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Review Article

Evaluating the efficacy and predictability of distalization protocols for maxillary molars in Class II treatment with clear Aligners: A narrative review

Raghad Hmud, Abdulaziz Alamri *

College of Dentistry, Imam Abdulrahman Bin Faisal University, Dammam 31441, Saudi Arabia

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A B S T R A C T

Introduction: Clear aligner therapy (CAT) has become a popular orthodontic treatment option for adolescent and adult patients for its aesthetic, patient's comfort, and convenient features. It involves a programmed and simulated virtual planning, tracking, and quantifying of tooth movement to target positions. Over the years, the therapeutic scope of CAT has increased dramatically to include a wider range of malocclusions with the aid of orthodontic auxiliaries as adjunctive biomechanics. This narrative review aims at summarizing and evaluating current practices, efficacy and predictability of sequential distalization protocol for maxillary molars in class II treatment using CAT.

Methods: A systematic search for this review included electronic literature databases of MEDLINE via Pubmed, Web of Science, ProQuest and Embase to include all available published articles including systematic reviews, books, cases reports, and narrative literature reviews.

Results: Most published studies are retrospective examining small sample size. Current literature should be interpreted carefully as studies differ in their outcome measurement process and timing. Although reports show 2-3 mm of molar distalization is possible, a distinguish between bodily movement and molar tip back should be made. There is a discrepancy between computer-assisted predicted outcome and actual clinical outcome reported in literature.

Conclusion: Molar distalization using CAT is possible. However, randomised trials with large sample size are necessary to draw more definitive conclusion about its efficacy and predictability. Due to the discrepancy between computer-assisted predicted outcome and actual clinical outcome, case refinement and possible altered treatment duration should be discussed with the patient in the planning stage. Since the process of molar distalization using CAT involves undesirable reaction force, it is essential to reinforce anchorage with suitable auxiliaries like composite attachments, class II/III elastics, and TADs.

1. Introduction

With the increased demand for more aesthetic, comfortable, and convenient orthodontic treatment, clear alignment therapy (CAT) has become a popular option for both adolescent and adult patients. The use of a series of clear-overlay appliances was first described by Kesling in 1946 (Kesling, 1946). In 1997, Zia Chishti and Kelsey Wirth, two students from Stanford University, incorporated the Kesling idea into modern technology as today's clear alignment therapy, co-founding Align Technology (Santa Clara, Calif, USA). Consequently, Invisalign was introduced and approved by the FDA in 1998 as the first clear aligner appliance.

Clear alignment therapy involves programmed and simulated orthodontic treatment, whereby virtual planning, tracking, and quantification of the required tooth movement and target positions are integrated into therapeutic success (Robertson et al., 2020, Vaid et al., 2022). First, CAT was utilized to treat mild to moderate orthodontic malocclusion. The scope of clear aligners has increased dramatically to include the treatment of a wider range of malocclusions, especially with the aid of auxiliaries (Caruso et al., 2021, Robertson and El-Bialy, 2022, Vaid et al., 2022). Simon et al. reported an overall efficacy of 59.3 % for premolar de-rotation, molar distalization, and incisor torque using CAT,

* Corresponding author at: Department of Preventive Dental Sciences, College of Dentistry, Imam Abdulrahman Bin Faisal University, P.O. Box 1982, Dammam, 3144. Saudi Arabia.

E-mail address: absalamri@iau.edu.sa (A. Alamri).

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with upper molar distalization being the most successful. (Simon et al., 2014). Haouili et al. reported a 50 % mean accuracy of Invisalign, with buccolingual crown tipping scoring the highest, and rotation scoring the lowest (Haouili et al., 2020).

Molar distalisation is a challenging task in orthodontics. In non-extraction Class II malocclusion treatment for non-growing patients, maxillary molar distalization is the typical treatment of choice (Bechtold et al., 2020, Chou et al., 2021, Li et al., 2021). It is employed to gain space for overjet correction and to establish a Class I molar relationship. Although headgears have been widely used since the 1950 s during molar distalization (Caruso et al., 2021, Al-Tayar et al., 2023), they require considerable patient compliance (Clemmer and Hayes, 1979, Egolf,BeGole and Upshaw, 1990), may increase the vertical dimension with clockwise mandibular rotation, maxillary molar tipping, and anterior anchorage loss (Byloff et al., 1997, Bolla et al., 2002, Lima Filho,Lima and de Oliveira Ruellas, 2003, Mariani,Maino and Caprioglio, 2014). Therefore, the concept of molar distalization using other appliances like Beneslider (Wilmes and Drescher, 2010), distal jets (Reis et al., 2019), pendulum appliances (Byloff and Darendeliler, 1997), Temporary Anchorage Devices (TADs) (Motoyoshi,Matsuoka and Shimizu, 2007, Bayome et al., 2021, Chang,Lin and Roberts, 2021, Ceratti et al., 2024), and aligners was advocated.

Rossini et al. reported bodily distalization as being the most predictable tooth movement by CAT (Rossini et al., 2015), with Simon et al. recorded an accuracy of 88 % for up to 2.7 mm molar distalization with attachment (Simon et al., 2014). However, this high percentage was measured immediately after molar distalization without considering vertical and angular molar movements or posterior anchorage loss when retracting the anterior teeth. This was later found to significantly affect the efficacy of molar distalization (Li et al., 2023). Sabouni et al. achieved molar bodily distal movement of 2.5 mm with no apparent vertical effect (Sabouni et al., 2023), which was in line with the conclusion drawn by Ravera et al., who reported possible molar distalization of 2–3 mm with no extrusion or intrusion and absence of mesiodistal tipping (Ravera et al., 2016). Similar findings were reported by Caruso et al., who observed good vertical dimension control while achieving a 3 mm molar bodily distalization (Caruso et al., 2019).

According to Newton's third law, for every action, there is an equal and opposite reaction; as the posterior teeth begin to distalize, there is an opposite and equal force exerted on the anterior teeth, causing them to incline labially (Bowman et al., 2015, Saif et al., 2022, Cui et al., 2023, Ji,Li and Wu, 2023) and vice versa. Most of the abovementioned studies evaluated CAT distalization efficacy without considering posterior anchorage loss because the anterior teeth were retracted. Li et al. investigated the maxillary molar distalization efficacy with/without anterior retraction and with the use of Class II elastics (Li et al., 2023). They reported distalization efficacies of 36.48 % and 41.94 % for the first and second molars, respectively. These findings were much lower than those reported by Simon et al.. who measured the outcome at the end of the molar distalizing phase without considering the effect of retracting other teeth from the arch. Li et al. achieved 0.88 mm maxillary molar distalization and 1.11 mm of the second molar distalization with buccal tipping and intrusion. These values are also much lower than those reported by Simon et al., Ravera et al., and Caruso et al. Moreover, Li et al. observed a difference during molar distalization efficacy between the anterior teeth retraction and non-retraction groups, with the latter being significantly higher (Li et al., 2023).

As there are various reports concerning molar distalization using CAT with different outcome measures, timing, and techniques, this narrative review aims to summarize and evaluate the current practices, efficacy, and predictability of a sequential distalization protocol for maxillary molars in Class II treatment using CAT.

2. Methodology

A systematic search for this review included the electronic literature databases of MEDLINE via PubMed, Web of Science, ProQuest, and Embase for all available published studies, systematic reviews, books, case reports, and narrative literature reviews. The following keywords were searched: "Clear aligner therapy," "distalization and aligners," "aligner auxiliaries," "aligner attachments," and "Invisalign review.".

3. Discussion

3.1. Protocols for molar distalization using clear alignment therapy

Fig. 1 summarizes the common sequential distalization techniques reported in the literature, which are discussed in detail below.

3.1.1. Sequential distalization

Sequential distalization is the most common protocol followed by molar distalization using CAT (Daher, Simon et al., 2014, Garino et al., 2016, Ravera et al., 2016, Lombardo et al., 2018, Ojima et al., 2018, Caruso et al., 2019, Loberto et al., 2023). It involves dividing the arch into two units, with a greater dental anchoring mass in the supporting segment than that in the active distalizing segment. This makes the movement of the posterior teeth with higher anchoring values more predictable (Loberto et al., 2023). In this protocol, aligners were set to distalize the teeth one at a time, beginning with the second molar staged at 0.25 mm of aligner. This is the default distalization protocol in the Invisalign treatment form, which requires that once the second molar reaches two-thirds of the desired distance, the first molar is distalized, followed by the premolars and canines. Finally, the four incisors were retracted to complete the treatment (Daher, Simon et al., 2014, Garino et al., 2016, Ravera et al., 2016, Lombardo et al., 2018, Ojima et al., 2018, Caruso et al., 2019, Loberto et al., 2023). Sequential distalization restricts the space opening between teeth, which is more aesthetic, and reduces undesirable aligner flexibility by maximizing aligner contact with the teeth (Ravera et al., 2016).

As distalization of the molar teeth causes labial inclination of the anterior teeth (Bowman et al., 2015, Inchingolo et al., 2023, Ji,Li and Wu, 2023), reinforcement of the anterior anchorage is crucial during the distalization stage. Ojima et al. suggested that sequential distalization endures prolonged treatment time, which imposes a higher risk for dental caries, periodontal complications, and reduced compliance (Ojima et al., 2018). As a result, the idea of simultaneous distalization of molars has been proposed by some scholars, but it requires an even larger anterior anchorage (Ji,Li and Wu, 2023).

3.1.2. Aligner wear period

Although Align Technology states that weekly changes in aligners are possible, a recent study evaluating this statement indicated that greater accuracy in posterior tooth movement was achieved when the aligner was worn for 14 days (Al-Nadawi et al., 2021). Most of the reported molar distalization studies suggest an aligner wear of 22 h/day with aligner tray change every 10–14 days (Simon et al., 2014, Ravera et al., 2016, Saif et al., 2022).

3.1.3. Auxiliaries

Various auxiliaries, including attachments, elastics, and TADs, have been employed in combination with clear aligners to enhance their function and efficacy (Simon et al., 2014, Rossini et al., 2015, Ravera et al., 2016, Rossini et al., 2017, Papadimitriou et al., 2018).

3.1.3.1. Composite resin attachments. Composite attachments are crucial for performing complex orthodontic movements with clear aligners (Comba et al., 2017). Attachments are small, geometrically shaped tooth-colored composite resins that are filled into an attachment template and bonded to the tooth structure. They provide greater retention and grip, assisting the aligner to exert the force required for tooth movement (Dasy et al., 2015, Comba et al., 2017).

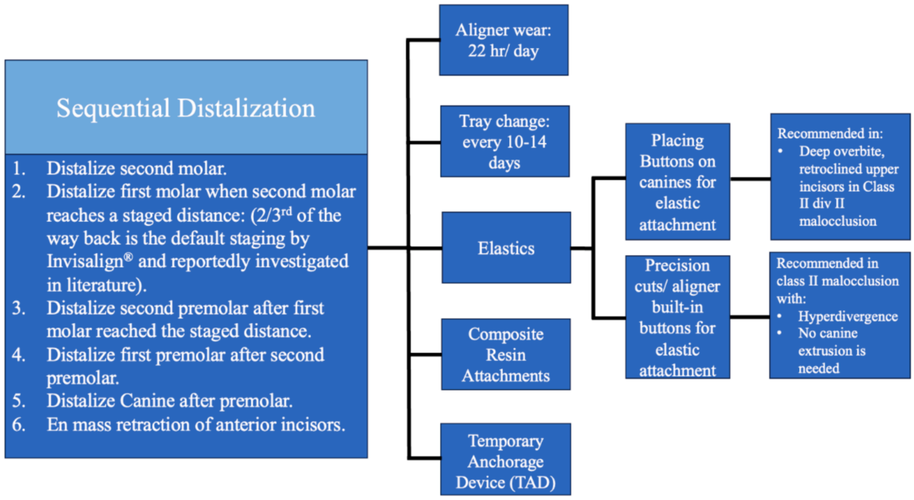

Fig. 1. Sequential distalization protocol using clear aligner therapy. Distalization commences with second molar, followed by first molar once second molar is 2/3rd of the way back. This is followed by distalizing the second premolar, first premolar, canines and en mass retraction of anterior teeth. This technique encompasses certain aligner wear regimen, and auxiliaries like elastics, attachment, and TADs.

Conventional attachments were first introduced using alignment technology. They have different dimensions, such as ellipsoidal, rectangular (horizontal or vertical), and bevelled (Karras et al., 2021, Moya and Zafra, 2021). Later, Optimized attachments were introduced as a SmarForce system as they include an active surface, where the aligner engages and applies force, and an inactive surface, where an intentional gap is created for unrestricted tooth movement (Karras et al., 2021).

Some studies have demonstrated better anchorage and treatment outcomes when using attachments with molar distalization, whereas others have reported no substantial effect (Simon et al., 2014, Galan-Lopez,Barcia-Gonzalez and Plasencia, 2019, Saif et al., 2022). Although Simon et al. (2014) showed greater distalization efficacy in the attachment group than in the non-attachment group, the difference was not statistically significant (88.4 % for attachment and 86.9 % for non-attachment) (Simon et al., 2014). Garino et al. compared the use of five vertical rectangular attachments per quadrant (canine to second molar) to three vertical rectangular attachments (both premolars and first molar) when using sequential distalization with CAT (Garino et al., 2016). Initially, as the second molar was distalized, no significant difference was observed in the amount of movement achieved between the attachment and non-attachment groups. However, when the first molar was distalized, posterior anchorage loss, resulting in reduced distal movement along with first molar tipping, was observed in the group lacking a second molar attachment (3-attachment group). This lack of posterior anchorage control also inhibits anterior tooth control during retraction, causing incisor tipping. In comparison, more controlled distal bodily movements of the first molars and central incisors were observed in the 5 teeth attachment group (Garino et al., 2016).

Rectangular horizontal attachments are reportedly the best for posterior anchorage (Nucera et al., 2022). In contrast, placing vertical rectangular attachments on the premolars and molars creates a sufficient moment that opposes tipping and allows for bodily distalization (Ravera et al., 2016). Sabouni et al. reported good long axes control during the distalization of upper canines when paired vertical root control attachments were placed bilaterally (Sabouni et al., 2023). To help achieve retention and a firm aligner grip, horizontal attachments were placed on the upper incisors. When comparing vertical and optimized root control attachments on the upper canines, Comba et al. observed buccal displacement with vertical composite attachments compared to bodily movement with optimized root control attachments (Comba et al., 2017). The use of optimized attachments on canines in their study resulted in bodily translation without uncontrolled tipping but with some degree of intrusion. This undesired intrusion was significantly reduced when using 4 oz Class II elastics, thereby improving the aligner efficiency (Comba et al., 2017).

3.1.3.2. Elastics. Some studies have advocated the use of Class II elastics for sequential distalization with CAT (Bowman et al., 2015). The attachment sites of elastics include bonding buttons, brackets, or hooks on specific teeth (Bowman et al., 2015), precision cuts (precise cutting on the clear aligners), or incorporating a button onto the aligner tray (Aligner, 2023).

A recent 3-D finite element study by Liu et al. examined maxillary molar distalization using CAT with different Class II elastic attachment techniques (Liu et al., 2022). They noted that, as the process of distalization began, there was a tendency for the anterior teeth to procline labially, which worsened as the first molar was distalized. However, with the use of Class II elastics during treatment, effective anchorage reinforcement was achieved. The application of Class II elastics with precision cutting produced greater anchorage control with less tooth displacement, alveolar bone, and periodontal ligament stress than the button technique. Furthermore, precision-cut attachment results in direct anchorage force transmission to the aligner as opposed to canines, which is often observed with the use of canine buttons (Liu et al., 2022). The latter applied force causes greater extrusion and rotation tendency toward the canines. Therefore, precision-cut elastics are superior in cases where good anchorage control is required with unwanted canine extrusion, such as in hyperdivergent patients (Liu et al., 2022). In contrast, in cases of deep overbite and retroclined incisors, such as Class II division 2 malocclusion, lower incisor proclination is considered the desired movement (Dianiskova et al., 2022, Liu et al., 2022). Thus, Class II elastics attached by buttons to the teeth would be more appropriate (Liu et al., 2022).

Although the aforementioned studies showed a benefit in the use of elastics with CAT, a recent study by Taffarel et al. reported no statistical difference in the outcome between patients who did or did not use elastics for Class II malocclusion treatment using sequential distalization (Taffarel et al., 2022).

3.1.3.3. Temporary anchorage devices. The use of TADs has increased the scope and predictability of orthodontic treatments. Recently, mini-implants have been widely used in conjunction with CAT to facilitate molar distalization. They require minimal patient cooperation and have minimal side effects (Cornelis and De Clerck, 2007, Kook et al., 2023).

A published case report by Greco et al. treating Class II malocclusion using CAT with the incorporation of TADs suggested a complete, 100 %

staging protocol, of second molar distalization before inserting TADs (Greco,Rossini and Rombola, 2022). This was performed to avoid possible root interference when placed between the first and second molars, thereby simplifying insertion.

It is believed that the buccal interradicular areas between the maxillary premolars and molars and that between the second and first molars are appropriate implantation sites, offering primary stability owing to the higher cortical bone density (Erbay Elibol et al., 2020, Cui et al., 2023). In addition to the buccal intraradicular region, the main implantation sites include the posterior palatal alveolar process, palatal bone, and infrazygomatic crest (Cui et al., 2023).

Mini-implants have improved the vertical control of the posterior teeth while avoiding lower anterior labial inclination (Janson et al., 2013). However, a study by Ji et al. demonstrated that, regardless of the traction method used with TADs, the anterior teeth show some degree of anterior anchorage loss, suggesting the need to increase their negative torque (Ji,Li and Wu, 2023). They also observed that the TADs height in the maxilla plays an important role in the torque control of the anterior teeth, such that torque control decreases as the height of the microimplant increases. A recent finite element study by Jia et al. showed improved anchorage control when elastics from mini-screws to the aligners (via lingual buttons, precision cuts, and patient-specific attachments) were used for maxillary arch distalization (Jia et al., 2023).

3.1.3.4. Angelbutton. AngelButton is an integrated structure of the aligner body introduced by Angelalign (China), providing an anchorage point to support elastic use (Aligner, 2023). Being an integral part of the aligner, it provides the advantages of reduced chair time and tray deformation. They are used as traction devices that provide functions similar to those of the traditional methods. Similar to precision cuts, AngelButtons have superior sagittal anchorage control to buttons when used with TADs, as they differ in their force transmission. They are also reported to be more effective in the vertical and bodily movements of the molar teeth than precision cuts and buttons (Ji,Li and Wu, 2023).

4. Clear aligner therapy Limitations

Although significant advancements have been made in the use of CAT to treat more complex malocclusions, several limitations still exist. This could be because of variations in tooth anatomy, properties of the aligner material, absence of specific force application points, slipping motions between contact shapes, geometrical mismatch between the aligner and dentition, patient compliance, and other biomechanical factors (Marya et al., 2020, Vaid et al., 2022). A recent study examining the compliance of more than 2000 patients treated with CAT showed that only 36 % were fully compliant (Timm et al., 2021).

Ongoing improvements and the evolution of aligner materials make it difficult to compare different published studies. For example, Simon et al. used the original material of Align Technology [Exceed30 (EX30)] in their 2014 study, when a new material was introduced in the market SmartTrack™ (LD30) at the same time (Simon et al., 2014). This new aligner material was later used in other studies (Patterson et al., 2021).

Current literature highlights the existence of discrepancies between computer-assisted predicted outcomes and actual clinical outcomes (Simon et al., 2014, Karras et al., 2021, Patterson et al., 2021, Taffarel et al., 2022, Li et al., 2023), resulting in additional treatment or multiple refinements and increased overall treatment duration (Charalampakis et al., 2018, Cortona et al., 2020, Haouili et al., 2020, Hartshorne and Wertheimer, 2022). Patterson et al. reported that the anterior-posterior correction amount of Class II malocclusion treatment using CAT was only 6.8 % of the predicted value. Similarly, a recent study by Taffarel et al. examined the distalization of maxillary molars using Invisalign aligners in non-extraction Class II malocclusion patients using auxiliaries (attachments, with or without elastics) by comparing three different phases of treatment (initial, predictive planning using ClinCheckPro software, and final time without refinement) using the American Board of Orthodontics (ABO) Model Grading System (MGS) (Taffarel et al., 2022). They noted that tooth movement and occlusion within the ABO standard were overestimated using the ClinCheckPro software, which was not accomplished in the post-treatment results. Therefore, they recommended increasing the treatment time using additional aligners to attain ABO standards, especially in end-on to full-step Class II malocclusion treatments. Their results also noted a lack of tooth movement control, resulting in greater crown than root tipping, which is in line with the findings of Drake et al. (Drake et al., 2012).

Predicted and clinical outcome discrepancies were also observed in other aligner systems compared to the Invisalign system. A recent prospective study by D'Anto et al., examined molar distalization using Ordoline aligners (UAB Ordoline, Vilnius, Lithuania) (D'Anto et al., 2023). They used a distalizing protocol similar to Invisalign by employing rectangular attachments on the first and second molars with elastics to be worn all day, instructed patients to wear the aligners for at least 22 h/day, and used a 50 % sequential distalization protocol, with aligner change every 10 days. They concluded that derotation and distalization of the maxillary molars using clear aligners was achievable. Like the Invisalign system, Ordoline aligners also required final refinements, as the movement predicted by computer software was not likely to be fulfilled at the end of the treatment (D'Anto et al., 2023).

With the evolutionary introduction of a direct aligner in CAT, many of the above-mentioned limitations could be diminished or even eliminated. One of the main advantages of printed aligners over thermoformed aligners is their ability to deliver a uniform force to all teeth owing to their uniform material thickness (Panayi, 2023). Moreover, with 3D and 4D printing being the future trend in orthodontics, better mechanical properties should be expected, leading to the possible elimination of excessive use of attachment, as well as the solution to loss of tracking in tooth movement (Panayi, 2023).

5. Conclusion

Current literature regarding molar distalization using CAT should be interpreted carefully, as the studies differ in their outcome measurement processes and timing. In some studies, the distalization outcome was measured immediately after the molar distalization process without considering the possible anterior anchorage loss, while others reported their findings after the whole treatment was complete, including anterior en-mass retraction. Most of these studies are retrospective, with small sample sizes, which could hold some degree of bias. Therefore, prospective randomized trials with larger sample sizes are required to draw definitive conclusions. Although reports show that 2–3 mm of molar distalization is possible, a distinction between bodily movement, and the backward molar tip should be made and investigated further. When using CAT during molar distalization, it is essential to reinforce the anterior anchorage with suitable auxiliaries, such as composite attachments, Class II/III elastics, and TADs. Similar anchorage loss has been reported in distalized molars as retraction of the anterior teeth occurs. It is important to note that several reports have shown a discrepancy between computer-assisted predicted outcomes and actual clinical outcomes with CAT. Therefore, case refinement and altered treatment duration should be discussed with patients during the planning stage.

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All authors have contributed significantly and agree with the present manuscript.

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Declaration of Competing Interest

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