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Effectiveness and Stability of Treatment with Orthodontics Clear Aligners: What Evidence?

Soukaina Sahim and Farid El Quars

Abstract

Clear aligners, as a transparent and removable appliance, offer an alternative to conventional fixed appliance to patients with high demands for esthetics and comfort. Only a few investigations have focused on the efficacy of clear aligner therapy in controlling orthodontic tooth movement. Furthermore, the stability after treatment has not been thoroughly investigated. The purpose of this chapter was to update the knowledge of the available evidence about effectiveness and stability of clear aligners in non-growing subjects. Searches was made in different databases from January 2015 to January 2021. Relevant articles that met the inclusion criteria were selected. The level of evidence of the studies was moderate. The vertical movements of tooth were difficult to accomplish. Mesiodistal tipping showed the most predictability (82.5%) followed by vestibulolingual tipping. Molar distalization was also recorded as the highest accuracy. Derotation was difficult to accomplish with aligners especially of rounded teeth. The effectiveness of aligners in achieving the simulated transverse goals was 45%. The stability of clear aligner therapy was assessed by only two studies. Refinements are likely needed in almost all cases and to ensure treatment stability a retention period using a specific protocol is necessary.

Keywords: clear aligners, effectiveness, efficacy, stability, outcomes

1. Introduction

Orthodontic developments, especially during the last years, have been accompanied by a significant increase in the esthetic demands of the patients [1]. With the significant recent improvements in computer-aided design/computer-aid-ed manufacturing (CAD/CAM) and dental materials, there has been an increase in the demand for plastic systems [2]. Clear aligners provide an esthetic and comfortable treatment experience, facilitate oral hygiene, cause less pain as compared to fixed orthodontic appliances, and reduce the number and duration of appointments [3–5]. The aligner therapy also involves a lower incidence of demineralization, enamel abrasion, periodontal lesions, and mucosal irritations [6].

The concept of clear aligners was introduced by Kesling in 1946 with a tooth positioner fabricated by thermoplastic material molding technology and designed for minor tooth movements during the finishing stages of orthodontic treatment. In 1993, Sheridan and colleagues developed a technique of giving new clear retainers to the patient at each visit, incorporating interproximal reduction to provide the necessary space for tooth movement [3, 7]. With further advancement in orthodontic technology, Align Technology introduced the clear aligner treatment (CAT) rendering Kesling's concept a feasible orthodontic treatment option [8]. A series of removable polyurethane aligners were introduced as an esthetic alternative to fixed labial appliances. Scanned images are converted to physical models by using different stereolithography (STL) techniques to fabricate a series of aligners that sequentially reposition the teeth. Each aligner is programmed to move a tooth or a small group of teeth 0.25–0.33 mm every 14 days [9, 10]. Align Technology provides orthodontists with ClinCheck (Align Technology Inc., Santa Clara, Calif) models, which reflect the treatment outcomes. The aligners incrementally shift the teeth into place based on the outcome the orthodontist expects to achieve [11].

The primary focus of the clear aligner system was initially to solve cases of low and moderate crowding and to close small spaces [1]. However, it has continually evolved through the development of new aligner materials, attachments on teeth, as well as new auxiliaries, such as "Precision Cuts" and "Power Ridges" to address a wider range of malocclusions and to enable additional treatment biomechanics [2, 5, 12].

Despite the available body of literature pertaining to aligner technology, only a few investigations have focused on the efficacy of clear aligner therapy in controlling orthodontic tooth movement. Furthermore, the stability after treatment has not been thoroughly investigated.

The purpose of this chapter was to update the knowledge of the available evidence about effectiveness and stability of clear aligners and to answer the following clinical research question: "Are clear aligners effective in controlling the orthodontic movement in non-growing subjects and what about stability of this treatment modality?"

2. Materials and methods

2.1 Search strategy

A systematic search in the medical literature produced between January 2015 and January 2021 was performed to identify all peer-reviewed articles potentially relevant to the review's question.

The following databases have been used: CENTRAL, MEDLINE, MEDLINE in Process, Embase and Cochrane Library databases.

The search strategy comprised use of the following terms: (invisalign OR clear aligners OR aligners OR transparent aligners) AND (effectiveness OR efficacy) AND (dental changes OR treatment outcome) AND (stability).

Additionally, a manual search was conducted in orthodontic journals of interest, such as *The Angle Orthodontist*, the *American Journal of Orthodontics* and the *European Journal of Orthodontics*. Title and abstract screening was performed to select articles for full text retrieval.

2.2 Eligibility criteria

The following inclusion and exclusion criteria were used:

2.2.1 Inclusion criteria

Study design: meta-analysis, systematic reviews, randomized and non-randomized clinical trials, prospective and retrospective studies were included.
Participants: non growing patients.
Intervention: articles that studied dental movement of cases treated with clear aligners.
Results: the efficacy of clear aligners in performing dental movements and the stability of treatment, superimposing virtual models or radiographs.

2.2.2 Exclusion criteria

We excluded for our study articles older than 6 years, samples with growing patients, articles written in a language other than English, in-vitro studies, author opinions, letters to the editor, isolated cases, series of cases, surgical cases, or reports of patients with syndromes.

2.3 Level of evidence

The grading system described by the Swedish Council on Technology Assessment in Health Care (SBU) [13] was used to assess the methodological quality and the level of evidence of the articles (Tables 1 and 2).

Grade A—high value of evidence
All criteria should be met:
Randomized clinical study or a prospective study with a well-defined control group
Defined diagnosis and endpoints
Diagnostic reliability tests and reproducibility tests described
Blinded outcome assessment
Grade B—moderate value of evidence
All criteria should be met:
Cohort study or retrospective case series with defined control or reference group
Defined diagnosis and endpoints
Diagnostic reliability tests and reproducibility tests described
Grade C—low value of evidence
One or more of the conditions below:
Large attrition
Unclear diagnosis and endpoints
Poorly defined patient material

Table 1.
Swedish Council on Technology Assessment in Health Care (SBU) criteria for grading assessed studies.

Level	Evidence	Definition
1	Strong	At least two studies assessed with level “A”
2	Moderate	One study with level “A” and at least two studies with level “B”
3	Limited	At least two studies with level “B”
4	Inconclusive	Fewer than two studies with level “B”

Table 2.
Definitions of evidence level.

3. Results

3.1 Study selection

The selection of articles included in this review is shown in the PRISMA flow chart (**Figure 1**). Study selection procedure was comprised of title-reading, abstract-reading, and full-text-reading stages. After exclusion of not eligible studies, the full report of publications considered eligible for inclusion by the authors was assessed. Eleven studies were included in the qualitative synthesis.

3.2 Study characteristics

Of the eleven included articles, there were five retrospective studies [6, 14–17], two prospective studies [7, 11], two randomized controlled trials (RCT) [18, 19], two systematic reviews [2, 20] and one meta-analysis [20]. Most of the included studies evaluated mild to moderate malocclusions except for one [17] that involved first premolar extraction cases. The majority of studies used the Invisalign® system except two studies that used Nuvola® system [15] and F22 aligners [14].

Data collected from each of the included articles are described in **Tables 3 and 4**. Nine of the covered studies assessed predictability of tooth movements comparing

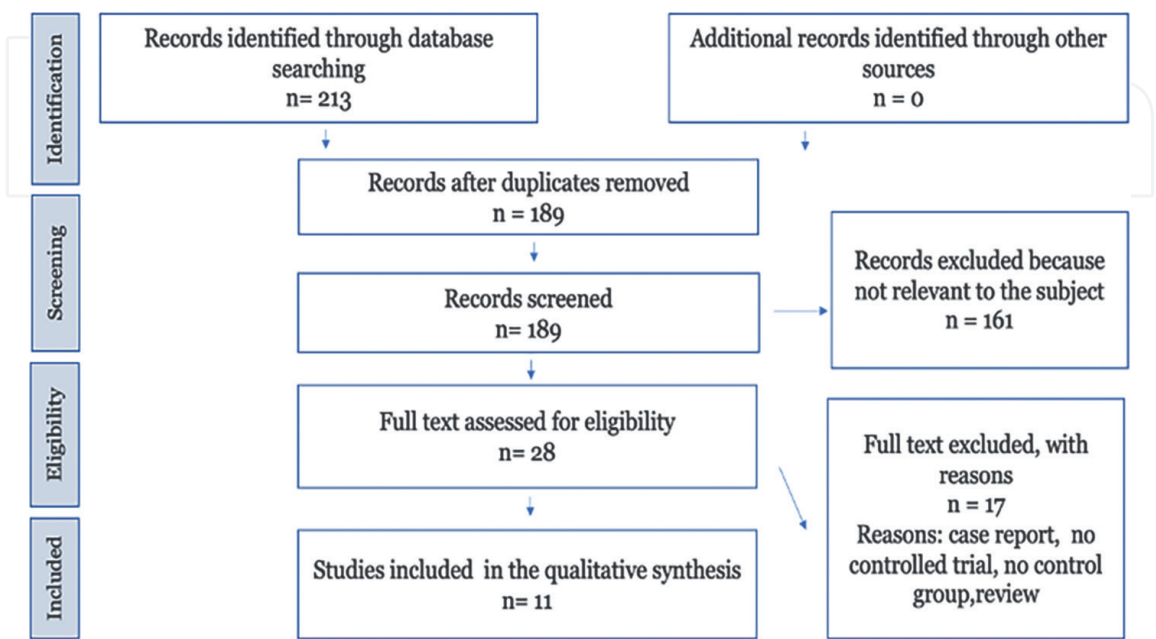


Figure 1.
Flow chart according to the PRISMA statement.

Study	Study design	Participants	Intervention	Results
Buschang et al. 2015 [11]	Prospective clinical trial	27pts	<ul style="list-style-type: none"> Post-treatment patient models compared with their ClinCheck models provided by Invisalign American Board of Orthodontics OGS 	<ul style="list-style-type: none"> The ClinCheck models overestimated alignment, buccolingual inclinations, occlusal contacts, and occlusal relations
Lombardo et al. 2017 [14]	Retrospective case series	16 pts. F22 aligners	<ul style="list-style-type: none"> Pre-treatment, ideal post-treatment and real post-treatment models were analyzed using VAM software Rotation, mesiodistal tip and vestibulo-lingual tip 	<ul style="list-style-type: none"> Mesiodistal tipping was the most predictable (82.5%) followed by vestibulolingual tipping Mesiodistal tip on upper molars and lower premolars was the most predictable Rotation of the lower canines was extremely unpredictable
Tepedino et al. 2018 [15]	Retrospective case series	39 pts. First phase of treatment made of 12 aligners by Nuvola® aligner system	<ul style="list-style-type: none"> Torque of anterior teeth was measured on digital models at T0 (pre-treatment), T1 (post-treatment), and TS (digital setup) 	<ul style="list-style-type: none"> Clear aligner system was able to produce clinical outcomes comparable to the planning of the digital setup relative to torque movements of the anterior teeth
Charalampakis et al. 2018 [16]	Retrospective case series	20 pts. Class I patients treated with Invisalign and needed refinement	<ul style="list-style-type: none"> Superimposition of predicted and achieved models over the initial ones 	<ul style="list-style-type: none"> Horizontal movements of all incisors seemed to be accurate The most inaccurate movements were intrusion of the incisors and rotation of the canines
Lopez et al. 2019 [2]	Systematic review	20 studies	<ul style="list-style-type: none"> Scientific evidence 	<ul style="list-style-type: none"> The expression of the programmed movement was not fully accomplished with Invisalign® Invisalign® was able to alter intercanine, interpremolar, and intermolar width in the presence of crowding Incisors tended to procline and protrude when crowding was > 6 mm Molar distalization was recorded as the highest accuracy Derotation was difficult to accomplish and IPR was recommended, especially in canines

Study	Study design	Participants	Intervention	Results
Dai et al. 2019 [17]	Retrospective case series	30 pts. First premolar extraction treatment with Invisalign	<ul style="list-style-type: none"> • Superimposition between predicted and achieved tooth positions • Influence of age, attachment and initial crowding 	<ul style="list-style-type: none"> • First molar anchorage control and central incisor retraction were not fully achieved as predicted • Age, attachment, and initial crowding affected the predictability of tooth movement
Zhou et al. 2020 [7]	Prospective clinical trial	20 pts. arch expansion with Invisalign aligners	<ul style="list-style-type: none"> • Digital models and CBCT records of pretreatment and immediately after the expansion phase 	<ul style="list-style-type: none"> • Aligners could increase the arch width, but expansion was achieved by tipping movement of posterior teeth • The efficiency of bodily buccal expansion for maxillary first molars averaged 36.35%.
Al-Nadawi et al. 2020 [18]	Randomized clinical trial	80 pts. three aligner wear protocols: 7 day, 10 day, and 14 day.	<ul style="list-style-type: none"> • Digital superimposition of posttreatment scans and final virtual treatment simulations 	<ul style="list-style-type: none"> • Fourteen-day changes were statistically significantly more accurate in some posterior movements • Clinically similar accuracy between the 7-day protocol and 14-day protocol in half the treatment time • 14-day protocol if challenging posterior movements are desired
Riede et al. 2021 [6]	Retrospective case series	30 pts. Aligner treatment (Invisalign®) with the current material (SmartTrack®)	<ul style="list-style-type: none"> • Pretreatment model, scan-based model, posttreatment clinical model, and CC model reflecting the treatment outcome as simulated were analyzed. • Thirteen transverse parameters • Occlusal contacts 	<ul style="list-style-type: none"> • The effectiveness of achieving the simulated transverse goals was 45% and was generally not found to be better with SmartTrack® than with the previously used Ex30® material • Out of 100 simulated occlusal contacts, 40 will never materialize, and achieving around 60 will adequately ensure a clinically favorable contact pattern

pts, patients; OGS, Objective Grading System; IPR, interproximal reduction; CBCT, Cone beam computed tomography.

Table 3.

Design, participants, type of intervention, and results of studies included in the qualitative analysis.

Study	Study design	Participants	Intervention	Results
Zheng et al. 2017 [20]	Systematic review and meta-analysis	<ul style="list-style-type: none">• 4 studies included in qualitative synthesis• 2 studies included in quantitative synthesis (meta-analysis)	Scientific evidence	<ul style="list-style-type: none">• Only one study compared the stability of treatment outcome with clear aligners to conventional brackets.• Patients treated with Invisalign relapsed more than those treated with conventional fixed appliances
Graf et al. 2021 [19]	Double-center trial	33pts	<ul style="list-style-type: none">• PAR Index measured at baseline (T0), after finishing orthodontic treatment with Invisalign® (T1) and after a mean retention period of 10 months (T2).	<ul style="list-style-type: none">• Treatment effects were stable throughout a short-term retention period using a specific retention protocol.• Effectiveness and stability were equally achieved in mild, moderate, and rather severe cases.

pts, patients.

Table 4.
Studies assessing treatment stability of clear aligners.

Study (first author, year)	Evidence level
Buschang, 2015 [11]	C
Lombardo, 2017 [14]	B
Tepedino, 2018 [15]	B
Charalampakis, 2018 [16]	C
Dai, 2019 [17]	C
Zhou, 2020 [7]	B
Al-Nadawi, 2020 [18]	A
Riede, 2021 [6]	C
Graf, 2021 [19]	B

Table 5.
Evidence grade according to Swedish Council on Technology Assessment in Health Care.

post-treatment patient models to the predicted digital planned tooth movement models [2, 6, 7, 11, 14–18]. Two studies assessed the stability of the clear aligner therapy [19, 20].

3.3 Level of evidence of studies

According to the SBU tool (Tables 1 and 2), among the selected studies, the methodological quality was low for four studies [6, 11, 16, 17], moderate for four others [7, 14, 15, 19] and high for one study [18] (Table 5). Thus, conclusions with a moderate level of evidence could be drawn from the review process.

4. Discussion

In this review, we aimed to provide data on the effectiveness and stability of treatment with clear aligners. The level of evidence was moderate as we identified one study with level «A» and four studies with level «B».

The effectiveness of clear aligners was judged by the predictability of tooth movement which varies with the type of tooth and the type of movement. Lopez et al. [2] found that the expression of the programmed movement was not fully accomplished with Invisalign®.

Concerning **vertical movements**, the study by Lopez et al. [2] revealed that vertical movements are difficult to accomplish with aligners. Extrusion of a single tooth is moderately difficult using clear aligners when compared to fixed-appliance systems, however, some auxiliaries such as buttons, elastics and optimized extrusion attachments can be used to facilitate this movement [5, 21].

Many studies showed that intrusion was the most unpredictable movement especially for the maxillary central and lateral incisors [16, 21]. Invisalign has a bite-block effect, because 2 aligners of 0.38-mm width are interposed between posterior teeth throughout treatment. Unexpected intrusion of the molars would cause the incisors to appear extruded on the posttreatment models after superimposition [16]. In fact, according to Grunheid et al. [22], mandibular incisors tend to be positioned more occlusally than predicted. The bite-block effect may make open bites easier to treat with Invisalign [16].

Concerning **horizontal movements**, mesiodistal tipping showed the most predictability especially of upper molars and lower premolars (82.5%) followed by vestibulolingual tipping [14]. Lingual crown tip (53%) was significantly more accurate than labial crown tip (38%), particularly for maxillary incisors [23]. According to Rossini et al. [8], aligners can easily tip crowns but cannot tip roots because these appliances cause tooth movement by tilting motion rather than bodily movement. In the anterior region, the elasticity of the aligner at the gingival margin results in difficulty in controlling the applied forces [24]. With the use of Power Ridges (Align Technology, Amsterdam, The Netherlands), the aligner can accurately control root torque according to the crown position in the virtual setup [17]. Tepedino et al. [15] also concluded that with Nuvola® aligners, in patients with moderate crowding up to 6 mm, the torque movements for central and lateral incisors and canines of both arches predicted in the digital setup were, in general, clinically achieved. However, molar torque may not be fully achieved, with maxillary second molars often having a clinically relevant magnitude of more facial crown torque than predicted [22].

Molar distalization was recorded as the highest accuracy with no need for attachments. Simon et al. [25] also reported a high accuracy (88%) of the bodily movement of upper molars when a distalization movement of at least 1.5 mm was prescribed.

Several studies agreed that derotation of rounded teeth especially canines was difficult to achieve with aligners [16, 22, 26]. An amount of rotation greater than 15° has been identified as a risk factor for decreased accuracy for rotational prediction [25]. Interproximal contacts of rotated canines might also be considered a significant predictor for the diminished efficacy of tooth movement, especially in the absence of interproximal reduction of the enamel (IPR) [26]. The direction of derotation has been also documented to influence the accuracy of the maxillary canine, with distal movement demonstrating less accuracy than mesial [21]. This is possibly due to the actual contact area between canine and premolar and the potential challenges of providing enamel reduction in this area.

It has been recommended to plan overcorrections, especially if rotations exceed 15° , to use attachments, and to reduce staging to less than 1.5° per aligner [8, 16, 25]. However, although various types or shapes of attachment grips or practices of interproximal enamel reduction have been reported as potential prognostic factors for better efficacy of rotational tooth movement, this does not necessarily translate into an identified substantial effect in practice [26].

Concerning **transverse movements**, the effectiveness of achieving the simulated transverse goals was 45% [6]. Aligners could increase the arch width, but expansion was achieved by tipping movement of posterior teeth rather than bodily expansion. In fact, Invisalign becomes less accurate going from the anterior to the posterior region being more effective in premolar area [27, 28]. Thus, according to the initial torque of the posterior teeth, an appropriate amount of negative torque in the crown could be preset in ClinCheck to improve bodily expansion efficiency. For patients who need a large amount of expansion, clinicians should consider reducing the amount of expansion for each aligner to ensure periodontal health [7].

According to Lopez and al. [2], Invisalign® was also able to alter intercanine, interpremolar, and intermolar width in the presence of crowding. Kravitz et al. [23] recommended to treat cases with severe lower crowding mostly by interproximal reduction (IPR) instead of dentoalveolar expansion. This recommendation comes from the finding that retraction is more accurate than dentoalveolar expansion of the lower anterior teeth. The expansion of the mandibular intercanine width also poses the greatest risk of relapse following treatment [29].

Concerning the effectiveness of the occlusal contacts with clear aligners, the study by Izhar et al. [10] found that the software models do not accurately reflect the patient's final occlusion immediately at the end of active treatment. Kassas et al. [30] also stated that clear aligners were not sufficient for providing ideal occlusal contacts. The deterioration in occlusal contacts was caused by the thickness of aligners, which interferes with the settling of the occlusal plane.

As far as the malocclusion type is concerned, the study by Graf et al. [19] showed that Invisalign® treatments are able to significantly reduce malocclusions in adult patients. The study found that all types of sagittal malocclusion (class I, class II, and class III) were 'greatly improved' with a rate of 77.44%. Graf and al. [19] also concluded that conventional attachments and the combination with optimized attachments equally led to treatment effectiveness regarding the total PAR score reduction with equally achieved effectiveness in mild, moderate, and rather severe cases. However, for Class II malocclusion, Patterson et al. [31] reported that there was no significant Class II correction or overjet reduction with elastics for an average of 7-month duration in the adult population. Additional refinements may be necessary to address problems created during treatment mainly posterior open bite.

One study of our review by Dai et al. [17] assessed the effectiveness of Invisalign in first premolar extraction treatment. According to this study, first molar anchorage control and central incisor retraction were not fully achieved as predicted. Only medium anchorage control was achieved as the first molars actually moved mesially. The G6-optimized attachment showed similar control in first molar angulation and mesiodistal translation as did 3- and 5-mm horizontal rectangular attachments. On the other hand, setting a distal tipping of 6.6 mm on the first molars might help clinically maintain the tooth angulation, leading to bodily tooth movement. According to the same study [17], the incisors inclined lingually under the retraction force.

Accordingly, the use of power ridges or attachments as well as overcorrection by setting greater buccal crown inclination during the virtual setup should be considered to achieve optimal incisor torque control.

Current evidence does not support the clinical use of aligners as a treatment modality that is equally effective to the gold standard of braces [32]. However, clear aligners have advantage in segmented movement of teeth and shortened treatment duration, but are not as effective as braces in producing adequate occlusal contacts, controlling teeth torque, and retention [5, 33].

Many variables influence the accuracy of dental movements, but very few studies have analyzed these parameters in treatments with clear aligners. According to Tepedino et al. [15], several factors determine successful tooth movement such as the attachment's shape and position, the aligner's material and thickness, the amount of activation present in each aligner, and the techniques used for the production of the aligners. Treatment outcomes depend also on the patient's characteristics, bone density and morphology, crown and root morphology of the teeth, as well as on factors related to the clinician. Orthodontists have to incorporate their expert knowledge in determining proper sequencing of tooth movements, tooth attachment design and placement, and prescribing overcorrection when needed for difficult tooth movements to increase efficiency and achieve better treatment outcomes [22, 34]. Patient compliance is also mandatory to achieve good results by wearing the aligners 22 hours a day or more [28].

One study from this review with a high level of evidence [18] evaluated the impact of wear protocol on the accuracy of clear aligners. It has concluded that fourteen-day changes were statistically significantly more accurate in some posterior movements mainly maxillary intrusion, distal-crown tip and buccal-crown torque, and in mandibular intrusion and extrusion.

As in all types of orthodontic treatment, stability is one of the most important issues to discuss regarding clear aligners. According to the systematic review by Zheng et al. [20], only one study compared the post-retention dental changes between patients treated with Invisalign and those treated with conventional fixed appliances. They found that the change in the total alignment score in the Invisalign group was significantly larger than that for the Braces group. There were significantly larger changes in maxillary anterior alignment in the Invisalign group than in the conventional bracket group. Tamer et al. [5] also reported that maxillary anterior leveling relapsed in the Invisalign group. On average, the posttreatment models lost twice as many points for alignment than the respective ClinCheck models. In other words, a full finishing phase of treatment may be needed to achieve the results indicated in the ClinCheck model [11].

The type and degree of tooth movement, the duration of active treatment and the retention protocol are among major influencing factors of posttreatment stability and relapse. The study by Graf et al. [19] is the first one to assess the stability of clear aligners outcome throughout a retention period of 10 months. The retention protocol involved a mandibular multistrand fixed retainer (0.0155 inch; stainless steel, 24 K gold plated) bonded on each lingual surface from canine to canine and a removable modified Hawley retainer for the upper arch (with mandatory Adams clasps on first molars). The study showed that the treatment outcome can be stable throughout this retention protocol. It has also concluded that treating patients with respect to their physiological boundaries and maintaining their original arch form would be key to treatment stability. Overexpansion of the dental arch, especially in the lower arch and in adult patients, is a potential risk for stable results.

5. Conclusion

There is current evidence with a moderate level of certainty regarding the effectiveness of clear aligner therapy for certain tooth movements. Clear aligners can safely straighten dental arches in terms of leveling and derotating the teeth, except for canines and premolars. The crown tipping can be easily performed. However, important limitations include arch expansion through bodily tooth movements, extraction space closure, corrections of occlusal contacts, and larger antero-posterior and vertical discrepancies. The use of additional attachments might be more effective for various types of movement, such as bodily expansion of the maxillary posterior teeth, canine and premolar rotational movements, incisors torque control and extrusion of maxillary incisors. Overcorrections might also improve the effectiveness of orthodontic movement. However, overcorrections are not as simple for all movements and need to be made on a case-by-case basis depending on the goal of treatment.

Studies on effectiveness of clear aligners had methodological heterogeneity as they assessed predictability of different types of tooth movements for different teeth by using different materials like Invisalign, F22 aligner and Nuvola system. Retention and stability studies regarding aligners also remain limited in the literature. Therefore, further well-designed and reported researches are required on this subject.

Acknowledgements

Special thanks to the department of Orthodontics of the Faculty of the dentistry of the University Hassan II of Casablanca. We would also like to acknowledge the support of Professor Farid Bourzgui for the realization of this work and for sharing and discussing the initial idea of the project.

Conflict of interest


The authors declare no conflict of interest.

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