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Original Article

Measurement of Aligner Thickness and Gap Width in Two Types of Clear Aligner Sheets Manufactured Using Two Different Thermoforming Machines - A Nano-CT Pilot Study

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Main Points

- Aligner material type and tooth morphology (especially in the molar region) are important factors influencing aligner fit and thickness.
- Both thermoforming machines generated aligners that were clinically acceptable in terms of fit, particularly in the anterior region.
- Aligner thickness generally decreased from the posterior (molar) to the anterior (incisor) tooth structures. Conversely, adaptation was greater in the anterior region (smaller gap width) than in the posterior region.
- The results underscore the importance of appropriate material selection and thermoforming precision for effective anchorage and force delivery, especially in the posterior segments of the dental arch.

ABSTRACT

Objective: The aim of this study was to compare the effects of two thermoforming machines on the gap width and thickness of passive aligners with the same nominal thickness from different manufacturers by using nano-computed tomography (CT).

Methods: An intraoral scan of a patient with Angle's Class I malocclusion was conducted, and a 3D maxillary arch model was printed. The aligners (n=16) were fabricated using two thermoforming machines: Ministar machine (n=8) and a Plastpress machine (n=8). Each group was subdivided on the basis of aligner material: polyethylene terephthalate glycol (PET-G) (Group A) and thermoplastic polyurethane (TPU) (Group B). Sheets with a nominal thickness of 0.75 mm were used. Nano-CT was performed, and the rendered 3D models were sliced into central incisor, canine, and molar regions to assess gap width and aligner thickness in the buccal, incisal, and palatal regions.

Results: Comparing thermoforming machines, PET-G (p=0.010) and TPU (p=0.004) aligners showed significant differences in gap width in the molar region. Similar results were found for aligner thickness (TPU, p=0.05; PET-G, p=0.004). Comparing PET-G and TPU sheets thermoformed via the same machine, significant differences were observed only in the molar region (p=0.004), with no differences in the canine and incisor regions. Adaptation in the anterior region was greater than in that of the posterior region, whereas aligner thickness increased from posterior to anterior.

Conclusion: Aligner material type significantly affected gap width and thickness only in the molar region, whereas the specific thermoforming machine did not substantially affect these characteristics.

Keywords: Gap width, aligner thickness, thermoforming procedures, thermoforming machines

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INTRODUCTION

Clear aligners (CAs) were initially introduced by Tooth Positioner Orthodontics in 1945,[1,2] facilitating tooth movement through the use of tooth positioners. They encompass a variety of devices, each with unique mechanisms, construction methods, and applicability in the treatment of malocclusions. Originally, CAs were designed to address minor tooth irregularities. While some aligner systems are effective in correcting minor malalignments, others are intended for more complex malocclusions.[3,4] However, there is a lack of published clinical evidence to substantiate these claims, and the available evidence is often of low scientific quality.[5] The integration of advanced transparent thermoplastic materials and computer technology, including computer-aided design (CAD)-computer aided manufacturing, stereolithography (STL), and tooth movement simulation software, has significantly enhanced the use of CA products in the correction of malocclusions. Materials such as polyethylene terephthalate glycol (PET-G) and thermoplastic polyurethane (TPU) are widely used in orthodontic aligners, and their properties influence clinical performance and patient satisfaction. Recent advancements in CA materials have prompted research into aligner properties, including temperature, humidity, thickness, elastic deformation duration, and thermoforming,[5,6] thereby validating the reliability of CAs in treating malalignment. These factors are linked to optical properties, force generation, retention, and movement predictability.[7,8] PET-G, a non-crystalline copolymer of PET modified with cyclohexanedimethanol, provides substantial strength and rigidity for effective tooth repositioning. Research has indicated that PET-G aligners exhibit decreased mechanical properties when exposed to extreme temperatures and high moisture exposure during use.[9] Nevertheless, they exhibit good mechanical behavior under cyclic loading with increased stiffness and low residual strain accumulation.[10] Although the thermoforming process and intraoral conditions reduce the thermomechanical properties of PET-G materials, they maintain greater stability than alternatives such as TPU.[11] The resistance of PET-G to deformation also aids in sustaining orthodontic forces, as well as superior resistance to staining and chemical changes compared with polyurethane, thereby preserving aligner aesthetics.[12] TPU aligners offer flexibility and consistent, gentle force delivery, which are beneficial for prolonged orthodontic treatment. They exhibit higher hardness and stiffness but are more susceptible to creep and stress relaxation, which affects longevity and force application.[13] Compared with PET-G aligners, TPU aligners are less resistant to staining. The biocompatibility and comfort of TPU provide a better patient experience, thereby improving treatment adherence and outcomes.[14]

The effectiveness of thermoformed aligners depends on several variables, including the manufacturing process (specifically, the temperature and pressure settings), modulus of elasticity of the materials used, presence of dimples and appendages, and hygroscopic swelling when the aligners are exposed to saliva or water.[15,16] The interplay between aligner thickness and adaptation is pivotal in determining the efficiency and range of movements achieved with CAs. Orthodontists strategically employ the aligner thickness to predict and precisely control the forces and torques applied to teeth, which are crucial for guiding bone remodeling outcomes, such as cell damage, hyalinization of the periodontal ligament, bone necrosis, and root resorption. Consequently, the inner surface of the aligner must fit accurately against the teeth to ensure effective delivery of the intended forces. Poor fit can also result in aligners detaching from the teeth, particularly during root movements that require torque, which interferes with establishing the force couple required for predictable tooth movement.[17] The thermoforming process may lead to a reduction in the thickness of the aligners compared with the original dimensions of the thermoplastic sheet.[18] Golkhani et al.[19] reported that thermoforming reduces material thickness and alters aligner geometry, thereby affecting force and torque delivery and diminishing mechanical strength. Conversely, Tamburrino et al.[20] reported that thermoforming PET-G increased its elastic modulus by 11% and yield strength by 9%, which was attributed to the alignment of the polymer chains ("drawing"). The authors further suggested that the thermal shock associated with thermoforming may modify the surface roughness, potentially influencing the optical and absorption characteristics of the material, thereby indirectly contributing to an increase in its optical density.

A consistent thickness is essential for applying the intended force necessary for precise tooth movement, whereas an appropriate thickness enhances aligner retention and patient comfort.[21-25] Furthermore, it affects an aligner's durability and resistance to deformation, ensuring uninterrupted treatment. Monitoring the thickness also aids in detecting manufacturing errors and ensures material consistency across different aligners. Various methodologies have been employed, ranging from non-destructive high-resolution micro-computed tomography (micro-CT), which provides intricate two-dimensional and three-dimensional evaluations of internal structures and thickness variations, to precise coordinate measuring machines for physical assessments and optical scanners that compare digital models with CAD schematics. Additional techniques include scanning electron microscopy of cross-sections, profilometers for surface and thickness evaluations, and less precise direct measurements via calipers. Collectively, these methods provide a comprehensive understanding of the physical dimensions of an aligner. Advanced techniques, such as nano-CT, are particularly beneficial in research and development for optimizing aligner design and materials, ultimately improving the clinical outcomes of patients. This technology allows highly detailed three-dimensional imaging at submicrometer resolution, significantly surpassing that of conventional micro-CT systems.[26]

Despite the widespread use of aligner systems with various materials in dentistry, studies addressing the reliability of thermoforming machines used in fabrication, which influences the properties of CAs, are lacking. Additionally, aligners from different manufacturers recommend diverse methods for manufacturing CA, potentially affecting the quality of aligners. The impact of operating conditions on the mechanical properties also varies from polymer to polymer.[20] This study aims to assess and contrast the thermoforming machine-induced variations in gap width and aligner thickness for passive aligners sourced from two different manufacturers, with identical nominal material thicknesses.

METHODS

Ethics Committee Information

The design of the nano-CT study was approved by the Institutional Ethics Committee of Tagore Dental College and Hospital (protocol number IEC/TDC/120/2022, date: 26.10.2022).

Digital Model Creation

An intraoral scan was performed on a patient diagnosed with Angle Class I malocclusion, characterized by the absence of crowding or spacing in the maxillary arch. An Aoralscan 3 intraoral scanner [Shining 3D Tech Co., Ltd., China, field of view (FOV) 16×12 mm, depth 22 mm] was used. This non-contact scanner operates based on structured light principles. The STL files were transmitted to a single aligner manufacturer (Wero Aligners, Chennai, Tamil Nadu) for treatment planning and 3D model production. All model bases were constructed with a uniform height of 5 mm.

Sample Size Calculation

The sample size was determined based on a previous study.[8] An a priori power analysis was performed to ascertain the sample size required for statistical comparison between the two independent groups. Using a two-tailed hypothesis test with an alpha level (α) of 0.05 and a desired statistical power (1-β) of 0.80, the analysis aimed to identify a significant effect size (d=1.67). Assuming an equal distribution ratio (N2/N1=1), the computed non-centrality parameter (δ=3.12) and critical t value (tcrit=2.18) at 12 degrees of freedom indicate the necessity of seven participants per group, culminating in a total sample size of 14. The actual power for this sample size was calculated to be 0.82, slightly exceeding the target power, which implies that a high likelihood of detecting a true effect of the specified magnitude should exist in the population.

Sample Preparation

Sixteen samples were used for thermoforming. The aligners were divided into two groups. Group 1 (n=8): aligners thermoformed using the Ministar, Group 2 (n=8): aligners thermoformed using the Plastpress. Each group was subdivided according to the type of aligner material used: Group A-PET-G (Erkodur AL, Erkodent Erich Kopp, GmbH, Germany) and GROUP B-TPU (Zendura FLX, CA, USA).

Aligner sheets with a thickness of 0.75 mm were used fabrication. The models were positioned at the center of the platform, with their midline aligned at the 12:00 position. The sheets were molded in accordance with the manufacturer's instructions using the same operator to reduce bias. The thermoforming machines employed were the Ministar (SCHEU Dental GmbH) and the Plastpress (BIOART).

The Ministar uses positive-pressure thermoforming combined with vacuum assistance. Initially, a fast infrared heating element was used to warm one side of the material to a maximum temperature of 60 °C. The softened material was subsequently pressed against a mold inside a pressure chamber at 4 bar, adopting the desired form. The system maintained consistent heating through thermostatic control, and the barcode scanner facilitated precise material-specific programming of the heating and cooling cycles. In contrast, PlastPress uses positive air-pressure thermoforming.

Data Acquisition

The aligners were maintained in situ on the model at ambient temperature until the completion of nano-CT scanning (Bruker Multiscale NANO CT-2214, Bruker Corporation, Billerica, MA, USA) to minimize potential distortion. The scanner was equipped with a flat-panel camera featuring a 140 mm FOV and a pixel size of 74.800 µm. The image pixel size was 35.00068 µm, with a depth of 16 bits, an exposure time of 1800 ms, a rotation step of 0.300°, and a scanning position of -34 mm. Following the scan, the raw data were reconstructed using NRecon software (version 2.1.0.2, Sky Scan Microphotonics, Inc., Allentown, PA). The reconstructed image dimensions were 3072 pixels in width and height, with an angular step of 0.300 s and cone beam angles of 40.23° horizontally and 26.097° vertically. The rendered 3D models were visualized using CTVox (version 3.3.0), and measurements were performed using Adobe Data Viewer (version 1.5.6.2).

2D Analysis

The 3D models were virtually divided into three anatomical regions, each corresponding to the central incisor, canine, and first molar to assess aligner thickness and the air gap (gap width) between the aligner and the cast. This division was essential for assessing the aligner thickness and air volume (gap width) between the aligner and the cast. For each tooth, a tangent was established between the mesial and distal contact points. The midpoint of these tangents, which was aligned with the tooth's long axis, served as the vertical reference plane. A horizontal line was drawn to connect the centers of the buccal and palatal surfaces positioned perpendicular to this plane served as the horizontal reference plane.

These reference lines functioned as reference lines, with tangents to these lines offering multiple reference points on each two-dimensional grid, including the following:

Five points for the central incisor (Figure 1), five points for the canine (Figure 2), and six points for the first molar (Figure 3).

The 2D reference points and slice planes were identified on the building grid for the (A) incisor, (B) canine, and (C) molar.

1. Buccal gingival edge,
2. Buccal surface center,
3. Incisal edge, buccal cusp,

3a. Palatal cusp,

4. Palatal surface center,
5. Palatal gingival edge.

Statistical Analysis

Statistical analyses were performed using the IBM (Armonk, New York, USA) SPSS Statistics V20. Wilks' normality test was conducted to evaluate the distribution of the data, which demonstrated a deviation from normality. As a result, non-parametric tests were employed, as they are more appropriate for datasets that do not satisfy parametric assumptions. Asymp. Sig. (2-tailed) was used to compare two independent groups with non-normally distributed data. This test was applied to analyze the gap width and aligner thickness between aligners manufactured by Ministar and Plastpress machines as well as between two thermoforming sheets in three different tooth types: incisors, canines, and molars. Statistical analyses were performed with a 95% confidence interval, and the findings were considered statistically significant when $p<0.05$.

RESULTS

Table 1 presents descriptive statistics (median and interquartile range) for PET-G and TPU sheets thermoformed using Ministar and Plastpress across various regions, namely, molars, canines, and incisors.

Analysis of aligner thickness (Table 2) revealed no significant differences between PET-G and TPU sheets in the canine (p=0.810 Ministar and p=0.378 for Plastpress) and incisor regions (p=0.422 for Ministar and p=0.470 for Plastpress) for both thermoforming machines. However, a significant difference was detected in the molar region (p=0.004) across all the sheets, independent of the thermoforming machine.

For gap width, no significant differences were observed in the canine (Ministar: p=0.229; Plastpress: p=0.128) or incisor regions (Ministar: p=0.128; Plastpress: p=0.575). In contrast, the molar region showed significant differences for both machines (Ministar: p=0.010; Plastpress: p=0.004).

Table 3 demonstrates that comparisons of aligner thickness between the two machines (Ministar vs. Plastpress) revealed no significant differences in the canine (TPU: p=0.810; PET-G: p=0.171) or incisor (TPU: p=0.936; PET-G: p=0.936) regions. However, the molar region again exhibited significant differences in thickness for both PET-G (p=0.004) and TPU (p=0.050).

Similarly, gap width comparisons between machines showed no significant differences in the canine (TPU: p=0.065; PET-G: p=0.936) or incisor regions (TPU: p=0.378; PET-G: p=0.173). In contrast, the molar region showed significant differences in gap width for PET-G (p=0.010) and TPU (p=0.004).

DISCUSSION

The increasing demand for CAs has led to the development of novel thermoplastic materials for their production.[27-31] The aligner sheets used in this study are among the most versatile

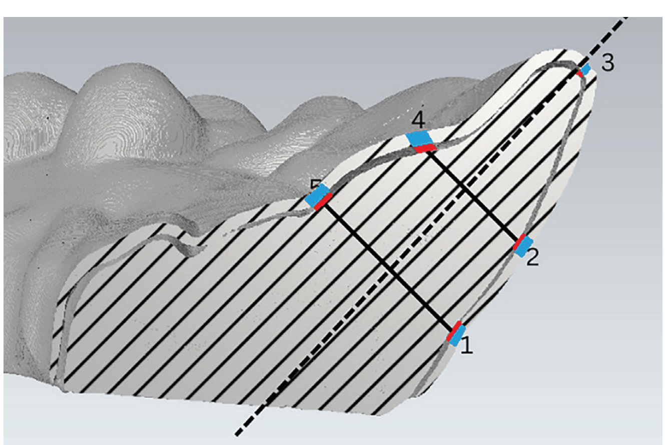

Figure 1. Measurement of aligner thickness and gap width in the central incisor

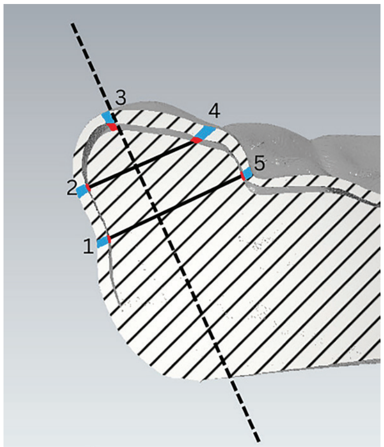

Figure 2. Measurement of aligner thickness and gap width in canines

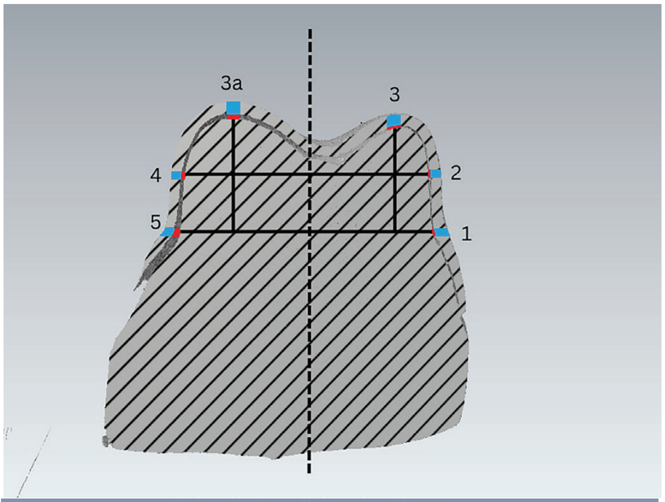

Figure 3. Measurement of aligner thickness and gap width in the first molar

Table 1. Frequency distribution of material thickness and gap width in three different tooth structures using different thermoforming machines and thermoforming sheets

Material	Tooth region	Thickness		Gap width	
		Median (mm)	IQR	Median (µm)	IQR
Ministar PET-G	Molar	0.303	0.083	146.5	97.5
	Canine	0.373	0.2191	182.0	103.25
	Incisor	0.358	0.302	127.125	109.31
Ministar TPU	Molar	0.538	0.0838	259.5	152.31
	Canine	0.325	0.251	228.667	282.25
	Incisor	0.403	0.2775	211.167	196.88
Plastpress PET-G	Molar	0.543	0.0484	263.125	159.31
	Canine	0.437	0.2391	173.375	129.43
	Incisor	0.337	0.1991	178.750	141.56
Plastpress TPU	Molar	0.45	0.0525	77.167	70.4
	Canine	0.273	0.3188	74.667	52
	Incisor	0.390	0.3687	143.000	107.33

PET-G, polyethylene glycol; TPU, thermoplastic polyurethane; IQR, interquartile range

Table 2. Comparison of material thickness and gap width between two thermoforming sheets in three different tooth structures

Tooth	Material	Mean rank	p-value
Material thickness			
Molar	Ministar PET-G	3.5	0.004*
	Ministar TPU	9.5	
Canine	Ministar PET-G	6.75	0.810
	Ministar TPU	6.25	
Incisor	Ministar PET-G	5.67	0.422
	Ministar TPU	7.33	
Molar	Plastpress PET-G	9.5	0.004*
	Plastpress TPU	3.5	
Canine	Plastpress PET-G	7.42	0.378
	Plastpress TPU	5.58	
Incisor	Plastpress PET-G	5.75	0.470
	Plastpress TPU	7.25	
Gap width			
Molar	Ministar PET-G	3.83	0.010*
	Ministar TPU	9.17	
Canine	Ministar PET-G	5.25	0.229
	Ministar TPU	7.75	
Incisor	Ministar PET-G	4.92	0.128
	Ministar TPU	8.08	
Molar	Plastpress PET-G	9.5	0.004*
	Plastpress TPU	3.5	
Canine	Plastpress PET-G	8.08	0.128
	Plastpress TPU	4.92	
Incisor	Plastpress PET-G	7.08	0.575
	Plastpress TPU	5.92	

Asymp. Sig. (2-tailed) test; 95% confidence interval
p<0.05, *statistically significant
PET-G, polyethylene glycol; TPU, thermoplastic polyurethane

Table 3. Comparison of material thickness and gap width between two thermoforming machines

	Material	Mean rank	p-value
TPU material thickness			
Molar	Ministar TPU	8.5	0.053
	Plastpress TPU	4.5	
Canine	Ministar TPU	6.75	0.810
	Plastpress TPU	6.25	
Incisor	Ministar TPU	6.42	0.936
	Plastpress TPU	6.58	
TPU Gap width			
Molar	Ministar TPU	9.50	0.004
	Plastpress TPU	3.50	
Canine	Ministar TPU	8.42	0.065
	Plastpress TPU	4.58	
Incisor	Ministar TPU	7.42	0.378
	Plastpress TPU	5.58	
PET-G material thickness			
	Material	**Mean rank**	**p-value**
Molar	Ministar PET-G	3.5	0.004
	Plastpress PET-G	9.5	
Canine	Ministar PET-G	5.08	0.171
	Plastpress PET-G	7.92	
Incisor	Ministar PET-G	6.58	0.936
	Plastpress PET-G	6.42	
PET-G Gap width			
Molar	Ministar PET-G	3.83	0.010
	Plastpress PET-G	9.17	
Canine	Ministar PET-G	6.42	0.936
	Plastpress PET-G	6.58	
Incisor	Ministar PET-G	5.08	0.173
	Plastpress PET-G	7.92	

Asymp. Sig. (2-tailed) test; 95% confidence interval
p<0.05, *statistically significant
PET-G, polyethylene glycol; TPU, thermoplastic polyurethane

elastomeric thermoplastics, such as TPU and PET-G, and consist of either amorphous or partially crystalline polymers with superior physical, chemical, abrasion, adhesion, and processing properties.[32] In CA fabrication, PET-G is frequently preferred owing to its superior transparency, robust fatigue resistance, and dimensional stability. TPU is a flexible and easily moldable elastomer that offers high elasticity and formability, providing comfortable wear and effective impact cushioning. Given the limitations of single-layer materials, innovations have led to the development of multilayer hybrid materials. These advanced materials have been engineered to integrate the advantageous properties of various materials. For example, layering a rigid outer material with a softer inner layer can improve tensile strength and reduce water absorption.[17] Aligner thickness and adaptation remain critical determinants of physiologic tooth movement, as they influence the magnitude and delivery of orthodontic forces. The transparency of aligner sheets is significantly influenced by their thickness, as structural deformation occurring at temperatures above the glass transition temperature and pressure leads to secondary bonding forces, transforming the amorphous structure into a crystalline structure.[33,34] The thermoforming process also results in a rough surface that can trap staining substances.[35]

Numerous studies have indicated that aligner thickness does not significantly affect the forces generated for movements such as tipping and rotation and that intraoral use or thermoforming does not produce clinically relevant changes in thickness or alter aligner shape. However, increases in aligner thickness may adversely affect labial and palatal tooth movements.[17,35,36] Iliadi et al.[37] reported that aligner thickness affects the rate of deflection under simulated intraoral conditions, with thicker materials generating greater force and moment on the tooth.

Several studies have indicated that CAs made from thicker sheets (0.75 mm or 0.8 mm) exert stronger forces than those made from thinner sheets (0.4-0.5 mm).[38-40] A study using finite element analysis (FEA) reported that aligners with different thicknesses affected the displacement tendency of teeth, particularly concerning incisor retraction and torque control.[41] Thicker aligners (0.75 mm) have been associated with enhanced torque control and palatal root torque, which are essential for achieving bodily retraction of the anterior teeth while minimizing the risk of root resorption. Li et al.[42] reported that increasing aligners thickness results in a more significant buccal displacement of the crowns and an increase in stress on the periodontal ligaments during expansion. Conversely, thinner aligners may provide less control but may be more comfortable for the patient.[43] Therefore, a thorough analysis of the aligner thickness is crucial in determining the predictability and success of orthodontic treatment.

The deformation of aligners in terms of thickness and gap width may be influenced by tooth morphology, the extent of intended tooth movement, and the thermoforming process. The aligner sheets were manufactured via vacuum-based thermoplastic molding and pressure-based thermoforming machines. Vacuum-based thermoforming is more time-consuming and technique-sensitive and may result in unpredictable changes in the mechanical and physical properties of the material Although pressure-forming machines are similar to vacuum-forming machines, they employ compressed air to heat aligner sheets, resulting in sharper and more precise details. Hahn et al.[33] reported that high-pressure thermoforming produces appliances with a more precise fit, leading to significantly stronger forces than those of vacuum-formed appliances.[44] As a result, pressure-forming systems have become widely adopted in clinical practice. Consequently, this study aimed to evaluate variations in the properties of CAs, such as gap width and thickness, using two different thermoforming machines, which are crucial in orthodontic tooth movement.

CA thickness can be evaluated using various methods, including non-invasive micro-CT, which is notable for its non-destructive and high-resolution capabilities in assessing the overall thickness distribution. We opted to use nano-CT because it is an emerging high-resolution, cross-sectional imaging technique that represents a technical advancement over micro-CT. Nano-CT achieves superior spatial resolution of up to 400 nm by utilizing a transmission target X-ray tube to achieve a focal spot size of less than 400 nanometers (nm), along with specific detectors and examination protocols. The enhanced resolution of this technique, achieved through a smaller focal spot of the transmission tube and closer sample positioning, enables more detailed imaging than typical micro-CT systems.[45] We employed a trim line positioned 1 mm above the gingival margin, as this design significantly affects the biomechanical efficacy of aligners in facilitating tooth movement. Evidence suggests that aligners with straight extended trim lines demonstrate greater force and provide superior control compared with scalloped designs. A FEA revealed that straight-cut trim lines produce greater forces than scalloped trim lines, which is crucial for effective tooth movement. The straight design optimizes the force distribution, thereby enhancing retention and reducing stress on the teeth during facial translation, distalization, and extrusion.[46,47]

In our study, the mean thickness of the aligner sheets was reduced to 0.5 mm, consistent with the findings of Min et al.[39] and Park et al.,[17] who reported a reduction in aligner thickness of approximately 57.5% following thermoforming. Moreover, TPU sheets exhibited superior adaptation in both thermoforming machines. This observation aligns with the study by Mantovani et al.,[15] who noted that during thermoforming, CA (PET-G) plastic sheets tend to thin at the gingival edge, resulting in reduced rigidity. Consequently, this thinning leads to a less optimal fit between the tooth and aligner at the gingival margin of clear CA aligners compared with the Invisalign material (SmartTrack material), which comprises multilayer aromatic thermoplastic aligners. Our study also demonstrated that the TPU experienced less thickness reduction than PET-G, corroborating Park et al.[17] (PET-G-504.68 μm, TPU-509.54 μm). This may be attributed to the copolyester-elastomer multilayer composition of TPU, which offers superior tensile strength than the PET-G materials. Consequently, this multilayer structure may be more amenable to stretching during heating and pressure thermoforming, resulting in more precise fitt. The study also indicated that the thermoforming machine does not significantly reduce the thickness of the aligner sheets, potentially due to the minimum air pressure of 3-4 bar used by both systems. Our 2D research further revealed that the aligner fit (gap width) was generally superior in the gingival regions of the first molar than in the occlusal regions. Compared with other areas, the molar tooth exhibited increased gap width and thickness changes between Ministar and Plastpress. The aligner thickness also decreased from the posterior to the anterior tooth structures, possibly due to greater stretching of the aligner sheets in the anterior region. These findings are consistent with those of Palone et al.,[8] Mantovani et al.,[15] Bucci et al.,[18] and Lee et al.[48] This could be advantageous for tooth movement because a decreased or minimal gap width with increased thickness may counteract the vertical dislodging.

In summary, the statistical analysis indicated that significant differences in aligner thickness and gap width were observed only in the molar region, whereas the incisor and canine regions exhibited no statistically significant variations, irrespective of the material or machine employed. Compared with PET-G aligners, TPU aligners demonstrate superior adaptation and less thickness reduction. This study further revealed that Ministar, which provides automated control of heating and pressure, produced more consistent results than Plastpress, which relies on manual settings. Nonetheless, both machines generate clinically acceptable aligners in terms of fit, particularly in the anterior region. A posterior-to-anterior thickness gradient was identified, which may have biomechanical implications for tooth movement and alignment retention. This finding may facilitate future research on a broader range of aligner materials, thermoforming systems, and malocclusion severities.

Study Limitations

This study considered only minor deformities, and severe malocclusions could have affected the results. In addition, grip points, attachments, or divots were not considered. The results may not be representative and could have been adversely affected by unfavorable temperature and pressure settings because only a small sample size was evaluated for each aligner brand. Future studies should examine a wider range of materials and machine systems to enhance the clinical applicability of these findings.

CONCLUSION

This study demonstrated that while PET-G and TPU materials performed similarly in the anterior tooth regions when thermoformed using either Ministar or PlastPress, the molar region exhibited significant variations in aligner thickness and gap width, influenced by aligner material and tooth morphology.

Among the two thermoforming machines, Ministar yielded more consistent outcomes, likely due to its automated temperature and pressure regulation. These findings underscore the importance of material selection and thermoforming precision, both of which are critical for effective anchorage and force delivery.

Ethics

Ethics Committee Approval: The design of the nano-CT study was approved by the Institutional Ethics Committee of Tagore Dental College and Hospital (protocol number IEC/TDC/120/2022, date: 26.10.2022).

Informed Consent: Researchers ensured the patient gave informed consent before using their intra-oral scan for the study.

Footnotes

Author Contributions: Concept - G.S., M.K., B.K.; Design - G.S., M.K., B.K., S.P.A.; Data Collection and/or Processing - G.S., M.K.; Analysis and/or Interpretation - G.S., M.K., S.P.A, S.R.; Literature Search - G.S., M.K., A.S.S., S.R.; Writing - G.S., M.K., A.S.S.

Conflict of Interest: The authors have no conflicts of interest to declare.

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