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Contemporary Developments in Clear Aligner Materials- A Comprehensive Review

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Abstract

Clear aligner therapy (CAT) emerged in 1990s and since then, has revolutionized orthodontic therapy. The evolution of aligner systems has been marked by noteworthy advancements in material science as well as digital workflows. Majority of the early generations relied solely on thermoformed plastics, whereas recent developments focus on multilayered polymers and direct 3D-printed aligners. However, the challenges faced include reduced efficiency in complex tooth movements, increased treatment cost and potential risks such as enamel hypocalcification and material degradation within the oral environment. To mitigate these drawbacks, a plethora of surface coatings and nanomaterial modifications are being tried and tested, aiming to reduce biofilm formation, bacterial adhesion and thus improving patient comfort. While in vitro investigations in the existing literature seem to show promising results, in vivo and long-term clinical studies remains limited. Moreover, the dynamic nature of the oral cavity demands robust invivo testing of these novel materials. As 3D printing technologies and biomaterial engineering science continue to expand, the horizon of aligner therapy widens thus enabling more predictable and personalized orthodontic care. Future research should focus on randomized controlled trials, long-term follow-up studies to optimize patient outcomes.

Keywords: biocompatibility, clear aligner materials, direct printed aligners, surface modifications

Introduction

The concept of clear orthodontics began in the 1940s when Dr. Harold Kesling developed the vacuum-formed ‘tooth positioning appliance’. Inspired by this, Dr. Nahoum introduced the first clear thermoplastic appliance with auxiliary components, such as acrylic buttons for intermaxillary elastics which is believed to be a forerunner for the use of attachments in the modern clear aligner therapy [1]. Later, in 1970s, Ponitz introduced the ‘Invisible retainer’ for finishing, detailing and retention. Finally, in 1993, Sheridan perfected the method by reducing the material thickness to 0.030 inches, leading to the development of the ‘Essix appliance,’ a key milestone in the development of clear aligner systems. [2]

The breakthrough for the modern clear aligner treatment modality came in the late 1990s when Zia Chishti and Kelsey Wirth, Stanford MBA graduates, in association with two orthodontists, developed the Invisalign clear aligner system[3]. This seemed to offer a discrete, nearly invisible treatment strategy while still relying on the orthodontic principles of bone biology, biomechanics, and occlusion.

With the increasing demand for more esthetic orthodontic treatment solutions, developments are skyrocketing in the field of clear aligners. This article reviews the current literature, highlighting key advancements in clear aligner materials.

Evolution Of Clear Aligner Materials

Aligners can be fabricated either by **vaccum thermoforming** or **direct 3D printing**.The polymers, commonly used, either individually or blended, for thermoformed orthodontic clear aligners include- polyester, polyurethane, polypropylene, polycarbonate, ethylene vinyl acetate, and polyvinyl chloride[4].

Numerous attempts have been made by the commercial forerunner in clear aligner therapy- Invisalign (Align tech, SanJose,California) to improve material properties and treatment outcomes [5]. The first generation aligners (G1) were fabricated using Proceed30 (PC 30) – polymer mixture; G2 and G3 using Exceed30 (EX 30); SmartTrack™ (LD30) has been used from G4 onwards. In addition to Invisalign, other commercial thermoformed orthodontic aligner providers include Clarity (3M ESPE Maplewood, USA), Clear correct (Institut Straumann AG, Basel, Switzerland), Spark (Ormco Corporation, Brea, USA), SureSmile (Dentsply Sirona, York, USA), Nuvola (GEO Srl Rome, Italy), F22 (Sweden and Martina Company, Padua, Italy).

The workflow for thermoformed clear aligner essentially involves digital image acquisition, virtual treatment planning in software, 3d printing models and vaccum thermoforming aligners. Two types of thermoforming machines are commonly available: **vacuum forming** (Erkoform 3D motion) which operates on the principle of air depression and **pressure forming** (Biostar, Ministar, Erkopress) which generates pressurized air above the thermoplastic sheet to press it against the model, with pressure forming being more efficient and accurate [6].

Across the world, in the last quinquennium, numerous orthodontists have established their '**IN-OFFICE ALIGNER**' production system. For IHAs, there are different thermoformed sheets currently available commercially, such as Zendura (Bay materials), Essix (Dentsplay), Biolon (Dreve Dentamid GmbH), Clearaligner (Scheu Dental), Taglus stuff (Allure Ortho), Duran (Scheu Dental), Erkodur-al (Erkodent GmbH). A study by Sam et al shows Inhouse aligners are equally effective as fixed appliances in managing malocclusions[7] .

However, the major pitfalls of the thermoforming aligners include increased surface roughness in some aligner sheets which might promote plaque accumulation, and altered water absorption dynamics which inturn might compound to aligner misfit [8]. Furthermore, the flexural strength of the aligner is also compromised [9]. In order to overcome these drawbacks as well as the rate limiting stage-printing models (over which aligners are thermoformed), direct printing aligners could be a viable alternative.

Recent Advances In Clear Aligner Materials-

1.3d printed aligner materials-

The only 3D printable material currently meeting most of the standards (as claimed by the manufacturer) is the **Tera harz-85** (GRAPHY,TC 85,Seoul, South Korea). **TC-85**, a bio-compatible photoreactive polymer has shape memory; and is available as TC-85 DAC (Direct Aligner Clear) and TC-85 DAW (Direct Aligner White). Recently, **TA-28 resin** and **TR-07** have also been developed. In addition to this, **LuxCreo** Inc., Chicago claims to offer multi thickness, smart active memory polymer material that requires no/fewer attachments[10] . However, no evidence is available in the current literature regarding LuxCreo aligner materials and its properties.

Recommended 3D printers for direct printing include Uniz SLASH 2, Uniz NBEE, Asiga MAX, SprintRay Pro 95/55 and Formlabs. Zinelis et al [11] have concluded that the type of 3d printer used influences the mechanical properties of the aligner printed. Post-printing, the aligners undergo a centrifugation process to remove excess material via centrifugal forces.

1.1-Properties of 3d printed aligner materials-

Koenig et al [12] compared the dimensional accuracy between thermoformed (Zendura FLX™ and ESSIX ACE™) and direct printed aligners (Tera Harz 85) in-vitro by using best fit alignment algorithm in Geomagic® Control X™ metrology software and concluded that the latter showed more precision and trueness than the former. However, the authors have stated that the small sample size, utilization of an optical spray on the aligner's intaglio and analyzing

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the findings by best-fit method rather than reference based method could have influenced the results.

Can et al [13] investigated the effect of intraoral exposure on the mechanical properties and chemical composition of In-house 3d printed aligners (Tera Harz 85 resin) and concluded that one week exposure doesn't significantly alter the abovesaid parameters. This could be attributed to the chemical nature of the aligner-Aliphatic vinyl ester–urethane (methacrylate functionalized). In addition to this, the author has correlated the findings of this study with earlier studies done by Bradley et al[14], Papadapoulou et al [15] , and observed that the elastic index of the 3d direct printed aligner material (29.4%) was way too lower than the conventional and commercial thermoformed aligner materials (34-35.9%) thus implying increased ductile behavior among 3d printed aligners group.

Simunovic et al [16] compared the water absorption, desorption kinetics as well as diffusion behavior between thermoformed- Invisalign (Align Technology, California), ClearCorrect (Institut Straumann, Basel, Switzerland) , and direct printed- Tera-Harz 85 (Graphy,Seoul, South Korea) and Clear A (Senertek, İzmir, Turkey) aligner materials. In clinical aspect, materials with faster desorption exhibit better dimensional recovery when removed (for example-while eating) whereas slower desorption could result in swelling induced aligner misfit. The findings of this study is summarized Table 1.

1.2-Biocompatability of 3d printed aligners

Biocompatibility is defined as 'the ability of a material to function in a specific application in the presence of an appropriate host response'[17]. For a material to be considered BIOCOMPATIBLE, the interaction between host, the material and its expected function must be in harmony [18].Numerous studies have been carried out to assess the biocompatibility and cytotoxicity of direct printed aligners. The factors that potentially influence the cytotoxicity of direct printed aligner materials include- post printing curing time, curing unit and aligner thickness.

a) **Post printing curing time**- Iodice et al [19], in their invitro study(conducted in saliva samples obtained from volunteers) evaluated the impact of three different curing times- 14, 24 and 50 minutes on **Tera Harz TC-85 DAC** resin using human gingival fibroblasts (HGF-1). They observed a linear association between curing time and cell growth implying that 3d printed aligners, **when cured for longer duration post printing, could exhibit high cytotoxicity.** Thus, the authors emphasize the importance of strictly adhering to the manufacturer's post production protocol.

Similarly, Bleilob et al [20] also reported that for **Tera harz TA-28 resin**, the **cell viability decreased with increasing curing time**. However, when cured for 60 minutes, there was a subsequent increase in cell viability. Thus, the authors recommend that if any prolonged curing must be done in the post printing phase, it should be extended to 60 minutes (if thickness >6 mm).

b) **Post printing curing unit-** Alessandra et al [21] compared the effect of two different curing procedures- **Tera harz cure** with nitrogen generator curing machine (THC2, Graphy, Seoul, Korea) and **Form cure machine** (FormLabs Inc, Somerville, USA) on the cytotoxicity of direct printed aligners. The cell viability was reduced in the Form cure group and the cytotoxicity was classified as mild based on Ahrari's classification [22]. The properties of the curing units are summarized in Table 2.

c) **Thickness of the aligner material-** Bleilob et al[20] analysed specimens measuring 0.5, 1, 2, 4 and 6 mm thick that were manufactured using **Teraharz TA-28** resin from **Asiga MAX 3D printer** (Asiga SPS ™ technology, Sydney, Australia). Human gingival fibroblasts (HGF-1)-CRL2014 were used to assess cytotoxicity. **Inverse relationship was noted between thickness and cell viability**. Nevertheless, the cell viability reduction was less than 30 percent even for thick specimens thus demonstrating that direct printed clear aligner resin meets the EN ISO 10993-5 standards [23] for non-cytotoxicity.

2.Orthofx NiTime aligners- claims that their patented HyperElastic polymer with AirShell technology maintains biologically appropriate level of force, thus allowing predictable tooth movement in 9 to 12 hours of continuous wear time [24]. The aligner has two shells- Flexible inner shell (aids in eliminating the

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need for refinements due to improper seating) and firm outer shell (compresses air and guide teeth gently towards intended position consistently)

3.Clear aligner surface modifications- Multiple coatings are being tried and tested over aligner materials in order to enhance their mechanical and microbiological properties. Table 3 depicts a chronological collation of the contemporary organic and inorganic coatings that have been used on aligners.

Future Directions- Oral cavity is a highly dynamic, multifactorial environment influenced by salivary flow and composition, diet, patient hygiene, biofilm ecology, and masticatory forces. Hence, it is essential to conduct robust clinical trials and long-term prospective follow up studies to evaluate biological, mechanical, and clinical performance of newer aligner materials and coatings.

Conclusion- Clear aligner therapy has revolutionized the field of orthodontics over the past 25 years, offering patients a more esthetic, comfortable, and convenient alternative to conventional fixed mechanotherapy. The advent of 3D-printed aligners represents another significant milestone, opening the window for enhanced customization and efficiency.

1. The relaxation index of direct printed aligners (29.4%) is lower than thermoformed aligners (34-35.9%). Hence, the former have to be changed every 7 days rather than 14 days.
2. The biocompatibility of 3d printed aligners is influenced by post curing time, post curing unit and the thickness of the clear aligner material.
3. Cytotoxicity increases with longer post printing curing time [19] as well as increased aligner thickness; Tera Harz curing unit exhibits less cytotoxicity compared to Formcure unit.
4. Further studies are required to translate laboratory findings to clinically relevant data and quantify real world risk.

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Table 1: Water absorption kinetics of various aligner materials

Brand of aligner	Chemical Composition	Water Absorption Kinetics	Reason / Explanation
Invisalign (Align Technology, USA)	Multilayer: TPU–PETG–TPU	Highest absorption (4.91% by day 14); Rapid desorption (93.7% in 1h, ~100% by 24h)	Outer TPU layer - highly hydrophilic, facilitating rapid water ingress and release. TPU's polar groups form hydrogen bonds with water. Loosely cross-linked TPU enables fast evaporation.
ClearCorrect (Straumann, Switzerland)	Multilayer: PETG–TPU–PETG	Moderate absorption (3.57% by day 14); Slower desorption (80% in 1h; ~97% by 24h)	Outer PETG layer - less hydrophilic and more crystalline, acting as a barrier to moisture entry and delaying both absorption and desorption. TPU is shielded inside.
Tera Harz TC-85 (Graphy, Korea)	Polyurethane-based acrylic photopolymer resin (3D printed)	Lower absorption (3.08% by day 14);); Slow early desorption (69% in 1h) but complete by 24h (~100%)	Dense cross-linked photopolymer network reduces free volume, limits water diffusion, and retains water in bound states. Slower release due

			to strong polymer-water interactions.
Clear A (Senertek, Turkey)	Polyurethane-based acrylic photopolymer resin (3D printed)	Lowest absorption (2.76% by day 14); Early plateau after day 10; Slow early desorption (68% in 1h) but complete by 24h (~100%)	Same dense cross-linked photopolymer as TC-85; tightly bound water molecules impede fast release. Earlier plateau suggests equilibrium between absorption and desorption.

Table 2 : Comparison between THC2 and Formcure unit

Parameter	THC 2 (Graphy)	Form Cure (FormLabs)	Clinical Implication
Light Source	UV LED	13 multi-directional LEDs	More uniform curing in FormCure, but THC 2 provides higher intensity per LED.
Wavelength	405 nm	405 nm	Both match Graphy resin requirements for polymerization.
LED Power Output	200 W	39 W	THC 2 ensures deeper and more complete curing, reducing residual monomers.
Operation Temperature	5 – 35 °C	18 – 28 °C (max 80 °C)	Higher temperatures in FormCure may alter surface roughness, potentially increasing cytotoxicity.
Design Purpose	Optimized for Graphy resins; nitrogen atmosphere curing	General-purpose curing unit	THC 2 recommended for Graphy aligners; FormCure may cause incomplete or inconsistent curing, leading to reduced biocompatibility.

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Table 3 :Chronological collation of clear aligner coatings

Author(s)	Year	Experimental Coating material	Results
Zhou, Ziemei et al [25]	2025	N-halamine polymer	Showed Broad-spectrum antimicrobial effects by releasing reactive chlorine and non-specifically targeting critical bacterial proteins
Gharibnavaz et al [26]	2025	ZnO, MgO and Combination of MgO and ZnO	Combination of ZnO and MgO demonstrated the highest antibacterial efficacy than separate ZnO and MgO coated aligners
Yun bai et al [27]	2024	Polydimethylsiloxane (PDMS)	PDMS remained stable in simulated oral environment. In addition to this, the stress release rate of the composite material was significantly lower (23.64 %) than that of PETG (62.29 %).
On- Yu Ha et al [28]	2024	Binder free Ti-O2-Cu composite powder coating	Inhibited 99.9 % Streptococcus mutans counts without compromising the transparency and visual appeal of the aligners
Ram Mundada et al [29]	2024	Silver (1%) and chitosan (1%) nanoparticles	Reduced the incidence of white spot lesion in attachment zones
Qi Qin et al [30]	2024	Renewable coating from metal–phenol network coating, and zwitterionic sulfonamethyldopamine	Demonstrated good durability against biofilm mainly by contact sterilization
Hemamalini et al [31]	2024	Selenium nanoparticles (SeNps)-from plant extract	Positive antibacterial effects on Lactobacillus species and S.mutans
Anita P et al [32]	2023	Zinc oxide (ZnO) nanocoating	Effective against S mutans, with the peak antibacterial effect observed until 2 days and lasting for 7 days. Minimally effective against Candida albicans.
C Yuxun et al [33]	2023	Hydrogen peroxide gel loaded thermoforming aligner film	Sustained release of hydrogen peroxide gel exerted bleaching effect on the teeth without affecting the shear bond strength for attachment
Botan barzer at al	2023	Chitosan nanoparticles	Added an antibiofilm element to the aligner without negatively influencing the material's

[34]			cytotoxicity, degree of conversion, accuracy, deflection force, and tensile strength.
Yan et al [35]	2023	Fluoride	Fluoride coated aligner Plastic released fluoride continuously for 14 days and could be recharged after immersing in NaF solution
Vas et al [36]	2023	6-gingerol incorporated chitosan biopolymer	Exhibited Antibacterial effect against S.mutans
Worreth et al[37]	2022	Cellulose-based clear aligner material loaded with essential oils, like cinnamaldehyde	The inhibition was more pronounced against S. Epidermidis, for which growth rate was reduced by 70%.For mutans streptococci and S. Mitis, the decrease in growth rate was 20% and 10%, respectively.
Zhang et al [38]	2020	4,6-diamino-2-pyrimidinethiol-modified gold nanoparticles	Decreased the number of living bacteria, the amount of EPS (extracellular polymeric substances), and total biofilm biomass; delayed biofilm formation and maturation
Xie et al [39]	2020	Quaternary ammonium (QA)-modified gold nanoclusters	Efficiently inhibited the adhesion of cariogenic pathogenic Streptococcus mutans
Park et al [40]	2018	Polysaccharide-based antibacterial multilayer films	Prevented the adhesion of bacteria and exhibited a bacterial reduction ratio of ~75%; improved the chemical resistance and mechanical stability of the PETG under simulated intraoral conditions