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PROPERTIES OF CLEAR ALIGNER MATERIALS- A REVIEW

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ABSTRACT-
The aligner market has experienced significant growth due to the increasing demand for aesthetic orthodontics. Clear aligners(CA) are removable, can gradually move teeth into their predetermined positions, and are custom-made based on patient-specific malocclusion configurations, providing additional benefits. However, it is important to note that not all aligners are created equal, as the ones currently available vary in construction materials, thickness, and clinical protocols.
The efficiency of CA can be influenced by multiple factors. Aligners are dental appliances that are worn for 22 hours a day, fitting over the teeth and the edge of the gums. Throughout the treatment period, new aligners are provided on a regular basis until the end of the therapy, which can take anywhere from 6 months to 2 years. It is important to note that the oral environment may change during treatment, which can affect the plastic materials used in the aligners.
The transparent thermoplastic materials(TM) used to create CA for orthodontic therapy have the required mechanical, chemical, and physical properties. The mechanical properties of the polymers used significantly affect the efficacy of the treatment. The ideal polymers for aligners exhibit low stiffness, excellent deformability, dimensional and environmental stability, and great biocompatibility. This comprehensive study aims to cover the various materials used in the production of CA and to explain the critical qualities of these materials that contribute to their effectiveness in an oral environment.
Keywords- Thermoplastic materials (TM), Mechanical properties, CA, Cytotoxicity

INTRODUCTION

The CA market has experienced significant growth due to the increasing demand for aesthetic orthodontics. Compared to traditional methods, CA offer better dental hygiene, improved comfort, and periodontal health, as well as fewer clinical visits, orthodontic emergencies, and enhanced aesthetics.[1]

During the treatment, patients are required to wear removable plastic trays, which are known as CA, for approximately 22 hours a day, for a period of 10 to 14 days. Each aligner can be removed only during eating and brushing teeth. The teeth experience a series of forces that move them into their correct position.[2] The materials used in the production of CA play a crucial role in evaluating properties.[3] This analysis aims to provide a comprehensive overview of the materials and their qualities utilized in the production of CA.

- **Materials used for clear aligners**

Clinical effectiveness of CA are influenced by the materials used to produce them. The manufacturing procedure determines the kind of material used to create the aligners. Aligners can be manufactured by directly 3D printing the material without the necessity of physical models.(Tartaglia et. al., 2021)[4]

At present, only thermoformed aligners are commercialized and used in clinical settings due to the lack of an approved photo polymerizable resin suitable for direct printing (Tartaglia et. al., 2021).[4] Summerization of all types of aligner material is given in figure 1.

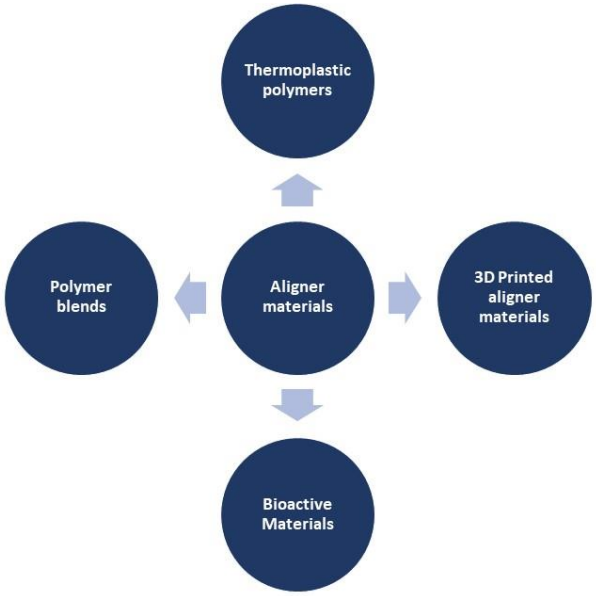

Fig 1: Schematic representation of Types of Aligner Materials

Thermoplastic polymers

Thermoplastic polymers are divided into two categories based on their molecular structure: amorphous or semi crystalline. Amorphous polymers have low molecular packing and asymmetric molecule structures, while semi crystalline polymers have both amorphous regions and crystalline domains. These crystalline domains act as fillers that give composite materials rigidity and hardness. Amorphous polymers tend to be more impact resistant, translucent,

softer, and shrink less. Conversely, semi crystalline polymers are rigid, opaque or translucent, have a sharp melting point, and exhibit strong chemical resistance. [5,6]

Polypropylene and polyester polyurethane are commonly used polymers in transparent orthodontic aligners.[7,6] Polyesters such as polyethylene terephthalate (PET) and its copolymer PET-G, which is non-crystallising, are commonly used to create clear aligners due to their exceptional mechanical and optical properties.

Because of its durability, hardness, and transparency, polycarbonate (PC) is also used (Zhang et. al., 2011).[7] Thermoplastic polyurethane (TPU) is a very adaptable material with a number of advantageous features, including superior mechanical and elastomeric properties, adhesive properties and resistance to chemicals and abrasion.[8,7]

Invisalign aligners were originally made from a single layer of polyurethane(PU) called Exceed-30. However, a new polymer called Smart Track, which is a multilayer aromatic thermoplastic polyurethane/ copolyester, replaced EX30 in 2013.[9,10] According to the manufacturer, this novel polymer is expected to enhance the elasticity and generate more consistent forces in the aligners, thereby refining their clinical effectiveness.[11,6] Amorphous materials such as PC and PET-G are also used to make aligners.[12]

Polymer blends

To achieve the desired movement of teeth, clear aligners need to apply regulated and constant forces. A mixture of different polymers such as polyester, polyurethane, and polypropylene can be used to increase the mechanical properties of the polymer. In fact, the commercial production of clear aligners commonly utilizes polymer blends that include these three polymers.[6,7] Through studies on thermoplastic polymer blending, it has been found that the mechanical and chemical properties of these polymer blends are improved. This ultimately enhances the clinical performance of clear aligners.

The proportion of polymers used in a blend significantly impacts its characteristics. Such as, coupling of PET-G/ PC/TPU showed better mechanical properties and demonstrated orthodontic forces that were both sufficient and sustainable compared to other commercial products.[7] Similarly, PET-G/PC2858 blend ratio of 70/30 showed the optimum tensile strength, impact strength, and elongation at break.[13]

3D printed aligner materials

Direct 3D printing provides greater accuracy and precision in shape, better fitting, higher effectiveness, mechanical durability, and reproducibility. Orthodontics employs various materials for 3D printing, including epoxy resins, polylactic acid, polyamide, glassfilled polyamide, silver, steel, titanium, photopolymers, wax, and PC.[14]

There have been numerous investigations regarding characteristics of resins appropriate for 3D printing CA.[15,16]

Bioactive materials used with clear aligners

Research has shown that during orthodontic therapy, there are significantly increased levels of intraoral pathogens such as mutant strains of Streptococcus and Porphyromonas gingivalis, indicating that microbial accumulation is a prevalent issue. There have been many efforts to improve the ability of orthodontic equipment to fight against microbes.

Recently, there has been a lot of research into using nano antibacterial materials in orthodontics.[17] CA therapy is often suggested as a more hygienic alternative to traditional braces because they can promote better oral hygiene. However, patients who wear aligners for around 20-22 hours a day, with a brief break for eating and cleaning, may be at an increased risk of bacterial growth. This can lead to damage to the teeth and surrounding periodontal tissues.

PROPERTIES OF ALIGNER MATERIAL

Various properties like optical, chemical resistance, biological, thermal and mechanical properties of aligners will be discussed below(Table 1)

Properties of aligner materials	**Optical properties**
	Chemical resistance properties
	Biological properties
	Thermal properties
	Mechanical properties

I. Optical properties

For the best clarity, aligner materials should have strong light transmittance—ideally, at least 80% of visible light should be transmitted. Due to their high translucency, amorphous thermoplastic polymers are chosen over crystalline polymers, which are unsightly and extremely opaque, as clear aligner materials. Several polymers, including polyester, polyvinyl chloride, polysulfone, PC, and PU, exhibit optical characteristics that make them suitable for use in the production of commercial aligners.[18]

The growing popularity of transparent orthodontic appliances has been largely driven by their aesthetic appeal. Prior to changing an aligner, its transparency should ideally last for one to two weeks of intraoral use.[18] However, it is important to note that the regular use of mouthwashs, drinking of colored beverages, and exposure to UV radiation can all affect the transparency and color stability of CA.[19]

Several types of CA materials have been evaluated in studies to determine how well they maintain their color and translucency when subjected to coloring substances.[18,20] The studies

found that, with the exception of SmartTrackTM material, which changed color when exposed to red wine and coffee, all types of materials did not show any color changes after a period of contact with coloring agents, according to visual inspection results on color stability.[18,20]

Studies have found that the color change values of Invisalign aligners made from PU are significantly higher than those made from polycarboxylate and PET-G. Many investigations have shown that polyurethane lacks sufficient color stability and is more likely to absorb pigment.[21]

II . Chemical resistance properties

To maintain their shape and function, CA should be resistant to temperature changes, saliva, enzymes, and exposure to beverages other than water. The aligners are made of thermoplastic polymers, and these materials need to withstand hydrolysis and water degradation to prevent any changes in their structure and properties.[22]

III. Biological properties

Biocompatibility and cytotoxicity of CA materials

Thermoplastic polymers are expected to be safe for intraoral use, as they are non carcinogenic, do not cause developmental abnormalities, and do not release harmful toxins that could trigger negative local or systemic reactions.[21]

In a reviewing study by FDA , the FDA has compiled a list of drawbacks during the use of Invisalign . The study, which spanned over ten years, found that the most commonly reported side effects of using aligners were breathing difficulties, sore throats, swollen tongues, throat swelling, rashes, itching, and anaphylaxis.[24]

When monomers are not fully converted into polymers, the remaining monomers can enter the saliva and cause harmful biological reactions in the tissues of oral cavity.[25] This is particularly relevant in dentistry where polymeric biomaterials are frequently used. Unpolymerized

monomers in these materials can result in various adverse effects such as inflammation, irritation, cell cycle disruptions, immunological responses and apoptosis.[26]

Many previous research has estimated the probable cytotoxicity of TM. In vitro study evaluated four different thermoplastic aligner materials for possible toxicity using human gingival fibroblasts (HGFs) cell lines, which are frequently used to assosiates the biocompatibility of dental materials. (Martina et. al., 2019)[2] These cell lines are particularly vulnerable to the harmful effects of aligner materials. The study concludes that all aligners examined had modest levels of in vitro toxicity on the cells tested. The cytotoxicity levels of various dental products, such as metallic brackets and bands, miniscrews, and bonding materials, were either equal to or lower than these results.

The cytotoxicity of aligner materials determined by the few studies. Eliades et. al. examined the materials used in the Invisalign system to check for possible BPA emission in 2009 (Eliades et. al., 2009).[27] The study found that there was no evidence of cytotoxicity on human gingival fibroblasts. However, according to Premaraj et. al. in 2014,[23] the isocyanate present in Invisalign aligners may have negative impacts on oral flora. Allergic manifestation reported after use of isocyanate. Isocyanates react with oral tissues and causes hypersensitivity reactions. These researches have shown that when gingival epithelial cells are exposed to plastic material in a saline environment, their ability to form connections between cells, metabolism, and membrane integrity are all undesirably affected.

Yazdi et.al.in (2023) performed a systematic review and finding showed that the in vitro investigations found very small amounts of released BPA, while the clinical trial showed a relatively high level.[28]

Numerous investigations have demonstrated that the cytotoxicity of the material is higher during the first few days of intraoral usage. Therefore, a shorter cytotoxic evaluation does not affect the quality of the investigation.[2,29]

IV . Thermal properties

TM are made of linear or slightly branched polymers with strong covalent connections within the molecules and mild Van der Waals interactions between the molecules. When heated to high temperatures, these connections melt, causing the polymers to become malleable. As the molecular chains cool, they solidify into new shapes. This process of softening with heating and hardening with cooling can be repeated because TM do not undergo additional chemical changes at different temperatures. The TM used to make CA are semi-crystalline in the solid state, with amorphous polymer strands dispersed throughout.[11]

V. Mechanical properties

The materials used in making aligners are thermoplastic polymers that have unique properties. These properties enable them to react contrarily to numerous forms of mechanical, physical and chemical stress, mouthwash, salivary enzymes, and colouring agents. A good aligner should possess desirable qualities such as exceptional transparency, low hardness, resilience, elasticity, resistance to mechanical stress over time, and biocompatibility (Ma et. al., 2016)[13]

The Influence of Thermoforming Process

Research studies [30,31] have shown that the transparency, hardness, and thickness of the material may all be affected during the thermoforming process. In study (2018)[30], it was found that the thickness of the material and its transparency are related. According to the investigation, thermoforming process results in a reduction of material transparency.

The hardness of a material can be affected by its solubility and absorption in water. According to a study by Ryu et. al. (2018), before thermoforming, no significant differences in hardness were observed among the four materials compared to control samples. However, after thermoforming, all four materials showed an increase in water absorption capacity and hardness.[30]

During the thermoforming process, the thickness of aligners can be altered. Another study conducted. in 2019, showed decrease in thickness of aligners after thermoforming . However, the clinical performance of the aligners remains unaffected despite the variation in thickness.[31]

Comparable outcomes are also found in study showed a decrease in hardness and thickness of aligners after thermoforming. The results showed that the reduction in thickness of aligners after thermoforming resulted in a reduction in their flexural modulus (Dalaie et. al., 2021).[20]

The Effect of Mechanical Stress and the Phenomenon of Stress Relaxation One important characteristic of aligners is that they are viscoelastic, meaning that their properties are halfway between those of viscous and elastic materials. This means that even when they are initially placed and before any tooth movement occurs, their behaviour can change significantly over time when under strain. Stress-relaxation is the phenomenon where loads decrease with constant deflection (Lombardo et. al., 2017).[11]

Both short-term and long-term pressures and strains can affect aligners. Stress relaxation is a phenomenon that reduces the forces applied by the aligner, ensuring that it maintains a continuous deflection before the tooth begins to move. Though, the amount of stress relaxation that occurs depends on the properties of the aligner material and the degree of the applied loads. To ensure that tooth movement occurs as expected, it is important to account for this reduction and measure it accurately.

The study conducted in 2017 found that multi-layered aligners had consistent stress relaxation but were four times less resistant to absolute stress compared to the mono-layered ones. All materials tested exhibited significant relaxation in the first eight hours, but after that, some materials plateaued while others declined. The mono-layered aligner made of PET-G showed the most notable stress relaxation rate over 24 hours, while the PU based aligner exhibited greater primary stress values and a rapid degeneration rate. Multi-layered aligners displayed lower stress relaxation rates and starting stress values compared to mono-layers (Lombardo et. al., 2017).[11]

Another study examines the stress relaxation characteristics of CA materials after a continuous deflection period of 14 days. They also showed in all materials, stress decayed quickly in the primary few hours of application beforehand entering a plateau phase (Albertini et. al., 2022).[32]

Kohda et. al. examined the mechanical properties, thickness, and degree of activation of three types of aligner materials to determine their effectiveness in producing orthodontic forces. Their research showed that the ability of the aligners to produce orthodontic forces was influenced by both the thickness of the material and the level of activation.[33]

Zhang et. al. conducted a study on the mechanical properties of a modified blend of PET/PC/TPU using a universal testing machine. They found that the material had an elongation at break of 155.99% and a tear strength of 50.23 MPa. When compared to two commercial thermoplastic materials, Erkodur and Biolon, the modified blend performed better. Additionally, the stress relaxation rate after one hour was 0.0136 N/s, which was significantly slower than that of Erkodur and Biolon.[7]

Study shows that commercially available TM can have varying mechanical properties. Among the materials tested, Erkodur and Track exhibited the lowest stiffness compared to Duran.

During a 24-hour stress decay test, all three materials showed similar behavior with higher initial stress in the first eight hours following loading, followed by a gradual decline, and then plateauing. However, Track displayed a rapid rate of stress reduction over the 24-hour period. In terms of degradation rates, Duran outperformed the other two materials. Although Duran's initial stress value was slightly higher than Erkodur's, it was still lower than Track's. (Ranjan et. al., 2020).[34]

Bakdach et. al.(2022) performed a systematic review and meta- analysis. The systematic review and meta- analysis includes four articles focusing on modifications to the Smart Track (LD30) material used in InvisalignTM whereas products. During use, LD30 showed distortion of the surface serrations and ion exchange, affecting surface morphology and chemical characteristics.[35]

Another systematic review performed by Srinivasan et. al.(2024) concluded that properties like color, stiffness, hardness, stress relaxation, and creep behavior differed among CA materials and decreased with intra-oral ageing and thermoforming. While polyurethane-based materials have higher level of hardness and stiffness, they also exhibit elevation in creep and stress relaxation characteristics.[36]

CONCLUSION-

The materials used for creating CA significantly impact their clinical performance, make CA therapy a widely accepted orthodontic treatment.

This narrative review aims to thoroughly understand the range of materials currently used in the production of CA. The focus is on their mechanical, optical, and biological properties, as these attributes are critical in defining the clinical performance of CA in an oral environment.

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