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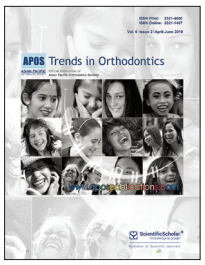

Review Article

Efficacy of clear aligners in producing molar distalization: Systematic review

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ABSTRACT

Objectives: The aim of this review is to systematically analyze the efficacy of molar distalization using clear aligners in non-growing Class II patients.

Materials and Methods: A complete search across the electronic database through PubMed, Cochrane, Google scholar, LILACS, and manual search of orthodontic journals were done till 2019. Studies were selected on the basis of PRISMA guidelines.

Results: A total of four articles were included in this review. The amount of molar distalization reported was 2–3 mm.

Conclusion: Out of the four studies included. In all the studies a significant amount of distalization was reported. Three retrospective studies concluded that distalization with aligners is the most effective of all tooth movements. One study concluded that aligners effectively achieved distalization with an efficacy of 87%, other two studies concluded that aligners effectively distalized the molars with good control over vertical dimension and mesiodistal tipping.

Keywords: Orthodontics, Clear aligner therapy, Molar distalization, Invisalign

INTRODUCTION

Over the past decade, adult patients seeking orthodontic treatment put forth the desire for more esthetic and a comfortable treatment alternative than fixed orthodontic appliances.[1] In 1997, Align Technology (Santa Clara, Calif) tailored and incorporated modern technologies to introduce the clear aligner treatment (CAT) as we know it, rendering Kesling's concept a feasible orthodontic treatment option.[2] CAT has been cited as a safe, esthetic, and comfortable orthodontic procedure for adult patients, but its predictability in carrying out complex movements such as extrusion, torquing, rotation and bodily movements such as distalization is questionable.[3,4] Only a few investigations have been carried to assess one of the complex movements, which is maxillary molar distalization using these clear thermoplastic trays.[5,6]

The distalization of maxillary molars is frequently required to treat mild skeletal Class II cases to correct a Class II molar relationships to a Class I molar relationship using non-extraction protocol.[7,8]

The upper molars can be distalized by means of extra or intraoral forces.[9] Since the 1950's headgear has been the most frequently used appliance for maxillary molar distalization.

Unfortunately, this appliance requires considerable patient compliance.[10] Recently, numerous techniques have been developed to reduce the dependence on patient compliance, such as intraoral appliances with and without skeletal anchorage. Despite the effectiveness of many of these appliances clinicians must consider many side effects: increase in lower facial height, clockwise rotation of the mandible, extrusion of first premolars, undesirable tipping of the maxillary molars, and loss of anterior anchorage during distalization.[7,11-13] Most of these side effects involve an increase of the vertical dimension of the treated subjects, keeping this treatment procedure generally contraindicated in hyperdivergents.[14,15]

Clear aligners are based on computer-aided design procedures. The orthodontic treatment with the Invisalign (Align Technology, San José, California, USA) system is a digitized process that starts from the acquisition of a 3D model of the dental arches allowing the planning of teeth movements with a proper software.[16] The aligner allows the control of 3D movements by holding teeth on all the surfaces (vestibular, palatal-lingual, and occlusal) and applying proper forces thanks to attachments of different size and shape and other specific features.[17]

Several case reports,[18,19] have shown the possibility of obtaining class II correction with a sequential maxillary molar distalization in non-growing patients. However, a sound clinical judgment should always be made on the basis of a higher level of evidence. Recently a few systematic reviews have been published focusing on clinical efficacy of clear aligners, only one SR reported that molar distalization is highly predictable,[20] however the focus on distalization per se for non-extraction Class II cases is a gray area.

The present systematic review was undertaken to update the knowledge of the available evidence about CAT and to answer the following clinical research question: "Is CAT effective in controlling the maxillary molar distalization?"

MATERIALS AND METHODS

Protocol

Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) checklist was followed in reporting this systematic review.

Search strategy and search databases

A systematic search in the medical literature produced between January 2000 and September 2019 was performed to identify all peer-reviewed articles potentially relevant to the review's question. In order to retrieve the list of potential articles to be included in the review, the following databases were searched: PubMed, PubMed Central, Cochrane Library, LILAC's, Scopus, and Google Scholar [Table 1]. A manual search was performed in the library of the institute and references of selected articles. Title and abstract screening were performed to select articles for full-text retrieval.

Eligibility criteria

Studies were selected based on the following Inclusion criteria: (i) Prospective and retrospective studies, (ii) studies done on human patients, (iii) studies on orthodontic treatment with clear aligners (Invisalign), (iv) studies on distalization with aligners and (v) studies with appropriate statistical analysis. Following exclusion criteria were followed (i) Studies with use of adjunct modalities other than aligners, (ii) Studies with surgical orthodontic techniques, (iii) Studies with sample size <10.

Table 1: Search strategy employed for various search engines for retrieving articles.

Search engine	Search strategy	Articles obtained
PubMed	#1 (Clear aligner)) OR (CAT) OR (Orthodontic aligners) OR (Aligner therapy)	165
	#2 (distalisation) OR (Distalization) OR (Molar distalisation)	735
	#3 (((Orthodontic aligners*[Title/Abstract]) OR orthodontic aligner [Title/Abstract]) OR aligner therapy [Title/Abstract]) OR transparent aligners [Title/Abstract]) OR clear aligner treatment [Title/Abstract])) AND ((distalisation[Title/Abstract]) OR molar distalization [Title/Abstract]) AND (((class 2 malocclusion [Title/Abstract]) OR class 2 molar [Title/Abstract]) OR angles class 2 molar)	8
Cochrane Library	#1 Orthodontic aligners	236
	#2 (Clear aligners) OR (Orthodontic Appliance) AND (Distalization) OR (Molar distalization)	53
	#3 (Clear Aligner) OR (Aligners) OR (Orthodontic aligner therapy) AND (Distalization) OR (Molar distalization)	39
LILACS	Clear aligner OR Orthodontic aligner AND Distalisation	0
Web of Science	Clear aligner OR Clear aligner therapy	98
	Clear aligner OR Clear aligner therapy OR CAT or Clear Trays AND Molar distalisation OR Distalization OR Distalisation	2
Google Scholar	Clear aligner + Aligner therapy + Molar distalisation	265

Data extraction and management

Data extraction was done using the PICOS approach. Single investigators screened the articles for titles and abstracts and relevant studies were selected for the review. When a definitive decision to include or exclude the study based on abstracts could not be made, full texts were read. Second review of the articles was done by the second examiner and in case of disparities, feedback from the third investigator was taken.

Level of evidence and quality assessment of included studies

Level of evidence for each study was determined based on "The Oxford Levels of Evidence 2" (OCEBM Levels of Evidence-Based Medicine). Based on study design, study can be categorized to any level from 1 to 5. The quality assessment of included trials was undertaken independently as a part of the data extraction process. Newcastle - Ottawa Quality Assessment Scale used to report on quality of evidence.

RESULTS

Study selection

Total 312 records were obtained through electronic search and one article was identified from the reference list of an identified literature. On removal of duplicate articles and record screening total of nine articles were assessed for eligibility after full text reading. Ultimately four studies were included to conduct the current study review: three articles were retrospective non randomized studies,[5,6,21] and one paper was a case report.[19] The article selection process is illustrated in the PRISMA flow chart [Figure 1].

Study characteristics

The included studies were by Simon *et al.*,[21] Ravera *et al.*,[5] Caruso *et al.*[6] and a case series by Fischer.[19] All the studies aimed to assess the efficacy of molar distalization as their primary outcome. All included studies assessed changes in treatment outcomes by comparing pre-treatment (T0) and post-treatment (T1) lateral cephalograms. The parameters

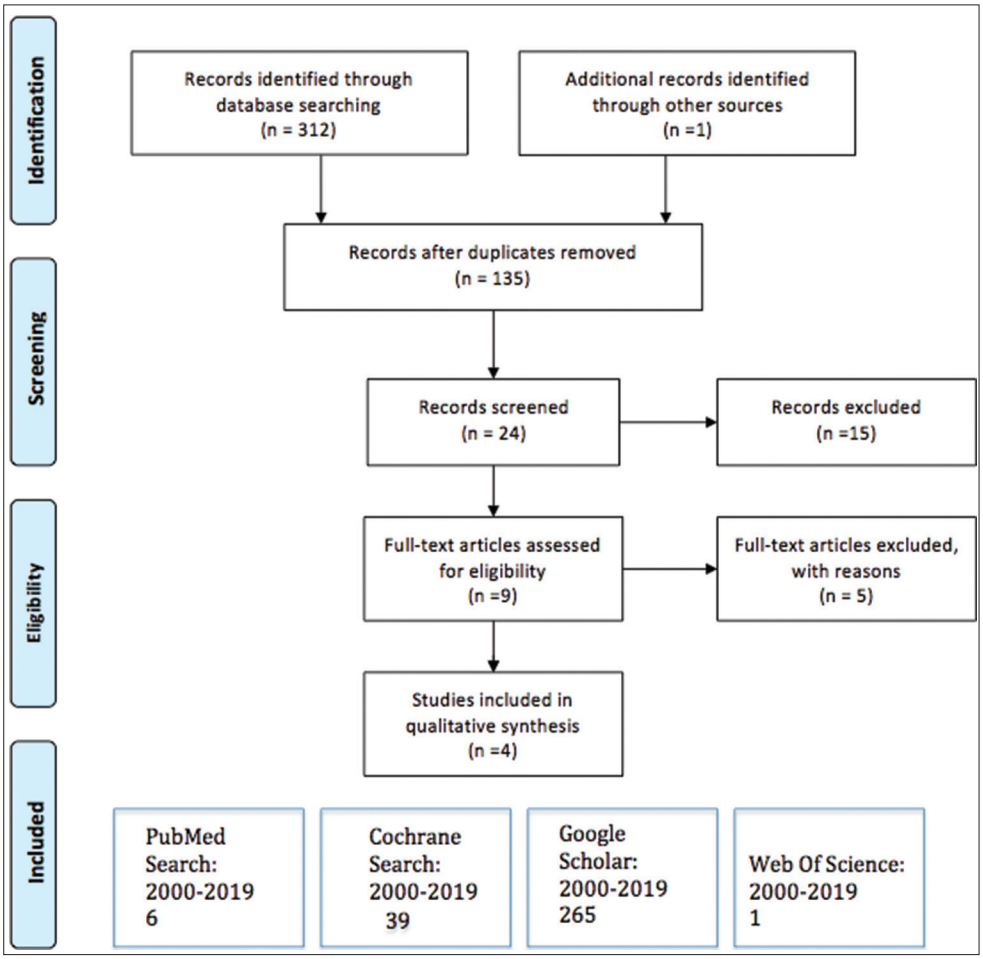

Figure 1: Flow chart for selection of studies based on PRISMA.

assessed for distalization were different in all studies. Sample size ranged for 3–30 in the included studies with a total of 63 patients. All patients in all the studies were non-growing adults. The clear aligner trays used in all the studies were by Invisalign® system. Characteristics of each study are discussed in [Table 2].

Report on quality analysis

Based on the Newcastle - Ottawa Quality Assessment Scale, the quality of one study[5] was good and the other two retrospective studies[6,21] were of average quality evidence [Table 3].

Report on level of evidence

Overall, the level of evidence for the selected studies was low [Table 4].

Results of included studies

Maxillary molar distalization

Simon *et al*. reported a mean molar distalization of 1.5mm. CAT with attachments effectively distalized maxillary molars with a mean accuracy of 88.4% (SD = 0.2) and mean accuracy of 86.9% (SD = 0.16) without attachments. Retrospective study by Ravera *et al*. reported mean distal movement of maxillary first and second molars. Four linear cephalometric parameters reported on sagittal position change of maxillary first molar: 16mcPtV (T0-T2 = −2.25 mm, $P < 0.01$), 16ccPtV T0-T2 = −2.03 mm, $P < 0.000$), 16praPtV (T0-T2= −1.84 mm, $P < 0.001$), and 16vmraPtV (T0-T1 = −1.48 mm, $P < 0.01$). A significant distal movement of 2.25 mm of maxillary first molar was reported. Similar linear parameters were used to assess change in linear position of second molar: 17mcPtV (T0-T2 = −2.52 mm, $P < 0.000$), 17ccPtV (T0-

Table 2: Study characteristics of included studies.

Author, Year	Type	Study design	Population	Intervention	Comparison	Outcomes	Result
Caruso *et al*., 2019	*In vivo*	Retrospective Study	*n*=10 Age=22.7±5.3 year	Group 1=Clear aligners at T0 and T1	Pre-treatment lateral cephalograms	6-Pp.7-Pp - *P*<0.0001	Relationship parameter (MR) with at least *P*<0.01 suggestive of effective molar distalization
Simon *et al*., 2014	*In vivo*	Retrospective Study	*n*=30 Age not specified (non-growing adults)	Group 1=For upper incisor torque, Group 2=Premolar derotation, Group 3=Molar distalization	Group A=Horizontal bevelled gingival attachment, Group B=No auxiliaries	Distalization accuracy-88.4% with attachment group, 86.9% without	Distalization of an upper molar was the most effective movement, with efficacy approximately 87% (SD=0.2).
Ravera *et al*., 2016	*In vivo*	Retrospective Study	*n*=20 Age=29.73 years	Group 1=Clear aligners at T0 And T1	Pre-Treatment Lateral Cephalograms	17mcptv, 17ccptv, 16ccptv=*P*<0.0001, 16mcptv=*P*<0.05	At the post-treatment point, the first molar moved distally 2.25 mm without significant tipping (*P*=0.27) and vertical movements (*P*=0.43). The second molar distalization was 2.52 mm without significant tipping (*P*=0.056) and vertical movements (*P*=0.25).
Fischer, 2010	*In vivo*	Retrospective Study	*n*=3 Age= Case 1=13 years Case 2=15 years Case 3=14 years	3 cases treated with invisalign	Pre-Treatment Lateral Cephalograms		CASE 1: Class I molar relationship achieved within 18 months. CASE 2: Corrected class II malocclusion, deep bite in 26 months. CASE 3: Corrected class II malocclusion, deep bite in 26 months.

Table 3: Quality assessment of included studies.

S. No.	Author	Year	Type of study	Level
1.	Caruso *et al.*	2019	Retrospective	Level 3
2.	Simon *et al.*	2014	Retrospective	Level 3
3.	Ravera *et al.*	2016	Retrospective	Level 3
4.	Fischer	2010	Case report	Level 4

Table 4: Level of evidence of included studies.

Study	Selection	Comparability	Outcome	Overall
Caruso *et al.*	**	**	***	Moderate
Ravera *et al.*	***	**	***	Good
Simon *et al.*	**	-	***	Moderate

T2 = −2.12 mm, $P < 0.000$), 17praPtV (T0-T2 = −1.50 mm, $P < 0.000$) and 17vmraPtV (T0-T1 = −1.67 mm, $P < 0.000$). High significant values were noted in terms of both first and second molars. Retrospective study by Caruso *et al.* reported significant change in linear position change of maxillary first and second molar from pre-treatment (T0) to post-treatment (T1) with aligners. 6-PP at T0 reduced from 25 ± 3 mm to 23 ± 3 mm at T1 ($P = 0.000$), and 7-PP distance which was 16 ± 3 mm at T0 was 13 ± 3 mm at T1 ($P = 0.000$) indicating significant distalization. Molar relationship (MR) parameter changed significantly ($P = 0.000$) from T0 to T1. Successful molar distalization was reported in case series by Fischer.

Vertical dimension

Study by Ravera *et al.* which demonstrated successful molar distalization reported no significant change in vertical movements of molars ($P = 0.43$). The pretreatment (T0) and post-treatment values for vertical craniofacial parameters, i.e., SN^GoGn° and SPP^GoGn° angles showed no significant differences ($P = 0.22$ and $P = 0.85$, respectively).

Caruso *et al.* aimed to assess the effect of molar distalization on vertical craniofacial relationships. The GoGn-SN angle was the primary parameter assessed. Vertical linear measurements recorded were S-Go height, N-Me height, and ratio of S-Go/N-Me. The pretreatment and post-treatment values for all vertical parameters: GoGn^SN°, S-Go, N-Me, S-Go/N-Me did not differ significantly. ($P = 0.45$, $P = 0.47$ $P = 0.43$ and $P = 0.42$ respectively).

Mesio-distal tipping of molars

Ravera *et al.* reported significant distalization of maxillary molars and reported no significant tipping of first ($P = 0.056$) and second molar ($P = 0.27$) post-treatment. The inclination was expressed as angle between long axis of either molar to palatal plane expressed as 16^PP° and 17^PP°. Same parameters were recorded in the study by Caruso *et al.*, where no significant changes in first molar inclination (16^PP°, $P = 0.22$) and second molar inclination (17^PP°, $P = 0.35$) was noted following distalization.

Upper incisor angulation

Ravera *et al.* and Caruso *et al.* reported-on change in upper incisor inclination (11^PP°). Ravera *et al.* reported a significant reduction in 11^PP° of 2.87° following treatment completion ($P = 0.013$). In the study by Caruso *et al.*, a significant reduction in 11^PP° was noted. From 118.3 ± 6.6° at T0, upper incisor angulation decreased to 104.8 ± 10.9° at T1 ($P = 0.006$).

Treatment duration

The mean treatment time reported was 24.3 ± 4.2 months, 1.9 ± 0.5 years (21 ± 5 months). In the case report by Fischer treatment duration for three patients were 18 months, 26 months, and 24 months.

DISCUSSION

This present systematic review attempted to report on the available literature pertaining to maxillary molar distalization with CAT. Extensive search yielded only a total of 4 articles: three retrospective studies[5,6,21] and one case series.[19] Of three included retrospective studies, one was a good quality study[5] and other two were of average quality.[6,21] Overall level of evidence was low (retrospective studies and case series). The available literature suggests that effective distalization with aligners is feasible as it provides excellent control over the vertical dimension, inclination of molars, and incisor torque (thereby preventing anchorage loss).

Maxillary molar distalization

One retrospective study of average quality[6] conducted on 10 subjects (8 females, 2 males; mean age 22.7 ± 5.3 years) reported effective maxillary molar distalization, expressed in terms of change in sagittal position of maxillary molars (6-PP, 7-PP) and MR ($P < 0.001$). A mean distalization of 2–3 mm was recorded. Another retrospective study of good quality evidence concluded significant change ($P = 0.000$) in the sagittal position of maxillary molars. The second molars demonstrated average distal movement of 2.52 mm and first molars were distalized by 2.25 mm. Another average quality study[21] demonstrated maxillary molar distalization by 2.6–2.7 mm, with efficacy of 87%. The fourth study,[19] which was a case series of three cases, corrected Class II malocclusion to a Class I relation by effective distalization of the upper molars in 2 cases. Superimposition of lateral cephalograms demonstrated molar distalization, but precise valued were not

mentioned.

Several systematic reviews and meta-analysis have been published focusing on complex tooth movement with aligners. However, data on distalization seems to be lacking.[16,22-24] The results of the included studies are in alignment with the conclusion given by Rossini *et al*. in their systematic review where they concluded that a controlled distalization of maxillary molars up to 1.5 mm is possible with CAT.[20]

Vertical control, anchorage loss, and change in molar angulation following distalization with aligners

Two retrospective studies, one good quality and one of average quality evidence reported that while maxillary molars distalized, vertical craniofacial parameters showed no significant alterations.[5,6] In the study by Caruso *et al*.,[6] primary outcome, i.e., SN^GoGn^0 demonstrated only a mean variation of 0.1 ± 2.0° at T1 ($P > 0.01$). Posterior facial height (S-Go), anterior facial height (N-Me), and ratio of PFH/AFH also did not differ significantly post-treatment ($P > 0.01$). Excellent control over maxillary incisors was noted, where the mean incisor angulation decreased by 13.5± 4.3^0 post-treatment. Ravera *et al*.,[5] as already mentioned, reported significant maxillary molar distalization without any significant tipping of first and second molars ($P = 0.056$, $P = 0.27$) and vertical movements of the crowns of first and second molars ($P = 0.25$, $P = 0.43$). The results also showed great anchorage control, where incisors were retracted by 2.23 mm ($P < 0.01$).

Clear aligners versus other distalizing appliances

In previous literature about distalization in class II cases, it has been observed that different orthodontic appliances caused undesired effects on the upper molars distalization procedure and on the sagittal vertical pattern as clockwise rotation of the mandibular plane and increase in the anterior facial height.[25-28] Distalizing appliances such as Distal Jet,[29] Pendulum Appliance,[30] Jones Jig[31] In the process of distalization leads to undue movements such as distal tipping of first molars, proclination of maxillary incisors, increased mandibular plane angle and lower facial height[32,33] Such after effects of distalization are not noted with clear aligner therapy.

Recently, skeletally anchored devices that are TADs and IZCs have become a popular alternative for distalization.[34,35] The literature has reported disto-palatal rotation of first molars and a mild protrusion of anteriors. However, mandibular plane angle and anterior facial height remain unchanged.[11] In a recent publication by Shahani *et al*. where comparison of distalization achieved by clear aligners and infra-zygomatic screw was assessed, the concluded a better overall control of distalization with aligners.

Distalization in hyperdivergent subjects

For above mentioned evidence, maxillary molar distalization is contraindicated for hyperdivergent patients. This admonition is based on the assumption that, when maxillary molars are distalized into the wedge of the occlusion, they will prop open the bite. This effect, combined with a backward rotation of the mandible, is said to increase the vertical dimension, especially in high angle cases. Patients with hyperdivergent growth patterns are important considerations while planning molar distalization. A clockwise rotation of the mandible due to premature contacts may worsen the profile and cause bite opening. The distal movement reported in our study was not associated with extrusion or intrusion movements of the teeth. However, the thickness of the aligners and the consequent bite block effect might explain the absence of any change of anterior vertical dimension. The present systematic review however suggests that successful molar distalization can be performed with clear aligners, with efficacy and without risking the vertical dimension, anchorage loss, and tipping of upper molars. Consequently, orthodontic aligners could represent an effective alternative for upper molar distalization especially in hyperdivergent or open bite patients at least for distalizing the maxillary molars by 2–3 mm.

Limitations of this review

There are certain limitations to the current systematic review. In spite of extensive literature search, the number of studies that reported on this topic is minimal. The available evidence is of average quality, only one article was good quality evidence. Three of the included articles were retrospective studies making a low level of evidence. Retrospective studies have some disadvantages with respect to prospective studies. Amongst the biases, which can negatively impact the veracity of this type of study, are selection bias and misclassification or information bias as a result of the retrospective aspect. This has an impact on the interpretation and results of systematic review.

Hence, high-quality studies are needed with the elimination of confounders in this field. Well-planned controlled trials with meticulous methodology, larger sample size and parallel groups are needed to confirm the findings of this review. Factors such as cost-effectiveness, treatment duration, and extent of distalization with aligners also need to be reported on.

Distalization of maxillary molars is frequently attempted, but distalization of mandibular molars for correction of Class III relationship to Class I is also indicated. Factor to consider is that D4 quality of bone is found in the posterior region of the maxilla which possibly makes it more convenient for distalizing maxillary molars. However, the denser bone of D2-D3 quality is found in the mandible, therefore, mandibular molar distalization can be further challenging especially with aligners. Although discussion of mandibular

molars is beyond scope of this review, this area must also be investigated further.

CONCLUSION

Available literature suggests that complex movement such as distalization of maxillary molars can be performed using Clear Aligner Therapy of nearly 2–3 mm is achievable with aligners, along with good control over vertical craniofacial parameters, mesio-distal angulation of molars, and anchorage loss. Within the limitations of the current review, evidence-based conclusions are difficult to extract and results should be interpreted with caution.

Declaration of patient consent

Patient's consent not required as there are no patients in this study.

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Conflicts of interest

There are no conflicts of interest.

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