

Clear Aligner Therapy (CAT) – Ethical and dento-legal risk considerations

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Summary

Rationale

- Dental practitioners with limited prior orthodontic knowledge and skills may be lured by the increasing demand for clear aligner therapy as an opportunity to augment practice income, but at the same time face an increased likelihood of complaints and claims when the treatment outcome is compromised, or patient expectations have not been met.
- The purpose of this narrative review is to provide clinicians with a good understanding of the limitations and potential risks of clear aligner therapy, the need for informed consent, and to highlight the ethical dilemmas and dento-legal risks faced by clinicians providing CAT.

Key points

- CAT is a viable and predictable alternative for mild to moderate malocclusions in non-extraction cases and non-growing patients.
- Limitations involve amount, type, stability and predictability of tooth movement.
- Key risk factors include inexperienced clinicians, case complexity, patient expectations, poor compliance, relapse, loss of composite attachments, and geometric inaccuracies.
- In appropriately selected cases, CAT is safe and results in significant aesthetic and functional benefits with relatively few risks.

Practice implications

- The practitioner makes the treatment recommendations, but the patient makes the final decision to undergo treatment.
- Clinical competence, appropriate case selection, effective communication of risks, adequate informed consent, patient compliance, supervision and retention, are critical elements of a successful treatment outcome and risk management.
- An adverse outcome may not necessarily be construed as negligence, whilst failure to properly inform a patient beforehand could be.
- In complex cases, patients need to be informed that refinements, re-treatment or referral may be required, and that these have time and cost implications.
- Clinicians taking on complex cases are obliged to update their skills with software applications and use of auxiliaries.

Introduction

CAT has gained popularity in modern clinical orthodontics. It is a 'relatively discreet' and removable alternative to traditional braces, and popularised due to its improved appearance, convenience, comfort, and flexibility compared with conventional fixed

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appliances.^{1,2} CAT is also likely to be accepted by patients due to pre-visualization of the treatment outcome and the claimed shortening of treatment duration.³

Globally, more than 27 brands of clear aligners are available and marketed to treat everything from mild to more severe malocclusions. The global clear aligner market size was USD 2,41 billion in 2020, and is expected to grow at a compound annual growth rate of 27,3% to reach USD 15,9 billion by 2028. A growing patient population suffering from malocclusions, and subjected to aggressive commercial marketing strategies, technological and biomaterials research and CAD/CAM software advancements, and the growing demand for CAT are driving the overall market growth.⁴

General dentists with limited knowledge or prior orthodontic training are increasingly offering CAT to their patients as an opportunity to grow their clinical skill set and to increase practice income.⁵ Because a third party provides the initial treatment planning for clear aligner cases, it may be appealing for a dentist to delegate the decisions in a patient's orthodontic treatment to an unseen party, who is relying on supplied photographs, scans, radiographs and models. Additional risks are introduced when the clinician is reliant on a remote technician and computer software, for the design and construction of aligners; effectively leading the diagnosis, treatment planning and fabrication of the appliances without ever seeing the patient. An inexperienced dentist may not recognise that targets for tooth movement are over-ambitious. However, regardless of the aligner system used, it remains the treating clinicians' responsibility to formulate the treatment plan, and to monitor and ensure that successful and predictable treatment meets the patient's expectations.⁶

Dental practitioners with limited prior orthodontic knowledge may therefore face an increased likelihood of complaints and claims if the treatment outcome is compromised or patient expectations are not met.^{5,7}

Purpose

The purpose of this narrative review is to provide clinicians with a good understanding of the limitations and potential risks of clear aligner therapy, the need for informed consent, to highlight the ethical dilemmas and dento-legal risks, and how to minimize and avoid patient dissatisfaction, complaints and claims.

Ethical principles in orthodontics

The four fundamental principles of ethical practice are beneficence (to act in the patients best interests), non-maleficence (to do no harm), respect for autonomy of patients (right to participate in decision making and to respect their preferences and right to choose), and justice

(treating patients fairly).⁸ These principles also delineate the moral duties and obligations that clinicians have towards their patients, colleagues, the dental profession, and society at large. A patient that initiates orthodontic treatment does so in a climate of trust, with the confidence that his/her dental health will be preserved, and that the treatment outcome will be favourable. Ethical practice necessitates that clinicians ensure that they have the requisite clinical knowledge and skills to deliver the best possible standard of care to their patients. In addition, clinicians must ensure that they practice with integrity, honesty, empathy and compassion. Clinicians are expected to communicate and inform their patients appropriately to enable them to participate in clinical decision making, and make informed decisions about their treatment. Treatment decisions must always be directed towards the patient's best interests, preventing harm, and avoid exploiting patient vulnerabilities. Respecting patients' vulnerabilities is at the core of professionalism.⁹ Above all, patients expect their clinician's advocacy to represent their interests effectively. Serving a patient's best interests should always take precedence over any consideration of profit or personal gain.

Limitations of CAT

Although clear aligners are based on very sophisticated technology and have some advantages for both patient and provider, they have numerous limitations with respect to what may be achieved in treating malocclusions with them.^{10,11}

• Treatment predictability and efficacy

As a general rule CAT is a viable and predictable alternative for mild and moderate malocclusions or tooth movements in non-extraction, non-growing patients.^{11,12}

CAT is effective and predicable at aligning and levelling arches¹³, and treatment of anterior crowding¹⁴. However, CAT is less effective and accurate for complex tooth movements and malocclusions compared with fixed appliances.^{10,15,16}

Tooth movements and malocclusions such as extrusion of teeth,^{2,10,13,17,18} rotations,^{10,13,18,19} anterior-buccal inclination (tipping),^{13,15,16} correcting overjet,^{15,16} overbite (deep bite),^{2,13,17,20,21} open bite,^{2,13,17,22} large antero-posterior discrepancies,^{23,24,25} midline discrepancies,^{2,13,17} mesial bodily movement of posterior teeth during extraction space closure,^{2,13,17,18,26,27,28} and correcting occlusal relationships,^{13,16,17} are very challenging with aligners. Furthermore, CAT is not as effective as fixed appliances in producing adequate occlusal contacts, controlling torque and achieving detailed and stable results.^{10,15,16}

Complex cases require sophisticated treatment planning and use of additional auxiliaries like composite attachments, intra-oral elastics, interproximal reduction, power ridges, auxiliary anchorage devices and over correction in some

tooth movements to improve the outcome of CAT,^{11,29} thus requiring greater skills and experience, and increased treatment duration and cost. It is therefore very important with CAT that practitioners know and understand what parameters affect treatment difficulty and predictability to ensure a successful treatment outcome and to manage potential risk.^{30,31} Clinicians are liable for any treatment they render,³² therefore it is imperative that they discuss these limitations with prospective patients prior to embarking on treatment, in order to avoid any untoward issues arising during treatment.³³

- **Contraindications**

CAT is generally not indicated in cases with multiple missing teeth, teeth with short clinical crowns, and where bridges and implants are present.¹² In cases with impacted and supernumerary teeth, CAT may also not be a good option. Crowns, veneers and partial dentures may need replacement after CAT.

Inconveniences associated with CAT

- **Lost or broken aligners**

Aligners are more likely to break in cases of multiple missing teeth.³⁴ Lost or damaged aligners can be replaced within a short period while the patient keeps wearing the previous aligner.^{2,17}

- **Salivation and mouth dryness**

Patients may experience increased salivation or mouth dryness with aligners.³⁴

- **Speech delivery**

Although CAT appears well tolerated, it may affect pronunciation and speech delivery in the short term.^{30,31,34}

- **Tenderness and discomfort**

Dental tenderness may be experienced during switching of aligners.³⁶ Mucosal irritation and masticatory muscle tenderness³⁵ may also arise during CAT, although this does not seem to be clinically significant or concerning to patients.³⁶ Patients with marked bruxing and clenching behaviour may experience greater jaw muscle tenderness during CAT.³⁵

- **Compliance and supervision**

Compliance in wearing aligners consistently for at least 22 hours each day, removing them only to eat, brush or floss is still the best predictor of success.³⁷ Missing and cancelling appointments may also lead to loss of tracking resulting in unpredictable tooth movement and incomplete treatment.¹⁰ Not following the practitioner's post-treatment retention instructions, which includes consistent wearing of

retainers, may also result in shifting of teeth. Poor compliance may lengthen treatment time, increase costs, and affect the outcome of treatment. In addition, dissatisfaction and complaints may be initiated if the clinician has to backtrack through the aligner sequence, thus increasing the projected treatment time.⁷

Potential adverse effects and risks

Orthodontic treatment and the movement of teeth are inherently associated with potential adverse effects and risks. The treating clinician must have a good understanding of these risks and how they relate to each patient, to ensure that the net benefit is always greater than the risks, and that the treatment selected is in the patients best interests. Failure to identify, inform and manage risks can result in patient dissatisfaction and potential litigation.³⁸

- **Safety and toxicity**

Bisphenol-A (BPA) is a synthetic industrial chemical used to make polycarbonate plastics and epoxy resins, with known disruptive endocrine and weak estrogenic properties. Quantifiable amounts of BPA have been observed in thermoformed orthodontic retainers and orthodontic adhesives.³⁹ In vitro studies have shown traces of BPA release from aligners for up to 8 weeks^{40,41} with the majority of BPA release occurring during the first 24 hours. A systematic review and meta-analysis of clinical and in-vitro research found no hormonal or cytotoxic effect from thermoplastic aligners or retainers.⁴² Furthermore, evidence of BPA release reported in clinical and laboratory studies was found to be insufficient and inconsistent.⁴²

- **Apical root resorption**

Apical root resorption (ARR) is described as one of the most undesirable clinical adverse effects of orthodontic treatment.⁴³ Liu, and co-workers⁴⁴ demonstrated that most teeth showed mild to moderate ARR after CAT. However, the amount of resorption is generally small, clinically insignificant, and does not appear to impair tooth longevity.⁴⁵ Recent systematic reviews support the view that neither CAT nor fixed appliances lead to clinically significant ARR (up to 1 mm) of the permanent maxillary incisors.⁴⁶ Despite the prevalence of orthodontically induced ARR, there is limited evidence in the literature on the long-term prognosis of teeth with shortened roots, and the implications thereof mentioned in the literature are hypothetical.⁴⁷

- **Tooth devitalization**

Although it is clear that orthodontic forces can cause ischemia and degenerative changes, evidence based research suggests that the pulp is very robust in resisting heavy orthodontic forces.⁴⁸ However, tooth devitalization

due to orthodontic therapy remains a rare phenomenon, and the effect of orthodontic forces on the pulp remains a poorly understood area.⁴⁹ Teeth with a history of dental trauma, particularly upper maxillary incisors with increased overjet,⁵⁰ and those showing signs of pulp obliteration should be considered as high risk for loss of vitality.⁵¹ It is important to screen potential orthodontic patients for a history of dental trauma, and to inform them about the potential risk of loss of pulp vitality before starting orthodontic treatment.⁴⁷

- **Enamel demineralization (white spot lesions)**

White spot lesions are one of the most common adverse effects of orthodontic treatment.⁵² Patients with poor oral hygiene who use clear aligners that cover up the enamel surfaces with accumulated plaque, especially in more complex cases where more attachments are needed, are at a greater risk of developing enamel demineralisation⁵³ and periodontal problems.⁵⁴ Less white spot lesions (enamel demineralization) occurred in CAT compared with fixed appliances, but were larger and shallower when compared with fixed appliances.⁵⁵ Although CAT is inherently more hygienic than conventional fixed appliances, special attention still needs to be paid to educating patients in proper oral hygiene techniques and dietary restrictions.⁵³ It is also suggested that clinicians should be prudent regarding starting orthodontic treatment in patients with low motivation, because this is often associated with poor oral hygiene.⁵⁶

- **Periodontal risks**

It is well established that orthodontic appliances can impair plaque control leading to gingivitis.⁵⁷ Orthodontic treatment may also impact on the periodontium leading to gingival recession. The labial aspect of the lower incisors is particularly vulnerable to recession.⁵⁸ However, the multifactorial nature of periodontal attachment loss, including plaque control, smoking, oral hygiene habits, age, frenal attachments and periodontal phenotype make it difficult to quantify the contribution of orthodontic therapy.⁴⁷

- **Enamel damage**

Enamel may be damaged during removal of composite or fixed attachments or during interproximal enamel stripping (IPR) with rotary instruments.⁵⁹ At present there are no methods to remove residual orthodontic resin that are completely atraumatic to the tooth surface.⁶⁰ Although it is postulated that there may be an increased risk of caries susceptibility and staining associated with IPR and removal of residual resin from composite attachments, there is no long-term clinical evidence to support such claims.⁴⁷

- **Temporo-mandibular joint dysfunction**

Current evidence-based literature has demonstrated that

there is insufficient evidence to suggest that orthodontic therapy prevents, causes or treats TMJ disorders.⁶¹ Considering that adults may be at increased risk of TMJD from orthodontic treatment, problems may occur with the temporo-mandibular joints during CAT, causing pain, muscle spasm, headache and ear problems.⁶² Past trauma or injury, tooth clenching and grinding, and osteoarthritis may contribute towards TMJ dysfunction (TMJD). Therefore a comprehensive history and examination is required before starting orthodontic treatment. Patients with a history of TMJD should understand that their condition could potentially stabilize, get worse, or improve as a result of orthodontic treatment.⁴⁷ It would therefore be prudent to avoid starting orthodontic treatment in cases where active TMJD already exists.⁶³

- **Serious or life-threatening events**

Although rare, serious or life threatening events, including difficulty breathing, itchy sore throat, swollen throat, swollen tongue, anaphylaxis, and feelings of throat closing/tight airway/airway obstruction, have been reported to be associated with use of aligner systems.⁶⁴ Practitioners should be aware of these events and know how to manage them if they arise in their practices.

Key dento-legal risk factors

- **Unmet expectations**

Adult orthodontic treatment can be costly, uncomfortable and time consuming for the patient. An adult making these sacrifices may therefore have unrealistic expectations regarding treatment outcome. Patient dissatisfaction may be a very real risk if expectations are not met, potentially leading to litigation. Inexperienced clinicians who don't have a clear understanding of what is achievable with orthodontics and CAT in an adult, or who skimp on the consent process, may be exposed to such risks.⁷ It is prudent that clinicians carefully manage patients' expectations prior to, as well as during treatment, as part of their overall risk management strategy.⁴⁷ Always provide an option of referral to a specialist colleague at the outset, or in a timely manner, should patient expectations be in conflict with the complexity of the case, or should treatment not be progressing as you or the patient had intended or expected.

- **Patient dislikes**

Adult orthodontic patients are frequently motivated by the desire for reduced appliance visibility.^{1,65,66} However, information from eye-tracking studies supports the view that clear aligners with attachments compromise appliance aesthetics.⁶⁶ Thai and co-workers⁶⁷ suggested that patients with complex tooth movements that require many

attachments, may be better suited for ceramic brackets or lingual appliances. Patients may also dislike using elastics or other adjuncts to treatment, or decline to undergo interproximal reduction. A prospective patient needs to be aware of these issues before and during treatment, so that there are no surprises and disagreements as the treatment progresses.⁵

- ***Inexperience and failure to recognize problems***

Inexperienced practitioners may underestimate case complexity, or fail to recognize that sequential targets for tooth movement, for example, de-rotation, intrusion or extrusion are not met, thus potentially compromising the achievement of a successful functional and aesthetic result.⁵ Parsons⁵ also pointed out that some aligner systems allow prediction of the final outcome and alteration or refinement of the treatment parameters to suit treatment outcome objectives of the patient and clinician. Such aligner systems are preferred over a 'one size fits all' approach.

Clinician time required for assessing the treatment program progress via platforms such as ClinCheck software, may impact on practice efficiency, and is also related to the experience and training of the treating clinician. Irrespectively, treating practitioners must ensure they have appropriate training, and realise that they will be responsible for the treatment outcome should it fail to meet patient expectations.⁵

- ***Loss of composite attachments***

Composite attachments serve as an important auxiliary device for clear aligners to better transfer forces from the aligner to the tooth root and crown. Attachments also improve the retention of the trays, thus providing better control over tooth movement.⁶⁸ However, loss of composite attachments during CAT is an adverse event that may occur. Attachment loss may prolong treatment time, increase the number of re-visits and the treatment time.⁶⁹ The patient should be informed about this so that there are no surprises.

- ***Unpredictable treatment outcome stability and relapse***

During post-retention time, patients treated with clear aligners relapsed more than those treated with braces.⁷⁰ The clinician may not recognise the risk of relapse in the original assessment and treatment plan, or may fail to obtain valid patient consent for extended retention or a fixed retainer from the very outset. When the patient is presented with this information without any prior warning at the end of treatment, they may be dissatisfied and complain. It may become necessary to place a fixed appliance at the end of CAT, to correct the position of roots and improve stability. Without the skills and knowledge to predict this eventuality and inform the patient of this potential complication, there

can be disappointment when the patient learns they will have to wear a fixed appliance after all. If the same clinician does not have the skills for fixed appliance therapy to finish the case, the patient may have to be referred to a specialist to complete treatment, which could be both inconvenient, disappointing and costly.⁷ Currently there is still insufficient evidence with regard to the effectiveness and stability of clear aligner therapy compared with conventional fixed appliance therapy.¹³

Ethical and dento-legal considerations arising from CAT

A study conducted by Dental Protection in the UK in 2010 revealed that claims arising from orthodontics were on the increase, and 20% of the new cases involved CAT.¹² Furthermore, general practitioners (dentists) accounted for 80-90% of all aligner related complaints and claims.⁷ This is a worrying development, given the increasing popularity of CAT with patients and amongst dentists who provide orthodontic treatment.⁷ An analysis of underlying causes of complaints and claims associated with CAT included (i) failures in case assessments, diagnosis and treatment planning; (ii) deficiencies in the consent process, especially in relation to discussing alternative options, (iii) inexperience and failure to anticipate and recognise problems, (iv) failure to recognise the significance of interproximal reduction (interdental stripping) as a means of space creation, and the associated risks, and (v) failure to manage the patient's expectations.

- ***Informed consent***

Obtaining consent is not only an ethical obligation, but also a legal obligation.⁷¹ Informed consent is a hallmark of the ethical principle of autonomy, as we give our patient's sufficient information to make an informed choice on their treatment.⁷² Respect for autonomy through the informed consent process is the foundation of establishing patient trust.⁷³

Any orthodontic treatment that may be considered ideal and beneficial for a patient, may have certain limitations and risks associated with it. Patients should be informed of, and understand the benefits as opposed to the limitations and risks of the proposed treatment, versus alternative orthodontic treatment and doing no treatment at all. In addition, patients must also be informed of, and understand their required obligations towards recommended compliance during and after treatment, relating to aligner wear protocols, oral hygiene practices, keeping follow-up visits, and fees associated with treatment. Full disclosure need not list every advantage or disadvantage or each treatment option, but it must highlight the salient points that may be beneficial, or that can affect the health of the patient, or the outcome of the treatment.⁷⁴

The importance of type of retainer, wearing retainers and duration of wear to maintain the corrected malocclusion should be explained prior to the start of treatment. Whilst, an adverse outcome may not necessarily be construed as negligence, failure to properly inform a patient beforehand could be.⁴⁷

- **Clinician responsibilities within a digitally controlled environment**

Advances in digital technology and CAD/CAM systems have revolutionised the practice and appliances used in orthodontics, and have become an integral part of case management in orthodontics.⁷⁵ Aligner technology incorporates the use of digital imaging and computer-controlled components for taking impressions, forwarding patient information, planning and design, visualisation of treatment goals, and fabrication of customized clear aligner appliances. Although aligners have become an essential part of everyday practice, relying excessively on aligner technology for a treatment decision is not without risks and ethical challenges. However, all cases do not simply fit the concepts of "digital flow" of treatment. Firstly, using digital flow technology requires a certain level of knowledge and skills development. Secondly, the haptic feedback function of seeing and feeling is still a critical part of treatment planning and delivery.⁷⁵ Furthermore, technical errors and material characteristics contribute towards inaccuracies with CAT that may result in patient dissatisfaction with clinical outcomes, and potential harmful effects. Clinicians involved in CAT should be aware of this responsibility, and play a more active role as a partner and evaluator of the technical support and treatment decisions provided by the digital environment of aligner design and manufacturing.³

- **Should dentists offer referral to an orthodontist?**

Many dentists provide orthodontic treatment to patients, solely using CAT. An ethical dilemma that arises is whether all patients seeking CAT from dentists be offered referral to a specialist orthodontist. Burns and Noar⁷⁶ noted that whilst there is an increasing amount of literature showing the value of CAT, short training courses for dentists undertaking CAT are unregulated and have extremely variable mentoring. They suggested that it was appropriate for dentist's that provide CAT to a patient to ensure that they are suitably competent. It was also noted that as part of the consent process, the patient needs to be given all the relevant information about his/her treatment options.⁷⁶ Thus where dentists do not use a range of orthodontic appliances or provide comprehensive treatment, they cannot obtain true informed consent. Therefore, referral to an orthodontist must be an option offered to a patient. It is also suggested that it is unethical practice not to advise patients that compromise

treatments may present with long-term risks.⁷⁶

- **When and how should treatment of a non-compliant patient be terminated?**

It is not uncommon for some patients to miss or cancel appointments regularly, not comply with aligner wear instructions, break appliances frequently or fail to maintain an adequate level of oral hygiene.⁷⁶ Compliance, regular supervision and following the instructions of the treating practitioner are key factors in ensuring a successful treatment outcome, and should be clearly communicated to the patient. If any of these are lacking, serious consideration needs to be given to whether ending treatment early is in the patient's best interests.⁷⁶ Good compliance starts before treatment commences. A patient who cannot, and does not maintain satisfactory oral hygiene, or keep appointments, is unlikely to do so once treatment starts. During treatment, poor compliance needs to be identified as soon as possible and the patient informed immediately once this is identified. Clear explanation and documentation on the patients record of what exactly needs to improve is essential. It is suggested that the seriousness of non-compliance issues and efforts made to address these should be documented in a letter of warning copied to all parties.¹¹⁵ Ultimately, the decision to end treatment, if necessary, should not come as a shock to either the patient or parent. It should be communicated clearly that ending treatment due to poor compliance is a necessary action with the patient's best interests in mind to prevent iatrogenic damage when treatment is not progressing.⁷⁶

- **Tele-orthodontics and the privacy and protection health information**

The exchange of healthcare-related information using digital technology is escalating and paving the way for teledentistry, potentially enhancing the scope in clinical orthodontics.⁴ Tele-orthodontics contrasts with traditional methods of dentistry which rely on direct patient contact and communication. It has been reported that tele-orthodontics facilitates easy access to orthodontic care for patients in remote or rural geographic locations, being more attractive and cost-effective for certain populations, and reducing the need for in-office visits.^{37,77,78} It has also been demonstrated that teledentistry is a cost-effective way to provide care by reducing expenditures, such as transportation and direct consultation with a specialist.⁴

However, the use of patient information through digital means raises various dento-legal issues regarding use and protection of personal information (confidentiality).⁷⁹ The Health Care Act and the recently introduced Protection of Personal Information Act (POPIA) is aimed at protecting the use and exchange of personal patient-related information.

Confidentiality and data breach of patient records is a concern in the modern health care industry. It is therefore important to mention in the consent form that there is a risk of breach of confidentiality when patients' photos, radiographs and other healthcare-related information are shared with a third-party during CAT treatment planning. Moreover, the consent should also clearly state that a breach and/or loss of electronic communication may also result in loss of services offered. It is crucial for the patient as well as the treating clinician to understand the limitations and risks of CAT, and both parties must consent to sharing patient-identifiable information using electronic communications.

- **Direct-to-consumer retail and tiered pricing**

Dental corporations (aligner companies) are increasingly commanding a higher percentage of practice revenue as they insert themselves into the doctor-patient relationship through offering direct-to-consumer services to patients, marketing, corporate referrals and tiered pricing.⁸⁰ Direct-to-consumer marketing and care is done without the supervision of a dentist or orthodontist, based on the claim that the same or similar treatment can be provided for a fraction of the cost and time through teledentistry, despite excluding dental examinations or radiographs.⁸¹ Retail aligner companies omit personal examinations, radiographs, discussions and informed consent. Thus, the fundamental ethical obligations of beneficence, non-maleficence and autonomy are abdicated in retail aligner sales.⁸¹

Dental aligner companies now frequently refer patients directly to select providers through their online portals. However, the relationship between the orthodontic provider and the dental aligner company begins to blur as laboratory cost per case is reduced with increasing number of cases submitted by the clinician.⁸⁰ The ethical question thus arises when the referrers objective is to increase sales of a particular product or aligner, as to who really dictates the choice of treatment and the treatment plan, the provider or the aligner company?

Dental aligner companies also commonly utilise what is known as 'tiered pricing' to subtly influence clinicians to treat more patients with CAT as well as a particular aligner system, irrespective of whether or not it is the best treatment option for the patient.⁸⁰ It is postulated that aligner technology is now being considered as disruptive technology, benefitting dental aligner companies that focus on market share and profits, rather than patient care.⁸⁰

- **What is an acceptable endpoint for completing CAT?**

For patients, dental appearance and functional improvement are expected from orthodontic treatment.⁸² It is suggested that an acceptable end-point of CAT will depend on the complexity of the case, the original objectives, the patients'

expectations, compliance and the clinicians experience.⁷⁶ There should also not be a different standard with respect to CAT than there is for conventional fixed treatment. It should be noted that patient's aesthetic and functional expectations are dynamic as they may change over the course of treatment. Towards the completion of treatment, the treating practitioner will need to closely evaluate the patient to assess how closely the treatment outcome matches the treatment projection, and whether the patients' expectations have been met. While all orthodontic treatment carries risks, some risks may persist upon treatment completion. It is the responsibility of every treating clinician to ensure that the patient has a stable occlusion at the end of treatment, and the retentive means to maintain the result long-term.⁷⁶ Patients need to be made aware that in most cases, retention is long-term, and that slight settling and shifting of teeth or relapse can be expected due to an inherently unstable final occlusion, broken retainers or poor retainer compliance.

Patients may be unhappy with the overall treatment outcome, or occurrence of relapse after treatment, and request refinement, retreatment or referral.⁵ Furthermore, unmet expectations, failure to achieve adequate occlusal contact, or relapse, may carry financial implications for both patient and dentist, and is best understood before treatment commences, rather than when treatment has finished.

It is essential that the period of supervised retention and possible need for an enhanced fixed retention regime be communicated to the patient before treatment. A retainer type which may give rise to future disagreement, is the fixed bonded retainer.⁷⁶ Patients also need to be aware that retainers may need to be replaced in the future, and that they would normally be liable for the cost. A copy of a long-term retainer advice, signed by the patient, is a useful document to protect against dento-legal risk.

- **What to say to patients seeking a second opinion?**

Patients who are unsure or unhappy with how their treatment is progressing may request a second opinion from another dentist or orthodontist. A second opinion is best given by a specialist and should be given in a thoughtful way, factual, and in the patient's best interests, and respect all parties.⁷⁶ Blame is rarely helpful, and it is unethical to criticize another professional deliberately without knowing the background of the specific case.⁷⁶

- **Where is the line between legitimate and unethical advertising/marketing of orthodontic services?**

Commercialism in marketing clear aligner therapy has increased drastically over the past decade because of the elective nature of clear aligner orthodontics, popularized by being 'faster' and more aesthetic than traditional braces. Inappropriate or deceptive advertising / marketing can make

a dental practitioner or orthodontist look more like a business person than a professional service provider.⁸³ Dentists and orthodontists generally advertise their services through their practice website, and more recently through social media. In general, patients as consumers, will base their decision to seek treatment, and where to access their treatment, on perceptions they form from advertising platforms.

Ethical marketing should always follow the principle of veracity, defined as being honest and telling the truth, and is related to the fundamental ethical principle of 'Autonomy'. Advertised information should be current and accurate, while claims should be backed by evidence. Statements likely to create unjustified expectations in the minds of patients should be avoided.⁷⁶ Many patients will understandably find the distinction between a 'specialist dentist' and 'dentist with a special interest in orthodontics' unclear. If this confusion is exploited merely to sell services, a practitioner could leave themselves open to an accusation of unethical conduct.⁷⁶

Unethical marketing is characterised by (i) misleading, deceiving, or influencing people in convincing them to purchase a service, (ii) adopting methods of misrepresentation, defaming, devaluing or degrading to portray supremacy, and (iii) being untruthful or false. Orthodontic practices and dentist's claiming CAT to reduce treatment times are increasingly being advertised and offered to patients.⁷⁶

Currently there is no robust evidence to support the use of CAT based on accomplishing treatment within a 'shorter timeframe'.⁷⁶ Lack of evidence would therefore suggest that it is imprudent for practitioners to promote CAT with such claims. Furthermore, deceptive advertising is a violation of the ethical principle of veracity (truth).⁸⁴ The most efficient method to advertise starts at the patient level through a satisfied patient, also referred to as 'word of mouth'. Patients who are satisfied with their orthodontic treatment will return and also refer their relatives and friends due to a positive experience they have had with a particular practitioner.⁸⁵

Conclusions

Many aligner brands are available today and marketed aggressively to treat everything from mild to more severe malocclusions. However, CAT is still a developing technique because of research and development in materials, manufacturing techniques, auxiliaries, and computer programming of tooth movement to improve the accuracy, effectiveness, predictability and scope of treatment. The harsh reality is that evolving clear aligner technology, commercial interests and aggressive marketing strategies are not going to diminish, but rather increase exponentially together with the increasing demand for CAT.

Delegation of diagnosis and treatment planning to an aligner manufacturer has the potential to invade patient privacy and to compromise the treatment process.

The final treatment decision, clinical outcome and legal authority is the responsibility of the practitioner, and not that of the aligner manufacturer. Clinicians need to consciously balance treatment goals against risk management strategies through developing a strong dentist-patient relationship built on the foundation of ethical principles, professionalism, and backed by knowledge, clinical competence and guided by professional judgement.

Dentists with limited prior orthodontic knowledge and skills may be lured to the attraction of clear aligner systems as an opportunity to augment practice income, but at the same time face an increased likelihood of complaints and claims when the treatment outcome is compromised or patient expectations have not been met. In addition, orthodontic treatment, including CAT is not an exact science. Thus, the clinician and the clear aligner manufacturer cannot make any guarantees or assurances concerning the outcome of treatment.

Practitioners should know and understand what parameters affect treatment difficulty and predictability to ensure a successful treatment outcome, and to manage potential risk. Furthermore, dentists with minimal recognised training in orthodontics and CAT are particularly vulnerable because they are unlikely to have the knowledge and expertise to diagnose complex cases, and to recognise if a treatment plan from the "remote" planner, is over ambitious and not in the patient's best interests. It remains the treating practitioner's responsibility with CAT to achieve an aesthetic and functional result that meets the standard of care and patients' expectations. It is in the patient's, orthodontic profession, and dental professions' best interests that dentists equip themselves with the necessary competence to be able to offer, treatment plan, manage, and monitor CAT safely, efficiently and predictably.

The importance of risk management cannot be overstated. In this regard, the importance of proper case selection, excellent communication and discussion of treatment options, risks and limitations of CAT, consent, regular monitoring, early recognition and anticipation of problems, compliance, and adequate retention cannot be overstated. Practitioners must always follow the dictum of professionalism with the patient's best interests at heart, rather than commercialism.

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