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Original Article

An in vitro evaluation of aligner force decay in artificial saliva

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KEYWORDS
Aligner;
Orthodontic force;
Artificial saliva;
Decay

Abstract *Background/purpose:* The present study aimed to compare the force decay of invisible aligners for maxillary anterior teeth with 0.1 mm (D_1), 0.2 mm (D_2), and 0.3 mm (D_3) labial movement within a simulated oral environment over 7 days.
Materials and methods: The prepared invisible aligners were immersed in saliva (S) and subjected to applied force (F) for 7 days. The aligners were set and placed on the maxillary right central incisor with 0.1 mm (D_1), 0.2 mm (D_2), and 0.3 mm (D_3) labial movement. Thin-film pressure sensors were used to measure the aligner force changes. The data were collected and analyzed by statistical methods.
Results: Significant differences were observed in the initial and first-day force between the D_2 and D_3 groups under simulated oral environment force (SF) ($P < 0.05$). There was a significant difference in force decay between Day 1 and Day 7 for all groups ($P < 0.05$). The SFD_1 group showed a significant decrease in force on Day 5 ($P < 0.05$), while the SFD_2 and SFD_3 groups showed significant force decay on Day 4 ($P < 0.05$). The force decay ratio on Day 7 was higher in the SFD_3 group than in the SFD_1 and SFD_2 groups, but no significant difference was observed.
Conclusion: Larger labial movement of the aligners resulted in higher force decay under artificial saliva environments, and the force decay of invisible aligners was increased by immersion time in artificial saliva.

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Introduction

The clear aligner therapy (CAT) technique originated in 1945 when Kesling first used an elastic polymer to create a tooth positioner for moving teeth.[1] In 1999, align technology was combined with Computer Aided Design and Computer-aided manufacturing (CAD/CAM) technology to automatically create models for each stage and produce thermoplastic aligners for tooth movement, leading to the development of the CAT technique.

The advantages of CAT include aesthetic appearance, comfort, easy cleaning, and precise and predictable correction, reducing the need for office visits. This treatment technique belongs to active orthodontic appliances, and similar to most active appliances, it applies intermittent force to the teeth,[2] which is sufficient to produce orthodontic tooth movement (OTM) while minimizing damage to periodontal tissue cells.[3,4]

An ideal aligner should have sufficient hardness and strength to provide continuous force to move teeth and enough elasticity to envelop and adhere to teeth for sufficient support. However, there is still a problem of hardness and strength degradation. Aligner materials are viscoelastic, and the initial stress is released over time, causing the mechanical properties of the aligner to gradually degrade.[5] The force exerted on teeth by both traditional PET-G material and modified PET-G material decreases as wearing time increases within 48 h.[6] Continuous and appropriate force is needed to achieve ideal tooth movement. However, excessive force may cause root absorption, while insufficient force cannot move teeth. Therefore, orthodontists need to understand the material properties of braces to design appropriate braces.The success rate of CAT in moving anterior teeth to be 41%, and the success rate of CAT for anterior tooth extrusion to be only 29.6%.[7] Thus, CAT technology still lacks control over the corrective force in the oral environment.

The optimal force for traditional body movement orthodontic correction is 0.75–1.25 N.[8] The conditions required for invisible aligners include high resilience, low hardness, good shaping ability, high energy storage capacity, biocompatibility, and good stability in the presence of the oral environment.[9] The frequency of invisible aligner removal affects their deformation and force control.[6] When used a thin film pressure sensor to measure the movement of the upper central incisor toward the tongue found that the corrective force of the invisible aligner significantly decreases on Day 1 and does not stabilize until Day 4 or Day 5.[10] The rebound pressure of aligner found no significant differences among the different brands.[11] Above studies were conducted their experiments with invisible aligners placed in air without considering the effects of humidity and temperature in the oral environment. The stress release of the thermal forming plate is accelerated in the humid and hot environment of the oral cavity compared to in air.[5]

Polymers absorb moisture from the air or when immersed in water, causing expansion or changes in mechanical properties.[12] The hygroscopic expansion of invisible aligners in the mouth changes their shape, resulting in poor fit with teeth and affecting the transmission of corrective force.[13–15] The hygroscopic expansion of thermoplastic plates destroys the adaptability of braces, leading to changes in corrective force.[12]

Current research on measuring the corrective force of aligner focuses on using thin film pressure sensors to measure the movement of the front teeth toward the tongue,[6,10,16,17] but there is a lack of research on movement toward the lips. The accuracy of the invisible aligner in moving the upper front teeth toward the lips is only 37%, which is lower than the accuracy of movement toward the tongue at 53%.[7]

The purpose of the present study was to measure the PETG aligner corrective force decay after being worn for 7 days in a simulated oral environment as well as to evaluate the movement of the upper front teeth toward the lips.

Materials and methods

Design and fabrication of the aligners

A maxillary model with 14 teeth was scanned and converted into a 3D digital model in STL format (M0). Using 3Shape orthodontic software (3Shape A/S Co., Copenhagen, Denmark), three sets of aligner models were designed with 0.1 mm, 0.2 mm, and 0.3 mm displacements of the right maxillary central incisor toward the labial direction, and they were defined as M1, M2, and M3, respectively. Finally, the M1, M2, and M3 models were fabricated using a light-cured resin 3D printer (Stratasys Co., Rock Hill, SC, USA).

After the models were printed, 0.75 mm Duran T PETG thermoplastic plate (Scheu Dental, Iserlohn, Germany) were thermoformed on a Mini Star machine (Scheu Dental Co.) using a vacuum press to create the aligners. The aligners, denoted as D_1, D_2, and D_3, were made based on the M1, M2, and M3 models, respectively. To ensure consistency between aligners made from the same model, two reference lines were drawn on the model, one at the bottom of the aligner and the other at the top of the model inserted into the thermoforming machine (Fig. 1), based on the method proposed by Ihssen et al.[18] After thermoforming, each sheet was trimmed and labeled according to the reference lines on the model.

Measurement of aligner force

The right central incisor was removed from the M0 model using 3Shape software, and a measuring base was added in front of the original position of the right central incisor to create the measurement model (M_t) (Fig. 2) according to the method of Nowak et al.[11] To measure the aligner force, a thin-film pressure sensor (Micro Sensor Co., Ltd. Thief River Falls, MN, USA) was placed in the position of the removed right central incisor in the M_t model, and the reading of the sensor was confirmed as zero. The aligner was then removed and reinserted into the M_t model, and the aligner force value was measured (Fig. 3).

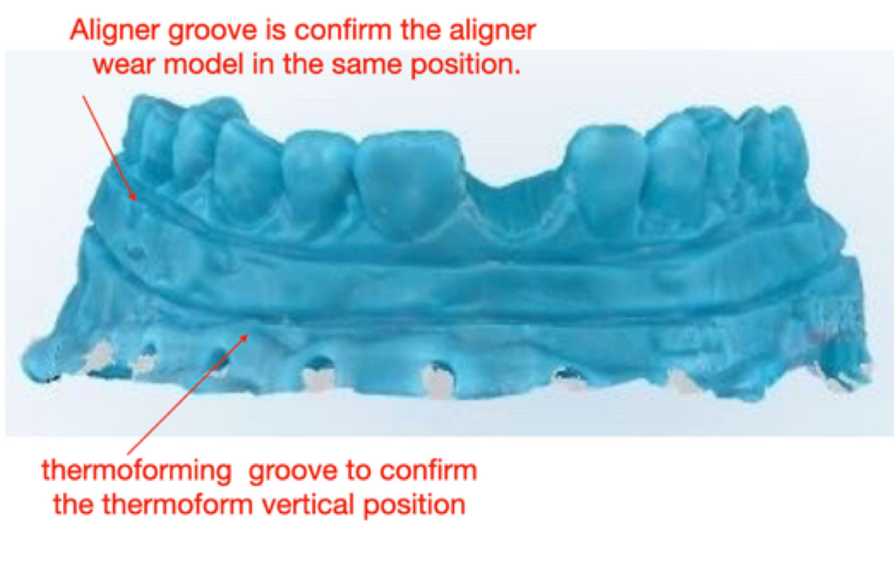

Figure 1 Reference line for standardization of orthodontic appliances.

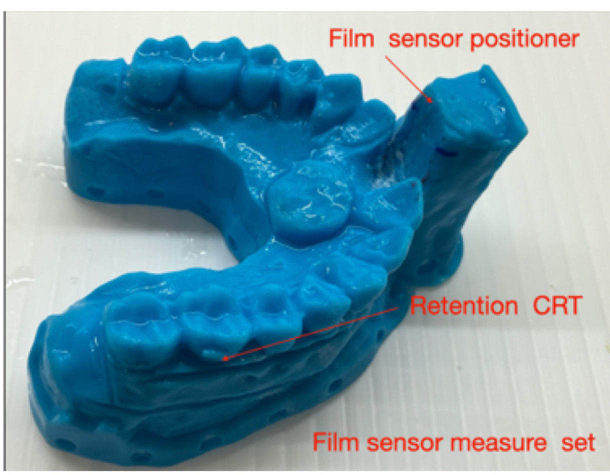

Figure 2 Measurement model (M_t) used for measuring corrective force.

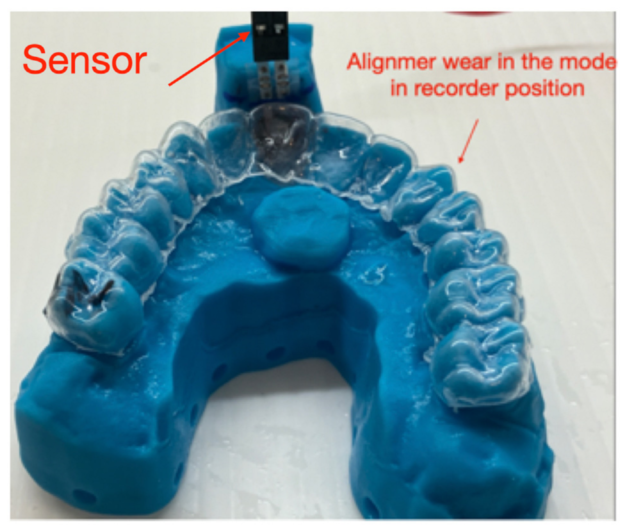

Figure 3 Illustration of measuring the corrective force of the invisible aligner.

Experimental environment

To eliminate the effect of temperature and simulate the oral environment, the orthodontic aligners were placed in a constant temperature bath at 37 °C if the experimental condition required soaking the orthodontic aligners in artificial saliva($NaCl$ = 0.6 g/L, KCL = 0.72 g/L, $CaCl_2.2H_2O$ = 0.22 g/L, KH_2PO_4 = 0.68 g/L, $Na_2HPO_2.12H_2O$ = 0.856 g/L, $KSCN$ = 0.06 g/L, $NaHCO_3$ = 1.5 g/L, $C_6H_8O_7$ = 0.03 g/L). The composition of the artificial saliva has been previously described by Tamburrino et al.[19]

Experimental procedure

The experimental groups consisted of 12 combinations based on soaking the orthodontic aligners in saliva (S), wearing the aligners on the M0 Model (F), and designing the aligners to move 0.1 mm (D_1), 0.2 mm (D_2), or 0.3 mm (D_3) toward the lip. Five sets of orthodontic aligners were used for each condition. The corrective force was measured by placing the aligners on the M_t, which was considered as the Day 0 value. Each aligner was left in the corresponding environment for 7 days. Every 24 h, the aligner was taken out of the environment, placed on the M_t to measure the corrective force, and returned to the same environment. The paired *t*-test with Bonferroni correction was used to analyze the decay of corrective force within 7 days under the SF condition. Three-way ANOVA was used to analyze the effect of S, F, and D on the residual corrective force on the same day, $P < 0.05$ was considered statistically significant.

Table 1 Measurement of corrective force (Standard deviation, Sd) of D_1, D_2, and D_3 over seven days in a simulated oral environment.

Group	SFD_1 (0.1 mm)	SFD_2 (0.2 mm)	SFD_3 (0.3 mm)
Initial force (g)	168.600 (18.569)[efg]	175.800 (13.180)[bcdefgh]	181.400 (8.764)[bcdefgh]
Day 1	160.800 (16.932)[fg]	169.200 (12.637)[aefgh]	174.400 (9.633)[aefgh]
Day 2	157.200 (16.498)[f]	165.400 (12.012)[aefg]	171.000 (8.888)[aefgh]
Day 3	152.600 (14.553)[fg]	162.000 (10.654)[aefgh]	168.600 (8.173)[aefgh]
Day 4	149.400 (14.311)[afg]	159.400 (10.621)[abcdfg]	165.400 (7.925)[abcdfgh]
Day 5	146.800 (13.773)[abcde]	156.400 (10.621)[abcde]	162.800 (8.228)[abcdeh]
Day 6	143.800 (13.293)[abde]	154.000 (10.149)[abcde]	160.800 (8.289)[abcde]
Day 7	139.600 (10.691)	151.000 (8.246)[abd]	157.400 (6.914)[abcdef]

Daily corrective force values (g) and standard deviations for the invisible aligners.[a] indicates significant differences are relative to the baseline value of 0, as well as days [b]1, [c]2, [d]3, [e]4, [f]5, [g]6, and [h]7 ($P < 0.05$, paired t-test with Bonferroni correction). S, immersion in artificial saliva; F, attachment of aligner on M0 model; D_1, D_2, and D_3 indicate design of the orthodontic appliance to move 0.1 mm, 0.2 mm, and 0.3 mm toward the lip, respectively.

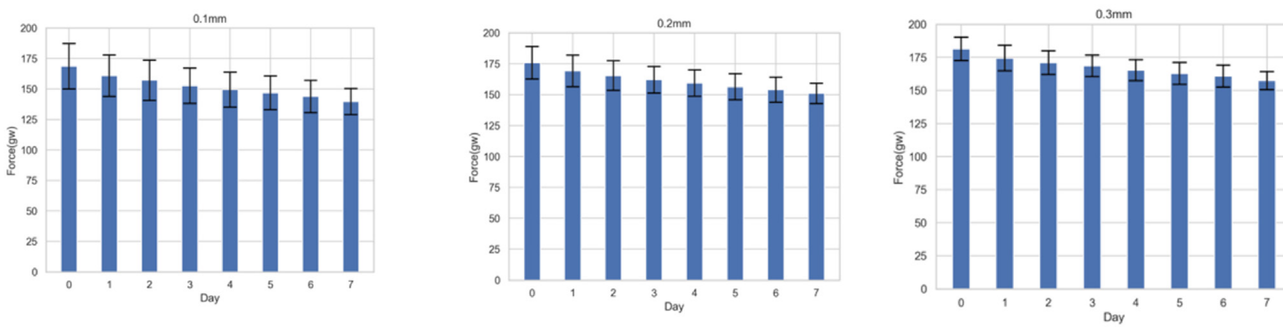

Figure 4 Average values of the D_1, D_2, and D_3 invisible aligners under simulated oral environment (SF) with respect to days of wear. S, immersion in artificial saliva; F, attachment of aligner on M0 model. The displacements amount of the right maxillary central incisor toward the labial direction, D_1: 0.1 mm, D_2: 0.2 mm, and D_3: 0.3 mm. The initial force of clear aligners increased with the distance of aligner movement, but there was no significant difference among the three groups ($P > 0.05$).

Results

In the simulated oral environment (SF), the measurement values of orthodontic force for the SFD_1, SFD_2, and SFD_3 clear aligners in the direction of maxillary incisors toward the lips changed within 7 days (Table 1). The initial force of clear aligners increased with the distance of aligner movement, but there was no significant difference among the three groups ($P > 0.05$) (Fig. 4).

All clear aligners showed a gradual decrease in orthodontic force over time. All three groups of clear aligners had significant decay between Day 0 and Day 1, but only SFD_2 and SFD_3 showed significant differences ($P < 0.05$, t-test with Bonferroni correction) (Fig. 5). In addition, the clear aligner force decay rate of SFD_3 was higher than that of SFD_1 and SFD_2 (Fig. 5). Table 1 shows that there was no significant difference in the correction force between Day 1 and Day 4 in the SFD_1 group in the simulated oral environment (SF), and the correction force for all 4 days was significantly different from that of Day 4. In the SFD_2 group, there was no significant difference in the correction force between Day 1 and Day 3, and the correction force for all 3 days was significantly different from that of Day 4. In the SFD_3 group, there was no significant difference in the correction force between Day 1 and Day 4, and the

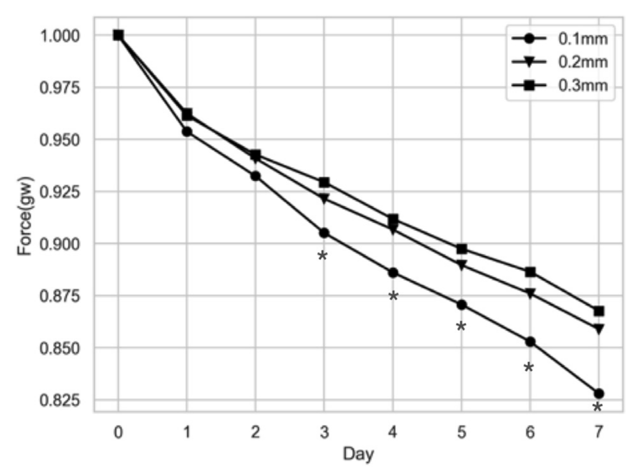

Figure 5 All clear aligners showed a gradual decrease in orthodontic force over time. the clear aligner force decay rate of SFD_3 was higher than that of SFD_1 and SFD_2. Mean residual percentage of D_1, D_2, and D_3 invisible aligners as a function of time in the simulated oral environment (SF). S, immersion in artificial saliva; F, attachment of aligner on M0 model. The displacements amount of the right maxillary central incisor toward the labial direction, D_1: 0.1 mm, D_2: 0.2 mm, and D_3: 0.3 mm *: $P < 0.05$.

Table 2 Original force values of each group, unit measured in grams (Standard deviation, Sd).

Group	Mean (Sd)	Group	Mean (Sd)
D_1	158.00 (1.87)	SD_1	168.40 (15.96)
D_2	162.00 (2.00)	SD_2	175.40 (12.10)
D_3	166.00 (1.87)	SD_3	180.80 (9.12)
FD_1	157.40 (1.82)	SFD_1	168.60 (18.57)
FD_2	162.20 (1.64)	SFD_2	175.80 (13.18)
FD_3	166.20 (1.64)	SFD_3	181.40 (8.76)

D_1, D_2, and D_3 indicate design of the orthodontic appliance to move 0.1 mm, 0.2 mm, and 0.3 mm toward the lip, respectively. S, immersion in artificial saliva, F, attachment of aligner on M0 model. Sd. Standard deviation.

correction force for all three days was significantly different from that of Day 5 ($P < 0.05$, paired *t*-test with Bonferroni correction).

The initial correction force of 12 different conditions of clear aligners is shown in Table 2, and the residual orthodontic force ratio within 7 days is shown in Table 3. The residual correction force of clear aligners demonstrated that immersion in saliva (S) had a significant effect on the residual correction force ratio of clear aligners on Days 1—7 ($P < 0.05$) (Table 4, Fig. 6). Additionally, the design of the clear aligner moving distance (D) had a significant effect on the residual correction force ratio of clear aligners from Day 3 onward ($P < 0.05$).

Discussion

According to the three-point bending test on 0.75 mm Duran forming sheets found a force of 16.39 N with a distance of 8 mm between two ends, a deflection of 0.25 mm, and a force of 2.33 N with a distance of 16 mm between two ends and the same deflection.[20] It indicating that the force increases as the distance between the two ends decreases. The force decreases by 1% after 24 h of water immersion and by 14% under dry conditions, whereas it decreases by 50% under water immersion with load.[20]

These results suggest that water immersion and load increase the degree of degradation of forming sheets. However, this report did not show a significant increase in the residual correction force under both load and water immersion. An amorphous polymer in PETG absorbs water, which acts as a plasticizer, thereby reducing its glass transition temperature (Tg). As the invisible aligner approaches Tg, its modulus of elasticity decreases, resulting in an unpredictable correction force.[19] The present study demonstrated that soaking in artificial saliva (S) had a significant impact on the residual correction force of the invisible aligner, which was consistent with the previous study. The residual correction force ratio after soaking in artificial saliva for 7 days in the present experiment was similar to the residual correction force of PETG aligners is 85% after 7 days of soaking in artificial saliva.[17]

After 7 days, the present study showed approximately 10% residual force in Groups D_1, D_2, and D_3. The results are similar with the stress released during thermal forming causes mechanical properties to gradually deteriorate over time.[5] Xiang et al. measured a pressure of 8 N on a 0.75 mm thick aligner that moved 0.2 mm toward the lingual side using a thin film pressure sensor.[17] Liu et al. measured a pressure of 1.25 N on a 0.75 mm thick aligner that moved 0.2 mm toward the lingual side using a thin film pressure sensor.[21] Naohisa et al. measured a pressure of 1.65 N on a 0.5 mm Duran aligner that moved 0.5 mm.[22] Barbagallo et al. measured a pressure of 5.12 N on a 0.8 mm Duran

Table 3 Residual orthodontic force ratio of clear aligners over time. [Mean (Standard deviation. Sd)].

	Residual orthodontic force ratio % (Sd)					
	D_1	D_2	D_3	FD_1	FD_2	FD_3
Day 0	100.00(0.00)	100.00(0.00)	100.00(0.00)	100.00(0.00)	100.00(0.00)	100.00(0.00)
Day 1	98.86(0.28)	99.01(0.34)	98.68(0.26)	98.35(0.34)	98.40(0.32)	98.08(0.49)
Day 2	96.84(0.63)	97.41(0.51)	96.87(0.49)	96.19(0.60)	96.30(0.73)	96.39(0.57)
Day 3	95.70(0.68)	96.55(0.68)	95.91(0.74)	94.80(0.90)	95.19(0.66)	95.19(0.91)
Day 4	94.31(0.86)	95.56(0.66)	93.64(3.16)	93.28(1.64)	94.08(0.91)	93.99(1.15)
Day 5	92.53(0.48)	93.46(0.75)	93.02(0.73)	91.50(1.68)	92.48(1.16)	92.43(1.18)
Day 6	90.64(0.72)	91.25(1.37)	91.33(0.92)	89.72(1.75)	90.63(1.55)	90.14(1.37)
Day 7	89.88(0.97)	90.63(1.37)	90.61(1.07)	88.58(1.77)	88.91(1.09)	89.06(1.41)
	SD_1	SD_2	SD_3	SFD_1	SFD_2	SFD_3
Day 0	100.00(0.00)	100.00(0.00)	100.00(0.00)	100.00(0.00)	100.00(0.00)	100.00(0.00)
Day 1	94.99(1.22)	95.91(0.94)	96.13(0.86)	95.42(1.21)	96.25(0.05)	96.12(0.90)
Day 2	93.34(1.40)	93.98(1.52)	94.91(1.02)	93.30(2.12)	94.10(0.85)	94.26(1.00)
Day 3	91.03(1.21)	92.40(1.38)	93.03(0.80)	90.65(2.19)	92.21(1.14)	92.95(0.79)
Day 4	88.92(1.64)	90.93(1.65)	91.59(0.55)	88.74(2.05)	90.72(1.31)	91.18(0.58)
Day 5	86.59(2.51)	89.08(1.53)	89.50(0.44)	87.21(2.15)	89.01(1.22)	89.74(0.42)
Day 6	84.93(2.59)	87.35(1.53)	88.51(0.75)	85.45(2.31)	87.65(1.01)	88.64(0.78)
Day 7	82.77(3.42)	85.36(1.89)	87.43(1.33)	83.10(4.03)	86.01(2.14)	86.79(0.64)

S, immersion in artificial saliva; F, attachment of aligner on M0 model; D_1, D_2, and D_3 indicate design of the orthodontic appliance to move 0.1 mm, 0.2 mm, and 0.3 mm toward the lip, respectively.

Table 4 Analysis of variance (ANOVA) for three-way comparison of residual correction force of clear aligners on the same day.

	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
S	0.001*	0.001*	0.001*	0.001*	0.001*	0.001 *	0.001*
F	0.3865	0.0985	0.0371*	0.2201	0.3899	0.4485	0.1787
D	0.0975	0.1114	0.0016*	0.0059*	0.001*	0.001*	0.0016*
S,F interaction	0.0296*	0.3193	0.1754	0.5687	0.1120	0.1225	0.1225
S,D interaction	0.0442*	0.2339	0.0355*	0.0373*	0.0718	0.0171*	0.0246*
F,D interaction	0.8405	0.9430	0.8597	0.6909	0.9010	0.9114	0.8681
S,F,C interaction	0.9022	0.5848	0.8858	0.5409	0.8687	0.9594	0.8490

Artificial saliva immersion (S), aligner attachment on M0 model (F), control (C) and the degree of lip movement of the aligner (D). * indicates statistically significant differences at ($P < 0.05$).

aligner that moved 0.5 mm.[23] Hahn et al. measured a pressure of 3.14 N on a 1.0 mm Erkodur aligner that moved 0.151 mm.[24]

Irreversible deformation of the material disrupts the forces between polymer chains on a microscopic level. The longer application forces have a higher likelihood to cause irreversible deformation.[20] However, the results of the present study showed that the effect of force on the residual correction force ratio of the aligner was not significant. According to Skaik, significant differences in the correction force of an aligner will only occur after it has been reworn more than 20 times.[6] As the aligners in the present study were only reworn 16 times during the force measurement process, there was no significant impact on the correction force.

The patients wearing aligner experience the most pain on the first day, which gradually decreases until the pain is relieved after Day 7.[25] The other study showed pain reaches its peak on Day 1 and then significantly decreases by Day 2.[26] In the present study, the corrective forces of D_2 and D_3 both showed a significant decrease between Day 0 and Day 1 under a simulated oral environment (SF), supporting the conclusions of above study.

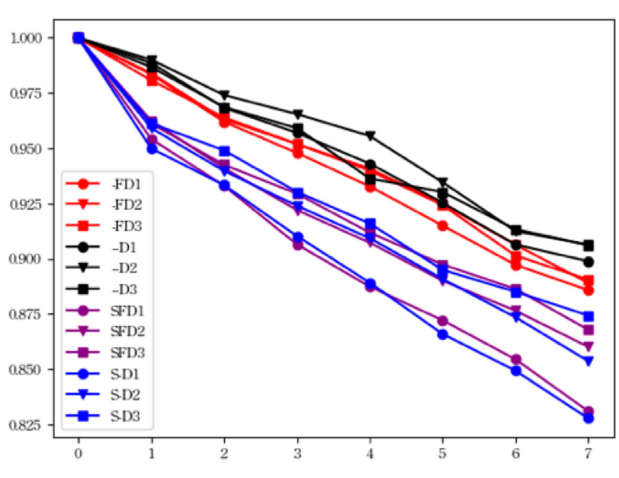

Figure 6 Graph showing the proportion decrease of residual orthodontic forces in the 12 groups. The displacements amount of the right maxillary central incisor toward the labial direction, D_1: 0.1 mm, D_2: 0.2 mm, and D_3: 0.3 mm. S, immersion in artificial saliva; F, attachment of aligner on M0 model.

The present study showed immersion in artificial saliva had a significant effect on orthodontic appliance degradation, which suggested that the clear aligners had a waterproof characteristic that reduced the degradation of force transmission. The degradation ratios of the 0.1 mm, 0.2 mm, and 0.3 mm orthodontic appliance designs were not significantly different, which may have been due to the internal hydration buffer effect of the orthodontic appliance, and the orthodontic appliance design had little effect on the degradation of the clear aligner strength.

Declaration of competing interest

The authors have no conflicts of interest relevant to this article.

Acknowledgments

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