

Effects of time and clear aligner removal frequency on the force delivered by different polyethylene terephthalate glycol-modified materials determined with thin-film pressure sensors

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Introduction: Many factors influence the force changes of clear aligners. The purpose of this study was to identify the various factors that influence the force changes generated by polyethylene terephthalate glycol-modified (PET-G) materials. Therefore, a force measurement system based on a flexible thin-film pressure sensor was established. **Methods:** A series of clear aligners with 2 material properties and different activations at the maxillary central incisor, maxillary second premolar, and maxillary permanent first molar was designed and fabricated. The first material was conventional PET-G; the second material was modified PET-G with a higher modulus of elasticity and greater abrasion resistance. Several models, including teeth and aligners, were produced. Then, a force change detection device, including a thin-film pressure sensor, a signal acquisition circuit board, and a computer, was applied to measure changes in the forces delivered by the conventional and modified PET-G materials with increased frequencies of appliance removal. Finally, the forces were repeatedly measured to detect the force changes over 48 hours. **Results:** The forces of both materials decreased similarly over time. These forces also decreased when the aligner removal frequency increased, but the forces decreased differently. The modified PET-G, with a higher modulus of elasticity and greater abrasion resistance, showed a more stable and lower force change than did the conventional PET-G. **Conclusions:** The forces delivered by both materials were within the orthodontic force range. Force changes were apparent when the appliance removal frequency increased. Compared with the conventional material, the modified PET-G material showed better stability. Therefore, the modified PET-G is a promising and applicable material with advantages for both orthodontists and patients. (Am J Orthod Dentofacial Orthop 2019;155:98-107)

Fixed orthodontic appliances have been the gold standard in orthodontics for years; however, the esthetic demands of patients have directed experts' attention toward the development of clear aligners. Moreover, compared with conventional fixed appliances, thermoplastic aligners have been reported

to be more comfortable, facilitate good oral hygiene, and cause less root resorption.¹⁻⁴ Over the years, these clear appliances have evolved to achieve improved tooth alignment and occlusion.⁵ In addition, because of adults' increased esthetic demands, the clear aligner industry has shown considerable growth in orthodontics.⁶ Most aligner manufacturers currently use polyethylene terephthalate glycol-modified (PET-G), polypropylene, polycarbonate, thermoplastic polyurethanes, ethylene vinyl acetate, and others.⁷ Clear aligners can have different thicknesses, ranging from 0.50 to 1.5 mm,⁸ which can affect their properties and performance while inducing tooth movement. Clear aligners should be able to exert constant light forces throughout their use, but this is generally difficult to achieve.⁹ Additionally, the thermoplastic materials used in clear aligners have different properties compared with the metal wires used for tooth alignment in fixed

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orthodontics. Orthodontists are more familiar with the elastic properties of nickel-titanium alloy and stainless steel archwires, where the forces exerted depend on the deflection of the wire, allowing them to exert a relatively constant force until the teeth move and change the deflection. Superelastic copper-nickel-titanium wires are even more applicable, since they exert constant forces over a wide deflection range to maintain the same load even as the teeth begin to align.^{9,10} Clear aligners, however, are viscoelastic and have intermediate properties between those of viscous and elastic materials.¹¹ Under force, their behavior varies considerably over time, even if the teeth have not yet moved.¹² Under constant force, the deflection of a viscoelastic material increases over time, and at constant deflection, its load decreases; therefore, creep and stress relaxation are properties of clear aligners. Aligner material properties, time, and amount of activation affect the orthodontic force. Aligners have been extensively applied in clinical practice. However, few studies have investigated their applied force. The amount of tooth movement at different stages is largely determined by orthodontists' clinical experiences. The force applied to the tooth can be either too high, causing pain, or too low, achieving little corrective effect.^{13,14} Therefore, the force delivery property of clear aligners is essential for producing a more effective final design. Orthodontists should have a thorough understanding of clear aligner properties such as the modulus of elasticity and abrasion resistance to provide appropriate treatment for their patients. Previous studies have investigated the force properties of thermoplastic clear aligners. Barbagallo et al¹⁵ investigated the force exerted by thermoplastic appliances on maxillary first premolars in vivo using a pressure-film approach. A German research group investigated the force delivery properties of thermoplastic clear aligners during tipping and intrusive forces and reported the effects of different materials and their thicknesses.¹⁶⁻¹⁸ Kwon et al¹⁹ investigated the force delivery properties and mechanical properties of thermoplastic clear aligners using a 3-point bending test and the Vickers hardness measurement to measure the forces delivered by clear aligners constructed from 3 materials and to investigate the factors influencing differences in force delivery. Clear aligner mechanical properties have been hypothesized to affect the orthodontic forces. Kohda et al²⁰ designed a force measurement system based on a small force sensor to measure the orthodontic force to investigate the effect of material thickness on this force. Hahn et al¹⁶ used a small 6-dimensional sensor called Nano17 to detect factors that affect thermoplastic clear aligners. Exploring force changes is a feasible approach for identifying factors that affect force



Fig 1. Experimental resin model.

delivery. The complex contacts between the aligner and the teeth complicate force measurements in certain regions, specifically due to the narrow surface area; therefore, the size of the sensor is limited to 1 cm². The sensor must be thin and sufficiently flexible to adapt to tooth surface irregularities. Typically, the force magnitude applied to the teeth is 100 g, which decreases gradually and completely diminishes within 2 weeks.²¹ Therefore, the force sensor should be sufficiently sensitive to measure the small static forces. The purpose of this study was to investigate the correlations between material properties, time, appliance removal frequency, and changes in force.

MATERIAL AND METHODS

A series of clear aligners was designed and fabricated by Smartee Denti-Technology, Shanghai, China. Two types of aligner materials were used; each type consisted of 3 activations of the same material thickness, but each had different material properties. Most manufacturers use PET-G materials; therefore, PET-G was selected for this study. The first material was conventional PET-G, and the second was modified PET-G with a higher modulus of elasticity and greater abrasion resistance. The modified PET-G material is under investigation and not commercially available. Both materials were composed of a 0.75-mm thick layer and consisted of 3 activations. Vinyl polysiloxane impressions were taken and scanned. A 3-dimensional digital model was established after a series of processing procedures, including surface treatment. Based on the 3-dimensional digital model, the force differences between the experimental and simulation results were limited to less than 0.2 N, which was considered acceptable.²¹ Models with 3 activations (0.0, 0.1, and 0.2 mm) for different tooth movements were designed under the supervision of Smartee Denti-Technology (Fig 1). Sensor thickness is the primary factor in measuring generated forces. To install

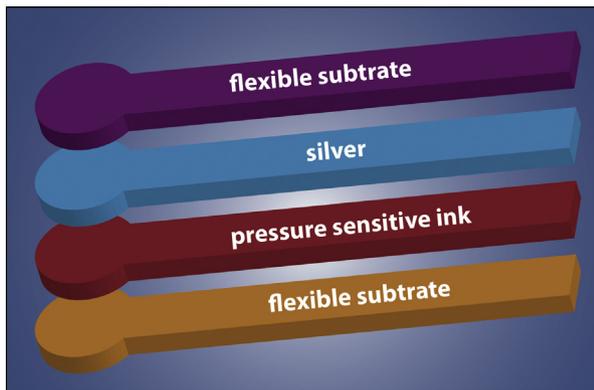


Fig 2. Structure model of the flex pressure sensor.

an appropriate sensor, the features of the model that face the sensor were especially designed and minimized to provide space for the sensor. Then, 0.2-mm thick sensors, the thinnest sensors ever constructed, were designed and fabricated by Yu Bo Intelligent Technology (Hangzhou, China). The sensor's structure is shown in [Figure 2](#). Three ultrathin flexible printed circuit sensors with superior specifications compared with conventional sensors, such as a soft and flexible material structure, minimal thickness, small size, and high sensitivity, were prepared. The specific working circuit of the sensors is shown in [Figure 3](#). The circuit formula was as follows: $R\text{-RFP} = (V+)/V\text{OUT}-1) * R1$, and the drive voltages $V+$ were constant. The reference resistance $R1$ ranged from 1 to 50 $K\Omega$. The sensor resistance $R\text{-RFP}$ without a load was greater than 8 $K\Omega$. The equation for the force determined by the sensor was as follows: $F = 1/R\text{-RFP} * A$, where A is the active sensing area. The goal of this study was to build a device that detects force changes in clear aligners based on multiple thin-film, single-force sensors to investigate the force delivered by clear aligners and the factors affecting force delivery, including material properties, time, frequency of appliance removal, and different amounts of activation using the same loading geometry and parameters. The efficiency of the sensors was determined by applying 10 calibrated forces. The results showed a maximal precision rate of 95%, indicating that the results were highly reproducible. The resistance force curve of the sensor is shown in [Figure 4](#).

The positions of the measuring points, located on the central incisor, second premolar, and first molar, were determined by Smartee Check, a software package provided by the aligner company that allows visualization of the digital model and the amount of tooth movement over time in 3 dimensions ([Fig 5](#)). The sensing area of the thin-film, single-force sensor was placed on a resin

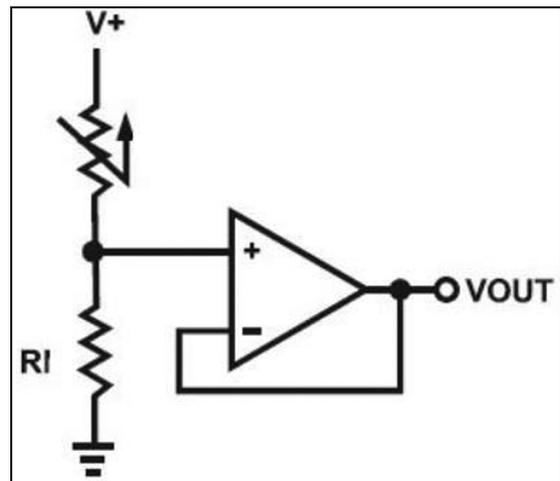


Fig 3. Working principle of the sensor circuit.

model, and then a clear aligner was placed on the model ([Fig 6](#)). The output end of the sensor was connected to the input port of the circuit board for signal acquisition. Finally, the export port of the circuit board was connected to a computer to measure forces ([Fig 7](#)). To obtain the corresponding orthodontic force, supporting software visually displayed the pressure data (Yu Bo Intelligent Technology), as shown in [Figure 8](#). All measurements depended on static values for each tooth using constant parameters. Experiments were conducted to determine the influencing factors that changed the static value of each aligner. Measurements were carried out at room temperature (25°C) and low humidity after the sensor was calibrated. First, we determined the force changes over time. Measurements were performed on both conventional and modified PET-G with 0.2-mm aligner activation on the first molar for 48 hours of continuous distalization. A bar chart of the measured force changes over time is shown in [Figure 9](#). The experiments were repeated on both materials with different amounts of activation. The correlation between patient appliance removal for eating and cleaning at a frequency of 5 times per day and the associated force changes was determined. A reference point on the sensing area of the model was used to facilitate repositioning of the sensor at the same location on the tooth. The force was measured during repeated removal of the appliance for a maximum of 50 times, with measurements every 10 times for further comparisons between values. The curve in [Figure 10, A](#), shows the mean values of the force changes as a result of frequent appliance removals for both materials (conventional and modified PET-G). The curve in [Figure 10, B](#), shows the mean values of the force changes as a result of increasing the amount of activation. The data were

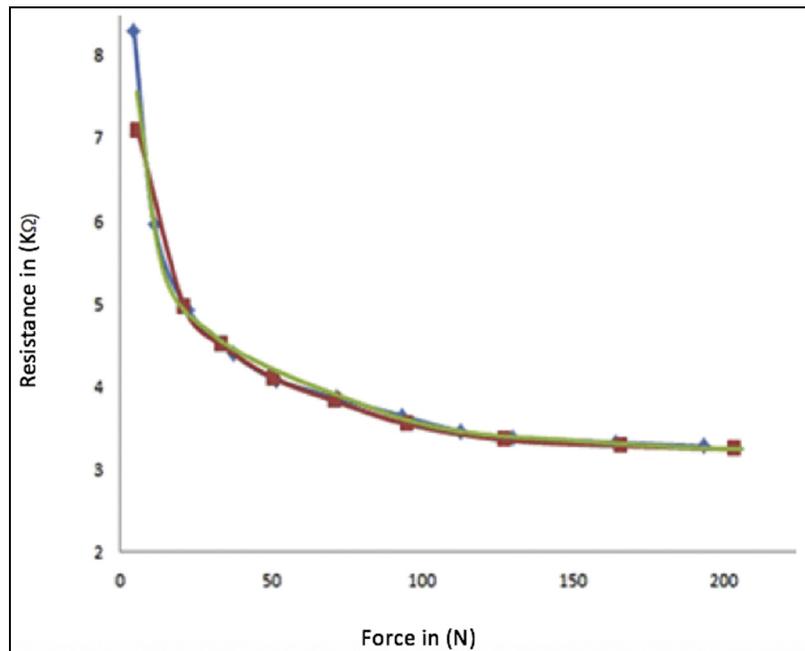


Fig 4. Resistance-force curve.

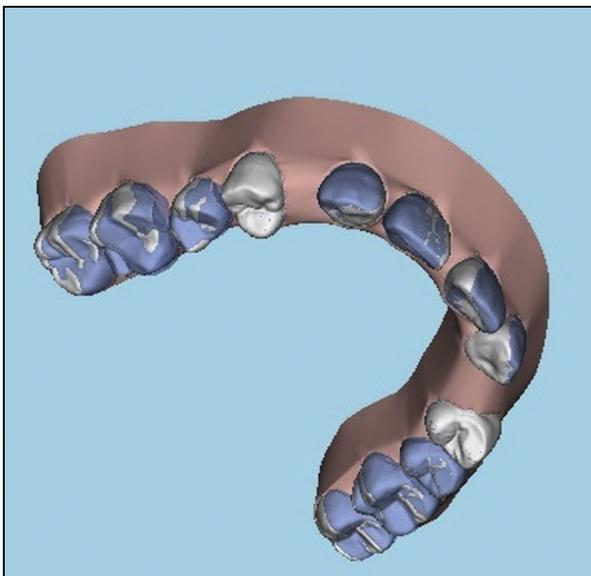


Fig 5. Stress areas on the third model.

used to compare the 2 materials to determine which material has superior properties.

Statistical analysis

The experimental results were analyzed using SPSS software (version 23 for Windows; IBM, Armonk, NY). A Kolmogorov-Smirnov test was applied and showed



Fig 6. Sensors on the model.

that the data were normally distributed. The means and standard deviations were calculated for each measurement, and analysis of variance for between-subject effects was performed to determine the level of

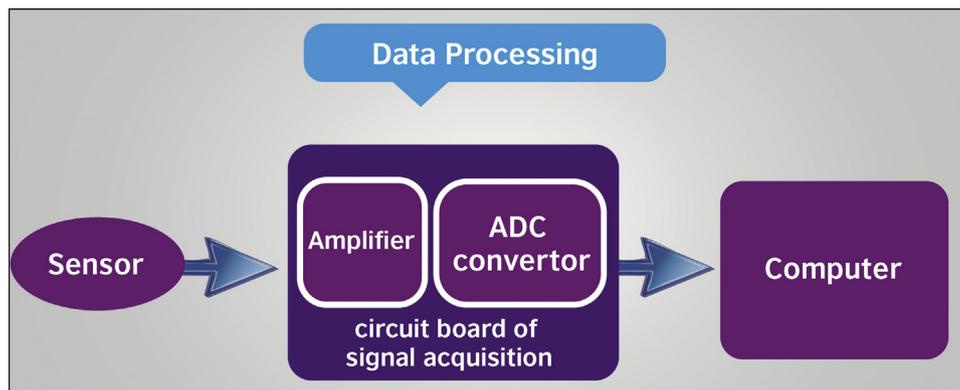


Fig 7. Data processing circuit.

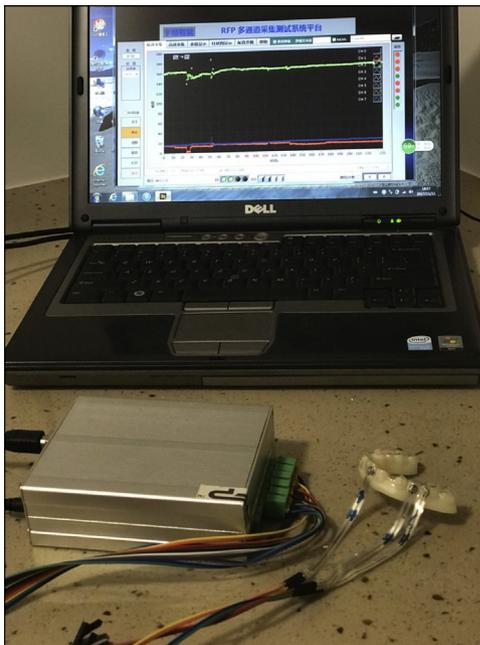


Fig 8. Data processing procedure.

significance between the values obtained from different measurements. The force change values obtained at different frequencies of appliance removal and with different amounts of activation were analyzed statistically (analysis of variance at a 95% confidence level; significant at $P < 0.05$) to determine the material with superior properties. Mauchly's test of sphericity showed a P value from 0.019 to 0.05, indicating that the dependent variable did not satisfy the spherical assumption and thus warranting epsilon (ϵ) correction. Therefore, we used the Huynh-Feldt method for calibration and then analyzed the effect of each factor separately using pairwise comparisons to determine statistical significance at different levels for each factor.

RESULTS

Figure 9 gives the measured force changes over time for the modified PET-G aligner with 0.2-mm activation on the first molar for 48 hours of continuous distalization, showing a nearly balanced state of inconstancy of the measured force, which indicates that the forces generated by both materials exhibited steady fluctuations. Forces with low precision rates were not considered, and the average group force was calculated. The experiment was repeated using the conventional PET-G aligner, which showed a balanced state similar to that of the modified PET-G aligner. Therefore, both materials were considered efficient during the first 2 days.

The measurements were repeated for both materials at different activation amounts to determine the effect of aligner removal frequency on the force generated by the aligners using a new series of materials to prevent effects from the first experiment. The force exerted by the aligner decreased with increasing aligner removal frequency for both materials; however, the results were different for the 2 materials. Table 1 summarizes the mean forces and standard deviations of the 2 materials at different aligner removal frequencies and different amounts of activation. Figure 10A shows the mean forces (in Newtons) of the modified and conventional PET-G aligners at different aligner removal frequencies, giving a clear force decrease for the conventional PET-G aligner. Based on these results, the modified material provided better stability than did the conventional material. Figure 10B shows the mean forces (N) of the modified and conventional PET-G aligners at different amounts of activation. The results showed that greater activation corresponds to a greater applied force in addition to greater force changes. The dependent variable did not satisfy the spherical assumption, as determined by Mauchly's test of sphericity; therefore, we used the Huynh-Feldt method, which showed

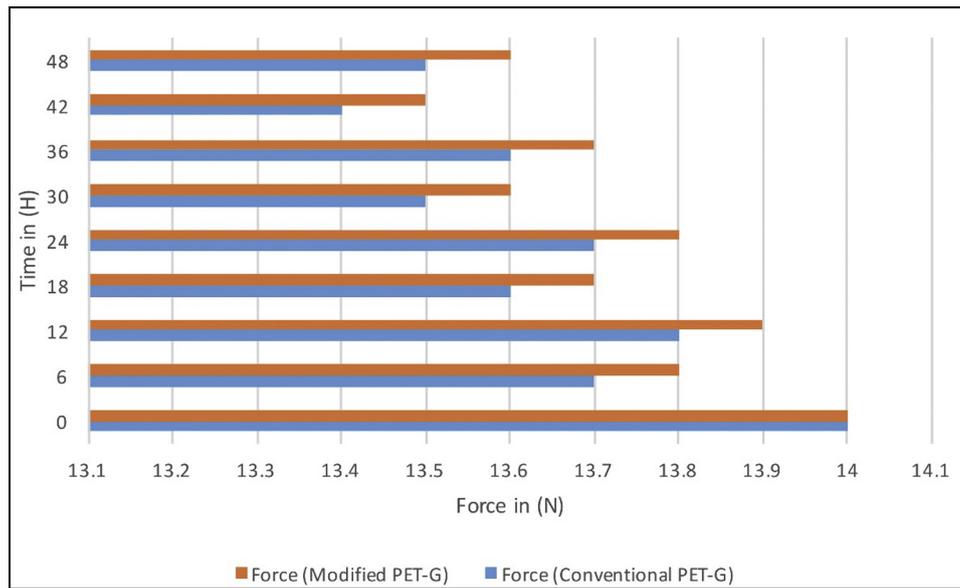


Fig 9. Force changes over time.

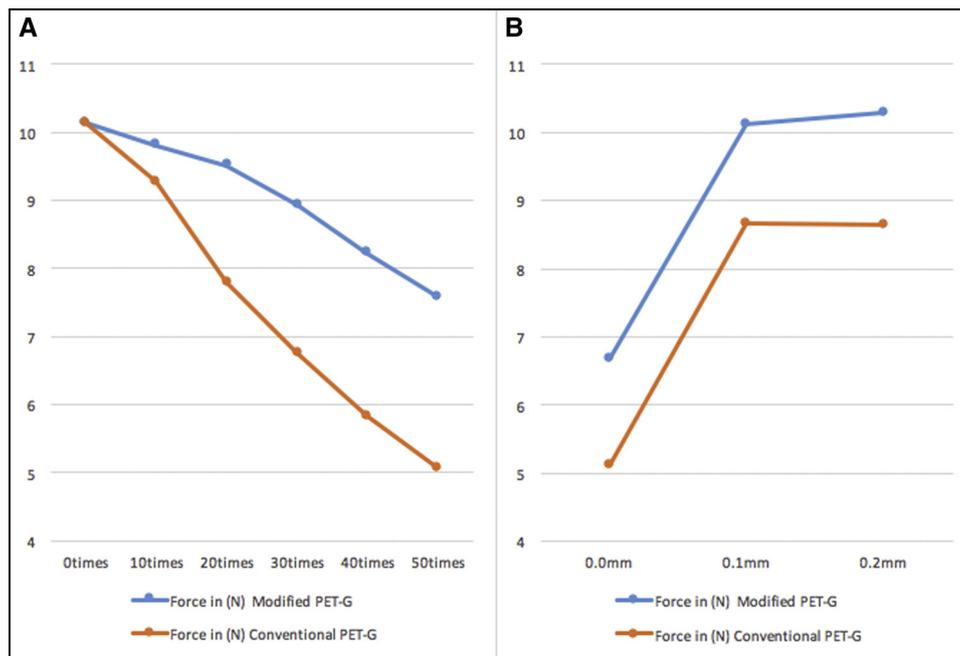


Fig 10. A, Force changes as a function of appliance removal frequency; B, force changes as a function of different amounts of activation.

statistically significant differences between aligner removal frequencies and the amounts of activation with respect to force changes ($P < 0.05$). Therefore, a pairwise comparison was conducted to determine the significance level of each aligner removal frequency

and level of activation. Table II shows that the force changed with frequency as follows: 0 time < 10 times < 20 times < 30 times < 40 times < 50 times, and that it changed with the amount of activation as follows: 0.0 mm activation < 0.1 mm < 0.2 mm.

Table I. Forces of the 2 materials at different aligner removal frequencies and activations

Type of material	N	Mean	SD	SE	95% CI for mean		Minimum	Maximum
					Lower bound	Upper bound		
Force in (N) modified PET-G								
0 times	9	10.1444	6.66710	2.22237	5.0197	15.2692	2.00	18.50
10 times	9	9.8111	6.49624	2.16541	4.8177	14.8046	1.90	18.00
20 times	9	9.5111	6.46074	2.15358	4.5449	14.4773	1.60	17.70
30 times	9	8.9333	6.15792	2.05264	4.1999	13.6667	1.40	17.00
40 times	9	8.2222	5.57579	1.85860	3.9363	12.5082	1.30	16.00
50 times	9	7.5889	5.34122	1.78041	3.4833	11.6945	1.10	15.50
Total	54	9.0352	5.90945	.80417	7.4222	10.6482	1.10	18.50
Force in (N) conventional PET-G								
0 times	9	10.1444	6.66710	2.22237	5.0197	15.2692	2.00	18.50
10 times	9	9.2778	6.21928	2.07309	4.4972	14.0583	1.70	18.00
20 times	9	7.7889	5.48280	1.82760	3.5744	12.0033	1.20	16.00
30 times	9	6.7556	4.67363	1.55788	3.1631	10.3480	1.10	12.00
40 times	9	5.8333	4.19285	1.39762	2.6104	9.0562	.80	11.00
50 times	9	5.0778	3.63792	1.21264	2.2814	7.8741	.70	9.50
Total	54	7.4796	5.32294	.72436	6.0267	8.9325	.70	18.50
Force in (N) modified PET-G								
0.0 mm	18	6.6889	4.05751	.95636	4.6711	8.7066	1.10	12.00
0.1 mm	18	10.1222	6.40327	1.50926	6.9380	13.3065	1.50	18.00
0.2 mm	18	10.2944	6.53060	1.53928	7.0469	13.5420	1.50	18.50
Total	54	9.0352	5.90945	.80417	7.4222	10.6482	1.10	18.50
Force in (N) conventional PET-G								
0.0 mm	18	5.1222	3.44922	.81299	3.4070	6.8375	.80	12.00
0.1 mm	18	8.6444	5.57672	1.31444	5.6396	11.6493	.90	18.00
0.2 mm	18	8.6722	6.04242	1.42421	5.8990	11.4455	.70	18.50
Total	54	7.4796	5.32294	.72436	6.0267	8.9325	.70	18.50

These results were used to compare both materials at different frequencies to determine the statistical significance of differences between the 2 materials (Table III).

DISCUSSION

In this study, a method was selected to verify the efficiency of thermoplastic aligners and to compare similar materials with different mechanical properties to determine these properties' correlations with appliance removal frequency. The complex contacts between the aligner and the model posed the greatest challenge; therefore, a special sensor that was small, thin, and sufficiently flexible was designed. As mentioned previously, earlier studies used different measurement methods¹⁶⁻¹⁹ and experimental factors from those used in our study. The aim of our study was to better understand aligner materials for comparison with a material that is currently under investigation. Therefore, we evaluated factors that potentially influence force changes. The study showed that time does not affect the force delivered by an aligner within 48 hours of wearing the appliance, whereas the amount of activation and the appliance removal frequency both affect changes in

force. The force changes that occurred with varying appliance removal frequency were observed for both PET-G materials. Therefore, the data showed that patients treated with clear thermoplastic aligners must wear the appliance for at least 20 hours per day and should not remove it because this affects treatment efficiency and leads to prolonged treatment time. However, the modified PET-G material showed fewer force changes than did the conventional PET-G material, indicating that, compared with materials with inferior elasticity and resistance, materials with a higher modulus of elasticity and greater abrasion resistance are less affected by removal frequency. Using alternative techniques for the measurements was difficult because of the complexity and high cost of testing. In this study, the force measured was the initial force. We used clear aligners on resin models because the force changes between the simulation and experimental models were only 0.2 N, which is acceptable.²¹ In this study, a few operating errors occurred due to insufficient equipment and inadequate operator skills. System errors also occurred; the system did not show 100% precision, and the contact surface between the model and the

Table II. Comparison of different aligner removal frequencies and activations

Group	Mean difference (I-J)	SE	Significance [†]	95% CI for difference [†]	
				Lower bound	Upper bound
0 time					
10 times	.628*	.133	.017	.100	1.155
20 times	1.494*	.369	.043	.035	2.953
30 times	2.300*	.458	.011	.488	4.112
40 times	3.117*	.485	.002	1.200	5.033
50 times	3.811*	.551	.001	1.631	5.991
10 times					
0 times	-.628*	.133	.017	-1.155	-.100
20 times	.867	.258	.127	-.155	1.888
30 times	1.672*	.374	.023	.194	3.150
40 times	2.489*	.401	.002	.904	4.074
50 times	3.183*	.481	.001	1.283	5.084
20 times					
0 times	-1.494*	.369	.043	-2.953	-.035
10 times	-.867	.258	.127	-1.888	.155
30 times	.806*	.192	.035	.045	1.566
40 times	1.622*	.213	.000	.780	2.464
50 times	2.317*	.289	.000	1.174	3.459
30 times					
0 times	-2.300*	.458	.011	-4.112	-.488
10 times	-1.672*	.374	.023	-3.150	-.194
20 times	-.806*	.192	.035	-1.566	-.045
40 times	.817*	.073	.000	.526	1.107
50 times	1.511*	.147	.000	.929	2.093
40 times					
0 times	-3.117*	.485	.002	-5.033	-1.200
10 times	-2.489*	.401	.002	-4.074	-.904
20 times	-1.622*	.213	.000	-2.464	-.780
30 times	-.817*	.073	.000	-1.107	-.526
50 times	.694*	.153	.022	.088	1.301
50 times					
0 times	-3.811*	.551	.001	-5.991	-1.631
10 times	-3.183*	.481	.001	-5.084	-1.283
20 times	-2.317*	.289	.000	-3.459	-1.174
30 times	-1.511*	.147	.000	-2.093	-.929
40 times	-.694*	.153	.022	-1.301	-.088
0.0 mm					
0.1 mm	-3.492*	.785	.005	-5.795	-1.188
0.2 mm	-3.550*	.785	.004	-5.854	-1.246
0.1 mm					
0.0 mm	3.492*	.785	.005	1.188	5.795
0.2 mm	-.058	.785	1.000	-2.362	2.245
0.2 mm					
0.0 mm	3.550*	.785	.004	1.246	5.854
0.1 mm	0.058	.785	1.000	-2.245	2.361

Based on estimated marginal means.

*Mean difference is significant at the 0.05 level; [†]Adjustment for multiple comparisons: least significant difference (equivalent to no adjustments).

aligner was curved rather than flat, resulting in a weight imbalance of the sensor. To reduce the sensor weight imbalance, we used surfaces that improved experimental performance. The deformation of the aligner surface was consistent with different tooth movements, and the force applied at every point on all teeth was also

consistent. Despite the distribution of the stresses, we were able to place the sensors in areas where measurements could be recorded with minimal measurement error.

Because the thickness of the aligner should be considered, the thermoplastic aligner material was

Table III. Comparisons of differences between both materials

Removal frequency levels	(I) Modified PET-G (J) conventional PET-G		Mean difference (I–J)	SE	P†	95% CI for difference‡	
	Lower bound	Upper bound					
0 times	1	2	0.000	0.000		0.000	0.000
	2	1	0.000	0.000		0.000	0.000
10 times	1	2	0.589*	0.184	0.019	0.138	1.040
	2	1	–0.589*	0.184	0.019	–1.040	–0.138
20 times	1	2	1.722*	0.406	0.005	0.728	2.716
	2	1	–1.722*	0.406	0.005	–2.716	–0.728
30 times	1	2	2.178*	0.360	0.001	1.297	3.059
	2	1	–2.178*	0.360	0.001	–3.059	–1.297
40 times	1	2	2.389*	0.387	0.001	1.443	3.335
	2	1	–2.389*	0.387	0.001	–3.335	–1.443
50 times	1	2	2.501*	0.761	0.004	0.755	4.267
	2	1	–2.501*	0.761	0.004	–4.267	–0.755

Based on estimated marginal means.

*Mean difference is significant at the .05 level; †Adjustment for multiple comparisons: Bonferroni.

fabricated with controlled heating time and temperature to ensure that the thickness of the aligner was uniform. Differences between this experiment and previous studies are due to the linear elasticity of the orthodontic forces delivered to the teeth through aligner elastic deformation. The thickness and activation of the aligner certainly affect the orthodontic force. Kohda et al²⁰ measured a force of 1.65 N with 0.5-mm activation using Duran 0.5-mm thick material, whereas Barbagallo et al¹⁵ measured a force of 5.12 N for the same amount of activation using 0.8-mm thick material. In addition, Hahn et al¹⁶ measured a force of 3.14 N for a 0.1-mm activation using 1.0-mm thick material. We concluded that the thickness of the materials and the amount of tooth activation had significant effects on the delivered force; thicker materials and larger activations delivered greater forces. This is why the force measured in this study was not substantially different from the results of previous studies. Despite inevitable force measurement errors, we determined the force changes associated with different materials with different mechanical properties and activation. The advantages of this force measuring system over previous studies included its simplicity, high precision rates, and low cost; the disadvantages included the lack of durability of the sensor, and the ability to test only some forces, whereas other forces could not be measured due to crown surface size, complexity, contact areas and points between teeth, and lack of force analysis in a 3-dimensional space.

CONCLUSIONS

Orthodontists must fully understand aligner force properties to provide appropriate treatment to their patients. In this study, a thin-film, single-force sensor was

used to determine force changes. Due to the simplicity of the method, it can be used to detect the delivered forces of aligners and to verify the efficiency of different aligner materials. We concluded that the mechanical properties of the material, the aligner removal frequency, and the amount of tooth activation are factors that influence the generated forces. An increased appliance removal frequency leads to decreased force delivery; therefore, wearing an appliance for a longer time will ensure its efficiency. A higher modulus of elasticity and greater abrasion resistance correspond to greater force stability and aligner efficiency, and greater activation will deliver a greater force.

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