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Review Article

Orthodontic Clear Aligners – A Review

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ABSTRACT:
Rapid advancements in biomaterials and computer-aided design and manufacturing (CAD/CAM) have firmly established clear aligner therapy (CAT) as a cornerstone of orthodontic treatment. This comprehensive review aims to cover the full spectrum of materials and innovations currently utilized in aligner fabrication. It explores historical developments, current fabrication protocols, the features of modern bioactive materials, and emerging trends in CAT. Progress in the chemistry and engineering of aligner materials holds the potential to revolutionize CAT's therapeutic applications. Without such advancements, clear aligners may continue to face limitations in clinical performance due to their inherent biomechanical constraints.In conclusion, advancements in aligner materials, including shape memory polymers, directly 3D-printed clear aligners, and bioactive composites, are vital for expanding the potential of clear aligner therapy (CAT). Equally important, however, is fostering greater environmental awareness among aligner manufacturers, prescribing clinicians, and users to align with climate change goals and promote a sustainable future.
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INTRODUCTION

Orthodontic clear aligners have revolutionized the field of dentistry by offering a discreet, comfortable, and effective alternative to traditional metal braces for teeth straightening. Comprising of a series of custom-made, virtually invisible plastic trays, clear aligners have gained popularity among both teenagers and adults seeking a less conspicuous orthodontic treatment option. Designed to be removable, they facilitate better oral hygiene compared to fixed braces, allowing users to maintain their regular eating habits without fear of breaking brackets or wiring. This innovation not only improves aesthetic appeal by eliminating the metallic smile associated with conventional braces but also underscores the advancements in dental technology aimed at enhancing patient experience and outcomes. As more people prioritize their oral health and aesthetics, clear aligners are becoming an increasingly sought-after solution, promising a seamless blend of function and appearance.[1,2]

Origin and Evolution: In 1945, Harold D. Kesling revolutionized orthodontics with the introduction of rubber-based tooth positioners. These were crafted from detailed wax setups of patients' teeth, allowing for precise adjustments in orthodontically treated cases. Kesling's methods enabled the sequential repositioning of misaligned teeth, laying down foundational principles for modern clear aligner

therapy (CAT). His innovation highlighted the potential of thermoplastic materials for significant orthodontic movements.

Building on Kesling's work, Henry Nahoum in 1964 developed a vacuum-formed appliance that enhanced the fit on a patient's dental cast. Nahoum's technique marked a significant improvement in the precision of orthodontic appliances.

By 1971, Ponitz brought forward the 'Invisible retainer', utilizing a material called Biocryl (polymethyl methacrylate), composed of cellulose acetate butyrate, polyurethane (PU), polyvinyl acetate-polyethylene polymer, polycarbonate-cycolac, and latex. This material offered an aesthetically pleasing and functional orthodontic solution.

In 1985, McNamara advanced Ponitz's methodology using 1 mm thick Biocryl™ polymers and a Biostar vacuum forming machine. This enabled the fabrication of invisible retainers tailored for retention and finer detailing in patients' teeth.

Jack Sheridan, in 1993, further refined the clear appliance fabrication process. He used polypropylene and a 0.030″ thermoplastic copolyester sheet from Raintree Products, coining the term "Essix appliance." This approach combined clear appliances with interproximal teeth reduction, providing an aesthetic alignment method for anterior teeth.

The watershed moment came in 1998 with Align Technology's introduction of Invisalign. Stanford graduates Zia Chishti and Kelsey Wirth developed this groundbreaking system. It featured a series of removable polyurethane aligners, designed digitally using advanced CAD/CAM technology. Invisalign was the first orthodontic appliance to effectively employ transparent thermoplastic polymer materials, marking a significant evolution in orthodontic treatment methods.

GENERATIONS OF CLEAR ALIGNERS

First-generation aligners: The earliest forms of clear aligner systems were solely reliant on the thermoformed plastic aligner material to achieve intended results without any auxiliary elements being incorporated into the aligner system. The material used to fabricate Invisalign aligners before September 2001 was a polymer mixture and the brand name was Proceed30 (PC 30), which failed to meet all the physical, chemical, and clinical requirements for orthodontic tooth movement.[2]

Second-generation aligners: With advances in aligner systems, manufacturers incorporated the use of attachments to provide better control of planned tooth movement. Clinicians could also request for composite buttons to be bonded on the teeth and utilize inter-maxillary elastics. Other features, including SmartForce™ attachments, Power Ridge™, Velocity Optimization, and interproximal reduction (IPR) became universal in the Invisalign system. A single layered polymer material Exceed30 (EX 30), an implantable medical-grade polymer made of polyurethane methylene diphenyl diisocyanate 1.6-hexanediol, tested for safety and biocompatibility by the United States Pharmacopeia, Class IV, was used to fabricate the aligners.[2]

Third-generation aligners: In 2010, the third-generation aligners included SmartForce™ features, such as optimized attachments, designed and placed automatically by commercial software as well as indentations in the polyurethane plastic that placed increased pressure on specified points on the crown to produce a moment of a couple and root torque (Power Ridge).[2]

Fourth-generation aligners: In 2011, G4 attachments were released to facilitate the clinical outcomes in open bite cases with improved optimized extrusion attachments on multiple teeth. New multi-plane movement features were available for upper laterals to enhance extrusion along with rotation and/or crown tipping. Optimized root control attachments were introduced for better mesiodistal root control of canines and central incisors. Since 2013, EX 30 has been replaced by a new multi-layer aromatic thermoplastic polyurethane/co-polyester material, called SmartTrack™ (LD30).[2]

Fifth-generation aligners: In late 2013, fifth-generation enhancement improved the predictability of deep bite correction by introducing pressure areas on the lingual of the upper and lower anterior teeth, precision bite ramps on the lingual of the upper incisors, and bevelled dome-shaped retention attachments on the premolars. However, a recent study by Blundellet al. found that the use of precision bite ramps does not appear to significantly improve the ability of SmartTrack™ material to predictably open the bite compared with EX30 materials.[2]

Sixth-generation aligners: In late 2014, sixth-generation clinical innovation for orthodontic treatment of first premolar extractions was introduced using new SmartStage™ technology and SmartForce™ features to provide vertical control and root parallelism that optimize the progression of tooth movements for extraction treatment planned for maximum anchorage.[2]

Seventh-generation aligners: Invisalign G7, a set of features designed to deliver greater control of tooth movements and improved treatment outcomes was released in 2016, particularly for teenage patients. It aimed to deliver better upper lateral incisor control, and improve root control and features to address the prevention of posterior open bites.[2]

Eighth-generation aligners: Around late 2020, the eighth-generation enhancements were announced aiming to further improve the predictability of deep-

bite correction with SmartForce™ aligner activation for anterior intrusion and improvements in the ClinCheck virtual proprietary software setup to level the Curve of Spee. G8 also minimizes unwanted crown tipping during posterior arch expansion with optimized expansion support and rotation attachments to reduce the potential for buccal crown tipping.[2]

Aligner Fabrication Process: The pioneering methods involving the manual fabrication of clear aligners, are no longer used for commercial aligner fabrication, and the current digital fabrication method employs CAD/CAM technology and digital workflow protocol. A digital image acquisition is obtained via either a direct approach (images from an intraoral scanner) or an indirect approach (high-quality polyvinyl siloxane (PVS) putty impressions that are then digitally scanned), eventually providing a digital representation of the patient's dentition that constitutes the basic framework for virtual planning of tooth movements desired with CAT. Virtual treatment planning and tooth movement manipulations are then performed using CAD platforms. Computer algorithms segment the individual clinical crowns of the digitized 3D model. Additional visualization of the tooth roots is now possible by importing and overlaying computerized tomography (CT) scan data.[5]

The position of teeth is manipulated through sequential movements towards the finally desired positions, resulting in the generation of sequential virtual models with teeth in positions planned for each stage. 3D model printing of each of these virtual setup models generates serial physical models via CAM technology, incorporating either subtractive (milling) or additive manufacturing (3D printing) techniques. Three-dimensional printing is currently the mainstream technology used for orthodontic model fabrication. The corresponding series of clear aligners are then thermoformed on the physical copies and finally trimmed and polished. The process of 3D printing of serial digital models and the thermoforming process itself is time-consuming, labor-intensive, and costly depending on the malocclusion type, aligner changing protocol and the number of refinements.[5]

Commercial Aligner Companies: Align Technology is the pioneering parent company of Invisalign that offers commercially produced clear aligners. The interactive software for tooth movement planning is known as ClinCheck. Invisalign provides a clinical guide on the complexity of malocclusion that governs the choice of the different delivery packages based on the number of aligners that are predicted by the ClinCheck software that simulates the CAT outcomes. The packages comprise Express, Lite, Moderate, and Comprehensive, with an increasing number of aligners for each respective package to treat the increasing complexity of the malocclusion. Besides Align Technology, other recent commercial companies that produce clear aligners include Henry Schein (Reveal), Straumann (Clear Correct), Angel Align, Ormco (Spark), and Smartee, to name a few. Each company has its proprietary interactive tooth movement planning software for communication between the clinician and the technician, assisting with the tooth movement planning process. Many companies incorporate clinical teeth that allow for the integration of 3D CBCT data into the crowns of the teeth. These revolutionary changes now mean that a true 3D virtual patient may be acquired for diagnosis, treatment planning, and appliance fabrication.[1]

Biomechanics of Aligner Treatment: Understanding the mechanics of tooth movement using aligners could lead to the more appropriate selection of patients and more accurate treatment sequencing, leading to better results. Tooth movement mechanism with clear aligners can be explained from two different perspectives: the displacement driven system and the force driven system. The displacement driven system mainly controls simple movements such as tipping or minor rotations. Aligners are formed according to the position of the tooth in the next staged location and the tooth continues to move until it lines up with the aligner. This system is known to be less effective in controlling tooth movement and is insufficient in producing root movements. The force driven system, however, requires biomechanical principles to facilitate tooth movement. Aligners are designed to apply desired forces on the tooth. The shape of aligners to produce such forces is not necessarily the same as the shape of the tooth. The movement required for each individual tooth, mechanical principles to accomplish this movement, and the aligner shape are determined via Clincheck® (Align Technology, Santa Clara, CA, USA) software.[5] The aligner shape is altered via pressure points or power ridges in order to apply the desired forces. Pressure points lead to more difficult uprighting and intrusion movements, whereas power ridges control axial root movements and torque. Despite the alterations in the shape of the aligner, movements such as root paralleling, extrusion, and rotation were still difficult to obtain using aligners until Align Tech. (Align Technology, Santa Clara, CA, USA) introduced smart force attachments for the Invisalign® system. These attachments are small composite bulges designed to produce a force system favorable for the designed movement. Their position and shape are determined via Clincheck® software according to the movement to be obtained. Extrusion attachment, rotation attachment, and root control attachments are currently used. Extrusion of a single tooth is moderately difficult using clear aligners when compared to fixed-appliance systems, however, some auxiliaries such as buttons and elastics can be used to facilitate this movement. Also, the extrusion of a group of teeth (i.e., maxillary incisors) can be

performed using aligners. The use of temporary anchorage devices in combination with clear aligners further widened the range of treatments possible with aligners.[5]

Golden Rules of Invisalign Bio-Mechanics: Willy Dayan gave golden rules of Invisalign bio-mechanics to approach treatment planning with clear aligners.

1. **Think like Plastic and Feel like a Tooth:** Invisalign is a removable appliance and thus cannot be glued to teeth to "pull" them; the aligner can only "push" on surfaces of the teeth or surfaces of attachments. When a force is placed upon a tooth, it will move according to the biomechanical principles that exist, no matter what the computer screen shows.[6]
2. **The ClinCheck Video is not Teeth Moving:** The software that shows the virtual arrangement of teeth is not the actual movement of teeth. Think of the images as representing the anatomy of the "changing inner aligner surfaces", and then analyze the resulting forces the aligner will exert upon the teeth.[6]

Effects Of Clear Aligners on Periodontal Status and Oral Health: As the number of adults treated with clear aligners increased, the periodontal effects of this treatment were found to be negative in the literature. Use of clear aligners facilitates oral hygiene, thus improving the periodontal status and causing a decrease in plaque levels, gingival inflammation, bleeding upon probing, and pocket depth. Fixed appliances and wires made plaque control difficult and had adverse effects on periodontal tissues, making orthodontic treatment a predisposing factor for periodontal diseases. However, according to the study of Han, with careful oral hygiene education and repeated plaque control, patients treated with fixed appliances and clear aligners showed similar gingival and plaque index. Clear aligners not only promote better oral hygiene, and better periodontal health but also reduce the plaque accumulation and the development of white spot lesions. According to the study of Azeem, orthodontic treatment with clear aligners showed a low incidence of newly developed WSL's.[7]

Efficacy and Efficiency of Clear Aligners: As the demand and interest toward the clear aligner system continue to grow, questions regarding the efficacy of the system remain. To date, published data include little clinical research on the effectiveness and efficacy of clear aligners. Previous literature primarily includes case reports or descriptions of the product, making it difficult to objectively characterize the efficacy of clear aligner systems.[5]

Post Orthodontic Treatment Stability of Clear Aligners: As in all types of orthodontic treatment, stability is one of the most important issues to discuss regarding clear aligners. One study investigated the post-retention stability outcomes of cases treated with clear aligners and fixed orthodontic appliances using the American Board of Orthodontics objective grading system. Retention protocol included only the use of removable thermoplastic Essix retainers and no fixed retainers were applied. Three years following the retention phase, relapse was seen in both groups in terms of total alignment, however, maxillary anterior leveling seemed to be stable in the fixed appliances group but relapsed in the Invisalign group. This data can only provide a preliminary insight for post-retention outcomes of clear aligners and the results cannot be generalized since only removable retention appliances were used and the researchers relied heavily on patient cooperation.[8]

Root Resorption and Clear Aligners: Root resorption is one of the chief problems of orthodontic treatment and it is known that fixed orthodontic appliances can give rise to root resorption, generating excessive pressure at the apical level and causing external apical root resorption. However, few studies have assessed root resorption caused by thermoplastic aligners. A systematic review conducted in 2017 that could include only three studies concluded that aligners could also causeroot resorption at the end of orthodontic treatment; however, the incidence and severity are lower as compared to fixed appliances. Another study stated that the incidence of root resorption caused by aligners is similar to the resorption caused by light orthodontic forces. According to the study by Gay, 41.81% of teeth showed signs of apical root resorption after clear aligner treatment, with upper and lower incisors being the most affected teeth. This situation is explained by the root structure and the great extent of movement shown by the incisors.[8]

Indications for Aligner Therapy

Simple Case Scenarios

1. Cases suitable for treatment include but are not limited to:
2. Adult patients with sufficient clinical crown height and minor diastema closure (<4mm).
3. Mildly crowded dental arches (<4mm).
4. Treatment of 2-4mm buccal expansion.
5. Treatment involving rotation of incisors with sufficient space.
6. Cases where extraction of mandibular incisors relieves crowding or mild crossbite of individual teeth.
7. Mild dental crossbite cases.
8. Cases of mild overbite without the need for extractions.
9. Deep overbite cases.[9]

Complex Case Scenarios

1. Root-controlled tooth movement (>2mm).

2. Moderate to severe dental arch crowding (>5mm).
3. Treatment with posterior distalization exceeding 4mm.
4. Treatment requiring intermaxillary traction.
5. Cases with poor periodontal conditions, accompanied by moderate to severe periodontal disease.
6. Adolescent cases with sufficient eruption height of dental crowns but poor compliance.
7. Cases of mild anterior open bite requiring anterior tooth retraction without extractions.
8. Cases of moderate anterior open bite requiring anterior tooth retraction with extractions.
9. Deep overbite cases.
10. Multidisciplinary treatment.
11. Individual posterior extrusion.[9,10]

Contraindications for Aligner Therapy

Conditions that can be difficult to treat with orthodontic clear aligners altogether are as follows.

1. Cases of crowding and spacing where the discrepancy is over 5 mm.
2. Skeletal anterior-posterior discrepancies of more than 2 mm (as measured by discrepancies in cuspid relationships).
3. Discrepancies of centric-relation and centric-occlusion.
4. Cases where rotation of teeth is severe (more than 20 degrees). • Open bites cases (both anterior and posterior) that need to be closed.
5. Cases where teeth need to be extruded.
6. Cases where there is severe tipping of teeth. (More than 45 degrees).
7. Teeth where clinical crown length is short.
8. Arches where in multiple teeth are missing.[9]

CONCLUSION

Clear aligner treatments provide significant benefits such as improved aesthetics, better oral hygiene, and reduced chair time, making them an excellent alternative for orthodontic care. Recent advancements in techniques and technology have addressed many of the initial limitations of this approach. Today, several companies have developed clear aligner systems.

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