71]
Chen et al. (2017) Left	2.58	0.2600	15	21.8%	2.58 [2.45; 2.71]
Zhang et al. (2017) Right	2.02	0.6600	7	18.2%	2.02 [1.53; 2.51]
Zhang et al. (2017) Left	1.77	0.6600	7	18.2%	1.77 [1.28; 2.26]
D'Anto et al. (2023)	1.30	0.8800	26	20.0%	1.30 [0.96; 1.64]
Total (95% CI)			70	100.0%	2.07 [1.38; 2.77]

Heterogeneity: Tau^2 = 0.2919; Chi^2 = 62.59, df = 4 ($P < 0.01$); I^2 = 94%

B. Amount of maxillary second molar mesiobuccal cusp distalization evaluated on post-distalization dental model

Study	Mean	SD	Total	Weight	Mean IV, Random, 95% CI
Chen et al. (2017) Right	2.68	0.5000	15	34.8%	2.68 [2.43; 2.93]
Chen et al. (2017) Left	2.57	0.2600	15	37.1%	2.57 [2.44; 2.70]
D'Anto et al. (2023)	1.76	1.1400	20	28.1%	1.76 [1.26; 2.26]
Total (95% CI)			50	100.0%	2.38 [1.19; 3.57]

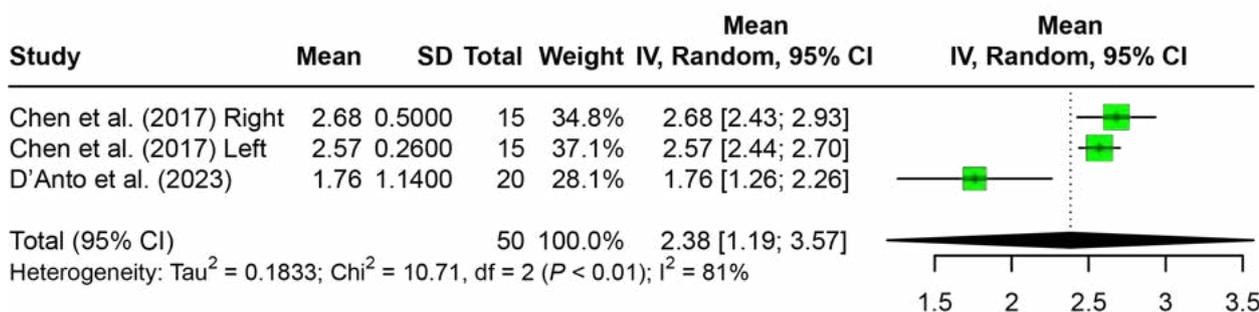Heterogeneity: Tau^2 = 0.1833; Chi^2 = 10.71, df = 2 ($P < 0.01$); I^2 = 81%

Figure 2. Forest plots for the amount of maxillary molar distalization evaluated on the dental model. SD: standard deviation; CI: confidence interval.[19,20,23]
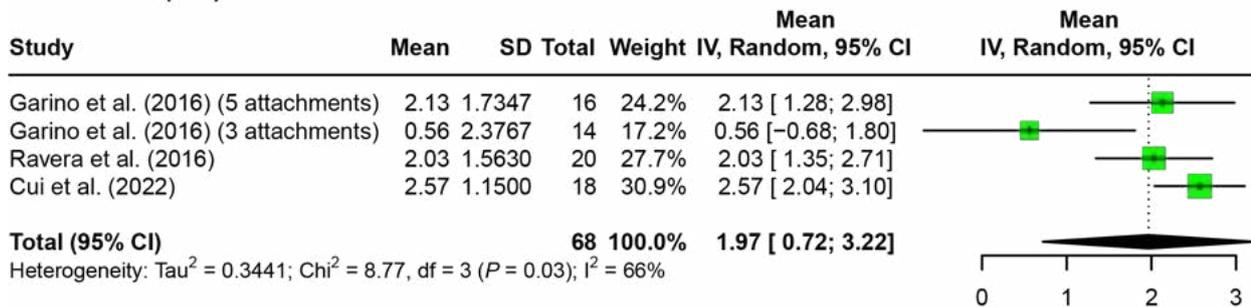
Table 5. The amount of maxillary molar distalization in millimeters (mm) was evaluated on the radiographic images. The data are reported as either mean ± standard deviation or mean [95% confidence interval].

Time Points	Tooth	Parameters	References	Amount of Distalization
Post-treatment	U6	PtV-CC (mm)	Garino et al. (2016) (5 attachments)[60]	2.13 [1.28, 2.98]
			Garino et al. (2016) (3 attachments)[60]	0.56 [−0.68, 1.81]
			Ravera et al. (2016)[61]	2.03 [1.35, 2.72]
			Cui et al. (2022)[64]	2.57 ± 1.15 *
		PtV-MC (mm)	Garino et al. (2016) (5 attachments)[60]	1.84 [−0.56, 4.24]
			Garino et al. (2016) (3 attachments)[60]	1.52 [−0.07, 2.97]
			Ravera et al. (2016)[61]	2.25 [0.29, 4.21]
		PtV-PRA (mm)	Garino et al. (2016) (5 attachments)[60]	1.71 [0.83, 2.60]
			Garino et al. (2016) (3 attachments)[60]	0.24 [−1.43, 1.91]
			Ravera et al. (2016)[61]	1.84 [0.82, 2.86]
		PtV-VMRA (mm)	Garino et al. (2016) (5 attachments)[60]	1.75 [0.78, 2.71]
			Garino et al. (2016) (3 attachments[60]	−0.20 [−1.62, 1.21]
			Ravera et al. (2016)[61]	1.48 [0.57, 2.40]
		UMD (mm)	Li et al. (2018)[62]	2.32 ± 0.84
	U7	PtV-CC (mm)	Garino et al. (2016) (5 attachments)[60]	1.71 [1.00, 2.42]
			Garino et al. (2016) (3 attachments)[60]	1.02 [−0.11, 2.15]
			Ravera et al. (2016)[61]	2.12 [1.48, 2.76]
			Cui et al. (2022)[64]	2.98 ± 1.84 *
		PtV-MC (mm)	Garino et al. (2016) (5 attachments)[60]	2.30 [1.53, 3.06]
			Garino et al. (2016) (3 attachments)[60]	1.54 [0.44, 2.64]
			Ravera et al. (2016)[61]	2.52 [1.79, 3.24]
		PtV-PRA (mm)	Garino et al. (2016) (5 attachments)[60]	1.47 [0.89, 2.06]

	Garino et al. (2016) (3 attachments)[60]	0.64 [−0.51, 1.78]
	Ravera et al. (2016)[61]	1.50 [0.94, 2.07]
PtV-VMRA (mm)	Garino et al. (2016) (5 attachments)[60]	1.68 [1.10, 2.25]
	Garino et al. (2016) (3 attachments)[60]	0.65 [−0.55, 1.86]
	Ravera et al. (2016) [61]	1.67 [1.03, 2.31]

U6: maxillary first molar; U7: maxillary second molar; PtV-CC: distance between the pterygoid vertical plane and the center of the crown of the maxillary molar; PtV-MC: distance between the pterygoid vertical plane and the mesial cusp of the maxillary molar; PtV-PRA: distance between the pterygoid vertical plane and the palatal root apex of the maxillary molar; PtV-VMRA: distance between the pterygoid vertical plane and the vestibulomesial root apex of the maxillary molar; UMD: upper molar distalization; *: data from lateral cephalometric radiograph extracted from CBCT.
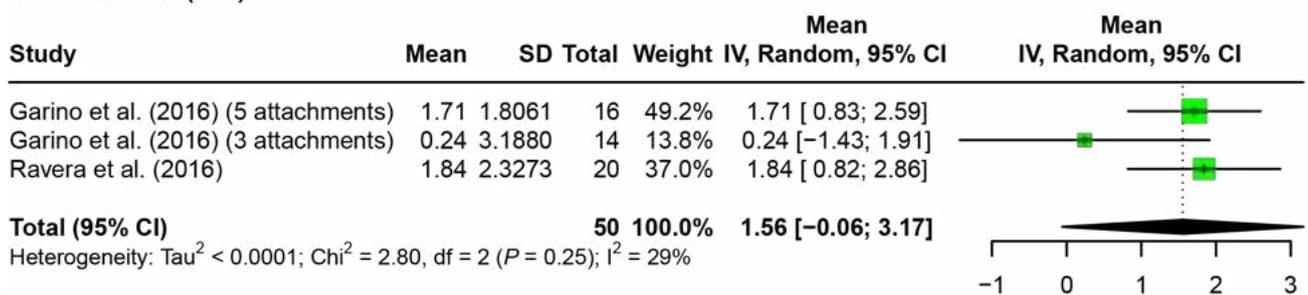
A. U6 PtV-CC (mm):

Study	Mean	SD	Total	Weight	Mean IV, Random, 95% CI
Garino et al. (2016) (5 attachments)	2.13	1.7347	16	24.2%	2.13 [1.28; 2.98]
Garino et al. (2016) (3 attachments)	0.56	2.3767	14	17.2%	0.56 [−0.68; 1.80]
Ravera et al. (2016)	2.03	1.5630	20	27.7%	2.03 [1.35; 2.71]
Cui et al. (2022)	2.57	1.1500	18	30.9%	2.57 [2.04; 3.10]
Total (95% CI)			68	100.0%	1.97 [0.72; 3.22]

Heterogeneity: $Tau^2 = 0.3441$; $Chi^2 = 8.77$, $df = 3$ ($P = 0.03$); $I^2 = 66\%$

B. U6 PtV-MC (mm):

Study	Mean	SD	Total	Weight	Mean IV, Random, 95% CI
Garino et al. (2016) (5 attachments)	1.84	4.8980	16	20.0%	1.84 [−0.56; 4.24]
Garino et al. (2016) (3 attachments)	1.52	2.9017	14	49.9%	1.52 [0.00; 3.04]
Ravera et al. (2016)	2.25	4.4721	20	30.0%	2.25 [0.29; 4.21]
Total (95% CI)			50	100.0%	1.80 [0.84; 2.77]

Heterogeneity: $Tau^2 = 0$; $Chi^2 = 0.33$, $df = 2$ ($P = 0.85$); $I^2 = 0\%$

C. U6 PtV-PRA (mm):

Study	Mean	SD	Total	Weight	Mean IV, Random, 95% CI
Garino et al. (2016) (5 attachments)	1.71	1.8061	16	49.2%	1.71 [0.83; 2.59]
Garino et al. (2016) (3 attachments)	0.24	3.1880	14	13.8%	0.24 [−1.43; 1.91]
Ravera et al. (2016)	1.84	2.3273	20	37.0%	1.84 [0.82; 2.86]
Total (95% CI)			50	100.0%	1.56 [−0.06; 3.17]

Heterogeneity: $Tau^2 < 0.0001$; $Chi^2 = 2.80$, $df = 2$ ($P = 0.25$); $I^2 = 29\%$

D. U6 PtV-VMRA (mm):

Study	Mean	SD	Total	Weight	Mean IV, Random, 95% CI
Garino et al. (2016) (5 attachments)	1.75	1.9694	16	36.0%	1.75 [0.79; 2.71]
Garino et al. (2016) (3 attachments)	−0.20	2.7012	14	26.9%	−0.20 [−1.61; 1.21]
Ravera et al. (2016)	1.48	2.0878	20	37.1%	1.48 [0.57; 2.39]
Total (95% CI)			50	100.0%	1.13 [−1.34; 3.60]

Heterogeneity: $Tau^2 = 0.5762$; $Chi^2 = 5.30$, $df = 2$ ($P = 0.07$); $I^2 = 62\%$
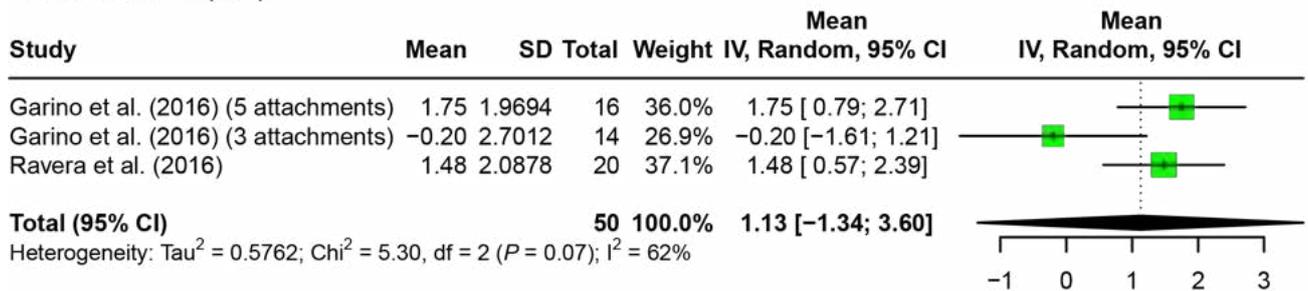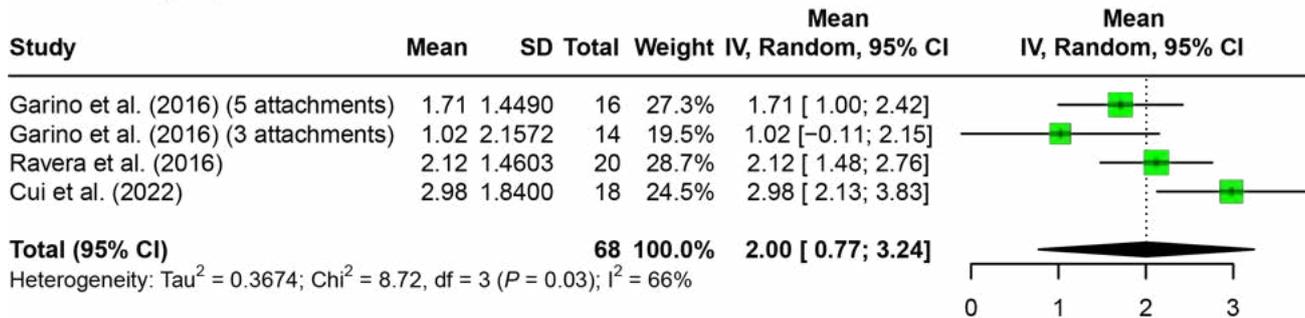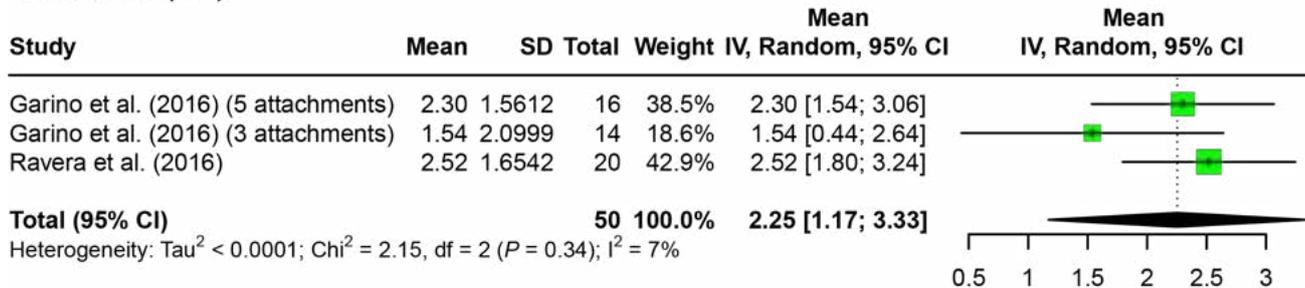
Figure 3. Forest plots for the amount of maxillary first molar distalization evaluated on the radiographic images. U6: maxillary first molar; PtV-CC: distance between the pterygoid vertical plane and the center of the crown of the maxillary molar; PtV-MC: distance between the pterygoid vertical plane and the mesial cusp of the maxillary molar; PtV-PRA: distance between the pterygoid vertical plane and the palatal root apex of the maxillary molar; PtV-VMRA: distance between the pterygoid vertical plane and the vestibulomesial root apex of the maxillary molar; SD: standard deviation; CI: confidence interval.[60,61,64]
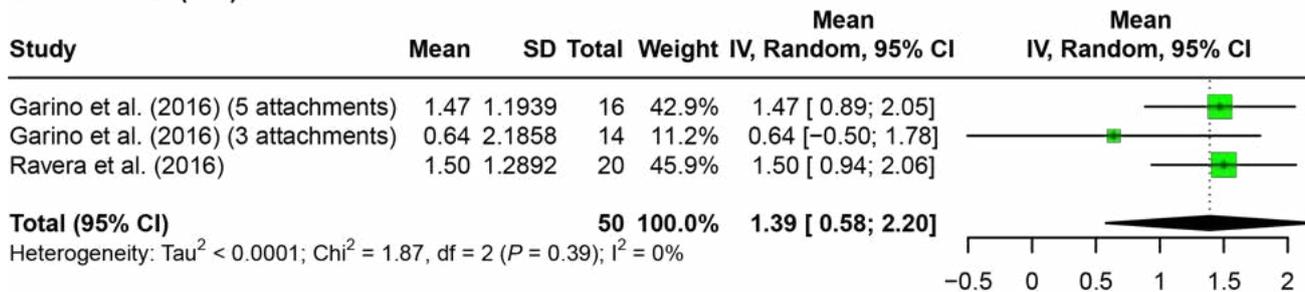
A. U7 PtV-CC (mm):

Study	Mean	SD	Total	Weight	Mean IV, Random, 95% CI
Garino et al. (2016) (5 attachments)	1.71	1.4490	16	27.3%	1.71 [1.00; 2.42]
Garino et al. (2016) (3 attachments)	1.02	2.1572	14	19.5%	1.02 [−0.11; 2.15]
Ravera et al. (2016)	2.12	1.4603	20	28.7%	2.12 [1.48; 2.76]
Cui et al. (2022)	2.98	1.8400	18	24.5%	2.98 [2.13; 3.83]
Total (95% CI)			**68**	**100.0%**	**2.00 [0.77; 3.24]**

Heterogeneity: $Tau^2 = 0.3674$; $Chi^2 = 8.72$, $df = 3$ $(P = 0.03)$; $I^2 = 66\%$

B. U7 PtV-MC (mm):

Study	Mean	SD	Total	Weight	Mean IV, Random, 95% CI
Garino et al. (2016) (5 attachments)	2.30	1.5612	16	38.5%	2.30 [1.54; 3.06]
Garino et al. (2016) (3 attachments)	1.54	2.0999	14	18.6%	1.54 [0.44; 2.64]
Ravera et al. (2016)	2.52	1.6542	20	42.9%	2.52 [1.80; 3.24]
Total (95% CI)			**50**	**100.0%**	**2.25 [1.17; 3.33]**

Heterogeneity: $Tau^2 < 0.0001$; $Chi^2 = 2.15$, $df = 2$ $(P = 0.34)$; $I^2 = 7\%$

C. U7 PtV-PRA (mm):

Study	Mean	SD	Total	Weight	Mean IV, Random, 95% CI
Garino et al. (2016) (5 attachments)	1.47	1.1939	16	42.9%	1.47 [0.89; 2.05]
Garino et al. (2016) (3 attachments)	0.64	2.1858	14	11.2%	0.64 [−0.50; 1.78]
Ravera et al. (2016)	1.50	1.2892	20	45.9%	1.50 [0.94; 2.06]
Total (95% CI)			**50**	**100.0%**	**1.39 [0.58; 2.20]**

Heterogeneity: $Tau^2 < 0.0001$; $Chi^2 = 1.87$, $df = 2$ $(P = 0.39)$; $I^2 = 0\%$

D. U7 PtV-VMRA (mm):

Study	Mean	SD	Total	Weight	Mean IV, Random, 95% CI
Garino et al. (2016) (5 attachments)	1.47	1.6800	16	26.7%	1.47 [0.65; 2.29]
Garino et al. (2016) (3 attachments)	0.64	0.6500	14	43.7%	0.64 [0.30; 0.98]
Ravera et al. (2016)	1.50	1.6700	20	29.6%	1.50 [0.77; 2.23]
Total (95% CI)			**50**	**100.0%**	**1.12 [−0.16; 2.39]**

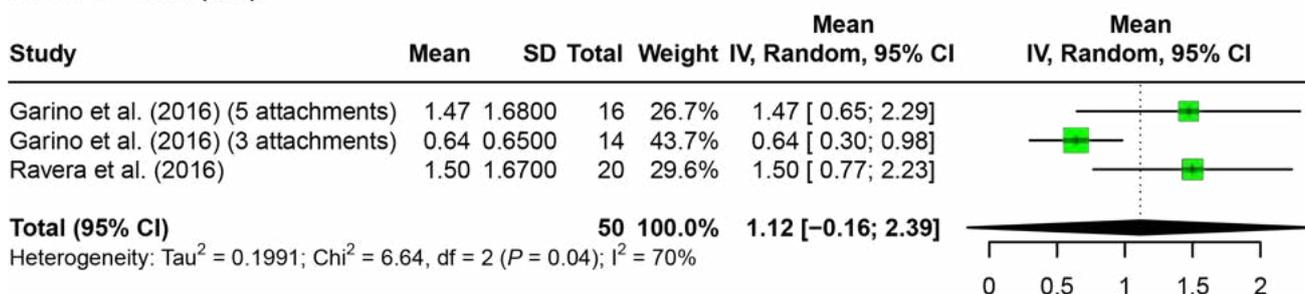Heterogeneity: $Tau^2 = 0.1991$; $Chi^2 = 6.64$, $df = 2$ $(P = 0.04)$; $I^2 = 70\%$

Figure 4. Forest plots for the amount of maxillary second molar distalization evaluated on the radiographic images. U7: maxillary second molar; PtV-CC: distance between the pterygoid vertical plane and the center of the crown of the maxillary molar; PtV-MC: distance between the pterygoid vertical plane and the mesial cusp of the maxillary molar; PtV-PRA: distance between the pterygoid vertical plane and the palatal root apex of the maxillary molar; PtV-VMRA: distance between the pterygoid vertical plane and the vestibulomesial root apex of the maxillary molar; SD: standard deviation; CI: confidence interval.[60,61,64]

3.5. Maxillary Molar Rotation and Tipping

Maxillary molar rotation accompanying maxillary molar distalization was only evaluated on post-distalization and post-treatment dental models (**Table 6**). Maxillary molar tipping accompanying maxillary molar distalization was evaluated on post-treatment radiograph images and dental models (**Table 7**).

Table 6. The amount of maxillary molar rotation in degrees (°) during maxillary molar distalization was evaluated on the dental model. The data are reported as mean ± standard deviation.

Time Points	Tooth	Parameters	References	Distal In–Mesial Out Rotation
Post-distalization	U6	MB-DP (°)	Chen et al. (2017) Right[20]	0.93 ± 3.51
			Chen et al. (2017) Left[20]	0.75 ± 1.74
		DB-MP (°)	D'Anto et al. (2023)[19]	8.09 ± 4.80
	U7	MB-DP (°)	Chen et al. (2017) Right[20]	0.85 ± 2.20
			Chen et al. (2017) Left[20]	0.86 ± 2.16
		DB-MP (°)	D'Anto et al. (2023)[19]	6.40 ± 4.14
Post-treatment	U6	Molar rotation (°)	Li et al. (2018)[62]	3.77 ± 4.88

U6: maxillary first molar; U7: maxillary second molar; MB-DP: mesiobuccal cusp–distopalatal cusp displacement angulation; DB-MP: distobuccal cusp–mesiopalatal cusp displacement angulation.

Table 7. The amount of maxillary molar tipping in degrees (°) during maxillary molar distalization. The data are reported as either mean ± standard deviation or mean [95% confidence interval].

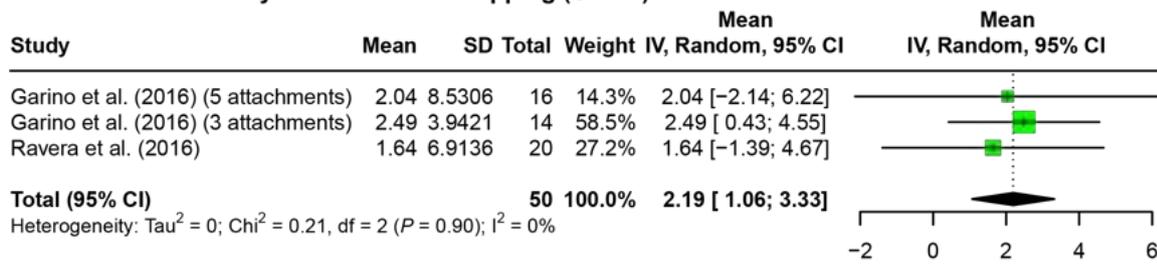| Time Points	Tooth	Parameters	References	Distal Tipping
Post-treatment	U6	UM-SN (°)	Li et al. (2018)[62]	3.83 ± 1.37
		U6-SN (°)	Cui et al. (2022)[64]	3.43 ± 2.71 *
		U6-PP (°)	Garino et al. (2016) (5 attachments)[60]	2.04 [−2.14, 6.22]
			Garino et al. (2016) (3 attachments)[60]	2.49 [0.42, 4.55]
			Ravera et al. (2016)[61]	1.64 [−1.39, 4.67]
			Caruso et al. (2019)[63]	1.3 &
		Distal tipping (evaluated on the dental model, °)	Zhang et al. (2017) Right[23]	5.70 ± 3.03 $
			Zhang et al. (2017) Left[23]	4.09 ± 3.30 $
	U7	U7-SN (°)	Cui et al. (2022)[64]	4.34 ± 3.28 *
		U7-PP (°)	Garino et al. (2016) (5 attachments)[60]	2.34 [−1.54, 6.22]
			Garino et al. (2016) (3 attachments)[60]	1.35 [−1.97, 4.66]
			Ravera et al. (2016)[61]	2.64 [−0.06, 5.37]
			Caruso et al. (2019)[63]	−0.6 &

U6: maxillary first molar; U7: maxillary second molar; UM-SN: maxillary molar sella-nasion angle; U6-SN: maxillary first molar sella-nasion angle; U6-PP: maxillary first molar palatal plane angle; U7-SN: maxillary second molar sella-nasion angle; U7-PP: maxillary second molar palatal plane angle; *: data from lateral cephalometric radiograph extracted from CBCT; &: data calculated based on post-treatment mean value—pre-treatment mean value provided in the article; $: average and standard deviation calculated based on the individual data of seven patients.

Due to the high heterogeneity of the parameters reported in the included studies, a meta-analysis could only be performed on the amount of maxillary first and second molar distal tipping in reference to the palatal plane on post-treatment radiographic images (**Figure 5**). The analysis revealed 2.19° [1.06°, 3.33°] of crown distal tipping of U6s and 2.17° [0.46°, 3.89°] of crown distal tipping of U7s.

3.6. Anterior Anchorage Loss after Maxillary Molar Distalization

The amount of anchorage loss on both upper and lower arches during maxillary molar distalization was evaluated on both dental models (**Table 8**) and radiographic images (**Table 9**).

A. Amount of maxillary first molar distal tipping (U6-PP)

Study	Mean	SD	Total	Weight	Mean IV, Random, 95% CI
Garino et al. (2016) (5 attachments)	2.04	8.5306	16	14.3%	2.04 [−2.14; 6.22]
Garino et al. (2016) (3 attachments)	2.49	3.9421	14	58.5%	2.49 [0.43; 4.55]
Ravera et al. (2016)	1.64	6.9136	20	27.2%	1.64 [−1.39; 4.67]
Total (95% CI)			50	100.0%	2.19 [1.06; 3.33]

Heterogeneity: Tau^2 = 0; Chi^2 = 0.21, df = 2 (P = 0.90); I^2 = 0%

B. Amount of maxillary second molar distal tipping (U7-PP)

Study	Mean	SD	Total	Weight	Mean IV, Random, 95% CI
Garino et al. (2016) (5 attachments)	2.34	7.9184	16	22.7%	2.34 [−1.54; 6.22]
Garino et al. (2016) (3 attachments)	1.35	6.3284	14	31.0%	1.35 [−1.96; 4.66]
Ravera et al. (2016)	2.64	6.1948	20	46.3%	2.64 [−0.07; 5.35]
Total (95% CI)			50	100.0%	2.17 [0.46; 3.89]

Heterogeneity: Tau^2 = 0; Chi^2 = 0.36, df = 2 (P = 0.84); I^2 = 0%

Figure 5. Forest plot for the amount of maxillary molar distal tipping after maxillary molar distalization. U6-PP: maxillary first molar–palatal plane angle; U7-PP: maxillary second molar–palatal plane angle; SD: standard deviation; CI: confidence interval.[60,61]

Table 8. The amount of anchorage loss during maxillary molar distalization was evaluated on the dental model. A positive value indicates the protrusion and proclination of the anterior teeth. The data are reported as mean ± standard deviation.

Time Points	Arch	Parameters	References	Amount of Change
Post-distalization	Same arch	U1 protrusion (mm)	Chen et al. (2017) Right[20]	0.34 ± 0.29
			Chen et al. (2017) Left[20]	0.34 ± 0.37
			Zhang et al. (2017) Right[23]	0.25 ± 0.85 *
			Zhang et al. (2017) Left[23]	0.14 ± 0.74 *
			Saif et al. (2022)[22]	0.48 ± 0.435
		U2 protrusion (mm)	Saif et al. (2022)[22]	0.45 ± 0.384
		U3 mesialization (mm)	Loberto et al. (2023) Right[21]	1.5
			Loberto et al. (2023) Left[21]	1.15
			Saif et al. (2022)[22]	0.27 ± 0.250
		U1 proclination (°)	Zhang et al. (2017) Right[23]	−1.94 ± 2.61 *
			Zhang et al. (2017) Left[23]	−1.02 ± 2.55 *
Post-treatment	Opposing arch	L1s incisal edge (mm)	Lin et al. (2023)[65]	1.21 ± 0.86 &
	Same arch	U1 incisal edge (mm)	Lin et al. (2023)[65]	−0.81 ± 0.89 &

U1: maxillary central incisor; U2: maxillary lateral incisor; U3: maxillary canine; L1s: mandibular central incisors; *: average and standard deviation calculated based on the individual data of seven patients; &: data from the model integrated into CBCT.

Table 9. The amount of anterior anchorage loss during maxillary molar distalization was evaluated on the radiographic images. A positive value indicates the protrusion and proclination of the anterior teeth.

Time Points	Arch	Parameters	References	Amount of Change
Post-treatment	Same arch	IE-PTV (mm)	Garino et al. (2016) (5 attachments)[60]	−2.48 [−4.00, −0.96]
			Garino et al. (2016) (3 attachments)[60]	0.13 [−1.82, 2.08]
			Ravera et al. (2016)[61]	−2.23 [−3.76, −0.70]
			Cui et al. (2022)[64]	−1.40 ± 0.25&
		CC-PTV (mm)	Garino et al. (2016) (5 attachments)[60]	−1.58 [−3.11, −0.05]
			Garino et al. (2016) (3 attachments)[60]	0.83 [−1.04, 2.69]
			Ravera et al. (2016)[61]	−1.31 [−2.83, 0.21]
		RA-PTV (mm)	Garino et al. (2016) (5 attachments)[60]	−1.31 [−3.06, 0.45]
			Garino et al. (2016) (3 attachments)[60]	1.86 [−0.28, 4.00]

		Ravera et al. (2016)[61]	−0.81 [−2.35, 0.73]
	U1D (mm)	Li et al. (2018) [62]	1.45 ± 0.94
	U1-PP (°)	Garino et al. (2016) (5 attachments)[60]	−1.57 [−5.57, 2.43]
		Garino et al. (2016) (3 attachments)[60]	−4.12 [−7.03, −1.21]
		Ravera et al. (2016)[61]	−2.87 [−5.06, −0.69]
		Caruso et al. (2019)[63]	−13.5 *
	U1-SN (°)	Li et al. (2018)[62]	1.72 ± 1.06
		Cui et al. (2022)[64]	−7.04 ± 1.27 [&]
		Lin et al. (2023)[65]	−5.03 *
Opposing arch	L1-MP (°)	Li et al. (2018)[62]	3.82 ± 2.19
		Lin et al. (2023)[65]	6.57 *

IE-PTV: incisal edge–pterygoid vertical; CC-PTV: center of crown–pterygoid vertical; RA-PTV: root apex–pterygoid vertical; U1D: upper incisor distalization; U1-PP: upper incisor–palatal plane angle; U1-SN: upper incisor–sella-nasion angle; L1-MP: lower incisor–mandibular plane angle; *: data calculated based on the difference between the mean value of post-treatment incisor angulation and the mean value of pre-treatment incisor angulation; [&]: data from CBCT.

Meta-analyses were conducted on the amount of maxillary central incisor protrusion based on the evaluation of pre-treatment and post-distalization dental models (**Figure 6**) as well as on the amount of maxillary central incisor protrusion and proclination based on the evaluation of pre- and post-treatment radiographic analysis (**Figure 7**). At the post-distalization time point, 0.39 mm [0.27 mm, 0.51 mm] of maxillary central incisor protrusion was observed (**Figure 6**). At the post-treatment time point, 1.50 mm [0.39 mm, 2.61 mm] of central incisor retraction at the incisal edge level (IE-PTV) was observed, while no significant amount of retraction was observed of the central incisor at the crown level (CC-PTV, −0.78 mm [−3.95 mm, 2.39 mm]) or at the root apex level (RA-PTV, −0.20 mm [−4.28 mm, 3.89 mm]). Slight incisal retroclination was observed based on the U1-PP angle (−3.40° [−5.61°, −0.47°]), but not based on the U1-SN angle (−2.66° [−58.31°, 52.99°]) (**Figure 7**). Meta-analyses could not be performed on the opposing arch evaluations due to insufficient data.

Figure 6. Forest plot for the amount of maxillary central incisor protrusion after maxillary molar distalization based on the evaluation of pre-treatment and post-distalization dental models. SD: standard deviation; CI: confidence interval.[20,22,23]
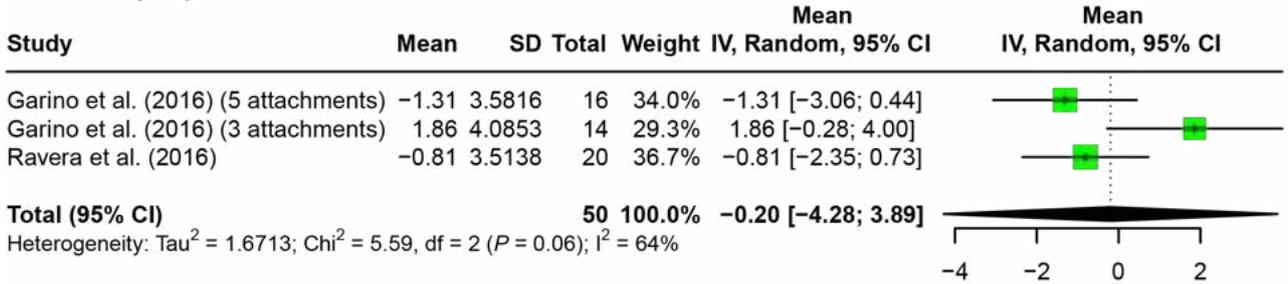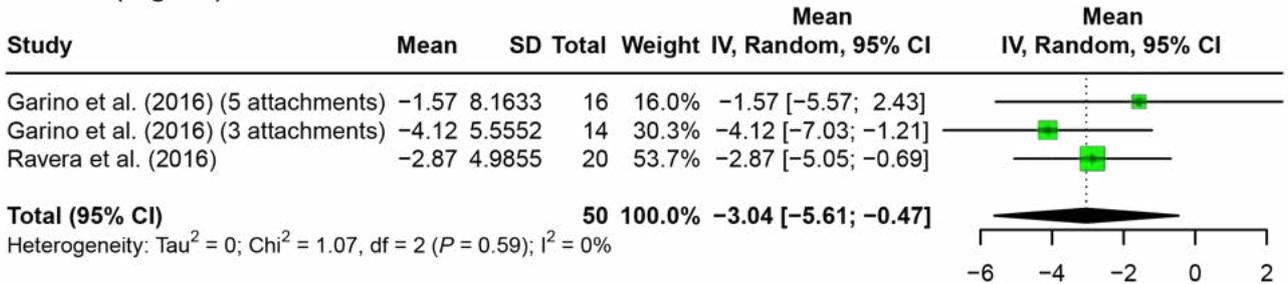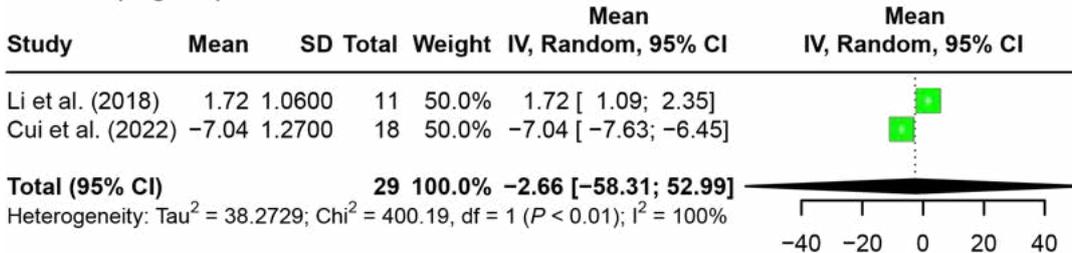
A. IE-PTV (mm)

Study	Mean	SD	Total	Weight	Mean IV, Random, 95% CI
Garino et al. (2016) (5 attachments)	−2.48	3.1020	16	11.2%	−2.48 [−4.00; −0.96]
Garino et al. (2016) (3 attachments)	0.13	3.7226	14	7.2%	0.13 [−1.82; 2.08]
Ravera et al. (2016)	−2.23	3.4910	20	11.0%	−2.23 [−3.76; −0.70]
Cui et al. (2022)	−1.40	0.2500	18	70.6%	−1.40 [−1.52; −1.28]
Total (95% CI)			68	100.0%	−1.50 [−2.61; −0.39]

Heterogeneity: $Tau^2 = 0.1087$; $Chi^2 = 5.43$, df = 3 ($P = 0.14$); $I^2 = 45\%$

B. CC-PTV (mm)

Study	Mean	SD	Total	Weight	Mean IV, Random, 95% CI
Garino et al. (2016) (5 attachments)	−1.58	3.1224	16	35.3%	−1.58 [−3.11; −0.05]
Garino et al. (2016) (3 attachments)	0.83	3.5603	14	29.3%	0.83 [−1.03; 2.69]
Ravera et al. (2016)	−1.31	3.4682	20	35.5%	−1.31 [−2.83; 0.21]
Total (95% CI)			50	100.0%	−0.78 [−3.95; 2.39]

Heterogeneity: $Tau^2 = 0.8283$; $Chi^2 = 4.34$, df = 2 ($P = 0.11$); $I^2 = 54\%$

C. RA-PTV (mm)

Study	Mean	SD	Total	Weight	Mean IV, Random, 95% CI
Garino et al. (2016) (5 attachments)	−1.31	3.5816	16	34.0%	−1.31 [−3.06; 0.44]
Garino et al. (2016) (3 attachments)	1.86	4.0853	14	29.3%	1.86 [−0.28; 4.00]
Ravera et al. (2016)	−0.81	3.5138	20	36.7%	−0.81 [−2.35; 0.73]
Total (95% CI)			50	100.0%	−0.20 [−4.28; 3.89]

Heterogeneity: $Tau^2 = 1.6713$; $Chi^2 = 5.59$, df = 2 ($P = 0.06$); $I^2 = 64\%$

D. U1-PP (degrees)

Study	Mean	SD	Total	Weight	Mean IV, Random, 95% CI
Garino et al. (2016) (5 attachments)	−1.57	8.1633	16	16.0%	−1.57 [−5.57; 2.43]
Garino et al. (2016) (3 attachments)	−4.12	5.5552	14	30.3%	−4.12 [−7.03; −1.21]
Ravera et al. (2016)	−2.87	4.9855	20	53.7%	−2.87 [−5.05; −0.69]
Total (95% CI)			50	100.0%	−3.04 [−5.61; −0.47]

Heterogeneity: $Tau^2 = 0$; $Chi^2 = 1.07$, df = 2 ($P = 0.59$); $I^2 = 0\%$

E. U1-SN (degrees)

Study	Mean	SD	Total	Weight	Mean IV, Random, 95% CI
Li et al. (2018)	1.72	1.0600	11	50.0%	1.72 [1.09; 2.35]
Cui et al. (2022)	−7.04	1.2700	18	50.0%	−7.04 [−7.63; −6.45]
Total (95% CI)			29	100.0%	−2.66 [−58.31; 52.99]

Heterogeneity: $Tau^2 = 38.2729$; $Chi^2 = 400.19$, df = 1 ($P < 0.01$); $I^2 = 100\%$

Figure 7. Forest plot for the amount of maxillary central incisor protrusion and proclination after maxillary molar distalization based on the evaluation of pre- and post-treatment radiographic analysis. IE-PTV: incisal edge–pterygoid vertical; CC-PTV: center of crown–pterygoid vertical; RA-PTV: root apex–pterygoid vertical; U1-PP: upper incisor–palatal plane angle; U1-SN: upper incisor–sella-nasion angle; SD: standard deviation; CI: confidence interval.[60-62,64]

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3.7. Mandibular Molar Distalization

The amount of mandibular molar distalization (**Table 10**), mandibular molar tipping (**Table 11**), and anterior anchorage loss after mandibular molar distalization (**Table 12**) was evaluated on post-distalization and post-treatment radiographic images with one study available from each time point. Further analysis of mandibular molar distalization with a clear aligner sequential distalization protocol was not possible due to insufficient data.

Table 10. The amount of mandibular molar distalization in millimeters (mm) was evaluated on the radiographic images. The data are reported as either mean ± standard deviation or mean ± standard error (SE).

Time Points	Tooth	Parameters	References	Amount of Distalization
Post-distalization	L6	MBC (mm)	Wu et al. (2021)[66]	0.78 ± 0.33
		DBC (mm)	Wu et al. (2021)[66]	0.91 ± 0.31
		MLC (mm)	Wu et al. (2021)[66]	0.56 ± 0.89
		DLC (mm)	Wu et al. (2021)[66]	0.62 ± 0.84
		MRA (mm)	Wu et al. (2021)[66]	0.29 ± 1.08
		DRA (mm)	Wu et al. (2021)[66]	0.28 ± 0.66
		CC (mm)	Wu et al. (2021)[66]	0.53 ± 1.37
		RC (mm)	Wu et al. (2021)[66]	0.41 ± 0.96
	L7	MBC (mm)	Wu et al. (2021)[66]	0.81 ± 1.46
		DBC (mm)	Wu et al. (2021)[66]	1.06 ± 0.65
		MLC (mm)	Wu et al. (2021)[66]	0.64 ± 1.19
		DLC (mm)	Wu et al. (2021)[66]	0.72 ± 1.07
		MRA (mm)	Wu et al. (2021)[66]	0.30 ± 1.01
		DRA (mm)	Wu et al. (2021)[66]	0.27 ± 0.82
		CC (mm)	Wu et al. (2021)[66]	0.59 ± 0.94
		RC (mm)	Wu et al. (2021)[66]	0.56 ± 0.91
Post-treatment	L6	mc-CoGo (mm)	Rota et al. (2022)[67]	1.07 ± 1.61 (SE)
		cc-CoGo (mm)	Rota et al. (2022)[67]	1.16 ± 1.49 (SE)
		mra-CoGo (mm)	Rota et al. (2022)[67]	0.15 ± 1.71 (SE)
	L7	mc-CoGo (mm)	Rota et al. (2022)[67]	1.79 ± 1.57 (SE)
		cc-CoGo (mm)	Rota et al. (2022)[67]	2.47 ± 1.48 (SE)
		mra-CoGo (mm)	Rota et al. (2022)[67]	0.85 ± 1.63 (SE)

L6: mandibular first molar; L7: mandibular second molar; MBC: mesiobuccal cusp; DBC: distobuccal cusp; MLC: mesiolingual cusp; DLC: distolingual cusp, MRA: mesial root apex; DRA: distal root apex; CC: center of crown; RC: center of root; mc-CoGo: mandibular left first molar mesial crown point–Condylion–Gonion line; cc-CoGo: mandibular left first molar central occlusal point–Condylion–Gonion line; mra-CoGo: mandibular left first molar mesial root apex point–Condylion–Gonion line.

Table 11. The amount of mandibular molar tipping in degrees (°) during mandibular molar distalization. The data are reported as either mean ± standard deviation or mean ± standard error (SE).

Time Points	Tooth	Parameters	References	Distal Tipping
Post-distalization	L6	L6 inclination (°)	Wu et al. (2021)[66]	1.62 ± 1.06
	L7	L7 inclination (°)	Wu et al. (2021)[66]	2.10 ± 1.74
Post-treatment	L6	ax-CoGo (°)	Rota et al. (2022)[67]	4.56 ± 2.03 (SE)
		ax-GoMe (°)	Rota et al. (2022)[67]	5.03 ± 1.59 (SE)
	L7	ax-CoGo (°)	Rota et al. (2022) [67]	4.56 ± 4.15 (SE)
		ax-GoMe (°)	Rota et al. (2022)[67]	4.47 ± 1.92 (SE)

L6: mandibular first molar; L7: mandibular second molar; ax-CoGo: mandibular left molar long axis and Condylion–Gonion line; [4] ax-GoMe: mandibular left molar long axis and Gonion–Menton line.

Table 12. The amount of anterior anchorage loss during mandibular molar distalization. A positive value indicates the protrusion and proclination of the incisor; a negative value indicates the retrusion and retroclination of the incisor. The data are reported as either mean ± standard deviation or mean ± standard error (SE).

Time Points	Arch	Parameters	References	Amount of Change
Post-distalization	Same arch	L1ie (mm)	Wu et al. (2021)[66]	1.02 ± 0.80 *
		L1ra (mm)	Wu et al. (2021)[66]	0.33 ± 1.24 *

		L1cc (mm)	Wu et al. (2021)[66]	0.56 ±0.59 *
		L1 inclination (°)	Wu et al. (2021)[66]	1.51 ±1.51 *
		31im-CoGo (mm)	Rota et al. (2022)[67]	−1.13 ± 1.52 (SE)
Post-treatment	Same arch	31ax-CoGo (°)	Rota et al. (2022)[67]	−4.18 ± 2.44 (SE)
		31ax-GoMe (°)	Rota et al. (2022)[67]	−4.78 ± 2.19 (SE)

L1ie: mandibular incisor incisal edge; L1ra: mandibular incisor root apex; L1cc: mandibular incisor center of crown; L1: mandibular incisor; 31im-GoGo: incisal margin of mandibular left central incisor and Condylion–Gonion line; 31 ax-CoGo: angulation between mandibular left first central incisor long axis and Condylion–Gonion line; 31ax-GoMe: angulation between mandibular left first central incisor long axis and Gonion–Menton line; *: data from CBCT.

4. Discussion

4.1. Summary of Evidence

Molar distalization has been a topic of ongoing debate in orthodontics. With the increase in popularity of clear aligners in the past two decades, whether clear aligners can effectively achieve a significant amount of molar distalization with the sequential distalization protocol has become a hot topic of discussion. Due to the varying evidence supporting the efficiency of molar distalization with clear aligners, this study further elucidates currently available data on clear aligner molar distalization and the accompanying side effects.

Our literature search showed high variability in study characteristics, limiting the data that could be utilized for each meta-analysis. Overall, about 2 mm of maxillary molar crown distalization was observed, accompanied by molar crown distal tipping and intra-arch anterior anchorage loss. There was not enough evidence on inter-arch anchorage loss, as well as on mandibular molar distalization with clear aligners. In addition, large variations in the amount of achieved molar distalization and anterior teeth movement were noticed among the reported studies.

Discrepancies between the distalization of the maxillary molars achieved by each study can be attributed to several factors. Primarily, differences in the time points may not be comparable due to changes in molar position during orthodontic treatment between the post-distalization and post-treatment stages. Additionally, studies contained data that varied greatly in the types of records, parameters, and time points, making comparisons difficult. Even within the same studies, variations were found in the amount of distalization achieved when different structures and measurement parameters were used (**Figures 2–4**). Tracing errors due to distortion, differences in magnification, and overlapping structures on radiographic image superimpositions were also important contributing factors in the variations in molar distalization determined in this study.

The varying attachment designs of each study may also have affected the amount of distalization achieved. Garino et al. [60] noted a significant difference in the distalization achieved with the three-attachment protocol compared to the five-attachment protocol, with approximately 1.54 mm and 2.3 mm of maxillary first molar distalization achieved, respectively. Though the attachment protocol could potentially influence the efficiency of molar distalization, most studies did not include specific information regarding the attachment design. This lack of crucial information may have contributed to the variance in reported molar distalization from the included studies, further challenging the analysis of the available literature.

It is worth noting that none of the included studies compared clear aligner therapy to other well-studied molar distalization strategies. Thus, to obtain a better sense of the efficiency of molar distalization with clear

aligners in comparison with fixed appliances, we can only compare the meta-analysis results with articles that report molar distalization with fixed appliances in adult patients. With a sample population of 33 adult patients that underwent molar distalization therapy using different types of intraoral distalizing appliances, including Pendulum, Distal Jet, and Fast Back appliances, 2.9 ± 0.6 mm maxillary first molar distalization was observed on post-treatment lateral cephalometric radiographs without significant molar crown distal tipping (U6-SN angle: −0.2° ± 1.8°).[69] In another study evaluating 46 non-growing patients treated with different types of distalizing appliances (Cetlin distalizing appliance, compressed Niti coil springs, Loca system wire, intraoral palatal distalizing appliances, and "Zig-Zag loops" in conjunction with intermaxillary elastics), 2.16 ± 0.84 mm maxillary first molar distalization was observed on post-treatment lateral cephalometric radiographs accompanied with 1.45° (range 2.22° to −6.45°) of molar crown distal tipping.[70] Thus, the sequential distalization protocol of clear aligners appears to provide a slightly reduced amount of maxillary molar distalization (2.07 mm [1.38 mm, 2.77 mm]) with more prominent molar crown distal tipping (2.19° [1.06°, 3.33°]) in adult patients when compared to non-TAD-supported fixed appliances. However, additional studies directly comparing different treatment strategies are needed to provide clear evidence on this aspect.

Regarding the anterior anchorage loss during molar distalization, our study found significant maxillary incisor protrusion at the post-distalization time point, but incisor retraction and retroclination at the end of treatment. However, it is unclear if the space achieved for retraction was due purely to whole arch distalization or if the retraction space was from interproximal reduction or arch expansion. Future studies should provide more details on the specific protocols for a more accurate comparison of retraction achieved following molar distalization. In addition, although there was insufficient data to run a meta-analysis on the mandibular incisor sagittal position changes, the available data consistently show proclination and protrusion of lower incisors at post-distalization and post-treatment time points (**Tables 8 and 9**), indicating significant mandibular anchorage loss during maxillary molar distalization with clear aligners.

4.2. Limitations

A major limitation of this study was the variation in the evaluation time points, the type of data collected, and the measurement parameters, which significantly affected the number of studies that could be incorporated into the meta-analysis. While both maxillary and mandibular molar distalization are pertinent in orthodontic treatment, only two of the 13 included studies included information regarding mandibular molar distalization.[66,67] Despite the inclusion of these two studies, mandibular molar measurements could not be analyzed via meta-analysis.

Secondly, none of the included studies provided details regarding the ClinCheck® set-ups. Studies may have had differing amounts of molar distalization programmed into the digital set-up, which could affect the amount of molar distalization achieved clinically.

Thirdly, this study did not explore the vertical control and transverse expansion aspects of molar distalization. Further studies exploring all aspects of molar distalization with clear aligners are necessary to better support the clinical use of clear aligners in molar distalization.

Nevertheless, the current study points to the glaring gaps in the available data on molar distalization with clear aligners. More comprehensive studies in molar distalization by clear aligners and the accompanying effects are recommended.

5. Conclusions

This study demonstrates that approximately 2 mm maxillary molar distalization is achievable with the sequential distalization protocol of clear aligners with a certain amount of crown distal tipping. However, the high risk of bias among current available studies and the high variations in the time points assessed, type of data collected, and parameters measured among the available studies point to the insufficient data currently available on molar distalization with clear aligners. Additional studies are needed to determine if a sequential distalization protocol with clear aligners alone is a viable option for molar distalization.

Chapter 2: Vertical Control in Molar Distalization by Clear Aligners: A Systematic Review and Meta-analysis

1. Introduction

Maxillary and mandibular molar distalization are commonly used strategies for correcting molar relationships, creating space for mild arch crowding, or correcting bimaxillary protrusion.[71] For the maxillary arch, molar distalization has historically been achieved by the use of appliances such as the pendulum or headgear, while for mandibular molar distalization, class III elastics and multiloop edgewise archwire (MEAW) are more commonly used.[72] However, without the usage of temporary anchorage devices (TADs), undesirable dentoalveolar consequences may result from distalizing molars, including extrusion of posterior teeth,[73] dental tipping,[74] and loss of anterior anchorage.[67,75] In addition, even without dental extrusion, clockwise mandibular rotation and an increase in skeletal vertical dimension could occur due to the "wedge effect" that results when molars are distalized to the posterior alveolar region.[76,77] Thus, molar distalization should be used with caution, especially for hyperdivergent patients.[64,78-80]

One of the more recent strategies for correcting molar relationships comes with the advent of clear aligner therapy. Due to its appearance and convenience, clear aligner therapy has grown in popularity amongst patients, especially adults.[81] Through sequential distalization strategy, clear aligners have been proven to achieve maxillary first molar distalization with a mean efficacy of 87%.[58] Regarding the efficacy of mandibular molar distalization, a systematic review suggests that 2-3 mm is possible for mandibular molar distalization with clear aligners in combination with TADs.[82] While the existing literature suggests promising implications of utilizing clear aligners to distalize molars, whether clear aligners can provide proper vertical control during molar distalization is still highly debated. Some clinicians state that by covering the occlusal surface of the maxillary and mandibular arches, the clear aligners function as posterior bite turbos, providing efficient molar intrusion.[61,83,84] However, this theory is not fully supported by others.[85] Especially during sequential distalization, the use of inter-arch elastics could extrude molars of the opposing arch[86,87] and increase the mandibular plane angle. Thus, the purpose of this study was to conduct a systematic review evaluating the amount of dentoskeletal changes in the vertical dimension that results from sequential molar distalization in clear aligner therapy without TADs and to provide clinical insight into the effectiveness and limitations when prescribing such treatments.

2. Materials and Methods

Registered with PROSPERO (registration number: CRD42023447211) on August 1st, 2023, this study is compliant with the 2020 Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)

guideline.[30] The following electronic databases were accessed for original articles: MEDLINE (PubMed), EBSCOhost, Web of Science, Elsevier (SCOPUS), Cochrane, LILACS (Latin American and Caribbean Health Sciences Literature), and Google Scholar. The literature search was finished on January 19th, 2024.

2.1. Study selection criteria

Following the population, interventions, comparison, and outcome (PICO) outline, a systematic literature search was conducted regarding the effects of molar distalization with clear aligners on vertical dimension both dentally and skeletally (**Table 13**). The inclusion criteria were (1) longitudinal studies (both prospective and retrospective) comparing pre- and post-distalization/treatment records, (2) participants with permanent dentition, and (3) molar distalization achieved by sequential distalization strategy without TADs. The exclusion criteria were (1) participants with congenital abnormalities or systemic pathologies, (2) case reports, (3) conference abstracts, (4) opinions, editorials, or letters to the editors, guidelines, (5) systematic reviews, (6) utilizing TADs or other auxiliaries during molar distalization, (7) no data reported about the dental or skeletal changes in the vertical dimension, and (8) inconsistent data within the manuscript. No language or date restrictions were applied. **Figure 8** depicts the PRISMA flow diagram to obtain the final included articles.

Table 13. The PICO questions of this study.

Criteria	Description
Population	Patients undergoing orthodontic treatment with clear aligners requiring molar distalization
Intervention	Molar distalization with sequential distalization protocol of clear aligner therapy
Comparisons	The control is pre-treatment models and X-rays
Outcome	The amount of dental and skeletal vertical changes introduced by molar distalization with clear aligners

2.2. Search strategy

Our search strategy in all the used databases is as follows: ("aligners" AND "molar distalization"), ("aligner" AND "molar distalization"), ("clear aligners" AND "molar distalization"), ("clear aligner" AND "molar distalization"), ("sequential distalization"), ("class II" AND "aligners"), ("class II" AND "aligner"), ("class II" AND "clear aligner"), ("class II" AND "clear aligners"), ("class III" AND "aligners"), ("class III" AND "aligner"), ("class III" AND "clear aligner"), ("class III" AND "clear aligners"), and ("invisible removable thermoplastic appliance"). This search was supplemented by a manual search of the references listed in the articles that included for full article reading. The full texts of the obtained articles were reviewed in detail and screened against the inclusion and exclusion criteria. Two authors (T.H.P. and C.S.) conducted the literature search and screening independently to ensure the reliability and completeness of the literature search results. When inconsistencies were encountered between the two authors, a third author was brought in for discussion (C.L.).

2.3. Data extraction and analysis

For all the articles finally included for further data analysis, relevant information was extracted from each article, including study type, sample size, gender, age, clear aligner brand, type of records, timing of treatment records, parameters evaluating molar changes in the vertical dimensions based on the dental model

superimposition or lateral cephalometric analysis, and parameters evaluating the mandibular plane angle changes based on the lateral cephalometric analysis.
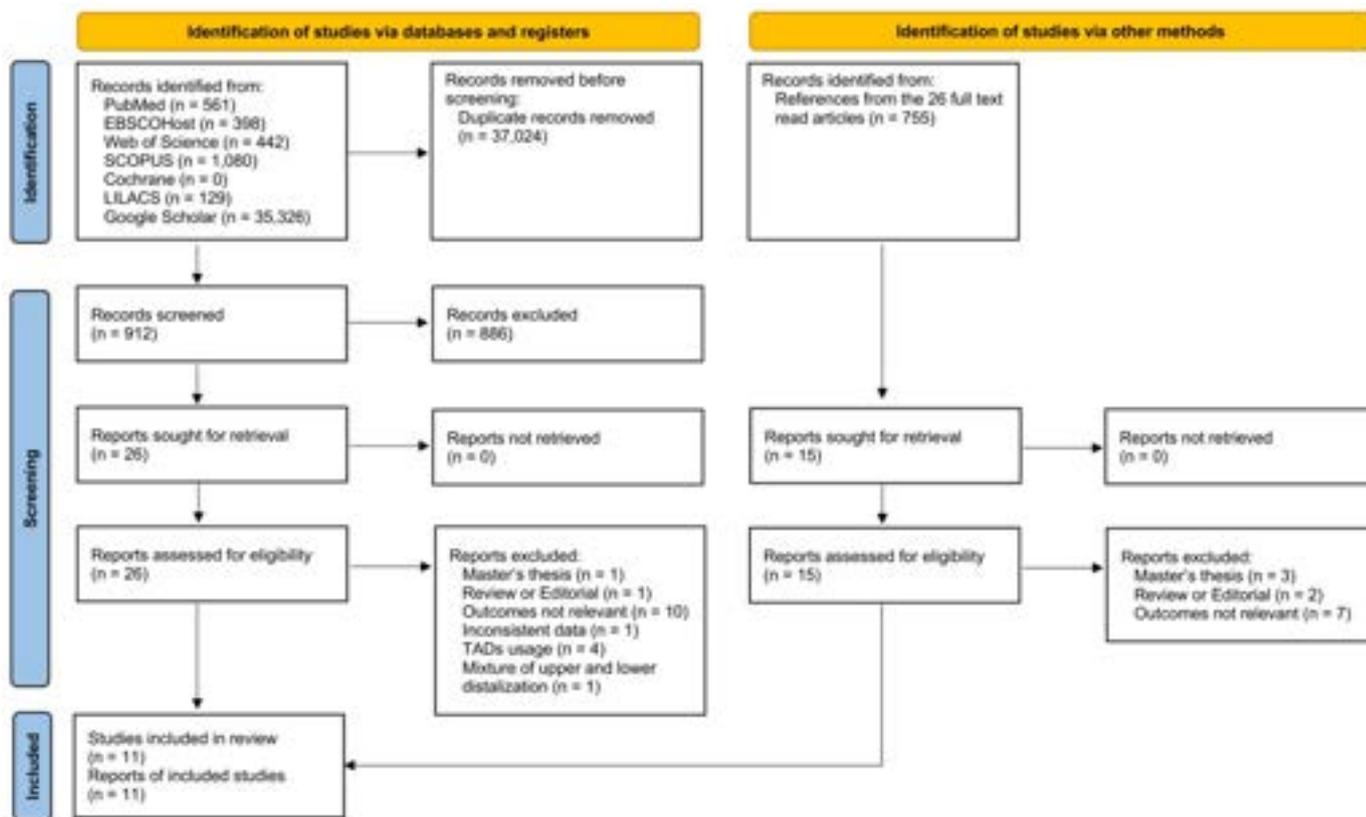

Figure 8. The PRISMA flow diagram demonstrating the study identification and screening.

2.4. Risk of bias/quality assessment

Modeling after the risk of bias protocol established in another study,[31] which shares a similar design to this study, 17 biases were evaluated into 4 categories: study design, study measurements, statistical analysis, and other (**Table 14**), which were scored by 2 authors (T.H.P. and C.S.) individually. A third author (C.L.) was consulted in the instances of disagreement. Individual article scores were determined by scoring the number of met divided by the total number of criteria. Low, medium, or high risk of bias was determined based on randomization and reliability testing. A low risk of bias was determined if both reliability and randomization were met. A high risk of bias was determined if inter-rater reliability was not assessed and if randomization was not conducted. All other studies were determined as medium risk of bias (**Table 14**).

2.5. Statistical analysis

The outcomes of the study were twofold: (1) the amount of dental vertical change following molar distalization by clear aligners, as well as (2) the amount of skeletal vertical change in the aspect of mandibular plane angle following molar distalization by clear aligners. Meta-analysis with the data from the included articles was conducted using RStudio (version 2023.09.1+494, Posit Software, PBC).[32,33] For articles that only reported mean difference and upper and lower 95% confidence intervals (95% CI), the standard deviation was calculated

Table 14. Risk of bias assessment of the eleven included studies.

		Maxillary									Mandibular	
		Garino *et al.* (2016)[60]	Ravera *et al.* (2016)[61]	Chen *et al.* (2017)[20]	Zhang *et al.* (2017)[23]	Li *et al.* (2018)[62]	Caruso *et al.* (2019)[63]	Cui *et al.* (2022)[64]	Balboni *et al.* (2023)[57]	Lin *et al.* (2023)[65]	Wu *et al.* (2021)[66]	Rota *et al.* (2022)[67]
1. Study Design (6)	A. Objective: objective clearly formulated	⊕	⊕	⊕	⊕	⊕	⊕	⊕	⊕	⊕	⊕	⊕
	B. Sample size: considered adequate and estimated before collection of data	⊕	⊕	?	⊖	?	?	?	⊕	⊖	?	⊕
	C. Baseline characteristics--similar baseline characteristics	⊕	⊕	?	?	⊕	?	⊕	⊕	⊕	⊕	⊕
	D. Co-interventions	⊕	⊕	⊕	⊕	⊕	⊕	⊕	⊕	⊕	⊕	⊕
	E. Randomization											
	Random Sampling	⊕	⊖	⊖	⊖	⊖	⊖	⊖	⊕	⊖	⊖	⊖
	Random Allocation of Treatment	⊕	⊖	⊖	⊖	⊖	⊖	⊖	⊖	⊖	⊖	⊖
2. Study Measurements (5)	F. Measurement method--appropriate to the objective	⊕	⊕	⊕	⊕	?	⊕	⊕	⊕	⊕	⊕	⊕
	G. Blind measurement -- blinding											
	Blinding (examiner)	⊕	⊕	⊖	⊖	⊖	⊕	⊖	⊖	⊖	⊖	⊕
	Blinding (statistician)	⊕	⊖	⊖	⊖	⊖	⊖	⊖	⊖	⊖	⊖	⊖
	H. Reliability											
	Reliability described? (Intra-rater reliability)	⊕	⊕	⊖	?	⊖	⊕	⊖	⊕	⊕	⊖	⊖
	Adequate level of agreement? (Inter-rater reliability)	⊖	⊕	⊖	⊖	⊖	⊖	⊖	⊖	⊖	⊖	⊖
3. Statistical analysis (5)	I. Statistical analysis											
	Appropriate for data	⊕	⊕	⊕	⊖	⊖	⊕	⊕	⊕	⊕	⊖	⊕
	Combined subgroup analysis	⊕	⊕	⊕	⊖	⊖	⊕	⊕	⊕	⊕	⊖	⊕
	J. Cofounders (co-interventions) -- confounders included in analysis	⊕	⊕	⊖	⊖	⊖	⊕	⊕	⊕	⊕	⊖	⊕
	K. Statistical significance level											
	P value stated?	⊕	⊕	⊕	⊖	⊕	⊕	⊕	⊕	⊕	⊕	⊕
	Confidence Intervals stated?	⊖	⊕	⊖	⊖	⊖	⊖	⊖	⊕	⊖	⊖	⊕
4. Other	L. Clinical significance	⊕	⊕	⊕	?	⊕	⊕	⊕	⊕	⊕	⊕	⊕
	Total Score	15	14	7	3	5	10	9	13	10	6	12
	Percentage of the Total	88.24	82.35	41.18	17.65	29.41	58.82	52.94	76.47	58.82	35.29	70.59
Risk of Bias		MED	MED	HIGH	HIGH	HIGH	HIGH	HIGH	MED	HIGH	HIGH	HIGH

using the definition of standard deviation $[SD = \sqrt{N} \times (\text{upper limit} - \text{lower limit})/3.92)]$, regardless of the normal distribution of the sample population.[34] Meta-analysis was performed using a random effects model and heterogeneity was assessed for variance between studies with the Tau2 method (τ^2). Data were presented with mean and 95% CI. Sensitivity analysis and selective reporting within studies were not assessed due to the limited number of studies included per analyzed variable.

3. Results

3.1. Literature searching and study selections

An initial search through seven electronic databases identified 37,936 potential articles (561 from PubMed, 398 from EBSCOHost, 442 from Web of Science, 1,080 from SCOPUS, 0 from Cochrane, 129 from LILACS, and 35,326 from Google Scholar) (**Figure 8**). After duplicate records were removed, 912 articles remained for abstract screening. From the abstract reading, 886 articles were excluded, and 26 reports were retrieved for full-text reading. 755 records were also manually retrieved from the references of these 26 articles, and 15 articles were retrieved for full-text reading in addition to the previous 26 reports.

Among the 41 reports, 30 were excluded because the articles were master theses,[35-38] were reviews or editorials [39-41], outcomes were not relevant,[18,19,21,22,25,27,47-56,58] had inconsistent data (and could not get the responses from the corresponding author),[42] utilized TADs,[43-46] or had a mixture of upper and lower distalization.[59] Therefore, after adhering to the guidelines presented by the PRISMA, eleven articles were included for final analysis.[20,23,57,60-67]

3.2. Risk of bias

The strength of evidence was assessed by performing a methodological risk of bias assessment on the eleven included studies (Table 2). Only one study[60] reported both random sampling and random allocation of treatment whereas another study[57] reported only random sampling in their study. The rest of the included studies did not report randomization. Four studies reported blinding completed by the examiner[60,61,63,67] but only one of those studies[60] completed blinding by the statistician. The other studies did not include blinding measurements. Intra-rater reliability was reported in five of the eleven studies.[57,60,61,63,65] One article[23] was unclear with its reporting of intra-rater reliability. Only one article[61] reported inter-rater reliability. Overall, no study scored low for risk of bias. Three studies[57,60,61] had a medium risk of bias score whereas the other eight[20,23,62-67] had a high overall risk of bias.

3.3. Demographic data

The main characteristics of the included studies are summarized in **Table 15**. Three of the studies were prospective,[57,60,66] five were retrospective,[61,63-65,67] and three were unclear of their study type.[20,23,62] Most of the studies utilized Invisalign as their choice of clear aligner but one article by Zhang et al.[23] used Angel Aligner, and the article by Cui et al.[64] was unclear with the clear aligner brand used. There are nine articles that used the sequential distalization strategy to distalize the maxillary molars with 138 subjects in total,[20,23,57,60-65] and two articles that used sequential distalization to distalize the mandibular molars with 36 subjects in total.[66,67] The overall sample population comprised of late adolescents and adults.

Regarding the type and timing of treatment records, high heterogeneity was noticed (**Table 15**). For instance, there are three articles that performed evaluations based on post-distalization (only after molars being distalized) records: two with digital dental models[20,23] and one with cone-beam computed tomography (CBCT) images;[66] eight articles performed

evaluations based on post-treatment records: one with both digital models and lateral cephalometric X-rays,[62] one with both digital models and CBCT,[65] five with lateral cephalometric X-rays only,[57,60,61,63,67] and one with CBCT only.[64]

Thus, the following data collection and analysis were sub-grouped based on the arch that distalization was being performed on and the timing and type of records provided in each included article.

3.4. Dental vertical changes from maxillary molar distalization

The amount of dental vertical control evaluated from dental models following maxillary molar distalization is summarized (**Table 16**), which shows the overall trend of slight maxillary first and second molar intrusion at both post-distalization and post-treatment time points. Limited by the number of available articles on this aspect, a meta-analysis could only be performed for the maxillary first molar changes evaluated on the post-distalization dental models. A random-effects model of meta-analysis revealed a minimal amount of maxillary first molar intrusion (-0.26 mm [-0.29 mm, -0.23 mm]) by clear aligners after sequential distalization (**Figure 9**).

Additionally, the amount of dental vertical control after maxillary molar distalization evaluated from lateral cephalometric radiographs is summarized in **Table 17**. Only data for the post-treatment timepoint was available. The included articles recorded the amount of intrusion or extrusion based on cusp or root reference points from the maxillary first and second molar in relation to the occlusal plane or palatal plane. Since the occlusal plane changes based on the position of the molars, further analysis focused on the relationship between the molars and the palatal plane.

While a definite trend cannot be determined from the range of reported changes (**Table 17**), a meta-analysis using a random-effects model overall revealed no vertical position change of the maxillary first (**Figure 10**) and second molars (**Figure 11**). Specifically, at the crown level, the maxillary first molar mesiobuccal cusp in relation to the palatal plane demonstrated -0.33 mm [-2.99 mm, 2.33 mm] vertical change (**Figure 10A**) and the center of the crown to the palatal plane showed -0.50 mm [-1.78 mm, 0.78 mm] (**Figure 10B**); at the root level, the distance between the maxillary first molar palatal root apex and the palatal plane showed intrusion of -0.51 mm [-1.00 mm, -0.03 mm] (**Figure 10C**) while the mesiobuccal root apex showed -0.75 mm [-2.57 mm, 1.08 mm] (**Figure 10D**). Similarly, the maxillary second molar mesiobuccal cusp in relation to the palatal plane demonstrated a change of -0.45 mm [-3.30 mm, 2.40 mm] (**Figure 11A**), the center of the crown of the maxillary second molar to the palatal plane showed a change of -0.60 mm [-1.62 mm, 0.42 mm] (**Figure 11B**). The distance between the maxillary second molar palatal root apex and the palatal plane showed a change of -0.60 mm [-2.50 mm, 1.30 mm] (**Figure 11C**) while the mesiobuccal root apex showed -0.16 mm [-0.58 mm, 0.25 mm] (**Figure 11D**).

3.5. Skeletal vertical changes from maxillary molar distalization

The amount of skeletal vertical control evaluated from lateral cephalometric radiographs following maxillary molar distalization is summarized (**Table 18**). Only data from the post-treatment time point were available. The data related to the mandibular plane were collected, but large variations among studies was noted.

A random-effects model was used for meta-analysis showed a change of -0.33° [-0.67°, 0.02°] for the SN-GoGn (sella-nasion ^ Gonion-gnathion) angle (**Figure 12A**), 0.23° [-0.30°, 0.75°] for the SN-MP (sella-nasion ^ mandibular plane) angle (**Figure 12B**), and 0.09° [-0.83°, 1.01°] for the PP-GoGn (palatal plane ^ gonion-gnathion) angle (**Figure 12C**). Thus, no significant changes were observed in the skeletal parameters.

Table 15. Characteristics of included studies. Max: maxillary; Mand: mandibular; F: female; M: male; CBCT: Cone-beam computed tomography

Study	Maxillary or Mandibular Molar Distalization	Study Type	Age (years)	Sample Size (F/M)	Clear Aligner Brand	Post-Distalization Records			Post-Treatment Records		
						Digital Model	Lateral Ceph	CBCT	Digital Model	Lateral Ceph	CBCT
Garino *et al.* (2016)[60]	Max	Prospective	30.5	30 (18F/12M)	Invisalign	-	-	-	N	Y	N
Ravera *et al.* (2016)[61]	Max	Retrospective	29.73 ± 6.89	20 (11F/9M)	Invisalign	-	-	-	N	Y	N
Chen *et al.* (2017)[20]	Max	Unclear	25.3 (14-43)	15	Invisalign	Y	N	N	-	-	-
Zhang *et al.* (2017)[23]	Max	Unclear	14.0 ± 3.1	7 (5F/2M)	Angel Aligner	Y	N	N	-	-	-
Li *et al.* (2018)[62]	Max	Unclear	25.3 (21-34)	11 (7F/4M)	Invisalign	-	-	-	Y	Y	N
Caruso *et al.* (2019)[63]	Max	Retrospective	22.7 ± 5.3	10 (8F/2M)	Invisalign	-	-	-	N	Y	N
Cui *et al.* (2022)[64]	Max	Retrospective	27.8 ± 5.38 (18-38)	18	Unclear	-	-	-	N	N	Y
Balboni *et al.* (2023)[57]	Max	Prospective	17.1 ± 3.2	20 (13F/7M)	Invisalign	-	-	-	N	Y	N
Lin *et al.* (2023)[65]	Max	Retrospective	26.64 ± 3.02 (23.1-31.5)	7	Invisalign	-	-	-	Y	N	Y
Wu *et al.* (2021)[66]	Mand	Prospective	>18	20 (12F/8M)	Invisalign	N	N	Y	-	-	-
Rota *et al.* (2022)[67]	Mand	Retrospective	25.6±4.5	16 (8F/8M)	Invisalign	-	-	-	N	Y	N

Table 16. The amount of dental vertical changes evaluated on the dental models after maxillary molar distalization. The data is presented as mean ± standard deviation. A positive value indicates molar extrusion while a negative value indicates molar intrusion.
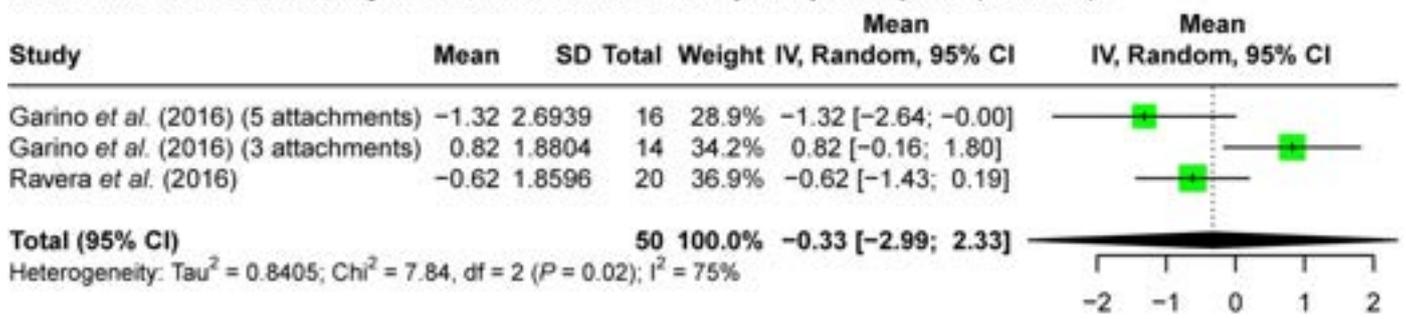
Time points	Parameters	References	Changes (mm)
Post-Distalization	Maxillary First Molar (U6s)	Chen *et al.* (2017)[20] Right	-0.26 ± 0.04
		Chen *et al.* (2017)[20] Left	-0.26 ± 0.22
		Zhang *et al.* (2017)[23] Right	-0.44 ± 0.34
		Zhang *et al.* (2017)[23] Left	-0.34 ± 0.41
	Maxillary Second Molar (U7s)	Chen *et al.* (2017)[20] Right	-0.36 ± 0.34
		Chen *et al.* (2017)[20] Left	-0.37 ± 0.46
Post-Treatment	Maxillary First Molar (U6s) MB cusp	Lin *et al.* (2023)[65]	-0.36 ± 0.66
	DB cusp	Lin *et al.* (2023)[65]	-0.36 ± 0.62
	MP cusp	Lin *et al.* (2023)[65]	0.01 ± 0.68

Figure 9. Forest plot of the amount of maxillary first molar vertical changes evaluated from the superimposition of pre-treatment and post-distalization dental models after maxillary molar distalization.[20,23]

Table 17. The amount of dental vertical changes evaluated on the lateral cephalometric radiograph after maxillary molar distalization. mcOP: distance between maxillary molar mesiobuccal cusp and occlusal plane; ccOP: distance between the maxillary molar center of crown and occlusal plane; praOP: distance between maxillary molar palatal root apex and occlusal plane; vmraOP: distance between maxillary molar mesiobuccal root apex and occlusal plane; mcPP: distance between maxillary molar mesiobuccal cusp and palatal plane, ccPP: distance between maxillary molar center of crown and palatal plane, praPP: distance between maxillary molar palatal root apex and palatal plane, vmraPP: distance between maxillary molar mesiobuccal root apex and palatal plane; UMVD: Maxillary first molar vertical dimension. The data were either presented in mean [95% confidence interval] or mean ± standard deviation. A positive value indicates molar extrusion while a negative value indicates molar intrusion.

Time points	Parameters	References	Changes (mm)
Post-Treatment	Maxillary First Molar (U6s)	U6ccOP Garino *et al.* (2016)[60] (5 attachments)	0.08 [-0.55, 0.72]
		Garino *et al.* (2016)[60] (3 attachments)	-0.37 [-1.01, 0.26]
		Ravera *et al.* (2016)[61]	0.05 [-0.46, 0.55]
		U6praOP Garino *et al.* (2016)[60] (5 attachments)	0.32 [-0.72, 1.37]
		Garino *et al.* (2016)[60] (3 attachments)	-1.44 [-2.52, -0.37]
		Ravera *et al.* (2016)[61]	-0.24 [-0.90, 0.43]
		U6vmraOP Garino *et al.* (2016)[60] (5 attachments)	-0.30 [-1.23, 0.64]
		Garino *et al.* (2016)[60] (3 attachments)	-1.12 [-2.07, -0.16]
		Ravera *et al.* (2016)[61]	-0.48 [-1.36, 0.41]
		U6mcPP Garino *et al.* (2016)[60] (5 attachments)	-1.32 [-2.07, 0.57]
		Garino *et al.* (2016)[60] (3 attachments)	0.82 [-0.17, 1.80]
		Ravera *et al.* (2016)[61]	-0.62 [-1.44, 0.19]
		Caruso *et al.* (2019)[63]	-2.00*

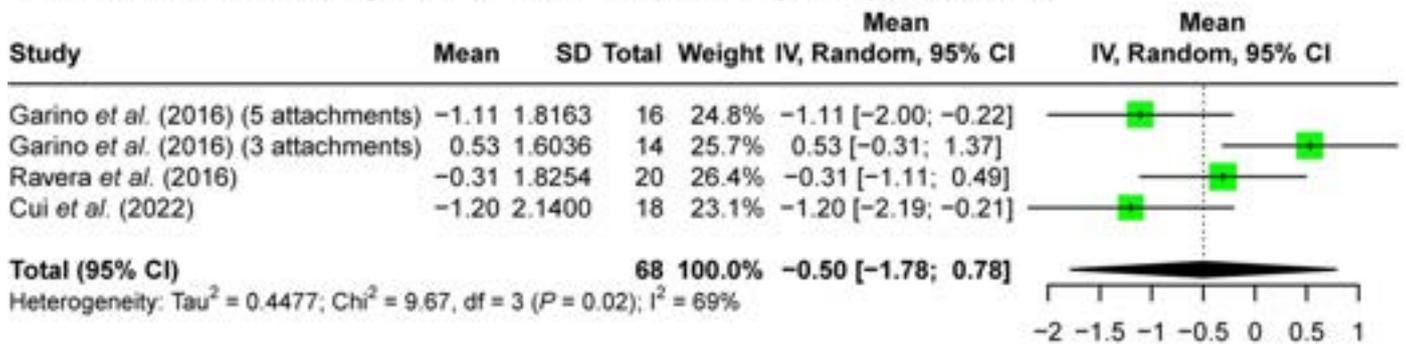|		Balboni *et al.* (2023)[57]	-0.9
	U6ccPP	Garino *et al.* (2016)[60] (5 attachments)	-1.11 [-2.00, -0.22]
		Garino *et al.* (2016)[60] (3 attachments)	0.53 [-0.31, 1.37]
		Ravera *et al.* (2016)[61]	-0.31 [-1.11, 0.49]
		Cui *et al.* (2022)[64&]	-1.20 ± 2.14
	U6praPP	Garino *et al.* (2016)[60] (5 attachments)	-0.84 [-2.21, 0.53]
		Garino *et al.* (2016)[60] (3 attachments)	-0.38 [-1.14, 0.39]
		Ravera *et al.* (2016)[61]	-0.55 [-1.45, 0.34]
	U6vmraPP	Garino *et al.* (2016)[60] (5 attachments)	-1.50 [-2.41, -0.59]
		Garino *et al.* (2016)[60] (3 attachments)	-0.04 [-0.78, 0.70]
		Ravera *et al.* (2016)[61]	-0.80 [-1.67, 0.06]
	UMVD	Li *et al.* (2018)[62]	-0.95 ± 1.22
Maxillary Second Molar (U7s)	U7mcOP	Garino *et al.* (2016)[60] (5 attachments)	0.06 [-0.58, 0.71]
		Garino *et al.* (2016)[60] (3 attachments)	0.14 [-0.35, 0.62]
		Ravera *et al.* (2016) [61]	0.29 [-0.23, 0.80]
	U7ccOP	Garino *et al.* (2016)[60] (5 attachments)	-0.01 [-0.93, 0.92]
		Garino *et al.* (2016)[60] (3 attachments)	-0.45 [-1.03, 0.13]
		Ravera *et al.* (2016)[61]	-0.01 [-0.74, 0.72]
	U7praOP	Garino *et al.* (2016)[60] (5 attachments)	0.33 [-0.52, 1.17]
		Garino *et al.* (2016)[60] (3 attachments)	-1.12 [-2.38, 0.14]
		Ravera *et al.* (2016)[61]	-0.13 [-1.09, 0.82]
	U7vmraOP	Garino *et al.* (2016)[60] (5 attachments)	-0.11 [-2.26, 2.04]
		Garino *et al.* (2016)[60] (3 attachments)	-1.16 [-2.48, 0.16]
		Ravera *et al.* (2016)[61]	-0.44 [-2.25, 1.27]
	U7mcPP	Garino *et al.* (2016)[60] (5 attachments)	-1.49 [-2.60, -0.37]
		Garino *et al.* (2016)[60] (3 attachments)	0.85 [-0.63, 2.33]
		Ravera *et al.* (2016)[61]	-0.49 [-1.59, 0.62]
		Caruso *et al.* (2019)[63]	-3.00*
	U7ccPP	Garino *et al.* (2016)[60] (5 attachments)	-1.25 [-2.12, -0.38]
		Garino *et al.* (2016)[60] (3 attachments)	0.16 [-0.86, 1.18]
		Ravera *et al.* (2016)[61]	-0.51 [-1.40, 0.39]
		Cui *et al.* (2022)[64&]	-0.81 ± 2.51
	U7praPP	Garino *et al.* (2016)[60] (5 attachments)	-1.54 [-3.82, 0.74]
		Garino *et al.* (2016)[60] (3 attachments)	-0.11 [-0.86, 0.65]
		Ravera *et al.* (2016)[61]	-1.28 [-3.09, 0.53]
	U7vmraPP	Garino *et al.* (2016)[60] (5 attachments)	-0.07 [-1.13, 1.00]
		Garino *et al.* (2016)[60] (3 attachments)	-0.44 [-1.04, 1.56]
		Ravera *et al.* (2016)[61]	-0.11 [-0.90, 0.68]

*: data calculated based on post-treatment mean value – pretreatment mean value provided in the article.
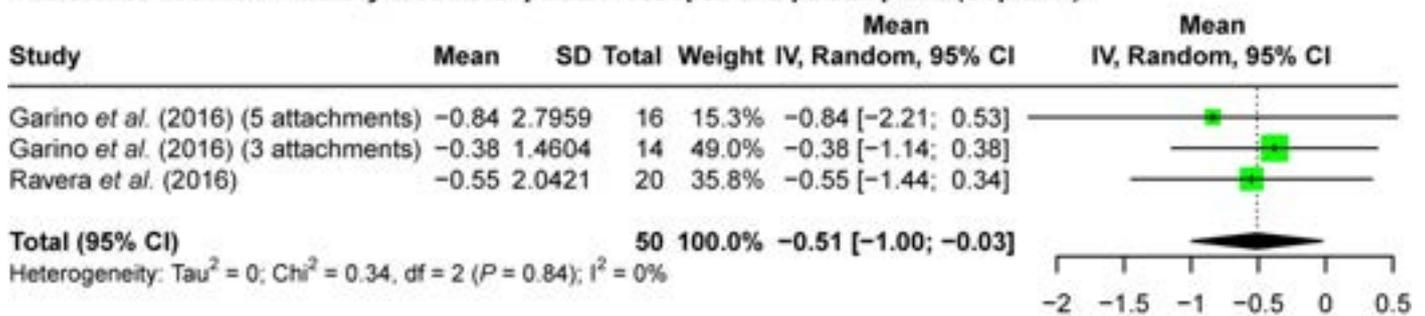&: three-dimensional cephalometric analysis on CBCT.

A. Distance between maxillary first molar mesiobuccal cusp and palatal plane (U6mcPP):

Study	Mean	SD	Total	Weight	Mean IV, Random, 95% CI	Mean IV, Random, 95% CI
Garino et al. (2016) (5 attachments)	−1.32	2.6939	16	28.9%	−1.32 [−2.64; −0.00]	
Garino et al. (2016) (3 attachments)	0.82	1.8804	14	34.2%	0.82 [−0.16; 1.80]	
Ravera et al. (2016)	−0.62	1.8596	20	36.9%	−0.62 [−1.43; 0.19]	
Total (95% CI)			50	100.0%	−0.33 [−2.99; 2.33]	

Heterogeneity: Tau^2 = 0.8405; Chi^2 = 7.84, df = 2 (P = 0.02); I^2 = 75%

B. Distance between maxillary first molar center of crown and palatal plane (U6ccPP):

Study	Mean	SD	Total	Weight	Mean IV, Random, 95% CI	Mean IV, Random, 95% CI
Garino et al. (2016) (5 attachments)	−1.11	1.8163	16	24.8%	−1.11 [−2.00; −0.22]	
Garino et al. (2016) (3 attachments)	0.53	1.6036	14	25.7%	0.53 [−0.31; 1.37]	
Ravera et al. (2016)	−0.31	1.8254	20	26.4%	−0.31 [−1.11; 0.49]	
Cui et al. (2022)	−1.20	2.1400	18	23.1%	−1.20 [−2.19; −0.21]	
Total (95% CI)			68	100.0%	−0.50 [−1.78; 0.78]	

Heterogeneity: Tau^2 = 0.4477; Chi^2 = 9.67, df = 3 (P = 0.02); I^2 = 69%

C. Distance between maxillary first molar palatal root apex and palatal plane (U6praPP):

Study	Mean	SD	Total	Weight	Mean IV, Random, 95% CI	Mean IV, Random, 95% CI
Garino et al. (2016) (5 attachments)	−0.84	2.7959	16	15.3%	−0.84 [−2.21; 0.53]	
Garino et al. (2016) (3 attachments)	−0.38	1.4604	14	49.0%	−0.38 [−1.14; 0.38]	
Ravera et al. (2016)	−0.55	2.0421	20	35.8%	−0.55 [−1.44; 0.34]	
Total (95% CI)			50	100.0%	−0.51 [−1.00; −0.03]	

Heterogeneity: Tau^2 = 0; Chi^2 = 0.34, df = 2 (P = 0.84); I^2 = 0%

D. Distance between maxillary first molar mesiobuccal root apex and palatal plane (U6vmraPP):

Study	Mean	SD	Total	Weight	Mean IV, Random, 95% CI	Mean IV, Random, 95% CI
Garino et al. (2016) (5 attachments)	−1.50	1.8571	16	31.4%	−1.50 [−2.41; −0.59]	
Garino et al. (2016) (3 attachments)	−0.04	1.4127	14	36.0%	−0.04 [−0.78; 0.70]	
Ravera et al. (2016)	−0.80	1.9737	20	32.6%	−0.80 [−1.66; 0.06]	
Total (95% CI)			50	100.0%	−0.75 [−2.57; 1.08]	

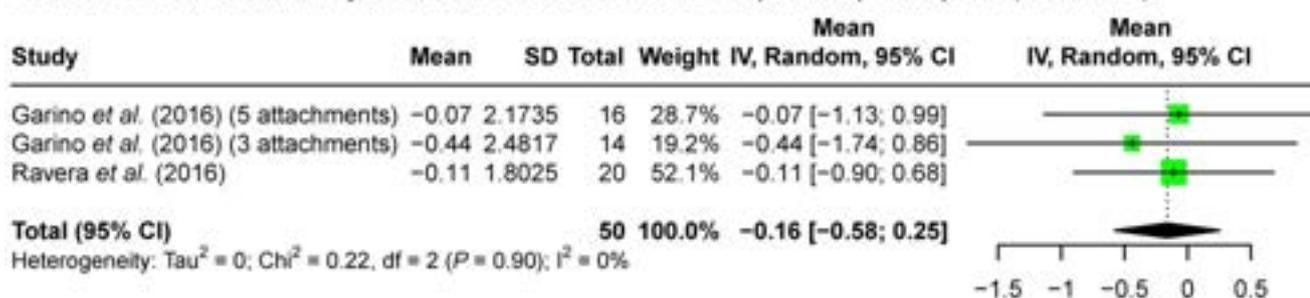Heterogeneity: Tau^2 = 0.3628; Chi^2 = 6.07, df = 2 (P = 0.05); I^2 = 67%
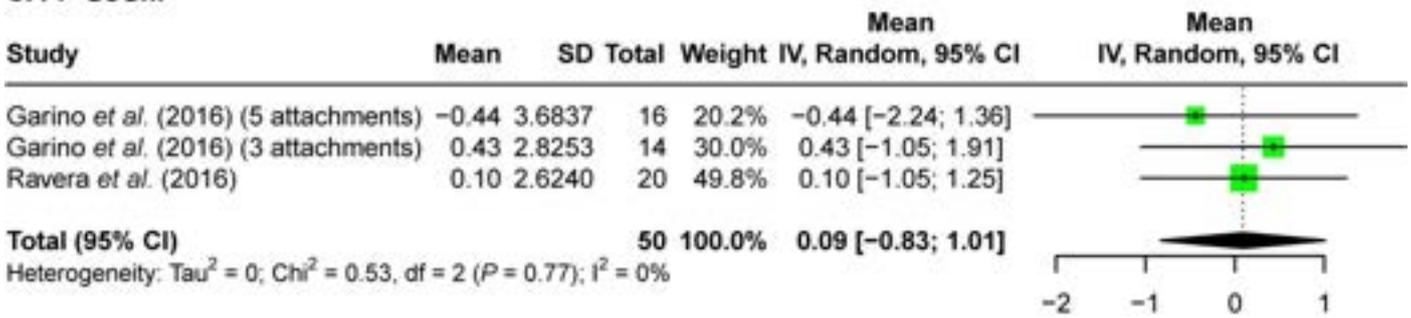
Figure 10. Forest plots of the amount of maxillary first molar vertical changes after maxillary molar distalization according to pre- and post-treatment lateral cephalometric analysis. A positive value indicates molar extrusion while a negative value indicates molar intrusion.

A. Distance between maxillary second molar mesiobuccal cusp and palatal plane (U7mcPP):

Study	Mean	SD	Total	Weight	Mean IV, Random, 95% CI	Mean IV, Random, 95% CI
Garino et al. (2016) (5 attachments)	−1.49	2.2755	16	35.3%	−1.49 [−2.60; −0.38]	
Garino et al. (2016) (3 attachments)	0.85	2.8253	14	29.2%	0.85 [−0.63; 2.33]	
Ravera et al. (2016)	−0.49	2.5213	20	35.5%	−0.49 [−1.59; 0.61]	
Total (95% CI)			50	100.0%	**−0.45 [−3.30; 2.40]**	

Heterogeneity: Tau^2 = 0.8684; Chi^2 = 6.17, df = 2 (P = 0.05); I^2 = 68%

B. Distance between maxillary second molar center of crown and palatal plane (U7ccPP):

Study	Mean	SD	Total	Weight	Mean IV, Random, 95% CI	Mean IV, Random, 95% CI
Garino et al. (2016) (5 attachments)	−1.25	1.7755	16	28.5%	−1.25 [−2.12; −0.38]	
Garino et al. (2016) (3 attachments)	0.26	1.9472	14	23.7%	0.26 [−0.76; 1.28]	
Ravera et al. (2016)	−0.51	2.0421	20	27.6%	−0.51 [−1.40; 0.38]	
Cui et al. (2022)	−0.81	2.5100	18	20.1%	−0.81 [−1.97; 0.35]	
Total (95% CI)			68	100.0%	**−0.60 [−1.62; 0.42]**	

Heterogeneity: Tau^2 = 0.1721; Chi^2 = 5.03, df = 3 (P = 0.17); I^2 = 40%

C. Distance between maxillary second molar palatal root apex and palatal plane (U7praPP):

Study	Mean	SD	Total	Weight	Mean IV, Random, 95% CI	Mean IV, Random, 95% CI
Garino et al. (2016) (5 attachments)	−1.54	4.6531	16	15.6%	−1.54 [−3.82; 0.74]	
Garino et al. (2016) (3 attachments)	−0.11	1.4413	14	61.8%	−0.11 [−0.86; 0.64]	
Ravera et al. (2016)	−1.28	4.1299	20	22.6%	−1.28 [−3.09; 0.53]	
Total (95% CI)			50	100.0%	**−0.60 [−2.50; 1.30]**	

Heterogeneity: Tau^2 = 0.2574; Chi^2 = 2.43, df = 2 (P = 0.30); I^2 = 18%

D. Distance between maxillary second molar mesiobuccal root apex and palatal plane (U7vmraPP):

Study	Mean	SD	Total	Weight	Mean IV, Random, 95% CI	Mean IV, Random, 95% CI
Garino et al. (2016) (5 attachments)	−0.07	2.1735	16	28.7%	−0.07 [−1.13; 0.99]	
Garino et al. (2016) (3 attachments)	−0.44	2.4817	14	19.2%	−0.44 [−1.74; 0.86]	
Ravera et al. (2016)	−0.11	1.8025	20	52.1%	−0.11 [−0.90; 0.68]	
Total (95% CI)			50	100.0%	**−0.16 [−0.58; 0.25]**	

Heterogeneity: Tau^2 = 0; Chi^2 = 0.22, df = 2 (P = 0.90); I^2 = 0%

Figure 11. Forest plots of the amount of maxillary second molar vertical changes after maxillary molar distalization according to pre- and post-treatment lateral cephalometric analysis. A positive value indicates molar extrusion while a negative value indicates molar intrusion.[60,61,64]

Table 18. The amount of skeletal vertical changes evaluated on the lateral cephalometric radiographs after maxillary molar distalization. SN-GoGn: sella-nasion-gonion-gnathion, SN-MP: sella-nasion-mandibular plane angle, PP-GoGn: palatal plane-gonion-gnathion angle, FMA (FH-MP): Frankfort horizontal-mandibular plane angle, Ar-Go-Me: articulare-gonion-menton angle (gonial angle). The data were presented in either mean [95% confidence interval] or mean ± standard deviation. A positive value indicates an increase in the mandibular plane angle after treatment, negative value indicates decrease in the mandibular plane angle after treatment.

Time Points	Parameters	References	Change (°)
Post-Treatment	SN-GoGn	Garino *et al.* (2016)[60] (5 attachments)	-0.44 [-1.37, 0.50]
		Garino *et al.* (2016)[60] (3 attachments)	0.01 [-1.28, 1.28]
		Ravera *et al.* (2016)[61]	-0.45 [-1.20, 0.30]
		Caruso *et al.* (2019)[63]	-0.1 ± 2.0
		Balboni *et al.* (2023)[57]	-0.3
		Lin *et al.* (2023)[65+]	0.51*
	SN-MP	Li *et al.* (2018)[62]	0.50 ± 3.78
		Cui *et al.* (2022)[64&]	0.22 ± 0.73
	PP-GoGn	Garino *et al.* (2016)[60] (5 attachments)	-0.44 [-2.24, 1.37]
		Garino *et al.* (2016)[60] (3 attachments)	0.43 [-1.05, 1.91]
		Ravera *et al.* (2016)[61]	0.10 [-1.05, 1.25]
	FMA (FH-MP)	Li *et al.* (2018)[62]	1.56 ± 3.15
		Balboni *et al.* (2023)[57]	-1.3
	Ar-Go-Me	Balboni *et al.* (2023)[57]	-3.4

*: data calculated based on post-treatment mean value – pretreatment mean value provided in paper.
&: three-dimensional cephalometric analysis on CBCT.
+: the authors of this article considered SN-GoGn and SN-MP as one parameter.

A. SN-GoGn :

B. SN-MP:

C. PP-GoGn:

Study	Mean	SD	Total	Weight	Mean IV, Random, 95% CI
Garino *et al.* (2016) (5 attachments)	−0.44	3.6837	16	20.2%	−0.44 [−2.24; 1.36]
Garino *et al.* (2016) (3 attachments)	0.43	2.8253	14	30.0%	0.43 [−1.05; 1.91]
Ravera *et al.* (2016)	0.10	2.6240	20	49.8%	0.10 [−1.05; 1.25]
Total (95% CI)			50	100.0%	0.09 [−0.83; 1.01]

Heterogeneity: Tau^2 = 0; Chi^2 = 0.53, df = 2 (*P* = 0.77); I^2 = 0%

Figure 12. Forest plots of the amount of skeletal vertical changes after maxillary molar distalization according to pre- and post-treatment lateral cephalometric analysis. A positive value indicates an increase in the mandibular plane angle after treatment, negative value indicates a decrease in the mandibular plane angle after treatment.

3.6. Dental vertical changes from mandibular molar distalization

While the number of articles that report vertical changes from mandibular molar distalization using sequential distalization are few, one article presented the amount of mandibular first and second molar vertical changes using 3D valuations on CBCT at the time point of post-distalization.[66] All the landmarks utilized in this study reported 0.29 – 1.06 mm intrusion of mandibular first and second molars based on the mean values of each parameter, but large standard deviations were noticed (**Table 19**).

Table 19. The amount of dental vertical changes evaluated on radiographic images following mandibular molar distalization. Mbc: mesiobuccal cusp; dbc: distobuccal cusp; mlc: mesiolingual cusp; dlc: distolingual cusp; mra: mesial root apex; dra: distal root apex; cc: center of the crown; rc: center of the root. The data is presented as mean ± standard deviation. A positive value indicates molar extrusion while a negative value indicates molar intrusion.

Time Points	Parameter		Reference	Change (mm)
Post-Distalization	Mandibular First molar (L6s)	L6mbc	Wu *et al.* (2021)[66*]	-0.78 ± 0.33
		L6dbc	Wu *et al.* (2021)[66*]	-0.91 ± 0.31
		L6mlc	Wu *et al.* (2021)[66*]	-0.56 ± 0.89
		L6dlc	Wu *et al.* (2021)[66*]	-0.62 ± 0.84
		L6mra	Wu *et al.* (2021)[66*]	-0.29 ± 1.08
		L6dra	Wu *et al.* (2021)[66*]	-0.28 ± 0.66
		L6cc	Wu *et al.* (2021)[66*]	-0.53 ± 1.37
		L6rc	Wu *et al.* (2021)[66*]	-0.41 ± 0.96
	Mandibular Second Molar (L7s)	L7mbc	Wu *et al.* (2021)[66*]	-0.81 ± 1.46
		L7dbc	Wu *et al.* (2021)[66*]	-1.06 ± 0.65
		L7mlc	Wu *et al.* (2021)[66*]	-0.64 ± 1.19
		L7dlc	Wu *et al.* (2021)[66*]	-0.72 ± 1.07
		L7mra	Wu *et al.* (2021)[66*]	-0.30 ± 1.01
		L7dra	Wu *et al.* (2021)[66*]	-0.27 ± 0.82
		L7cc	Wu *et al.* (2021)[66*]	-0.59 ± 0.94
		L7rc	Wu *et al.* (2021)[66*]	-0.56 ± 0.91

3.7. Skeletal vertical changes from mandibular molar distalization

Two articles reported the amount of skeletal vertical changes evaluated from lateral cephalometric analysis following mandibular molar distalization with sequential distalization (**Table 20**). For both post-distalization and post-treatment records, the included studies demonstrate an overall trend of increase in mandibular plane angle. Only Wu et al.[66] reported SN-MP angle from post-distalization records showed a decrease of -0.99°. Large standard deviations or large ranges of the 95% confidence interval were also noticed from the reported parameters.

Table 20. The amount of skeletal vertical changes evaluated on the lateral cephalometric radiograph after mandibular molar distalization. SN-MP: sella-nasion-mandibular plane angle, PP-MP: palatal plane-mandibular plane angle, SN-GoGn: sell-nasion-gonion-gnathion angle, FMA (FH-MP): Frankfort horizontal-mandibular plane angle. The data were presented in mean ± standard deviation or mean [95% confident interval]. A positive value indicates an increase in the mandibular plane angle after treatment, negative value indicates a decrease in the mandibular plane angle after treatment.

Time Points	Parameter	Reference	Change (°)
Post-Distalization	SN-GoGn	Wu *et al.* (2021)[66*]	1.73 ± 5.37
	SN-MP	Wu *et al.* (2021)[66*]	-0.99 ± 5.85
	PP-MP	Wu *et al.* (2021)[66*]	0.66 ± 2.54
	FMA (FH-MP)	Wu *et al.* (2021)[66*]	1.97 ± 4.58
Post-Treatment	SN-MP	Rota *et al.* (2022)[67]	0.14 [-3.82, 4.09]
	PP-MP	Rota *et al.* (2022)[67]	0.81 [-3.95, 5.56]

[*]: three-dimensional cephalometric analysis on CBCT.

4. Discussion

4.1. Summary of evidence

Clear aligner therapy in orthodontics has experienced a surge in the recent decades. Besides the advantages of aesthetics, comfort, and oral hygiene maintenance for patients, some clinicians claim that one of the clinical benefits of clear aligners is vertical control due to the "bite block" effects.[88-90] In fact, vertical control has been a challenging problem in orthodontics, especially for patients with a hyperdivergent skeletal pattern because fixed appliances tend to extrude the teeth and cause clockwise rotation of the mandible.[91] In addition, when molars are distalized into the wedge of the occlusion, clockwise rotation of the mandibular plane is further introduced despite maintaining the molars in the same vertical position.[76] Thus, better vertical control during molar distalization implies the opportunity for predictable success with clear aligners and less room for detrimental side effects. However, there is no solid evidence to confirm such claims. The articles in this study, therefore, shed more light on the ongoing conversation about vertical control following molar distalization with the sequential distalization strategy of clear aligner therapy.

During the literature search and analysis, we noticed high heterogeneity in the time points and types of records used in each study. Such heterogeneity significantly increased the complexity of data analysis and reduced the amount of data that could be utilized for each meta-analysis. To perform a meta-analysis, data stratification based on the arch, timepoint, and type of record needed to match. In addition, none of the included studies performed a comparison between clear aligner therapy and fixed appliances. Consequently, no direct evidence could be provided regarding which type of appliance provides better vertical control during molar distalization.

Through meta-analysis, our study revealed 0.26 mm [0.23 mm, 0.29 mm] maxillary first molar intrusion based on the pre-treatment and post-distalization dental model superimposition after maxillary molar distalization (**Figure 8**). While the post-treatment timepoint revealed no significant vertical change from the landmarks on the crown of the maxillary first molars, but slight intrusion of the palatal root apex of the maxillary first molar (-0.51 mm [-1.00 mm, -0.03 mm]) was observed (**Figure 10**). The differences between these two time points may be the result of several factors. First, the molar position may continue to change from post-distalization to post-treatment time points. Second, the use of different types of records also indicates the use of different reference landmarks. Third, tracing errors may have occurred from distortion, magnification, and overlapping structures on the lateral cephalometric X-rays. Such errors are likely as different results were found at the crown and root levels when meta-analysis was performed with data from the same studies (**Figure 10 A and C**). These findings also suggest that cautions need to be taken when comparing the treatment effects of different appliances among studies with variant types of records.

Skeletally, no significant changes were observed with the SN-GoGn angle, SN-MP angle, and PP-GoGn angle (**Figure 12**), which indicate proper skeletal vertical control during the orthodontic treatment for maxillary molar distalization with clear aligner sequential distalization strategy.

Patients with a hyperdivergent skeletal pattern have weaker bite force and muscle efficiency than patients with a hypodivergent skeletal pattern.[92] As a result, the molar intrusion effects from the clear aligners may be less efficient in patients with a hyperdivergent pattern than in patients with a hypodivergent one. A previous study shows that the unplanned maxillary intrusion after clear aligner treatment was negatively associated to the mandibular plane angle.[83] However, molar intrusion is more favorable in hyperdivergent patients and molar extrusion is more favorable in hypodivergent patients during orthodontic treatment. Thus, it would be more critical for clear aligners to provide proper vertical control during sequential distalization in patients with a hyperdivergent pattern. For the studies included in the current review, none considered the influence of skeletal vertical pattern on treatment effects. From the literature search, only one available study compared the efficiency of vertical control from clear aligners with sequential distalization in patients with different skeletal vertical patterns.[59] Interestingly, this study stated that there was a slight but not significant increase in the mandibular plane angle in low- and normo-angle patients and a decrease in the mandibular plane angle in high-angle patients after clear aligner treatment with sequential distalization.[59] However, this study, comprised of a mixture of samples with both maxillary and mandibular molar distalization as well as a large age range (10 – 53 years old), had an unclear sample distribution among three vertical pattern groups.[59] In addition, all three groups showed an increase in lower anterior facial height (ANS-Me),[59] making it unclear whether the changes in SN-MP angle were directly related to the skeletal vertical pattern of the patients. Thus, further studies in this aspect are required.

4.2. Limitations

To cautiously consider the results of this study as well as plan future studies, several limitations must be considered. First, out of the included studies, only one article stratified the respective results based on attachment design.[60] In fact, by comparing a group that had 5 attachments per quadrant to a group that had only 3 attachments per quadrant, Garino et al. stated that the 5 attachments protocol provided better vertical control than the 3 attachments protocol during maxillary molar distalization. However, not all the included studies provided information about attachment design. For the included studies that did not report attachment design[20,57,61-63], different numbers of attachments ranging from 3 to 5 per quadrant were described. Even when the same number of attachments was used, different teeth were included. Therefore, directly combining studies from different groups with potentially different designs on attachments may overlook the true effects of clear aligners with different mechanical setups.

Second, it is unclear if specific amounts of active molar intrusion were programmed in the digital setups of each study. For instance, some studies may have built in a specific amount of molar intrusion into the digital setup to enhance the vertical control during molar distalization as indicated in the study from Peng et al..[59] Thus, whether the 0.26 mm of molar instruction observed in the post-distalization model was from the complete or incomplete expression of molar intrusion built-in the digital setup, or from the bite block effects of the clear aligners[83,89] remains unclear.

Lastly, although this current study did not discuss the amount of distalization achieved in each study, a potential correlation between the amount of distalization and resulting vertical changes should be explored. Future studies can also incorporate comparisons between clear aligners and other molar distalization strategies regarding vertical control, ultimately aiming to enhance clinical judgment and decision-making for treatment.

5. Conclusions

This study demonstrates that no significant changes in vertical dimension were observed both dentally and skeletally after maxillary molar distalization with clear aligner sequential distalization. However, the high risk of bias in the currently available studies, the large variation in the measurement protocol among the studies, and the limited available evaluations on vertical changes after mandibular molar distalization, implies the need for additional studies to confirm the efficiency of vertical control following molar distalization with clear aligners. In addition, future studies can categorize the vertical pattern of patients as well as correlate the potential relationship between the amount of molar distalization and subsequent vertical control using clear aligners.

Chapter 3: Maxillary Molar Distalization with Clear Aligner Therapy and Infrazygomatic Temporary Anchorage Devices System

1. Introduction

Maxillary molar distalization is a widely used orthodontic approach to gaining or re-gaining space in the dental arch and addressing Class II molar and canine relationships.[93] Appliances used in maxillary molar distalization are categorized as inter-arch or intra-arch based on whether anchorage is derived from both arches or solely from the maxillary arch.[94] Inter-arch appliances can lead to extrusion of the mandibular molars, causing undesired bite opening and a downward, backward mandibular rotation.[86] In cases where mandibular incisors are positioned or inclined labially and where gingival phenotype is thin, inter-arch appliances may not be indicated, as they can cause unfavorable proclination and periodontal complications in the mandibular anterior dentition.[29] With intra-arch appliances, such as the Pendulum,[7] Jones jig,[8] first-class appliance,[9] and distal jet,[10] unwanted side effects on the mandibular dentition can be avoided. However, these appliances are linked to maxillary anterior proclination[76] as well as distal tipping of the maxillary molars,[95] that can result in significant relapse when retracting the maxillary anterior teeth. To address this issue, skeletal anchorage with temporary anchorage devices (TADs) has been applied either in tandem with distalizing appliances[96] or used directly[97] to distalize molars, both yielding promising results.[48,98,99]

In the past two decades, clear aligner therapy (CAT) has attracted the attention of orthodontic professionals and patients by offering an esthetic and more hygienic choice for patients seeking orthodontic treatment.[100,101] Although CAT can reduce the discomfort associated with traditional orthodontic treatment,[102,103] tooth movement accuracy and efficiency with CAT are still questionable.[17,18] In general, any movement requesting radicular control shows less than 50% predictability.[17] The sequential distalization protocol with Class II elastics is one of the most popular strategies for maxillary molar distalization with CAT. However, the amount of molar distalization achieved by the CAT sequential distalization protocol is limited. At the crown level, up to 2.25 mm distalization of the maxillary first molar mesial buccal cusp has been reported,[19,22,24,25,42,44,60,63] while the minimum reported amount of molar distalization was 0.25 ± 0.63 mm – only 6.8% of predicted amount of anterior-posterior correction.[24] It is important to note that significant variations have been observed across current publications regarding the effectiveness of the CAT sequential distalization protocol for molar distalization, likely due to the differing treatment stages evaluated in the studies. For example, some studies only compared the pre-treatment stage with the timepoint directly following molar distalization (before anterior teeth retraction), noting a more remarkable amount of achieved molar distalization. Other studies compared the pre-treatment and post-treatment timepoints, revealing less significant molar distalization. Given the varied amounts of molar distalization reported across different studies, a previous systematic review and meta-analysis summarized that the maxillary first molar mesiobuccal cusp was distalized 2.07 mm [1.38 mm, 2.77 mm] based on the post-distalization dental model superimposition, and the maxillary first molar crown was distalized 2.00 mm [0.77 mm, 3.24 mm] based on the post-treatment lateral cephalometric evaluation, accompanied with crown distal tipping.[104] The mesiobuccal root of maxillary first molar was distalized 1.13 mm [-1.34 mm, 3.60 mm] based on the post-treatment lateral cephalometric evaluation.[104] With the usage of Class II elastics, mandibular anterior proclination was also observed.[65,104,105]

To improve the efficacy of molar distalization with clear aligners, the usage of TADs has been suggested with a variety of mechanical configurations.[106] However, few clinical evaluations on the CAT + TADs system exist. By rigidly

connecting the TADs to the maxillary second premolar as anchorage reinforcement, Cheng et. al.[43] reported 3.41 ± 0.28 mm maxillary first molar distalization at the crown level, and 1.52 ± 0.58 mm distalization at the root level at the termination of treatment. A disadvantage of this design is that it involves reinsertion of TADs after molar distalization, which may unnecessarily increase patient discomfort. In contrast, Miao et. al.[45] used TADs as direct anchorage by connecting to the precision cut of the tray with Class I elastics, and reported 1.25 ± 0.79 mm maxillary first molar distalization when evaluating the pre- and post-molar distalization (before premolar and anterior teeth retraction) digital models. Limitations of this study include the fact we did not have information regarding the amount of root distalization as well as whether molar distalization was maintained after anterior teeth retraction. In addition, different brands of aligners were used in these two studies.

It is worth noting that a majority of existing studies on maxillary molar distalization with CAT rely on three-dimensional (3D) models and lateral cephalometric radiographs to determine the change in molar position.[19-23,60-64] While digital model studies have been shown to provide high accuracy,[107] they do not allow visualization of the roots of the teeth making it difficult to determine the achieved amount of bodily distalization. Lateral cephalometric radiograph superimpositions, though widely used by orthodontists, are often distorted and show overlapping bilateral structures which can lead to inaccurate measurements.[108] Cone-beam computed tomography (CBCT) addresses these limitations by allowing detailed 3D evaluation of tooth movement, including root position and alveolar bone response.[109] Thus, the current study aimed to evaluate the efficacy of intra-arch maxillary molar distalization with the CAT+ TADs system by using TADs as direct anchorage. Specifically, by utilizing 3D CBCT and digital model superimpositions of pre- and post-treatment (after maxillary anterior teeth retraction) records, we intended to provide deeper insights into the efficacy and predictability of molar distalization with this system, as well as to determine the reliability of current model measurement methods.

2. Materials and Methods

The study protocol (IRB protocol # 853655) was reviewed by the Institutional Review Board at the University of Pennsylvania on June 2nd, 2023. It was determined that the proposal met eligibility criteria for IRB review exemption authorized by 45 CFR 46.104, category 4. All methods were performed according to regulations and guidelines.

2.1 Sample collection

This is a retrospective study including adult patients who started clear aligner treatment at a single private practice between January 2019 and January 2022. All patients were treated with Invisalign® (Align Technology, Inc., San Jose, California, USA) clear aligners. On each side requiring distalization, an infrazygomatic TAD (1.7 x 8 mm, TGA titanium alloy material; Xi'an Zhongbang Titanium Biomaterials Company, Shaanxi, China) was placed buccally between the maxillary first molar and second premolar, with the insertion route angled upward to place the whole TAD buccal to the tooth roots. Power chain (Ormco Clear Generation II Power Chain, Closed, catalog # 639-0002, Brea, California, USA) were placed from the buccal button on maxillary first premolar to the TAD (**Figure 13**). Rectangular attachments were designed for each maxillary tooth. The patients were instructed to wear their aligners for at least 22 hours a day. Each tray was worn for 7 days. Patients were recalled every 3 months.

The inclusion criteria were as follows: 1) side with at least 1 mm of maxillary first molar distalization planned in the ClinCheck® plan; 2) sequential distalization protocol/"V" pattern tooth movement was utilized in the ClinCheck® plan; 3) absence of or extraction of maxillary third molars prior to the start of treatment; 4) presence of both maxillary first (U6) and second (U7) molars on the side undergoing distalization; 5) non-extraction of the maxillary teeth (except

third molars); 6) high quality intraoral scan and CBCT taken prior to treatment (T1) and at the end of the first set of active aligners (T2).

The exclusion criteria were as follows: 1) patient showed poor compliance with aligner and elastic wear; 2) side with TAD failure during the treatment; 3) side with less than 1 mm of maxillary first molar distalization planned in the ClinCheck® plan; 4) side with missing first or second maxillary molar; 5) patient refused third molar extraction prior to the start of orthodontic treatment; 6) low image quality, such as missing palatal structure in the intraoral scan or significant scatter in the CBCT images, that interfered with landmark identification and measurements.

Figure 13. Intraoral photos of patient with CAT + infrazygomatic TAD for maxillary molar distalization.

2.2 CBCT superimposition and measurement

All CBCT images were taken on the same machine (Carestream 9300, Carestream Health, Inc, Rochester, New York, USA) with 17 × 13.5 cm FOV (field of view), at 90 kV, 5.0 mA, and 0.300 mm voxel size. The CBCT images were taken as the routine clinical protocol of clinical records in this particular practice office. No radiographic images were taken for research purpose. The CBCT datasets were exported as DICOM files and imported into Dolphin 3D Imaging Software (Dolphin Imaging; version 12.0.61, Chatsworth, California, USA) for analysis.

The CBCT images were first oriented with the Frankfort plane as the horizontal plane and the mid-palatal suture plane as the mid-sagittal plane (**Figure 14A**). Following the protocol described by Dai et. al. and Qiang et. al.,[110,111] the T1 and T2 CBCT images were auto-superimposed on the cranial base (**Figure 14B**). The superimposed scans were then re-oriented to the T1 occlusal plane, defined as the plane connecting the mesial buccal cusp of the maxillary first molars and the incisal edge of the maxillary central incisors, serving as the horizontal plane (**Figure 14C**).

The anteroposterior direction was referred to as the X-axis, the occlusal-gingival direction was referred to as the Y-axis, and the medial-lateral direction was referred to as the Z-axis. The X and Y reference lines were marked on the CBCT at the porion from the sagittal view (**Figure 14C**). All landmarks were marked in all 3 planes (axial, coronal, and sagittal views). The distance from the landmarks to the X and Y axis reference lines was recorded for the linear measurements (**Figure 14D**).

The following landmarks were used for the measurements:

For the anteroposterior and vertical measurements of maxillary first (U6) and second (U7) molars: mesiobuccal cusp (MBC); distobuccal cusp (DBC); mesiopalatal cusp (MPC); distopalatal cusp (DPC); center of the crown (CC), mesial root apex (MRA); distal root apex (DRA); palatal root apex (PRA); center of the root/furcation (RC).

For the transverse measurements of U6 and U7: the distance bilaterally between the MPCs.

For the anteroposterior and vertical measurements of maxillary central incisors (U1s): center of incisal edge (IE); root apex (RA).

The distance from maxillary molar and central incisor landmarks to the X and Y reference lines were measured from the sagittal view. The transverse measurements of the maxillary molars were measured from the coronal view (**Figure 14D**).

For the angular evaluations including tooth rotation, torque, and tipping, following measurements were performed (**Figure 14E**): the maxillary molar rotation was measured on the axial view with the angle between the center of the crown and a line parallel to the mid-sagittal plane; the maxillary molar torque was measured on the coronal view with the angle between the long axis of the tooth and a line parallel to the Y-axis line; the maxillary molar tipping was measured on the sagittal view with the angle between the long axis of the tooth and a line parallel to the Y-axis line; the maxillary central incisor torque was measured on the sagittal view with the angle between the long axis of the tooth and a line parallel to the Y-axis line.

Figure 14. CBCT measurement protocol. (A) The CBCT images were first oriented with the Frankfort plane as the axial plane and the mid-palatal suture plane as the mid-sagittal plane. (B) The T1 (white) and T2 (green) CBCT images were

auto-superimposed based on the cranial base. (C) The superimposed scans were then re-oriented to the T1 occlusal plane as the axial plane. The X (yellow, horizontal) and Y (blue, vertical) reference lines were marked on the CBCT at the porion from the sagittal view. (D) Demonstration of linear measurements. All the measurements were performed on both T1 and T2 images by referring to the same X (yellow) and Y (blue) reference lines. (E) Demonstration of angular measurements. All the measurements were performed both T1 and T2 images by referring to the lines parallel to the midsagittal plane or to the Y reference line U6: maxillary first molar; U1: maxillary central incisor; MBC: mesiobuccal cusp; IE: incisal edge.

2.3 Intraoral scan superimposition and measurement

All the intraoral scans were performed with iTero Element 2 Scanner (Align Technology, Inc.). The stereolithography (STL) files generated from the intraoral scans obtained at T1 and T2 were imported into 3D Slicer[112] (CMF 5.8.1 version) for analysis.

The T1 models were oriented to the occlusal plane (mesial buccal cusp of the maxillary first molars to the incisal edge of the maxillary central incisors) as the horizontal plane from the lateral view. From the occlusal view, the model was oriented to the palatal suture as the mid-sagittal plane (**Figure 15A**). As the stable region of the maxillary model was defined as the medial ⅔ of the third rugae and the regional palatal vault,[113] following the model superimposition protocol described by Anacleto et. al.,[114] nine palatal fiduciary landmarks, including six points on the maxillary palatine rugae and three points on the palatine suture were marked on the T1 and T2 models (**Figure 15B**). After the landmarks were selected, a size of Region of Interest (ROI) was assigned to each point. All six points on the rugae were assigned a ROI of size 30. The three suture points were assigned a ROI of size 15. The T2 model was superimposed onto the T1 model based on the area generated by the landmarks chosen (**Figure 15B**).

After superimposition, the following landmarks were placed on maxillary first and second maxillary molars: MBC: mesiobuccal cusp, DBC: distobuccal cusp, MPC: mesiopalatal cusp, DPC: distopalatal cusp, CC: center of the crown. The center of the incisal edge of the central incisor was also marked. Each marked point was recorded in the (A, S, R) coordinate system. Differences in the coordinate were used to determine the movement of each landmark in the anterior-posterior (A), vertical (S), and transverse (R) directions, respectively (**Figure 15C**).

For the angular measurements on intraoral scans, Dolphin 3D Imaging Software was used, and the maxillary first and second molars were measured from the occlusal view to evaluate the rotation changes of the molars (**Figure 15D**).

Figure 15. Intraoral scan measurement protocol. (A) In the 3D Slicer, the T1 models were oriented to the occlusal plane (mesial buccal cusp of the maxillary first molars to the incisal edge of the maxillary central incisors) as the horizontal plane

from the lateral view. From the occlusal view, the model was oriented to the palatal suture as the mid-sagittal plane. (B) Nine palatal fiduciary landmarks were marked on the T1 and T2 models. All six points on the rugae were assigned a Region of Interest (ROI) of size 30. The three points on the suture were assigned a ROI of size 15. The T2 model superimposed onto the T1 model based on the area generated by the landmarks chosen. (C) The landmarks were placed on the maxillary first and second maxillary molars as well as the central incisors. Each marked point was recorded in the coordinate system. Differences in the coordinate were used to determine the movement of each landmark in the anterior-posterior (A), vertical (S), and transverse (R) directions, respectively. A: anterior, P: posterior, S: superior, I: inferior, R: right, L: left. (D) For the evaluation of rotation of the molars on intraoral scans, the occlusal view image of each molar in the 3D Slicer was uploaded into Dolphin 3D Imaging Software, the rotation of the molars was defined as the angulation between the line bisecting the mesial-buccal width of the molar crown (blue) and the vertical line parallel to the midsagittal plane (green).

2.4 Data interpretation

Changes in all landmarks measured on the CBCT and 3D models were calculated by subtracting T1 measurements from T2 measurements, to present the obtained tooth movement through the treatment. The planned tooth movement was obtained from the ClinCheck tooth movement tables. Tooth distalization/retraction, intrusion, mesial-out rotation, crown-buccal torque, and crown-distal tipping data were presented as positive values. Tooth mesialization/protrusion, extrusion, mesial-in rotation, crown-palatal torque, and crown-mesial tipping data were presented as negative values.

The treatment efficacy was expressed as the percent of planned movement achieved and was calculated by the following equation:

percentage of efficacy = (achieved movement)/(planned movement) × 100%

2.5 Statistical Analysis

All the CBCT and intraoral scan measurements were performed by one examiner. To test the reliability and consistency of current superimposition and measurement system, five samples were randomly selected and analyzed by the same examiner one month after the first round of measurement. The intraclass correlation coefficient (ICC) of each parameter was calculated using IBM SPSS Statistics (version 30.0.0.0, Chicago, IL, USA).

Sample size estimation was calculated by using $\alpha = 0.05$ and 80% power with an effect size of 1.2, which showed a minimum sample size of 13.

The Shapiro-Wilk normality test was performed by OriginPro 8 (Origin Lab Corp., Northampton, MA, USA). As some data did not pass the normal distribution test, results are presented as median [minimum, maximum]. For the comparisons between CBCT and intraoral scan, between CBCT and ClinCheck, as well as between intraoral scan and ClinCheck, the Wilcoxon matched-pairs signed rank test and paired comparison plot were used. In addition, the Pearson correlation coefficients test was performed to test any correlation between treatment efficacy and planned tooth movement.

For all data presented in this study, $P < 0.05$ was considered a suggestive difference, while $P < 0.005$ was recognized as a statistically significant difference based on a recent recommendation.[115]

3. Results

3.1 Demographic information

38 sides from 21 patients (17 females, 4 males) met the inclusion & exclusion criteria. The average ± standard division age at T1 was 28.71 ± 4.19 years old. The time that elapsed between the T1 (initial) and T2 (end of the first set of active aligners) data collection was on average 15.33 ± 4.14 months, with the median and range as 14.0 months [11 months, 30 months].

Both CBCT and digital model measurements showed high ICC (**Table 22**).

Table 22. The interclass correlation coefficient (ICC) of each parameter in CBCT and digital model measurements. U1: maxillary central incisor, U6: maxillary first molar, U7: maxillary second molar, IE: incisal edge, MBC: mesiobuccal cusp, DBC: distobuccal cusp, MPC: mesiopalatal cusp, DPC: distopalatal cusp, CC: center of the crown; MRA: mesial root apex, DRA: distal root apex, PRA: palatal root apex, RC: center of the root.

		CBCT	Digital Model
Anterior-Posterior	U1-IE	0.999 [0.995, 1.000]	0.996 [0.985, 0.999]
	U6-MBC	0.990 [0.960, 0.997]	0.975 [0.897, 0.994]
	U6-DBC	0.993 [0.971, 0.998]	0.967 [0.879, 0.992]
	U6-MPC	0.977 [0.911, 0.994]	0.942 [0.782, 0.985]
	U6-DPC	0.956 [0.837, 0.989]	0.948 [0.811, 0.987]
	U6-CC	0.987 [0.946, 0.997]	0.974 [0.902, 0.994]
	U6-MRA	0.980 [0.921, 0.995]	-
	U6-DRA	0.985 [0.936, 0.996]	-
	U6-PRA	0.988 [0.953, 0.997]	-
	U6-RC	0.937 [0.765, 0.984]	-
	U7-MBC	0.992 [0.972, 0.998]	0.984 [0.940, 0.996]
	U7-DBC	0.897 [0.639, 0.973]	0.983 [0.909, 0.996]
	U7-MPC	0.877 [0.594, 0.968]	0.953 [0.827, 0.988]
	U7-DPC	0.990 [0.961, 0.997]	0.948 [0.811, 0.987]
	U7-CC	0.979 [0.922, 0.995]	0.974 [0.902, 0.994]
	U7-MRA	0.956 [0.838, 0.989]	-
	U7-DRA	0.990 [0.961, 0.998]	-
	U7-PRA	0.963 [0.867, 0.991]	-
	U7-RC	0.953 [0.832, 0.988]	-
Vertical	U6-MBC	0.929 [0.755, 0.982]	0.930 [0.573, 0.984]
	U6-DBC	0.944 [0.794, 0.986]	0.961 [0.855, 0.990]
	U6-MPC	0.960 [0.856, 0.990]	0.954 [0.830, 0.988]
	U6-DPC	0.983 [0.937, 0.996]	0.970 [0.892, 0.992]
	U6-CC	0.826 [0.468, 0.953]	0.931 [0.756, 0.982]
	U6-MRA	0.981 [0.925, 0.995]	-
	U6-DRA	0.991 [0.963, 0.998]	-
	U6-PRA	0.774 [0.333, 0.938]	-
	U6-RC	0.983 [0.938, 0.996]	-
	U7-MBC	0.941 [0.392, 0.988]	0.962 [0.500, 0.965]
	U7-DBC	0.968 [0.877, 0.992]	0.865 [0.543, 0.965]
	U7-MPC	0.902 [0.673, 0.974]	0.864 [0.541, 0.964]
	U7-DPC	0.983 [0.936, 0.996]	0.801 [0.393, 0.946]
	U7-CC	0.912 [0.703, 0.977]	0.772 [0.316, 0.938]
	U7-MRA	0.973 [0.897, 0.993]	-
	U7-DRA	0.419 [-0.273, 0.818]	-
	U7-PRA	0.993 [0.973, 0.998]	-
	U7-RC	0.957 [0.836, 0.989]	-
Transverse	U6-6	0.997 [0.974, 1.000]	0.996 [0.963, 1.000]
	U7-7	0.971 [0.803, 0.997]	0.840 [-0.011, 0.982]
Rotation	U6	0.956 [0.843, 0.989]	0.991 [0.962, 0.998]
	U7	0.986 [0.949, 0.996]	0.994 [0.976, 0.999]
Torque	U1	0.999 [0.996, 1.000]	0.998 [0.993, 1.000]
	U6	0.973 [0.899, 0.993]	-
	U7	0.997 [0.990, 0.999]	-
Tipping	U6	1.000 [0.999, 1.000]	-
	U7	0.988 [0.957, 0.997]	-

3.2 Molar distalization

There was a median value of 0.8 mm (based on model) – 0.85 mm (based on CBCT) of U6 distalization measured at the center of the crown (**Table 23**). The median amount of the U7 distalization was 0.8 mm (based on model) – 1.3 mm (based on CBCT) (**Table 23**). As the planned movement can influence the outcomes, we compared the achieved movement at the MBC, a commonly used landmark, with the planned movements in the ClinCheck system.[44,65,111] All comparisons showed that the achieved molar crown distalization of both the U6 and U7 were statistically significantly lower than the planned movement (planned: 3.05 mm [1.0 mm, 5.6 mm] for the U6 and 3.05 mm [0.9 mm, 6.1 mm] for the U7, **Figure 16A,B,F,G**). The median efficacy of maxillary molar crown distalization was 32.44% (based on CBCT) - 37.40% (based on model) for the U6 and 30.97% (based on model) - 32.92% (based on CBCT) for the U7 (**Table 24**). In addition, the efficacy of U6 crown distalization was negatively correlated with the amount of planned distalization (**Table 24**).

Crown mesial-out rotation is a commonly observed tooth movement when applying distalization force buccally. We evaluated the amount of distalization at each molar cusp tip (**Table 23**) as well as the mesial-out rotation of each molar (**Figure 16C,D,H,I**). The buccal cusps showed slightly larger amounts of distalization than the palatal cusps for both the U6 and U7 (**Table 23**), indicating a mesial-out rotation of the molars. Based on the angular measurements, the U6s rotated 5.4° [-1.5°, 19.3°] (based on CBCT) / 5.5° [-3.9°, 21.9°] (based on model) in the mesial-out direction. 3.25° [-8.3°, 14.4°] (based on CBCT) / 3.15° [-11.2°, 21.3°] (based on model) of mesial-out rotation was observed on the U7s. Although a wide range of rotations was recorded, they were consistent with prescribed tooth rotations (**Figure 16C,D,H,I**) with high efficacy (**Table 24**).

When evaluating the amount of molar root distalization on the CBCT, 0.6 mm [-0.9 mm, 1.9 mm] and 0.85 mm [-1.2 mm, 3.5 mm] of root distalization were achieved at the center of the root for U6 and U7, respectively (**Table 23**). The amount of root distalization was slightly less than the amount of crown distalization, indicating that crown distal tipping may have occurred. 1.45° [-2.0°, 16.0°] of U6 crown distal tipping and 0.85° [-8.7°, 6.9°] of U7 crown distal tipping was observed (**Figure 16E,J**). Interestingly, the achieved crown distal tipping was statistically significantly less than the planned crown distal tipping for the U6 (**Figure 16E**), with an efficacy of 63.45% [-500%, 1333%] for U6 crown distal tipping and 79.31% [-2150%, 325%] for U7 crown distal tipping (**Table 24**).

Table 23. The amount of distalization achieved at the crown and root levels of maxillary molars. MBC: mesiobuccal cusp, DBC: distobuccal cusp, MPC: mesiopalatal cusp, DPC: distopalatal cusp, CC: center of the crown; MRA: mesial root apex, DRA: distal root apex, PRA: palatal root apex, RC: center of the root. All the data are presented as median [minimum, maximum] in mm. Wilcoxon matched-pairs signed rank test was used to compare the data between CBCT measurements and model measurements. *: P < 0.05, **: P < 0.005.

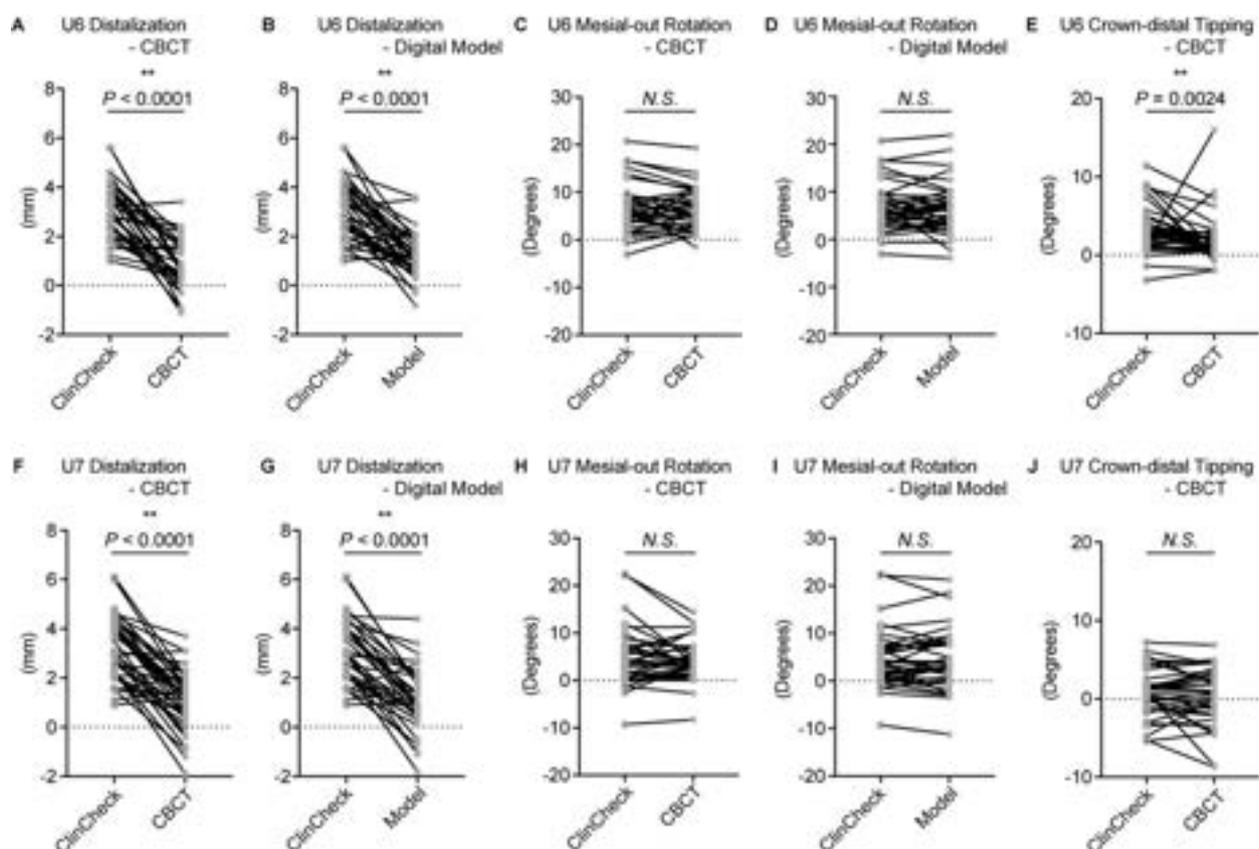|		U6				U7			
		CBCT	Model	CBCT *vs* Model		CBCT	Model	CBCT *vs* Model	
Crown	MBC	0.80 [-1.1, 3.4]	1.05 [-0.8, 3.6]	0.0873	-	1.25 [-1.9, 3.7]	0.95 [-1.8, 4.4]	0.8624	-
	DBC	0.95 [-1.1, 3.4]	1.15 [-1.1, 3.4]	0.0664	-	0.90 [-1.0, 4.4]	1.05 [-1.5, 4.7]	0.4908	-
	MPC	0.35 [-2.1, 3.6]	0.60 [-2.6, 2.2]	0.7860	-	0.95 [-2.1, 4.4]	0.65 [-3.2, 3.7]	0.1611	-
	DPC	0.75 [-2.1, 2.6]	0.60 [-2.4, 2.0]	0.2493	-	0.95 [-2.7, 4.1]	0.80 [-2.7, 3.5]	0.4521	-
	CC	0.85 [-1.5, 3.3]	0.80 [-1.8, 2.6]	0.2958	-	1.30 [-1.7, 3.7]	0.80 [-2.4, 3.8]	0.3390	-
Root	MRA	0.50 [-0.9, 2.3]	-	-	-	1.05 [-0.9, 3.0]	-	-	-
	DRA	0.90 [-2.1, 2.4]	-	-	-	1.15 [-1.2, 3.4]	-	-	-
	PRA	0.00 [-2.4, 2.1]	-	-	-	0.80 [-1.4, 2.8]	-	-	-
	RC	0.60 [-0.9, 1.9]	-	-	-	0.85 [-1.2, 3.5]	-	-	-

Figure 16. The amount of achieved (based on CBCT or model measurements) and planned (ClinCheck) distalization of maxillary molars. The achieved (A, B, F, G) crown distalization, (C, D, H, I) mesial-out rotation, and (E, J) crown-distal tipping of maxillary first molar (U6) and second molar (U7) were compared to each planned movement, respectively. The molar crown distal tipping cannot be measured on the models due to missing root structures. All the data are presented as paired comparison plot to visualize the condition of each sample. N.S.: not statistically significant. *: P < 0.05, **: P < 0.005.

Table 24. The efficacy of distal movements at the crown level of maxillary molars. The efficacy data are presented as median [minimum, maximum]. The r value of Pearson correlation coefficients was listed if the P value was less than 0.05. *: P < 0.05, **: P < 0.005.

		Efficacy based on CBCT (CBCT/Clincheck, %)	Correlation Between Clincheck & Efficacy (CBCT)		Efficacy based on Model (Model/Clincheck, %)	Correlation Between Clincheck & Efficacy (Model)	
			r	P Value		r	P Value
U6	Distalization	32.44 [-34.62, 106.70]	-0.3289	0.0438 *	37.40 [-26.03, 140.30]	-0.3625	0.0265 *
	Mesial-out Rotation	82.62 [-300.00, 380.00]	-	0.7975 -	97.17 [-30.56, 314.30]	-0.3313	0.0422 *
	Crown-distal Tipping	63.45 [-500.00, 1333.00]	-	0.3064 -	-	-	- -
U7	Distalization	32.92 [-82.61, 140.00]	-	0.3902 -	30.97 [-78.04, 173.50]	-	0.7081 -
	Mesial-out Rotation	67.78 [-1300.00, 1040.00]	-	0.5791 -	106.10 [-966.70, 1500.00]	-	0.7461 -
	Crown-distal Tipping	79.31 [-2150.00, 325.00]	-	0.7240 -	-	-	- -

3.3 Incisor retraction

Since the achieved maxillary molar distalization was significantly less than the planned movement, we further examined whether the retraction of the maxillary incisors was influenced. As shown in **Figure 17**, achieved U1 retraction was 0.3 mm [-7.3 mm, 2.9 mm] based on the CBCT and 0.4 mm [-4.9 mm, 4.4 mm] based on the model, both were statistically significantly less than planned U1 retraction (1.65 mm [-0.6 mm, 4.8 mm]). The achieved buccal crown torque of U1 (1.90° [-13.2°, 23.1°]) was also significantly less than the planned torque (4.7° [-12.0°, 28.2°]).

Figure 17. The amount of achieved (based on CBCT or model measurements) and planned (ClinCheck) retraction of maxillary central incisor. (A, B) Comparison of achieved and planned central incisor retraction based on the measurements at the incisal edge. (C) Comparison of achieved and planned central incisor crown buccal torque. The incisor crown buccal torque could not be measured on the models due to missing root structures. All the data are presented as paired comparison plot to visualize the condition of each sample. N.S.: not statistically significant. **: P < 0.005.

3.4 Transverse movement of molars

As the discrepancy between achieved and planned retraction/distalization for the U1s (median of differences as 1.75 mm based on CBCT) was less than that for the maxillary molars (median of differences of 2.20 mm for both U6s and U7s based on CBCT), the spaces for anterior retraction may have been created from unwanted arch expansion.

In fact, the achieved inter-molar width increase (U6: 3.3 mm [0.8 mm, 5.9 mm] based on the model and 2.2 mm [-1.0 mm, 4.9 mm] based on the CBCT; U7: 1.5 mm [-1.0 mm, 3.9 mm] based on the model and 0.8 mm [-2.6 mm, 2.9 mm] based on the CBCT) was significantly greater than planned (U6: 1.4 mm [-2.5 mm, 4.3 mm]; U7: -0.1 mm [-2.1 mm, 2.3 mm]) (**Figure 18A,B,D,E**). This unplanned lateral movement of the molars was accompanied with higher buccal crown torque (U6: 2.70° [-4.8°, 9.1°]; U7: 1.75° [-9.0°, 7.8°]) than planned torque (U6: 0.40° [-6.4°, 7.5°]; U7: -2.40° [-13.8°, 2.5°]) (**Figure 18C,F**), indicating poor transverse control.

3.5 Molar intrusion

Vertical control is one of the key factors to be considered when performing molar distalization, especially in skeletal Class II patients.[105] Thus, the amount of molar movement in the vertical dimension was also evaluated in the current study (**Table 25, Figure 19**). A median value of 1.2 mm (based on CBCT) – 1.6 mm (based on model) of U6 intrusion was noticed when evaluating based on the center of the crown (**Table 25**). The median amount of U7 intrusion was 0.8 mm (based on CBCT) – 1.4 mm (based on CBCT) (**Table 25**). When comparing the achieved molar intrusion to the planned molar intrusion based on the MBC (**Figure 19**), both the U6 and U7 showed larger amounts of intrusion than planned (-0.1 mm [-0.8 mm, 1.5 mm] for U6; -0.3 mm [-1.4 mm, 1.3 mm] for U7).

Figure 18. The amount of achieved (based on CBCT or model measurements) and planned (ClinCheck) intermolar width changes and the crown buccal torque changes of the maxillary molars. The achieved (A, B, D, E) intermolar width change and (C, F) molar crown buccal torque of maxillary first molar (U6) and second molar (U7) were compared to each planned movement, respectively. The molar crown buccal torque could not be measured on the models due to missing root structures. All the data are presented as paired comparison plot to visualize the condition of each sample. *: P < 0.05, **: P < 0.005.

Table 25. The amount of intrusion achieved at the crown and root levels of maxillary molars. MBC: mesiobuccal cusp, DBC: distobuccal cusp, MPC: mesiopalatal cusp, DPC: distopalatal cusp, CC: center of the crown; MRA: mesial root apex, DRA: distal root apex, PRA: palatal root apex, RC: center of the root. All the data are presented as median [minimum, maximum] in mm. Wilcoxon matched-pairs signed rank test was used to compare the data between CBCT measurements and model measurements. *: P < 0.05, **: P < 0.005.

| | | U6 | | | | U7 | | | |
		CBCT	Model	CBCT *vs* Model		CBCT	Model	CBCT *vs* Model	
	MBC	1.65 [-0.4, 3.6]	1.70 [-0.5, 3.5]	0.0328	*	1.45 [0.0, 2.8]	1.70 [0.0, 3.3]	0.0995	-
	DBC	1.50 [-0.4, 3.6]	1.70 [-0.2, 3.6]	0.1988	-	1.20 [-0.7, 3.0]	1.40 [0.0, 3.3]	0.0043	**
Crown	MPC	1.00 [-0.9, 2.4]	1.30 [-0.7, 2.6]	0.0581	-	1.05 [-0.3, 2.1]	1.10 [0.1, 2.9]	0.0040	**
	DPC	1.20 [-0.8, 2.7]	1.40 [-0.5, 2.6]	0.0559	-	1.00 [-0.3, 2.4]	1.10 [0.3, 3.1]	0.3180	-
	CC	1.20 [-0.7, 3.4]	1.60 [-0.3, 3.0]	0.0998	-	0.90 [-0.2, 2.8]	1.40 [0.1, 3.1]	0.0027	**
	MRA	0.85 [-0.3, 2.7]	-	-	-	0.90 [-0.5, 3.4]	-	-	-
Root	DRA	0.90 [-1.3, 3.0]	-	-	-	0.85 [-0.6, 2.0]	-	-	-
	PRA	0.60 [-1.5, 3.0]	-	-	-	0.60 [-2.4, 3.1]	-	-	-
	RC	1.10 [-1.5, 3.0]	-	-	-	1.00 [0.0, 2.7]	-	-	-

Figure 19. The amount of achieved (based on CBCT or model measurements) and planned (ClinCheck) intrusion of the maxillary molars. The intrusion of the maxillary first molar (A, B, U6) and second molar (C, D, U7) based on the measurements of mesiobuccal cusp. **: $P < 0.005$.

4. Discussion

The current retrospective longitudinal study evaluated the amount and efficacy of maxillary molar distalization with the CAT + TADs system at the end of anterior teeth retraction. Overall, when evaluating at the MBC, the median amount of maxillary molar distalization was 0.85 mm for the U6 and 1.30 mm for the U7, with low median efficacy of distalization of 32.44% for the U6 and 32.92% for the U7 based on evaluations on CBCT. The unsatisfied amount of molar distalization significantly influenced the amount of anterior teeth retraction achieved.

As previous studies have shown, approximately 2 mm of maxillary first molar distalization can be achieved at the crown level with CAT alone.[104] The limited amount of molar distalization observed with the CAT + TADs system shown in the current study raises questions regarding the benefits of using TADs in conjunction with CAT. It is important to highlight that, although previous studies reported high molar distalization efficacy with a sequential distalization

protocol without TADs, the timepoints and the methods of evaluation differed from those used in the current study. For example, D'Antò et. al. found that U6s and U7s were distalized with efficacies of 69% and 75%, respectively.[19] However, their study performed digital model evaluations immediately after the molar distalization phase prior to anterior teeth retraction, while anterior teeth retraction would significantly reduce the molar distalization efficacy.[44] Another study by Simon et. al. reported a molar distalization efficacy of up to 87%.[58] Their study again, used the records immediately after the molar distalization without anterior teeth retraction. In addition, instead of using the palatal rugae area for model superimposition, their study used untreated teeth as stable reference points, despite the fact that premolar and anterior teeth mesialization is commonly observed when performing molar distalization.[116]

When looking at studies that shared similar timepoints as the current study (after anterior teeth retraction) and used model superimpositions, lower amounts of distalization were described. Li et. al.[44] reported 0.88 mm ± 0.83 mm maxillary first molar distalization with an efficacy of 36.48%. Lin et. al.[65] reported 0.67 mm ± 0.5 mm of the maxillary first molar distalization with efficacy ranging from 31.1% to 40.1%. These values were slightly lower than the amount and efficacy of molar distalization observed in the current study (1.05 mm, 37.40% based on model evaluation of MBC). In addition, Lin et. al. also highlighted side effects such as mandibular first molar extrusion as well as mandibular incisor proclination and protrusion caused by Class II elastics.[65] Thus, when evaluating solely on the crown level, the current study suggests that adding TADs as anchorage only slightly enhances the amount of distalization achieved with CAT. However, eliminating the use of Class II elastics could be beneficial in avoiding adverse effects on the opposing arch.

Other than linear movement, molar rotation and tipping are also key factors when evaluating molar distalization, as large amounts of crown mesial-out rotation and crown distal tipping are associated with unstable treatment outcomes.[117] The current study demonstrated that the CAT + TADs system showed good control in terms of molar mesial-out rotation and molar crown distal tipping, with even less U6 crown-distal tipping than planned. The 1.45° [-2.0°, 16.0°] crown distal tipping of the U6 observed in the current study was significantly less than that of other conventional and skeletal anchorage supported intra-arch distalizers (the mean value ranging from 1.15° to 18.5° for molar crown distal tipping).[117] Thus, adding TADs to CAT provided better bodily movement of the molars, potentially increasing long-term treatment stability.

When employing mechanics slightly different from the current study, with Class I elastics between a buccal TAD in the molar region and a precision cut in the canine region, Miao et. al. found that prior to anterior retraction, the maxillary first molar achieved 1.25 mm ± 0.79 mm distalization with an efficacy of 55.9%.[45] Distalization was accompanied by 0.47 mm ± 0.79 mm intrusion, 5.30° ± 4.56° distal tipping, and 1.95° ± 4.18° crown buccal torque of the maxillary molars, which differed significantly from the planned movement.[45] With the slightly decreased amount of molar distalization and crown distal tipping as well as increased amount of molar intrusion and crown buccal torque reported in the current study, we can surmise that there was still anchorage loss of the maxillary molars when retracting the anterior teeth even with the usage of TADs. In addition, since the infrazygomatic TAD was more gingival than the button on the first premolar, the continuous usage of power chain introduced an intrusion force and clockwise rotation moment to the maxillary arch. This force and moment led to maxillary molar intrusion, as the observed intrusion in the current study (1.70 mm) was significantly larger than that reported in studies using CAT without TADs (0.63 mm[65] and 0.36 mm[44]). Thus, adding TADs can potentially benefit vertical control when performing molar distalization.

One significant side effect of the mechanics of the current setup is the unplanned arch expansion and crown buccal torque of the molars despite the usage of rectangular attachments on all the posterior teeth. This unintended arch expansion may have been caused by distortion of the aligners. While the buccal crown torque observed in the current study (2.70° [-4.8°, 9.1°]) is larger than that reported in the study conducted by Miao et. al. (1.95° ± 4.18°),[45] it

is important to note that different brands of aligners were used in the two studies. The increased maxillary molar crown buccal torque observed in the current study may be attributed to differences in aligner flexibility and rigidity.

Lastly, the current study allowed us to compare the treatment outcomes derived from CBCT superimpositions with those from digital molar superimpositions. When looking at the consistency between two times of measurements, both CBCT measurements and digital model measurement showed high ICC. No statistically significant differences were observed on the molar distalization, rotation, and tipping measurements between CBCT and model method. However, discrepancies between these two methods were observed when assessing molar vertical and lateral movements, with the model method generally yielding larger treatment effect values. In addition, although CBCT provides the most accurate and comprehensive data,[118] it is not routinely used in orthodontic practice and is not considered a standard diagnostic tool.[119] Thus, most existing studies on molar distalization rely on digital models or lateral cephalometric radiographs rather than CBCT superimpositions.[19,20,22,23,60-64] However, the accuracy of lateral cephalometric radiographs in measuring molar movement remains a topic of debate.[118,120] Thus, comparisons between studies that use different records for treatment outcome evaluation should be made cautiously, particularly regarding parameters in the vertical and transverse dimensions.

4.1 Limitations

A key limitation of this study, as with any research involving clear aligners, is the inherent dependence on patient compliance with aligner and elastic wear. Although the fitting of aligners was checked at each re-call visit, verifying full adherence to the prescribed wear was not feasible. Artifacts and poor contrast resolution in CBCT records may have caused errors in measurements. In addition, this study included a wide range of planned distalization values, spanning from 1 mm to 5.6 mm for the maxillary first molar. Due to the biological variability and limitations of tooth movement, smaller amounts of distalization may not be directly comparable to larger planned amounts when evaluating efficacy. Future studies could benefit from comparing planned distalization within a more restricted range to provide a more precise assessment of the efficacy of molar distalization using the CAT + TADs system.

5. Conclusions

The findings of this study demonstrate that incorporating infrazygomatic TADs into CAT enhances bodily movement as well as significant amounts of intrusion of the maxillary molars during distalization. However, overall efficacy of maxillary molar distalization was still low. Notably, a negative correlation was observed between the prescribed amount of maxillary molar distal movement and the efficacy of distalization. As all patients in this study were treated with TADs, further studies with comparative designs are needed to isolate and evaluate the specific contribution of TADs to treatment outcomes. This study highlights inherent limitations in the amount of maxillary molar distalization achievable with the clear aligner + TADs system.

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