Clear Aligner Therapy: Understanding Risks and Limitations

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INTRODUCTION

Clear Aligner Therapy (CAT) has experienced a boom in demand from patients seeking orthodontic treatment. Over the past two decades CAT is increasingly becoming the preferred modality of treatment for orthodontic patients.[1,2] It is highly favored because the treatment is esthetically pleasing in comparison to traditional appliances, and that drives otherwise reluctant orthodontic candidates toward it. Patients today, owing to easy access to information on social media platforms and heavy direct-to-consumer marketing by CAT system companies, are well informed of their options. As the demographic of patients seeking orthodontics grows to encompass young adults and adults, the popularity of these systems continues to increase.

At first, these CAT options were utilized as an esthetically palatable treatment option to satisfy the treatment needs of an adult patient population increasingly seeking orthodontic treatment. As society becomes more esthetically conscious, recent years have shown a progressively growing demand for CAT in the younger demographic of orthodontic patients.[3] CAT systems offer other advantages to the patient as well – they are more friendly to oral hygiene practices and require a decreased appointment frequency.

Clinicians also favor CAT as it allows for digital treatment planning and decreased chair time. CAT systems may also provide mechanical advantages in treatment of certain malocclusions. Literature has reported various potential advantages with CAT, such as better oral hygiene, improved periodontal health, reduction in the extent and incidence of root resorption as opposed to traditional orthodontic therapy, and the improvement of TMD-related pain and headaches.[1, 2, 4, 5]

Historically the first use of clear overlay orthodontic appliances was in 1946, when Kesling used a series of thermoplastic tooth positioners to progressively move misaligned teeth into improved positions.[6] Align Technology (Santa Clara, CA, USA) introduced the product "Invisalign" in 1998 as the pioneering clear aligner system to utilize digital design and manufacturing.[7] The burgeoning use of computer-aided design technology and manufacturing capacity in dentistry has motivated many companies to create their own aligner products. There continues to be an exponential growth of companies in this space.

Despite the increasing popularity and many advantages of CAT systems to both the clinician and the patient, there remain a wide variety of risks associated with their use and several limitations in their ability to deliver optimal treatment outcomes. An informed clinician can design treatment plans while taking these risks and limitations into account to both manage patient expectations and deliver successful outcomes.

The purpose of this paper is to highlight the risks and limitations of CAT systems so the clinician can be better prepared to prevent or handle any untoward or unexpected clinical scenarios.

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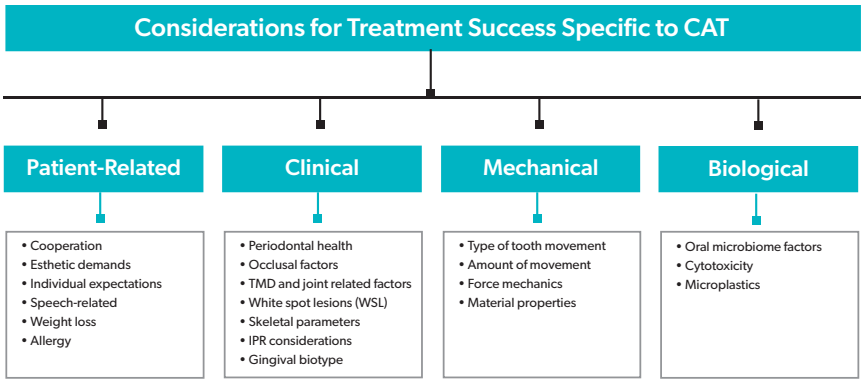

Figure 1.

CONSIDERATIONS FOR TREATMENT SUCCESS WITH CLEAR ALIGNERS

The success of orthodontic treatment with clear aligners depends on the complex interplay of multiple factors that must be carefully considered during treatment planning and execution. *(Fig 1 illustrates the breakdown of these factors.)* These factors can be broadly categorized into four main areas: patient-related, clinical, mechanical, and biological factors, each playing a crucial role in determining treatment outcomes or long-term implications.

1. Patient-Related Factors

CAT systems are removable systems geared toward patient convenience by design. They also demand a high level of discipline and cooperation from the patient. For an appliance system to be effective, most systems recommend about 20-22 hours of wear per day.[8] Movement prescriptions that are built into the aligners cannot be delivered to the tooth if this time is not adhered to as prescribed. This makes patient compliance with aligner wear the cornerstone of a successful treatment.

A very small percentage of patients may have allergic reactions to aligner materials.[5] Information about plastic allergies can be gained by asking questions about reactions or sensitivities to similar polymers. More often these are discovered after treatment initiation. Some CAT system laboratories offer alternate material for patients with allergies.[9, 10]

CAT and Speech considerations

CAT systems have full coverage aligners that deliver forces for treatment. These can transiently affect a patient's clarity of speech. This factor must be discussed with the patient prior to initiating treatment. Patients whose occupations require extensive verbal communication, for example, professional speakers, teachers, media anchors, etc, must be cognizant of this prior to starting treatment. This prevents a distressful experience for the patient once treatment is initiated and allows them to organize their work engagements to navigate the process with greater comfort.[11, 12]

The presence of aligners may temporarily affect phonation, particularly during the initial adaptation period, with specific impact on sibilant sounds such as /s/ and /sh/. The thermoplastic material's thickness and extension onto the palatal surfaces can interfere with tongue positioning and airflow patterns necessary for clear speech production.[13,14] While most patients adapt to these changes within the first few weeks of treatment,[11] some may experience persistent speech alterations that are limiting to their professional and social interactions.[15]

Studies have shown that sound distortions are most pronounced immediately after aligner insertion and improve with continued wear. The adaptation period varies significantly among individuals. While removing aligners can afford many conveniences to the patient, it can complicate or delay speech adaptation, as removal and reinsertion throughout the day may lead to brief periods of speech readjustment. Variations of thickness of aligner material during a treatment sequence can necessitate ongoing adaptation to maintain clear speech patterns. Some patients may require modified wear schedules or alternative treatment options if speech adaptations significantly impact their daily activities.[15]

Clear Aligners and Weight loss

The discipline of wearing aligners 20-22 hours a day by patients for a successful orthodontic outcome limits eating time and possibly the caloric intake for some patients who may then experience transitional weight loss.[16,17] In line with the current fashion of sharing experiences on social media platforms, this has given rise to anecdotal claims about weight loss during CAT and has popularized the term, "The Invisalign Diet."

Recent research has challenged these claims about weight loss during clear aligner therapy. While some patients and practitioners have suggested the requirement to remove aligners for eating might reduce snacking frequency and lead to weight loss, clinical evidence does not support these claims.[18] A 2024 prospective cohort study by Morgan et al.[16] demonstrated no statistically significant differences in weight changes between patients using clear aligners versus fixed bracket systems during the initial 3-4 months of treatment. Although the CAT group showed a mean weight loss of 0.8 kg (~1.7 pounds) over this period, there was considerable individual variability (SD ±2.9 kg), indicating that individual responses vary substantially.

Additionally, compliance with aligner wear decreased from 86 percent at 6-8 weeks to 73 percent at 12-16 weeks, suggesting the window for being able to consume food increased, implying weight loss associated with aligner wear by means of a restricted feeding time may not be sustainable for many patients. Treatment discomfort showed a significant association with reduced compliance, which could impact both treatment efficacy

and any potential dietary modifications.[16]

Furthermore, marketing CAT as a weight loss strategy is negligent and misleading, as the primary purpose of orthodontic treatment is to improve dentofacial aesthetics and occlusion. Clinicians must inform and counsel patients who are embarking on treatment with the secondary goal of weight loss that while CAT may temporarily affect eating patterns, it is not a method for weight loss or weight management.

2.Clinical Considerations for CAT

CAT and Periodontal health

CAT systems offer distinct periodontal advantages and disadvantages to the orthodontic patient. Careful management can ensure the useful characteristics of the system are best utilized and side effects minimized. Research demonstrates generally favorable periodontal outcomes compared to fixed appliances, with lower plaque indices and reduced gingival inflammation.[19] Challenges specific to clear aligners include inconsistent gingival margin adaptation during tooth movement and potential recession, particularly with excessive proclination.[20]

Periodontal tissue response to intermittent force application also differs from traditional mechanics and may affect periodontal ligament compression and blood flow patterns under aligner coverage.[21] Studies have identified modifications in the subgingival microbiome and gingival crevicular fluid composition during treatment.[20, 22] This necessitates careful monitoring of periodontal health.

Patients with compromised periodontal support or thin biotypes require particular attention, with evidence suggesting the need for modified protocols including reduced force levels, careful attachment placement, and enhanced professional maintenance schedules. The presence of composite attachments creates additional considerations for gingival health, requiring strategic placement relative to gingival margins and modified cleaning protocols.[19, 23]

Success in maintaining periodontal health during CAT depends on proper case selection, patient compliance with hygiene protocols, careful prescription of movement of teeth, and regular monitoring of treatment progress. Much like with traditional appliance treatments, current evidence emphasizes the importance of a comprehensive pretreatment periodontal evaluation and ongoing assessment of attachment levels, particularly in cases involving significant tooth movement or preexisting periodontal compromise.

CAT systems give the clinician the ability to vary the velocity of tooth movement through digital treatment plan design and length of time of aligner wear for a given patient. It would be useful to investigate how these variables affect the periodontal status of a patient.

CAT and Occlusal Limitations

Owing to effective marketing and esthetic advantages, patients are driven to seek orthodontic treatment resulting in near ideal outcomes via CAT. While CAT is a more comfortable and esthetic treatment modality for the patient, it is important to note that it has demonstrated significant limitations in achieving optimal occlusal outcomes for a host of orthodontic problems. The clinician must have knowledge of these limitations and manage patient expectations accordingly at the outset of treatment to prevent friction in the doctor-patient relationship later.

Clinical research consistently highlights that attaining ideal posterior occlusal is a challenge with CAT, and there is a notable prevalence of posterior open bites as treatment sequelae.[24-26] The technology demonstrates weakness in delivering forces required to correct posterior crossbites and to achieve complete resolution of deep overbites.[27] Studies examining cases that were evaluated by criteria of the American Board of Orthodontics (ABO) for treatment excellence report lower passing rates for cases treated with CAT than those treated with fixed appliances. Scores were lower particularly for occlusal relationships and contacts.[26, 28]

The biomechanical limitations of aligners become especially apparent in posterior segments, where achieving proper torque control and extrusion remains challenging. This difficulty extends to establishing proper intercuspation and maintaining predictable vertical control throughout treatment. While aligners demonstrate acceptable effectiveness in treating mild to moderate crowding and simple non-extraction cases, their predictability diminishes significantly when addressing complex malocclusions requiring substantial occlusal modifications.[10, 27]

Recent systematic reviews and clinical studies indicate that successful occlusal outcomes with CAT are most predictable in cases requiring primarily alignment without major occlusal changes. The technology shows reduced effectiveness in achieving proper canine guidance and maintaining stable posterior relationships. These limitations become particularly relevant in cases requiring precise three-dimensional control of tooth movement, especially in the vertical dimension. While developing the treatment plan these limitations must be considered carefully even though the digital working model sequences may show an ideal outcome. The importance of considering these inherent limitations is paramount when treating cases with significant occlusal discrepancies or those requiring precise posterior settling.[26, 28]

A sound understanding of the force delivery system

offered by CAT systems and their biomechanical expression is essential for effective digital planning. Case selection continues to remain crucial, and it is important that the patient has realistic expectations of treatment outcomes. It is better to consider alternate treatment modalities like fixed appliances if CAT systems are unlikely to deliver desired outcomes. This is especially important in complex cases.

Interproximal Reduction and CAT

Interproximal enamel reduction (IPR) is one of the most common procedures that is either prescribed by the clinician or suggested by preliminary digital plans from CAT system labs. IPR remains an invaluable tool for creating required space for delivering optimal treatment outcomes.[29-31]

IPR, however, can be employed to the patient's benefit safely only when the clinician has engaged in proper case selection and meticulous and technically sound execution of this technique.[32, 33]

The primary concern with IPR is the structural integrity of the tooth enamel, as the procedure demands removal of enamel from interproximal surfaces of teeth. Research indicates a maximum of 50 percent as a guideline for removal proximal enamel thickness without compromising dental health.[34] Clinicians must observe and adjust the amount of IPR based on natural variations in enamel thickness, tooth shape, and morphology.[35, 36] It is important to note that distal surfaces of anterior teeth typically have 0.10 mm more enamel than mesial surfaces.[32] Reduction of enamel beyond biologically sound parameters can lead to dentin hypersensitivity and especially to temperature variations. This dooms the patient to long-term discomfort, sensitivity, and other potential long-term complications.[32, 37, 38]

If the technique used in executing the procedure is not followed strictly, irreversible enamel furrows may form, which create a risk for the patient. These furrows can create surfaces that are particularly susceptible to plaque accumulation, leading to increased caries risk and periodontal complications. Patients with poor oral hygiene are at higher risk. A thorough pretreatment assessment of the patient's oral hygiene habits is an important consideration prior to employing IPR.[29, 38]

Bone remodeling considerations add another layer of complexity to IPR-related risks. Recent research using CBCT imaging has shown varied effects on interradicular bone volume following IPR procedures. While some areas show minimal impact, specific regions such as the lower canine-lateral area and upper central-lateral area demonstrate significant bone volume changes. The full extent of these changes may not be immediately apparent, as bone remodeling continues well after the active treatment phase.[29]

IPR is contraindicated in cases of severe crowding. The procedure's effectiveness diminishes with increased crowding severity and attempting IPR in such cases may lead to excessive enamel reduction without alleviating crowding. It is important to note that the predictability of tooth movement following IPR varies significantly between the upper and lower arches. Studies show predictability rates of only 49 percent for the upper arch and 42 percent for the lower arch.[39]

Changes in tooth inclination following IPR must also be carefully monitored. Research demonstrates that IPR can lead to significant changes in incisal inclination, with documented changes of 4.8 degrees in upper incisors and 4.2 degrees in lower incisors. These changes can affect both aesthetic outcomes and functional occlusion and therefore treatment plans must take into account these angular changes prior to prescribing movements in CAT systems for final tooth positions.[32]

CAT and TMD

Current evidence regarding temporomandibular joint (TMJ) disorders and pain during clear aligner therapy shows varying clinical outcomes. Research indicates that while clear aligners may offer certain advantages over fixed appliances in terms of TMJ loading, they also have their share of complications.[40] Studies have documented both improvement and exacerbation of TMD symptoms during aligner therapy, suggesting the presenting malocclusions and other factors unique to an individual play a significant role in outcomes.[41-43]

The intermittent nature of aligner wear creates a unique pattern of force application that differs from traditional fixed appliances. Some studies suggest that this intermittent force application may lead to periodic changes in joint loading patterns, potentially affecting TMJ function. Patients with pre-existing TMD may experience varying degrees of symptom modification during treatment, with some reporting temporary increase in discomfort during aligner changes.[40, 44, 45]

Research has shown certain patient populations may be more susceptible to TMJ complications during aligner therapy. Those with a history of myofascial pain, joint clicking, or limited opening may experience temporary exacerbation of symptoms, particularly during the initial adaptation period. However, long-term studies suggest that most patients do not develop significant TMJ problems attributable solely to aligner therapy.[8, 46]

Current evidence suggests that proper case selection and careful monitoring of TMJ status throughout treatment are

essential. Practitioners should implement comprehensive pretreatment screening for TMD risk factors and maintain regular assessment of joint function during therapy. Patient education regarding proper aligner wear and awareness of potential TMJ symptoms is important for managing patient expectations and altering treatment course when necessary.[2, 40, 41]

While clear aligners may offer the advantage of reduced overall joint loading compared to fixed appliances, they require careful management for each individual patient. Future research that explores and identifies specific patient populations most susceptible to TMJ complications during CAT system treatments and develops methods to mitigate these problems would allow the clinician to better serve these patients.

CAT and WSL

White spot lesions (WSLs) during orthodontic treatment with traditional appliances present a significant concern.[47] Current literature reports that clear aligner therapy is a favorable appliance of choice compared to fixed appliances to decrease their incidence.[48] Studies indicate substantially lower incidences of WSL with aligners, ranging from 1.2 percent to 6 percent, in contrast to the 25.6 percent to 49.6 percent reported with fixed appliances.[49]

This reduced risk can be attributed to the ability to perform oral hygiene practices without hindrance as aligners are removal appliances. The lack of brackets bonded to the teeth decreases plaque retention sites and also facilitates a more effective fluoride application during the course of treatment.[49, 50]

While the risk of WSL is reduced with aligner use, it is not eliminated.[49] Some risks remain during treatment with CAT that may lend themselves to formation of WSL. Extended wear time of the aligners beyond the recommendation of the clinician and the potentially lower movement of saliva beneath the appliance may contribute to an environment that is conducive to development of WSL and caries. This is especially likely in patients who frequently consume sugar-sweetened beverages while wearing their aligners. CAT often requires placement of composite attachments and, depending on their size and shape, these too can serve as retentive surfaces for plaque. Much like with traditional appliances, the treating clinician should reinforce good oral hygiene, and routine checks for prophylactic care. Early detection of WSL is crucial as these lesions can progress rapidly if the problem is not addressed.[23, 50, 51]

3. Mechanical Considerations

Magnitude of Tooth Movement

Clear aligners have demonstrated varying degrees of effectiveness depending on the amount of tooth movement required. For mild to moderate malocclusions involving movements between 1-5mm, clear aligners show results with predictability rates of 87 percent in the upper arch and 81 percent in the lower arch. However, when movements exceed 5mm, particularly in cases requiring significant crowding correction or space closure, the effectiveness of the movement decreases and becomes less predictable. This limitation stems from the inherent properties of the thermoplastic materials. They are unable to maintain consistent force application over larger ranges of tooth movements.[52]

Types of Tooth Movements

CAT systems operate best when the movements designed in the digital plan leverage to advantage the properties of the material. It has been found that simple tipping movements are highly predictable, as they require less complex biomechanical control. More sophisticated movements are far more challenging to execute. Rotational movements, especially of conical teeth like premolars and canines, show accuracy rates of 77.5 percent for first molars and 62.7 percent for second molars. Extrusion movements, particularly in the anterior region, demonstrate limited success compared to intrusion movements.

The movements that are least effective in delivery through CAT systems usually involve torque control and root movements. The ability to generate effective couples (paired forces) is compromised significantly due to the removable nature of the aligners.[25, 52-55]

Force Mechanics and Biomechanical Challenge

The fundamental limitation of clear aligners lies in their force delivery system. Traditional fixed appliances can generate continuous forces through bracket-wire interactions, creating effective couples for torque control. Clear aligners, however, operate primarily through a displacement-driven system that relies on the aligner's fit to generate forces. This presents several challenges:

1. Anchorage control is compromised due to the absence of rigid connections between teeth;
2. Force application is intermittent due to the removable nature of the appliances;
3. Complex movements requiring three-point force systems are difficult to achieve; and
4. The "walking" movement pattern seen in extraction space closure with fixed appliances cannot be replicated effectively.[1, 2]

Material Properties

Most aligner materials utilized currently are of uniform thickness on each individual tooth and remain the same during the course of treatment. The construction of the aligner itself cannot change in these aspects at each stage of treatment, thereby limiting customization of movement of teeth to a higher degree or fulfilling the specific requisites of each stage of treatment (example leveling and aligning or finishing etc.) with greater sophistication. Modern aligners utilize materials with specific characteristics:

- Low hardness and high resilience for patient comfort;
- Adequate elasticity for force generation;
- Resistance to warpage for maintaining fit; and
- Optimal transparency for aesthetics.

However, these materials face challenges including:

- Degradation of force delivery over time;
- Decreased effectiveness with mechanical stress;
- Limited ability to maintain complex force systems; and
- Susceptibility to deformation under masticatory forces.

The key to successful outcomes lies in understanding these limitations and treatment planning accordingly. A creative clinician can utilize many auxiliaries available in the orthodontic arsenal when needed in conjunction with CAT systems to maintain efficiency and quality of treatment.[56]

4. Biological Considerations

Effects of Aligners on Oral Health and Oral Microbiome

Aligners utilized in CAT systems create a cascade of microbiological changes when introduced into the oral environment. At the macro level, they create additional surfaces for bacterial colonization, with biofilm formation beginning within 24 hours of aligner placement. At a microbial level, they alter the flora of the oral environment.[23, 57]

Literature reports increased levels of both cariogenic bacteria, particularly Streptococcus mutans, and periodontal pathogens such as Porphyromonas gingivalis during CAT.[58,59] Thermoplastic materials used for aligner fabrication have specific surface properties that influence bacterial adhesion and enable progressive increases in bacterial load during the usually prescribed one to two week period of aligner wear. These microbiome alterations are influenced by multiple factors, including daily wear duration, oral hygiene practices, aligner cleaning protocols, and individual patient characteristics such as diet and salivary flow.[23, 58, 60]

While studies suggest the oral microbiome generally returns to baseline post-treatment for most patients, for some of the patient pool, these alterations may persist. Patients with poor compliance with oral hygiene protocols are more susceptible. The risk of adverse microbiological changes necessitates implementation of diligent practice of oral hygiene protocols, regular professional monitoring in the form of routine checks and prophylaxis, and adherence to proper aligner cleaning techniques.[57]

Current research is exploring the possibilities of developing antimicrobial aligner materials and optimizing cleaning protocols to minimize these risks. Nevertheless, significant knowledge gaps remain regarding long-term impacts of an altered microbiome on oral health or what factors make an individual more prone to these alterations.[61]

CAT and Cytotoxicity/Microplastics

Clear aligners are predominantly manufactured from thermoplastic polyurethane (TPU) and similar materials.[62] They present unique challenges related to their biological interaction with oral tissues and the potential environmental consequences when they are discarded after use. As the adoption of clear aligner therapy in orthodontics increases, material safety aspects, particularly regarding cytotoxicity and environmental impact, require careful consideration.[63]

Recent research has identified concerns regarding the biocompatibility of aligner materials. During treatment, these appliances may release various compounds, including bisphenol-A (BPA) and its analogs.[64, 65] While studies typically report the levels of release of these particles as below regulatory thresholds, the cumulative exposure to them throughout treatment duration warrants attention. The oral environment subjects these materials to complex degradation processes through enzymatic activity, mechanical stress, and temperature fluctuations.[63] This potentially facilitates the release of estrogenic compounds and other bioactive substances that may affect cellular viability.

Local tissue response to aligner materials represents another significant consideration. In vitro studies have demonstrated varying degrees of cellular response to these materials, with some research indicating mild cytotoxic effects on human gingival fibroblasts and other oral tissue cells.[63]

An emerging concern with clear aligner use is the breakdown of aligner material leading to generation and release of microplastics both in the oral cavity and eventually into the environment.

Microplastics (MPs) are defined as synthetic polymer particles or fibers with a diameter of 1-5000 µm.[66] During the last decade, MPs have emerged as "novel" pollutants. They have attracted increased attention due to their toxicity and their detrimental effects on human health.[67]

Evidence from recent studies in animal models reports that ingestion of MPs resulted in oxidative stress and inflammatory processes.

Their hazardous effects are compounded due to the inability of the immune system to remove synthetic particles.[67, 68] This leads to chronic inflammation and increases the risk of neoplasias. The potential toxicity of microparticles depends on their shape, chemical composition, and size. Size is a crucial factor for the uptake of these microparticles.[69] It has been observed that very small particles are able to passively cross cell membranes, while larger ones require active endocytosis. [63, 69]

As aligners undergo degradation in the oral environment, they contribute to microplastic pollution through multiple mechanisms. Mechanical wear from normal use, masticatory forces, and cleaning procedures lead to surface degradation. Chemical processes, including exposure to salivary enzymes and pH variations, further contribute to material breakdown. These degradation products ultimately enter wastewater systems, eventually accumulating in aquatic environments and contributing to the growing global challenge of microplastic pollution.[63]

Researchers and developers in the field have started to address these concerns through various approaches. Material development efforts focus on creating more biocompatible and environmentally sustainable alternatives while improving manufacturing processes to reduce chemical leaching and enhance material stability. Clinical protocols increasingly emphasize proper handling and disposal procedures, though comprehensive solutions to protect the environment from the waste post-treatment remain an ongoing challenge.

Future investigations must focus on long-term biocompatibility assessment, the development of sustainable materials, and understanding and mitigating the cumulative effects of aligner wear on both patient health and the environment. The challenge lies in balancing the clinical benefits of clear aligner therapy with responsible management of these emerging biological and environmental concerns.[1, 70-72]

The daily wearing of aligners by patients inevitably leads to the continuous frictional contact between the occlusal aligner surfaces. This frictional wear can possibly detach plastic fragments from the thermoplastic material in the oral cavity. This, coupled with the large number of hours per day and the treatment duration of orthodontics to achieve desired outcomes, increases the possible exposure of the patient to these particles.[63, 73]

The clinician can explore the materials and the methods of printing of an aligner system prior to electing its use. An effort can be made to choose systems with polymers that are less susceptible to disintegrate and release microplastics in the mouth and are likely to deliver quality orthodontic outcomes.[72, 74]

ADVERSE EVENTS REPORTED WITH ALIGNERS

There have been several adverse clinical events reported with aligner use, for example, difficulty breathing, swollen throat, anaphylactic reaction, swollen lips, laryngospasm, and blisters.[5] These have been reported in the medical device reports (see the Manufacturer and User Facility Device Experience database of the United States Food and Drug Administration).[5, 75]

The align technology product "Invisalign" is manufactured with polyurethanes, and isocyanate is a critical component required for polyurethane synthesis. Health effects of isocyanate have been well documented in the literature, including but not limited to increased risk of asthma and contact dermatitis. In an in-vitro cytotoxicity study, oral epithelial cells exposed to these aligners showed increased cell death, compromised membrane integrity, and reduced cell-to-cell contact and mobility, which may be the mechanism for isocyanate allergy.[76, 77]

Adverse events to aligners are also grossly under-reported.[5]

FUTURE OF CAT (CAT CURRENT PERSPECTIVES)

The latest trend in the development of CAT is the shape-memory polymers (SMPs) and direct 3D printing of the aligners. SMPs are a type of smart material or stimuli-responsive polymer material.[78,79] These materials have the ability to favorably react with external stimuli, such as thermal, electrical, or magnetic input, producing a predictable repeatable output. SMPs can change their macroscopic shape under a proper stimulus.

Direct 3D printed aligners may eliminate the errors resulting from thermoplastic workflow, apart from the errors that result from analog impressions. Compared to the manufacturing method of existing aligners, model output is not required. It also eliminates manual work such as thermoforming, cutting, and finishing, thereby decreasing waste during the manufacturing process. This also allows manufacturing cost to decrease. It has also been reported that this newer material can be heat sterilized, and that may allow the patients to boil the aligners to keep them clean.[74]

Newer technologies will allow customization of each aligner not only to the movement required at each stage but also variations in rigidity based on the movement needed or stability needed for individual teeth that are being moved. The sophistication of the software and the manufacturing process will allow more detailed and complex movements to be executed with greater accuracy.

CAT systems are poised to continue to evolve, advance, and cement their position as one of the key treatment modalities to deliver orthodontic care.

References

1.Castroflorio T, Parrini S, Rossini G. Aligner biomechanics: Where we are now and where we are heading for. J World Fed Orthod. 2024;13(2):57-64.
2.Upadhyay M, Arqub SA. Biomechanics of clear aligners: hidden truths & first principles. J World Fed Orthod. 2022;11(1):12-21.
3.Meade MJ, Weir T. A survey of orthodontic clear aligner practices among orthodontists. Am J Orthod Dentofacial Orthop. 2022;162(6):e302-e11.
4.Kau CH, Soh J, Christou T, Mangal A. Orthodontic Aligners: Current Perspectives for the Modern Orthodontic Office. Medicina (Kaunas). 2023;59(10).
5.Allareddy V, Nalliah R, Lee MK, Rampa S, Allareddy V. Adverse clinical events reported during Invisalign treatment: Analysis of the MAUDE database. Am J Orthod Dentofacial Orthop. 2017;152(5):706-10.
6.Kesling HD. Coordinating the predetermined pattern and tooth positioner with conventional treatment. Am J Orthod Oral Surg. 1946;32:285-93.
7.Caruso S, De Felice ME, Valenti C, Pagano S, Caruso S, Gatto R, et al. An evaluation of the Invisalign(R) Aligner Technique and consideration of the force system: a systematic review. Syst Rev. 2024;13(1):43.
8.AlMogbel A. Clear Aligner Therapy: Up to date review article. J Orthod Sci. 2023;12:37.
9.Ho CT, Huang YT, Chao CW, Huang TH, Kao CT. Effects of different aligner materials and attachments on orthodontic behavior. J Dent Sci. 2021;16(3):1001-9.
10.Tamer I, Oztas E, Marsan G. Orthodontic Treatment with Clear Aligners and The Scientific Reality Behind Their Marketing: A Literature Review. Turk J Orthod. 2019;32(4):241-6.
11.Al-Dboush R, Al-Zawawi E, El-Bialy T. Impact of clear aligner therapy on speech: does clear aligner therapy cause any speech difficulty? Evid Based Dent. 2024;25(1):27-8.
12.Ali Baeshen H, El-Bialy T, Alshehri A, Awadh W, Thomas J, Dhillon H, et al. The effect of clear aligners on speech: a systematic review. Eur J Orthod. 2023;45(1):11-9.
13.Wang D, Firth F, Bennani F, Farella M, Mei L. Immediate effect of clear aligners and fixed appliances on perioral soft tissues and speech. Orthod Craniofac Res. 2023;26(3):425-32.
14.Fraundorf EC, Araujo E, Ueno H, Schneider PP, Kim KB. Speech performance in adult patients undergoing Invisalign treatment. Angle Orthod. 2022;92(1):80-6.
15.Pogal-Sussman-Gandia CB, Tabbaa S, Al-Jewair T. Effects of Invisalign((R)) treatment on speech articulation. Int Orthod. 2019;17(3):513-8.
16.Morgan D, Leong C, Barmak AB, Rossouw PE, Michelogiannakis D. Weight changes during the initial phase of orthodontic treatment with clear aligners versus fixed appliances: a pilot prospective cohort study. Clin Oral Investig. 2024;28(11):602.
17.Carter LA, Geldenhuys M, Moynihan PJ, Slater DR, Exley CE, Rolland SL. The impact of orthodontic appliances on eating - young people's views and experiences. J Orthod. 2015;42(2):114-22.
18.Sayers MS, Newton JT. Patients' expectations of orthodontic treatment: part 2--findings from a questionnaire survey. J Orthod. 2007;34(1):25-35.
19.Kim JE, Kim S, Kim DH. Comparison of oral health status, oral hygiene management behaviours and satisfaction of patients with fixed orthodontic appliance and clear aligner: A quasi-experimental design. Int J Dent Hyg. 2024;22(4):939-48.
20.Romito M, Nota A, Ferrini F, Porto GD, Mangano FG, Tecco S. Dimensional changes of the gingival tissues induced by clear aligners and fixed orthodontic appliances. J Dent. 2024;151:105335.
21.Zhang H, Bi S, Zhang X. Impact of clear aligners on gingivitis incidence and prevention strategies in adolescents and adults: a prospective observational study. BMC Oral Health. 2025;25(1):75.
22.Xia Q, Wang W, Wang C, Feng G, Wang C, Song J, et al. Comparative assessment of orthodontic clear aligner versus fixed appliance for anterior retraction: a finite element study. BMC Oral Health. 2024;24(1):80.
23.Rouzi M, Zhang X, Jiang Q, Long H, Lai W, Li X. Impact of Clear Aligners on Oral Health and Oral Microbiome During Orthodontic Treatment. Int Dent J. 2023;73(5):603-11.
24.Clements KM, Bollen AM, Huang G, King G, Hujoel P, Ma T. Activation time and material stiffness of sequential removable orthodontic appliances. Part 2: Dental improvements. Am J Orthod Dentofacial Orthop. 2003;124(5):502-8.
25.Phan X, Ling PH. Clinical limitations of Invisalign. J Can Dent Assoc. 2007;73(3):263-6.
26.Cohen-Levy J, Boulos C, Rompre P, Montpetit A, Kerstein RB. Is the quality of occlusal contacts comparable after aligner and fixed orthodontic therapy? A non-randomized cohort comparison using computerized occlusal analysis during 6 months of retention. Cranio. 2024;42(6):788-800.
27.Kravitz ND, Kusnoto B, BeGole E, Obrez A, Agran B. How well does Invisalign work? A prospective clinical study evaluating the efficacy of tooth movement with Invisalign. Am J Orthod Dentofacial Orthop. 2009;135(1):27-35.
28.Lin E, Julien K, Kesterke M, Buschang PH. Differences in finished case quality between Invisalign and traditional fixed appliances. Angle Orthod. 2022;92(2):173-9.
29.Darwiche FH, Tashkandi NE, AlGhamdi M, AlMuhaish LA, Shahin SY. Effect of interproximal enamel reduction on interradicular bone volume in clear aligner therapy: a three-dimensional cone-beam computed tomography study. Clin Oral Investig. 2024;28(10):552.
30.Hariharan A, Arqub SA, Gandhi V, Da Cunha Godoy L, Kuo CL, Uribe F. Evaluation of interproximal reduction in individual teeth, and full arch assessment in clear aligner therapy: digital planning versus 3D model analysis after reduction. Prog Orthod. 2022;23(1):9.
31.Butrus DJ, Chawshli OF. Evaluation of the enamel nano-topography influenced by different techniques of interproximal reduction: An atomic force microscopic study. J Orthod. 2023;50(2):196-204.
32.Dahhas FY, Almutairi NS, Almutairi RS, Alshamrani HA, Alshyai HS, Almazyad RK, et al. The Role of Interproximal Reduction (IPR) in Clear Aligner Therapy: A Critical Analysis of Indications, Techniques, and Outcomes. Cureus. 2024;16(3):e56644.
33.Gomez-Aguirre JN, Argueta-Figueroa L, Castro-Gutierrez MEM, Torres-Rosas R. Effects of interproximal enamel reduction techniques used for orthodontics: A systematic review. Orthod Craniofac Res. 2022;25(3):304-19.
34.Lapenaite E, Lopatiene K. Interproximal enamel reduction as a part of orthodontic treatment. Stomatologija. 2014;16(1):19-24.
35.Sharma NS, Shrivastav SS, Hazarey PV. Mastering interproximal stripping: with innovations in slenderization. Int J Clin Pediatr Dent. 2012;5(2):163-6.
36.de Harfin JF. Interproximal stripping for the treatment of adult crowding. J Clin Orthod. 2000;34(7):424-33.
37.Zachrisson BU, Minster L, Ogaard B, Birkhed D. Dental health assessed after interproximal enamel reduction: caries risk in posterior teeth. Am J Orthod Dentofacial Orthop. 2011;139(1):90-8.
38.Zachrisson BU, Nyoygaard L, Mobarak K. Dental health assessed more than 10 years after interproximal enamel reduction of mandibular anterior teeth. Am J Orthod Dentofacial Orthop. 2007;131(2):162-9.
39.Fiori A, Minervini G, Nucci L, d'Apuzzo F, Perillo L, Grassia V. Predictability of crowding resolution in clear aligner treatment. Prog Orthod. 2022;23(1):43.
40.Uzuncibuk H, Marrapodi MM, Meto A, Ronsivalle V, Cicciu M, Minervini G. Prevalence of temporomandibular disorders in clear aligner patients using orthodontic intermaxillary elastics assessed with diagnostic criteria for temporomandibular disorders (DC/TMD) axis II evaluation: A cross-sectional study. J Oral Rehabil. 2024;51(3):500-9.
41.Sondhi A. Orthodontics and patients with temporomandibular disorders: inform before you perform. Am J Orthod Dentofacial Orthop. 1999;115(5):551-2.
42.Antunes Ortega AC, Pozza DH, Rocha Rodrigues LL, Guimaraes AS. Relationship Between Orthodontics and Temporomandibular Disorders: A Prospective Study. J Oral Facial Pain Headache. 2016;30(2):134-8.
43.Michelotti A, Iodice G. The role of orthodontics in temporomandibular disorders. J Oral Rehabil. 2010;37(6):411-29.
44.Luther F. Orthodontics and the temporomandibular joint: where are we now? Part 1. Orthodontic treatment and temporomandibular disorders. Angle Orthod. 1998;68(4):295-304.
45.Bales JM, Epstein JB. The role of malocclusion and orthodontics in temporomandibular disorders. J Can Dent Assoc. 1994;60(10):899-905.
46.Aldayel AM, AlGahnem ZJ, Alrashidi IS, Nunu DY, Alzahrani AM, Alburaidi WS, et al. Orthodontics and Temporomandibular Disorders: An Overview. Cureus. 2023;15(10):e47049.
47.Akin M, Tezcan M, Ileri Z, Ayhan F. Incidence of white spot lesions among patients treated with self- and conventional ligation systems. Clin Oral Investig. 2015;19(6):1501-6.
48.Malhi G. Clear aligners vs fixed appliances: which treatment option presents a higher incidence of white spot lesions, plaque accumulation and salivary caries-associated bacteria? Evid Based Dent. 2024;25(1):21-2.
49.Liu Q, Song Z. Incidence, severity, and risk factors for white spot lesions in adolescent patients treated with clear aligners. Orthod Craniofac Res. 2024;27(5):704-13.
50.Hussain U, Wahab A, Kamran MA, Alnazeh AA, Almoammar S, Alshahrani SSM, et al. Prevalence, Incidence and Risk Factors of White Spot Lesions Associated With Orthodontic Treatment - A Systematic Review and Meta-Analysis. Orthod Craniofac Res. 2024.
51.Raghavan S, Abu Alhaija ES, Duggal MS, Narasimhan S, Al-Maweri SA. White spot lesions, plaque accumulation and salivary caries-associated bacteria in clear aligners compared to fixed orthodontic treatment. A systematic review and meta- analysis. BMC Oral Health. 2023;23(1):599.
52.Katib HS, Hakami AM, Albalawei M, Alhajri SA, Alruwaily MS, Almusallam MI, et al. Stability and Success of Clear Aligners in Orthodontics: A Narrative Review. Cureus. 2024;16(1):e52038.
53.Aragon M, Mendes Ribeiro SM, Fernandes Fagundes NC, Normando D. Effectiveness of dental arch expansion in the orthodontic treatment with clear aligners: a scoping review. Eur J Orthod. 2024;46(6).
54.Li W, Wang S, Zhang Y. The effectiveness of the Invisalign appliance in extraction cases using the the ABO model grading system: a multicenter randomized controlled trial. Int J Clin Exp Med. 2015;8(5):8276-82.
55.Rossini G, Parrini S, Castroflorio T, Deregibus A, Debernardi CL. Efficacy of clear aligners in controlling orthodontic tooth movement: a systematic review. Angle Orthod. 2015;85(5):881-9.
56.Vaid NR, Sabouni W, Wilmes B, Bichu YM, Thakkar DP, Adel SM. Customized adjuncts with clear aligner therapy: "The Golden Circle Model" explained! J World Fed Orthod. 2022;11(6):216-25.
57.Shokeen B, Viloria E, Duong E, Rizvi M, Murillo G, Mullen J, et al. The impact of fixed orthodontic appliances and clear aligners on the oral microbiome and the association with clinical parameters: A longitudinal comparative study. Am J Orthod Dentofacial Orthop. 2022;161(5):e475-e85.
58.Jiang Q, Li J, Mei L, Du J, Levrini L, Abbate GM, et al. Periodontal health during orthodontic treatment with clear aligners and fixed appliances: A meta-analysis. J Am Dent Assoc. 2018;149(8):712-20 e12.
59.Levrini L, Mangano A, Montanari P, Margherini S, Caprioglio A, Abbate GM. Periodontal health status in patients treated with the Invisalign((R)) system and fixed orthodontic appliances: A 3 months clinical and microbiological evaluation. Eur J Dent. 2015;9(3):404-10.
60.Campobasso A, Lo Muzio E, Battista G, Ciavarella D, Crincoli V, Lo Muzio L. Taxonomic Analysis of Oral Microbiome during Orthodontic Treatment. Int J Dent. 2021;2021:8275181.
61.Zhang M, Liu X, Xie Y, Zhang Q, Zhang W, Jiang X, et al. Biological Safe Gold Nanoparticle-Modified Dental Aligner Prevents the Porphyromonas gingivalis Biofilm Formation. ACS Omega. 2020;5(30):18685-92.
62.Daniele V, Macera L, Taglieri G, Di Giambattista A, Spagnoli G, Massaria A, et al. Thermoplastic Disks Used for Commercial Orthodontic Aligners: Complete Physicochemical and Mechanical Characterization. Materials (Basel). 2020;13(10).
63.Quinzi V, Orilisi G, Vitiello F, Notarstefano V, Marzo G, Orsini G. A spectroscopic study on orthodontic aligners: First evidence of secondary microplastic detachment after seven days of artificial saliva exposure. Sci Total Environ. 2023;866:161356.
64.Stocker L, Zervou SK, Papageorgiou SN, Karakousoglou S, Triantis T, Hiskia A, et al. Salivary levels of eluents during Invisalign treatment with attachments: an in vivo investigation. Prog Orthod. 2024;25(1):22.
65.Azhagudurai N, Rajendran R, Aishwarya K, Rajendrababu S, Kumar S, Reddy M. Detecting Bisphenol A Leaching from Four Different Commercially Available Clear Aligner Sheets: An Ex Vivo Study. J Contemp Dent Pract. 2024;25(6):535-9.
66.Frias J, Nash R. Microplastics: Finding a consensus on the definition. Mar Pollut Bull. 2019;138:145-7.
67.Prata JC. Microplastics in wastewater: State of the knowledge on sources, fate and solutions. Mar Pollut Bull. 2018;129(1):262-5.
68.Ragusa A, Svelato A, Santacroce C, Catalano P, Notarstefano V, Carnevali O, et al. Plasticenta: First evidence of microplastics in human placenta. Environ Int. 2021;146:106274.
69.Kettiger H, Schipanski A, Wick P, Huwyler J. Engineered nanomaterial uptake and tissue distribution: from cell to organism. Int J Nanomedicine. 2013;8:3255-69.
70.Bakdach WMM, Haiba M, Hadad R. Changes in surface morphology, chemical and mechanical properties of clear aligners during intraoral usage: A systematic review and meta-analysis. Int Orthod. 2022;20(1):100610.
71.Turkalj M, Ghosh M, Cokic SM, Hoet PHM, Vanoirbeek J, Van Meerbeek B, et al. Cytotoxicity assessment of eluates from vacuum-forming thermoplastics. Clin Oral Investig. 2024;28(10):570.
72.Martina S, Rongo R, Bucci R, Razionale AV, Valletta R, D'Anto V. In vitro cytotoxicity of different thermoplastic materials for clear aligners. Angle Orthod. 2019;89(6):942-5.
73.Al-Nadawi M, Kravitz ND, Hansa I, Makki L, Ferguson DJ, Vaid NR. Effect of clear aligner wear protocol on the efficacy of tooth movement. Angle Orthod. 2021;91(2):157-63.
74.Tartaglia GM, Mapelli A, Maspero C, Santaniello T, Serafin M, Farronato M, et al. Direct 3D Printing of Clear Orthodontic Aligners: Current State and Future Possibilities. Materials (Basel). 2021;14(7).
75.Alexandropoulos A, Al Jabbari YS, Zinelis S, Eliades T. Chemical and mechanical characteristics of contemporary thermoplastic orthodontic materials. Aust Orthod J. 2015;31(2):165-70.
76.Premaraj T, Simet S, Beatty M, Premaraj S. Oral epithelial cell reaction after exposure to Invisalign plastic material. Am J Orthod Dentofacial Orthop. 2014;145(1):64-71.
77.Eliades T, Pratsinis H, Athanasiou AE, Eliades G, Kletsas D. Cytotoxicity and estrogenicity of Invisalign appliances. Am J Orthod Dentofacial Orthop. 2009;136(1):100-3.
78.Alkhamees A. The new additive era of orthodontics: 3D-printed aligners and shape memory polymers-the latest trend-and their environmental implications. J Orthod Sci. 2024;13:55.
79.Lee SY, Kim H, Kim HJ, Chung CJ, Choi YJ, Kim SJ, et al. Thermo-mechanical properties of 3D printed photocurable shape memory resin for clear aligners. Sci Rep. 2022;12(1):6246.

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