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Name(s) of Principal Investigator(s): Prof. Benjamin M. Wu

Institution: UCLA

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Summary/Abstract: see next page

Standardized Mechanical Characterization of

Clear Orthodontic Aligner Materials

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Abstract

Introduction: The performance of thermoplastic clear orthodontic aligners is affected by their composition, form factor, processing history, and use environment. Many studies have reported aligner properties, but direct comparison between studies is precluded by differences in testing protocols and processing history. Recognizing the need for standardized testing, the American Association of Orthodontists Foundation funded this project to characterize the mechanical properties of aligner materials. This report evaluates the stress relaxation, yield stress, yield strain, elastic modulus, and failure energy of 13 different aligner materials with validated protocols and is the first in a series of reports from this team.

Methods: Aligner sheet materials were thermoformed onto standardized rectangular blocks using heating/cooling codes suggested by their respective manufacturers. The thermoformed materials were subjected to standardized testing as per ISO 527-3. Stress

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strain and stress relaxation were evaluated with a universal testing machine. Crack resistance was measured by a customized impact tester that enabled greater testing resolution and enabled the differentiation of impact resistance among aligner materials.

Results: The mechanical properties of the commercial aligner materials differed significantly in elastic modulus, yield stress, yield strain, stress relaxation, and failure energy. With some notable exceptions, TPU materials generally exhibited a higher yield stress, higher elastic modulus, and greater crack resistance, but suffer greater stress relaxation than other materials. While some single-layer materials show superior combination of mechanical properties to multilayered materials, most single-layers are not as optimized as multilayers.

Conclusions: These methods provide a reference for the research community to perform similar testing on other orthodontic aligner materials. There is a large variability among materials in key mechanical properties. This work may provide the orthodontist with a data-driven approach to select materials based on clinical needs. Using common lab equipment that are accessible to most investigators, future expansion of this standardized testing data can inform the orthodontist in the selection of clear aligner materials based on their clinical parameters such as force delivery over time (stress-strain; stress relaxation), aligner durability for heavy bruxers (crack resistance), patient comfort and ease of insertion and removal (elastic modulus), and shape predictability (yield point and creep). Future work will develop standardized mechanical testing for finished 3D aligners. Practical testing of optical, chemical, and biological properties will further enable orthodontists to select materials based on scientific data.

Keywords: Clear aligners, thermoforming, stress strain, stress relaxation, elastic modulus, crack resistance, clinic application

INTRODUCTION

Clear aligners are currently widely used for mild to moderate treatment of dental malocclusion [1]. Compared to traditional metal aligners, plastic clear aligners are more convenient, aesthetic, and hygienic [2, 3]. Aligners are made of thermoplastic materials that exhibit a viscoelastic behavior, with a series of intermediate stages between the viscous and elastic phases. The viscoelastic nature of clear aligners determines their time-dependent mechanical properties and, in turn, governs the actual orthodontic force vector and magnitude during the treatment time (usually 22 h per day and wear 2 weeks).

All thermoplastic materials undergo stress relaxation. Previous studies have evaluated the clinical effectiveness of clear aligners [4-6]. Lombardo et al. [7] investigated the stress relaxation of bilayer materials and single-layer aligner materials using a customized setup. Their study found that bilayer materials undergo less force relaxation, but can only provide significantly smaller absolute forces. Fang et al. [8] reported significant differences in stress relaxation among 5 aligner materials using a sophisticated machine (Bose ElectroForce). Jaggy et al. [9] compared 4 aligner materials using a customized instrument for relaxation testing and an ATR-FTIR to assess their chemical composition. Regardless of findings, these studies evaluated only a few materials and employed customized devices under distinct test conditions. These differences preclude direct comparison between publications. Few studies have systemically investigated the mechanical properties of aligner materials using simpler instruments.

Besides stress strain relations and stress relaxation, crack resistance is another important parameter that affects the survival of clear aligners. Regardless of strength, aligners with poor crack resistance tend to rupture under heavy occlusal load, and during insertion/removal over undercuts and attachments. Aligners material with high crack-resistance can provide more durability and survive longer prior to catastrophic failure.

With the growing popularity of clear aligners, the American Association of Orthodontists Foundation (AAOF) supported this team to develop standard mechanical characterization protocol to evaluate the mechanical properties of clear aligner materials. Our previous reported to AAOF the feasibility of using dynamic mechanical analysis (DMA) and time temperature superposition to investigate complex viscoelastic polymers. Since DMA may not be available in many orthodontic departments, we developed a more practical method. The aim of the present study is to validate well-defined mechanical properties test protocols to measure the stress strain, yield point, stress relaxation and crack resistance of clear aligners, using common instruments and practical laboratory protocols. The parameters obtained in the present study include normalized relaxation, stress relaxation rate, elastic modulus, yield stress, yield strain, and failure energy. With growing interest in precision orthodontics, a collection of clear aligner's detailed mechanical properties can inform orthodontists and serve as an aid to precisely move patients' teeth and achieve desired treatment outcomes. These methods and our growing database serve as a point of reference for other researchers and allows them to replicate the testing protocols by using accessible equipment on current and future orthodontic aligner materials. The resulting large data set can potentially enable orthodontists and laboratory technicians to better select clear aligner materials and optimize their clinical needs by defining force delivery over time (stress-strain; stress relaxation), aligner durability for heavy bruxers (crack resistance), patient comfort and ease of insertion/removal (elastic modulus), and shape predictability (yield point and creep). For example, the orthodontic team may favor materials with a higher crack resistance for heavy bruxers and choose materials with higher stress retention for patients requiring challenging tooth movements. Future studies on optical, chemical, and biological properties will further enable orthodontists to select materials based on scientific data.

MATERIAL AND METHODS

Materials

In this study, 13 commercially available sheet aligner materials were utilized. The manufactures and brief product description are listed in Table 1. The thickness of aligner material is included because it has a significant influence on the stress that can be generated and retained. It is reported that thicker aligners can deliver higher orthodontic forces [29, 30]. Three materials (Zendura A, Zendura FLEX, REVA-2) contain thermoplastic polyurethane (TPU) as either the main material or as one layer in a multiple layer structure. Two materials (REVA-1, REVA-2) contain polyethylene terephthalate (PET) and other components. The remaining nine materials are made of polyethylene terephthalate glycol (PETG). The specimen preparation procedure is shown in Fig. 1.

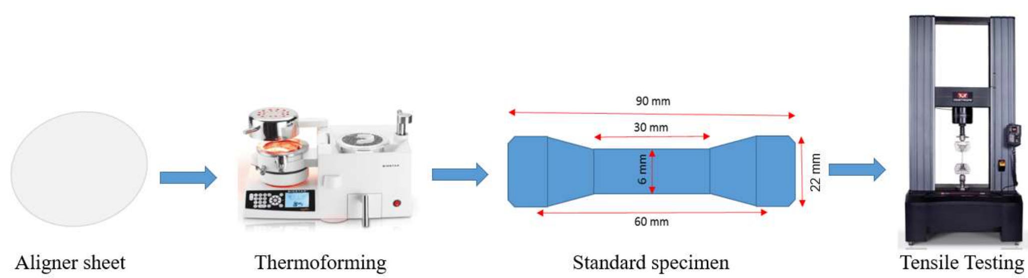

Figure 1 – Specimen preparation procedure

The materials were subjected to a thermoforming process using a Biostar pressure molding machine (Scan with LCD Display; Great Lakes Orthodontics, NY, US). Each material sheet was thermoformed under specific heating/cooling codes provided by its manufacturer over a standardized rectangular block (L*W*H=90*25*25 mm). The two long vertical side surfaces of the thermoformed materials were cut into “dog bone” shape per ISO standard 527-3. This geometry ensures that stress concentration and breakage phenomenon occurs at the thinner, mid-section of the specimen, far away from the grips on either end.

Table 1. Aligner materials used in current study.

Aligner materials		**Company**	**Descriptions**
Single layer materials			
	Biolon	Dreve Dentamid GmbH	0.75 mm/120 mm, Round
	ComfortTrack	Great Lakes dental technologies	0.76 mm/125 mm, Round
	Duran	Sheu Dental GmbH	0.76 mm/125 mm, Round
	Essix ACE	Dentsply International	1.0 mm/125 mm, Round
	Essix Plus	Dentsply International	1.0 mm/125 mm, Square
	GT FLEX Original	Good Fit Technologies	0.80 mm/125 mm, Round
	GT FLEX Pro	Good Fit Technologies	0.80 mm/125 mm, Round
	REVA-1	Reva Innovations, Inc.	0.67 mm/125 mm, Round
	Taglus P	Voxel Dental	0.75 mm/125 mm, Round
	OrthoClear	DenMat Holdings, Inc.	0.76 mm/125 mm, Round
	Zendura A *	Bay Materials LLC	0.76 mm/125 mm, Round
Multilayer materials			
	REVA-2 *	Reva Innovations, Inc.	0.75 mm/125 mm, Round
	Zendura FLX *	Bay Materials LLC	0.76 mm/125 mm, Round

* These materials contain TPU, and must be used within 30 minutes of opening the package. 3 materials (Zendura A, Zendura FLEX, REVA-2) use TPU as either the main material or as one layer in a multiple layer structure. 2 materials (REVA-1, REVA-2) contain PET and other components. The remaining 9 materials contain PETG.

Stress strain relations

The stress-strain curve of specimens was measured using a common universal testing machine Instron (Model 5564, Instron Ltd, Norwood, MA, US). Briefly, the dog-bone shape specimen was clamped on the Instron, and the distance between the two clamps was fixed to 60 mm. The test was conducted using the following parameters: ramp rate: 5 mm/min; stop displacement: 10 mm. After the measurement was completed, the yield strength, yield strain, and elastic modulus of the material were calculated using the Instron based Bluehill software on the stress-strain curves. Three specimens were used for each material.

Stress relaxation

The stress relaxation of specimens was measured by conducting a tension test using Instron model 5564. Briefly, the ends of thermoformed specimens were fixed onto the pneumatic clamps and stretched to 70% of their respective yield strain (previously obtained from the stress strain test). The specimen was held at this constant strain for 1.0 h. The stress within the material was recorded continuously during this time period. Initial Stress (R_o), and Remaining Stress (R_1) after 1 hour were determined, and Stress Relaxation was calculated using the following formula: $[R_o - R_1] / R_o$. Stress Relaxation Rate was calculated by the equation $[R_o - R_1] / t$, where t = time in hours.

Crack resistance

The crack resistance of aligner materials was determined by a customized Gardner impact tester (Cole-Parmer, Vernon Hills, IL, US). The diameter and weight of the customized impact head were 3.0 mm, and 100 g; respectively. Thermoformed specimens (L*W =80*20 mm) were used in the crack resistance test. After measuring the thickness (δ) at the specimen's target impact spot, the specimen was placed on the anvil of the impact tester and the impact head was placed on the target impact spot. The customized impact head was raised to a desired height and dropped onto the target impact spot. The obtained indentations after impact were carefully examined for presence of cracks. Upon no crack detection, a new specimen target impact spot was chosen and measured, and the customized impact head was raised to the next height increment. This sequence was repeated until a visible crack was observed on the specimen. This height (h) was used to determining the failure energy of the material according to the equation (1):

$$E = m * g * h \tag{1}$$

Where, E is the failure energy of the aligner material, m is the mass of the weight, g is the gravitational constant, and h is the minimum height that produced a crack by the custom impact head.

Since materials are supplied in various thicknesses and manufacturers recommend various thermoforming codes, the final thermoformed specimens are different in thickness. It is known that the crack resistance of thermoplastics varies with their thickness [31, 32]. Therefore, we normalized the failure energy using their thickness in order to compare the crack resistant ability and durability of aligner materials with different thicknesses. The normalized failure energy (E/δ) was calculated by dividing failure energy (E) by the thickness (δ) at the target impact spot.

Statistical analysis

The results of yield stress, yield strain, elastic modulus and stress relaxation rate were statistically analyzed by one way ANOVA or student's t-test. The level of significant difference was set as $p \leq 0.05$.

RESULTS

Stress strain behavior of different aligner materials

Representative stress-strain curves for one of the aligner materials are shown in Fig.2. The slope of the initial linear region is the elastic modulus of the material. At the top of the linear region the materials approximate the yield point, after which plastic deformation, necking, and failure occurs. Table 2 lists the elastic modulus of the thirteen thermoformed materials in decreasing order. Clearly, the thirteen materials differ greatly in elastic modulus. Statistical analysis reveals three materials with statistically higher stiffness (Zendura A, Taglus Premium, GT FLEX Original) than the rest ($p<0.05$), and one material with the lowest stiffness (ComfortTrack). The variability is significant among aligner materials. The eleven single-layer materials have modulus values ranging from 641 MPa to 1548 MPa, with some stiffer materials exhibiting over 2.4 times higher elastic modulus than the softer materials. The two bilayer materials exhibit less variability in elastic modulus, ranging from 975 MPa to 1043 MPa.

Table 2. Elastic modulus of thirteen thermoformed materials. Materials with greater elastic modulus are stiffer. Asterisk denotes statistically difference (* $p<0.05$) between aligners in different vertical bars.

Aligner materials	Young's Modulus (MPa)	
Zendura A	1548.86 ± 82.39	*
Taglus Premium	1543.83 ± 44.70	
GT FLEX Original	1530.04 ± 15.91	
OrthoClear	1414.67 ± 32.50	
Duran	1385.46 ± 98.06	
Biolon	1371.52 ± 68.07	
Essix ACE	1253.58 ± 96.22	
GT FLEX Pro	1177.77 ± 90.78	
REVA-1	1162.60 ± 62.44	
Essix Plus	1060.62 ± 77.07	
Zendura FLX	1043.00 ± 18.38	
REVA-2	975.09 ± 12.34	
ComfortTrack	641.00 ± 0.47	

The yield point, as defined by the yield stress and yield strain on the stress strain curve, determines the transition from linear elasticity to permanent plastic deformation. Statistical analysis ($p<0.05$) reveals one material with statistically highest yield stress

(Zendura A); a group of five aligners with moderately high yield stress (Taglus Premium, REVA-1, Biolon, Essix Plus, Duran); a group of 5 aligners with medium yield stress (GT FLEX Original, OrthoClear, Essix Ace, GT FLEX Pro, REVA-2), and two materials with the lowest yield stress (Zendura FLX and ComfortTrack). Figure 3 shows the linear regression analysis between elastic modulus and yield stress for the thirteen thermoformed aligner materials. The R-square value of 0.6 suggest a modest correlation.

The variability in yield stress is also significant among aligner materials. Table 3 lists the yield stress of the thirteen thermoformed materials in decreasing order. The yield stress of the thirteen materials exhibits a two-fold range of difference. The yield stress of the eleven single-layer materials ranges from 22 MPa to 47 MPa, while the two bilayer materials exhibit less differences from each other, ranging from 24 MPa to 32 MPa. While yield stress is important, this parameter cannot be used in isolation without considering other factors.

Table 3. Yield stress of thirteen thermoformed materials. Asterisk denotes statistically difference (* $p<0.05$) between aligners in different vertical bars.

Aligner materials	Yield Stress (MPa)	
Zendura A	47.02 ± 2.11	*
Taglus Premium	40.09 ± 0.82	
REVA-1	38.80 ± 0.97	
Biolon	38.01 ± 1.97	
Essix Plus	37.75 ± 1.41	
Duran	37.42 ± 1.54	
GT FLEX Original	35.51 ± 1.53	
OrthoClear	34.99 ± 0.23	
Essix ACE	34.36 ± 1.02	
GT FLEX Pro	33.67 ± 0.36	
REVA-2	32.79 ± 0.44	
Zendura FLX	24.09 ± 0.34	
ComfortTrack	22.08 ± 0.28	

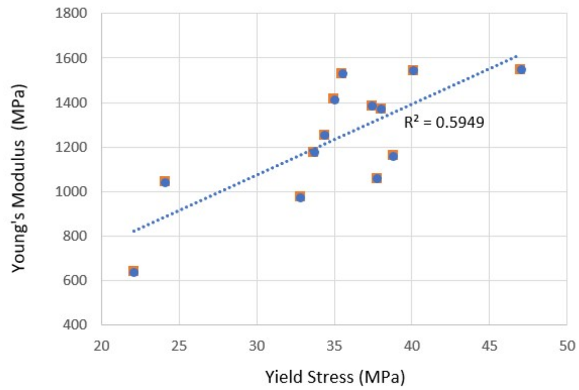

Figure 3. Linear correlation of elastic modulus and yield stress, showing a weak correlation for thermoformed aligner materials (R-square value ~ 0.6)

Table 4 lists the yield strain of the thirteen thermoformed materials in decreasing order. Statistical analysis ($p<0.05$) reveals a group of 4 materials with higher yield strain (REVA-1, Essix Plus, ComfortTrack, REVA-2); followed by a large group with intermediate yield strain, and two materials with the lower yield strain (Taglus P, GT GLEX Original). The eleven single-layer materials have yield strain ranging from 2.85% to 5.17% strain, while the two bilayer materials range from 4.31% to 4.82%.

Table 4. Yield strain of thirteen thermoformed materials. Asterisk denotes statistically difference (* $p<0.05$) between aligners in different vertical bars.

Aligner materials	Yield strain (%)	
REVA-1	5.17 ± 0.16	*
Essix Plus	5.03 ± 0.12	
ComfortTrack	4.96 ± 0.05	
REVA-2	4.82 ± 0.30	
OrthoClear	4.64 ± 0.45	
Zendura A	4.60 ± 0.13	
Zendura FLX	4.31 ± 0.35	
GT FLEX Pro	3.98 ± 0.26	
Duran	3.81 ± 0.04	
Essix ACE	3.81 ± 0.31	
Biolon	3.47 ± 0.60	
Taglus P	3.25 ± 0.12	
GT FLEX Original	2.85 ± 0.25	

Stress relaxation

Figure 4 showcases the stress relaxation curves of the different aligner materials tested. When loaded to a constant strain consisting of 70% their yield strain, all 13 thermoformed aligners undergo a rapid stress reduction during the first 15 minutes, and then a linear gradual relaxation throughout the end of the experiment. Table 5 lists the Stress Relaxation Rate and magnitude of the thirteen thermoformed materials in decreasing order of Remaining Stress after one hour of loading to 70% constant strain. Statistical analysis reveals a group of seven materials with the highest relative Remaining Stress %, or lowest stress relaxation %: (Zendura FLX, OrthoClear, REVA-2, Essix Plus, REVA-1, GT FLEX Pro, Comfort Track); followed by a group of four materials with intermediate relaxation (GT Flex Original, Taglus Premium, Duran, Essix ACE); and a group of two materials that exhibit the most relaxation (Biolong, Zendura A).

Table 5. Stress Relaxation of 13 commercial aligner materials. Asterisk denotes statistically difference (* $p<0.05$) between aligners in different vertical bars.

Aligner materials	Initial Stress at t=0 hr (R_0, MPa)	Remaining Stress at t=1 hr (R_1, MPa)	Relaxation Rate (MPa/hr)	Remaining Stress After 1 Hr (%)	Constant Strain (70% Yield Strain)
Zendura FLX	22.92 ± 0.22	15.22 ± 1.19	7.7 ± 0.05	67.60 ± 0.20 *	3.02% strain
OrthoClear	31.94 ± 1.24	21.56 ± 0.27	10.38 ± 0.33	67.58 ± 1.78	3.25% strain
REVA-2	31.71 ± 1.37	21.39 ± 1.63	10.32 ± 0.76	67.49 ± 1.03	3.37% strain
Essix Plus	33.07 ± 0.30	22.14 ± 1.24	10.94 ± 0.52	66.94 ± 1.29	3.52% strain
REVA-1	33.91 ± 0.98	22.35 ± 0.89	11.56 ± 0.19	65.90 ± 0.84	3.62% strain
GT FLEX Pro	27.50 ± 0.26	18.03 ± 0.93	9.47 ± 0.67	65.55 ± 2.77	2.79% strain
ComfortTrack	22.00 ± 1.27	14.08 ± 1.17	7.92 ± 0.09	63.95 ± 1.66	3.47% strain
GT FLEX Original	31.37 ± 1.50	19.01 ± 1.67	12.37 ± 0.77	60.52 ± 3.17	2.00% strain
Taglus Premium	35.47 ± 1.07	21.25 ± 1.10	14.23 ± 1.13	59.94 ± 1.95	2.28% strain
Duran	30.83 ± 1.70	18.22 ± 0.97	12.61 ± 1.50	59.17 ± 3.26	2.67% strain
Essix ACE	31.23 ± 1.84	17.36 ± 1.43	13.87 ± 0.42	55.55 ± 1.37	2.67% strain
Biolon	34.58 ± 1.37	18.99 ± 0.53	15.59 ± 1.11	54.94 ± 1.66	2.43% strain
Zendura A	43.30 ± 1.39	22.88 ± 1.96	20.43 ± 0.57	52.77 ± 2.83	3.22% strain

Table 5 lists both absolute (MPa) and relative Remaining Stress (%) side-by-side in order to depict notable differences. For example, Zendura A presented the highest initial stress (43.30 ± 1.39 MPa), but also showed the highest Relaxation Rate (20.43 MPa/hr) and the lowest relative Remaining Stress (52.77%) after one hour. In contrast, ComfortTrack had the lowest initial stress (22.00 ± 1.27 MPa), much higher intermediate relative Remaining Stress (63.95%) and Relaxation Rate (7.92 MPa/Hr), but also the lowest final stress (14.08 ± 1.17 MPa) and therefore lowest orthodontic force.

Crack resistance

Table 6 lists the measured Impact Energy (J) and Normalized Impact Energy (J/mm) with respect to thickness of the tested thermoformed aligner materials using the customized impact tester. Statistical analysis reveals a group of five materials with the highest resistance to impact failure and cracking (OrthoClear, Essix Plus, Zendura A, Comfort Track, GT FLEX Pro); followed by REVA-1; then a group of four materials with intermediate resistance (REVA-2, Biolon, Duran, Taglus Premium). A group of three materials exhibit the lowest resistance (GT FLEX Original, Zendura FLX, Exxis ACE) to crack failure during impact testing.

Table 6. Crack resistance (Impact Energy) of 13 commercial aligner materials. Asterisk denotes statistically difference (* $p<0.05$) between aligners in different vertical bars.

Aligner materials	Impact Energy (J)	Normalized Impact Energy (J/mm)	
OrthoClear	0.687 ± 0.067	1.81 ± 0.00	*
Essix Plus	0.687 ± 0.000	1.81 ± 0.07	
Zendura A	0.687 ± 0.000	1.81 ± 0.00	
ComfortTrack	0.662 ± 0.025	1.74 ± 0.07	
GT FLEX Pro	0.636 ± 0.067	1.67 ± 0.07	
REVA-1	0.607 ± 0.047	1.60 ± 0.07	
REVA-2	0.541 ± 0.024	1.42 ± 0.14	
Biolon	0.534 ± 0.025	1.41 ± 0.07	
Duran	0.534 ± 0.025	1.41 ± 0.07	
Taglus Premium	0.509 ± 0.067	1.34 ± 0.07	
GT FLEX Original	0.484 ± 0.067	1.27 ± 0.07	
Zendura FLX	0.484 ± 0.000	1.27 ± 0.00	
Essix ACE	0.458 ± 0.000	1.21 ± 0.00	

DISCUSSION

This study presents refined characterization protocols to test the mechanical behavior of clear aligner materials. The stress strain behavior, stress relaxation, and crack resistance of 13 commercial aligner materials were determined using the developed protocols. Yield stress, yield strain, and elastic modulus were obtained under tensile load. The yield point in stress-strain curve is the transition of the material from elastic to plastic deformation [10]. The elastic modulus is a measure of the material stiffness, responsible for force generation as well as patient compliance to due to the comfort provided by materials with lower stiffnesses. If the elastic modulus of the clear aligner material is too low, the orthodontic force may be insufficient. If elastic modulus is excessively high, the patient may feel discomfort or even pain during the orthodontic treatment. Moreover, it would be difficult for the patient to insert and remove the aligners, especially when undercuts and attachments are present [11].

Prior to the yield point, deformation is mostly reversible unless time-dependent creep deformation takes place. Although it is generally observed that stiffer materials (higher elastic modulus) tend to deliver greater force per unit thickness than those with materials with lowest yield stress, linear correlation of elastic modulus and yield stress is weak for thermoformed aligner materials, with a R-square value of 0.6 (Figure 3). This is expected since macromolecular resistance to linear elastic deformation involves different mechanisms than the resistance against plastic deformation. In general, the aligner ideal material exhibits both high yield strength and yield strain for maximal area under the linear region of the stress-strain curve.

Beyond the yield point, the aligner polymer undergoes an increased displacement without significant increase in stress value. However, the deformation of the aligner in this region is permanent. Both creep and plastic deformation can result in aligner distortion and shape changes that deviate from the designed treatment. In general, aligners that exhibit higher yield strains are less likely to undergo permanent plastic deformation during insertion and removal over undercuts such as attachments and misaligned teeth. However, most aligner planning software stage the movements to be below the material yield strains. Besides, the use of smaller movement increments (0.1-0.2 mm) between aligner stages is more comfortable for the patient, and more efficient than larger movement increments (0.5-1.0 mm) [28]. Since smaller movement increments requires lower orthodontic force and aligner deformation, the yield point is typically less critical as a direct determinant of clinical aligner success. Therefore, time dependent changes such as stress relaxation and creep are more common failure modes. Due to the high variability among materials' yield strains, a relative strain value using 70% of each materials' actual yield strain was used for stress relaxation experiments.

Stress relaxation is another important property of thermoplastic materials used for orthodontic treatment. Materials with slower relaxation will provide more constant orthodontic force, and potentially more predictable tooth movement during treatment if the force is adequate [7]. Stress relaxation and creep share common macromolecular mechanisms, and therefore share the same activation energies [12, 13]. Stress relaxation and creep can be related using the following reciprocal equation (2) [14]:

$$\left(\frac{\varepsilon(t)}{\varepsilon(0)}\right) creep = \left(\frac{\sigma(0)}{\sigma(t)}\right) relaxation \qquad (2)$$

where *ε(0)* and *σ(0)* are the initial strain and initial stress response of the material, respectively. Correspondingly, *ε(t)* and *σ(t)* are the strain and stress response at time *t* during continuous loading, respectively. Therefore, the analysis of stress relaxation is similar to the creep analysis. Creep and yield point can be used to predict the shape change of aligners. Aligners that move teeth predictably with minimal unintended shape distortion can potentially reduce the need for re-scan and mid-course correction during orthodontic treatment. Furthermore, the use of 70% yield strain ensures that all specimens are tested at a similar region of the stress strain curve below the yield point. Therefore, it Is important to consider the actual strain value that each material was loaded. For thermoplastics, increases in constant strain would increase the absolute and relative relaxation, and relaxation rate, resulting in lower remaining stress, and force delivery per unit thickness.

Cracking of aligners is considered a catastrophic failure because the defect changes the force profile of the aligner, and acts as stress concentration to accelerate additional failure. Materials with higher failure energy and better durability are desirable for reducing aligner breakage and mid-course corrections [11]. High crack resistance is especially critical for patients with severe bruxism and other occlusal scenarios that overload the aligners.

Therefore, detailed characterization of aligner mechanical properties characterization may provide clinicians with insightful information that bridges the material properties and their clinic behavior. The data can also inform clinicians to choose materials based on patient factors (comfort, etc) and clinical factors (difficult vs simple movements, etc). Many previous researchers have been investigated the stress relaxation and elastic modulus of clear aligner materials using various machines and testing conditions [7, 8, 15, 16]. This project evaluated 13 commercially available aligner materials under the same testing conditions using protocols that most labs can replicate.

The mechanical properties of clear aligner materials depend on polymer composition and structural parameters such as molecular weight, polymer chain orientation, crystalline / amorphous structure, cross-links, and steric configurations. Processing history and environmental factors such as moisture, temperature, pressure, etc., also contribute to mechanical properties [11]. Thermoplastic materials, such as polyethylene terephthalate glycol (PETG), thermoplastic polyurethane (TPU), polyethylene terephthalate (PET), polycarbonate (PC), and ethylene vinyl acetate (EVA), etc., are usually used as clear aligner materials [17]. Among these materials, PETG and TPU are most commonly used due to their distinct structures [18, 19]. TPU has a semicrystalline structure, consisting of alternative hard and soft segments [20]. PETG is typically amorphous, consisting of polyethylene terephthalate (PET) and 1,4-cyclohexylenedimethylene terephthalate (PCT) [15]. Series of TPU or PETG with different mechanical properties can be produced by adjusting the ratio of hard/soft segments, molecular weight, additives, etc.

Like most semicrystalline polymers, TPU typically contains at least two microstructural phases: crystalline phase and amorphous phase. The crystalline phase exhibits highly organized, tightly packed polymer domains that are dispersed within the amorphous phase. This kind of structure significantly reinforces the mechanical strength of the polymers [21, 22] because of the strong intermolecular forces in the crystalline phase. The crystallinity degree of semicrystalline polymers plays an important role in their physical and chemical properties [23]. Therefore, as a semicrystalline polymer, TPU aligners have excellent mechanical strength [24]. This was confirmed in our stress strain testing, where TPU material (Zendura A) showed the highest elastic modulus and yield stress among the 13 materials tested. However, TPU is highly hygroscopic and can absorb atmospheric moisture quickly. In order to prevent bubble formation during thermoforming, most TPU manufacturers recommend immediate processing within 30 minutes of opening the package and exposing the material to normal environmental conditions.

In contrast, PETG and other amorphous polymers contain no or limited crystalline region. The intermolecular forces in amorphous materials are typically weak secondary bonds such as Van der Waals or dispersion forces that are significantly smaller than the intermolecular forces formed between polar groups within the crystalline regions of semicrystalline polymers. The weak intermolecular forces prevent the tightly packing of polymer chains and limit the elastic modulus and tensile strength of amorphous polymers. Table 3 shows that compared to TPU, PETG aligner materials usually have smaller yield stress and elastic modulus. An advantage of amorphous polymers is that they usually have higher clarity due to the lack of crystalline regions [17, 25].

The present results suggest that aligner materials prepared with TPU (such as Zendura A) exhibit a higher elastic modulus. On the other hand, aligner materials made out of PETG have a lower elastic modulus. The different materials with PETG as main component showed different elastic moduli too. These differences among PETG may be explained by their different additives, molecular weight, or relative ratio of different polymer segments in their structures, which could lead to a broad range of elastic moduli in these materials [19, 33]. Although PETG has less mechanical strength than TPU, PETG aligners offer more than sufficient forces to move teeth orthodontically. For example, the ideal orthodontic force ranges from 0.35 to 0.60 N based on Proffit's theory [26]. A typical PETG material, Biolon (a PETG aligner material with a yield stress of 38.01 MPa), can easily provide 4 to 16 times more force than the ideal force [16]. Based on these values, the PETG material ComfortTrack with lower yield stress (22.08 MPa), can provide 2-9 times the required force to move patient's teeth for treatment purposes, assuming uniform intimate contact between aligner and dentition [27].

The more important question is whether these forces are sustained. Due to the viscoelastic nature of the clear aligner material, clear aligners cannot provide constant orthodontic forces even under low-strains within the elastic deformation regime. This results in creep deformation, stress relaxation, and diminishing forces throughout clinical use. Therefore, materials that undergo lower stress relaxation may be more likely to promote accurate and precise tooth movement [7]. Therefore, a protocol that can accurately measure the stress relaxation rate of aligner polymers is crucial for their relaxation evaluation. A small deflection amount (low strain) during the relaxation testing would lead to a small relaxation rate. Thus, it may be unable to identify differences between various materials. Too high of a deflection (high strain) may lead to specimen "necking" or even rupture during testing and produce inaccurate relaxation result due to the permanent deformation. Since stress relaxation highly depends on the mechanism of macromolecular rearrangement under load, we limited the deformation to the elastic regime for all 13 aligner materials by testing specifically at a relative constant strain equal to 70% of each material's yield strain. This approach overcomes the problem of using one fixed strain, which is complicated by the large range of yield strains for these 13 materials (from 2.85% for GT FLEX Original – 5.17% for REVA-1). If the arbitrary constant strain is set too low, e.g. 1%, testing time becomes impractically long. If an arbitrary constant strain, e.g. 2.5%, is fixed for all materials, the same 2% strain results in different macromolecular deformations for the low and high yield strain materials. Furthermore, when new aligner materials with lower yield strain (e.g. 2.4%) become available in the future, a comparison against legacy materials is not possible by using the fixed-strain approach. The relative-strain approach allows for the evaluation of all materials inducing similar elastic deformations at the macromolecular level. Moreover, in our study no “necking” phenomenon was observed for any material during stress relaxation testing, allowing for straightforward comparison among various materials. These findings are consistent with previous reports of rapid stress relaxation during the initial 60 minutes. It should be noted that for the same polymer composition and all else kept constant, thicker samples of the same material tend to undergo less stress relaxation. The two Essix materials are supplied in sheets with a thickness of 1.0 mm, the two GT FLEX materials were 0.80 mm in thickness, and the rest were supplied as sheets with a thickness between 0.75-0.76 mm. Some of the thickness differences persisted even after thermoforming and contributed to stress retention.

From this study, we can see that the manufacturers were continuously improving their materials. GT FLEX Pro is the next generation material of GT FLEX Original produced by Good Fit Technologies Inc. The upgraded GT FLEX Pro had a similar yield stress as GT FLEX Original, but showcased significantly reduced stiffness when compared to GT FLEX Original (1177.77 MPa vs 1530.04 MPa, $P < 0.05$). Therefore, the aligners made of GT FLEX Pro are expected to deliver less orthodontic forces, and have increased patient comfort. The yield strain of GT FLEX Pro increased from 2.85% to 3.98% ($P < 0.05$), and extended the elastic region of the material during mechanical loading. The upgraded GT FLEX Pro exhibited a smaller relative relaxation compared to the previous material (34.45% vs 39.48%), therefore, it can exert more constant, albeit lower, orthodontic forces over time relative to GT FLEX Original. Most importantly, the crack resistance of the upgraded material improved from 1.273 J/mm to 1.674 J/mm, increasing the durability and toughness.

A similar product offering exists for Essix materials produced by Dentsply International. Essix generally consists of 95% copolyester and 5% of patent proprietary components [34]. There are over 10 types of Essix brand plastics. Essix ACE combines the features of Essix A+ and C+, and usually behaves well in clear aligners and retainers, with the exception of occasional cracking events [35, 36]. Essix Plus was released subsequently to increase its durability and make it more crack resistant than standard Essix materials. Our testing found that when compared to Essix ACE, Essix Plus has a much higher failure energy (1.808 vs 1.206 J/mm), higher yield strain (5.03% vs 3.81%). and less stress relaxation (33.06% vs 44.45%). These materials were described to illustrate their differences, and there is no intent in any way to endorse any one product. Besides Essix ACE and GT FLEX Pro, several other materials also provide similar combination of high crack resistance, low stress relaxation, intermediate modulus, and high yield strain. Also, there are other products with similar profiles as Exxis ACE and GT FLEX Original. This report merely provides objective test data to inform clinicians.

Recently, several multilayers aligner materials were introduced into the market. These are typically engineered by laminating two or more different materials to form a unique composite sheet, which has the potential to combine the advantages of various materials. The tri-layer Zendura FLX consists of a middle TPU layer sandwiched between two outer PETG layers. Compared to the single-layer TPU material Zendura A, Zendura FLX showed relatively lower elastic modulus and yield stress (thus better patient comfort), but greater yield strain (thus better ductility). Most importantly, the relative remaining stress of Zendura FLX after one-hour relaxation was significantly higher than that of Zendura A (67.60% vs 52.77%). However, Zendura A still delivered higher forces (22.88 MPa for Zendura A vs only 15.22 for Zendura FLX) after one-hour due to a much higher initial stress profile (43.30 MPa for Zendura A vs only 22.92 for Zendura FLX). However, the single layer TPU material (Zendura A) has significantly higher crack resistance (1.81 J/mm vs 1.27 J/mm).

Similarly, REVA-1 is a single-layer PET copolyester, and REVA-2 is a double layer material containing PET copolyester and TPU . Similar to the Zendura pairing, the bilayer REVA-2 material also exhibits a lower elastic modulus, a lower yield stress, less relative stress relaxation, and less crack resistance than the single layer REVA-1. Therefore, the multilayer materials from Zendura and REVA can potentially provide more patient comfort and more constant orthodontic forces due to more gradual stress relaxation than their single-layer counterparts, which are more resistant to cracking and can deliver greater forces. The REVA and Zendura materials were described to illustrate the influence of material properties, without any intent to endorse any products. Indeed, some single layer materials surpass the multi- layer materials in the tested parameters.

The mechanical properties of clear aligner materials can also be affected by the environment conditions during storage and clinical application. A major limitation of this study is that it just focused on the physical properties of pure aligner materials, but ignored the environmental conditions involved during clinic application, such as the oral temperature, abrasive wear, the contact with human saliva containing bacteria, water, ions, enzymes, etc. These parameters may alter the order of mechanical properties of the materials, and the impact could be quite variable even within each polymer class, since most of the formulations are proprietary. As reported by Fang et al [8], water immersion at elevated temperature would significantly accelerated the stress relaxation of aligner materials. While the relative rank order from dry testing should be preserved, future work will evaluate the biomechanical properties of aligner materials under various storage and simulated oral environmental conditions.

Another major limitation is the inability to obtain flat aligner sheets from manufacturers who will only provide finished net-shape aligners, including the direct 3D printed aligners. This precludes direct head-to-head comparison between flat sheet providers and finished aligner manufacturers. Our team has previously reported the feasibility of using dynamic mechanical analysis (DMA) and time temperature superposition to characterize miniature specimens extracted from finished aligners. Our team will be presenting our DMA findings in a future report, but DMA is a relatively complex equipment that only a few orthodontic departments have appropriate expertise and access to. In order to maximize the data collection from other investigators, we are currently developing and sharing a more practical method to characterize miniature specimens using common instruments that are more accessible. This development will allow objective testing of all aligner materials properties before, during, and after clinical use, regardless of manufacturers ability to provide flat sheets.

This study also did not evaluate other important parameters that influence processing ease, such as the easy of trimming and polishing after thermoforming. Parameters such as visual clarity and stain resistance are outside the scope of this study. Also, how these materials interact with oral bacteria and the cleaning agents were not included in this report.

The differences in mechanical behavior among commercial aligner materials provide orthodontist more choices during material selection. The orthodontists need to strike a balance between force required to move teeth, patient comfort, patient compliance, and crack resistance. The large variability in aligner properties is exceeded only by the large variability in patient needs. Cases requiring high orthodontic forces may require materials with high elastic modulus and yield strength, crack resistance, and low stress relaxation. For heavy bruxers, the use of highly crack resistant materials is most critical. For highly sensitive patients, materials with low modulus, and staging with smaller incremental movements may be preferred. The data presented in this paper may provide the orthodontist with a data-driven approach to select materials based on clinical needs. The informed clinician may use this data for materials selection, or relate the findings with treatment outcome and patient surveys to confirm or debunk existing beliefs.

CONCLUSIONS

The findings of this study show that the commercial aligner materials from different manufactures offer wide ranges significant differences throughout important mechanical properties. Even though this study did not consider their application conditions (oral temperature, saliva, bacteria, etc.), the following conclusions can be drawn:

a. The thirteen materials differ greatly in elastic modulus. Statistical analysis reveals three materials with statistically higher stiffness (Zendura A, Taglus Premium, GT FLEX Original) than the rest ($p<0.05$), and one material with the lowest stiffness (ComfortTrack). The eleven single-layer materials have modulus values ranging from 641 MPa to 1548 MPa, with some stiffer materials exhibiting over 2.4 times higher elastic modulus than the softer materials. The two bilayer materials exhibit less variability in elastic modulus, ranging from 975 MPa to 1043 MPa.

b. One material has the highest yield stress (Zendura A); followed by a group of five aligners with moderately high yield stress (Taglus Premium, REVA-1, Biolon, Essix Plus, Duran); a group of 5 aligners with medium yield stress (GT FLEX Original, OrthoClear, Essix Ace, GT FLEX Pro, REVA-2), and two materials with the lowest yield stress (Zendura FLX and ComfortTrack).

c. The data identifies a group of 4 materials with higher yield strain (REVA-1, Essix Plus, ComfortTrack, REVA-2); followed by a large group with intermediate yield strain, and two materials with the lower yield strain (Taglus P, GT GLEX Original). The eleven single-layer materials have yield strain ranging from 2.85% to 5.17% strain, while the two bilayer materials range from 4.31% to 4.82%.

d. Statistical analysis reveals a group of seven materials with the lowest stress relaxation (Zendura FLX, OrthoClear, REVA-2, Essix Plus, REVA-1, GT FLEX Pro, Comfort Track); followed by a group of four materials with intermediate relaxation (GT Flex Original, Taglus Premium, Duran, Essix ACE); and a group of two materials that exhibit the most relaxation (Biolong, Zendura A).

e. The data shows a group of five materials with the highest resistance to impact failure and cracking (OrthoClear, Essix Plus, Zendura A, Comfort Track, GT FLEX Pro); followed by REVA-1; then a group of four materials with intermediate resistance (REVA-2, Biolon, Duran, Taglus Premium). A group of three materials exhibit the lowest resistance (GT FLEX Original, Zendura FLX, Exxis ACE) to crack failure during impact testing

f. The aligner materials made primarily of TPU have high yield strength, stiffness, and crack resistance, but several non-TPU materials also offer high crack resistance with lower stiffness that may improve patient comfort.

g. The aligner materials made primarily of TPU materials undergo faster rates of stress relaxation, but several non-TPU materials also relaxed rapidly.
h. The multilayer materials combined the advantages of several materials, and usually exhibit a more optimal blend of mechanical properties. While some single-layer materials show superior combination of mechanical properties to multilayered materials, most single-layers are not as optimized as multilayers.

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Respond to the following questions:

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