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Force Assessment of Thermoformed and Direct-printed Aligners in a Lingual Bodily Movement of a Central Incisor Over Time: A 14-day *In Vitro* Study

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Purpose: This study aims to investigate the force delivery profile of thermoformed aligners (TFA) compared with direct-printed aligners (DPA) and to explore the effect of different activation amounts on forces and moments of respective groups. A secondary objective is to observe the amount of stress relaxation that occurs over the 7~14 days when aligners are maintained in a simulated intraoral environment.

Materials and Methods: An *in vitro* setup was created to quantify forces and moments. It consisted of a three dimensional-printed base plate and segmented maxillary teeth, placed in a semi-enclosed chamber to maintain a temperature of 37°C. Ninety clear aligners were divided into nine groups of ten aligners each based on material types (Zendura, ATMOS, TC-85) and activation amounts. Aligners were created with 0.00, 0.25- and 0.50-mm activations for lingual bodily movement of the upper left central incisor and kept on models in the "stressed" position in a 37°C water bath. Three force components acting on the upper left lateral incisor, upper left central incisor, and upper right central incisor were measured for each time point, beginning from the initial baseline measurement, 8 hours, 16 hours, 24 hours, 2 days, 3 days, 4 days, 5 days, 6 days, 7 days, and lastly, 14 days.

Result: TC-85 aligners in every activation group showed less force on teeth than Zendura and ATMOS. Significant force levels from 0.0 mm activation were present and stayed consistent over the course of 14 days. Comparisons made for baseline measurements to 7-days and 14-days showed statistically significant change from the baseline force level.

Conclusion: TC-85 aligners demonstrated lower, more consistent forces with fewer side effects. Aligners can generate forces even when no activation is programmed. No major decreases in force levels over time were observed; the intra-oral clinical simulated environment and length of observation time could contribute to this.

Key Words: Clear aligners; Orthodontic tooth movement; Shape memory polymer

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Introduction

Patients' increasing desire for more esthetic treatment forms have contributed to the popularization of clear aligner therapy worldwide[1-3]. The force system produced by aligners is yet poorly explored, and the biomechanics of conventional fixed appliances cannot be directly applied to aligner therapy. Whereas fixed appliances have discrete force application points at brackets and archwires, clear aligners encompass the whole tooth crown, and the exact locations of force application are challenging to assess[4,5]. Furthermore, the engagement of the tooth and the aligner can change throughout orthodontic tooth movement and alter the force system. The physical properties of clear aligners can change in the intraoral environment due to the presence of saliva[6], masticatory forces, and occasional removal by the patient[7]. Attachment shape, position, and bonding accuracy also play a role. All these factors result in complex and dynamic contact mechanics, which make theoretical predictions of forces and moments in aligner therapy challenging[8].

New technological developments and market demands have rapidly increased the availability and affordability of intraoral scanners and three dimensional (3D) printers, allowing the fabrication of aligners chairside. Clear aligner treatment has previously been limited to printing 3D models with staged tooth movements and subsequently thermoforming plastic sheets to create the desired aligners. The possibility of direct 3D printing of aligners pushes us toward a new era of innovation[9], offering the unique opportunity to directly control material dimensions[10], structure, and properties while also reducing waste and being more environmentally friendly[7]. Despite the current improvements and increased use of direct 3D printing technologies, publications that describe the direct 3D printing of orthodontic clear aligners or adequate research on suitable materials for such printing are limited[11]. Before direct-printed aligners (DPA) can be adopted, they must be compared to traditional thermoformed aligners (TFA). The previous studies that have dealt with the stress released by orthodontic aligners were limited by the observation time, with times ranging from 60 minutes to 24 hours at the longest[11], which cannot provide a meaningful representation of the mechanical behavior of aligners worn in the mouth for 22 hours per day for up to 14 consecutive days. This study aims to investigate the force delivery profile of TFA compared with DPA and to explore the effect of different activation amounts on the force delivery profile of the respective aligner types while also observing the percentage of stress relaxation that occurs over the 7~14 days of an intraoral application when aligners are maintained in a simulated intraoral environment.

Materials and Methods

1. Experimental Apparatus

An *in vitro* hardware/software setup was used to quantify forces and moments generated by clear aligners. The setup consisted of a 3D-printed base plate and segmented maxillary teeth that allowed different designs and dental alignment modification as needed for different experimental protocols (Fig. 1). The maxillary arch was 3D printed from a digital scan of a typodont with ideal alignment. Three AFT20-D15 multi-axis force/moment transducers (Aidin Robotics, Anyang, Korea) were mounted to the base plate and fixed to simulated teeth 11, 21, and 22. Tooth 21 was printed with a 0.5 mm displacement in the labial direction to simulate the alignment restoration through lingual bodily movement. The setup was placed in a semi-enclosed chamber with a thermometer to maintain the human body temperature of 37°C.

The software measured forces and moments in three axes: x (–buccal/+lingual direction), y (–mesio/+distal direction), and z (–gingival/+occlusal direc-

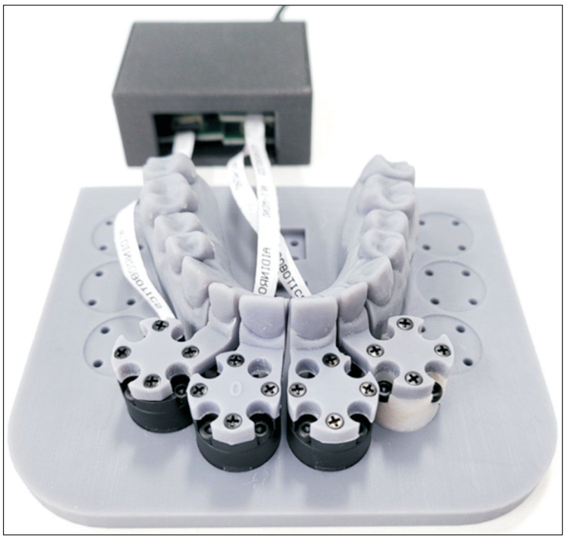

Fig. 1. Three-axis force and moment sensor.

tion) on the following teeth: UL2 (upper left 2), UL1 (upper left 1), UR1 (upper right 1). The fourth tooth from the left is not connected to the sensor, and it was not measured. For this study, the forces and moments for only the upper left central incisor were included in the analysis. All force axes were analyzed, focusing on the Fx axis of force.

2. *Sample Preparation*

Ninety clear aligners were divided into nine groups based on material types and activation amounts. Each group consisted of ten aligners. A custom version of uDesign 6.0 digital treatment planning software (uLab Systems, Memphis, TN, USA) was used to design aligners with 0.00-, 0.25- and 0.50-mm activations for lingual bodily movement of tooth 21.

For TFA aligners, the corresponding models were printed with SprintRay Pro 95 (SprintRay, Los Angeles, CA, USA) in 100-μm layers using SprintRay Die and Model 2 gray resin. Next, aligners were fabricated using 0.030″ (0.76 mm)-thickness sheets of ATMOS (American Orthodontics, Sheboygan, WI, USA) and 0.030″ (0.76 mm)-thickness sheets of Zendura FLX (Bay Materials, Fremont, CA, USA) materials through the thermoforming process with a Biostar machine (Scheu Dental, Iserlohn, Germany) according to the manufacturer's instructions. Ten aligners were fabricated for each material and activation amount. ATMOS is a mono-layer polyethylene terephthalate glycol polymer. Zendura FLX is a multi-layer thermoplastic polyurethane plastic that consists of two hard outer shells and an inner elastomeric layer, the exact composition of which is proprietary.

For DPAs, the same custom version of uDesign 6.0 was used to generate stereolithography files of aligners of 0.50-mm uniform thickness and 0.05-mm offset from tooth surfaces. The aligner files were imported into UnizMaker (Uniz Technology, San Diego, CA, USA) to prepare for printing. The occlusal plane of each aligner was rotated 120° from the build platform, and supports were added only to the cameo surface. The aligners were printed with SprintRay Pro 95 printer using TC-85 clear photocurable resin (Graphy, Seoul, Korea) in 100-μm layers and later processed according to the resin manufacturer's recommendations.

3. *Data Collection*

Each group of TFA and TC-85 aligners were stored on a model in the stressed position in an airtight bag within a body temperature-controlled water bath (37℃) until they were inserted into the test apparatus. All groups were placed in the water bath at the same time, precisely 8 hours before the first time point was measured to simulate the intraoral environment. For each measurement, the force and moment readings were all initialized to 0 to remove mechanical influences from installation and previous appliance insertion. At each time point, TFA aligners were shaken dry at ambient room temperature once removed from the water bath and inserted immediately on the setup. The TC-85 group of aligners were placed in a warm water bath set at a temperature of 69.4℃ for 5 seconds shortly before insertion.

These different protocols were performed to simulate clinical insertion for each material type; TFAs are typically placed into the oral environment directly from ambient settings, whereas DPAs printed from TC-85 are recommended by the resin manufacturer to be heated in warm water prior to insertion to fully take advantage of their shape memory property, reducing force decay from deformation, increasing flexibility, and ensuring a better fit[12]. The water bath temperature of 69.4℃ corresponds to the glass transition temperature of TC-85.

All groups were inserted by first seating the aligner on the anterior teeth and then placing pressure in the posterior direction. Following insertion, three force and three moment components acting on teeth 11, 21, and 22 were measured in real time at a sample rate of 600 Hz. Upon initial stabilization of the force and moment readings, the last seconds of data were recorded for further analysis. After the reading was captured, the aligners were removed, re-inserted on their respective model, and placed back into the appropriate airtight bag in the 37℃ water bath until the subsequent measurement.

This exact procedure was completed for each time point, beginning from the initial baseline measurement and then at 8 hours, 16 hours, 24 hours, 2 days, 3 days, 4 days, 5 days, 6 days, 7 days, and lastly, 14 days.

4. Statistical Analysis

Forces (Fx, Fy, Fz) at all different time points were summarized using means and standard deviations (SD). For each movement and aligner type, baseline vs. day-7 and baseline vs. day-14 comparisons were made for Fx, Fy, and Fz using the ttest (proc ttest). For the baseline period, changes in the force with movement (0.00 mm, 0.25 mm, and 0.50 mm) were compared for each aligner separately. The differences in the forces by aligner type for each movement were also compared for the baseline period. Analysis of variance was used for the comparisons using PROC ANOVA with Bonferroni for multiple comparisons (post-hoc) tests. All analyses were conducted using SAS version 9.3 (SAS Inc, Cary, NC, USA). Significance tests were performed using a 2-tailed hypothesis, and the level of significance (α) was set to 0.05.

Result

Tables 1~3 show the force levels measured in Newtons at each time point. Table 1 shows the mean force of the 10 aligners in the group with the SD for ATMOS, TC-85, and Zendura groups at the 0.00 mm activation. Tables 2 and 3 show the results in the

Table 1. Forces over time by aligner type for 0.00 movement in Newtons

Time	0.00								
	ATMOS			TC-85			Zendura		
	Fx	Fy	Fz	Fx	Fy	Fz	Fx	Fy	Fz
Baseline	2.88±0.86	–20.45±4.63	–9.46±3.39	0.33±0.18	–0.62±0.35	–0.07±0.13	1.58±0.75	–25.89±2.43	–13.09±2.00
8 hours	2.71±1.73	–12.12±8.77	–4.82±3.85	0.31±0.34	–0.20±0.54	–0.31±0.57	2.40±1.74	–10.30±8.39	–4.58±4.25
16 hours	1.87±1.64	–11.85±10.91	–5.55±5.31	0.22±0.28	–0.07±0.42	–0.16±0.32	1.69±1.70	–8.81±8.80	–4.10±4.12
24 hours	2.10±2.06	–8.30±8.57	–3.26±3.74	0.19±0.32	–0.01±0.41	–0.19±0.35	2.01±2.04	–7.95±8.04	–3.50±3.73
48 hours	2.48±2.19	–7.98±7.23	–2.69±2.79	0.07±0.26	–0.17±0.27	–0.16±0.19	1.87±2.00	–8.74±8.62	–4.01±4.30
Day 3	2.33±2.18	–6.74±6.05	–2.24±2.26	0.24±0.48	–0.13±0.51	–0.26±0.56	1.95±1.95	–8.83±8.70	–4.02±4.25
Day 4	2.49±2.08	–6.11±5.44	–1.94±1.86	0.29±0.42	–0.15±0.42	–0.20±0.32	2.15±2.00	–5.77±5.41	–2.50±2.48
Day 5	2.31±2.00	–6.48±5.79	–2.26±2.24	0.27±0.29	–0.01±0.45	–0.19±0.34	1.94±2.05	–5.79±6.04	–2.65±2.96
Day 6	2.22±2.01	–7.17±6.69	–2.75±2.79	0.13±0.29	0.03±0.37	–0.09±0.24	2.00±1.77	–9.79±8.06	–4.49±3.85
Day 7	2.64±2.02	–8.57±6.56	–2.96±2.58	0.15±0.48	–0.09±0.59	–0.12±0.63	2.10±1.86	–10.57±8.66	–4.83±4.27
Day 14	2.55±1.60	–10.29±7.22	–4.417±3.23	0.36±0.48	–0.33±0.51	–0.14±0.17	2.34±1.45	–13.17±8.32	–6.14±3.98

Values are presented as mean±standard deviation.

Table 2. Forces over time by aligner type for 0.25 movement in Newtons

Time	0.25								
	ATMOS			TC-85			Zendura		
	Fx	Fy	Fz	Fx	Fy	Fz	Fx	Fy	Fz
Baseline	3.82±2.33	–0.65±8.06	4.09±2.30	0.99±0.33	–0.64±0.39	–0.10±0.18	3.00±2.22	–5.97±6.98	3.32±2.88
8 hours	3.84±2.31	–6.39±4.57	–0.14±0.64	0.56±0.36	–0.12±0.47	–0.20±0.37	3.04±1.97	–9.49±6.79	–2.38±1.98
16 hours	3.44±2.79	–4.89±5.67	–0.20±1.15	0.44±0.34	–0.15±0.45	–0.26±0.41	2.29±2.17	–7.48±7.59	–2.14±2.29
24 hours	3.08±2.75	–5.33±5.47	–0.58±1.52	0.40±0.36	–0.12±0.36	–0.11±0.27	2.32±2.42	–5.19±5.83	–1.15±1.89
48 hours	3.06±2.66	–5.43±5.32	–0.40±1.25	0.33±0.28	–0.27±0.37	–0.15±0.22	2.89±2.45	–5.44±5.33	–1.10±1.64
Day 3	3.36±2.70	–4.98±4.75	–0.30±1.66	0.40±0.54	–0.13±0.55	–0.21±0.54	2.51±2.42	–6.38±6.32	–1.58±2.14
Day 4	3.08±2.50	–4.01±3.67	–0.06±1.19	0.66±0.41	–0.24±0.40	–0.23±0.27	2.55±2.37	–4.19±4.34	–0.98±1.76
Day 5	3.08±2.53	–3.36±2.98	0.05±1.40	0.52±0.39	–0.14±0.43	–0.13±0.28	2.68±2.30	–3.14±3.21	–0.75±1.58
Day 6	2.97±2.47	–4.49±4.24	–0.55±1.20	0.37±0.52	–0.03±0.53	–0.06±0.52	2.89±2.11	–7.01±5.79	–2.02±2.04
Day 7	3.34±2.53	–5.46±4.12	–0.51±1.30	0.46±0.56	–0.34±0.55	–0.17±0.58	3.10±2.17	–8.40±6.00	–2.33±1.99
Day 14	3.43±2.13	–6.70±4.96	–1.43±1.36	0.36±0.49	–0.08±0.45	–0.04±0.14	3.28±1.90	–9.23±6.39	–1.47±5.59

Values are presented as mean±standard deviation.

Table 3. Forces over time by aligner type for 0.50 movement in Newtons

Time	0.50								
	ATMOS			TC-85			Zendura		
	Fx	Fy	Fz	Fx	Fy	Fz	Fx	Fy	Fz
Baseline	7.70±4.91	–3.54±7.73	–18.94±13.85	1.53±0.40	–0.32±0.45	0.06±0.27	8.23±5.61	–1.84±7.37	–14.27±17.10
8 hours	4.38±1.57	–3.48±2.82	3.30±1.68	0.94±0.47	–0.14±0.66	–0.16±0.52	2.96±2.27	–4.83±4.98	0.10±1.27
16 hours	4.10±2.67	–2.36±2.38	1.56±1.45	0.67±1.29	–0.01±1.13	–0.13±1.27	2.73±2.41	–5.30±5.67	–0.55±1.39
24 hours	3.33±4.08	–2.31±3.16	0.81±1.53	0.59±0.51	–0.09±0.38	–0.18±0.34	3.04±2.55	–5.01±5.14	–0.63±1.64
48 hours	3.50±2.94	–3.10±3.87	0.77±1.168	0.56±0.38	–0.11±0.43	–0.17±0.28	2.80±2.56	–4.01±4.22	–0.69±1.53
Day 3	3.38±2.95	–2.81±3.42	0.86±1.49	0.36±0.43	–0.22±0.41	–0.17±0.45	3.15±2.28	–5.91±5.71	–1.05±1.77
Day 4	3.15±2.74	–2.57±2.78	0.80±1.42	0.67±0.43	–0.10±0.46	–0.25±0.29	2.58±2.45	–3.01±3.30	–0.53±1.57
Day 5	2.88±2.91	–0.98±3.08	2.01±3.61	0.77±0.68	–0.18±0.58	–0.23±0.59	2.58±2.40	–2.59±3.00	–0.52±1.61
Day 6	3.59±2.51	–2.46±2.57	0.81±1.02	0.42±0.46	–0.24±0.45	–0.06±0.24	2.93±2.35	–5.14±4.49	–1.27±1.72
Day 7	3.22±2.58	–3.54±3.54	0.50±1.15	0.47±0.46	–0.21±0.40	–0.06±0.21	3.24±2.26	–6.00±4.50	–1.32±1.49
Day 14	3.52±2.26	–3.17±4.56	0.18±1.20	0.94±0.47	0.08±0.50	–0.10±0.26	3.17±2.09	–7.21±4.80	–1.96±1.59

Values are presented as mean±standard deviation.

same way for the 0.25 mm and 0.50 mm activations.

TC-85s in every activation group showed less force on teeth than the ATMOS and Zendura, with forces mainly ranging between 0.3~1 Newton. All the thermoforming groups exhibited force levels higher than ideal.

Even with 0.0 mm activation, some active force stayed consistent over the course of 14 days in all groups (Table 1).

For the 0.25 mm activation group, ATMOS aligners exhibited unwanted force in the Fy and Fz axes by significant mesial crown force and intrusive force (Table 2). Fx remained relatively stable over the 14 days. For the TC-85 0.25 mm activation group, Fx force levels at mean±SD 0.33±0.28~0.99±0.33 N were maintained. Fy did not fluctuate, while Fz initially showed an intrusive force that lessened over the 14 days. Zendura showed less force than ATMOS in this activation group. Fx remained steady near the mean±SD 2.29±2.17~3.28±1.90 N but exhibited a slight increase over time. Fy showed significant mesial crown force. Fz displayed an unpredictable trend over time.

For the 0.5 mm activation groups, ATMOS showed heavy forces that decreased some over time in the Fx axis. Fy fluctuated throughout the experiment period, however, baseline and day 14 measurements were the same, showing consistent force. Fz showed an intrusive force that decreased over time. The TC-85 group showed a decrease in force levels over time in the Fx axis. Fy exhibited a mesial crown force for this group that remained consistent until the 14-day measurement. The Fz axis for TC-85s at 0.50 mm activation at baseline showed a small extrusive force in contrast with the remaining time points, which exhibited a small intrusive force. The Zendura aligners showed significant relaxation over time in the Fx axis, reaching less than 50% of the initial force level by 14 days. Measurements in the Fy and Fz axes were unpredictable. The Fy axis exhibited a mesial crown force that fluctuated over the 14 days. The Fz axis showed a large intrusive force at the initial time point, which decreased from –14.27 to –1.96 N over time.

Comparisons were performed for the baseline measurement with 7 days and the baseline measurement with 14 days. All changes in force levels between the baseline measurements and the 7- and 14-day measurements were significant among all force directions and aligner materials (>0.001) (Tables 4 and 5).

Table 6 shows the initial force levels for each material at 0.00, 0.25, 0.50 mm activations. For Fx, force levels increase with increasing activation or movement of the tooth, which has been shown in previous studies. For ATMOS aligners, 0.00 mm movement showed 2.88 N of force, while 0.25 mm and 0.50 mm showed 3.82 N and 7.70 N, respectively. TC-85 showed lower force levels for all activations. The passive aligners showed a mean of 0.33 N, 0.25 mm activation delivered 0.99 N, and 0.50 mm delivered 1.52 N of force. Zendura aligners at 0.00 mm delivered a mean of 1.58 N of force. The 0.25 mm group showed a mean of 3.00 N, and the 0.50 mm group showed a mean of 8.23 N of force. The comparison between all three groups was statistically significant.

Table 7 compares force levels delivered by all three aligner materials in each activation group. For the "passive" aligner group at 0.00 mm activation, TC-85 revealed a mean force of 0.33 N, while ATMOS and Zendura aligners exhibited much higher force levels of 2.88 N and 1.58 N, respectively. At 0.25 mm activation, TC-85 again showed lower force levels for a

Table 4. Baseline to day-7 comparison for each movement and by aligner type

Time	Baseline vs. day-7 comparison								
	ATMOS			TC-85			Zendura		
	Fx	Fy	Fz	Fx	Fy	Fz	Fx	Fy	Fz
0.00	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
0.25	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
0.50	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001

Table 5. Baseline to day-14 comparison for each movement and by aligner type

Time	Baseline vs. day-14 comparison								
	ATMOS			TC-85			Zendura		
	Fx	Fy	Fz	Fx	Fy	Fz	Fx	Fy	Fz
0.00	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
0.25	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
0.50	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001

Table 6. Baseline comparison of force change by movement for ATMOS, TC-85, Zendura

Material	Force	0.00 movement	0.25 movement	0.50 movement	P-value[a]	P-value[b]	P-value[c]
ATMOS	Fx	2.88±0.86	3.81±2.33	7.70±4.91	<0.001	<0.001	<0.001
	Fy	–20.45±4.63	–0.65±8.06	–3.54±7.73	<0.001	<0.001	<0.001
	Fz	–9.46±3.39	4.09±2.30	–18.94±13.85	<0.001	<0.001	<0.001
TC-85	Fx	0.33±0.18	0.99±0.33	1.53±0.40	<0.001	<0.001	<0.001
	Fy	–0.62±0.35	–0.64±0.39	–0.32±0.45	<0.001	<0.001	<0.001
	Fz	–0.07±0.13	–0.10±0.18	0.06±0.27	<0.001	<0.001	<0.001
Zendura	Fx	1.58±0.75	3.00±2.22	8.23±5.61	<0.001	<0.001	<0.001
	Fy	–25.89±2.43	–5.97±6.98	–1.84±7.37	<0.001	<0.001	<0.001
	Fz	–13.09±2.00	3.32±2.88	–14.27±17.10	<0.001	<0.001	<0.001

Values are presented as mean±standard deviation.

[a]P-value: comparison between 0.00 vs. 0.25, [b]P-value: comparison between 0.25 vs. 0.50, [c]P-value: comparison between 0.00 vs. 0.50.

Table 7. Baseline comparison of force change by aligner for 0.00,0.25 and 0.50 activation

Activation	Force	ATMOS	DPA	Zendura	P-value[a]	P-value[b]	P-value[c]
0.00	Fx	2.88±0.86	0.33±0.18	1.58±0.75	<0.001	<0.001	<0.001
	Fy	–20.45±4.63	–0.62±0.35	–25.89±2.43	<0.001	<0.001	<0.001
	Fz	–9.46±3.39	–0.07±0.13	–13.09±2.00	<0.001	<0.001	<0.001
0.25	Fx	3.82±2.33	0.99±0.33	3.00±2.22	<0.001	<0.001	<0.001
	Fy	–0.65± 8.06	–0.64±0.39	–5.97±6.98	<0.001	<0.001	<0.001
	Fz	4.09±2.30	–0.10±0.18	3.32±2.88	<0.001	<0.001	<0.001
0.50	Fx	7.70±4.91	1.53±0.40	8.23±5.61	<0.001	<0.001	<0.001
	Fy	–3.54±7.73	–0.32±0.45	–1.84±7.37	<0.001	<0.001	<0.001
	Fz	–18.93±13.85	0.06±0.27	–14.27±17.10	<0.001	<0.001	<0.001

DPA: direct-printed aligners.

Values are presented as mean±standard deviation.

[a]P-value: comparison between ATMOS vs. DPA, [b]P-value: comparison between DPA vs. Zendura, [c]P-value: comparison between ATMOS vs. Zendura.

mean of 0.99 N, with ATMOS and Zendura materials revealing mean force levels of 3.82 N and 3.00 N, respectively. Lastly, the 0.50 mm activation group revealed higher force levels than the 0.00 mm and 0.25 mm activation groups. The TC-85 group exhibited a mean force level of 1.53 N, while ATMOS aligners exhibited a mean 7.70 N of force. Zendura aligners for this group showed the highest force levels with a mean of 8.23 N. The comparisons between all three groups are statistically significant.

Fig. 2~4 show the force levels over time for each aligner material at all three activation groups for the x axis. The decrease of force levels over time is observed as the ATMOS baseline measurement of 2.88 N falls to 2.55 N at 14 days for 0.00 mm activation. Similar trends are seen in the 0.25 mm and 0.50 mm activation as baseline measurements are 3.82 N and 7.70 N and decrease to 3.43 N and 3.52 N at 14 days. The TC-85 aligners showed baseline measurements of 0.33 N, 0.99 N, and 1.53 N for the three activation groups. For the 0.00 mm group, the force level slightly increased to 0.36 N from 0.33 N at 14 days. The force levels in the 0.25 mm activation group fell to 0.36 N from 0.99 N. The 0.50 mm activation group decreased from 1.53 N to 0.96 N. For Zendura aligners, the 0.00 mm and 0.25 mm activation groups both showed increases in force levels from the baseline measurement to 14 days, rising from 1.58 N to 2.34

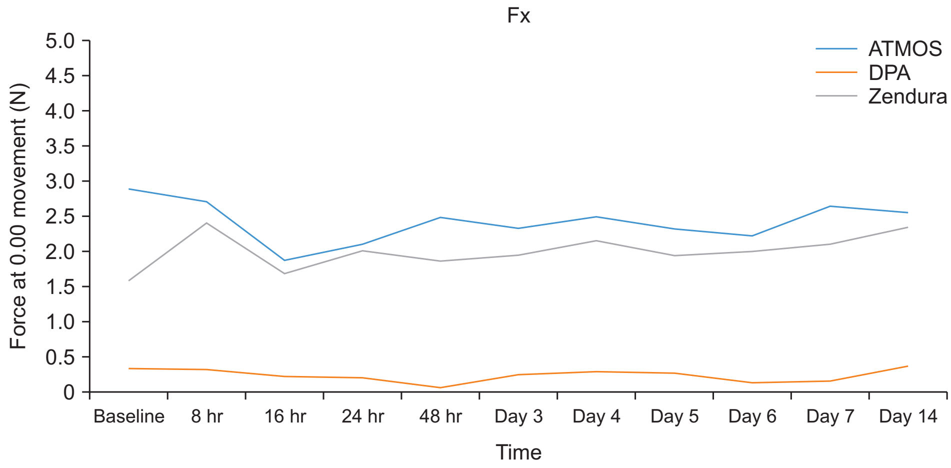

Fig. 2. Forces over time by aligner type for 0.00 movement for Fx axis. DPA: direct-printed aligners.

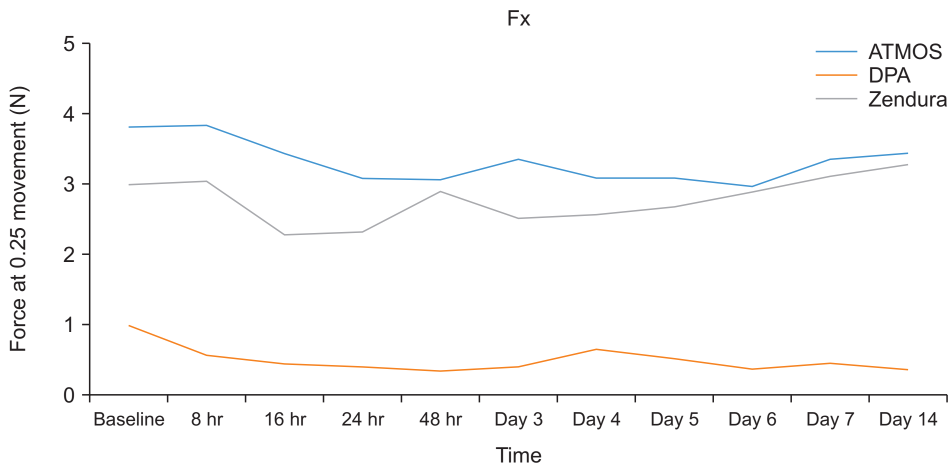

Fig. 3. Forces over time by aligner type for 0.25 movement for Fx axis. DPA: direct-printed aligners.

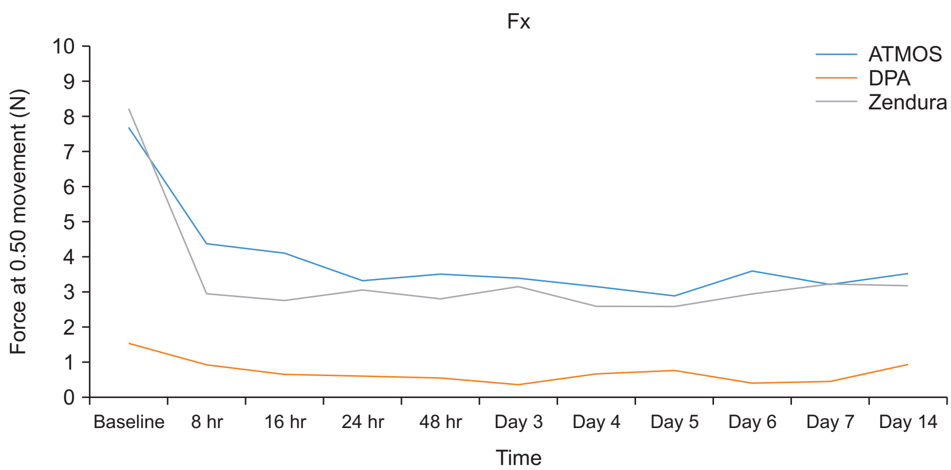

Fig. 4. Forces over time by aligner type for 0.50 movement for Fx axis. DPA: direct-printed aligners.

N and from 3.00 N to 3.28 N. The 0.50 mm activation group decreased in force levels from 8.23 N at baseline to 3.17 N at 14 days.

Discussion

This study attempted to represent the mechanical behavior of DPAs printed from TC-85 and TFAs worn in an *in vitro* simulated environment for 14 consecutive days. Even though few other articles have attempted to analyze forces and moments of clear aligners[11,13,14], none of them, to the best of our knowledge, have a follow-up of this long period and did not investigate TC-85 mechanical properties and force levels for lingual bodily movement.

Our data demonstrated that the movement of teeth with aligners is unpredictable and behaves differently depending on the material used for its fabrication. In agreement with that, a prospective clinical study showed that aligners from the leading aligner company only have 41% accuracy for the programmed movement[15], followed by a more recent paper showing that this rate has evolved to only 50% in 2009[16]. Our data could help explain this inaccuracy. The results of this study clearly show that forces and moments generated by aligners express differently than they were programmed, leading to this lack of precision in treatment results.

Our findings also go beyond that; we could prove that many unprogrammed movements may arise during treatment. Even though we only staged a lingual movement, all groups showed some degree of intrusion or mesial movement, with the severity depending on the material of choice. Clinically, this fact has a critical relevance; now, the orthodontist can use this information to anticipate potential undesired forces and prevent them during planning/staging or when selecting a specific type of plastic/resin.

Some papers attempt to look for answers to the movement's unpredictability. A review of the literature concluded that a series of different movements could not be effectively achieved and controlled[8] as a buccal-lingual anterior movement, the same sort we have attempted to simulate in our study. Another article states that different from fixed appliances, aligners do not have a specific point of force application, but the entire crown is covered by the plastic material and susceptible to changes, and it is harder to predict the action of force[5].

The unintentional creation of a force system in aligners has been reported in previous studies, but mainly describing the effects on the adjacent teeth[2,17]. In our study, we can report an unexpected finding—a passive aligner is not passive; it creates forces on teeth that were not planned. The 0.0 mm activation aligners in this study showed force levels between 0.33~2.88 N for all three materials, which stayed consistent over the 14 days. This fact has a severe clinical implication, where the orthodontist can face an unwanted movement in a 0.0 mm activation force system leading to some degree of failure during treatment.

A future study could observe the force levels received by the adjacent teeth, UL2 and UR1, but the current study only looked at the one tooth with planned movement[2].

Our results confirm that the aligners will perform differently depending on their construction material, a fact previously stated by Bichu et al.[7], where he affirmed that the biomechanics behavior of the aligner correlated with the material it was produced from. A critical goal of providers in orthodontic treatment is to deliver treatment within the biomechanically acceptable therapeutic range. Significant differences could be seen between the 3 groups in our study. For the baseline measurements, ATMOS aligner material exhibited the highest force levels for the 0.00 mm and 0.25 mm activation groups, reaching means of 2.88 and 3.82 N. Zendura aligners also had force levels greater than ideal for all three activation groups at the initial time point. Zendura aligners showed the highest force level for the 0.50 mm activation group with a mean of 8.23 N. TC-85 aligners had consistent force levels closer to ideal for all three activation groups at baseline. The data suggests that the forces delivered by TC-85 aligners are more aligned with the biomechanically desired force levels recommended by Proffit et al.[18] and deliver a more consistent force profile. A recent study assessing the force profile of DPAs confirms our findings, demonstrating that the force profile delivered by DPA was significantly lower than the ones demonstrated by TFA[9]. In a sense, DPAs could be considered analogous to Nickel-Titanium wires delivering gentle, consistent forces over a range of displacements. The force level delivery by an appliance should guide the practitioner on what material to select, and considering the findings of this paper, TC-85 should be the material of choice.

One objective of this study is to observe the percentage of stress relaxation that occurs from baseline to the 7~14 days of an intraoral application when aligners are maintained in a simulated intraoral environment. The results of this study did not show the significant decreases in force levels over time that other studies have suggested[11]. The intra-oral clinical simulated environment could contribute to this finding and set this study apart from others. A study by Lombardo et al.[11] investigated the stress release properties of four thermoplastic materials and reported that stress release might exceed 50% of the initial stress value in the early hours of wear. In the current study, ATMOS materials in all three activation groups showed only a slight decrease over the 14 days; however, the change in force was still statistically significant. TC-85 stayed consistent with some fluctuation throughout the 14 days but experienced a decrease of force levels over time. The results for Zendura aligners were not as clear cut. The force levels increased over time for the 0.00- and 0.25-mm activation groups and this increase in force levels from baseline to 14 days could be due to the aligner not fitting well or not being fully seated on the teeth. For the activated central incisor, increasing the activation resulted in a more significant amount of force decay for the TFA. Based on these results and considering possible clinical implications, TC-85 appears to be capable of maintaining the force throughout the treatment and should be considered a stable material.

Comparisons were made for baseline measurements to 7-days and 14-days because some clinicians recommend weekly changes for aligner patients while others recommend two-week changes. Both comparisons showed statistically significant changes from the baseline force level. Other studies have reported similar findings. A randomized controlled trial by Al-Nadawi et al.[19] looked at 7-, 10-, and 14-day wear schedules. They concluded that achieving a clinically similar accuracy between the 7-day protocol and 14-day protocol in half the treatment time suggests that a 7-day protocol is an acceptable treatment protocol[19]. A study by Stephens et al.[14] also revealed no difference in rotation efficiency between 1- or 2-week aligner wear.

The current study had its limitations. First, it should be noted that this investigation was performed *in vitro* and did not consider clinical factors such as saliva or masticatory forces. Water absorption can increase the thickness of plastic and change the material properties. Masticatory forces can change the amount of intrusive force that is applied by an aligner. Another limitation of this methodology includes the lack of periodontal ligament (PDL) in the experimental teeth; thus, the force generated may be of a higher magnitude than would generally be expected in a system where all teeth have degrees of freedom corresponding to the PDL space. The current study also did not account for the varying bone quality found in patients. Patient compliance and the frequency of removal, which has been shown to affect force delivery of aligners, were also not considered. The experimental apparatus used in this study also has its limitations. Ninety different aligners were used in this study, and while careful attention was paid to the path of insertion on the sensor, there could have been some discrepancy upon seating the aligner from the anterior to posterior each time.

Conclusion

The force levels of three different aligner materials on a labially displaced central incisor over 14 days were measured, and the following conclusions were made:

- Clear aligners with no prescribed movements (0.0 mm activation) can generate active forces and moments.
- Aligners printed with TC-85 material generated lower, more consistent, and closer to the ideal forces, with fewer side effects.
- Comparisons were made for baseline measurements to 7-days and 14-days; both comparisons showed statistically significant change from the baseline force level.

Conflict of Interest

No potential conflict of interest relevant to this article was reported.

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