Force decay in thermoformed aligner plastic sheets: An in vitro comparison study

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Abstract

Force Decay in Thermoformed Aligner Plastic Sheets: an in-vitro comparison study

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Clear aligner therapy has fundamentally changed with the integration of computer-aided design (CAD) and manufacturing (CAM) technology. The efficacy of aligner treatment is impacted by numerous factors among which the properties of aligner material play a significant role. A plastic sheet property is a function of its structure (multi vs monolayer sheet), composition and type of material, and thickness. All these factors collectively influence the levels of force induced by the aligner. Given the increasing popularity of clear aligners and the multitude of companies producing different aligner plastic trays, a need for a comparison study of various aligner plastics becomes evident. This study aimed to evaluate the force decay levels of an array of commonly used aligner plastic sheets to determine how structure, thickness, and material type influence the force decay signature of an aligner plastic sheet.

The force decay signatures of 10 aligner plastics (five single-layered and five multilayer) were plotted using a stress-relaxation test. The test was conducted via a three-point bending apparatus (Chatillon Digital Force Measurement CS2-225, AMETEK unit), applying a constant and controlled pre-set load. Each sample was thermoformed and subjected to a deflection of 1.5mm (5% strain level) while being immersed in water at a controlled temperature (set at 37 Celsius degrees) for a total of 24 hours period. The same test was repeated three times on the different thermoformed samples.

Mean force decay as a function of time was evaluated between different samples using repeated measures analysis of variance (ANOVA) followed by post-hoc testing using Holm's

method. The force decay of each plastic sheet was analyzed based on the force decay levels in Newtons (N) and the percentage of retained force (%). Within the same structure and thickness, significant variations were found among distinct brands. Monolayer 0.75mm plastic sheets exhibited significant differences in the percentage of retained force (p-value= 0.0160) and the absolute force loss in Newtons (p-value=0.045), while the differences in multi-layer 0.75mm sheets were marginally significant (p-value=0.061 and p-value=0.213, respectively). For 1mm plastic sheets, both the percentage of retained force (p-value= 0.0020) and the force decay levels in Newtons (p-value=0.0010) were significant. Regarding the structure of aligner sheets and the force decay, a significant difference between multi-layer and single-layer in the percentage of retained force was noticed (p-value = 0.025; 95% CI 1.4N to 21.3N), with the multi-layer plastic sheets exerting less initial force loads and demonstrating lower levels of force decay over 24 hours. Plastic thickness significantly influenced force decay levels (p value=0.0031). However, individual brand analysis revealed significant differences. Specifically, for Z Classic both the percentage of retained force (p-value=0.0040) and the force loss in Newtons (p-value=0.000153) were significant. Taglus aligner plastic exhibited a significant difference in the force loss in Newtons (p-value=0.0380), but not in the percentage of retained force. No statistical difference was found between the 0.75mm and 1mm replicates for the Atmos plastic.

This study underscores aligner plastics' distinct force decay signatures, influenced by structure, brand variation, and thickness. It was concluded that the multi-layer plastic sheets exhibit lower initial force loads with a more controlled force decay for 24 hours. Aligner sheets with similar thickness and structure exhibit differing force decay behaviors, influenced by both material composition and manufacturing process. Plastic thickness is also a factor that affects the force decay signatures, especially evident in specific brands. The unique behavior of each plastic sheet could signal performance differences during active aligner treatment and retention post-treatment. Implementing a universal force level protocol for measuring the plastic force levels is crucial. This would standardize testing methods, allowing clinicians to accurately compare the commercially available plastic sheets.

Table of Contents

LIST OF FIGURES:

LIST OF TABLES:

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INTRODUCTION:

The public interest in esthetic orthodontics has led to an exponential growth in the demand for clear aligner treatment hence the introduction of numerous aligner systems and aligner plastics[1]. A recent report states that orthodontic treatment with aligners now represents 30-45% of an orthodontic practice caseload, and patient preferences and awareness of aligner treatment are increasing.

Evolution of clear aligner therapy

The origin of aligner therapy goes back to the early 1920s, with Orrin Remensnyder introducing an appliance made of soft rubber, covering the clinical crowns and the marginal gingiva. This device was designed to stimulate inflammatory gingiva and lead to minor tooth movements through the pressure of the masticatory forces on the soft rubber[2]. In 1945, Harold D. Kesling refined Remensnyder's approach by developing an appliance, regarded by some as the precursor of clear aligner therapy. The appliance was known as the *Tooth Positioning Appliance*, designed to serve minor finishing adjustments and function as an active retainer. Composed of a one-piece vulcanite rubber mold based on a wax-up treatment simulation (setup), these positioners were pivotal in orthodontic practice[3]. A decade later, Henry Nahoum introduced the first ever documented thermoplastic appliance[4]. The appliance was fabricated using an industrial grade vacuum former and the creator named it the *Dental Contour Appliance* [5]. Subsequently, Robert J. Ponitz introduced a more efficient process to manufacture an *invisible* retainer, using a vacuum unit[4]. The proposed material for the fabrication of the *invisible* retainer was Biocryl (polymethyl methacrylate), which was made of cellulose acetate butyrate, polyurethane (PU), polyvinyl acetate-polyethylene polymer, polycarbonate-cycolac, and latex[6].

In 1993, John J. Sheridan introduced the *Essix* appliance. The philosophy behind the *Essix* retainers was to provide a more efficient and esthetic way of retaining the anterior canine-to-canine segments while allowing for molar band space closure and settling in the occlusion after the end of treatment[7]. It was not until 1998 that aligner treatment started more traction in the orthodontic community with the introduction of the *Invisalign* aligner system. It has been reported that over two million patients were treated with Invisalign worldwide[8]. Currently, about seventy-five aligner systems provide comparable products to clinicians delivering aligner treatment to their patients[7]. In addition to mass-manufactured aligner systems, such as Invisalign or Sure Smile aligners, in-office and local lab aligner systems exist on the market.

Thermoforming Plastic Types in Orthodontics

Thermoforming plastics are used in orthodontics for active tooth movement and retention post-treatment. The orthodontic thermoplastic materials should have specific characteristics including biocompatibility, transparency, low hardness, good elasticity, resilience, and resistance to the intra-oral environment[9]. The polymers (either individual or blended) most frequently used for aligner plastics are polyester or co-polyester, polyurethane, polypropylene, and polycarbonate among others[7,10]. Among the polyesters, polyethylene terephthalate (PET) and polyethylene terephthalate glycol (PETG), a non-crystallizing amorphous copolymer of PET, are chosen for aligner sheets primarily due to their high fatigue resistance, dimensional stability, and transparency[10]. Thermoplastic polyurethane plastic sheets (TPU) are also frequently used for the fabrication of aligners, mainly due to their excellent elasticity and durability[11]. TPU composition is described as a combination of linear segmented block copolymers having hard and soft segments, and they are versatile biomaterials with a wide range of applications in medical devices and orthodontics[12]. More specifically, under load thermoplastic polyurethane plastic sheet undergoes deformation but can revert to its original shape when the load is removed due to the material's flexibility[7]. The material also exhibits high tear resistance and a wide range of resiliency[13].

Clear aligner materials have evolved significantly from single sheets to multilayer materials that often comprise hard and soft layers[7]. In the earlier years, the plastic sheet used in the Invisalign appliance was initially composed of a single-layered polyurethane (EX-30) (methylene diphenyl diisocyanate, and 1,6 hexanediol) thermoplastic material, claimed for its flexibility, breakage resistance, and transparency[1]. As part of the ongoing enhancement of the Invisalign system, align technology introduced *SmartTrack* clear aligner material, a multilayer thermoplastic polyurethane co-polyester plastic material. Based on Li et. al.'s patent, this multilayer plastic comprises a hard polymer layer disposed between two soft polymer layers[14]. While the soft layers offer elasticity, the hard layer ensures strength and durability[15]. Several aligner systems report using multilayer plastic sheets similar to the ones used by align technology. The nature of difference among various three-layer aligners is inconclusive since companies are withholding the information. Alternative to SmartTrack structure, Bay Materials, LLC has developed an alternative aligner sheet called Zendura FLX. This material consists of three layers with an inner elastomeric layer encapsulated between two hard outer shells. The exact composition is proprietary, but it is reported that the core is polyurethane[16]. The two patents around three-layer plastics currently belong to Covestro/Aligner Technologies and Bay Materials, LLC.

Mechanical behavior of the plastic

The mechanical performance of the plastic sheet is one of the main factors contributing to achieving successful clinical outcomes. The mechanical properties are influenced by the elastic modulus, the tensile yield strength, and the stress relaxation or force decay levels. Elastic modulus is described as the ability of the material to resist a deforming force, by returning its original shape when the force is removed[9]. Tensile stress refers to the force applied per unit area of the material, where plastic deformation starts to occur. Finally, stress relaxation or force decay of the aligner is regarded as one of the most critical mechanical properties associated with the aligner's clinical performance. Stress relaxation is defined as the decrease in the force load of the aligner over time, under constant deflection[17].

The in-vitro assessment of force decay levels

Multiple studies quantifying the stress relaxation and performance of materials with different compositions are reported in the literature. Most of these studies evaluating the mechanical properties of the aligner's materials are predominately in vitro, due to sample size and shape limitation of the processed plastics[16].

Studies comparing the stress relaxation between different material structures revealed that the dual-layer sheets experience less decay compared to the monolayer ones [1]. Additionally, Zhang et al. emphasized the importance of the blending ratio between the layers of the thermoplastic material, with blending PETG/PC/TPU at the 70/10/20 ratio showing improved mechanical properties compared to other blending ratios[10]. Jia et. al. also concluded that the ratio of the soft layer to the lard layer is important for fabricating a multilayer aligner sheet, and it should be more than 50% when designing multilayer aligners[18]. The properties of the aligner materials are also reported to be influenced by the molecular design and chemical structure of each polymer in the blend[12]. Moreover, several studies noticed that the aligner materials demonstrated a rapid force decay during the initial loading cycles[17].

The influence of different material thicknesses on aligner-induced force level

The literature also focuses on the effect of aligner thickness on its clinical performance. More specifically, a study investigated the effects of the mechanical properties of thermoplastics during the exertion of the initial force by comparing three materials (Duran/PETG, Erkodur/PETG, Hardcast/PP) with two different thicknesses. It was concluded that the *Hardcast* had significantly lower elastic modulus and hardness. Furthermore, it was stated that appliances made from a thicker material always produced greater force than those from thinner and the reduced amount of the aligner's activation produced higher force[19]. More specifically, a thicker material which exerts greater force would necessitate less activation compared to a thinner material to achieve similar force levels. Additionally, it was stated that the forces and moments by the PET-G (Polyethylene terephthalate glycol) aligner materials on teeth vary and depend on the material thickness, width of the aligner edge, and direction of tooth movement [20]. Moreover, Iliadi et al. found no clear difference between 0.5mm and its counterpart of 0.625 mm or 0.750 mm in the moment-to-force ratio[21].

The mechanical properties of aligner materials are highly associated to the efficacy of aligner treatment, thus investigating the factors that influence their performance is crucial. An ideal aligner sheet should exert constant and low force, to efficiently produce the intended tooth movement[10]. The current literature supports that factors such as the thickness, chemical composition, and structure of aligner materials are highly related to the force decay signature of the aligners.

Purpose of the Study

The project's purpose was to evaluate the force decay signatures (force reduction as a function of time) of a wide array of frequently used aligner materials in a consistent experimental protocol mimicking the oral environment. Plastic sheet's force decay signature of various brands at different thicknesses and structures was studied. The brand of an aligner is a proxy measurement of its material type and plastic composition. The most clinically used thicknesses of all the thermoplastic materials were included in this study. The aim was to provide clinicians with a dataset of common aligner force decay signatures, offering an objective tool assisting with the decision of selecting their aligner plastic of choice.

MATERIALS AND METHODS:

Aligner plastic sheets in this study

Ten different commonly used thermoforming plastic sheets in clinic were used in our study.

Table 1 presents the details of these plastic sheets.

Table 1 Aligner plastic sheets

Brand	Company	Thickness	Material	Structure
Zendura FLX	Bay Materials LLC	0.75mm	Polyurethane (PU) & Polyester (PES)	Three layers
Tristar	Tristar	0.75mm	Polyurethane (PU) & polyethylene terephthalate glycol (PETG)	Three layers
CA Pro	Scheu-Dental	0.75mm	Polyester (PES)	Three layers
Max Flex II	Max Flex	0.75mm	Polyurethane (PU) & Polyester (PES)	Three layers
Max Flex I	Max Flex	0.75mm	Polyurethane (PU) & Co-Polyester (PES)	Three layers
Zendura A	Bay Materials LLC	0.75 & 1mm	Polyurethane (PU)	Single layer
Taglus	Taglus	0.75 & 1mm	Polyurethane (PU)	Single layer
Atmos	American Orthodontics	0.75 & 1mm	Polyethylene terephthalate glycol (PETG)	Single layer
Essix ACE	Dentsply Sirona	0.75mm	Co-polyester	Single layer
Essix Plus	Dentsply Sirona	1mm	Polypropylene	Single layer

Test apparatus

Measurements were conducted using a Chatillon Digital Force Measurement CS2-225, AMETEK unit, in a three-point bending test setup. The loading capacity of the sensor was 10 lbf and a resolution of 0.001 lbf. An upper roller anvil with a 2mm diameter was utilized, along with a similar-sized roller fixture. Data was automatically recorded on the unit computer. The CS2-225 unit provided a large working area with a 180mm throat depth and a 500mm crosshead speed.

Increased temperature and immersion time of the plastic in an intra-oral environment affect the behavior of the thermoplastic material[22,23]. Hence for this study, every material was tested in a wet environment with a controlled temperature. To mimic the average oral temperature, all the experiments were conducted within a water bath filled with distilled water and a temperature controller set at 37 Celsius degrees. The water bath consists of a metal alloy heating element that is fused directly to the surface of the bath and then covered with a tough silicone rubber layer and fabric insulation layer that serves as a thermal barrier, according to the manufacturers[24]. The temperature controller was the model 250 Heating and Cooling outlets, with the heating outlets supplying 1800 watts of power for large equipment and heating units up to 22L[25].

Sample preparation

A block of 30mm x 60mm x 10mm (height x length x width) was designed to partially mimic the dentition and how these plastics morph around the tooth unit. The blocks were printed on a Sprint Ray 3D printer. Plastic sheet samples were thermoformed on a 3D-printed version of this block. Thermoforming was performed using a positive pressure former with a thermally controlled infrared heater, which is programmed digitally with a three-digit code that specifies temperature, heating, and cooling times[26]. For each material, we used thermoforming codes recommended by the manufacturers. After the thermoforming of the sheets was completed, a flat section of thermoplastic plastic sheets was used in all experiments. The dimensions of each specimen were 60mm x 30mm (height x length). Each plastic sheet was marked with its respective brand and thickness and stored in a lab setting, before mounting on the bending test. The study used ten commercially available aligner plastics comprising five monolayer and five multilayer plastic sheets. The multilayer thermoforming plastics included in this project were three-layer plastic sheets. We use both formats of a flexible elastomer core in a hard-elastic double shell, or one hard layer encased within two flexible elastomer outer shells.

Experimental Set-up and Procedure

Thermoformed and trimmed plastic sheets at 60mm x 30mm were loaded on the fixture for the experiment's initiation. The water bath temperature reached 37 degrees and a stable read-out for 30 minutes before starting each three-point bending test. The loading pin was moved toward the sample until the 5 Newton force detection was achieved. At that point, the unit was set to zero. The amount of initial deflection was calculated based on the 5% strain of plastic sheets at the experiment setting, which corresponded to a 1.5mm displacement of each plastic sheet. The loading cell recorded the data for 24 hours, with a data interval of 10 Hz.

Data collection

The load cell readouts over 24 hours were stored in the Chatillon Digital Force Measurement unit. A plot of force levels as a function of time was generated for each experiment. The 24-hour graph for each experiment was visually evaluated to avoid potential experimental glitches. Three replicates for each experiment were conducted and the mean average and standard deviation were reported. The force values at immediate loading (T0), 1, 3, 6, 12, 18, and 24 hours were analyzed.

Statistical Analysis

Statistical analyses were done using the R statistical software (R Foundation for Statistical Computing, Vienna, Austria). Assessment of the force decay of individual materials was conducted, considering both the absolute loss of force in Newton (N) and the percentage of retained force (%). Through the measurement of the initial force applied during the three-point bending test and subsequent comparison with the force recorded at later stages, we were able to evaluate the absolute change in the force decay of each plastic sheet. Assessing the percentage of retained force overtime allows us to compare various plastic sheets based on their initial force levels. In other words, a reduction of 5 N force in the first three hours in a plastic sheet with an initial 20 N of force is different than a plastic sheet with a 10 N initial force.

The data analysis includes three phases. Initially, emphasis was placed on investigating the impact of various brands possessing similar thickness and structure on the levels of force decay. This involved segmenting the data from 0.75mm multi-layer aligner plastic sheets from the 0.75mm and 1mm mono-layer polymers included, enabling an independent evaluation of their respective behaviors. Secondly, a comparative analysis was conducted to assess discrepancies among aligner plastics of identical thickness (0.75mm) but different structures (monolayer versus multi-layer aligner sheets). Lastly, our study aimed to evaluate the impact of varying thicknesses on aligner plastics of consistent structure and brand.

Descriptive statistics were employed to analyze the mean force decay of each thermoforming aligner plastic, utilizing a one-way analysis of variance (ANOVA) method, followed by post hoc analysis. The predetermined level of significance was established at $p \leq 0.5$. To be more specific, descriptive statistics were implemented to assess the average force decay at seven distinct time points (T0, T1, T3, T6, T12, T18, T24) across the 24-hour experiments, between the three replicates of each plastic sheet. Standard deviations were computed to measure the dispersion of data around the mean force decay value for each time point, while the range of force decay values was used to determine the variability within the dataset. Linear regression was conducted to explore the relationship between force decay and time. Post hoc analysis was included to further elucidate any observed trends from the one-way ANOVA and linear regression statistics.

RESULTS:

Part 1: Force decay levels in plastic sheets with similar structure and thickness.

This study investigated the impact of brand variation on the force decay of aligner sheets with comparable properties. This analysis was divided into three categories: 0.75mm three-layer plastic sheets, 0.75mm single-layer, and 1mm single-layer aligner plastics.

<u>What are the most important findings in all three-layer plastics at 0.75mm thickness?</u>

Force decay signatures of five three-layer plastics, measured in absolute force (Newtons). Our findings revealed statistically significant variations in force decay levels among each aligner brand throughout the 24-hour experiments (p-value = 0.0060), with each sheet demonstrating a distinct force decay signature (Figure 1.). More specifically,-post hoc analysis unveiled that the force decay signatures of the brands Z FLX, Tristar, and Max Flex I were significantly different from those of CA Pro and Max Flex II. However, there were no significant differences observed between Z FLX, Tristar, and Max Flex I. Similarly, there were no significant differences between CA Pro and Max Flex II (Table 2.). Additionally, post hoc analysis indicated that the five three-layer aligner plastics experienced a rapid decline in force within the first 3-6 hours, followed by a slower rate thereafter (Table 3.).

The percentage of retained force was then analyzed for these five three-layer plastic sheets. The overall test for differences in the percentage of retained force between the aligner brands did not reach significance (p-value=0.213). However, the retained force curves demonstrated distinct behaviors with MaxFlex I, revealing less drop in the force levels (Figure 2.). Post hoc analysis revealed a significant difference in the percentage of retained force between CA Pro and Max Flex I (adjusted p-value = 0.0199) (Table 4.). The observation of a rapid force decay during the initial 3-6 hours of each experiment, followed by a slower rate was consistent in the percentage of retained force levels (Table 5.).

<u>What are the most important findings in all single layer plastics at 0.75mm thickness?</u>

Force decay signature of five single-layer plastics, measured in absolute force levels (N). Our data revealed statistically significant variations in force decay levels among each aligner brand throughout the 24-hour experiments (p-value = 0.00170), with each sheet demonstrating a distinct force decay signature (Figure 3.). More specifically, post hoc analysis indicated that the force decay signature for Atmos was significantly different from Essix ACE (adjusted p-value = 0.00657) and Z Classic (adjusted p-value = 0.009). The difference between Atmos and Taglus was marginally significant (adjusted p-value = 0.0744) (Table 6.). Similar to the 0.75mm multi-layer sheets, post hoc analysis indicated that the four mono-layer aligner plastics exhibited a rapid decline in force within the first 3-6 hours, followed by a slower rate after that (Table 7.).

The percentage of retained force was then analyzed for these five single-layer plastic sheets. The overall test for the differences in the force decay signatures between the monolayer plastics of this study, measured in the percentage of retained force was significant (p-value = 0.045), with each sheet demonstrating a distinct force decay signature (Figure 4.). However, the post hoc analysis did not reveal significant differences between different pairs of brands (p-value= 0.045) (Table 8.). The finding of rapid decay for all plastic sheets during the initial hours of each experiment was consistent (Table 9.).

What are the most important findings in all single-layer plastics at 1mm thickness?

The overall test for differences in the force decay signature between the four 1mm single-layer aligner sheets yielded significant results when measured in Newton and the percentage of retained force, with p-values of 0.0020 and 0.0010, respectively. For both the force decay levels and retained force, the force levels plotted as a function of time for Essix Plus were different than the other three 1mm plastic sheets (Figure 5., Figure 6.). Post hoc analysis also revealed that Essix Plus was significantly different from the 3 other brands (adjusted p-value <.05) (Table 10., Table 11.). This research question also revealed statistically significant variations in the force decay levels among each aligner brand throughout the 24-hour experiments, with a rapid decline in force within the first 3-6 hours (p-value = 0.000167) (Table 12., Table 13.).

Part 2. Force decay levels between three-layer and single-layer plastic sheets with similar thickness (0.75mm).

To assess the impact of the aligner structure, a comparison was made between the five single-layer aligner plastics and the five multilayer aligner plastics, all with a thickness of 0.75mm. The force decay curves of the monolayer and the multilayer plastic sheets demonstrated unique behaviors for both absolute and percentage of retained force, with the single-layer sheets exhibiting more rapid force decay and increased initial force loads (Figure 7., Figure 8.). In terms of statistical significance, the linear regression analysis comparing the force decay signatures measured in Newton, between the monolayer and multilayer aligner plastics did not reveal any statistically significant differences (p-value =0.50; multilayer- single layered difference=1.3, 95% CI 2.4 to 5.0). On the contrary, the regression analysis comparing the percentage of retained force revealed statistically significant differences (p-value=0.025; multilayer-single layered difference= 11.4, 95% CI 1.4 to 21.3). Similar to the other findings, our results demonstrated a significant interaction between time and the multilayer and mono-layered aligner plastics with rapid decay during the initial hours of the experiments (p-value <.001) (Table 14., Table 15.).

Part 3: Force decay levels between single-layer plastic sheets with different thicknesses (1mm and 0.75mm).

To assess the impact of aligner thickness, a comparison was conducted between three types of monolayer aligner plastics, Z Classic, Taglus, and Atmos, at both 0.75mm and 1mm thicknesses. Due to brand variation, descriptive statistics were analyzed for each brand separately.

When comparing the force decay signatures of Z Classic, the force decay curves differed for the 0.75mm and 1mm thickness with the thicker sheet exhibiting increased force loads and a more controlled force decay (Figure 9., Figure 10.). More specifically, post hoc analysis verified the significant difference between the two thicknesses in Newton and the percentage of retained force, p-value = 0.000153 and p-value = 0.0040, respectively. The decay was rapid during the initial hours of each experiment (Table 16., Table 17.).

The evaluation of the force decay curves for the Taglus plastic sheet revealed, a significant difference in the force decay signatures measured in Newton (Figure 9.), p-value= 0.0380, however, the results were not significant in the percentage of retained force between the two different thicknesses, p-value = 0.973 (Figure 10.). The decay was rapid during the initial hours of each experiment (Table 18., Table 19.).

Lastly, for Atmos, the force decay signatures measured in Newton and the percentage of retained force were not significantly different (Figure 9., Figure 10.), with a p-value = 0.386 and p-value = 0.195 retrospectively. The decay was rapid during the initial hours of each experiment (Table 20., Table 21.).

Part 1: Force decay levels in plastic sheets with similar structure and thickness.

<u>Three-layer plastics at 0.75mm thickness</u>

Figure 1. Force Decay curves of five common three-layer plastic sheets (N).

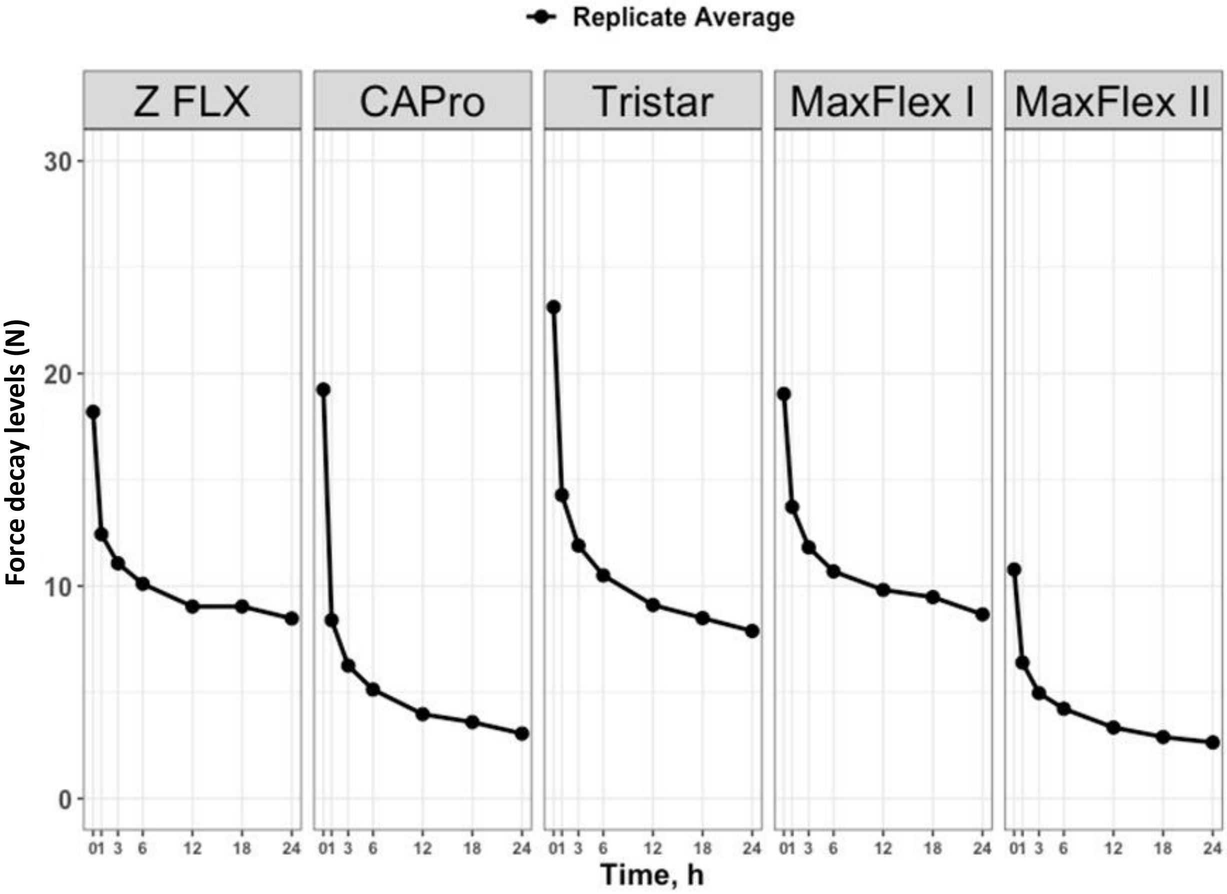


Table 2. Post ad-hoc bi-variate analysis of force levels (N) in five different three-layer plastics.

Brand	Brand	p. significance	p. adjusted
CA Pro	Max Flex I	**	1.2 e-2
CA Pro	Max Flex II	ns	7.07e-1
Max Flex I	Max Flex II	****	1.45e-4
CA Pro	Tristar	**	7.53e-3
Max Flex I	Tristar	ns	1 e+0
Max Flex II	Z FLX	****	7.42e-5
CA Pro	Z FLX	**	3.94e-2
Max Flex I	Z FLX	ns	1
Max Flex II	Z FLX	****	7.44e-4
Tristar	Z FLX	ns	1 e+0

Table 3. Descriptive analysis of Force decay levels (N) in five common three-layer plastic sheets over 24 hours.

	Time						
Brand	**0**	**1**	**3**	**6**	**12**	**18**	**24**
Z FLX							
Mean (SD)	18.2 (1.5)	12.4 (3.1)	11.1 (2.9)	10.1 (2.7)	9.0 (2.8)	9.0 (2.1)	8.5 (2.7)
Range	17.1, 19.9	9.2, 15.4	7.9, 13.6	7.2, 12.5	6.0, 11.5	6.8, 11.0	5.4, 10.8
CAPro							
Mean (SD)	19.2 (5.0)	8.4 (3.3)	6.3 (2.3)	5.1 (1.8)	4.0 (1.4)	3.6 (1.1)	3.1 (0.9)
Range	15.4, 24.9	5.0, 11.7	4.1, 8.7	3.7, 7.1	2.9, 5.6	2.6, 4.9	2.2, 4.1
Tristar							
Mean (SD)	23.1 (2.9)	14.3 (5.1)	11.9 (5.6)	10.5 (5.8)	9.1 (6.0)	8.5 (5.8)	7.9 (5.6)
Range	20.7, 26.4	8.5, 18.2	5.6, 16.6	4.2, 15.6	2.8, 14.7	2.3, 13.8	2.0, 13.2
MaxFlex I							
Mean (SD)	19.0 (2.4)	13.7 (3.0)	11.8 (2.9)	10.7 (3.0)	9.8 (3.0)	9.5 (3.0)	8.7 (2.8)
Range	17.6, 21.8	11.5, 17.2	9.3, 14.9	7.8, 13.8	7.1, 13.0	6.4, 12.4	6.1, 11.6
MaxFlex II							
Mean (SD)	10.8 (0.6)	6.4 (1.7)	5.0 (1.5)	4.2 (1.7)	3.3 (1.5)	2.9 (1.3)	2.6 (1.4)
Range	10.0, 11.2	4.8, 8.2	3.4, 6.5	2.6, 5.9	1.9, 4.8	1.6, 4.2	1.3, 4.2

Figure 2. Force Decay curves of five common three-layer plastic sheets (%).

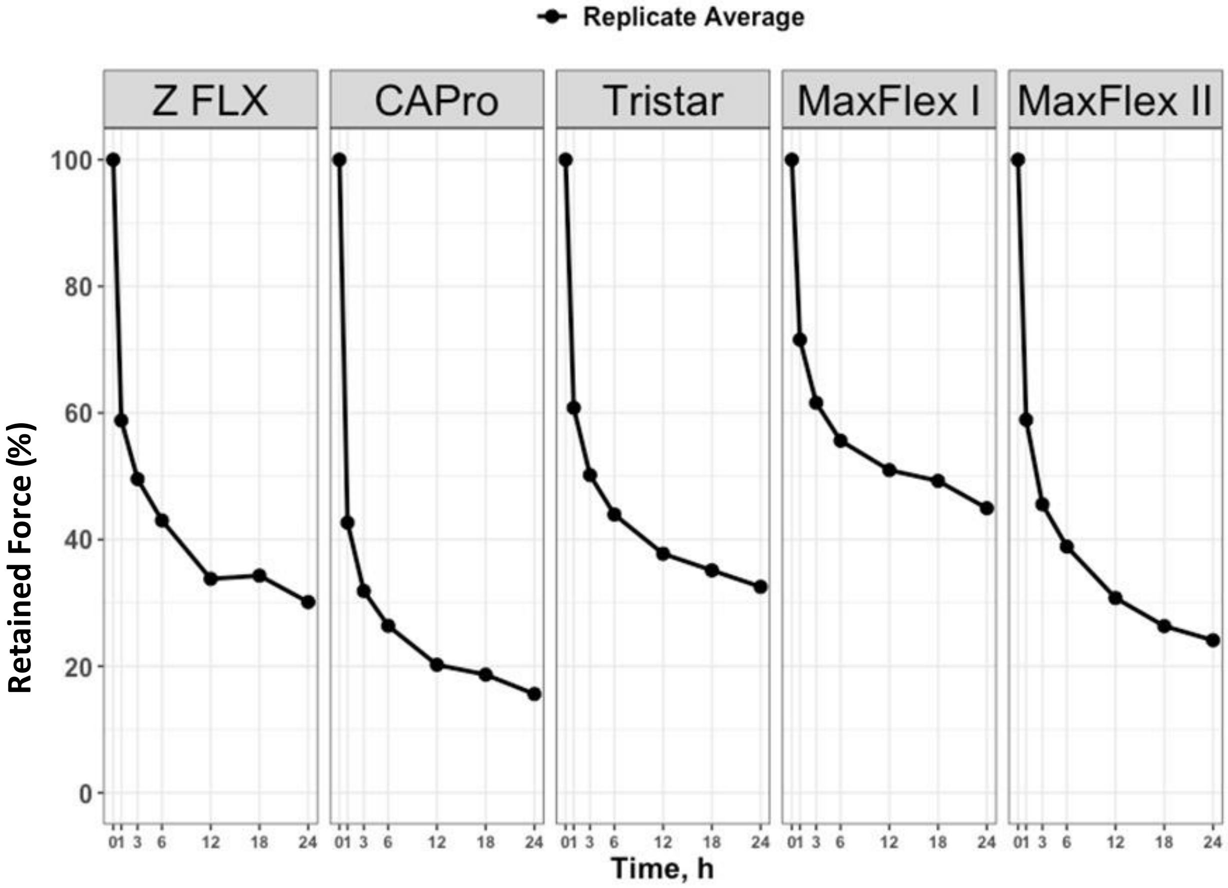


Table 4. Post ad-hoc bi-variate analysis of force levels (%) in five different three-layer plastics.

Brand	Brand	p. significance	p. adjusted
CA Pro	Max Flex I	**	0.0199
CA Pro	Max Flex II	ns	0.968
Max Flex I	Max Flex II	ns	0.491
CA Pro	Tristar	ns	0.491
Max Flex I	Tristar	ns	0.491
Max Flex II	Tristar	ns	1
CA Pro	Z FLX	ns	0.679
Max Flex I	Z FLX	ns	0.82
Max Flex II	Z FLX	ns	1
Tristar	Z FLX	ns	1

Table 5. Descriptive analysis of Retained Force (%) in five common three-layer plastic sheets over 24 hours.

	Time						
Brand	**0**	**1**	**3**	**6**	**12**	**18**	**24**
Z FLX							
Mean (SD)	100.0 (0.0)	58.8 (11.8)	49.6 (15.6)	43.0 (16.6)	33.8 (21.2)	34.3 (22.0)	30.1 (23.2)
Range	100.0, 100.0	51.0, 72.4	36.0, 66.7	27.0, 60.1	12.0, 54.4	10.0, 52.9	6.0, 52.4
CAPro							
Mean (SD)	100.0 (0.0)	42.7 (8.6)	31.9 (4.3)	26.4 (2.4)	20.2 (1.6)	18.7 (1.5)	15.6 (0.9)
Range	100.0, 100.0	32.7, 48.3	26.9, 35.0	24.2, 29.0	19.2, 22.0	17.0, 20.0	14.6, 16.2
Tristar							
Mean (SD)	100.0 (0.0)	60.8 (17.3)	50.2 (19.9)	44.0 (20.9)	37.7 (21.8)	35.1 (21.3)	32.5 (20.7)
Range	100.0, 100.0	41.0, 72.6	27.2, 62.9	20.1, 59.1	13.6, 55.8	11.3, 52.4	9.7, 50.0
MaxFlex I							
Mean (SD)	100.0 (0.0)	71.6 (7.2)	61.6 (8.3)	55.6 (10.4)	51.0 (10.2)	49.3 (11.6)	44.9 (9.8)
Range	100.0, 100.0	64.5, 78.9	52.5, 68.6	43.8, 63.3	39.8, 59.6	35.9, 56.9	34.1, 53.1
MaxFlex II							
Mean (SD)	100.0 (0.0)	58.9 (13.1)	45.6 (12.1)	38.9 (13.5)	30.8 (12.1)	26.3 (10.9)	24.1 (12.3)
Range	100.0, 100.0	47.5, 73.3	34.4, 58.3	25.8, 52.9	18.6, 42.7	16.1, 37.9	13.0, 37.3

Single-layer plastics at 0.75mm thickness

Figure 3. Force Decay curves of four common single-layer plastic sheets (N).

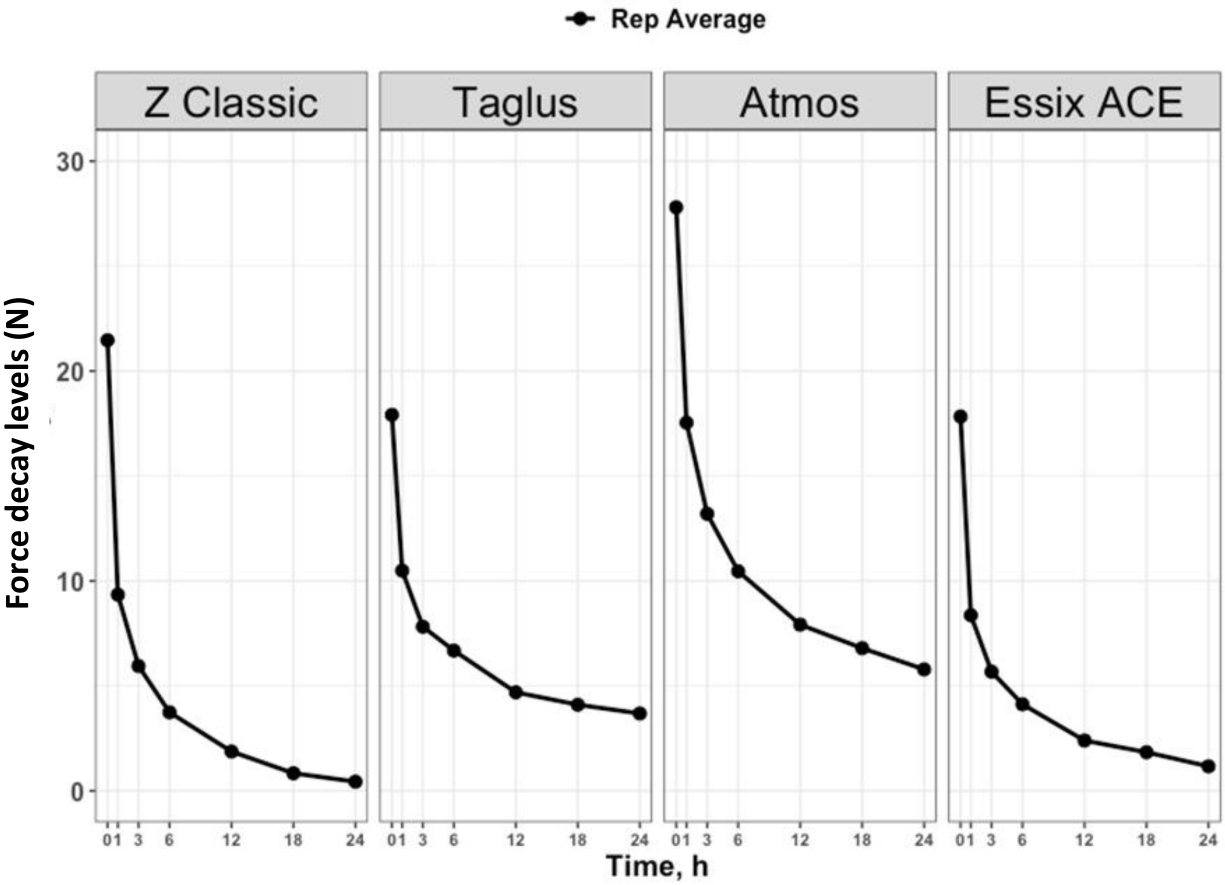


Table 6. Post ad-hoc bi-variate analysis of force levels (N) in four different single-layer plastics.

Brand	Brand	p. significance	p. adjusted
Atmos	Essix ACE	**	0.00657
Atmos	Taglus	*	0.0744
Essix ACE	Taglus	ns	0.983
Atmos	Z Classic	**	0.009
Essix ACE	Z Classic	ns	0.983
Taglus	Z Classic	ns	0.983

Table 7. Descriptive analysis of Force decay levels (N) in four common single-layer plastic sheets over 24 hours.

	Time						
Brand	**0**	**1**	**3**	**6**	**12**	**18**	**24**
Z Classic							
Mean (SD)	21.5 (0.3)	9.3 (0.9)	5.9 (0.4)	3.7 (0.6)	1.9 (0.5)	0.8 (0.1)	0.4 (0.1)
Range	21.3, 21.8	8.3, 9.9	5.5, 6.2	3.0, 4.1	1.3, 2.2	0.7, 0.9	0.4, 0.5
Taglus							
Mean (SD)	17.9 (3.2)	10.5 (3.8)	7.8 (3.5)	6.7 (2.9)	4.7 (3.0)	4.1 (2.9)	3.7 (2.6)
Range	14.4, 20.7	7.2, 14.7	4.9, 11.7	5.0, 10.0	2.5, 8.1	2.0, 7.5	1.8, 6.7
Atmos							
Mean (SD)	27.8 (0.9)	17.5 (2.2)	13.2 (2.6)	10.5 (2.9)	7.9 (3.3)	6.8 (3.1)	5.8 (3.0)
Range	26.8, 28.5	15.7, 20.0	11.1, 16.1	8.4, 13.8	5.6, 11.7	4.6, 10.3	3.8, 9.3
Essix ACE							
Mean (SD)	17.8 (4.8)	8.4 (2.8)	5.7 (1.6)	4.1 (1.2)	2.4 (1.0)	1.8 (1.0)	1.2 (0.5)
Range	12.4, 21.6	6.3, 11.6	4.5, 7.5	3.4, 5.5	1.5, 3.5	1.2, 3.0	0.8, 1.7

Figure 4. Force Decay curves of four common single-layer plastic sheets (%).

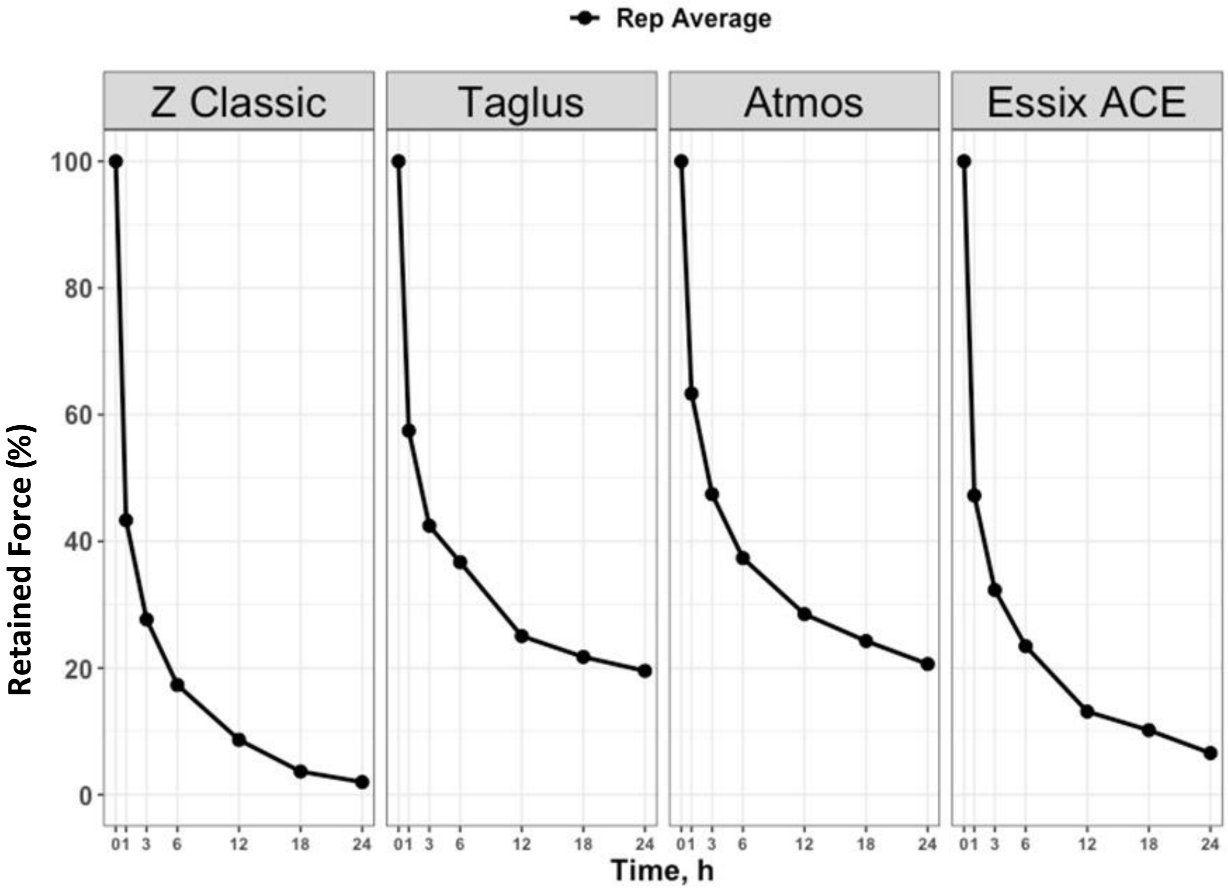


Table 8. Post ad-hoc bi-variate analysis of force levels (%) in four different single-layer plastics.

Brand	Brand	p. significance	p. adjusted
Atmos	Essix ACE	ns	0.707
Atmos	Taglus	ns	1
Essix ACE	Taglus	ns	0.853
Atmos	Z Classic	ns	0.428
Essix ACE	Z Classic	ns	1
Taglus	Z Classic	ns	0.634

Table 9. Descriptive analysis of Retained Force (%) in four common single-layer plastic sheets over 24 hours.

	Time						
Brand	**0**	**1**	**3**	**6**	**12**	**18**	**24**
Z Classic							
Mean (SD)	100.0 (0.0)	43.3 (4.6)	27.7 (2.3)	17.3 (2.9)	8.7 (2.3)	3.7 (0.6)	2.0 (0.0)
Range	100.0, 100.0	38.0, 46.0	25.0, 29.0	14.0, 19.0	6.0, 10.0	3.0, 4.0	2.0, 2.0
Taglus							
Mean (SD)	100.0 (0.0)	57.5 (11.6)	42.5 (12.2)	36.7 (10.7)	25.1 (12.1)	21.8 (12.4)	19.6 (11.0)
Range	100.0, 100.0	50.0, 70.8	34.2, 56.5	27.2, 48.3	17.2, 39.0	14.0, 36.0	12.8, 32.2
Atmos							
Mean (SD)	100.0 (0.0)	63.3 (6.6)	47.4 (8.6)	37.4 (10.1)	28.5 (11.3)	24.3 (10.9)	20.6 (10.6)
Range	100.0, 100.0	59.0, 71.0	42.0, 57.3	31.0, 49.1	21.0, 41.5	17.0, 36.8	14.0, 32.9
Essix ACE							
Mean (SD)	100.0 (0.0)	47.3 (9.1)	32.3 (5.7)	23.4 (5.0)	13.1 (2.5)	10.2 (3.5)	6.6 (1.3)
Range	100.0, 100.0	36.9, 54.0	25.8, 36.1	17.9, 27.5	11.3, 16.0	7.1, 14.0	5.5, 8.0

Monolayer plastics at 1mm thickness

Figure 5. Force Decay curves of four common single-layer plastic sheets (N).

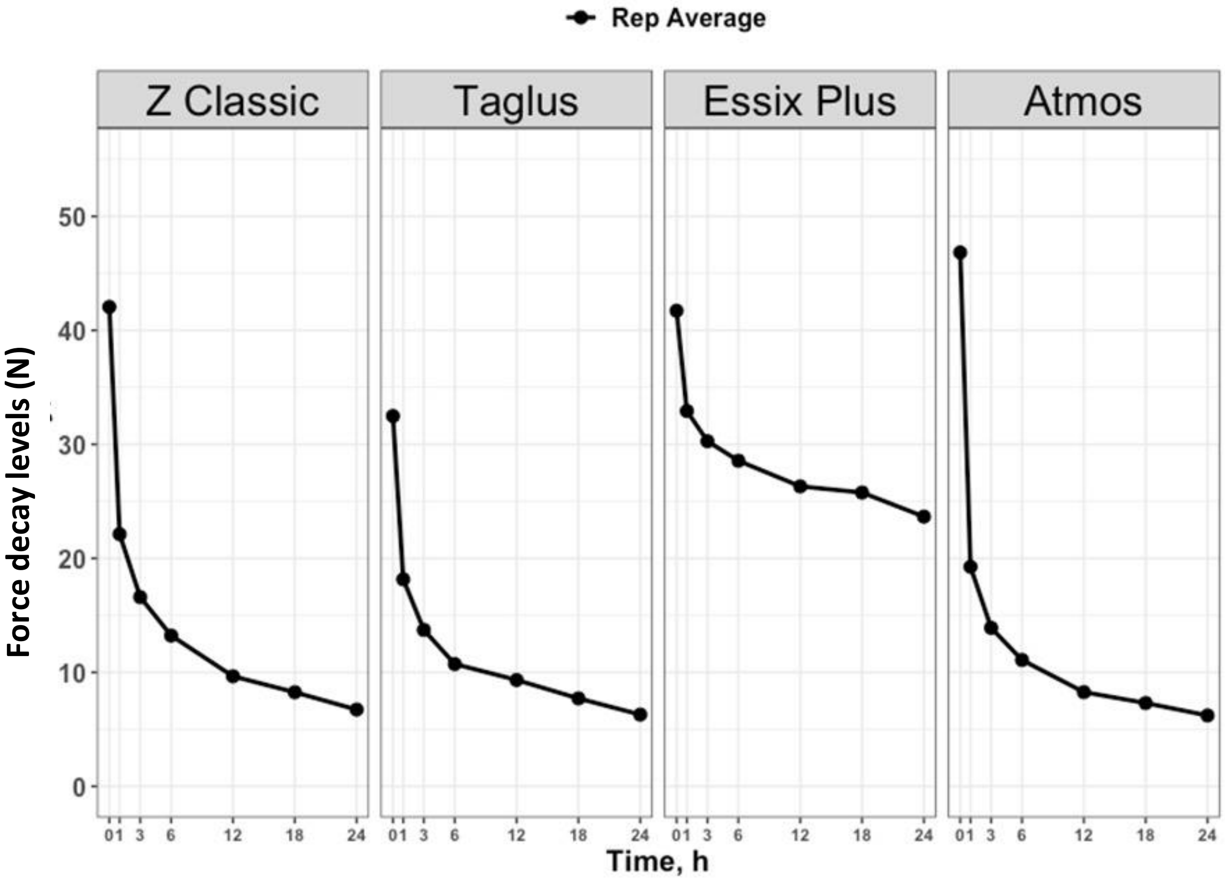


Figure 6. Force Decay curves of four common single-layer plastic (%).

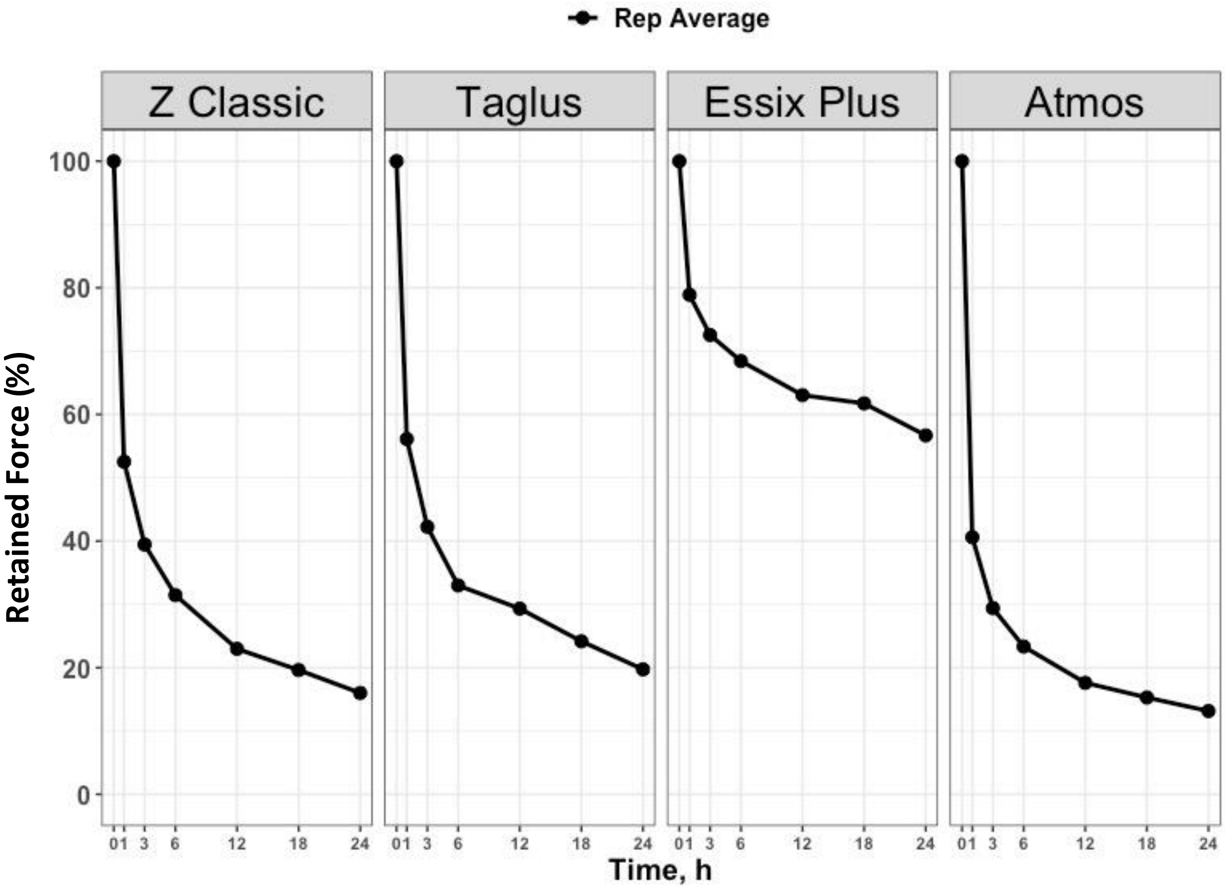


Table 10. Post ad-hoc bi-variate analysis of force levels (N) in four different single-layer plastics.

Brand	Brand	p. significance	p. adjusted
Atmos	Essix Plus	****	4.83e-5
Atmos	Taglus	ns	1 e+0
Essix Plus	Taglus	***	5.92e-5
Atmos	Z Classic	ns	1 e+0
Essix Plus	Z Classic	***	9.17e-4
Taglus	Z Classic	ns	1 e+0

Table 11. Post ad-hoc bi-variate analysis of force levels (%) in four different single-layer plastics.

Brand	Brand	p. significance	p. adjusted
Atmos	Essix Plus	****	7.14e-5
Atmos	Taglus	ns	7.46e-1
Essix Plus	Taglus	***	2.96e-3
Atmos	Z Classic	ns	8.98e-1
Essix Plus	Z Classic	***	9.59e-4
Taglus	Z Classic	ns	8.98 e-1

Table 12. Descriptive analysis of Force decay levels (N) in four common single-layer plastic sheets over 24 hours.

	Time						
Brand	**0**	**1**	**3**	**6**	**12**	**18**	**24**
Z Classic							
Mean (SD)	42.1 (1.5)	22.1 (4.0)	16.6 (2.1)	13.2 (1.2)	9.7 (0.8)	8.3 (0.1)	6.7 (0.4)
Range	41.0, 43.8	17.5, 24.9	14.3, 18.3	12.0, 14.4	9.0, 10.5	8.1, 8.4	6.2, 7.1
Taglus							
Mean (SD)	32.5 (4.4)	18.2 (2.1)	13.7 (2.0)	10.7 (1.7)	9.3 (2.7)	7.7 (1.9)	6.3 (1.6)
Range	28.9, 37.4	16.4, 20.5	12.3, 16.0	9.6, 12.7	6.8, 12.1	5.7, 9.6	4.6, 7.9
Essix Plus							
Mean (SD)	41.7 (0.4)	32.9 (4.4)	30.3 (4.7)	28.6 (4.9)	26.3 (4.7)	25.8 (5.4)	23.7 (4.3)
Range	41.3, 42.0	29.7, 37.9	26.9, 35.7	25.1, 34.2	22.5, 31.6	22.2, 31.9	20.1, 28.5
Atmos							
Mean (SD)	46.8 (4.5)	19.3 (10.6)	13.9 (7.4)	11.1 (5.6)	8.3 (4.6)	7.3 (3.5)	6.2 (3.5)
Range	43.7, 52.0	7.5, 28.1	5.4, 18.9	4.7, 14.8	3.0, 11.4	3.4, 9.9	2.2, 8.8

Table 13. Descriptive analysis of Retained Force (%) in four common single-layer plastic sheets over 24 hours.

	Time						
Brand	**0**	**1**	**3**	**6**	**12**	**18**	**24**
Z Classic							
Mean (SD)	100.0 (0.0)	52.5 (8.9)	39.5 (4.7)	31.5 (3.0)	23.0 (2.1)	19.6 (0.5)	16.0 (1.0)
Range	100.0, 100.0	42.8, 60.2	34.9, 44.2	29.1, 34.8	21.7, 25.4	19.1, 20.1	15.2, 17.1
Taglus							
Mean (SD)	100.0 (0.0)	56.1 (4.4)	42.3 (2.6)	33.0 (1.9)	29.3 (11.0)	24.2 (8.0)	19.7 (6.7)
Range	100.0, 100.0	52.4, 61.0	39.4, 44.5	30.8, 34.1	21.7, 41.9	18.3, 33.3	14.9, 27.4
Essix Plus							
Mean (SD)	100.0 (0.0)	78.9 (10.2)	72.5 (11.1)	68.4 (11.5)	63.0 (11.1)	61.7 (12.7)	56.7 (10.2)
Range	100.0, 100.0	71.9, 90.6	65.1, 85.3	60.7, 81.7	54.6, 75.6	53.8, 76.4	48.7, 68.1
Atmos							
Mean (SD)	100.0 (0.0)	40.6 (20.5)	29.4 (15.2)	23.3 (11.7)	17.6 (9.2)	15.3 (7.2)	13.2 (7.1)
Range	100.0, 100.0	17.0, 54.0	12.0, 39.8	10.0, 31.5	7.0, 23.8	7.0, 19.9	5.0, 17.5

Part 2. Force decay levels between three-layer and single-layer plastic sheets with similar thickness (0.75mm).

Figure 7. Force Decay curves of four common one-layer and four multi-layer plastic sheets (N).

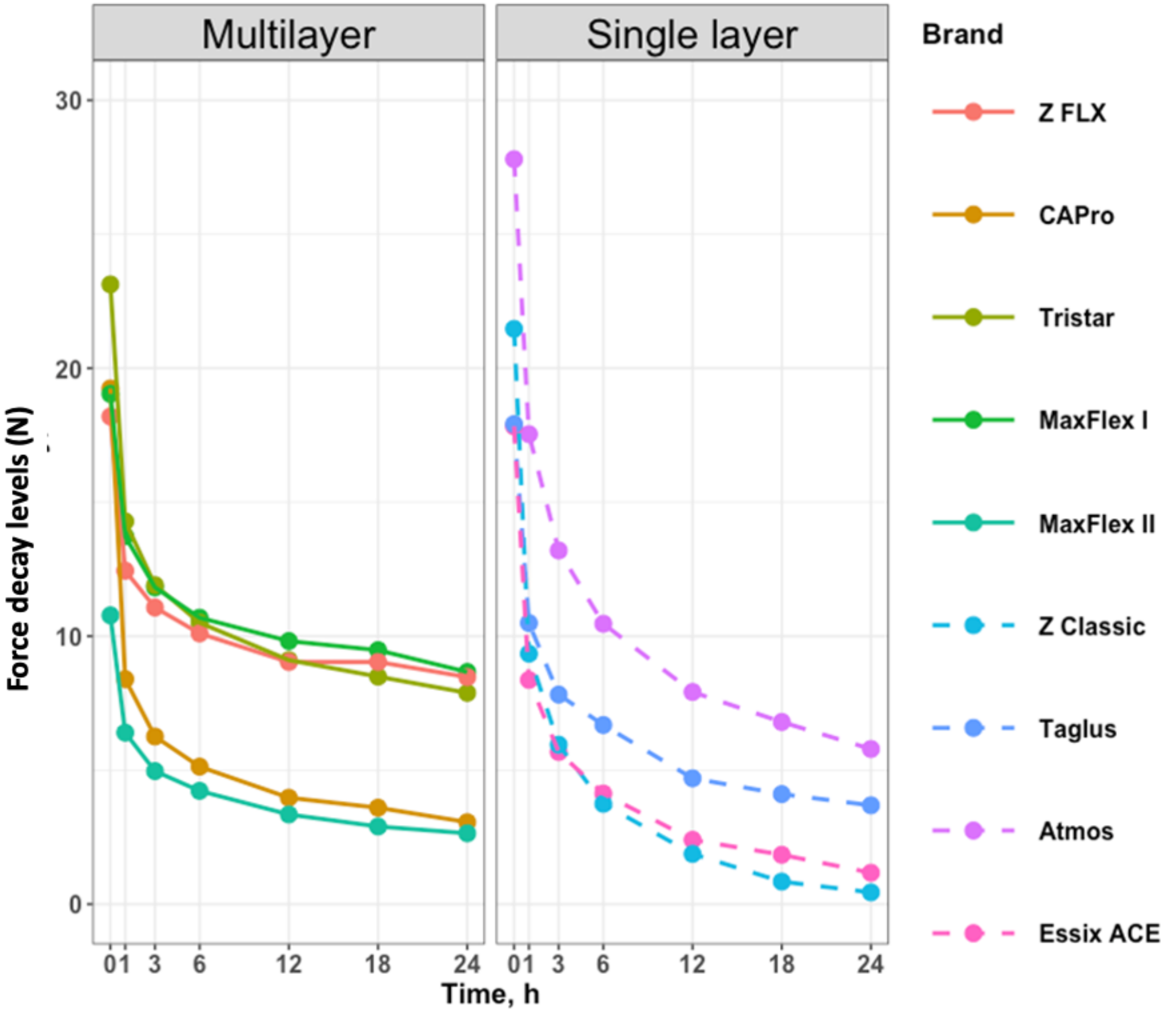


Figure 8. Force Decay curves of four common single-layer and four multi-layer plastic sheets (%).

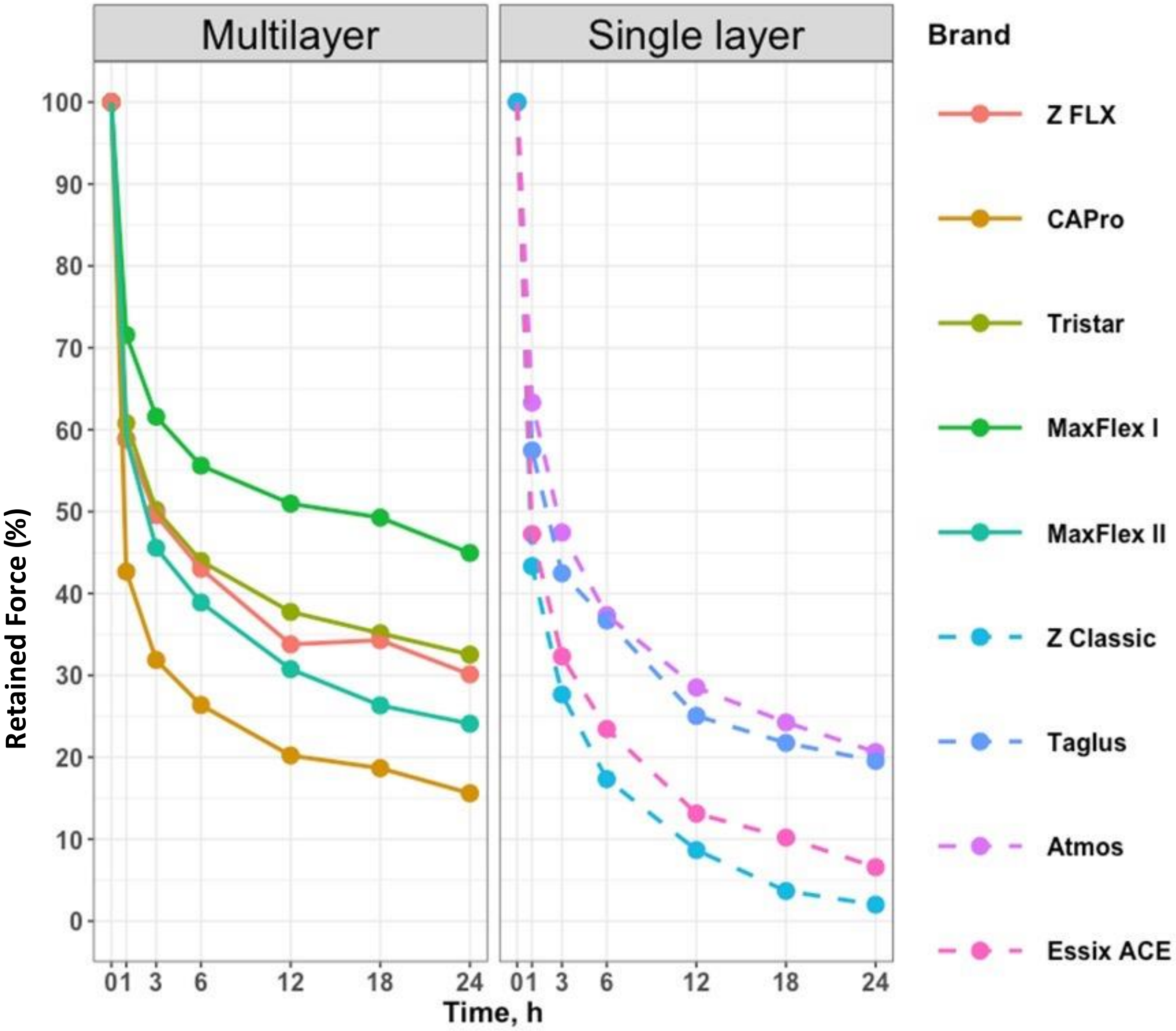


Table 14. Descriptive analysis of Force decay levels (N) in four common single-layer and multilayer plastic sheets over 24 hours.

	Time						
Structure	**0**	**1**	**3**	**6**	**12**	**18**	**24**
Multilayer							
Mean (SD)	18.1 (4.5)	11.0 (3.5)	9.2 (3.3)	8.1 (3.2)	7.1 (3.1)	6.7 (3.2)	6.1 (3.0)
Range	10.8, 23.1	6.4, 14.3	5.0, 11.9	4.2, 10.7	3.3, 9.8	2.9, 9.5	2.6, 8.7
Single layer							
Mean (SD)	21.3 (4.7)	11.4 (4.2)	8.2 (3.5)	6.3 (3.1)	4.2 (2.8)	3.4 (2.6)	2.8 (2.4)
Range	17.8, 27.8	8.4, 17.5	5.7, 13.2	3.7, 10.5	1.9, 7.9	0.8, 6.8	0.4, 5.8

Table 15. Descriptive analysis of Retained Force (%) in four common single-layer and multilayer plastic sheets over 24 hours.

	Time						
Structure	**0**	**1**	**3**	**6**	**12**	**18**	**24**
Multilayer							
Mean (SD)	100.0 (0.0)	58.6 (10.3)	47.8 (10.7)	41.6 (10.5)	34.7 (11.2)	32.7 (11.4)	29.5 (10.8)
Range	100.0, 100.0	42.7, 71.6	31.9, 61.6	26.4, 55.6	20.2, 51.0	18.7, 49.3	15.6, 44.9
Single layer							
Mean (SD)	100.0 (0.0)	52.8 (9.2)	37.5 (9.1)	28.7 (9.9)	18.8 (9.5)	15.0 (9.7)	12.2 (9.3)
Range	100.0, 100.0	43.3, 63.3	27.7, 47.4	17.3, 37.4	8.7, 28.5	3.7, 24.3	2.0, 20.6

Part 3: Force decay levels between single layer plastic sheets with different thicknesses (1mm and 0.75mm).

Figure 9. Force Decay curves of Z Classic, Taglus and Atmos (N)

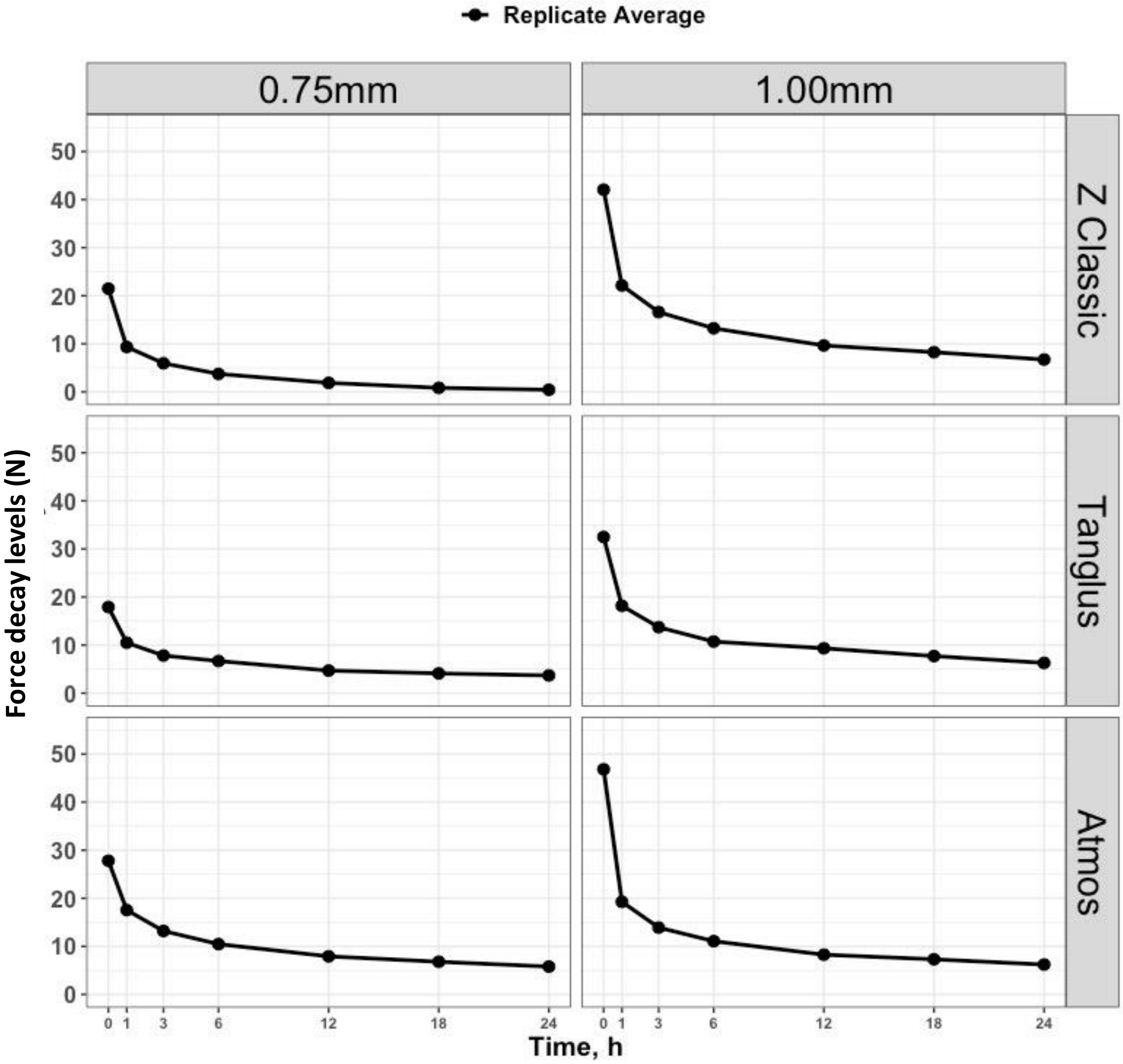


Figure 10. Force Decay curves of Z Classic, Taglus, and Atmos (%).

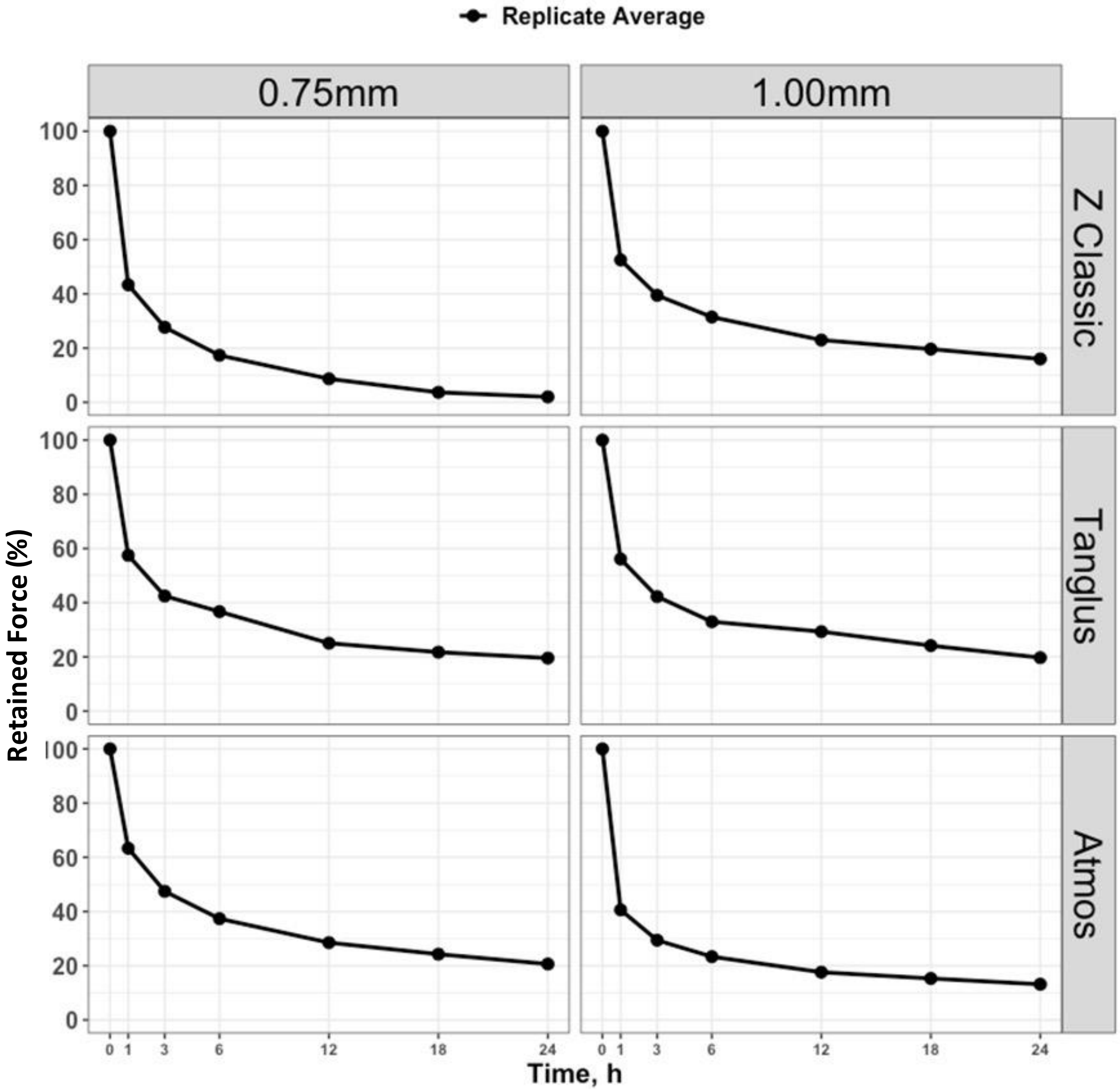


Table 16. Descriptive analysis of Force decay levels (N) in Z Classic over 24 hours.

	Time						
Structure	**0**	**1**	**3**	**6**	**12**	**18**	**24**
0.75mm							
Mean (SD)	21.5 (0.3)	9.3 (0.9)	5.9 (0.4)	3.7 (0.6)	1.9 (0.5)	0.8 (0.1)	0.4 (0.1)
Range	21.3, 21.8	8.3, 9.9	5.5, 6.2	3.0, 4.1	1.3, 2.2	0.7, 0.9	0.4, 0.5
1.00mm							
Mean (SD)	42.1 (1.5)	22.1 (4.0)	16.6 (2.1)	13.2 (1.2)	9.7 (0.8)	8.3 (0.1)	6.7 (0.4)
Range	41.0, 43.8	17.5, 24.9	14.3, 18.3	12.0, 14.4	9.0, 10.5	8.1, 8.4	6.2, 7.1

Table 17. Descriptive analysis of Retained Force (%) in Z Classic over 24 hours.

	Time						
Structure	**0**	**1**	**3**	**6**	**12**	**18**	**24**
0.75mm							
Mean (SD)	100.0 (0.0)	43.3 (4.6)	27.7 (2.3)	17.3 (2.9)	8.7 (2.3)	3.7 (0.6)	2.0 (0.0)
Range	100.0, 100.0	38.0, 46.0	25.0, 29.0	14.0, 19.0	6.0, 10.0	3.0, 4.0	2.0, 2.0
1.00mm							
Mean (SD)	100.0 (0.0)	52.5 (8.9)	39.5 (4.7)	31.5 (3.0)	23.0 (2.1)	19.6 (0.5)	16.0 (1.0)
Range	100.0, 100.0	42.8, 60.2	34.9, 44.2	29.1, 34.8	21.7, 25.4	19.1, 20.1	15.2, 17.1

Table 18. Descriptive analysis of Force decay levels (N) in Taglus over 24 hours.

	Time						
Structure	**0**	**1**	**3**	**6**	**12**	**18**	**24**
0.75mm							
Mean (SD)	17.9 (3.2)	10.5 (3.8)	7.8 (3.5)	6.7 (2.9)	4.7 (3.0)	4.1 (2.9)	3.7 (2.6)
Range	14.4, 20.7	7.2, 14.7	4.9, 11.7	5.0, 10.0	2.5, 8.1	2.0, 7.5	1.8, 6.7
1.00mm							
Mean (SD)	32.5 (4.4)	18.2 (2.1)	13.7 (2.0)	10.7 (1.7)	9.3 (2.7)	7.7 (1.9)	6.3 (1.6)
Range	28.9, 37.4	16.4, 20.5	12.3, 16.0	9.6, 12.7	6.8, 12.1	5.7, 9.6	4.6, 7.9

Table 19. Descriptive analysis of Retained Force (%) in Taglus over 24 hours.

	Time						
Structure	**0**	**1**	**3**	**6**	**12**	**18**	**24**
0.75mm							
Mean (SD)	100.0 (0.0)	57.5 (11.6)	42.5 (12.2)	36.7 (10.7)	25.1 (12.1)	21.8 (12.4)	19.6 (11.0)
Range	100.0, 100.0	50.0, 70.8	34.2, 56.5	27.2, 48.3	17.2, 39.0	14.0, 36.0	12.8, 32.2
1.00mm							
Mean (SD)	100.0 (0.0)	56.1 (4.4)	42.3 (2.6)	33.0 (1.9)	29.3 (11.0)	24.2 (8.0)	19.7 (6.7)
Range	100.0, 100.0	52.4, 61.0	39.4, 44.5	30.8, 34.1	21.7, 41.9	18.3, 33.3	14.9, 27.4

Table 20. Descriptive analysis of Force decay levels (N) in Atmos over 24 hours.

	Time						
Structure	**0**	**1**	**3**	**6**	**12**	**18**	**24**
0.75mm							
Mean (SD)	27.8 (0.9)	17.5 (2.2)	13.2 (2.6)	10.5 (2.9)	7.9 (3.3)	6.8 (3.1)	5.8 (3.0)
Range	26.8, 28.5	15.7, 20.0	11.1, 16.1	8.4, 13.8	5.6, 11.7	4.6, 10.3	3.8, 9.3
1.00mm							
Mean (SD)	46.8 (4.5)	19.3 (10.6)	13.9 (7.4)	11.1 (5.6)	8.3 (4.6)	7.3 (3.5)	6.2 (3.5)
Range	43.7, 52.0	7.5, 28.1	5.4, 18.9	4.7, 14.8	3.0, 11.4	3.4, 9.9	2.2, 8.8

Table 21. **Descriptive analysis of Retained Force (%) in Atmos over 24 hours.**

	Time						
Structure	**0**	**1**	**3**	**6**	**12**	**18**	**24**
0.75mm							
Mean (SD)	100.0 (0.0)	63.3 (6.6)	47.4 (8.6)	37.4 (10.1)	28.5 (11.3)	24.3 (10.9)	20.6 (10.6)
Range	100.0, 100.0	59.0, 71.0	42.0, 57.3	31.0, 49.1	21.0, 41.5	17.0, 36.8	14.0, 32.9
1.00mm							
Mean (SD)	100.0 (0.0)	40.6 (20.5)	29.4 (15.2)	23.3 (11.7)	17.6 (9.2)	15.3 (7.2)	13.2 (7.1)
Range	100.0, 100.0	17.0, 54.0	12.0, 39.8	10.0, 31.5	7.0, 23.8	7.0, 19.9	5.0, 17.5

DISCUSSION:

This in vitro study aimed to precisely compare the force decay signatures of commonly used aligner plastics prevalent worldwide. To comprehensively understand the behavior of the aligners, all measurements were conducted in Newtons and in percentage terms to represent the reduction in force. By measuring the initial force applied during the three-point bending test and comparing it with the force at later stages, the absolute change in force decay experienced by the plastic material can be quantified. Moreover, by expressing the force decay as a percentage of retained force, it adjusted for variations in initial force levels, enabling direct comparison of the stress relaxation levels. Measuring absolute force and the percentage of retained force over 24-hour experiments may allow clinicians to assess the performance of several aligner sheets, facilitating the selection of the most suitable material for each case. For instance, a material that exerts very high initial force loads might lead to patient discomfort and potential compliance issues in the earlier stages of treatment compared to a material that exhibits less force at the beginning of treatment. However, if the material applying a lower initial force exhibits a rapid decline in force percentage during treatment, that might lead to an overall weaker performance of the aligner. In that case, it is crucial for the orthodontist to monitor the aligner's performance closely and evaluate which orthodontic movements will be successfully expressed.

In terms of environmental settings, we aimed to compare distinct aligner sheets in a wet environment, with a controlled temperature of 37 Celsius, mimicking the oral environment. According to Eliades et al., even though the removable aligners are exposed to the oral cavity for short periods, a wide array of aging phenomena, including an increase in Vickers hardness occurs as well as surface modification by intraorally deposited integuments[27]. Therefore, comparing force decay levels in a wet environment provides a more accurate representation of their behavior. This approach accounts for the effects of moisture on aligner performance, offering insights into how aligners may degrade or undergo changes over time in a more realistic setting.

This study investigated the changes in the aligner material's mechanical properties caused by internal stress. More specifically, to compare the behavior of a wide array of aligner materials, stress relaxation levels were observed for 24 hours. Stress relaxation is a time-dependent decrease of the force load, under constant deflection. An important observation of this study across all experiments, was a rapid force decay exerted by each aligner material within the first 3 to 6 hours of each trial. Similar findings were supported by Li et al., mentioning that the rapid decay occurred during the first 8 hours of the 14-day experiments conducted for this study. The immediate reduction in the force levels of the aligner materials was followed by a lower rate of reduction until a plateau-like level was reached[8]. Moreover, Zhang et al.[10] also noticed a rapid force decay during the initial 60 minutes of application of the force load, while Lombardo et al. highlighted the exponential decrease in force after 8 hours, tending to diminish to a plateau thereafter[1]. Bichu et al. also reported that the reduction in the force noted with removable aligners is not linear with time and the prompt drop in the force levels is indicative of material fatigue[7]. This behavior of thermoplastic aligner materials can be explained by their viscoelastic nature, with their properties constituting the middle ground between the properties of purely viscous and purely elastic materials[7,28]. The behavior of viscoelastic materials can change significantly over time when subjected to a force load. According to Proffit, the ideal force to efficiently move teeth should be light and continuous[29]. In other words, the stress relaxation curves of the tested aligner materials should be flat, demonstrating constant force levels. However, that does not appear to be the case, due to the exponential force decay demonstrated by all the materials. One could argue that the plateau phase, as well as the amount of force degradation before the plateau is reached, is of crucial importance. In that phase, the relaxation curves are relatively flat, indicating that the aligner material exerts more constant force to orthodontically move the teeth.

During the evaluation of the force decay signatures of distinct aligner sheets, an important finding of this study was that the aligner brand can influence the plastic sheet's mechanical performance. More specifically, as an aligner brand, we refer to the material type and composition that each company produces. One could argue that aligner materials of similar thickness and structure should demonstrate consistent force decay signatures. However, this was rejected due to disparate behaviors exhibited by the various aligner brands. To be more specific, regarding the three-layer plastic sheets of the same thickness, the stress relaxation measured in Newton of Z FLX, Tristar, and Max Flex I was significantly different from that of the brands CA Pro and Max Flex II. While the percentage of retained force revealed a significant difference between CA Pro and Max Flex I. Our literature review revealed that the three-layered aligner plastics that were tested, demonstrate a fundamental structural difference. Z Flex, CAPro, Tristar, and MaxFlex II all shared the same structure of an elastomeric inner core to provide elasticity encapsulated between two harder layers, while MaxFlex I followed the opposite structure initially proposed by Li et al. with a harder inner polymer layer comprised between two elastomeric layers[14]. The exact composition is proprietary, but it is reported that the elastomeric layer is usually polyurethane. Despite the variations in the inner structure of the multilayer materials, it was deduced that the level of brand divergence makes it challenging to make definitive conclusions when comparing materials. Similar findings were noticed when comparing the stress relaxation of monolayer aligner materials of 0.75mm. The brand variation revealed distinct force signatures, with Atmos being significantly different from Essix ACE and Z Classic. Post hoc analysis for the percentage of retained force did not reveal significant differences between the brands, however, there is a trend of different stress relaxation behaviors. Lastly, when comparing the monolayer aligner materials of increased thickness (1mm), the findings were consistent for the force decay levels measured in Newtons and the percentage of retained force, highlighting that Essix Plus was significantly different from the other three brands of the same thickness. Interestingly, even though the force decay of the other 1mm aligner brands ranged from 59% to 44% of force loss within the first 3 hours, Essix Plus lost only 21% of the initial force load. Nonetheless, clinicians should exert caution, as the consistent force loads provided by Essix Plus may also constitute high forces, potentially resulting in patient discomfort and other adverse effects throughout treatment.

Moreover, aligner structure was also proven to influence the behavior and potentially the clinical efficacy of the aligners. This study compared the force decay levels between 5 monolayer and 5 multilayer plastic sheets, all in 0.75mm thickness. The percentage of loss in force between the monolayer and multilayer aligner plastics was statistically significant, even though the differences in the force measured in Newton were not significant. This project unveiled a general trend indicating decreased levels of force decay among multilayer aligner plastics, despite their initial forces not reaching the same magnitude as those exerted by the monolayer aligner plastics. Similar findings were observed by Lombardo et al., with the multilayer materials generally demonstrating lower stress relaxation rates and lower initial stress values than the monolayer aligner plastics[1]. Albertini et al., also found that the single-layered plastic sheets demonstrated the greatest values for both absolute stress and stress decay speed compared to the double-layered aligner plastics[30]. A recent study evaluating the biomechanical effects of various multilayer aligner sheets on en-masse retraction of anterior maxillary teeth supported that they should be the material of choice for efficient tooth movement, stress distribution, and mechanical loading of the alveolar bone. Interestingly, our findings align with the recommendations from various companies worldwide, which also advocate for using multilayer aligner materials in active orthodontic tooth movement.

This project also revealed that the plastic sheet thickness can influence the force decay behavior of the aligner. More specifically, three single-layered materials were chosen, and their stress relaxation levels were compared, in the two commonly used thicknesses of 0.75mm and 1mm. A significant difference in the decay levels of 0.75mm and 1mm Z Classic aligner plastics was noticed both in the absolute force and the percentage of retained force over 24 hours. Moreover, the difference was also significant for the force decay levels measured in Newton for Taglus, but not significant for Atmos. Regarding, the percentage of retained force the results did not reveal significance for either Taglus, or Atmos materials. However, given the sample size, we cannot draw definitive conclusions regarding the impact of thickness on the aligner stress relaxation. It is evident, though, that there was an overall tendency of the aligner plastic with increased thickness to exert higher force levels. For instance, at time 0 the force exerted by the 0.75mm Atmos plastic was 27.8 Newton, whereas by the 1mm Atmos plastic, it was 46.8 Newton. The magnitude of this trend varies among different aligner brands. According to Min et. al, the thickness and the amount of plastic deflection are crucial for efficient tooth movement[31]. According to Kwon et. al, thinner materials (0.508mm) exerted higher resilience to deflection compared to thicker materials (0.762 or 1.016mm); thus, thinner materials should be the material of choice for active tooth movement[32]. According to Kohda et al., thicker materials (0.75mm or 0.8mm) always produced greater force than thinner materials (0.4mm or

0.5mm), a finding that was also supported by this study[19]. Aligner materials of increased thickness might produce higher forces, however in clinical settings material thickness is not consistent and is influenced by several factors including the tooth surface, clinical crown, width, and several other considerations.

In conclusion, this study revealed that the stress relaxation levels of commonly used aligner plastics are influenced by the different aligner brands and the manufacturing process and composition, the aligner structure particularly the number of plastic sheet layers, and the thickness. Of course, the extent of variation within the 10 aligner sheets that were included differs in levels of statistical significance. Nevertheless, it is imperative to acknowledge that the force decay levels of the plastic sheets represent only one component for the efficacious application of clear aligner therapy. To be more specific, patient compliance is of crucial importance. A recent cohort study revealed that 38.3% of the included patients showed fair compliance while 25.7% demonstrated poor compliance during clear aligner therapy; thus, patient selection should be carefully considered by the orthodontist[33]. Another factor that influences the efficacy of the clear aligner treatment is the planned tooth movement. Numerous studies highlight the reliability and predictability of certain tooth movements attainable with clear aligners, while also outlining movements that are challenging with aligners, such as controlling rotations and achieving an effective amount of intrusion[34, 35]. Additionally, the crown morphology and the surface of the teeth might influence the efficacy of the movements achieved with aligners. The aligner activation is another factor that the clinician should consider while treatment planning, with recent studies reporting that the activation of lingual bodily movement of the maxillary central incisors should not exceed 0.5mm[8]. Moreover, Lyu et al., reported that the margin design also influences the efficacy of clear aligner treatment, suggesting that the ideal aligner material should have differential margin designs according to the tooth surface and the planned tooth movement[36]. These are only some of the factors that might influence the success of the treatment with clear aligners. The objective of this study is to elucidate the unique force decay characteristics exhibited by various aligner materials. Ultimately, this research aims to provide clinicians with the ability to compare these properties, thereby facilitating informed decisions regarding the selection of aligner materials.

As the clear aligner industry continues to experience exponential growth, a greater variety of aligner plastics will inevitably be introduced in the near future. Thus, by establishing a universal plastic force level protocol, companies can ensure consistency in testing methodologies, enabling more accurate comparisons between different plastics. This protocol should outline standardized procedures for measuring initial force, monitoring force decay over time, and interpreting the results; offering the ability to the clinician and eventually to the patient to decide which material to use and for what purpose.

LIMITATIONS:

The present study has some limitations. It was an in vitro study assessing the behavior of ten thermoformed aligner plastics in a water bath with distilled water set at 37 Celsius degrees. There was no stimulation of the viscoelastic periodontal ligament, capturing its complex multiphasic properties during tooth movement. Moreover, the wet environment was created with distilled water and not with saliva, meaning that the surface modification by intraorally deposited integuments was not accurately captured, as well as the plastic deformation from the masticatory and chemical stress during treatment. Another limitation of this study was the 24-hour duration. The average duration of aligner wear is between 7 to 14 days. However, we know most changes in the mechanical behavior of the aligner occur during the first 6-8 hours of deflection, while the main objective of the study was to compare the force decay signatures of the aligner plastics during the initial loading cycle. Moreover, the force decay signatures of the aligner sheets were evaluated post-thermoforming. That might have altered the mechanical behavior of the aligner plastics. Lastly, the aligner plastics of the study were deflected until 5% of the maximum strain was achieved which was calculated to be 1.5mm, according to the protocol of the three-point bending test. In clinical settings, we know that the deflection of the plastic ranges between 0.2mm-0.5mm, thus direct clinical correlations can be challenging.

CONCLUSIONS:

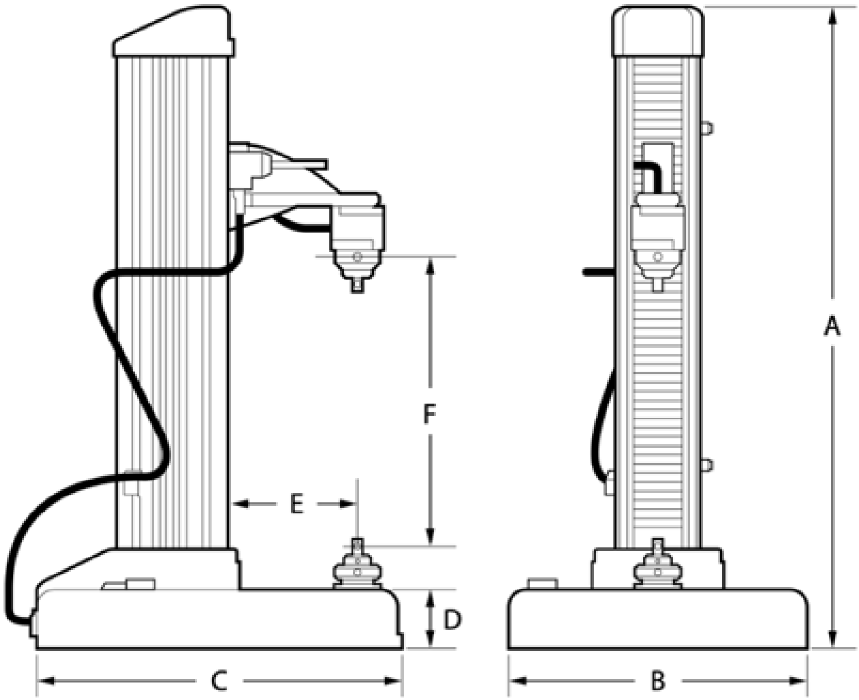
The present study suggests that the aligner plastics demonstrate unique force decay signatures, even if they have many common properties such as structure and thickness. Additionally, it was concluded that multi-layered plastics exert less initial force and demonstrate lower levels of force decay compared to mono-layered plastics. These findings suggest that multilayer aligner plastics might be the material of choice during active orthodontic tooth movement. Moreover, it has been reported that the increase in thickness of the material results in increased force loads compared to the thinner aligner sheets, with the magnitude of the observation varying among different aligner brands. It is recommended that by establishing a universal plastic force level protocol, companies can promote consistency in testing methods, thereby facilitating more accurate comparisons between the commercially available aligner plastics.

APPENDIX I

Test apparatus

Dimensions of the CS2-225 Chatillon Force unit

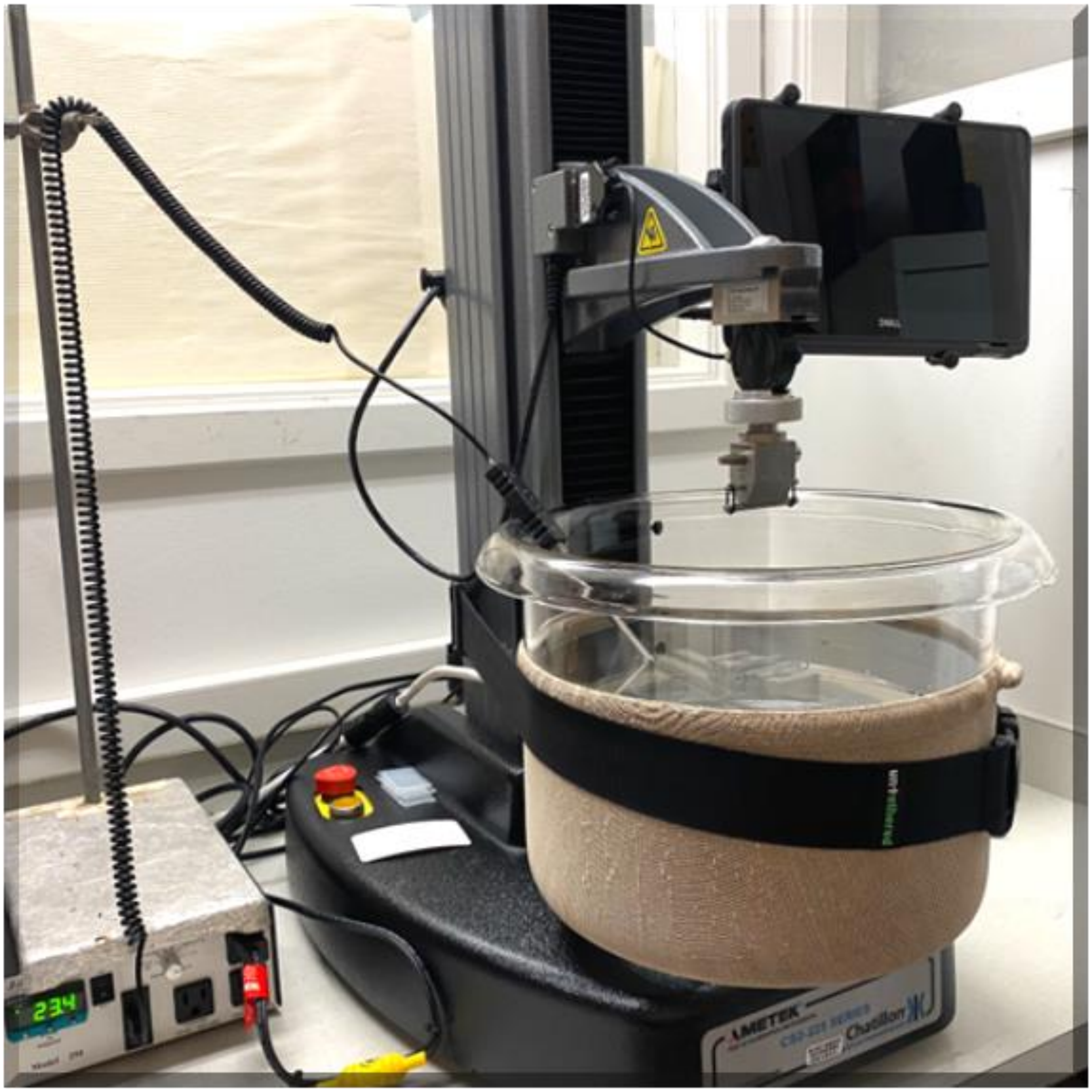
Dimensions



A	Height	**CS2-225**	39.4 in / 1001 mm
		CS2-1100	51.6 in / 1310 mm
B	Width (excluding console)	**CS2-225**	18.1 in / 460 mm
		CS2-1100	18.1 in / 460 mm
C	Depth	**CS2-225**	21.9 in / 557 mm
		CS2-1100	21.9 in / 557 mm
D	Base Height	**CS2-225**	4.3 in / 108 mm
		CS2-1100	4.3 in / 108 mm
E	Throat Depth	**CS2-225**	7.1 in / 180 mm
		CS2-1100	5.9 in / 150 mm
F	Crosshead Travel	**CS2-225**	19.7 in / 500 mm
		CS2-1100	31.5 in / 800 mm

Three-point bending test apparatus

Temperature controller connected to the water bath



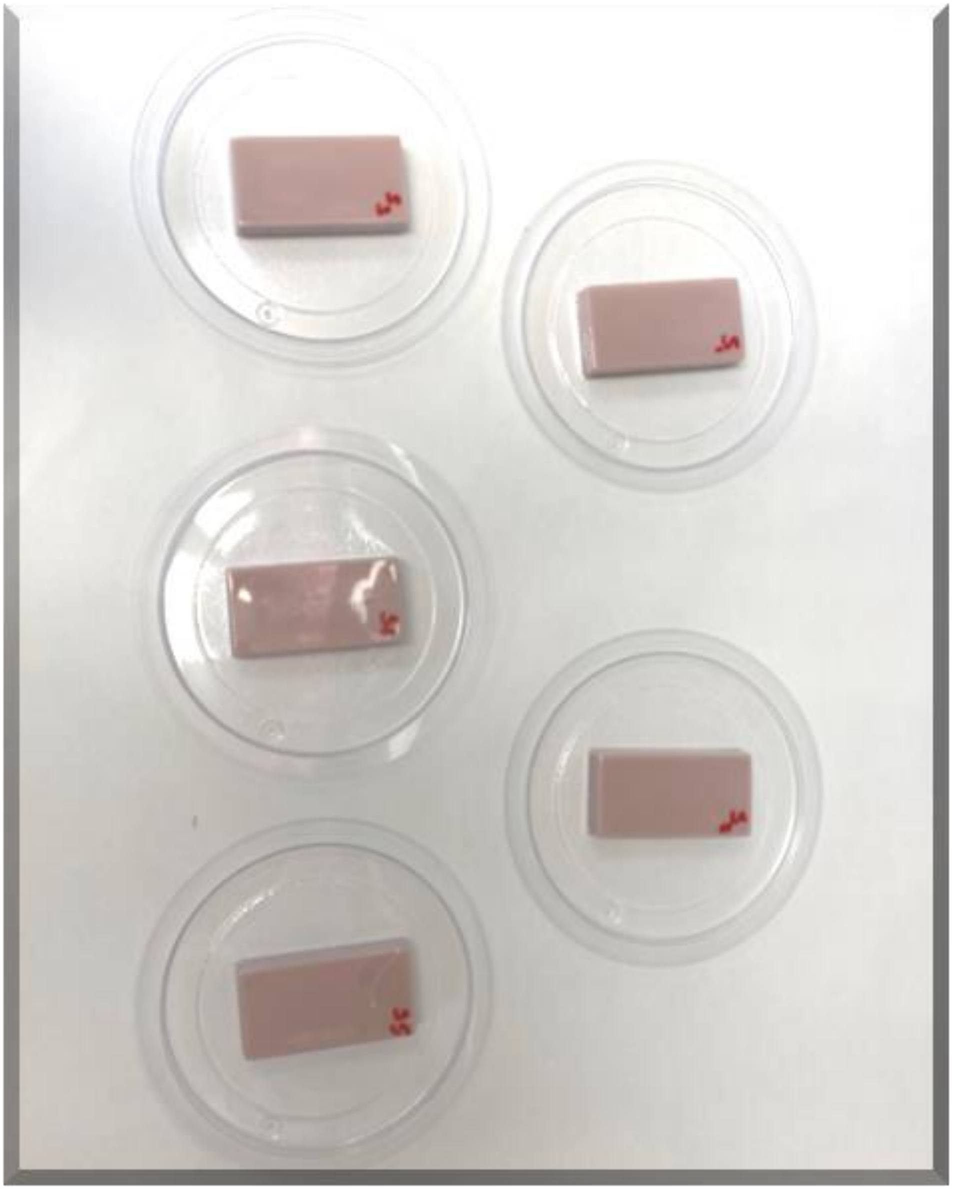
Immersion of the thermoformed plastic in the water bath

APPENDIX II

Sample preparation

3D printed blocks

Thermoformed plastic sheets over the 3D printed blocks



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