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Initial Force Expression of Different Clear Aligner Systems in a Simulated Maxillary Canine Distalization Model with Lateral Incisor Agenesis: An In Vitro Comparative Study

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Abstract

Background: This in vitro study compared initial force release by different clear aligner systems during simulated maxillary canine distalization with lateral incisor agenesis and evaluated attachment effects. Methods: Five aligner systems were tested: SmartTrack™ (Invisalign®, Align Technology Inc., Santa Clara, CA, USA), TruGEN™ (Spark®, Ormco Corporation, Brea, CA, USA), Essix® (SureSmile®, Dentsply Sirona Inc., Charlotte, NC, USA), MasterControl S (Angel Aligner®, Angelalign Technology Inc., Shanghai, China), and a directly 3D-printed aligner fabricated with TC-85 DAC resin (Graphy®, Graphy Inc., Seoul, Republic of Korea). Ten identical aligners per configuration were tested for 1 h at 37 °C in physiological solution. The ElectroForce® system measured the translational force at the canine's root-level support. Data were analyzed using descriptive statistics and two-way ANOVA. Results: TruGEN™ with attachments generated the highest mean force (1.25 N), followed by SmartTrack™ (0.61 N), Essix® (0.42 N), MasterControl S (0.39 N), and TC-85 DAC resin (0.01 N). Without attachments, forces were minimal for all systems. Force decay was observed in groups expressing measurable forces. Conclusions: Attachments enabled measurable translational force components in thermoformed systems. Force expression differed among systems, while TC-85 DAC resin produced negligible forces with or without attachments under experimental conditions. Further clinical validation is warranted.

Keywords: 3D-printed aligners; aligner biomechanics; force measurement; digital orthodontics

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1. Introduction

Orthodontic therapy with clear aligners is now a consolidated modality for the treatment of numerous malocclusions, with clinical indications progressively extended also to complex dental movements [1,2]. However, aligners do not constitute a biomechanically

uniform system: differences in materials, manufacturing processes and design result in distinct mechanical behaviors between the different systems available, making it more accurate to speak of aligner systems rather than a single therapeutic category [3].

From a biomechanical point of view, an intrinsic limitation of aligners is the way in which the forces, mainly exerted at the coronal level, are applied. This can result in difficulty in generating controlled bodily movements, with a tendency to produce tilts (tipping) rather than pure translations, especially in the movements of single teeth adjacent to edentulous spaces [4–8]. Under such conditions, root control becomes critical, and the ability of the aligner to convert the programmed displacement into a force that is actually transmitted to the tooth is a key determinant of the system's biomechanical effectiveness.

Attachments are one of the main tools to improve the mechanical coupling between the aligner and the tooth surface, increasing retention and changing the way forces are applied. Finite element analyses have shown how specific configurations of attachments can significantly influence the distribution of forces and moments during canine movement, while highlighting that obtaining a complete bodily displacement remains biomechanically complex even under optimal conditions [9]; in fact, a measurable force component alone does not demonstrate bodily translation, which requires an appropriate moment-to-force ratio about the center of resistance. In parallel, the design of the aligner in the presence of edentulous spaces affects the local stiffness of the system and the control of unwanted tooth tilt towards the free space [10].

In addition to the geometric design, the manufacturing process can also affect the aligner's mechanical behavior. Traditional thermoformed systems and those obtained by direct 3D printing have structural differences that can be reflected in the ability to generate and maintain forces over time [11,12]. In particular, photopolymer resins developed for direct aligner printing, such as TC-85 DAC (Graphy Inc., Seoul, Republic of Korea), have aroused interest for their thermo-mechanical properties, but data on their actual force expression under controlled conditions are still limited [13–15].

Despite the growing literature on clinical outcomes and predictability of aligner movements, the characteristics of the initial force expressed by the different systems under standardized experimental conditions are less investigated [16]. Quantifying this force is an essential step in understanding the biomechanical behavior of the aligner before interaction with biological tissues.

In this context, the distalization of the maxillary canine in the presence of lateral incisor agenesis constitutes a biomechanically challenging model. The movement of a canine adjacent to an edentulous space requires accurate tipping control and effective force transmission to achieve a predominantly translational displacement, making this clinical condition particularly suitable for evaluating the mechanical performance of aligners in a simulated model.

The objectives of the present in vitro comparative study are therefore:

- To quantify and compare the initial force component detected in the direction of the programmed translational displacement in a maxillary canine, across different commercial clear aligner systems under identical geometric and set-up conditions;
- To evaluate the influence of the presence or absence of attachments on the expression of a measurable force component in the direction of the programmed displacement.

The null hypothesis is that there are no significant differences in the magnitude of the initial force generated between the different aligner systems, nor between configurations with and without attachments.

2. Materials and Methods

2.1. Study Patient Selection

For this study, a patient from the database of the Orthodontics department of the Dental School of Turin was selected, strictly respecting the clinical and ethical criteria defined a priori and the CRIS guidelines (Checklist for Reporting in vitro Studies) [17]. The study has received ethical approval from the Ethics Committee of the Città della Salute e della Scienza di Torino (no. 27/2022). Informed consent for the processing of personal data for research and scientific publication purposes has been provided by the patient in written form, and no minor patients were involved in the study.

The inclusion criteria for patient selection included: presence of complete permanent dentition (with or without third molars), high-quality digital scan of the upper arch, absence of dental crowding, absence of bone-dental discrepancies, absence of the right or left upper lateral incisor, and presence of distal space of at least 2 mm to the upper canine ipsilateral to agenesis. Exclusion criteria included: presence of deciduous teeth, bone-dental discrepancies or significant dental crowding, multiple or different agenesis from those specified, and dental anatomical alterations capable of interfering with the biomechanics of the movement analyzed.

Based on these criteria, a patient whose digital model of the upper arch met all the required conditions was selected, and the digital scan of this patient, obtained by an intraoral scanner, was the reference model for the entire in vitro study.

2.2. Preparation of the Experimental Model and Criteria in the Realization of the Orthodontic Set-Up

The digital scan was obtained with the iTero Element® 5D Plus Series intraoral scanner (Align Technology Inc., San Jose, CA, USA), providing a three-dimensional STL model used as the basis for the digital design and physical realization of the experimental model (Figure 1).



Figure 1. STL scan of the upper arch. Three-dimensional representation of the upper arch obtained from the intraoral digital impression, used as a basis for the design of the in vitro experimental model.

This digital model was used as the basis for the realization of a virtual orthodontic set-up that involved a bodily movement of 0.25 mm in the distal direction of tooth 2.3 only. Two identical set-ups have been created, differentiated by the presence or absence of attachments. The attachments used were:

- Rectangular horizontal vestibular on the anchor teeth (11, 21, 24–27): length 3 mm, height 1.5 mm, thickness 1 mm.
- Rectangular vertical vestibular on the canine 2.3: length 1.5 mm, height 4 mm, thickness 1 mm (Figure 2).

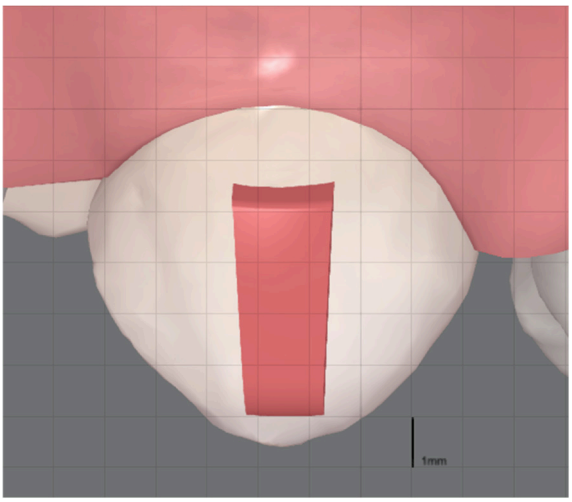


Figure 2. Digital design of the vertical attachment on tooth 2.3.

2.3. Realization of the Aligner Testers

Five commercial clear aligner systems made from different polymer materials were evaluated:

- SmartTrack™ (Invisalign®, Align Technology Inc., Santa Clara, CA, USA);
- TruGEN™ (Spark®, Ormco Corporation, Brea, CA, USA);
- Essix® (SureSmile®, Dentsply Sirona Inc., Charlotte, NC, USA);
- MasterControl S (Angel Aligner®, Angelalign Technology Inc., Shanghai, China);
- TC-85 DAC resin (Graphy®, Graphy Inc., Seoul, Republic of Korea).

Planning software provided by the manufacturers of the respective aligner materials was used for the design of the digital set-up. In particular, the set-up for the aligners in SmartTrack® was carried out using the ClinCheck software® (Align Technology Inc., Santa Clara, CA, USA); the set-up for aligners in TruGEN™ by Spark Approver® software (Ormco Corporation, Brea, CA, USA); the set-up for aligners in Essix® material by means of SureSmile® Aligner Software (Dentsply Sirona Inc., Charlotte, NC, USA); the set-up for aligners in MasterControl S material by the iOrtho® software (Angelalign Technology Inc., Shanghai, China). For the directly 3D-printed aligners in TC-85 DAC resin, the Direct-Aligner software uDesign® beta version (Graphy Inc., Seoul, Republic of Korea) was used.

The sample size of each group of aligner systems was determined by reference to a previous in vitro study by Elshazly et al. [18], which investigated the effect of trimming line design and gingival edge extension of orthodontic aligners on force transmission to the tooth. In that study, a sample size of n = 10 aligners per experimental group was used. Accordingly, a sample size of 10 aligners per experimental group was pragmatically selected for this study, while considering experimental feasibility.

So, for each set-up (with and without attachments), the manufacturers were asked to make 10 identical active aligners, each including the programmed distal displacement of 0.25 mm of the canine. For each set-up, a template for the attachments was also provided, used for the correct positioning of the attachments on the experimental model needed to measure the forces generated by the aligners.

For the 3D-printed aligners with TC-85 DAC resin (Graphy Inc., Seoul, Republic of Korea), the 10 active copies were produced internally in the Orthodontics department of the Dental School of Turin, following the manufacturer's instructions. The uDesign® beta version Direct-Aligner software (Graphy Inc., Seoul, Republic of Korea) was used, setting the aligner design with a 0.5 mm thickness and an offset of 0.05 mm [19]. Their 3D production was made with the SprintRay Pro95 printer (SprintRay Inc., Los Angeles, CA, USA), using a thickness of 100 µm per layer and configuring the printer on the "SprintRay US—SprintRay Splint" program.

At the end of the process, the print supports were manually removed using digital pressure. Excess resin was eliminated through two centrifugation cycles, each lasting six minutes. Subsequently, cotton pellets were used to remove the residual resin inside the aligners. Finally, the aligners were cured in a nitrogen-saturated atmosphere for 14 min using the Cure M machine (Graphy Inc., Seoul, Republic of Korea), in accordance with the manufacturer's specifications [20]. To allow the precise positioning of the attachments, an additional 3D-printed aligner with the same resin and the same protocol as the aligner testers was fabricated and used as an attachment template.

All aligners were made with the same juxta-gingival festooned cutout.

2.4. Realization of the Test Model and Measurement System

The patient's digital model was imported into the Blender® 4.2 software (Blender Foundation, Ámsterdam, The Netherlands), where a programmed separation of 2 mm was performed mesially and distally to the canine, to allow the freedom of movement necessary for the experimental test.

In order to be able to perform the next measurements, an assumed biomechanical reference point was defined 10 mm apical to the apical limit of the clinical crown of tooth 2.3. The choice to use the apical limit of the clinical crown visible on the intraoral scan was preferred over the identification of the amelo-cementitious junction, given the impossibility of locating the latter precisely on an intraoral scan. This point was intended solely as a geometric reference for positioning the mechanical components and should not be interpreted as the patient's actual center of resistance, which depends on anatomical and biomechanical factors; the localization of the center of resistance in monorooted teeth is described in the literature as variable as a function of anatomical and biomechanical factors, generally falling within the coronal-median portion of the root [21,22].

Subsequently, two anchor blocks were designed and integrated into the model for attaching the sample to the force measurement system. The blocks were rectangular in shape, with the major axis oriented parallel to the direction of the programmed distal translational displacement of the canine and were positioned in the same plane, so that the geometric center of their vertical dimension coincided with a plane located 10 mm apical to the apical limit of the clinical crown of tooth 2.3.

One of the blocks was joined to the entire maxillary arch, which remained static during the test, while the other was mobile and connected to the canine by means of a rotating post oriented perpendicular to the direction of the distal translational displacement, also positioned 10 mm apical to the apical limit of the clinical crown of tooth 2.3. The two blocks were separated by a distance of 2 mm (Figure 3).

This configuration reproduces a virtual hinge capable of allowing the canine a mesio-distal rotation around the defined biomechanical reference point, located 10 mm apical to the apical limit of the clinical crown of tooth 2.3. In this way, when the clamping pliers of the measuring system (ElectroForce® Test Bench, TA Instruments, New Castle, DE, USA) grip the anchor blocks, tooth 2.3 remains free to tilt without shifting if the aligner is unable to exert an adequate grip on the crown. In this scenario, the application of the aligner

produces only an inclination, without root movement, and therefore the measuring system does not register any translational force. Conversely, if the aligner is able to correctly transmit the force necessary to achieve the programmed bodily movement, the canine moves in translation and the support structure connected to the tooth moves with it, allowing the system to detect the forces actually expressed in translation by the aligner.

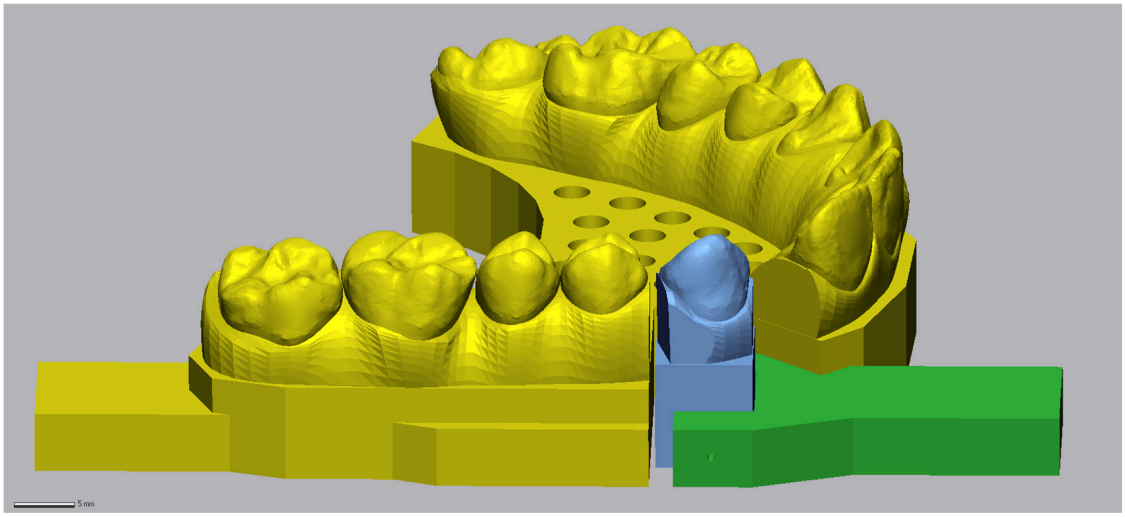


Figure 3. Superior model design. Display of the two blocks, in yellow the fixed portion and in green the mobile portion. The canine (in blue) is separated from the rest of the arch.

The two portions thus designed were 3D printed using a model resin (SprintRay Study Model 2 White) and the SprintRay Pro 95® printer (SprintRay Inc., Los Angeles, CA, USA), with a layer thickness of 50 microns, ensuring high precision and anatomical fidelity. Ten identical copies of the model were produced. On five of these, the attachments were bonded using the templates provided by each manufacturer, using the flow Tetric Evoflow composite (© Ivoclar Vivadent, Schaan, Liechtenstein) after applying the Adhese® Universal adhesive (© Ivoclar Vivadent, Liechtenstein) and light-curing according to the manufacturer's instructions. For aligners produced with TC-85 DAC resin (Graphy Inc., Seoul, Republic of Korea), the additional copy of the 3D-printed aligners was used as a template; after the composite was cured, the model was soaked in hot water to soften the 3D-printed aligner material and remove it without compromising the attachments transferred to the composite.

Having therefore positioned the models described above in the ElectroForce® Test Bench machine (TA Instruments, New Castle, DE, USA) [23] (Figure 4a,b), each aligner was inserted into the corresponding model and held in place for one hour (Figure 4d,e), during which time the forces generated on the upper left canine were recorded by the system. The data were acquired at a frequency of 1 Hz, generating a dynamic and comprehensive profile of the force release.

The tests were carried out in a thermostatic bath at 37 °C with saline solution, in order to reproduce intraoral conditions (Figure 4c). This temperature was also chosen because the TC-85 DAC material (Graphy Inc., Seoul, Republic of Korea) expresses the programmed force at this temperature [13].

Thermoformed aligners with the various materials (SmartTrack™, TruGEN™, Essix® and MasterControl S) were inserted directly into the test model. Instead, to make it easier to insert the 3D-printed aligner, the manufacturer suggests preheating the aligner to 60 °C. Each aligner of the two TC-85 DAC resin groups (Graphy Inc., Seoul, Republic of Korea) was then immersed in a thermostatic bath at 60 °C for 2 min before insertion on the test model.

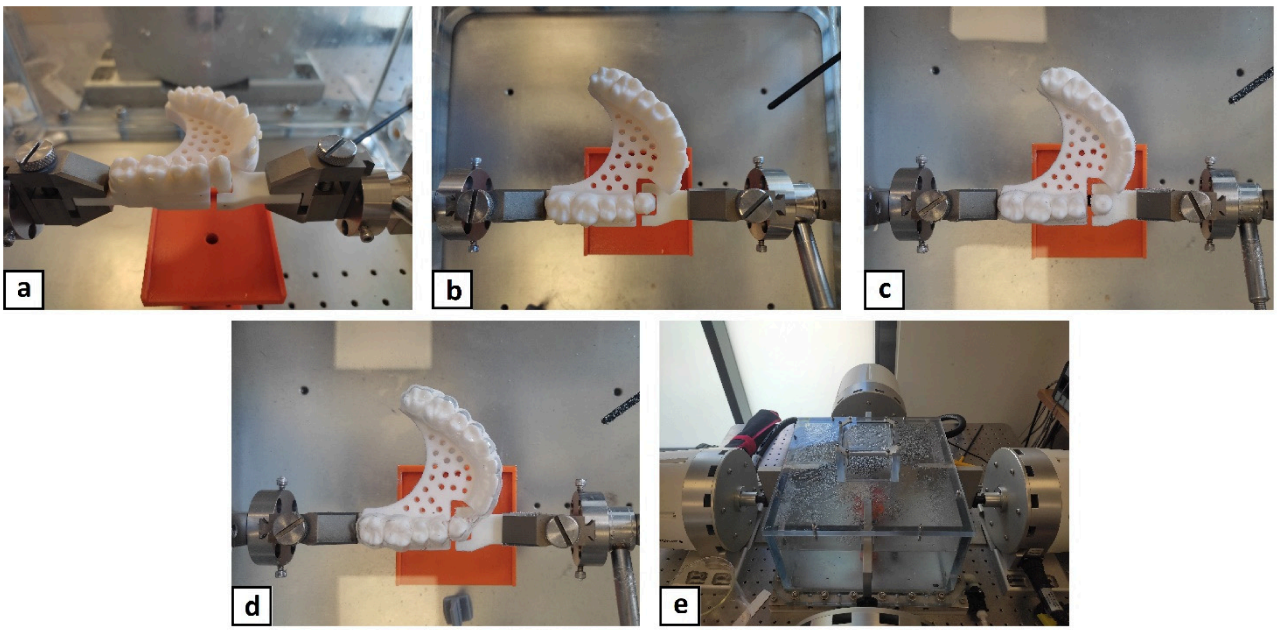


Figure 4. Customized mechanical test device used for measuring the force on the tooth 2.3. Printed model attached to the ElectroForce® Test Bench measurement system (TA Instruments, New Castle, DE, USA), from a side view (**a**) and a top view (**b**). View of the tank filled with saline solution to allow thermostatic bathing of the aligners at 37 °C (**c**). View of the aligner inserted in the test model (**d**) and view of the tank closed to limit water evaporation (**e**).

For each aligner system, 20 individual aligners were tested: 10 with attachments and 10 without attachments. Before each insertion, a 2 mm thick gauge bar was used as a spacer between the two anchor blocks, in order to calibrate the machine with a correct alignment of the canine with respect to the rest of the model.

The measurements were exported to an Excel sheet for subsequent statistical processing and for the construction of Force x Time graphs.

2.5. Statistical Analysis

The recorded forces (in N) were summarized by calculating, for each experimental group (5 materials × 2 conditions: with and without attachments), the mean and the standard deviation on a temporal basis. In particular, for each second, the mean of the values obtained in the 10 individual aligner specimens for the same group was determined; the means thus obtained were then averaged over the entire recording interval (1 h) to obtain the final mean value. Similarly, for each second, the standard deviation of the values obtained in the 10 individual aligner specimens for the same group was determined, and these values were averaged over the entire recording interval (1 h) to obtain a synthetic estimate of intra-group variability.

For the factorial analysis, the mean force over the entire recording period was also calculated separately for each individual aligner. The resulting 10 individual values per experimental group (100 observations in total) were used as independent observations in the two-way ANOVA, in order to assess the variability between the various aligner groups, taking into account the aligner system (five levels) and the presence/absence of attachments (two levels). This test allows us to identify whether there are statistically significant differences between the different combinations of brand and use of attachments, considering a significance level of 5% ($p < 0.05$).

Post hoc multiple comparisons tests (Šídák's multiple comparisons test) were conducted to compare the variable "with attachments" vs. "without attachments" within

each clear aligner brand. Residual normality and variance patterns were assessed using residual diagnostics, including the Shapiro–Wilk test and Spearman's correlation between predicted values and absolute residuals. Because these diagnostics indicated deviations from normality and heteroscedasticity, a sensitivity analysis was performed using the same factorial model with HC3 heteroscedasticity-consistent covariance estimates and Type III tests. Between-brand comparisons were additionally performed separately for the two attachment conditions using Welch's one-way ANOVA followed by Dunnett's T3 multiple comparisons test. Kruskal–Wallis tests followed by Dunn's multiple comparisons test were also performed as rank-based sensitivity analyses. A significance level of 5% was adopted ($p < 0.05$).

Finally, the force data generated during the tests (3600 measurements for each aligner, one per second for a total of one hour) were normalized and grouped according to the experimental group (aligner material and presence/absence of attachments). For each group (10 groups in total), an average force decay curve was calculated, obtained as an average of the instantaneous values recorded in each second by the 10 aligners belonging to the same group.

The mean curve of each group was then analyzed by nonlinear regression ("one-phase exponential decay" model), using GraphPad Prism (version 10, GraphPad Software, San Diego, CA, USA). The model used is described by the function:

$$F_{(t)} = Plateau + (F_0 - Plateau) \times {}^{-kt}$$

where "F(t)" represents the force exerted over time, "F_0" the initial force, "Plateau" the long-term residual force, "e" is Euler's number, "k" the decay constant and "t" the time (in seconds). The half-life was also derived from the parameter k.

The best-fit values and 95% profile-likelihood confidence intervals were obtained for each group. Model fit was evaluated using R^2, the standard error of the regression (Sy.x), and residual diagnostics, including normality, runs and homoscedasticity assessments, together with graphical inspection of residual patterns. Temporal dependence was further assessed using lag-1 residual autocorrelation and the Ljung–Box test (50 lags). Since each regression was performed on a group-averaged curve, the resulting parameters were considered descriptive and were not subjected to inferential comparisons between groups.

3. Results

Descriptive force summaries were calculated for each aligner group (n = 10 per group) over the entire measurement period (1 h).

Table 1 reports the mean force values (in Newtons) and the corresponding intra-group standard deviations, obtained by averaging, for each second, the variability across the 10 individual aligner specimens, both in the presence and absence of attachments. The results show clearly quantifiable differences in the amount of force exerted between the different experimental conditions (Figures 5 and 6).

Inferential analyses were performed using the individual aligner-level mean force values. The two-way ANOVA analysis showed significant effects of attachment condition ($F(1, 90) = 314.5$, $p < 0.0001$) and aligner brand ($F(4, 90) = 47.82$, $p < 0.0001$), with a significant interaction between the two factors ($F(4, 90) = 45.47$, $p < 0.0001$). Aligners with attachments generated significantly higher forces on average than those without attachments (0.535 N versus 0.0077 N; mean difference = 0.5273 N; 95% CI: 0.4682–0.5864 N). Multiple post hoc comparisons (Šídák's multiple comparisons test) showed that attachments significantly increased average force in four of the five brands analyzed: SmartTrack™ (+0.609 N, $p < 0.0001$), TruGEN™ (+1.224 N, $p < 0.0001$), Essix® (+0.425 N, $p < 0.0001$) and MasterControl S (+0.380 N, $p < 0.0001$). In contrast, no statistically significant difference

was found between the two conditions in TC-85 DAC resin aligners ($p > 0.9999$). Residual diagnostics indicated deviations from normality (Shapiro–Wilk $W = 0.7792$, $p < 0.0001$) and heteroscedasticity (Spearman's $Rs = 0.7343$, $p < 0.0001$). Nevertheless, the HC3-robust sensitivity analysis retained significant effects of brand ($F(4, 90) = 185.95$), attachment condition ($F(1, 90) = 283.08$) and their interaction ($F(4, 90) = 192.10$; all $p < 0.0001$).

Table 1. Mean temporal force (N) and intra-group standard deviation (N) of the different aligner systems in the presence and absence of attachments. The values represent the temporal mean calculated over 1 h starting from the mean of the 10 tests performed for each group.

	With Attachments		Without Attachments	
	Mean Temporal Force	**Intra-Group Standard Deviation**	**Mean Temporal Force**	**Intra-Group Standard Deviation**
SmartTrack™	0.6054 N	±0.0920 N	−0.0038 N	±0.0084 N
TruGEN™	1.2487 N	±0.1891 N	0.0249 N	±0.0190 N
Essix®	0.4241 N	±0.3220 N	−0.0006 N	±0.0152 N
MasterControl S	0.3864 N	±0.2691 N	0.0059 N	±0.0112 N
Resin TC-85 DAC	0.0102 N	±0.0182 N	0.0120 N	±0.0102 N

Between-brand comparisons were performed separately according to attachment condition. In the presence of attachments, Welch's ANOVA showed significant differences among aligner systems ($W(4, 18.36) = 193.1$, $p < 0.0001$). Dunnett's T3 test showed that TruGEN™ generated significantly higher mean forces than SmartTrack™, MasterControl S, Essix® and TC-85 DAC (all adjusted $p < 0.0001$). TC-85 DAC also showed significantly lower values than SmartTrack™ ($p < 0.0001$), MasterControl S ($p = 0.0143$) and Essix® ($p = 0.0237$). No significant differences were found among SmartTrack™, MasterControl S and Essix®. In the absence of attachments, Welch's ANOVA also indicated significant differences among systems ($W(4, 22.06) = 7.290$, $p = 0.0007$). Dunnett's T3 comparisons identified significant differences between TruGEN™ and SmartTrack™ (mean difference = 0.02873 N, $p = 0.0063$), TC-85 DAC and SmartTrack™ (mean difference = 0.01580 N, $p = 0.0064$), and TruGEN™ and Essix® (mean difference = 0.02554 N, $p = 0.0306$). Other pairwise comparisons were not significant. As a rank-based sensitivity analysis, Kruskal–Wallis tests also identified significant differences among aligner systems in both conditions (with attachments: $H(4) = 36.91$, $p < 0.0001$; without attachments: $H(4) = 20.86$, $p = 0.0003$). Dunn's post hoc test identified four significant pairwise differences in the with-attachment condition (SmartTrack™ vs. TC-85 DAC, adjusted $p = 0.0035$; TruGEN™ vs. MasterControl S, $p = 0.0050$; TruGEN™ vs. Essix®, $p = 0.0026$; and TruGEN™ vs. TC-85 DAC, $p < 0.0001$). In the without-attachment condition, three comparisons were significant (SmartTrack™ vs. TruGEN™, $p = 0.0003$; SmartTrack™ vs. TC-85 DAC, $p = 0.0171$; and TruGEN™ vs. Essix®, $p = 0.0412$). These results were fully consistent with the Welch's ANOVA and Dunnett's T3 findings in the without-attachment condition, whereas partial agreement was observed in the with-attachment condition.

The one-phase exponential decay model was fitted separately to the mean force–time curve of each experimental group; the following parameters represent model-derived estimates from group-averaged curves and were not subjected to inferential comparisons between groups. A good numerical fit was obtained for the four thermoformed systems with attachments ($R^2 = 0.9882$–0.9943). In these groups, the estimated initial force (Y0) ranged from 0.471 to 1.411 N, while the estimated plateau ranged from 0.356 to 1.188 N. The decay constants (k) ranged from 0.000812 to 0.001034 s^{-1}, corresponding to estimated half-lives of approximately 671–853 s (11–14 min). This indicates that, for these groups, the

exerted force tended to gradually decrease but stabilize at a significant residual value after approximately a quarter of an hour.

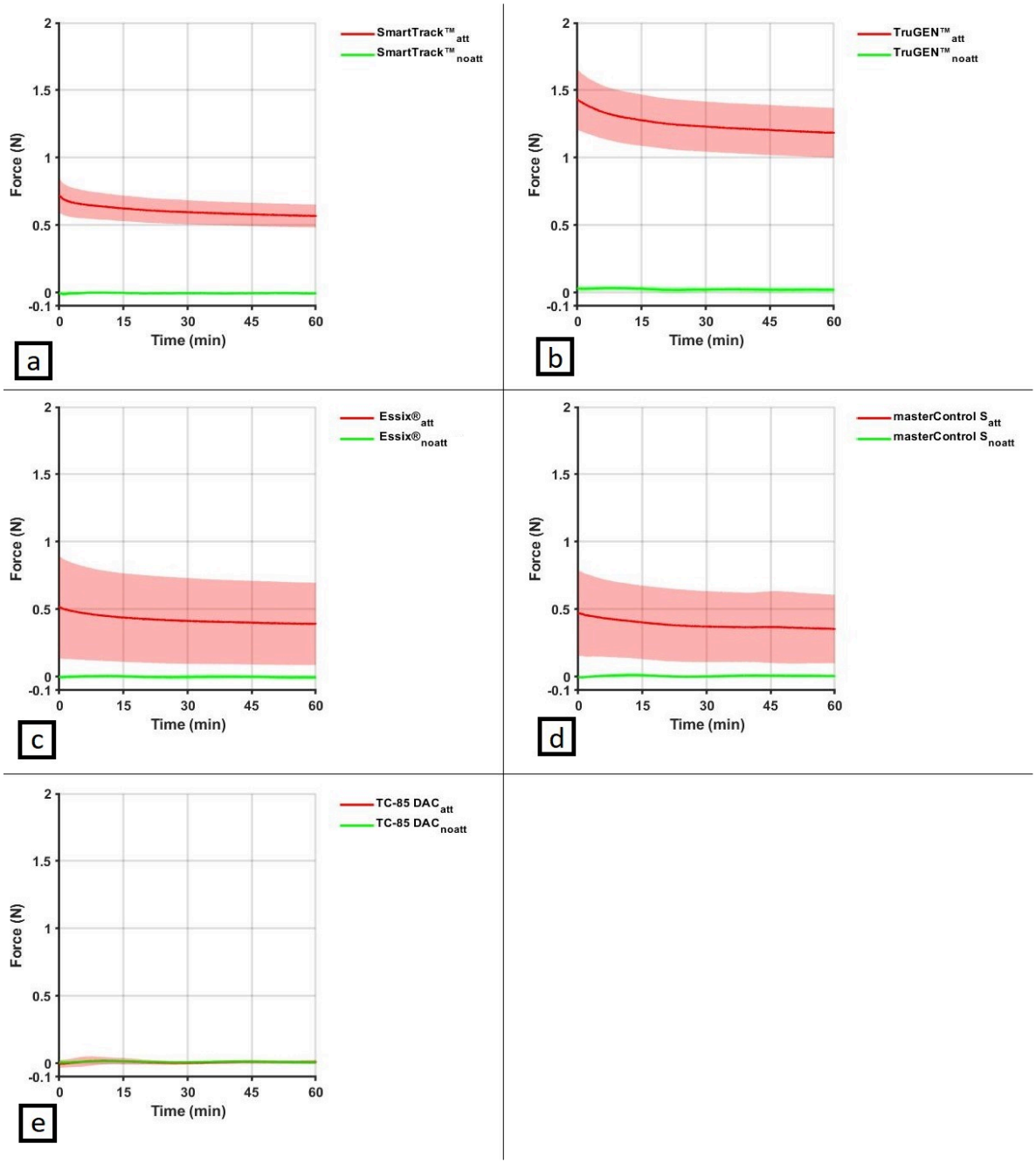


Figure 5. Graphs showing the force (in N) detected over time (in min) by different commercial aligner systems in the presence and absence of attachments (n = 10 aligners per experimental group). The force × time graphs for the SmartTrack™ (**a**), TruGEN™ (**b**), Essix® (**c**), MasterControl S (**d**) and TC-85 DAC (**e**) aligners are shown. Both the mean force over time (opaque line) and the intra-group standard deviation (transparent area around the opaque line) are represented.

On the contrary, in groups without attachments, the model adapted less satisfactorily. TruGEN™ without attachments showed a partially describable trend ($R^2 = 0.6547$), with a low initial force ($F_0 = 0.034$ N) and a Plateau of about 0.021 N. Essix® without attachments showed a weak fit ($R^2 = 0.4252$), while MasterControl S without attachments also showed a poor fit ($R^2 = 0.2765$). The fit was extremely poor for TC-85 DAC with attachments ($R^2 = 0.0037$), whereas fitting procedures for SmartTrackTM and TC-85 DAC without at-

tachments returned unstable parameter estimates (negative plateaus or extremely high half-lives).

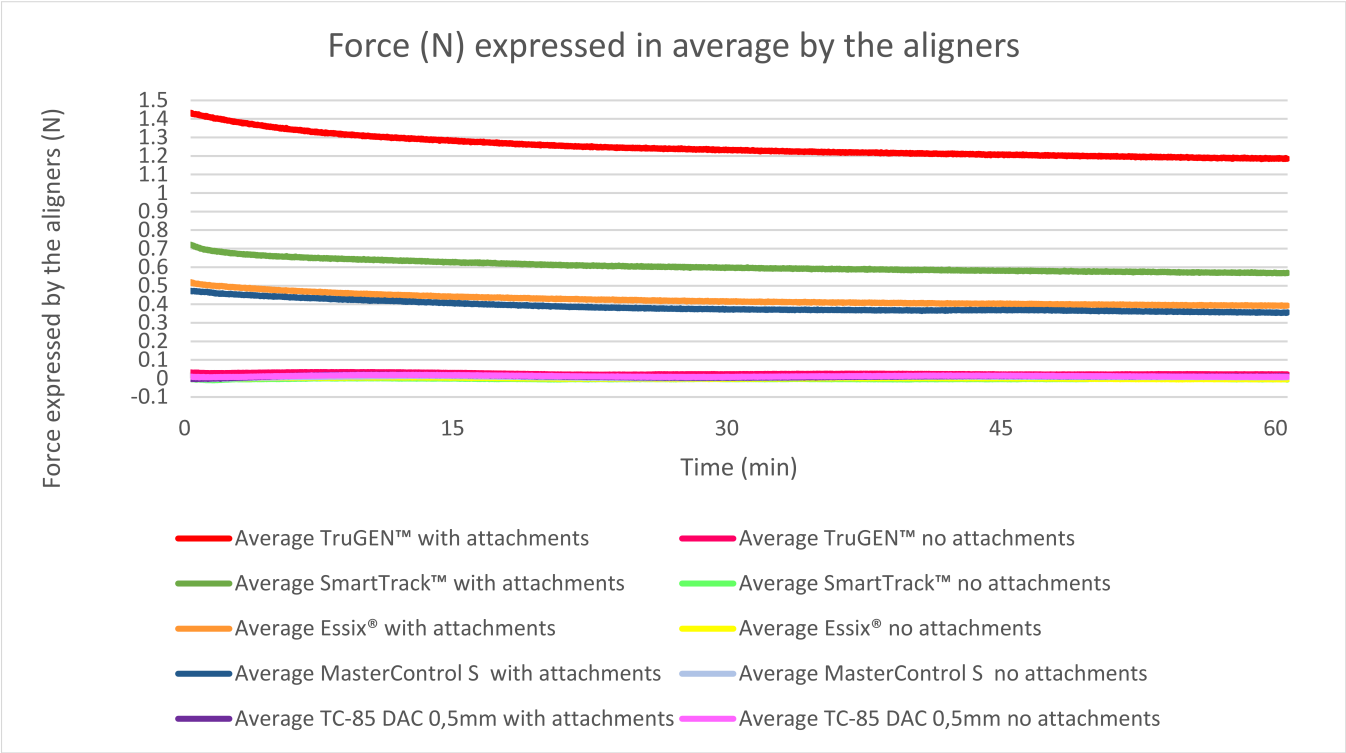


Figure 6. Summary graph showing the averages of the forces (in N) detected over time (in min) by the different aligner systems (SmartTrack™, TruGEN™, Essix®, MasterControl S and TC-85 DAC resin) in the presence and absence of attachments. Each curve represents the mean force of 10 aligners per experimental group (n = 10).

In summary, the one-phase exponential model adequately described the numerical trend of the four thermoformed groups with attachments, but was less suitable for the other experimental conditions. Residual diagnostics also indicated non-normality and non-random temporal patterns. Lag-1 residual autocorrelation ranged from 0.781 to 0.988, and Ljung–Box tests (50 lags) were significant ($p < 0.001$). Therefore, the fitted parameters should be interpreted as descriptive estimates rather than as definitive characterizations of the underlying force-relaxation kinetics.

Based on the results of the two-way ANOVA and post hoc tests, the null hypothesis (no differences between systems and between configurations with/without attachments) can be rejected for the thermoformed systems examined, while no statistical evidence of difference was found for the TC-85 DAC resin sample ($p > 0.99$). The clinical implications of these findings are discussed in the following section.

4. Discussion

During the technological evolution of digital orthodontics, the production of clear aligners has seen a progressive transition from the conventional method of thermoforming on physical models to direct production by 3D printing. This change reflects a broader effort in bioengineering to exploit additive technologies to make custom devices with strict geometric control and potentially better mechanical properties than thermoformed materials. Recent systematic reviews underline how printed aligners have potential advantages in terms of geometric reproducibility, dimensional accuracy and the possibility of differential

thickness control, while highlighting that experimental tests comparable with traditional systems are still limited and of variable quality [24].

From a biomechanical perspective, thermoformed fabrication involves heating and cooling processes of the thermoplastic material onto a physical model, resulting in variations in thickness, fit, and potential distortions of the designed geometry, which can affect the aligner's ability to predictably transfer planned forces [12,25]. In contrast, direct 3D printing eliminates some intermediate steps and offers the ability to locally control geometry and thickness, allowing for a more customized aligner design, although it requires critical post-processing protocols to ensure consistent mechanical properties and stable biocompatibility [24].

More broadly, biomechanical studies of polymer-based dental systems highlight that mechanical outcomes depend not only on material properties but also on geometry, structural interfaces, boundary conditions, and model assumptions [26,27]. Although these studies concern restorative rather than orthodontic systems, they support interpreting the present measurements as the response of the complete aligner–attachment–model assembly rather than as an isolated material property.

In parallel, the literature has highlighted the importance of attachments as mechanical elements that improve the coupling between the aligner and the tooth surface, contributing to a more effective transmission of forces compared to configurations without such auxiliaries. Recent reviews on the biomechanical role of attachments indicate that their presence can influence the moments generated and the direction of force vectors, underlining the relevance of specific designs according to the desired type of movement [28].

Despite growing interest in alternative materials and manufacturing technologies, the comparative investigation of the forces actually expressed in different systems, and, in particular, the contribution of attachments to force transmission, remains a poorly explored area in vitro. This study fits within this context, focusing on the mechanical quantification of force components measured in the direction of the programmed displacement for thermoformed and 3D-printed aligners, with and without attachments, in a standardized experimental model.

The present study analyzed the initial force expression of different clear aligner systems in a simulated maxillary canine distalization model with lateral incisor agenesis, designed to detect only the force component in the direction of the programmed displacement. The main finding was that the ability to express a measurable force was not uniform among the aligner systems analyzed and was strongly dependent on the presence of attachments.

In the absence of attachments, all systems exhibited very low mean force values (ranging from −0.0038 to 0.0249 N), which were markedly lower than those observed in the corresponding attachment configurations. Although some between-brand comparisons reached statistical significance, the absolute differences were small and should be interpreted cautiously in terms of their biomechanical relevance. This is consistent with the intrinsic biomechanics of aligners, which tend to apply forces at the coronal level with the prevalent production of tipping moments rather than force components effectively transmitted along the tooth axis [4–8]. In the experimental model adopted, the restraint configuration was made to ensure that pure tipping did not determine displacement of the moving block, highlighting how, in this condition, the aligner–tooth interface was not able to convert the programmed bodly distalizzation into a measurable force component along the programmed direction at the root level.

This result is coherent with previous finite element analyses [29]. The introduction of attachments has substantially changed the mechanical behavior of the system. The attachments likely increased the contact area and retention between the aligner and the tooth surface, improving mechanical coupling and allowing for more effective force transmission.

This result is in line with evidence derived from finite element analysis, which indicates that attachments can significantly alter the distribution of forces and moments during canine movement, while not completely eliminating the biomechanical complexity of bodily movement [9].

Among thermoformed systems, thanks to the addition of attachments, significant quantitative differences emerged. The TruGEN™ material showed the highest initial force values (1.24 ± 0.19 N), followed by SmartTrack™ (0.61 ± 0.09 N), Essix® (0.42 ± 0.32 N), and MasterControl S (0.39 ± 0.27 N). Between-brand comparisons confirmed that TruGEN™ generated significantly higher mean forces than all other systems, whereas SmartTrack™, Essix® and MasterControl S did not differ significantly from one another. TC-85 DAC showed significantly lower values than the other systems in several pairwise comparisons, although these differences were not all confirmed by the rank-based sensitivity analysis. These differences may reflect several system-specific factors, including polymer properties, actual thickness after thermoforming, aligner design, manufacturing processes, and viscoelastic behavior [3]. Importantly, the study evaluated the initial expression of force under controlled static conditions, prior to interaction with periodontal tissues.

Aligners directly 3D printed in TC-85 DAC resin (Graphy Inc., Seoul, Republic of Korea) did not generate an appreciable translational force component at the root level, even in the presence of attachments (0.01 ± 0.02 N). A possible explanation is related to dimensional distortions introduced during the centrifugation and post-press curing phases, partially operator-dependent procedures that require manual manipulations for the removal of excess resin and print supports [30]. These factors can compromise the geometric accuracy of the aligner and its coupling with the tooth surface and attachment. In addition, insufficient material stiffness or reduced accuracy in the reproduction of attachments [31] may limit the aligner's ability to establish an effective mechanical grip on attachments and transmit force along the tooth axis. These hypotheses suggest that the lack of measurable translational force components may be multifactorial, potentially involving material properties, manufacturing and post-processing procedures, dimensional accuracy, and aligner–tooth fit.

In aligner systems that expressed measurable translational force components (SmartTrack™ with attachments, TruGEN™ with attachments, Essix® with attachments, MasterControl S with attachments), mean values were associated with a non-negligible intra-group standard deviation, indicating intra-system variability among the aligners tested. Since 10 nominally identical aligners were analyzed for each group, this dispersion reflects differences in the force transmitted by theoretically equivalent devices and is an indicator of the repeatability of the system. The magnitude of the intra-group standard deviation (Table 1 and Figure 5) indicates that the observed variability differed among aligner systems, although some variability was found to be present among all aligner systems that generated measurable translational force components. This variability can be attributed to multiple factors, including tolerances in manufacturing processes, variations in aligner thickness or fit, differences in thermoforming technique, and possible sources of instrumental error or calibration error during force measurement.

From the results of the present study, it is also observed that, in the groups in which a measurable translational force component was detected, the analysis of the time decay showed that the initial force tends to decrease rapidly in the first few minutes, then stabilizing at a constant residual value. This behavior may be consistent with stress relaxation phenomena typical of viscoelastic polymeric materials used in clear aligners, where the force generated by the device is reduced over time due to the internal redistribution of the stresses of the material [32]. In vitro studies conducted under simulated conditions show that thermoplastic thermoformed aligners lose a significant fraction of their initial force after exposure to simulated environmental conditions, with a gradual exponential decrease

in residual force over time [33]. These observations are compatible with the force-decay patterns described by our one-phase exponential decay model, which provided a good numerical fit for the thermoformed systems with attachments, with estimated half-lives of approximately 11–14 min.

Although the one-phase exponential model provided high R^2 values for the four thermoformed systems with attachments, residual diagnostics revealed non-random temporal patterns and marked serial autocorrelation. It must therefore be said that the estimated half-lives and plateaus should be considered descriptive characteristics of the group-averaged curves and not definitive estimates of the intrinsic viscoelastic properties of the materials.

The observed force-decay behavior may therefore reflect the combined influence of material viscoelasticity and other system-related factors, including aligner seating adaptation, changes at the aligner–attachment and aligner–tooth interfaces, and geometric relaxation. Therefore, the contribution of intrinsic material stress relaxation cannot be isolated from the present measurements.

A relevant aspect of the present study is that it focused on a clinically challenging configuration: the distalization of a canine adjacent to an edentulous space. In such conditions, the lack of interproximal support and the reduced local rigidity of the system facilitate the tendency to tilt towards free space [10], making the aligner's ability to generate an effective translational force component particularly critical.

From the results obtained, the null hypothesis of the present study is not supported. Significant differences in the magnitude of the initial force between the different aligner systems and between the configurations with and without attachments have emerged. These findings highlight the influence of attachments on mechanical coupling and on the force component detected by the present experimental system under the simulated canine-distalization condition. The effect varied across aligner systems, with significant increases in the measured force component in the four thermoformed systems, whereas no significant difference was observed between the two configurations for TC-85 DAC resin.

It must be said that from a biological point of view, the mere presence of a measurable force is not sufficient to predict the clinical outcome, since the orthodontic response depends on the interaction between the entity, direction, duration of the force and viscoelastic behavior of the periodontal ligament. However, starting forces that are too low may not exceed the threshold needed to induce an effective cellular response, while excessive forces may increase the risk of side effects. Clinical evidence also highlights discrepancies between programmed and achieved movements with clear aligners, often reaching crown tipping rather than bodily movement [34]. The results obtained therefore describe the initial mechanical behavior of the tested systems, without directly implying clinical superiority.

Limitations

This study has some limitations inherent in the experimental design. The model used was rigid and did not include periodontal ligament simulation or alveolar support simulation. The periodontal ligament contributes not only to viscoelastic damping but also influences tooth displacement, the effective location of the center of resistance, and the relationship between applied forces and moments and initial tooth movement; consequently, the present set-up should be regarded as a device-level mechanical characterization of force transmission rather than a simulation of the tooth-periodontium response.

No a priori power calculation was performed. The sample size of 10 aligners per experimental group was pragmatically selected based on a previous in vitro study and experimental feasibility, rather than on a formal power analysis.

The measurements were carried out in static conditions for 60 min in a thermostatic bath, without reproducing cyclic loads, thermal cycling, progressive alignment adaptation and

variability of the intraoral environment, such as saliva, intraoral aging, thermal variations and functional interference.

The experimental system was designed to detect only the translational component of the force, without directly measuring global moments or tilt components. In addition, the study was based on a single patient's maxillary arch, and therefore included only one maxillary morphology, one canine anatomy, one edentulous-space configuration, and one programmed distal displacement; consequently, the findings characterize the behavior of the tested aligner systems within this specific geometry and experimental configuration and cannot be directly generalized to other anatomical conditions or orthodontic movements. The reference point was an assumed geometric location rather than an individually determined center of resistance. Since actual tooth displacement was not measured, bodily movement cannot be inferred from the present results.

Another limitation concerns the comparability of the tested systems. As each commercial system incorporates different material compositions, thicknesses, designs, manufacturing workflows, planning software, and post-processing procedures, the individual contribution of these factors could not be isolated. Therefore, the observed differences should be attributed to the overall performance of the tested aligner systems rather than to specific material properties. Furthermore, aligner thickness and aligner–tooth fit were not directly measured. Their potential contribution to the observed differences, particularly the low force values recorded for TC-85 DAC, remains speculative and should be investigated in future studies.

Regarding the 3D-printed aligners, a single type of resin and a single production protocol were tested. Differences in printing parameters such as print resolution, aligner thickness, post-curing processes, or the use of next-generation resins (TA-28 resin, Graphy Inc., Seoul, Republic of Korea) [35] could significantly affect the observed mechanical behavior.

The nonlinear regressions were performed on group-averaged force–time curves rather than on individual aligner recordings. Consequently, the estimated parameters describe group-level trends and do not account for between-aligner variability. Residual diagnostics also revealed deviations from normality and significant temporal dependence, including marked serial autocorrelation. Therefore, the fitted parameters and their confidence intervals should be interpreted cautiously, and no inferential comparisons between decay parameters across systems can be drawn.

Finally, all tests were performed under strictly controlled laboratory conditions, with calibrated equipment and stable environmental parameters. Such optimal conditions may not fully reflect the operational variability found in daily clinical practice.

Therefore, the results should be interpreted as a characterization of the initial mechanical behavior of aligners under controlled conditions, useful for cross-system comparison but not directly overlapping with the in vivo clinical response.

5. Conclusions

Within the limits of the present in vitro study, the following conclusions can be drawn:

- The ability to express an initial measurable translational force during canine distalization was found to depend on the aligner system used and the presence of attachments.
- Without attachments, the systems tested generated a poor translational force component detectable in the experimental model, suggesting that the programmed displacement is mainly converted into tipping components that cannot be measured with the constraint system adopted.
- The presence of attachments significantly increased the force component detected by the experimental system in the four thermoformed systems, supporting their role in enhancing aligner–tooth mechanical coupling under the simulated conditions.

- Aligners directly 3D-printed in TC-85 DAC resin (Graphy Inc., Seoul, Republic of Korea) did not show a measurable translational force under the experimental conditions adopted, indicating a distinct mechanical behavior compared to the thermoformed systems used in the present study.

Supplementary Materials: The following supporting information can be downloaded at https://www.mdpi.com/article/10.3390/bioengineering13111326/s1.

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Informed Consent Statement: Informed consent was obtained from the subject involved in the study. Informed consent for the processing of personal data for research and scientific publication purposes has been provided by the patient in written form.

Data Availability Statement: The anonymized dataset supporting the findings of this study is available from the corresponding author upon reasonable request (see also Supplementary Materials).

Conflicts of Interest: The authors declare no conflicts of interest.

Abbreviations

The following abbreviations are used in this manuscript:

3D	Three-Dimensional
ANOVA	Analysis of Variance
CRIS	Checklist for Reporting in vitro Studies
STL	Standard Triangulation Language
DAC	Direct Aligner Clear
N	Newton

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