

Quality Resource Guide

Aligner-Based and “Mail-in” Orthodontic Therapy

Author Acknowledgements

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Dr. Karakousglou has no relevant
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Educational Objectives

Following this unit of instruction, the learner should be able to:

1. Discuss the history and development of clear aligner therapy (CAT)
2. Explain the effectiveness of CAT for treating mild to moderate malocclusions,
3. Discuss CAT advancements in digital technology, 3D printing, and biomaterial science.
4. Identify and describe the advantages of clear aligner treatment for patients.
5. Recognize the potential disadvantages of clear aligner treatment for patients.
6. Compare and contrast the benefits and potential drawbacks of clear aligner treatment for providers.
7. Distinguish between patients who are or are not candidates for CAT.
8. Identify and explain the potential risks and complications associated with direct-to-consumer (DTC) aligner treatments, and evaluate the importance of professional supervision in orthodontic treatment.

MetLife designates this activity for **1.0 continuing education credits** for the review of this Quality Resource Guide and successful completion of the post test.

The following commentary highlights fundamental and commonly accepted practices on the subject matter. The information is intended as a general overview and is for educational purposes only. This information does not constitute legal advice, which can only be provided by an attorney.

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Published August 2023. Expiration date: August 2026.

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Introduction

Clear aligner therapy (CAT) has become very popular as an orthodontic therapy approach in the United States. Consumers are often bombarded by information regarding why CAT may be appropriate for their or their children's dental condition and seek advice from their general dentist or the office staff. This Quality Resource Guide is designed to assist the general dentist's office in appropriately addressing those questions.

CAT is a contemporary orthodontic treatment approach introduced in the mid-1990s as an alternative to traditional braces to treat mild to moderate malocclusions. CAT is designed to give patients an option for straightening their teeth that is more esthetic during treatment. CAT has been shown to be effective in treating various malocclusions and has gained popularity with patients due to its convenience and relative comfort. It continues to grow in popularity and is a viable option for many individuals seeking orthodontic treatment.¹

CAT was first used as a treatment option for mild to moderate malocclusions. It has more recently gained widespread acceptance due to significant advancements in its use of digital technology, appliance customization, 3D printing, and biomaterial science. These advances have allowed for the creation of customized aligners that may be tailored to a patient's needs. Digital impressions and 3D-printing technology have made it possible to manufacture aligners more efficiently and accurately. At the same time, the development of new thermoplastic materials has improved the durability and flexibility of the aligners.²

Align Technology introduced its Invisalign system in 1997. The company reported in 2020 that its aligners had been used to treat over 9.6 million patients worldwide.³ A diverse range of other CAT products and appliances are available on the market, including Spark by Ormco, ClearCorrect, and uLab. It must be noted that each brand offers distinct options, services, and materials, which can vary significantly. The provider must carefully select a brand and its associated product or appliance, considering individual patient needs and treatment goals.

Figure 1 - CAT Treatment Workflow Diagram



Clear Aligner Therapy Workflow⁴

Despite the differences between the variety of CAT options available on the market, most systems exhibit a similar workflow for designing, manufacturing, and using clear aligners in orthodontic therapy. Stages in the workflow are:

1. Initial Examination

In every orthodontic treatment, the care process begins with the initial visit. This involves conducting a comprehensive medical and dental history assessment to pinpoint any potential systemic or localized factors that might negatively impact tooth movement, alongside addressing the patient's primary concerns. Additionally, a

thorough examination of the intraoral and paraoral regions is essential to gauge the patient's oral health status. It's of utmost importance to ensure the complete absence of any ongoing dental or periodontal diseases before commencing orthodontic treatment. Lastly, an evaluation of dentofacial characteristics and malocclusion takes place, allowing the clinician to determine the patient's suitability for CAT treatment.

2. Initial Orthodontic Records

The collection of digital records and diagnostic data typically includes the patient's intraoral and extraoral photographs, panoramic and cephalometric radiographs, and digital scans of the teeth and occlusion. CBCT X-rays may also be necessary in some situations.

3. Digital treatment planning and Computer-Aided Design

Various software programs, including 3Shape Ortho Analyzer and BlueSkyBio Plan, facilitate the visualization of treatment objectives and staging of tooth movement. However, due to the time-consuming nature of this process and the need for specialized training, many providers opt for third-party options at this stage. Many labs offer interactive online platforms, like ClinCheck Pro by Align Technology, that enable providers to submit digital records, prescribe desired treatment, and adjust treatment plans according to their preferences. The role of the provider is to design the appropriate force system that will be applied to the teeth to ensure that the final result is attainable and safe.

4. Manufacturing of Thermoformed Plastic Aligners

The thermoforming process involves heating a sheet of medical-grade plastic to a precise temperature, which makes it malleable. The softened plastic sheet is then formed over a 3D-printed model of the teeth using a vacuum or pressure system to create a custom aligner for the patient uniquely. The aligners are trimmed to fit the patient's oral anatomy after the thermoforming process. This aligner is designed to generate the appropriate forces and direction of movement necessary to move the teeth.

Recently, newer materials and techniques have been developed to enhance this process's efficiency and the biomechanical properties of the aligners. Notable among these are the SmartTrack thermoplastic material by Align Technology⁵ and the direct 3D-printing of aligners with shape memory polymers.⁶

5. Bonding of Precision Attachments

Many CAT systems incorporate bonded resin attachments on the teeth to enhance the accuracy and efficiency of the aligners by providing a more targeted direction of forces when needed. Typically, these attachments are placed on the teeth during the initial appointment prior to the delivery of the aligners. However, the specific timing and approach for placement of attachments can vary considerably among providers based on the individual treatment plan and patient needs.

6. Delivery of Aligners and Activation of Treatment

Based on the prescribed treatment plan and the intended adjustments for the teeth, the healthcare provider provides the patient with a series of clear aligner trays. The CAT trays come with specific instructions and a schedule outlining the progression of the treatment. For instance, the patient might receive six sets of aligners, each set numbered, and be directed to wear each set for a week before moving on to the next. After completing the recommended duration for each aligner set, the patient returns to the office for a follow-up appointment.

It's crucial to guide the patient on how to determine whether an aligner fits properly before moving forward. In cases where tooth movement is not progressing as expected, the patient should contact the provider for further instructions. Additionally, the patient should be educated on aligner care, addressing scenarios such as aligner loss or damage, discomfort, and dental pain.

7. Regular Follow-up Visits

Similar to conventional orthodontic treatments, patients undergoing CAT require periodic follow-up visits throughout the active treatment phase to monitor the progress of tooth movement, ensure compliance with treatment protocols, make required adjustments, apply interarch elastics, perform interproximal reduction procedures, and address concerns or questions raised by the patient.

Multiple sets of aligners may be necessary for comprehensive orthodontic treatment to achieve the final result.

8. Completion of treatment and retention

After achieving the desired outcome, maintaining the results becomes essential. The approach to retention can differ significantly among providers, and it might involve either removable or fixed methods, or a combination of both. This retention strategy is determined by the provider and is applied for a duration they consider necessary to prevent any relapse. Additionally, follow-up retention appointments might be needed in the following years to assess the stability of the achieved outcome.

Advantages & Disadvantages of CAT

Compared to traditional orthodontic therapy utilizing fixed appliances, clear aligner treatment presents distinct advantages and disadvantages (TABLE 1). Nevertheless, ongoing research efforts continue to enhance CAT technology, address its limitations, and enable more complex malocclusions to be successfully treated by experienced clinicians.

FOR PATIENTS

ADVANTAGES

Esthetic Appeal: Compared to most fixed orthodontic appliances (except lingual braces), clear aligners are less visible to the naked eye⁷, and can be easily removed for photos or important events.

Removability & Oral Health: Clear aligners can also be removed for eating, drinking, brushing, and flossing, leading to better oral hygiene and greater dietary flexibility. However, compliance is critical, as successful aligner therapy requires patients to wear the aligners for at least 22 hours daily.⁸

Comfort & Emergencies: As clear aligners lack brackets and wires, patients typically experience greater comfort and experience fewer emergencies resulting from debonded brackets or wire irritation.⁹

Predictability & Customization: The use of advanced digital intraoral scanners in clear aligner treatment enhances customization for patients.

Less Frequent Office Visits: While clear aligners generally require less frequent office visits than traditional braces, the frequency of visits can depend on the complexity of the treatment, patient compliance, and the clinical protocols followed by the treating clinician.¹⁰

Online Resources & Digital Monitoring Tools: Online resources and digital monitoring tools are available for patients undergoing CAT. Many patient resources can be accessed online, and AI-based digital monitoring devices have been developed to facilitate clinicians' remote monitoring of CAT progress.¹¹

DISADVANTAGES

Compliance-Dependent: Clear aligners require high patient compliance to be effective. Like traditional edgewise appliances, the teeth still need light continuous forces to move. If the patient can remove the force due to discomfort or other reasons, this interrupts the basic biologic principle of orthodontic movement. Additionally, people forget to wear or even lose and damage their aligners. These factors have proven to be some of the most significant drawbacks of removable orthodontic appliances.

The patient is responsible for the following:

- Ensuring the aligners are worn at least 22 hours per day. Failure to wear the aligners as directed can lead to slower or less effective treatment and an increased risk of relapse after treatment is complete.
- Removing the aligners to consume food or beverages
- Maintaining a schedule to progress to the next aligner stage at the time specified by the provider
- Monitoring tooth movement and confirming adequate fit of one stage before moving to the next
- Bringing multiple aligners with them at every office visit
- Applying inter-arch elastics as prescribed by the provider
- Maintaining good oral health with excellent oral hygiene and regular dental check-ups
- Keeping the aligners clean and adjusting their diet to prevent staining or deformation

Cost: Clear aligner therapy can be more expensive than traditional braces, particularly for more complex cases requiring longer treatment or multiple aligners. Insurance coverage for clear aligners may also be more limited.

Speech difficulties: Patients may experience temporary speech difficulties when first beginning

treatment with clear aligners due to the presence of a foreign object in their mouth. This usually resolves with time and practice. Additionally, aligners can be susceptible to deformation, tearing and staining. In such cases, a patient might find the aligner uncomfortable and choose to remove it.

Risks: CAT does not eliminate the conventional risks associated with orthodontic treatment, such as root resorption, tooth decay, periodontal diseases, discomfort and soft tissue irritation.¹²

FOR PROVIDERS

ADVANTAGES

Increased Case Acceptance and Patient Satisfaction: The growing use of CAT has increased patient preference for this treatment modality, resulting in greater case acceptance and patient satisfaction. Providing a range of treatment options and achieving satisfactory treatment outcomes using the patient's preferred appliance are considered significant positive impact factors.⁷

Digital Tools for Patient Communication: Incorporating virtual tools, such as Clincheck, iTero Outcome Simulator, and Smile Design, in conjunction with CAT, has enhanced provider/patient communication. These tools enhance patient-practitioner communication and promote treatment efficiency by visualizing the occlusal issues, predicting possible treatment outcomes, and staging treatment movements for patients throughout the treatment process.

Reduced Chair Time - Fewer Patient Visits: One unique advantage of appliance customization, digital planning, and staging of treatment is that, generally, the practitioner requires less time at the chairside since the need to adjust the appliances at each visit is reduced. Buschang, *et al.* found that CAT is associated with a reduced frequency of follow-up appointments, shorter emergency appointment duration and decreased chair-side adjustment time.¹⁰

Treatment Staging - Simultaneous Treatment Objectives: Treatment is typically accomplished

in three distinct phases during traditional fixed appliance orthodontic therapy: 1) initial alignment and arch development, 2) correction of occlusion and space closure, and 3) finishing. Each stage must be completed before implementing the next stage. For example, interarch elastics are usually implemented after the initial alignment is completed to avoid undesired side effects due to the wires' flexibility.

The thermoformed plastic aligners used in CAT possess the same properties throughout the treatment. Therefore, some of the objectives traditionally accomplished after the initial alignment of the teeth, such as Class II or III correction with interarch elastics, distalization, and space closure, can be integrated at the beginning of the treatment. Compliance is considerably better at this time, and ample time is available to achieve complete correction of the issue.

Patients with Special Needs: CAT can offer several benefits for special needs patients, including those with physical or cognitive disabilities. Compared to traditional braces, clear aligners have fewer sharp edges or wires that can cause discomfort or injury to the lips, cheeks, or tongue. Additionally, clear aligners can be easily removed, which can be especially beneficial for special needs patients who may have difficulty with manual dexterity or sensory issues. CAT may offer a more discreet and socially acceptable option for special needs patients who feel self-conscious about traditional braces.

Abnormal Dental Morphology: Some patients with enamel abnormalities, such as those with conditions like amelogenesis imperfecta or extensive enamel wear, face difficulties with bonding traditional fixed appliances due to inadequate enamel strength for effective attachment. Clear Aligner Therapy (CAT) provides a viable solution in such cases, making orthodontic correction feasible for individuals whose enamel conditions might hinder the success of traditional braces.

DISADVANTAGES

Limited Efficacy in Specific Malocclusions:

Despite notable advancements in the efficacy of clear aligners, particularly with the incorporation of bonded composite attachments, CAT may not be as effective as traditional braces for some complex orthodontic cases^{13,14} including:

- Malocclusions requiring extensive root displacement, such as tooth extraction or the closure of gaps caused by congenitally missing teeth.¹⁵
- Patients in late mixed dentition - the continuous and unpredictable eruption and exfoliation of teeth make it challenging to plan and stage the treatment accurately, leading to poor fitting of the aligners and compromised treatment outcomes.
- Highly complex cases with impacted teeth - initiating the eruption requires an appliance to be attached with a fixed method on the teeth.
- Teeth with extremely short clinical crowns make retention and fitting of the aligners difficult.
- Cases where significant extrusion of the posterior teeth or rotational movements of premolars and canines are needed.¹⁶

Cost: Increased Lab Fees and Equipment Costs:

Clear aligners require specialized equipment and materials, such as 3D scanners, software, and 3D printers, which can be expensive to acquire and maintain. In addition, there are increased lab fees associated with CAT, as a specialized laboratory must fabricate the aligners. These factors can increase the cost of providing clear aligner treatment, which may not be financially feasible for some patients.

Treatment Planning Time: While CAT may reduce chair time, it typically requires more time for initial planning, designing and consultation, and additional time is required for the fabrication and delivery of the aligners.

Specialized Training: Most U.S. postgraduate orthodontic residency programs have integrated CAT clinical training over the past decade.

Table 1 - Clear Aligner Therapy Advantages/Disadvantages

FOR PATIENTS		FOR PROVIDERS	
ADVANTAGES	DISADVANTAGES	ADVANTAGES	DISADVANTAGES
Aesthetic appeal	Compliance-dependent treatment	Increased case acceptance and patient satisfaction	Limited efficacy in specific types of malocclusions
Removability & oral health	Cost	Digital tools for patient communication	Cost: Increased lab fees and equipment
Comfort	Speech difficulties	Reduced chair time - fewer patient visits	Treatment planning & manufacturing time
Predictability & customization	Risks of orthodontic tooth movement	Treatment staging & simultaneous treatment objectives	Need for specialized training
Fewer emergencies		Patients with special needs	
Less frequent office visits			
Online resources & digital monitoring tools			

However, providers who graduated in the past will require specialized training in digital treatment planning and the utilization of CAD/CAM technology, which may require substantial time and financial investment. With the rapid progression of this technique, even recent graduates need to stay informed and pursue continuing education to incorporate the latest technological advancements in CAT.

"Mail-in" - DIRECT-to-CONSUMER Orthodontic Therapy (DTCO)

Direct-to-consumer orthodontic (DTCO) treatment has become increasingly popular in recent years, with companies offering at-home clear aligner therapy without needing in-person visits to a

licensed dentist. In some cases, teleorthodontic consultations are utilized, where patients can receive a diagnosis and treatment plan remotely. In most cases, the patients are asked to produce their digital records themselves (photos, scans/impressions) or visit an in-store technician. This approach has been heavily advertised and promoted as offering the convenience of receiving treatment from home and being more affordable than traditional orthodontic treatment.¹⁷

Several dental boards and orthodontic organizations have attempted to caution patients regarding the risks associated with a lack of in-person supervision and monitoring, which can lead to potential complications, including ineffective treatment, dental and gingival injury, and occlusal problems. Additionally, DTCO aligner

companies may have less rigorous standards for selecting patients, resulting in patients being treated without adequate assessment of their dental health and suitability for aligner therapy. The American Dental Association adopted a policy (October 2018) strongly discouraging direct-to-the-consumer dental laboratory services because of the potential for irreversible harm to patients.¹⁸

It is essential for patients considering DTCO aligner treatment to weigh the potential benefits and risks carefully and seek advice from a licensed oral health care provider before proceeding with any treatment.

According to the American Association of Orthodontists "Consumer Alert" publication regarding DTCO Companies, patients that are deciding to proceed with DTCO treatment are advised to consider the following:¹⁹

- Initiating orthodontic tooth movement without obtaining high-quality, comprehensive orthodontic records may result in a misdiagnosis and potentially harmful outcomes for oral health. Radiographs play a crucial role in diagnosing various factors necessary to identify cases that may initially appear suitable

for simple alignment with a few aligners but may have skeletal discrepancies, impacted teeth, severe root resorption, periodontal disease and bone loss, and implants. Therefore, obtaining radiographs is crucial in identifying and preventing complications during CAT treatment.

- DTCO treatment may not involve supervision by a licensed dentist or include in-person visits to monitor the patient's progress, identify potential problems, such as root resorption, and adjust the fit of the aligners. Additionally, in cases where the DTCO company claims that every case is assigned and monitored by a licensed dentist, their name, contact information or credentials may not be readily available to the patients.
- Without a licensed dentist supervising DTCO treatment, patients may experience financial and health damages. Dental laboratory technicians and businesses are not typically licensed to provide oral health care, making it difficult for state dental boards to regulate their practices and hold them to professional standards for safety and quality. Some DTCO companies may also ask patients to sign a form that releases them from liability.

Summary

This guide aims to assist general dentist offices in addressing Clear Aligner Therapy (CAT) Treatment inquiries. It provides a comprehensive breakdown of the CAT Treatment process and its advantages while acknowledging its limitations. The guide explains the clinical workflow involved in CAT, then highlights its benefits compared to traditional braces, including improved oral hygiene due to the removable nature of aligners, enhanced esthetics, and the convenience of fewer in-office visits. It points out that CAT may not be suitable for complex tooth movements and that success relies on patient compliance. The guide acknowledges the growing popularity of CAT. It stresses the need for patients to be well-informed and capable of weighing the advantages and limitations when considering aligner options like direct-to-consumer orthodontics.

This Quality Resource Guide equips the entire general dentistry office team with the necessary information to guide patients through CAT decisions, ensuring they understand its benefits and potential drawbacks.

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POST-TEST

Internet Users: This page is intended to assist you in fast and accurate testing when completing the "Online Exam." We suggest reviewing the questions and then circling your answers on this page prior to completing the online exam.

(1.0 CE Credit Contact Hour) Please circle the correct answer. 70% equals passing grade.

1. **What technology(ies) made CAT more efficient?**
 - I. CAD/CAM Technology
 - II. Cone Beam Computed Tomography
 - III. 3D-Printing
 - a. i only
 - b. i and ii only
 - c. i and iii only
 - d. ii only
 - e. All of the above
2. **Which of the following diagnostic pre-treatment records should be taken before initiating orthodontic treatment?**
 - I. Medical and Dental History
 - II. Digital Intraoral Scans or Diagnostic Models
 - III. Periapical Radiographs
 - a. i only
 - b. i and ii only
 - c. i and iii only
 - d. ii only
 - e. All of the above
3. **When an external company designs and fabricates the aligners, what is the provider's role in designing and manufacturing clear aligners?**
 - a. Submit the diagnostic records and write the prescription
 - b. Relay the treatment plan with detailed instructions to the technician
 - c. Check the anticipated plan through the digital platform and ensure that all the desirable orthodontic forces are applied to the teeth
 - d. Approve the plan and the manufacturing of the appliances
 - e. Check the quality of the final products prior to delivering to the patients
 - f. All of the above
4. **Which of the following is an advantage of CAT compared to treatment with traditional braces?**
 - a. Esthetic appeal
 - b. Fewer Compliance Issues
 - c. Reduced Cost
 - d. Reduced Speech Issues
 - e. Reduced Root Resorption
5. **Which of the following is a type of malocclusion for which CAT may be less effective than traditional braces?**
 - a. Cases with highly complex impacted teeth
 - b. Malocclusions requiring extensive root displacement
 - c. Cases with short clinical crowns
 - d. Significant rotational movements of posterior teeth
 - e. All of the above
6. **What are some responsibilities of patients undergoing CAT?**
 - I. Approving the digital design of appliances
 - II. Ensuring the aligners are worn at least 20-22 hours per day
 - III. Deciding the timing between each aligner change
 - a. i only
 - b. i and ii only
 - c. i and iii only
 - d. ii only
 - e. All of the above
7. **Which of the following is an advantage of clear aligner therapy compared to traditional braces regarding oral hygiene?**
 - a. Clear aligners allow for better brushing and flossing access
 - b. Clear aligners require less frequent dental check-ups
 - c. Clear aligners eliminate the risk of tooth decay and gum disease
 - d. Clear aligners provide stronger support for oral tissues
8. **What is a potential disadvantage of CAT regarding treatment planning?**
 - a. Increased chair time
 - b. Limited availability of specialized laboratory services
 - c. Higher cost of specialized equipment and materials
 - d. Longer duration for initial treatment stages
9. **Why is the lack of in-person supervision and monitoring a concern in DTC aligner treatment?**
 - I. It may lead to tooth and gum damage
 - II. It can increase the risk of ineffective treatment outcomes
 - III. Lack of monitoring for potential complications, such as root resorption
 - a. i only
 - b. i and ii only
 - c. i and iii only
 - d. ii only
 - e. All of the above
10. **Dental laboratory technicians and businesses involved in DTCO treatment are typically licensed and regulated by state dental boards.**
 - a. True
 - b. False

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