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Clear Aligners - An Update

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ABSTRACT:
Aesthetic demand and patients' needs have been the priority for orthodontic treatment. With the introduction of Clear aligners in the market the aesthetic needs of the patients have been highly satisfied. Clear aligner fabrication has been evolving with technology since its introduction, indirectly printed aligners have been fabricated on 3D printed models for years now. Recently, directly printed aligners have been introduced in the market easing the fabrication process by eliminating the fabrication of 3D printed models and hence overcoming the shortcomings of the 3D printed thermoformed aligners. Various resins have been introduced since the introduction of the concept of directly printed aligners. This article covers the various resins available in the market and the literature regarding the same. Studies have been performed to understand the mechanical properties of these materials and it has been found that further refinements and improvements are required.

KEYWORDS
Clear Aligners, Clear Aligner Therapy, CAT, Indirectly printed aligners, Thermoformed Aligners, Directly printed aligners, TC 85DAC, Shape memory aligners

INTRODUCTION

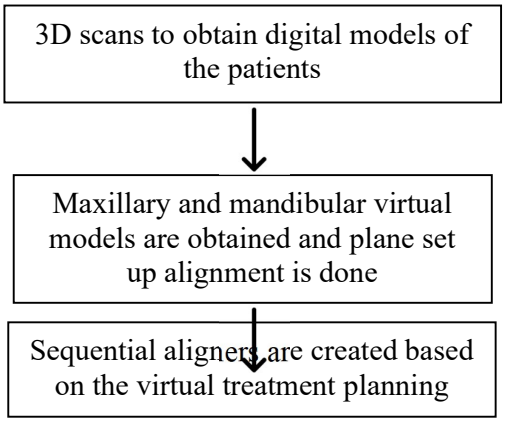
Aesthetic demand and patients' needs have been dictating orthodontic treatment decisions and preferences for years following both clinician's and patient's views. It has been reported that seeking 'invisible' orthodontic modalities, especially by adult patients, has attained an increasing interest over the recent years, as also documented by clinicians' files and records worldwide.[1,2] The use of orthodontic aligners as a primary representative of 'invisible' orthodontics has gained much attention from researchers, in an attempt to frame the basis over their efficacy to achieve the desirable treatment outcome compared to the 'gold standard' of fixed orthodontic appliances.[3,4] In addition, oral hygiene, safety considerations and further material properties characterization parameters of aligners have been studied under the prism of potential risk identification for the patients[5,6,7] Indirectly printed orthodontic aligners are manufactured by traditional thermoforming process, but it has certain disadvantages such as it

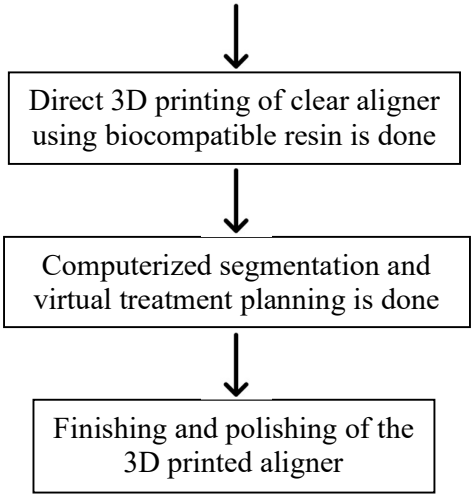
is time consuming, labour intensive, can result in geometric inaccuracies, thermal deformations and inconsistent fitting and layer thickness[8,9] . Direct 3-dimensional (3D) printing of orthodontic aligners is emerging as the next paradigm shift in clear aligner therapy.[10] The shortcomings related to the thermoforming technique of clear aligner manufacturing have been well documented. The process of thermoforming affects the thickness and the properties of the material. As noted from the observations of a clinical trial by Bucci et al., thermoplastic sheets of 0.75mm before processing were measured to vary between 0.38-0.69mm at different regions after processing.[11] Reduction in thickness of aligner material by 10% could reduce exerted forces by up to 30% theoretically.[12] Thermoforming is an important way to alter material properties like transparency, surface hardness, water solubility, water absorption ability, flexural modulus, and elastic modulus of various aligner material brands and thicknesses.[13,14,15] Furthermore, literature evidence[12,16] indicates that the dental model's height and thickness can affect the dimensional accuracy of the thermoformed appliance. Ihessen et al [12] detected that aligners made from the high (i.e., 5 mm) base height of 3D-printed models were significantly thinner and more homogenous compared to those made from narrow ones (i.e., without a base). In an attempt to reduce the resin material quantity consumed, hollow models were investigated as an alternative. However, hollow models without adequate thickness (i.e. <2mm) underwent deformation during thermoforming, thus compromising the clinical utility of the appliance.[16] Though improvements have been incorporated with newer materials and auxiliary designs in aligner orthodontics, the vast majority of manufacturing has remained to be the thermoforming technique so far.[17] Leading global providers like Invisalign (Align Technology, San Jose, CA, USA), K-line (K Line Europe GmbH, Düsseldorf, Germany), and ClearCorrect (Straumann, Texas, USA) digitally plan tooth movement and print staged 3D models to make aligners using the thermoforming technique.

With the evolving digital technology and material science, the utilization of integrated systems manufacturing is widening the horizons of clear aligner manufacturing by directly printing the aligners rather than being limited to working model preparation. Hence, this technique is being explored as a solution to address the drawbacks of the traditional thermoforming process.

"Rapid prototyping" (RP) is the term for the process of quickly creating physical prototypes through computer-aided manufacturing. It has 2 types, Additive and Subtractive. Additive method builds the object layer by layer while subtractive method does the same by removal to generate the same. Directly printed aligners are fabricated by additive method of Rapid prototyping. A 3D printer with integrated slicing software and appropriate photosensitive resin are used in computer-aided manufacturing of Directly printed aligners. The printing resin material should possess adequate physical, mechanical, optical, and biological properties for aligner material fabrication.

THE WORKFLOW FOR DIRECTLY PRINTED ALIGNERS





RESINS FOR DIRECTLY PRINTED ALIGNERS

Graphy, a South Korean-based company of 3D printable photopolymer resins, has revealed a dental 3D printing material mark, Tera Harz, intending to overcome the constraints posed by other 3D printable resins used within the dental field. Graphy's Tera Harz has obtained CE, FDA, and KFDA medical device certification and is available in clear (TC-85DAC) or white (TC-85DAW). It is an aliphatic vinyl ester–urethane polymer, with methacrylate functionalization[18] that exhibits shape memory.[19] The clear Tera Harz resin is fully transparent and has high durability agreed with orthodontic treatment device purposes. In comparison, the white Tera Harz material features esthetics alongside durability. However, Willi et al [20] have detected the release of UDMA (urethane di-methacrylate) from in-vitro samples that assessed the biocompatibility of its clinical usage. 83% degree of conversion polymerization was found, and UDMA level was in the range of 29-96 micro grams. Pratsinis et al [21] assessed the cytotoxicity, antioxidative activity, and estrogenicity of the direct 3Dprinting aligner resin material of the TC 85 aligner resin, it was found that, the eluents released during the 14- day aging of 3D-printed aligners in water were not cytotoxic for human gingival fibroblasts and did not affect their intracellular reactive oxygen species levels. Based on an E-screen assay, the putative eluates had no estrogenic effects. In a study by Lee et al,[19] the thermo-mechanical and viscoelastic properties of TC-85 clear aligner resin were assessed which was photocured twice for 25 min under N2 with UV light (wavelength: 385–405 nm) using a post-curing chamber (CureM U102H, Graphy Inc), it was found that The material was capable of exerting light continuous force with shape memory property and geometric stability at higher temperatures. Koenig et al[25] estimated and compared the dimensional accuracy of clear aligners made by thermoforming and direct 3D printing, it was concluded that, direct-printed aligners exhibited greater accuracy and precision than the thermoformed counterparts.

Nakano et al [22] in 2019 conducted a study to develop a biocompatible resin specifically for manufacturing directly printed aligners namely 3D-1M (Okamoto chemicals). The printer used was MiiCraft 125 (Young Optics Inc., Hsinchu City, Taiwan) –DLP technology. The outcome of the study was successful development of resin and manufacturing of clear aligner. But, mechanical improvements and regulatory approval are required. They produced acrylic-epoxy hybrid light-curing resins that have optimal safety profiles composed of water-soluble monomers alone. The results of cytotoxicity testing and proliferation testing showed that all the water-soluble monomers used for 3D printing (3D-1M) exhibited low cytotoxicity, but the cell survival rates suggested that the composition ratio of the raw materials could be an issue. The results of mechanical testing demonstrated that the 3D-1M met the mechanical strength

requirements for base polymers used in orthodontics. Direct aligners using these biocompatible resins were successfully produced. However, their middle sections were fragile, suggesting that their physical properties must be improved if they are to be used as aligners for orthodontic treatments.

Dental LT clear resin is another material used as Directly printed resin material developed by Formlabs, Somerville, Mass., USA. Formlabs currently offers two materials for splint production. Dental LT Clear Resin is a fracture-resistant material for long-term rigid occlusal splints and guards. Dental LT Comfort Resin is a durable material for flexible occlusal splints, night guards, and bleaching trays. It is suggested by them that the materials are easily polished to high optical transparency and resist discoloration over time. Jindal et al[23] compared compressive mechanical properties and geometric inaccuracies between thermoformed Duran aligners and 3D-printed Dental Long Term (LT) resin-based clear aligners. It was found that, the direct 3D-printed aligners were dimensionally more accurate to the STL file than the Duran thermoplastic aligners and, cured 3D-printed aligners were stiff with higher yield and lower displacement with reversible deformation. Another study by Jindal et al[24] investigated the aligner performance subjected to non-linear cyclic mechanical loading equivalent to human biting forces. The resulted suggested that the maximum von mises stress distribution of the Dental LT aligner was within a range of 0.2%–7.7% as compared to Duran and Durasoft.

CONCLUSION

Currently the level of research in the area of 3D Directly printed Clear aligners should proceed to validate the evidence for the clinical application of these aligners.

Improvements in mechanical properties are highly recommended.

Further research and improvements must allow the delivery of more durable, and cost effective, easily accessible 3D Directly printed Clear Aligners.

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