Original Article

Micro computed tomography evaluation of Invisalign aligner thickness homogeneity

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ABSTRACT

Objectives: To measure the thickness homogeneity of Invisalign (Align Technology Inc, San José, Calif) aligners with micro-computed tomography (micro-CT) scans.

Materials and Methods: Starting from micro-CT scanning of 20 different aligners, multiplanar reconstructions were obtained. An orthodontist blinded about the study measured aligner thickness in different regions (molar, canine, incisor) and in different sites (gingival–buccal, buccal, occlusal, lingual, and gingival–lingual). To assess various thicknesses in different aligner sites and regions, the sample was stratified into subgroups and linear regression analysis was performed.

Results: Descriptive analysis showed that mean thickness of aligners in the incisor region ranged from 0.582 mm to 0.639 mm, in the canine region from 0.569 mm to 0.644 mm, and in the molar region from 0.566 mm to 0.634 mm. Student's *t*-tests showed no significant differences in the aligner thickness of different regions when data were stratified by different sites. Student's *t*-tests showed significant differences in thickness homogeneity for the molar region when the data were stratified by tooth (mean difference = 0.068 mm; 95% confidence interval, 0.009–0.126 mm; $P = .024$).

Conclusions: Invisalign aligner thickness is characterized by small differences. The only significant difference was revealed in the molar region where thickness of the gingival–lingual edge is significantly thinner than that measured at the occlusal aspect. From a clinical perspective, the results of the present study could be considered to explain the reduced predictability of several orthodontic tooth movements in the molar region. (*Angle Orthod.* 2021;91:343–348.)

KEY WORDS: Thickness; Aligners

INTRODUCTION

The Invisalign system of aligner treatment (Align Technology, San José, Calif) was introduced in the late 1990s in response to a growing request for an alternative to fixed appliances.[1,2] Despite the advantages in terms of patient comfort and esthetics,[3,4] ease of oral hygiene procedures,[5] lower risk of developing white spot lesions,[6] and despite widespread use of the technique, there are few good quality articles analyzing the predictability of orthodontic tooth movement (OTM) with clear aligner therapy (CAT).[7,8] Although the use of auxiliaries can expand the application of CAT from minor to mild malocclusions,[9,10] several types of OTM, such as buccolingual inclination, extraction space closure, sagittal changes, overjet correction and expansion have been identified as being less efficient with clear aligners than with fixed braces.[8] OTM with aligners is more complex than with fixed appliances because of the lack of specific points of force application.[11] Several aspects, such as material me-

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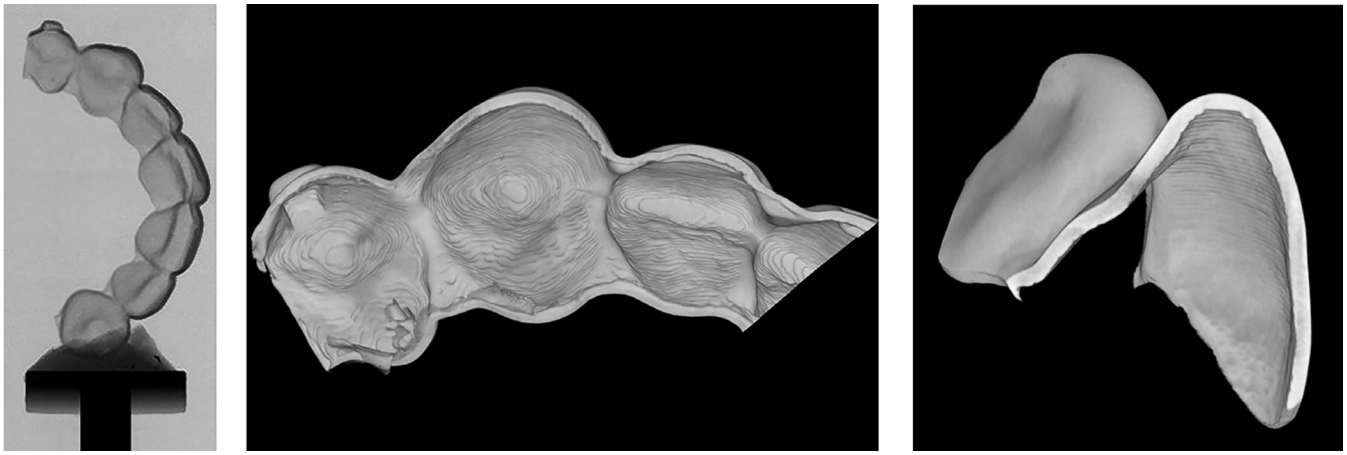

Figure 1. MICRO-CT optimization and basic three-dimensional reconstruction.

chanical properties, are still not clear in aligner orthodontics. Previous studies showed that the amount of activation and aligner thickness have a great influence on the orthodontic force produced by the appliance.[12,13] Despite the fact that Invisalign was cited as the most common system used for aligner orthodontics in a recent systematic review,[14] independent data regarding material properties and thicknesses are scarce.

Lombardo et al[15] and Gao and Wichelhaus[16] investigated aligner mechanical properties and considered, for their initial experimental setups, the aligner thickness stated by the manufacturer after thermoforming, that is, 0.75 mm. However, Lombardo et al. reported variable thicknesses of Invisalign aligners among different regions of the arch: 0.55 mm in the incisor and canine regions and 0.62 mm in the molar region. Because aligner thickness significantly affects force release and subsequent moment generation, it has been suggested that the physical properties of plastic materials used for the fabrication of aligners should be evaluated after thermoforming to characterize their clinical application.[17,18]

Several studies have demonstrated that material thickness is affected by thermoforming procedures.[19–21] However, little is known about the effects of thermoforming on Invisalign aligners. Micro-computed tomography (μCT) technology offers the advantage of being noninvasive, thus not altering any physical property of the material.[15] Therefore, the aim of this investigation was to measure the thickness of Invisalign aligners using μCT technology and answer the following clinical/research questions:

1. What is the actual thickness of Invisalign aligners after the thermoforming process?
2. Are there different thicknesses between the anterior and posterior regions?
3. Are there different thicknesses among different sites on the same tooth?

The null hypothesis was that Invisalign aligners did not present significant differences in thickness between buccal and lingual surfaces with respect to the occlusal surface in different regions of the arch.

MATERIALS AND METHODS

A sample of 20 (10 upper and 10 lower) passive and unused Invisalign aligners collected from 10 different patients were evaluated in this study. Aligners were collected from patients with Class I malocclusions. Inclusion criteria were (1) age $>$18 years, (2) crowding $<$3.5mm, and (3) presence of all teeth with the exception of third molars. Exclusion criteria were (1) presence of periodontal disease, (2) presence of signs and/or symptoms of temporomandibular disorders, and (3) syndromes or history of craniofacial trauma. ClinCheck (Align Technology Inc) treatment plans were reviewed by the same expert orthodontist. Only aligners for which attachments were not planned for the incisor, canine, and molar regions were selected.

Corresponding STereoLithography (STL) files (initial stage) were exported from the ClinCheck software and transferred to a lab (Novadental Lab, Venaria Reale, Italy) to obtain physical resin casts (methacrylic acid esters, proprietary pigment; form 2 three-dimensional printer [Formlabs, Somerville, Mass]). The aligners were positioned on casts and sectioned with a cutting machine (Well Diamond Wire Saw Inc, Norcross, Ga) to allocate a proper sample for μCT analysis. The procedure was described in previous studies.[22,23]

The Skyscan model 1172 μCT system (Bruker Corporation, Billerica, Mass) was used to obtain X-ray images after stabilization of the aligner in the sample holder (Figure 1). High-resolution scans were performed, and images were reconstructed using

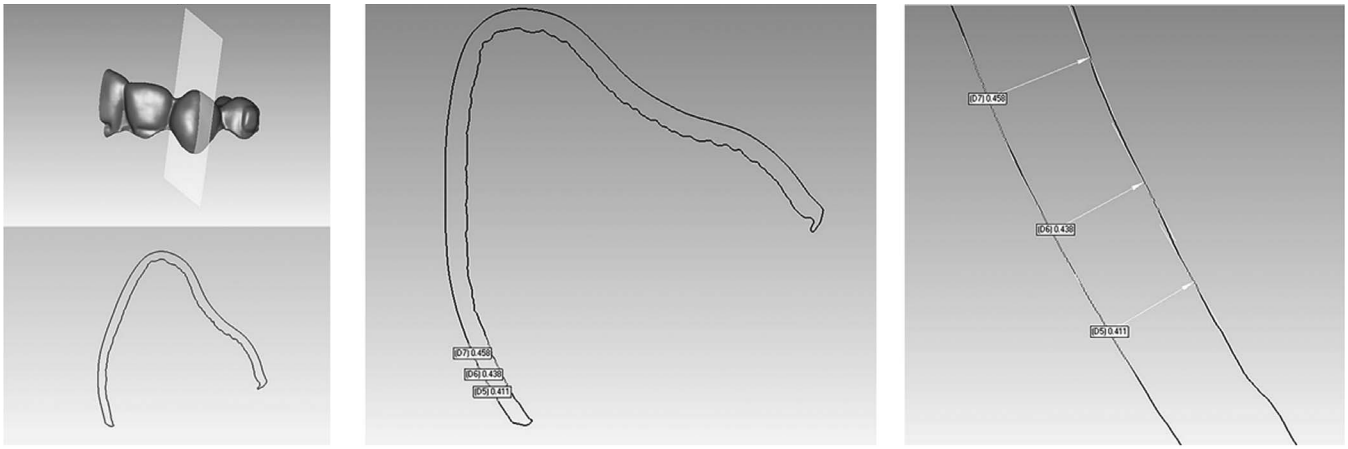

Figure 2. Basic two-dimensional analysis with linear measurements.

NRecon software (Bruker) to obtain Digital Imaging and Communications in Medicine files with standardized parameters. Three-dimensional rendering of the obtained files was performed with CTvox 3.3.0 software (Bruker). To ensure consistency across the data, the same protocol with the same Houndsfield unit parameters was applied to all samples. A section at the mid-point of the mesio-distal axis was considered for one incisor (I), one canine (C) and one molar (M).

For each tooth, the following sites were analyzed:

- gingival–buccal (GB; inferior gingival buccal margin of the aligner)
- buccal (B; mid-point between the inferior gingival margin of the aligner and the top of the cusp)
- occlusal (O; top of the cusp)
- lingual (L; mid-point between the inferior lingual margin of the aligner and the top of the cusp)
- gingival–lingual (GL; gingival lingual margin of the aligner)

The thickness of each aligner was visually evaluated by an orthodontist blinded to the study using two-dimensional orthogonal projections with Data Viewer software (Micro Photonics Inc, Allentown, Pa). Data were then exported to Geomagic Studio software e (3D Systems, Rock Hills, S.C.) and the "parallel distance" function of a two-dimensional analysis that automatically calculated the distance between two counterposed segments was used (Figure 2). The technical errors of measurement were calculated for all aligners analyzed from four randomly selected patients. All measurements were reassessed by the same operator after a memory washout period of 3 months.

Statistical Analysis

The sample size was defined using $\alpha = 0.0025$ (Bonferroni correction for multiple comparisons 0.05/20), power $= 0.80$, and an effect size of 0.066 considering an average variation of the thickness related to the expected value and a standard deviation (SD) of 0.100. A sample size of at least 20 measurements was determined to be adequate with *t* statistic and noncentrality parameters.[24]

Homoscedasticity and autocorrelation of the variables were assessed by the Breusch-Pagan and Durbin-Watson tests. The normality assumption of the data was evaluated with the Shapiro-Wilk test. To assess thickness differences among different regions of Invisalign clear aligners, the sample was stratified into subgroups and Student's *t*-test analyses were performed.

Differences between upper and lower measures were also evaluated using Student's *t*-test. The analyses were focused on mean differences among different teeth (incisors, canines, and molars) and mean differences among different sites of the same tooth (GB, B, O GL, L). Significance was set at $P < .05$.

Two values of Dahlberg's formula were used as methods of quantifying error. The first considered all collected measurements, providing an overall evaluation, whereas the second considered stratified measurements by specific variables.[25]

Systematic differences between repeated measurements were evaluated with paired Student's *t*-tests with the type I error set at $P < .05$. Data were analyzed as mean and SD and reported in millimeters. Statistical analysis was performed using the R statistical package (version 3.0.1; R Core Team, Foundation for Statistical Computing, Vienna, Austria).

RESULTS

Descriptive analysis showed that overall mean thickness of unused Invisalign aligners ranged between 0.582 mm and 0.639 mm in the central incisor region, between 0.569 mm and 0.644 mm in the canine

Table 1. Descriptive Analysis of Aligner Thickness (mm) at Different Teeth[a]

	Incisor					Canine					Molar				
	GB	B	O	L	GL	GB	B	O	GL	L	GB	B	O	L	GL
Minimum	0.4465	0.4190	0.4961	0.4465	0.4465	0.4190	0.4465	0.3930	0.3350	0.3960	0.4190	0.4197	0.4190	0.4778	0.3583
First Quarter	0.5333	0.5829	0.5953	0.5829	0.5333	0.5333	0.4961	0.5451	0.5457	0.5932	0.5457	0.5829	0.5967	0.5440	0.5118
Median	0.5953	0.6201	0.5953	0.5976	0.5953	0.5953	0.5953	0.5953	0.5953	0.5953	0.6201	0.6449	0.6449	0.5953	0.5953
Mean	0.5820	0.6113	0.6396	0.6238	0.5831	0.5694	0.5705	0.5998	0.5974	0.6006	0.6202	0.6121	0.6340	0.5971	0.5664
Third Quarter	0.5960	0.6449	0.6573	0.6945	0.5965	0.5965	0.6330	0.6449	0.6945	0.6449	0.6449	0.6449	0.6945	0.6449	0.6449
Maximum	0.8390	0.8390	0.8930	0.8390	0.8434	0.7441	0.7130	0.8000	0.7441	0.7937	0.7441	0.7441	0.7441	0.7441	0.7441

[a] For each tooth, the following sites were analyzed: GB, B, O, L, and GL.

region, and between 0.566 and 0.634 in the molar region (Table 1). The method error varied from 0.001 to 0.002 mm for both Dahlberg's formula analyses. No differences between repeated measurements were found with paired Student's *t*-tests.

Stratifying by different sites, no significant differences were found among aligner thickness on the incisors, canines, and molars. Stratifying data by tooth, a significant difference was detected only in the molar region when comparing occlusal (0.634 mm) and GL sites (0.566 mm; mean difference = 0.068 mm; 95% confidence interval [CI], 0.009–0.126 mm; $P = .024$; Table 2). If stratification was considered by arch, then a significant difference was detected only in the molar lingual region when comparing upper (0.631 mm) and lower aligners (0.563 mm) (mean difference = 0.067 mm; 95% CI, 0.008–0.126 mm; $P = .038$; Table 3).

Table 2. Differences Among Sites Stratified by Tooth

Tooth	Site	Mean Difference	Lower 95% CI	Upper 95% CI	*P* Value
Incisor	GB-B	0.0282	–0.0841	0.0264	.297
	GB-O	0.0571	–0.1188	0.0045	.068
	GB-L	0.0413	–0.0967	0.0141	.139
	GB-GL	0.0006	–0.0568	0.0555	.981
	O-B	0.0282	–0.0320	0.0885	.347
	L-B	0.0125	–0.0413	0.0662	.641
	GL-B	0.0282	–0.0827	0.0263	.301
	O-L	0.0158	–0.0446	0.0762	.599
	O-GL	0.0565	–0.0045	0.1175	.069
	L-GL	0.0407	–0.0140	0.0953	.14
Canine	GB-B	0.0012	–0.0513	0.0489	.962
	GB-O	0.0304	–0.0854	0.0246	.269
	GB-L	0.0312	–0.0807	0.0182	.208
	GB-BL	0.0280	–0.0877	0.0317	.347
	O-B	0.0292	–0.0272	0.0857	.301
	L-B	0.0300	–0.0210	0.0812	.24
	GL-B	0.0268	–0.0342	0.0878	.378
	O-L	0.0008	–0.0567	0.0550	.976
	O-GL	0.0024	–0.0625	0.0674	.94
	L-GL	0.0032	–0.0572	0.0638	.913
Molar	GB-B	0.0099	–0.0663	0.0464	.723
	GB-O	0.0318	–0.0863	0.0227	.245
	GB-L	0.0051	–0.0469	0.0572	.843
	GB-GL	0.0358	–0.0239	0.0955	.232
	O-B	0.0218	–0.0328	0.0766	.423
	L-B	0.0150	–0.0673	0.0372	.562
	GL-B	0.0460	–0.1057	0.0142	.13
	O-L	0.0369	–0.0133	0.0872	.145
	O-GL	0.0676	0.0094	0.1260	.024*
	L-GL	0.0307	–0.0253	0.0866	.273

* $P = 0.024$

DISCUSSION

Aligners are produced by a thermoforming process.[26] Thermoplastic polymers melt and then flow because of heating. SmartTrack (LD30; Align Technology) material is a multilayer aromatic thermoplastic polyurethane/copolyester.[19] With respect to the previous EX30 material used, LD30 exhibited a more amorphous structure and a greater elastic recovery,[27] and its use is considered safe.[28] Polymer structures can be affected by different processes of production (molding, cooling, trimming).[18] To characterize their clinical application, the mechanical properties of clear plastic materials used for the fabrication of aligners should always be evaluated after thermoforming.[20]

The present study demonstrated that the thickness of Invisalign aligner material after the thermoforming process was not homogeneous, although the observed differences were not significant except at the molar sites. SmartTrack thickness after thermoforming should be 0.03″, which corresponds to 0.762 mm.

Table 3. Differences Between Upper and Lower Aligners

Tooth	Site	Mean Difference	Lower 95% CI	Upper 95% CI	*P* Value
Incisor	GB	–0.04	–0.11	0.04	.373
	B	0.001	–0.07	0.07	.975
	O	–0.03	–0.12	0.06	.508
	L	–0.02	–0.10	0.05	.554
	GL	–0.06	–0.14	0.01	.093
Canine	GB	–0.02	–0.09	0.04	.510
	B	0.0004	–0.07	0.07	.990
	O	–0.02	–0.10	0.06	.715
	L	–0.09	–0.08	0.06	.810
	GL	–0.07	–0.15	0.02	.175
Molar	GB	0.01	–0.06	0.09	.720
	B	–0.01	–0.09	0.07	.750
	O	–0.01	–0.09	0.06	.652
	L	0.07	0.01	0.13	.038*
	GL	0.01	–0.08	0.09	.854

* $P = 0.038$

Results from this study showed that the actual thickness of Invisalign aligners after thermoforming ranged from 0.582 mm to 0.639 mm on incisors, from 0.569 mm to 0.644 mm on canines, and from 0.566 mm to 0.634 mm on molars. The only statistically significant difference was detected in the molar region, where the GL site analyzed was thinner than the occlusal site.

To provide a more consistent load increase on the periodontal ligament, the use of a thinner, less stiff, initial aligner has been recommended.[29] The thermoforming process stretches the plastic foil on the cast model, leading to reduction of its original thickness, especially in the anterior region; 0.4 mm has been evaluated as the minimum aligner thickness associated with reasonable shape stability.[30] However, when aligners are used for palatal tipping and rotation of a central incisor, thickness of the appliance does not affect the initial moment to force ratio.[31]

The results of a recent in vitro study regarding polyethylene terephthalate and polyurethane foils showed up to a 50% reduction of aligner thickness after thermoforming, especially in buccal–gingival regions,[32] where the plastic foil was thinned out, thus representing the area where aligners are less rigid. This reduced rigidity can also be argued from the current data: the thickness inhomogeneity observed in the molar region could be considered to explain why Invisalign aligners are not efficient in controlling the buccolingual inclination of molars.[10,33]

However, it should be considered that molars are the terminal teeth, and greater flexibility of the aligners has been described for this region. Similar behavior has been reported for fixed appliances in relation to the decreasing amount of force released by the terminal ends of the wire as interbracket distance and flexibility of the wire increase. Cattaneo et al. demonstrated that occlusal forces influenced orthodontic movement especially in the molar region.[34] In other words, aligners should be resilient enough to overcome the resistance of the system to better control molar tipping.

Results from the current study showed a value of thickness on molars comparable with molar relative intrusion data from previous research.[35] When treating anterior open bite in adult patients with a hyperdivergent skeletal pattern using aligners, it appears that posterior occlusal coverage on both arches can prevent molar and premolar extrusion, thus controlling the vertical dimension.

Because poor final occlusal contacts are among the limitations of clear aligner treatment in normo- and hypo-divergent patients,[36] data derived from this study could be useful to improve the accuracy of case finishing. To avoid posterior open bite at the end of orthodontic treatment, aligner thickness on posterior teeth should be one of the parameters taken into account, planning posterior extrusion of at least 1.2 mm in all normo- and hypo-divergent patients.

The in vitro design was the main limitation of this study. Clinical speculations should be confirmed by future research. Another shortcoming was the small sample size that could not account for manufacturing tolerances, even if the analyzed aligners were all unique and originating from 10 different patients. In addition, several elements of aligner production, with particular reference to the thermoforming procedure as well as the original thickness of the foil from which aligners were obtained, were not disclosed by Align Technology, limiting possible explanations of the observed results.

CONCLUSIONS

- Analysis showed that the thickness of aligners is not homogeneous, although the observed differences were not significant with the exception of the molar sites.
- In the molar regions analyzed, the GL site was significantly thinner than the occlusal site.
- Results of the present study have possible clinical relevance: they could be considered to explain the reduced predictability of some orthodontic movements. The actual thickness of Invisalign aligners could be one way to quantify the amount of "bite-block" effect.

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