



Clear Aligner Therapy: A Paradigm Shift in Orthodontics

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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ABSTRACT

Using Clear Aligner Therapy (CAT) in adult orthodontics is a prime example of how cutting-edge technology is being incorporated into the dental healthcare industry. CAT is becoming more and more popular as a more comfortable and aesthetically pleasing substitute for traditional fixed appliances. Because clear aligners are removable, patients can maintain proper daily oral hygiene. CAT represents a significant shift in modern orthodontics in the patient's periodontal health by providing a convenient and aesthetically pleasing alternative to traditional fixed appliance treatments for formalized dentition. The purpose of this study is to examine the suitability of CAT by defining its biomechanics, indications, contraindications, scope, limitations, and factors that affect successful outcomes and long-term stability. A thorough search of the literature was carried out using the Cochrane Library, PubMed, and Google Scholar, databases. The articles addressed a wide range of instances to determine the breadth and limitations of CAT and were chosen based only on their applicability to clear aligners and without regard to specific brands. This review

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comprises individual case studies, systemic reviews, comparative analyses, case reports, finite element calculations, and prospective and retrospective analyses, all adding to sophisticated knowledge of CAT's applicability and long-term treatment stability. The conclusion emphasizes how CAT is becoming more and more popular in orthodontics. The expanding number of adult patients receiving orthodontic therapy has led to a considerable increase in aesthetic concerns regarding orthodontic appliances in recent years.

Keywords: Clear aligner therapy (CAT); orthodontics; biomechanics; oral hygiene.

1. INTRODUCTION

Since orthodontics started as a dental specialty in the early 1900s, it is currently on the verge of becoming a fancy and attractive future. [1] From metal ring cemented to the teeth to the bondable metal brackets to the monocrySTALLINE ceramic brackets to clear aligners. [2] This incredible advancement in technology is a revolution. The first aligners used for orthodontic reasons were introduced towards the close of the previous century and the beginning of the current one. [3] The patient's need for an orthodontic treatment that was more aesthetically pleasing, comfortable, and inconspicuous led to this ground-breaking discovery. Aligners have gained a lot of popularity since they were first offered as an orthodontic treatment option, and the number of patients using them for orthodontic treatment is continuously rising. The use of aligners in orthodontics has created a paradigm shift in orthodontics and encourages people of all ages, including the elderly, to seek treatment for malocclusion. Contrary to expectations, orthodontic products are often clinically adopted without appropriate clinical evidence. However, if the specialty has to obtain precision and proficiency with this modality, a thorough investigation of existing clear aligner literature is imperative. This will make it possible for further research to focus on areas where this discipline is lacking [4,5]. With clear aligner therapy (CAT), the difference between expected and actual clinical outcomes is approximately 50%, requiring midcourse adjustments, refinements, extra aligners, or even a switch to fixed appliances before treatment completion [6]. It was also discovered that the program that used the registration technique for the superimposition of digital models had less of an impact. Numerous factors, such as biological features, therapy outcomes, geometrical and biomechanical considerations, biomaterials, and patient-related outcomes, were evaluated in studies to determine the usefulness of CAT [7]. The need for clear aligners increased as a result of the growing demand for orthodontic treatment from

adult patients and the push for tailored therapy, to the point that all orthodontic practices now provide them [8]. Nevertheless, research indicates that the efficacy of orthodontic tooth movement (OTM) with aligners like Invisalign® (Align Technology, San José, CA, USA) is not very promising. Research has shown that what is virtually planned does not always translate into what is clinically feasible [9]. Even though the appliance system still has certain restrictions, it's important to remember that orthodontists and patients alike can benefit from tailored clear aligner orthodontic treatments. Thus, virtual treatment plan design—that is, the design and placement of attachments for OTM staging. The understanding of aligners' biomechanics—plays a critical role in determining the effectiveness of orthodontic treatment with aligners. It should be highlighted that the number of treatments initiated does not always correlate with the biomechanics knowledge of aligners [10,11,12]. This is a crucial point for investigators gathering cases from private practitioners whose therapeutic preferences are unknown. The purpose of this review is to evaluate CAT's application, constraints, and extent critically. To assess the overall stability of therapy using clear aligners, it aims to establish a connection between the results from different malocclusion therapies. Additionally, the review will pinpoint important factors that support this therapy modality's long-term effectiveness.

2. CLEAR ALIGNER BIOMECHANICS

Clear aligners are the most effective at performing the most basic of all tooth movements because they are removable appliances. Further evidence of their sporadic efficacy in root uprighting in extraction instances for space closure, regulating tooth rotations, and extrusion came from a study conducted by Tamer et al. [13]. Two methods operate clear aligners. The first type of system is displacement-driven, which is more suited for simpler motions such as minor rotation control and tipping. This approach allows the tooth to move or shift until it aligns with the

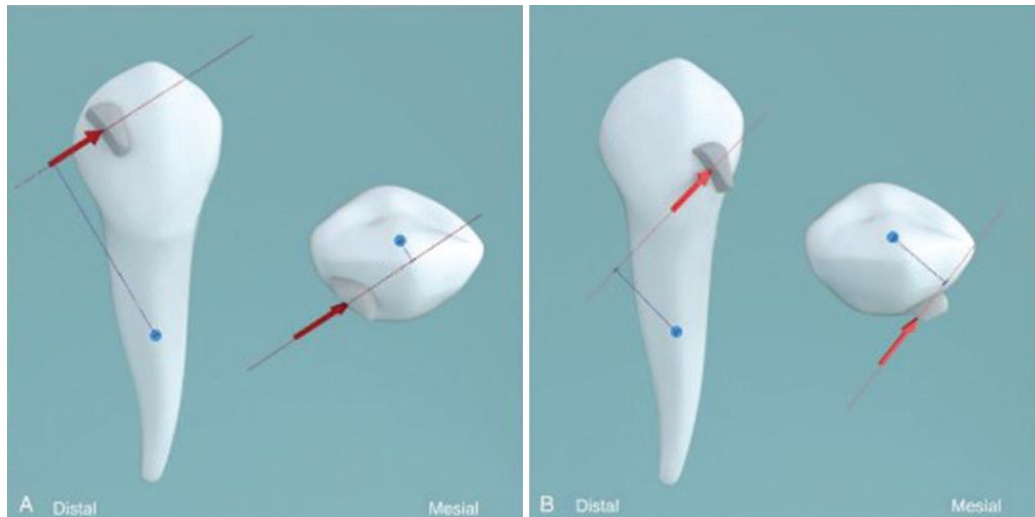


Fig. 1. Tooth movements using attachments to transmit forces. The center of resistance is blue, while the line of action is red [22]

aligner because the aligners are made based on the anticipated final location of the tooth. The second system uses biomechanical principles and is known as the force-driven system. Each tooth receives a different magnitude and kind of force, which is determined by ClinCheck software, depending on the form of the aligners. Power ridges are utilized to control root torque, while aligner details like pressure points enable more intricate tooth movements like intrusion and uprighting [14-18]. On the other hand, simpler tooth movements are better achieved with the earlier approach. Before delving into the biomechanics of CAT, it could be beneficial to examine the stresses and pressures involved in tooth formation. When those forces are applied incorrectly, they cause teeth to become misaligned, thus any artificial realignment must balance those forces. The pressure that teeth in this situation apply to the gums primarily comes from the tooth's growing. The pressure that the growing tooth puts on the gingival tissue around it helps to form and sculpt the gingiva to fit the tooth [19]. Force of eruption: The force of the tooth pushing the gingiva tissue up and away from the tooth occurs as it passes through the gingiva tissue [20]. Force of attachment: When a tooth erupts completely and starts to work, it puts pressure on the gingiva tissue around it, which keeps the tooth firmly in place. The force that opposing teeth apply to one another when biting and chewing is known as the force of occlusion, and it aids in keeping the teeth in their right alignment. It is significant to remember that the surrounding bone and ligament structure, which are critical to the stability and healthy

operation of the teeth, also control these forces [21].

Naturally, as teeth are pushed into the proper positions during orthodontic treatment, the gingival tissue around them is subjected to force. Using specially-made aligners that are structured to guide teeth into desirable positions is the biomechanics of clear aligners. Usually constructed of flexible materials like polyurethane or ethylene vinyl acetate, these aligners are modified to apply the forces required to reposition teeth. The initial stage in using clear aligners is to modify the movement of the target teeth to conform to the shape of the aligner. When the aligner is installed, it deflects and stretches over the teeth with tiny, progressive movements, producing the shape-molding action. Once the aligner is placed, its force features apply pressure to the teeth to realign them into place [23]. Attachment devices, including buttons or power ridges, are frequently utilized to improve or support particular tooth movements as well as to keep the aligner in place. The success of Clear Aligner Therapy depends on the ability to apply the appropriate force to the teeth, which is made possible by the use of attachments. To accomplish teeth alignment through orthodontics, the biomechanics of Clear Aligner Therapy is utilized, especially for anterior tooth movements. It can also be applied to retention following therapy. Three-dimensional digital evaluation tools are used to closely monitor the accuracy of force delivery, and the results are integrated into the treatment plan. The capacity of clear aligners to exert pull force,

which enables more predictable tooth movements, sets them apart from traditional braces [24]. The secret to the clear aligner's success lies in the biological force it produces. This is because it is made to pre-activate its attachment interface with a particular tooth and then optimize attachment form morphology to exert a desired orthodontic force for moving the tooth in a predetermined direction. Ultimately, though, it's crucial to remember that the underlying forces required to align and straighten teeth are complicated and multifaceted [25]. This begs the question of accuracy: to put it another way, how effective are aligners at moving teeth, and to what extent does the readout match the prediction of their function? It may be because of the type of material utilized, but recent research indicates that fixed appliances are still superior in terms of precision and treatment predictability. A distal tipping force is applied to the first molar extraction area in certain instances with the application of attachments [Fig. 1]. To achieve the least amount of tooth displacement, the middle dental arch is extruded using these attachments. The use of attachments allows for the exertion of the desired force on the teeth, which is crucial for the success of clear aligner therapy: [22].

Indications Clear aligner Therapy (CAT):

- CAT includes managing crowding and spacing issues between 1 mm and 5 mm,
- CAT addressing deep overbites, particularly in class 2 division 2 cases that require intrusion or proclination of incisors, and treating narrow arches that are 4-6 mm due to non-skeletal reasons and need expansion with moderate, tipping of the teeth [13].
- In nongrowing patients (late teenagers or adults), CAT is also recommended for individuals with completely erupted permanent teeth to address relapse cases following fixed appliance treatment.
- It is also appropriate for space closure when a lower incisor is extracted, and for tooth movements after interproximal reduction (IPR) and phased distalization.

Contraindications of Clear aligner Therapy (CAT):

- The cases with crowding and spacing greater than 5 mm,

- Skeletal anterior-posterior (AP) discrepancies greater than 2 mm,
- Centric relation (CR) and centric occlusion (CO) mismatch,
- Severely rotated teeth (more than 20 degrees),
- Anterior and posterior open bite cases,
- Extrusion of teeth,
- Severely tipped teeth (more than 45 degrees), teeth with short clinical crowns,
- Cases involving multiple missing teeth.

Aligners were initially used as a treatment option for non-extraction cases, mild to moderate malocclusions, and non-growing adult patients. A study conducted by Lin et al. provided uncertain results about the efficiency of CAT as a therapeutic technique for small orthodontic patients but established that fixed appliance therapy had a larger likelihood of success in maintaining occlusal contacts [19]. To further illustrate its limitations in extraction situations for space fulfillment, CAT has also shown limited success in tipping second molars for space closure. CAT has been investigated in developing people, and this review goes into more detail about it. By using bonded resin attachments to teeth to increase the aligner's range of motion, it has been connected to moderate to severe malocclusions. CAT alone is not sufficient to achieve the most complex tooth motions; additional adjustments to aligners' geometry and auxiliaries are required. To improve the appliance's range, they include adding biting ramps, pressure points, power ridges for complex root motions, and intermaxillary elastics while considering inter-proximal reduction (IPR). Temporary anchoring devices (TADs), power arms, and fixed expanders are also used [20].

Many companies, including well-known brands in orthodontic equipment, produce clear aligner systems globally (Table 1). Numerous factors can impact the therapeutic effectiveness of clear aligners. Undoubtedly, the properties of materials used to produce clear aligners are among the essential aspects in determining their mechanical and clinical features.

Manufacturers and materials of aligners that are widely used:

Table 1. Chemical (molecular) structure of some widely mass-marketed aligners and retainers

Aligner	Material	Manufacturer
Biolon	PET-G (Polyethylene terephthalate glycol)	Dreve dentamid GmbH. Unna, Germany
Duran,	PET Scheu dental	Iserlohn, Germany
EasyDU	PET (PFb/PFc)	BenQ Co., Taipei, Taiwan
F22	Polyurethane	Sweden-Martina, Due Carrare, PD, Italy
Invisalign	SmartTrack (multi-layer aromatic thermoplastic polyurethane)	Align Technology, Santa Clara, CA, United States
MaxFlex	TPU	Maxflex Co., Taipei, Taiwan
Nuvola	Polyethylene terephthalate glycol (PET-G)	GEO srl, Rome, RM, Italy
Spark	Trugen (multi-layer polyurethane)	Ormco Orange, CA, United States
ClearCorrect®	ClearQuartz Tri-layer material	Straumann Group, Round Rock TX, United States

3. CLEAR ALIGNER MATERIALS

Materials employed to produce Clear Aligners can affect their clinical performances; Lombardo et al. [12]. The type of material used depends on the manufacturing process. Aligners can be produced by molding the material on physical models, derived from virtual planning software through 3D printing, or generated directly by 3D printing, without physical models.

Thermoplastic Materials: Because of their superior mechanical and optical qualities, polyester polyurethane, polypropylene polyethylene terephthalate (PET), and polyethylene terephthalate glycol (PETG), an amorphous copolymer of PET that does not crystallize, are the most frequently used polymers for the creation of transparent orthodontic aligners [13].

Thermoplastic polyurethane (TPU) is a very adaptable material with advantageous qualities, including superior elastomeric and mechanical capabilities, resistance to chemicals and abrasion, adhesive qualities, and ease of machining. advantageous qualities, including superior elastomeric and mechanical capabilities, resistance to chemicals and abrasion, adhesive qualities, and ease of machining.

Invisalign aligners were initially produced from a single layer of polyurethane, Exceed-30 (EX30). In 2013, EX30 was substituted by a new polymer, named Smart Track (LD30) a multilayer aromatic thermoplastic polyurethane/copolyester. According to the producer, the new material should provide the aligners with more elasticity and produce more constant forces, improving their clinical efficacy [24].



Fig. 2. Transparent clear aligner material

Polymers Blends: For proper tooth motions, thermoplastic orthodontic devices should apply consistent, regulated forces. By mixing different types of polymers, one can improve their mechanical properties. The most common materials found in polymer blends used to make clear aligners are polyester, polyurethane, and polypropylene. In recent years, a great deal of research on blends of thermoplastic polymers has been produced. Blending polymers has shown to be a practical method of increasing their chemical and physical characteristics, which in turn improves the clinical efficacy of aligners. The proportion of polymers used in the mix determines a lot of the blend's characteristics. When compared to alternative mixing ratios, the superior mechanical qualities offer more sustainable and adequate orthodontic forces than other commercialized goods. The optimal blend of tensile strength, impact strength, and elongation at break was expressed by the PETG/PC2858 blend at a 70/30 ratio [25].

3D Printed Aligners: Some authors claim that 3D-printed aligners have several benefits over thermoformed ones. Direct 3D printing offers more geometric accuracy and precision, better fit, higher efficacy, mechanical resistance, and reproducibility while avoiding the negative impacts of thermoforming procedures, such as changing the mechanical, dimensional, and aesthetic features of the material [22]. A variety of 3D printing methods, including stereolithography, selective laser sintering (SLS), and laser sintering melting (SLM), can be used to create directly produced aligners (SLA). However, it appears that the most appropriate method for 3D printing is photo-polymerization of transparent liquid resin [26]. In orthodontics, the materials used for 3D printing might differ greatly. These include plastics made of acrylonitrile-butadiene-styrene, epoxy resins used in stereolithography, polylactic acid, nylon-based polyamide, glass-filled polyamide, silver, steel, titanium, photopolymers, wax, and polycarbonate [27]. There is currently no authorized polymerizable material for the fabrication of directly printed aligners, despite numerous studies looking into the mechanical and biological qualities of resins suited for the 3D printing of transparent aligners.

4. THE EFFECT OF THE THERMOFORMING PROCEDURE

The performance of the material is also altered by the thermoforming process. Several studies show the variations in the aligner's transparency,

hardness, and thickness before and after the thermoforming process. The relationship between the materials' thickness and transparency before and after the thermoforming process shows how four distinct material types—two pet-g-based, Duran and eClinger, and two copolyester-based, Essix A + and Essix ACE—changed. The investigation's findings show that thermoforming lessens the material's transparency. The eClinger samples, which are 0.5 and 0.75 mm thick, respectively, exhibit a significant reduction in transparency after thermoforming as compared to the Duran and Essix A + samples of the same thickness. Transparency is noticeably reduced when comparing the 0.75 mm thick Essix ACE sample to the 0.75 mm thick eClinger. Furthermore, upon thermoforming, the Duran and Essix A + samples' wall thickness and transparency are noticeably less than their pre-forming values. In contrast, there are no significant differences observed between the pre-and post-thermoforming states for the eClinger and Essix ACE samples. The material's hardness is also determined by how soluble it is in water and how much of it it absorbs. Transparency is noticeably reduced when comparing the 0.75 mm thick Essix ACE sample to the 0.75 mm thick eClinger. Furthermore, upon thermoforming, the Duran and Essix A + samples' wall thickness and transparency are noticeably less than their pre-forming values. On the other hand, no appreciable variations are seen between the eClinger and Essix ACE samples' pre- and post-thermoforming states that absorption depends upon the hardness of the materials [28].

5. BIOCOMPATIBILITY OF MATERIALS USED AS ORTHODONTIC ALIGNERS

The FDA (Food and Drug Administration) examined the adverse clinical events that were reported when using active aligners in a retrospective analysis. The most commonly reported side events during the 10-year observation period with the usage of Invisalign Technology are breathing difficulties, sore throats, swelling throats, swollen tongues, hives, itching, and anaphylaxis [29].

6. CYTOTOXICITY OF THE MATERIALS

The paucity of scientific literature resulting from the limited number of studies available and the inconsistent findings has allowed the question of whether using invisible aligners can have harmful side effects to remain unresolved. Furthermore, testing the cytotoxicity of the materials used by

different manufacturers has become necessary due to the increasing introduction of novel aligners. Studies conducted in vitro have assessed the possible toxicity of thermoplastic polymers used by various brands. Four distinct aligner materials—Duran (Germany), Biolon (Germany), Zendura (United States), and SmartTrack—were assessed (United States). Frequently employed cell lines for confirming the biocompatibility of dental materials are Human Gingival Fibroblasts (HGFs). Because they are the primary cell line found in oral tissues and are most exposed to the harmful effects of aligner materials due to their close contact with periodontal tissues when in place, the International Standards Organization (ISO) (Martina et al., 2019) recommends using them in vitro. Of the four materials tested, Biolon exhibited the highest toxic action on HGFs, followed by Zendura, SmartTrack, and Duran, which showed the lowest toxic activity. In this study, it appears that all tested materials exhibit low in vitro toxicity on the tested cells.

7. CONCLUSION

Modern orthodontic treatment options like clear aligner therapy have become more and more popular recently because of their comfort, convenience, and almost invisible look. The biomechanics of clear aligner therapy employs a series of custom-made, clear plastic aligners to apply a gentle, regulated force to the teeth. This force corrects a variety of problems, such as mild to moderate crowding or spacing, straightening rotated or pointed teeth, filling gaps between teeth, and aligning the anterior teeth, by gradually moving the teeth into the ideal position. For mild to moderate tooth movements, clear aligner therapy has an 80–90% success rate. It might be a useful substitute for traditional braces or other orthodontic procedures. For more complicated orthodontic cases, such as those involving severe crowding or spacing abnormalities, intricate bite issues, or notable jaw discrepancies, it might not be the best choice. Patients should weigh their unique orthodontic demands and preferences against fixed braces and clear aligner therapy, as well as the knowledge and advice of their orthodontist. Patients who value comfort, convenience, and discretion might find clear aligners more appealing than fixed braces, which might be a better option for people with more complicated orthodontic needs or those who would rather have a more predictable course of treatment. With ongoing developments in materials and technology, clear aligner therapy appears to

have a bright future with more effective and efficient treatment outcomes. When the first clear aligner systems were released in the late 1990s, clear aligner therapy began. Since then, a growing number of patients have chosen clear aligner therapy as their preferred orthodontic treatment choice, and the procedure has developed and grown in popularity. In summary, clear aligner therapy provides patients with an almost invisible means of achieving a straighter, more attractive smile. It is a safe, efficient, and practical orthodontic treatment alternative. The future of clear aligner therapy appears bright, with ongoing technological developments and an increasing amount of data demonstrating its efficacy.

8. LIMITATIONS

CAT is not indicated in all cases of dental realignment, and the technology has some limitations as well.

- When there are extreme crowding or spacing problems that call for extractions, CAT should not be used. Additionally, even though anterior crossbites have shown promising results, some biting issues may be too complicated for CAT to be effective.
- If the patient requires considerable multidirectional tooth movement or has complicated jaw discrepancies or structural difficulties.
- If the patient has uncontrolled decay, gingivitis, or active periodontal disease, CAT is probably not going to be strong enough and may even be contraindicated [30]. Regarding the drawbacks of CAT, it may require more time to complete treatment than traditional braces, even though it makes wearing aligners more comfortable. This is because traditional braces can make quicker, more significant alterations than clear aligners, which operate more gradually and make minor adjustments over time.
- Success also depends on compliance, which means that patients must wear their aligners for 22 to 23 hours a day and replace them every two weeks or less per their orthodontist's instructions. Treatment times may increase and the intended outcomes could not be realized if a patient is not consistent in wearing their aligners.
- One of the primary reasons CAT is not recommended for complex dental issues is its inability to achieve considerable tooth motions. This is just one of many limitations. In some situations, bite-specific orthodontic

procedures, such as regular braces or jaw surgery, could be required to properly address these abnormalities.

- Furthermore, and this is crucial, realigning the teeth won't fix the bite issue if the dental issues stem from some other area, like the jaw joints. Finally, the cost of clear aligners may exceed that of conventional fixed aligners. This is particularly true in more complicated cases when it could take more than one set of aligners to get the desired outcomes.
- Furthermore, because CAT may not offer the stability and control required for healthy tooth and jaw growth, it may not always be appropriate for young patients or those with developmental issues. Conventional braces or other orthodontic treatments might be more suitable in these situations [31].
- Since CAT is still a new technology, application protocols, and material quality will continue to develop. To address the most serious problems, it might even be able to begin with a fixed aligner and subsequently transition to transparent aligners. Starting early in development is also probably a good idea whenever issues with dental alignment begin to appear [32].

CONSENT AND ETHICAL APPROVAL

It is not applicable.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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