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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-

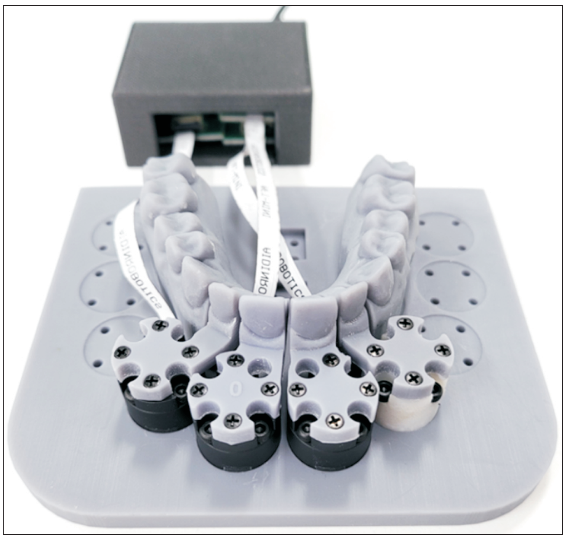

Fig. 1. Three-axis force and moment sensor.

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