Review Article

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Contemporary Clear Aligner Therapy: A review

Abstract:
Clear Aligner Therapy (CAT) has revolutionized orthodontic speciality by providing an esthetic and comfortable treatment option to patients of all age groups. Though the notion of aligner therapy came as early as 1940s, rapid technological advancements in 3 Dimensional (3D) printing, computer-aided design (CAD) and manufacturing (CAM) and material advancements over the past two decades has increased the scalability and access to patients making it a popular treatment choice. Aligners consist of a series of custom-made clear plastic trays each worn for a period of 1-2 weeks to bring about necessary tooth movements to correct malocclusion. Various attachments and auxiliaries are employed to exert the desired forces and enhance specific tooth movements or to aid in retention of aligner. Inspite of numerous different aligner brands upcoming in this field, proper patient selection, treatment planning, patient compliance, material used and its manufacturing method and clinician experience remain the mainstay of treatment outcome. This review paper comprehensively explores the origin, types of clear aligners, different materials available along with their properties and behavior in oral environment, clear aligner biomechanics, advantages,clinical effectiveness and latest advancements to provide an understanding of role of CAT in modern orthodontic practice and its future directions.

Key-words: Clear Aligner Therapy (CAT), invisalign, biomechanics, 3D printing, polymers, biocompatibility

Introduction:

Clear aligner therapy (CAT) is emerging as a modern orthodontic treatment option for adults seeking more esthetic and comfortable alternative to conventional fixed appliance.[1] Easier hygiene maintenance, superior esthetics, less discomfort, better quality of life are some of the claimed advantages of CAT.[2]

The incorporation of digital technology has revolutionized the practice and appliances used in orthodontics.[3] Aligners are manufactured by 3D printing, also known as additive manufacturing which can be further classified into different methods, i.e. Fused Deposition Modeling (FDM), Selective Laser Sintering/Melting (SLS/SLM), Vat-Photopolymerisation (VP). Based on employed light source and pattern, VP can be further categorised into techniques such as stereo lithography (SLA), Liquid Crystal Display (LCD) and Digital Light Processing (DLP).[4]Besides these, direct 3D printed aligners are becoming popular nowadays like Dental Long Term Resin (LT), [5]TC-85 (Graphy, Seoul Republic of Korea),[6,7] claiming to be requiring less time and effort and with fewer geometric inaccuracies.[5]

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Despite of all technological advancements, patient compliance, proper case selection, careful selection of aligner material, use of attachments and power ridges to improve biomechanics play key role in the success of aligner therapy.[4,8]

History:

The notion of progressive repositioning of malaligned teeth using "Flexible tooth positioners" was brought in 1945 by H. D. Kesling.[9] In 1971, Ponitz proposed a vacuum-formed clear plastic appliance "invisible retainer" to be used for

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finishing and retention of orthodontic cases.[10]Similar more refined techniques were developed by Nahoum,[11] Mc Namara,[12] and Sheridan.[13]

The idea of introducing contemporary CAD/CAM based clear aligner system was first conceived by Zia Chishti and Kesley Wirth (MBA Students from Stanford University). They along with two orthodontists founded Align Technologiy in 1997 in a garage in Palo Alto. Invisalign was introduced by Align technology in 1999.[14] It consists of a series of custom made clear thermoplastic aligners that are worn for 1-2 weeks each to bring about 0.25-0.3 mm of orthodontic tooth movement. Invisalign has rapidly evolved with the introduction of improved technologies, namely Smartforce features (optimised attachments, customised staging) and Smarttrack multilayered aligner material.[2]

Currently, many companies are providing clear aligner solutions like Clear Correct (Institute Straumann AG, Switzerland), Reveal (Henry Schein, NY), SureSmile (Dentsply Sirona, Penn), Clarity Aligner Flex (3M, 3MESPE, Minn), Spark (Ormco Corp, Calif).[2]

Types of Clear Aligners

Aligners can be categorised into 4 basic categories:[15]

1. Positioners and Guides eg. Orthodontic Positioner (TP Orthodontics Inc), Myobrace
2. Activation Aligners and Appliances eg. Essix Retainers, Spring Aligners
3. Teeth manually set - Aligners made from models that have had teeth cut out and manually moved to correct position. They can be used for minor tooth movements using 3-5 aligners eg. Triple Play (Ortho Organizers)
4. Teeth digitally set - Aligners fabricated from digitally manipulated models to treat malocclusions ranging from minor to complex eg. Invisalign, Clear Correct

Clear Aligner Materials:

Mechanical properties of materials used for clear aligner fabrication affects the force exerted by it. [16]The material used in turn is influenced by the manufacturing process employed which can be categorised into : conventional vaccum thermoforming on physical models or direct 3D printing without intermediary physical models.[17,18]

The desirable properties of orthodontic force are large springback, low stiffness, good formability, high stored energy, biocompatibility and environmental stability.[19]Clear aligner materials have evolved from single-layered or monophasic plastic to second-generation polyurethane materials, to the currently used third generation multilayered materials that often comprise of hard and soft layers.[7]

Common categories of materials employed for aligner fabrication are thermoplastic materials/polymers, polymer blends and 3D printed materials.[18]

Commonly used polymers are polyesters, polyurethane, polypropylene, polycarbonate, polyvinylchloride.[16,20] Among polyesters, polyethylene terephthalate (PET) and polyethylene terephthalate glycol (PET-G), a non-crystallizing amorphous copolymer of PET are widely used as clear aligner materials due to their excellent mechanical and optical properties.[21] Thermoplastic polyurethane (TPU) is a versatile polymer with excellent mechanical and elastomeric characteristics, abrasion resistance and adhesion properties.[22] Blending of different types of polymers such as polyester, polyurethane and polypropylene has been shown to improve chemical and mechanical properties of aligners.[16,23]

Various materials that can be used in orthodontics for direct 3D printing are stereolithography materials (Epoxy resins), polylactic acid, polyamide (Nylon), glass filled polyamide, polycarbonate etc.[24]Tera Harz TC-85 is a photopolymer material introduced by Graphy (South Korea) for direct 3D printing.

Properties of Clear Aligner Materials

Mechanical Properties

Material selection, aligner thickness, force delivery, stress relaxation are the factors to be considered for proper treatment through aligners.[4]

1. Resiliency and Force Delivery - An ideal aligner material should ideally possess adequate stiffness to exert the required orthodontic force.[7] Aligners absorb less energy since they deform permanently under moderate to heavy loads and have less resiliency compared to metal archwires.[25,26] Predictability of bodily movement in CAT is limited as stresses are dispersed over a broader contact area.[27] Aligners move teeth through pushing with better intrusion than extrusion and involves crown tipping, while rooth torquing is less predictable.[28] Variation in aligner thickness affects the force magnitude with thicker aligners delivering notably higher forces than thinner ones.[27]
2. Viscoelasticity and stress relaxation - Viscoelasticity is an important property as it determines the aligner's ability to absorb shocks, vibrational forces and this allows the

aligner to deform and stretch and generate forces onto the teeth.[28]The little energy that aligner absorbs, is mostly dissipated as heat with a relatively small amount transferred to dentition.[28] The deflection of viscoelastic materials increases over time when subjected to constant loads, whereas constant deflection occurs if the load decreases, this phenomenon is called as "Stress-relaxation",i.e. time-dependant decrease in stress under constant strain conditions. This stress-relaxation is affected by the composition of thermoplastic material, thickness of material, temperature of oral cavity and the forces applied on aligner.[29]

No	Clear Aligner Brand Name	Commercial Manufacturer	Aligner Material Composition	Aligner Material Thickness	Aligner Material Properties and Commercial Claims	Associated Software
1.	Invisalign https://www.aligntech.com/solutions	Align Technology Inc, San Jose, USA	SmartTrack™ Material: LD30 A multi-layer aromatic thermoplastic polyurethane from methylene diphenyl diisocyanate and 1,6-hexanediol plus additives	Aligner thickness stated by the manufacturer after thermoforming is 0.75 mm.	SmartTrack™ material: applies gentle, constant force to improve control of tooth movement Comfortable and fits snugly around the teeth In comparison to EX30 used previously, LD30 exhibits a more amorphous structure and a greater elastic recovery SmartForce™: customized attachments, bite ramps and power ridges SmartStage™ technology: programs sequential tooth movement to straighten teeth more predictably	ClinCheck Global cloud-based treatment visualization
2.	Clarity https://www.3m.com/3M/en_US/orthodontics-us/featured-products/clarity-eos/clear-aligners/	3 M ESPE Maplewood, USA	3 M™ Clarity™ Aligners Flex Flexible 5-layer material 3 M™ Clarity™ Aligners Force: Rigid material Proprietary 5-layer copolymer blend	Flex: 0.625 mm Force: 0.75 mm	Clarity Aligners Flex indicated a wire-sequencing approach Recommended for correction of rotation and proclination, when used in two-material Clarity Aligners Force indicated for a segmental mechanical approach Recommended for expansion, torque, sequential bodily movement, and segmental intrusion, when used in two-material treatment designs Outer layers resist staining and scratching, inner layers provide flexibility and resilience Overall structure provides durability even with reduced thickness	Tx Design (TxD) Oral Care portal
3.	Clear Correct https://www.straumann.com/clearcorrect/en/patients/about-the-aligners.html	Institut Straumann AG, Basel, Switzerland	ClearQuartz Material: Zendura Polyurethane Tri-layer proprietary material	0.75 mm	ClearQuartz material features an elastomeric layer between two resilient, low-porosity shells The outer layers allow the aligner to be tough and stain-resistant owing to its low porosity The shells also help grip the teeth firmly The inner layer is engineered to provide consistent and continual force due to its enhanced elasticity and enhances patient comfort ClearQuartz retains 10x more of its initial force than other aligners and retains its shape throughout the wear time of the aligner	Clear Pilot ClearComm portal
4.	Spark https://ormco.com/spark/	Ormco Corporation, Brea, USA	TruGEN™ and TruGEN XR Material:	0.75 mm	More sustained force retention Better surface contact area with the tooth More efficient and effective tooth movement Clearer, more comfortable and stains less	Approver
5.	SureSmile https://www.dentsplysirona.com/en-us/categories/orthodontics/suresmile-aligner.html	Dentsply Sirona, York, USA	Essix Plastics: Plus, C plus Polypropylene/ethylene copolymer (>95%), stabilizers (<5%)	Plus: 0.035 and 0.040 C plus: 0.040 inches/1 mm	Essix Plus Plastic combines clarity with durability It is effortlessly removed from models and trims with ease Essix C plus: When making retainers and aligners for bruxers, a more flexible plastic provides additional strength to help withstand mastication pressure	SureSmile Aligner
6.	Argen Clear Aligners https://argen.com-clear-aligners	Argen Corporation, San Diego, USA	Argen Clear Aligners are made from premium thermoformed plastic material consisting of elastomeric layer encased in a dual shell construction	Unspecified	Engineered for a precise fit, ongoing force retention, and exceptional durability Premium Material – a continual force for faster treatment and greater comfort for patients Improved Stain Resistance – starts clear, stays clear The consistent pressure produced by the dual-shell construction accurately moves teeth over the prescribed period of time	Unspecified
7.	Reveal https://www.henryschein.com/us-en/dental/supplies/reveal.aspx	Henry Schein, Melville, USA	Proprietary ClearWear™ material	Unspecified	Provides ultimate in aesthetics with precise force levels for speed of treatment Superior clarity compared to other aligners Guaranteed not to stain or cloud Zero to minimal unsightly attachments	DDX SLX Approver portal
8.	Nuvola https://www.nuvolaworld.com/nuvola-clear-aligners	GEO Srl Rome, Italy	Polyethylene terephthalate glycol (PET-G)	0.75 mm	Tough and elastic Resistant to the aggressive chemical agent Proof against wear and tear Precisely designed to fit firmly Easy to wear and maintain Fidelity to their original conformation Long-lasting transparency and hygiene	Unspecified
9.	F22 https://www.f22aligner.com/en/	Sweden and Martina Company, Padua, Italy	F22 Polyurethane: Evoflex:	0.75 mm	An innovative polymer that ensures up to 17% greater transparency than other aligners on the market	Unspecified

Table 1. Commercially available Aligner brands and their materials, properties and software

Thermal Properties:

Temperature can have a significant impact on polymers, especially if their glass transition temperature is low.[30] Hence it is critical to consider the glass transition temperature while selecting aligner material as exposure to humid environments may deteriorate the mechanical properties of the aligner.

Optical Properties and Color Stability:

Transparency of a clear aligner dictates its esthetics. Ideally, the material used should be able to transmit at least 80% of visible light and it should remain consistent for one to two weeeks of intraoral useage.[31] However, consumption of colored beverages, exposure to ultraviolet radiation and use of mouthwashes affect the transparency and color stability of aligners.[32] Polyurethane is more susceptible to pigment adsorption and provides less than optimal color stability as compared to polycarboxylate and PET-G materials.[33,34]

Biocompatibility and Cytotoxicity:

Biocompatibility of aligner material implies that it should not leach out any potential toxins producing local or systemic adverse reactions, not be carcinogenic in nature and not produce any developmental defects.[35]

The types of biocompatibility tests to ensure the safety of aligners as a surface contacting medical device are explained in ISO 10993-01[36] and ISO 7405.[37] Generally, it includes cytotoxicity, active toxicity, irritation, sensitisation and genotoxicity. Scarcity of literature and flooding of market with newer aligner companies necessiates the rigorous testing regimen for cytotoxicity assessment.[7]

Eliades et al[38] evaluated the potential release of Bisphenol-A (BPA) for thermoplastic material used for Invisalign aligners and demonstrated the non-existence of any estrogenic and toxic effect of aligner material on Human Gingival Fibroblasts (HGFs).

The degree of polymerisation during the curing process affects the residual monomer content,[39]which may release toxic monomers or dangerous materials. So thorough washing and meticulous post curing processes are imperative to ensure biocompatibility.[40]

Advantages of CAT:

- Customised, esthetic treatment option.
- More comfortable and removable allowing patient to maintain good oral hygiene.
- Minimal impact on lifestyle.
- Low constant gentle force.
- Multiple tooth movements can take place simultaneously.
- Less chairside time and fewer emergencies for the clinician.

Figure 1. 3D printed clear aligner

Biomechanics of CAT:

The biomechanics of clear aligner involves the use of custom made aligners that are specifically shaped to guide teeth into desired positions.[8]

Tooth movement mechanics with aligners involves mainly 2 systems:[41,42]

1. **Displacement driven system -** Controls simple movements like tipping and minor rotations. Aligners are formed according to next stage position of tooth and tooth coninues to move till it lines up with the aligners. This method is less effective with no root movement.
2. **Force driven system -** The movement required for each tooth, mechanical principles needed to achieve that movement and aligner shape are determined via Clincheck software (Align Technology). Pressure points, power ridges and attachments are used to accomplish the required movements.

The movement with aligners is brought about by 2 primary mechanisms :[28]

1. **Shape molding effect -** It refers to molding the movement of target teeth to complement the shape of aligner being used. Pre-established mismatches (activation) between aligner shape andteeth surfaces generate 3 dimensional (3D) force systems distributed all over the contact surfaces. So, multiple aligners with sequentiually varying shapes, from initial anatomic geometry to final intended tooth positions complete the treatment.
2. **Auxiliary elements -** Various auxiliaries like attachments of different shapes and power ridges are often used to enhance or assist a specific tooth movement and to enhance aligner retention.

Figure 2. Various attachments on tooth surfaces

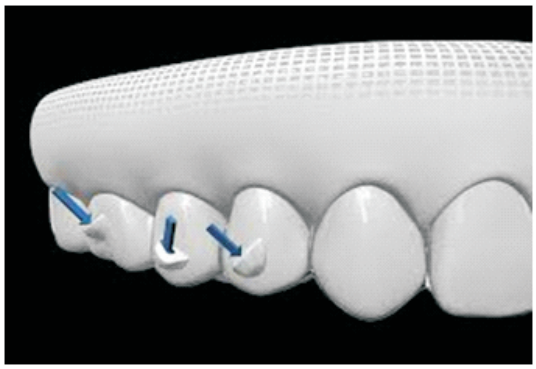

Figure 3. Force directed perpendicular to attachments for effective tooth

Clinical Effectiveness of Aligners

In a study of Djeu et al,[43] ABO objective grading system was used to assess treatment outcome of Invisalign and traditional fixed braces and it was concluded that Invisalign was deficient in its ability to correct large anteroposterior discrepancies and occlusal contacts but both systems are equally efficient in space closure, marginal ridge alignment and correction of anterior rotations.

In a systematic review by Rossini et al,[44] it was concluded that CAT is effective in controlling anterior intrusion but extrusion was the most difficult movement to control, followed by rotation. It is effective in controlling posterior buccolingual inclination and upper molar bodily movments but not anterior buccolingual inclinations.

Kravitz et al[45] evaluated the efficacy of tooth movement with Invisalign and reported a mean accuracy of 41% predicted tooth movement. The most effective tooth movement was lingual constriction (47%) and extrusion was the least accurate movement (29.6%), followed by mesio-distal tipping of mandibular canines (26.9%).

An evaluation of integrated 3D digital models showed tipping of crowns to be the most predictable tooth movement and root torquing the least predictable.[46]

On an average, CAT is successful for mild to moderate tooth movements, but this can vary based on individual case.

Latest Advancements

4D Technology - K Line Europe featured 4D technology in their ClearX Aligners. This approach reduces plastic waste by up to 50%.The ClearX Classic package includes a non-electric booster the patient uses to move the aligner into the next stage of teeth movement. Patients place the ClearX aligner they have been wearing into a small container—the booster— and fill it with boiling water. The water activates the 10-minute shape-shifting process. Once completed, the patient puts the aligner back in their mouth and wears it for the second stage of teeth movement. ClearX Classic also features an optional mobile app that provides patients notifications when it is time to boost and change to the next aligner.

Integration of CBCT in treatment planning - Various companies like Invisalign and Henry Schein Orthodontics and softwares like Maestro 7.0, OnyxCeph, ClinCheck, Deltaface are utilizing CBCT for true root visibility and improved treatment predictability.

SmartT rack Technology - Continuing the pursuit of improvement, Invisalign incorporated SmartTrack technology into its aligners. This proprietary material ensures a more precise and comfortable fit, enhancing the overall effectiveness of the treatment. Smart Track technology enables better control over tooth movements, reducing treatment duration and improving patient comfort.

Direct 3D printed aligners - To overcome the limitations of the conventional vacuum thermoforming manufacturing process, the method of direct 3D printing of aligners has been developed. This presents more advantages than simply avoiding a two-step process, whereby the model needs to be printed first before aligners are thermoformed. The direct printing process using shape memory plastic (TC-85, Graphy, Seoul, South Korea) offers new and improved biomechanical options.[47]Shape memory aligners can apply constant orthodontic force to the teeth at normal body temperature without force decay caused by aligner deformation. Layer thickness can be modified depending on the force required on each individual tooth and greater tooth movement is possible per step.

AI-Driven Treatment Planning - One of the most anticipated innovations in clear aligner technology is the integration of Artificial Intelligence (AI) in treatment planning. AI algorithms are being developed to analyze dental scans with unprecedented precision, enabling more accurate predictions of tooth movement and treatment outcomes. This

technology promises to personalize treatment plans to an even greater extent, taking into account the unique dental structure and alignment goals of each patient.

Adjuncts with CAT - Variouscreative and customized adjuncts are being used recently to improve the predictability of CAT. The bootstrap, mini pin-supported mesialization or distalization, YinYang attachments, Beneslider, Mesialslider, BMX Expander, and Computer-Aided Design (CAD) / Computer-Aided-Manufacturing (CAM)–based innovative appliance designs among others, are being used either concomitantly with the aligners or planned as a separate phase of treatment before the commencement of the actual CAT, based on the type of tooth movement required and whether the planned tooth movement is indicated for a single tooth or a group of teeth. [49].

Integration af aligners with orthognathic surgeries - Surgery-first approaches and clear aligner technology are becoming popular therapies in the orthodontic armamentarium. All these technological advances have been successfully incorporated with modifications such as the use ofclear aligner orthognathic splints (CAOS)in combination with custom maxillary fixation plates for surgery-first and surgery-only patients.[48]

OrthoAligner "NAM" - Presurgical infant orthopedics (PSIO) is done to reduce the size of the cleft defect along with improving the arch alignment and nasolabial aesthetics in patients with cleft lip and palate. Compass 3D (Belo Horizonte, Brazil) developed the OrthoAligner NAM system with 3-dimensional (3-D) diagnosis, treatment planning, and 3-D Printing services,. The use of an intraoral scanner for recording details in patients with cleft lip and palate has been shown to be less hazardous. The use of clear aligners also simplify the molding process as the lab procedures (addition of soft liner, selective trimming) involved in the Grayson technique are eliminated; this makes the overall process more convenient for the patient and the caregiver as multiple visits for lab adjustments are eliminated. Additionally, the complications of an acrylic plate like pressure ulcers, laceration, and so on are also eliminated; thereby making the process more comfortable for patients.[50]

Conclusion:

Clear aligner therapy is one of the modern orthodontic treatment option which is becoming popular recently due to its virtual invisible appearance, comfort and convenience.

Aligners can be used for mild to moderate cases with predictable success but complex cases requiring root control are difficult to treat due to inherent material properties and biomechanics of aligners. Among the various factors that determine the predictability of treatment success, proper case selection, patient compliance, material used and fabrication process, possibility of using attachments and auxiliaries, gingival margin design, clinician experience all play important role. Continued advancements in technology and research on biomaterials and biomechanics of aligners hold promise for their bright future ahead. Further robust clinical studies to evaluate different aligner brands, materials used and their efficacy would be required to provide more comprehensive clear orthodontic solutions to the patients, along with long term stability of results.

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