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Original Research

Assessment of change in thickness of aligner using vacuum and pressure thermoforming techniques: An in –vitro study

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ABSTRACT:
Background: Clear aligners are among the most chosen orthodontic therapy for an invisible treatment. Aligners are formed using different polymers and thermoforming techniques. Previous studies have shown that the thermoforming process might alter the physical properties of clear aligners. From various studies in literature it was found that the thickness of aligner material is directly related to the applied force by the aligner on the tooth surface. Thicker material reduces aligner flexibility, enhances its rigidity, and leads to an increase in the force generated. The forces produced by aligners made from the 0.75-mm thick material were significantly higher than those made from 0.5mm-thick material. Our aim of this study was to assess the change in thickness of clear aligners after using different thermoforming technique (vacuum and pressure technique) with polyethylene terephthalate glycol (PET-G) and Polyurethane (PU). **Aim:** The aim of the study was to evaluate changes in thickness of aligner after thermoforming using different techniques, evaluated at different occlusal points.**Materials and methods:** In-house clear aligners were thermoformed using different thermoforming technique (vacuum and pressure technique) with PET-G and PU aligner material. In-house clear aligners of the patients were scanned with 3-D scanner (Shining 3D) using developer. The thickness of the clear aligners was measured at different occlusal points on a 3D model with software (Mesh mixer).The data in this study were obtained and statistically examined.**Results:** The thermoforming process showed good reproducibility for both the aligner. The thickness in both the process showed significant changes in both the thermoforming process at various selected points. PU aligners exhibited significantly greater thickness compared to PET-G aligners.**Conclusion:** Our findings underscore the importance of thermoforming methods in determining aligner performance, as even minor thickness differences can affect treatment effectiveness and patient comfort. The pressure thermoforming technique produced aligners with superior consistency and precision, enhancing the accuracy and predictability of tooth movements
Key words: Clear Aligners, Thermoforming Techniques, Aligner Thickness, Vacuum Forming, Pressure Forming, Orthodontic Treatment

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INTRODUCTION

Orthodontic treatment has evolved significantly in recent years, with a growing emphasis on aesthetics alongside traditional considerations like comfort and efficiency.[1]Patients—both adolescents and adults—are increasingly prioritizing visual appeal, seeking orthodontic solutions that effectively move teeth while being discreet. This shift in demand has led to the rising popularity of clear aligners as an alternative to conventional braces.[2]In era of digital dentistry, particularly through the emergence of computer-aided design and manufacturing (CAD/CAM) technologies has benefitted in advancement of clear aligners.[3] These innovations have improved the production of clear, removable aligners made from thermoplastic materials, enabling the creation of customized dental devices that guide teeth from their misaligned positions to desired final alignments.[4]Align Technology, Inc.'s introduction of clear aligner systems marked a significant shift in orthodontic treatment, building on foundational work by early innovators like Kesling and Nahoum.[5] The performance of clear aligners is influenced by several factors, including the choice of thermoplastic materials and the fabrication techniques employed.[6]Common materials used in aligners include polyurethane (PU), polyethylene terephthalate (PET), and polyethylene terephthalate glycol (PET-G), all of which are favored for their transparency, flexibility, and biocompatibility.[7] However, these thermoplastic materials are not chemically inert; they can be affected by factors in the oral environment, such as temperature, humidity, and saliva, which may lead to material degradation and reduce the effectiveness of the aligners.[8] A critical aspect of clear aligner therapy is the thickness of the aligners, which significantly affects the distribution of forces on the teeth and, consequently, the predictability of treatment outcomes.[9]

Research has shown that variations in aligner thickness can influence the efficacy of tooth movement. [10]For example, studies indicate that successful tooth movement typically occurs at aligner thicknesses ranging from approximately 0.25 to 0.33 mm.[11] Moreover, the technique used in thermoforming aligns affects both the accuracy and fit of the aligners.[12] Common methods include vacuum forming, which uses negative pressure to adapt heat-softened plastic over a cast, and pressure forming, which employs both positive and negative air pressures to achieve precise contours.[13] Aligner thickness can also vary between segments, with research suggesting that thickness decreases post-thermoforming, particularly in the anterior segments compared to the posterior ones.[14] Optimizing aligner thickness is essential for controlled and predictable tooth movements while ensuring patient comfort and durability. Given these considerations, this study aims to evaluate the changes in aligner thickness when employing vacuum versus pressure thermoforming techniques.[15]By systematically comparing these methods, the study aims to gain insights into their effects on aligner reproducibility and overall treatment efficiency. The findings will contribute to a deeper understanding of how fabrication techniques can be optimized to enhance the effectiveness of clear aligner therapy, ultimately leading to improved patientoutcomes.Aligners are fabricated by thermoforming aligner sheets using either pressure or vacuum techniques, both of which can alter the thickness of the aligner sheet and impact its biomechanics. Understanding the effects of different thermoforming methods on aligner thickness is crucial to ensure the selection of appropriate materials and techniques without compromising aligner performance. This study assesses the reproducibility of these thermoforming techniques and their impact on aligner thickness, evaluating measurements at various occlusal points. By examining the changes in thickness after thermoforming and comparing the results of pressure and vacuum techniques, the research aims to provide insights into how these methods influence the final aligner thickness. Ultimately, this investigation seeks to enhance the understanding of aligner fabrication processes and offer valuable information for orthodontic practitioners in choosing the most effective thermoforming techniques and aligner materials.[16]

AIM

The aim of the study was to evaluate changes in thickness of aligner after thermoforming using different techniques, evaluated at different occlusal points.

OBJECTIVES

- To assess the change in thickness of aligner sheet after pressure and vacuum thermoforming.
- To compare the change in thickness of PET-G and PU sheets after pressure and vacuum thermoforming technique.
- To compare the change in thickness at different occlusal points between right and left side of the aligner.
- To assess the reproducibility of thermoformed aligner.

METHODOLOLOGY

Sample size estimation: The samples consisted of 20 aligners which were thermoformed in the department of Orthodontics and Dentofacial Orthopaedics in Shree Bankey Bihari Dental College and Research Centre, Ghaziabad, Uttar Pradesh, India.

Armamentarium: PET-G sheets, PU sheets, Ideal cast model, Pressure thermoforming machine, Vacuum thermoforming , Aligner trimming burs, Scanner, Contrast spray , Meshmixer software, Anycubic Resin (**Figure 1-8**)

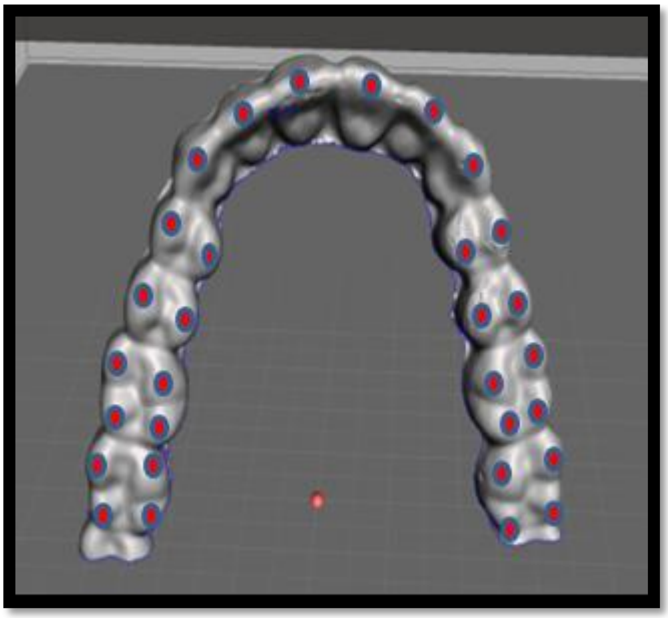


Figure 1: Left and right reference points adopted for the measurement of the thickness of the aligners

Figure 2: Vacuum thermoforming machine (Plastvac-Pt)

Figure 3: Pressure thermoforming machine (Ministar)


Figure 4: 3D Printed Model

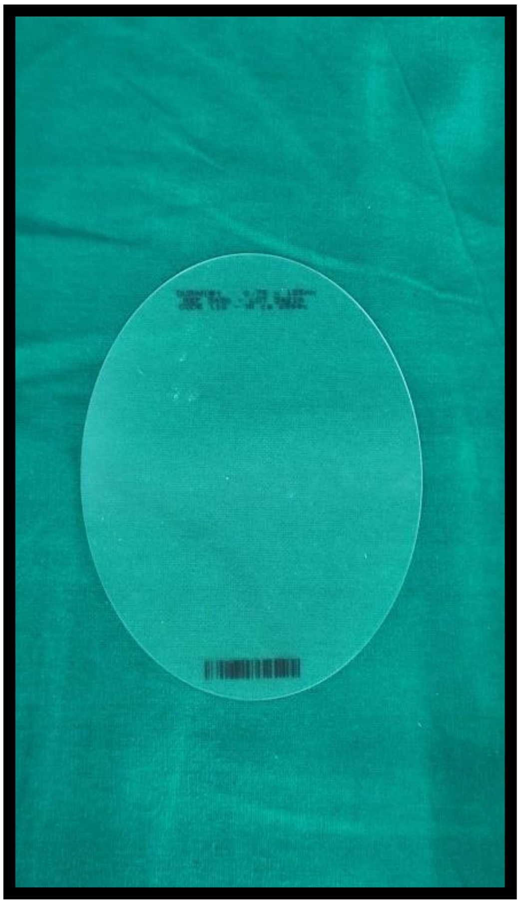


Figure 5: Aligner sheet

Figure 6: Contrast Spray (Telescan)

Figure 7: Scanner (Shining -3D)

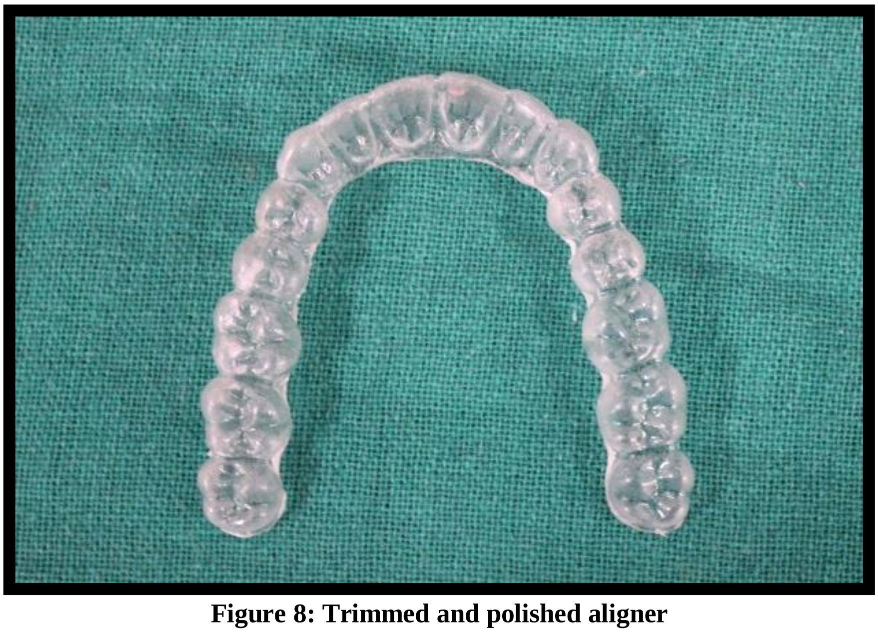


Figure 8: Trimmed and polished aligner

Procedure:Creation of Ideal Resin Cast Model: The ideal cast models were scanned using an optical scanner (Shining 3D), and the resulting scans were converted into Stereolithographic (STL) files. These STL files were then imported into Chitu Box for printing with Anycubic Resin, resulting in the production of 3D printed resin casts.

Thermoforming of Aligners: Twenty aligners were thermoformed using pressure thermoforming and vacuum thermoforming techniques. The pressure thermoforming machine (e.g., Ministar) was used to thermoform the PET-G and PU sheets. The vacuum thermoforming machine (PLASTOVIT PT) was used for the vacuum thermoforming process.

Aligner Trimming: After thermoforming, the aligners were meticulously trimmed using Scheu trimming burs to achieve the desired shape and fit. To facilitate scanning, a contrast spray was applied, as the translucent nature of the aligners made them unsuitable for direct scanning. The spray was applied from a distance of 15mm to ensure even coverage. The aligners were then positioned on an optical scanner, and the scanning process commenced. The optical scanner captured three-dimensional (3D) images of the aligners, generating STL files.

Data analysis involved importing scanned STL files into Meshmixer software (version 3.5.474), where a single operator focused on the cameo and intaglio surfaces of the aligners. Various reference points were established on the incisors, canines, premolars, and molars on both the left and right sides of the maxillary arch, including midpoints on incisal edges and centers of buccal and palatal cusps.

The collected data were analyzed to evaluate aligner thickness at different occlusal points, comparing thermoformed aligner thickness with the original dimensions, assessing thickness differences between the right and left sides, and evaluating changes post-thermoforming. The study specifically compared the thickness of PET-G and PU sheets after pressure and vacuum thermoforming. Statistical analysis was conducted using SPSS (version 21.0), applying the Shapiro-Wilk test for normal distribution assessment. Given that the data was normally distributed, bivariate analyses were performed using the Independent t-test and Paired t-test for intergroup and intragroup comparisons, with a significance level set at $p < 0.05$.

RESULTS

The study aimed to assess thickness variations in aligners produced using pressure and vacuum thermoforming techniques with PET-G and PU materials. Normal distribution of the data was confirmed through the Shapiro-Wilk test, revealing significant thickness variations due to different thermoforming methods and materials. Detailed analyses presented in **Tables 1 -4** highlighted these differences, while intergroup comparisons (**Table 5-7**) using independent t-tests indicated statistically significant distinctions between PU and PET-G aligners ($p < 0.05$), underscoring the material's impact on fabrication. The thickness sequences for the different groups varied significantly (**Table 7-9 and graph 1-2**). The greatest thickness was observed in the 5P sample of Group 2 V, while the least thickness was recorded in the 4P sample of Group 1 V, emphasizing the complexities involved in aligner fabrication and the influence of both technique and material on final outcomes.In Group 1 P, the order was 2M > 1M > 2PM > 1PM > 2I > 1I > 3C. For Group 2 V, the thickness sequence was 1M > 2M > 2PM > 2I > 1I > 3C > 1PM, while in Group 2 P, the order was 1I > 2I > 7M > 1M > 2PM > 1PM > 3C. Notably, in Group 2 V, the thickness sequence reiterated as 1M > 2M > 2PM > 1PM > 3C > 1I > 2I, highlighting the distinct thickness characteristics across the various aligner configurations. A comparative analysis of thickness between the right and left sides showed no substantial differences for both aligner types (**Table 10-11**). Regional variations were noted; although thickness in the incisor region was consistent for both materials, significant differences emerged in the canine, premolar, and molar regions (**Table 12**).

Table 1: ± Mean in mm of Group 1P at different reference points

REFERENCE POINTS	Sample 1		Sample 2		Sample 3		Sample 4		Sample 5		Mean (±mm)
	LEFT	RIGHT	LEFT	RIGHT	LEFT	RIGHT	LEFT	RIGHT	LEFT	RIGHT	
1I	0.55	0.56	0.59	0.58	0.5	0.54	0.54	0.52	0.59	0.49	0.546
2I	0.54	0.5	0.64	0.59	0.57	0.58	0.59	0.58	0.56	0.59	0.574
C3	0.59	0.55	0.45	0.51	0.51	0.53	0.55	0.53	0.56	0.57	0.535
B4	0.51	0.54	0.59	0.53	0.59	0.56	0.56	0.51	0.57	0.51	0.547
P4	0.53	0.58	0.47	0.48	0.43	0.47	0.52	0.48	0.41	0.42	0.479
B5	0.63	0.42	0.57	0.45	0.57	0.46	0.53	0.45	0.49	0.43	0.5
P5	0.61	0.55	0.59	0.49	0.58	0.56	0.61	0.45	0.59	0.47	0.55
MB6	0.75	0.55	0.69	0.45	0.55	0.53	0.55	0.51	0.54	0.52	0.564
MP6	0.78	0.58	0.7	0.48	0.58	0.57	0.58	0.54	0.56	0.56	0.593
DB6	0.78	0.58	0.74	0.54	0.46	0.56	0.55	0.59	0.53	0.55	0.588
DP6	0.71	0.59	0.68	0.53	0.54	0.59	0.51	0.57	0.49	0.51	0.572
MB7	0.62	0.53	0.65	0.56	0.52	0.51	0.52	0.53	0.54	0.53	0.551
MP7	0.59	0.55	0.47	0.59	0.59	0.54	0.59	0.55	0.56	0.56	0.559
DB7	0.62	0.56	0.49	0.52	0.62	0.58	0.59	0.53	0.59	0.53	0.563
DP7	0.64	0.57	0.59	0.55	0.63	0.58	0.54	0.57	0.52	0.59	0.578

Table 2: ± Mean in mm of Group 1 V at different reference points

REFERENCE POINTS	Sample 1		Sample 2		Sample 3		Sample 4		Sample 5		Mean (±mm)
	LEFT	RIGHT	LEFT	RIGHT	LEFT	RIGHT	LEFT	RIGHT	LEFT	RIGHT	
1I	0.45	0.44	0.43	0.51	0.49	0.53	0.51	0.49	0.43	0.47	0.475
2I	0.36	0.47	0.44	0.49	0.51	0.52	0.49	0.51	0.48	0.49	0.476
C3	0.51	0.42	0.44	0.34	0.45	0.44	0.44	0.42	0.46	0.43	0.435
B4	0.43	0.44	0.45	0.43	0.45	0.46	0.46	0.47	0.4	0.45	0.444
P4	0.47	0.39	0.45	0.31	0.37	0.36	0.38	0.33	0.26	0.36	0.368
B5	0.47	0.48	0.37	0.44	0.37	0.43	0.37	0.38	0.38	0.35	0.404
P5	0.41	0.52	0.43	0.51	0.44	0.43	0.32	0.49	0.36	0.46	0.437
MB6	0.6	0.65	0.57	0.55	0.54	0.55	0.56	0.59	0.53	0.58	0.572
MP6	0.56	0.61	0.56	0.59	0.56	0.59	0.48	0.6	0.5	0.61	0.566
DB6	0.59	0.54	0.57	0.57	0.53	0.51	0.49	0.53	0.49	0.54	0.536
DP6	0.57	0.41	0.49	0.4	0.56	0.41	0.47	0.41	0.49	0.45	0.466
MB7	0.65	0.46	0.45	0.42	0.55	0.45	0.58	0.47	0.57	0.44	0.504
MP7	0.63	0.64	0.53	0.54	0.62	0.64	0.59	0.54	0.56	0.56	0.585
DB7	0.62	0.52	0.57	0.51	0.67	0.51	0.62	0.48	0.61	0.44	0.555
DP7	0.64	0.34	0.58	0.54	0.64	0.44	0.64	0.34	0.63	0.36	0.515

Table 3: ± Mean in mm of Group 2P at different reference points

REFERENCE POINTS	Sample 1		Sample 2		Sample 3		Sample 4		Sample 5		Mean (±mm)
	RIGHT	LEFT	RIGHT	LEFT	RIGHT	LEFT	RIGHT	LEFT	RIGHT	LEFT	
1IE	0.6	0.63	0.63	0.59	0.58	0.6	0.63	0.57	0.67	0.69	0.619
2IE	0.62	0.67	0.63	0.66	0.5	0.63	0.58	0.61	0.6	0.66	0.616
3C	0.56	0.6	0.61	0.6	0.62	0.57	0.58	0.57	0.52	0.62	0.585
4B	0.62	0.56	0.54	0.55	0.56	0.5	0.68	0.58	0.66	0.55	0.595966
4P	0.59	0.51	0.5	0.54	0.5	0.57	0.67	0.61	0.57	0.51	0.557
5B	0.61	0.64	0.64	0.55	0.51	0.54	0.61	0.66	0.68	0.61	0.605
5P	0.62	0.56	0.55	0.59	0.5	0.51	0.65	0.6	0.64	0.52	0.574
6MB	0.64	0.69	0.56	0.6	0.59	0.48	0.58	0.7	0.66	0.62	0.612
6ML	0.66	0.6	0.59	0.55	0.61	0.6	0.6	0.6	0.66	0.6	0.607778
6DB	0.64	0.65	0.54	0.56	0.51	0.56	0.57	0.56	0.64	0.61	0.584
6DL	0.65	0.64	0.59	0.57	0.55	0.55	0.6	0.58	0.62	0.65	0.6
7MB	0.69	0.63	0.61	0.59	0.62	0.58	0.59	0.6	0.59	0.61	0.611
7ML	0.6	0.6	0.6	0.63	0.63	0.59	0.6	0.62	0.61	0.62	0.61
7DB	0.68	0.61	0.56	0.6	0.62	0.6	0.53	0.63	0.58	0.63	0.604
7DL	0.64	0.62	0.62	0.61	0.6	0.61	0.55	0.61	0.58	0.64	0.608

Table 4: ± Mean in mm of Group 2V at different reference points

REFERENCE POINTS	Sample 1		Sample 2		Sample 3		Sample 4		Sample 5		Mean
	RIGHT	LEFT	RIGHT	LEFT	RIGHT	LEFT	RIGHT	LEFT	RIGHT	LEFT	
1IE	0.52	0.52	0.43	0.43	0.48	0.37	0.55	0.45	0.42	0.42	0.418
2IE	0.43	0.43	0.42	0.38	0.39	0.39	0.44	0.43	0.43	0.44	0.48
3C	0.47	0.41	0.49	0.52	0.51	0.48	0.49	0.46	0.49	0.48	0.572
4B	0.55	0.56	0.54	0.58	0.54	0.55	0.54	0.63	0.61	0.62	0.58
4P	0.4	0.52	0.6	0.52	0.62	0.63	0.62	0.65	0.62	0.62	0.55
5B	0.61	0.47	0.52	0.55	0.53	0.52	0.53	0.55	0.59	0.63	0.62
5P	0.62	0.61	0.58	0.63	0.64	0.65	0.61	0.63	0.59	0.64	0.611
6MB	0.63	0.62	0.64	0.6	0.62	0.6	0.6	0.62	0.58	0.6	0.61
6ML	0.67	0.61	0.61	0.58	0.61	0.61	0.59	0.61	0.6	0.61	0.606
6DB	0.63	0.62	0.63	0.54	0.62	0.6	0.61	0.6	0.61	0.6	0.611
6DL	0.65	0.63	0.62	0.59	0.6	0.59	0.62	0.6	0.6	0.61	0.612
7MB	0.6	0.62	0.61	0.63	0.61	0.62	0.62	0.61	0.6	0.6	0.605
7ML	0.55	0.63	0.62	0.62	0.62	0.6	0.6	0.62	0.59	0.6	0.596
7DB	0.56	0.59	0.63	0.6	0.61	0.59	0.61	0.58	0.58	0.61	0.588

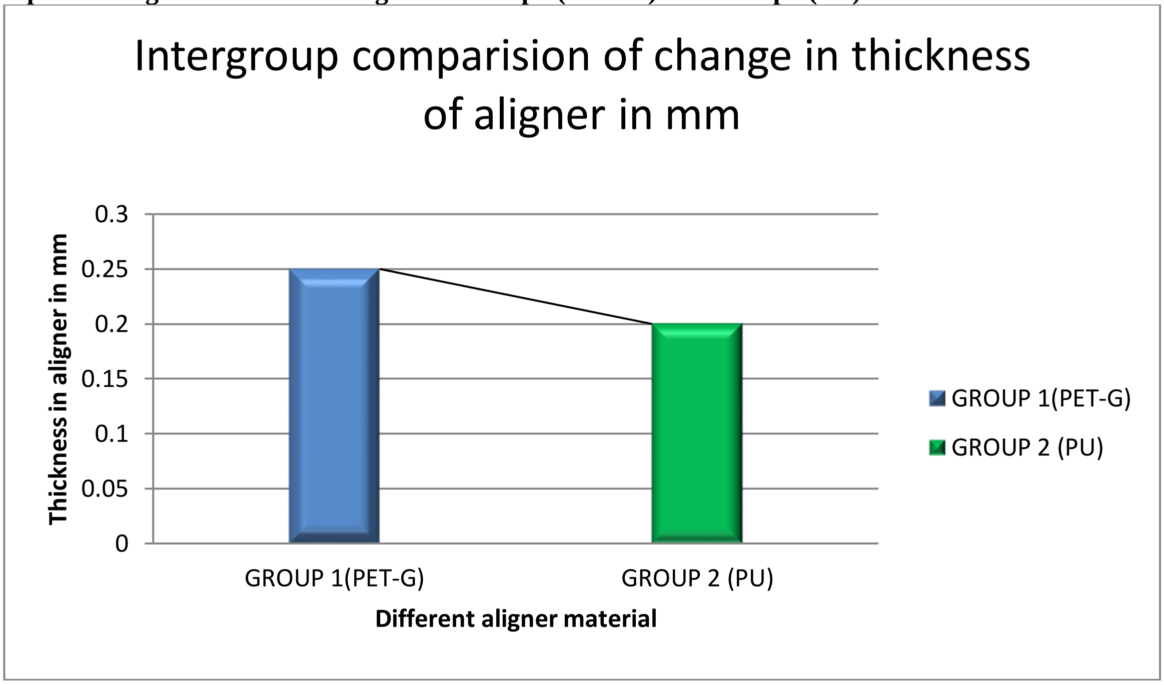
7DL	0.53	0.58	0.6	0.61	0.6	0.6	0.62	0.59	0.56	0.59	0.459

Table 5: Comparison of thickness of aligners after thermoforming in Group 1 and Group 2

		N	**Mean**	**Std. Deviation**	**Std. Error Mean**
THICKNESS	PET-G	10	0.5091	0.04381	0.00980
	PU	10	0.5664	0.04297	0.00961
P VALUE					0.046*

Independent t test, statistical significance at p<0.05-*

Graph 1 Change in thickness of aligner in Group 1(PET-G) and Group 2(PU)



Group 1 showed greater change in thickness when compared with Group 2

Table 6: Comparison of thickness between Group 1 P and Group 1 V

	PET-G	**N**	**Mean**	**Std. Deviation**	**Std. Error Mean**
THICKNESS	PRESSURE THERMOFORMING	10	0.5453	0.03011	0.00952
	VACCUMM THERMOFORMING	10	0.4729	0.01521	0.00481
P VALUE					0.028*

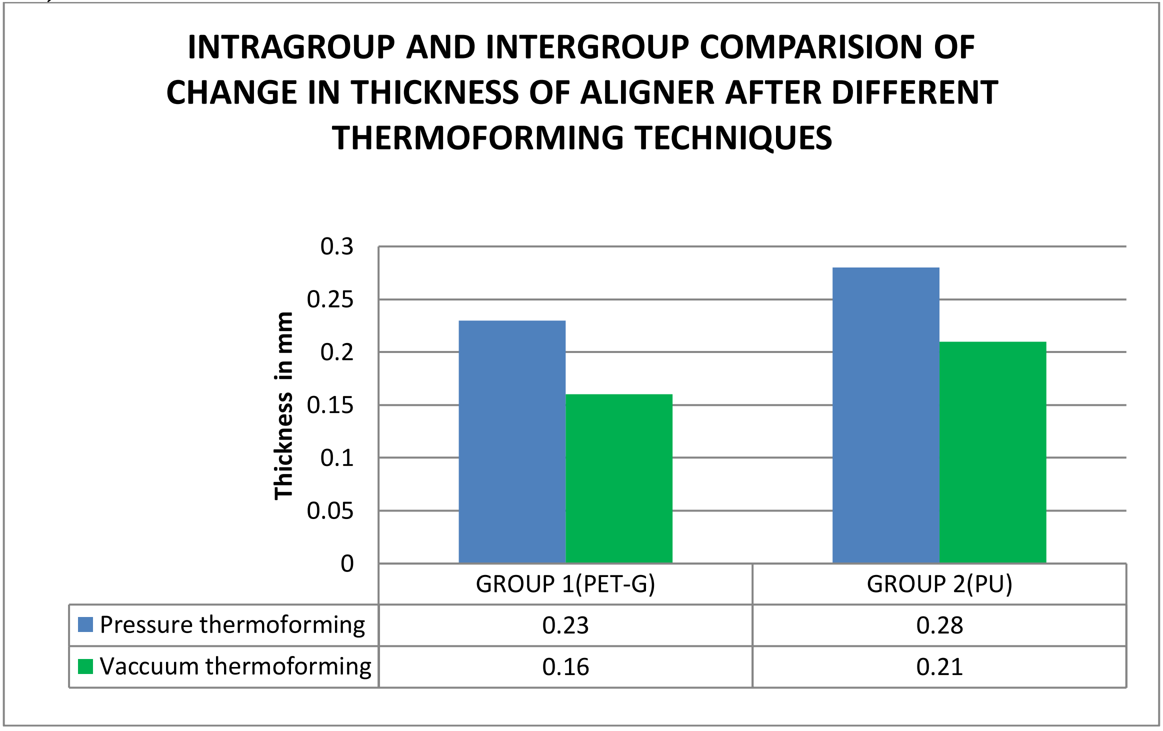
Paired t test, statistical significance at p<0.05-*

Table 7: Comparison of thickness of aligners between Group 2 P and Group 2 V

	PU ALIGNERS	**N**	**Mean**	**Std. Deviation**	**Std. Error Mean**
THICKNESS	PRESSURE THERMOFORMING	10	0.6040	0.02480	0.00784
	VACCUMM THERMOFORMING	10	0.5289	0.01212	0.00383
P VALUE					0.001***

Paired t test, statistical significance at p<0.05-*

GRAPH 2: Change in the thickness of aligners after thermoforming in Group1 (P&V) and Group 2 (P&V)



The blue colour denotes the pressure thermoforming and green colour denotes vacuum thermoforming.

Table 8: Comparison of thickness of aligners with pressure thermoforming

		N	Mean	Std. Deviation	Std. Error Mean
PRESSURE THERMOFORMED	PU	10	0.6040	0.02480	0.007
	PET-G	10	0.5453	0.03011	0.009
P VALUE					0.001*

Independent t test, statistical significance at $p<0.05$-*

Table 9: Comparison of thickness of aligners with vacuum thermoforming

		N	Mean	Std. Deviation	Std. Error Mean
VACUMM THERMOFORMED	PU	10	0.5289	0.01212	0.00383
	PET-G	10	0.4729	0.01521	0.00481
P VALUE					0.001*

Independent t test, statistical significance at $p<0.05$-*

Table 10: Comparison of aligners on right and left side in PU samples

PU		N	Mean	Std. Deviation	Std. Error Mean
MEAN	RIGHT	10	0.5686	0.04150	0.01312
	LEFT	10	0.5643	0.04654	0.01472
P VALUE	0.830				

Table 11: Comparison of aligners on right and left side in PET- G samples

PET G		N	Mean	Std. Deviation	Std. Error Mean
MEAN	RIGHT	10	.5216	.05342	.01689
	LEFT	10	.4966	.02919	.00923
P VALUE	0.210				

Table 12: Comparison of aligner thickness in different regions among PU and PET- G sample

		N	Mean	Std. Deviation	Std. Error Mean	P VALUE
Incisors	PU	10	0.5390	0.09470	0.02117	0.242
	PET-G	10	0.5105	0.05042	0.01127	
Canine	PU	10	0.5325	0.06163	0.01378	0.023

	PET-G	10	0.4850	0.06485	0.01450	
Premolars	PU	10	0.5760	0.04604	0.01030	0.0001
	PET-G	10	0.4955	0.05880	0.01315	
Molars	PU	10	0.6115	0.04682	0.01047	0.021
	PET-G	10	0.5680	0.06574	0.01470	

DISCUSSION

The study aimed to investigate the thickness of aligners post-thermoforming using diverse techniques and materials, providing critical insights into the variations in aligner thickness and their implications for orthodontic treatment planning and fabrication.To our knowledge, no prior research has compared pressure thermoforming and vacuum thermoforming using PET-G and PU aligner materials.[17] Significant differences in aligner thickness were identified between the two thermoforming methods, with vacuum thermoforming yielding thinner aligners than pressure thermoforming.[18] This variation can be attributed to the exposure of thermoplastic materials to inconsistent temperatures and durations, leading to a reduction in thickness.[19] Furthermore, the study revealed a noteworthy difference in thickness between PU and PET-G materials, with PU aligners demonstrating greater thickness.[20] This discrepancy is likely due to the intrinsic properties of the materials and their behavior during thermoforming; PU may exhibit higher elasticity or stretch characteristics, resulting in increased thickness post-process.[21]The choice of aligner material is crucial as it has significant impact on the accuracy of toothmovements and treatment efficacy.[22] Orthodontic practitioners should meticulously evaluate material properties and the associated variations in thickness when choosing materials for aligner fabrication.[23] A comprehensive analysis of aligner thickness at various reference points highlighted the importance of uniform thickness distribution across the arch.[24] Consistent thickness is essential for achieving predictable and reliable tooth movements.[25]Significant thickness discrepancies were also observed among different regions within both materials. A similar study by Bucci et al. using PET-G identified variability in thickness across the occlusal surface, ranging from 0.35 to 0.69 mm.[26]This finding underscores the need for customized aligner designs tailored to the specific requirements of each region, including incisors, canines,premolars, and molars.[27] Recognizing regional thickness variations facilitates optimized treatment planning and the attainment of desired outcomes.[28]Overall, the study underscores considerable variations in aligner thickness arising from different thermoforming techniques and materials.[29] The distinctions between pressure and vacuum thermoforming methods, as well as between PU and PET-G materials, emphasize the necessity for careful consideration in manufacturing processes and material selection during aligner fabrication.[30]Practitioners must acknowledge these variations and their implications for treatment efficacy, accuracy of tooth movement, and overall predictability.[31]Future research should prioritize determining the optimal aligner thickness for specific treatment objectives and evaluating the long-term effects of thickness variations on orthodontic outcomes.[32] Our findings are consistent with previous studies, including Mantovani et al., who reported mean thickness values for unused Invisalign aligners in the central incisor region ranging from 0.582 mm to 0.639 mm.[33] Similarly, Palone et al. assessed the effects of thermoforming across six aligner systems, noting reduced thickness and gap width in anterior teeth compared to posterior regions.[34]Further investigations by Hahn et al. highlighted how aligner materials and the thermoforming process influence the force delivered by appliances, while Kwon et al. recommended setup increments between 0.2 mm and 0.5 mm to prevent excessive force on teeth.[35, 36] Ryokawa et al. studied forces exerted by various aligner specimens under simulated intraoral conditions, observing thickness reductions of 7.4% to 25.1% due to thermoforming and water absorption, with notable increases in thickness after absorption.[37] Elkholy et al. explored the viscoelastic behavior of PET-G aligners, finding that initial loads diminish following intraoral insertion.[38]These collective studies emphasize the critical importance of aligner material selection and the implications of thickness variations(**Table 13**).[1-42]While our study has limitations, such as a small sample size and a focus on specific measurement points, larger studies with broader criteria are needed to validate and generalize these findings. Numerous studies have investigated changes in aligner thickness due to vacuum and pressure thermoforming, revealing significant insights into the effects of material selection and manufacturing methods on treatment efficacy.[43]Notably, vacuum thermoforming often yields thinner aligners than pressure thermoforming, with distinct differences in thickness and mechanical properties between materials like PET-G and polyurethane (PU).[44] Research has shown that thickness variations, particularly in canines, premolars, and molars, can influence the predictability of tooth movements. Advanced imaging and statistical analysis techniques have enhanced understanding of orthodontists and dentists how these variables optimize aligner performance and overall orthodontic outcomes.[45]

Table 13: Implications of various studies on assessment of change in thickness of aligner using vacuum and pressure thermoforming techniques

Study	Year	Objective	Materials	Methods	Key Findings	Implications
Bergstrom K et al.	1998	Analyze perceptions of dental arrangement in young adults	Orthodontically treated and untreated	Questionnaire sent to participants	121 treated individuals and 76 untreated; perceptions varied based on treatment received.	Highlights importance of patient perceptions in treatment outcomes
Ryokawa H et al.	2006	Assess mechanical properties of dental thermoplastic materials	EVA, PE, PETG, PP, PC, A+, C+, PUR	Simulated intraoral environment tests	Water absorption increased over time; thickness changes ranged from 74.9% to 92.6%. Elastic moduli varied significantly; behavior influenced by environmental factors.	Understanding material properties is crucial for orthodontic applications
Johal A et al.	2007	Compare fit of different thermoform retainer materials	ACE, C+, True Tain, Iconic Clear	Laboratory-based study with master dental casts	Significant differences in fit among the four materials ($P < 0.001$). C+ showed the greatest difference.	Importance of material selection for optimal retainer fit
Kwon J et al	2008	Evaluate force and energy delivery properties of thermoplastic materials	Three types of thermoplastic materials	Three-point bending-recovery tests, Vickers hardness	Optimal force delivery deflection was 0.2 to 0.5 mm; thin Materials delivered higher energy. Thermocycling affected properties, but repeated load cycling showed significant differences.	Thin materials may be preferable for effective force delivery
Hahn et al.	2009	Quantify forces delivered by thermoplastic appliances during tipping	Erkodur (1.0, 0.8 mm), Biolon (1.0, 0.75 mm)	Force measurement on a standardized resin model	Forces applied were often higher than ideal; thickness and thermoforming process significantly	Highlights the need for careful material and thickness selection

					influenced force magnitude.	
Walton D K et al.	2010	Evaluate preferences and acceptability of orthodontic appliances in children and adolescents	Various orthodontic appliance images	Computer-based survey with 139 children	Clear aligners and twin brackets with colored ties were rated most attractive. Preferences varied by age and sex, with significant differences noted among age groups.	Understanding patient preferences can guide appliance selection
Shalish M et al.	2011	Examine adult patient perception of recovery after appliance insertion	Buccal, Lingual, and Invisalign appliances	Health-Related Quality of Life questionnaire	Lingual appliances caused the most pain and dysfunction; Invisalign had the lowest oral symptoms despite some initial discomfort.	Important for guiding patient treatment choices based on recovery experience
Kohda N et al	2013	Measure forces from thermoplastic appliances and investigate properties	Duran, Erkodur, Hardcast with two thicknesses	Force measurement with a custom sensor	Thicker appliances generated greater forces; mechanical properties correlated with force delivery; significant differences among materials based on thickness and activation.	Material and thickness selection crucial for effective force application
Dasy et al.	2015	Evaluate retention of aligners on dental arches with various attachments	Clear-Aligner soft, medium, hard, Essix ACE	Vertical displacement force measurement during removal	Ellipsoid attachments did not significantly affect retention; Essix ACE had less retention than CA-hard; beveled	Insights into design for improved aligner retention

					attachments improved retention compared to others.	
Bradley G et al.	2016	Investigate mechanical and chemical changes in Invisalign after aging	Invisalign appliances (used and unused)	Mechanical testing and ATR-FTIR spectroscopy	Intraoral aging negatively impacted mechanical properties; no detectable chemical changes were found.	Importance of monitoring appliance durability over time
Elkholy F et al.	2017	Quantify forces and moments during derotation of a maxillary central incisor	0.3 mm, 0.4 mm, and conventional PET-G aligners	Force and moment measurement on an acrylic model	Thinner aligners significantly reduced moments; 0.3 mm aligner showed instability during handling; recommended a sequence of increasing thickness for better performance.	Supports the use of thinner aligners in treatment protocols
Ekşi O, Karabeyoğlu S S	2017	Investigate thickness distribution in thermoformed sheets	Thermoplastic sheets (1.5 mm thickness)	Digital caliper measurement on molds with/without plug assist	Plug assist thermoforming produced more uniform thickness distributions than negative forming.	Indicates the benefits of plug assist in aligner manufacturing.
Gao L and Wichelhaus A	2017	Evaluate effects of thickness and gingival edge width on forces	Duran foil (PET-G) aligners of various thicknesses	Force and moment measurement using a six-component device	Higher forces observed with thicker aligners; gingival edge width influenced force delivery.	Important for customizing aligners based on patient needs
Lombardo L et al.	2017	Investigate stress release properties of thermoplastic materials	Various thermoplastic aligner materials	Stress release measurement under constant load	All materials released significant stress over time; single-layer materials exhibited higher stress	Material choice is critical for aligner performance over ti

					decay speed than double-layer materials.	
Mantovani E et al.	2018	Evaluate fit of Invisalign vs. CA-Clear Aligner	Invisalign and CA-Clear Aligner	Scanning electron microscopy (SEM) for measurement	Invisalign showed a better fit on lower incisors and molars; CA-Clear Aligner fit better on complex occlusal surfaces.	Implications for choosing aligner systems based on fit.
Ryu J et al.	2018	Evaluate thermoforming effects on properties of thermoplastic materials	Four types of thermoplastic materials	Tests on transparency, hardness, bending, tensile strength	Thermoforming affected transparency and water absorption; mechanical properties changed significantly after thermoforming.	Highlights the need for property evaluation post-thermoforming.
Condo R et al	2018	Analyze structural properties of EX30 and LD30 aligners	Exceed30 (EX30) and Smart Track (LD30)	Various structural analysis tests	LD30 showed better adaptability and consistency in orthodontic force application compared to EX30; both materials underwent structural changes post-use.	Indicates potential for selecting more stable aligner materials.
Papadimitriou A et al	2018	Assess clinical effectiveness of the Invisalign system	Literature review of studies on Invisalign	Systematic review following PRISMA guidelines	Invisalign is effective for mild to moderate malocclusions; limited efficacy in certain cases; substantial heterogeneity across studies affects conclusions.	Caution in making broad recommendations for aligner use.

Dalaie K et al.	2018	Assess thermo mechanical properties post-thermoforming and aging	Duran and Erkodur PETG aligners	Mechanical testing after thermoforming and aging	Thermoforming significantly impacted. Duran showed greater stability than Erkodur.	Important for material selection based on durability.
Elkholy F et al.	2019	Standardize three-point-bending tests for aligner materials	PET-G Duran foils of varying thicknesses	Three-point bending tests under different conditions	Proposed thickness-dependent deflection ranges to avoid microcracks; water storage significantly reduced bending forces.	Guidelines for more reliable material testing in orthodontics.
Jindal P et al.	2019	Compare mechanical properties of thermoformed vs. 3D printed aligners	Duran thermoplastic vs. Dental LT resin aligners	Compression loading and geometric accuracy assessment	3D printed aligners showed better geometric accuracy and mechanical strength than conventionally thermoformed aligners.	Suggests 3D printing as a superior alternative for aligner fabrication.
Weckmann J et al.	2019	Bonding protocols for attachments in aligner treatments	To evaluate bonding protocols for aligner attachments	Five bonding protocols were tested using one ellipsoid and one rectangular attachment. 30 repetitions per protocol were performed. Attachments were laser scanned for precision analysis using surface/surface matching algorithms.	Identified the two-phase procedure with high viscous composite as the most precise; low viscous composite showed similar precision with less excess area.	Selecting appropriate bonding protocols can enhance the precision of attachment placement, improving treatment outcomes.
Suter et al.	2020	Surface roughness	To characterize	Four thermoplasti	Thermoforming increased	Material selection based

		and energy of thermoplastic materials	surface roughness and energy	c materials were tested using reflected light microscopy and optical profilometry to assess roughness parameters. Contact angle measurements were taken to estimate surface energy. Statistical analysis included ANOVA and Tukey's post hoc test.	roughness; significant differences in surface energy parameters among materials affecting plaque retention.	on surface properties can influence oral hygiene and aligner effectiveness.
Lombardo L et al.	2020	Gap and thickness comparison of aligner systems	To compare gap and thickness of different aligner systems	Six aligner brands were fitted to a single resin cast and analyzed using high-resolution micro-CT. 204 linear 2D measurements were made for gap and thickness analysis. ANOVA and Tukey's post hoc analysis were applied.	Significant differences in gap volume and thickness among six aligner systems; F22 had the lowest gap and thickness measurements.	Choosing aligner systems with better fit can enhance treatment predictability and comfort for patients.
Edelmann A et al.	2020	Effect of design thickness on 3D-printed aligners	To investigate thickness accuracy of 3D-printed aligners	Three different thickness designs were printed in two resins. Aligners were scanned pre-	3D-printed aligners were thicker than designed; thickness deviations varied by resin type.	Awareness of fabrication inaccuracies is crucial for optimizing aligner design and effectiveness.

				and post-application of contrast spray, and average wall thickness was measured with metrology software.		
Tamburrino F et al.	2020	Mechanical properties of thermoplastic polymers	To evaluate mechanical properties of different polymers	Three thermoplastic polymers were tested through tensile tests (ISO527-1) after thermoforming and storage in artificial saliva. Elastic modulus and yield stress were characterized.	Thermoforming impacted mechanical properties differently among materials; Zendura showed a significant decrease in yield stress.	Material characteristics should be evaluated to ensure aligners withstand intraoral forces during treatment.
Mantovani E et al.	2021	Thickness homogeneity of Invisalign aligners	To measure thickness homogeneity across aligners	Micro-CT scans of 20 different Invisalign aligners were conducted, and thickness measurements were made in various regions. Statistical analysis included Student's t-tests and linear regression.	Small thickness differences; significant variation noted in molar region affecting predictability of tooth movements.	Understanding thickness variability can guide clinicians in predicting treatment outcomes, particularly in molar movements.
Zinelis S et al.	2021	Mechanical properties of aligners from different 3D printers	To compare mechanical properties of aligners from different printers	Aligners were produced using five different 3D printers and evaluated	Mechanical properties varied by 3D printer; differences may affect clinical	Clinicians should consider the printer used when assessing aligner

				for Martens-Hardness, indentation modulus, and elastic index as per ISO14577-1:2002. Differences among printers were analyzed using generalized linear regressions.	efficacy of the aligners.	performance and durability.
Golkhani B et al.	2021	Mechanical properties of aligner materials	To compare mechanical properties before and after thermoforming	Four aligner film sheets from three manufacturers (Duran Plus®, Zendura®, EssixACE®, Essix® PLUS™) were tested in 3-point bending with support distances of 8, 16, and 24 mm. Specimens were 10 × 50 mm².	Three-point bending is an appropriate method to compare mechanical properties.	Understanding the impact of thermoforming on mechanical properties can inform material selection in clinical practice.
Ho C et al.	2021	Orthodontic tooth movement using different aligner materials	To evaluate tooth movement behavior with different aligner materials and attachments	3D-printed resin typodont models were used with three types of attachments (ellipsoid thick/thin, bar) and aligner materials (BIOSTAR, BenQ, TPU). Movement was simulated in a water bath.	BENQ group showed less change in the long axis angle; attachment shape had little influence on bodily tooth movement.	High-modulus materials may be more effective in clinical applications for tooth movement.
Tartaglia	2021	Advantages	To discuss	Review of	3D printed	Encouragemen

GM et al.		of 3D printed aligners vs. thermoformed ones	the benefits and challenges of 3D printed aligners	the state of the art in aligner production, focusing on accuracy, load resistance, and material limitations.	aligners offer superior accuracy and stability compared to thermoformed aligners.	t for further in vitro and in vivo studies on 3D printed aligners.
Palone M et al.	2021	Effects of thermoforming on aligner thickness and gap width	To assess thickness and gap width in various aligner systems	Six passive upper aligners were adapted to a single printed cast and evaluated using high-resolution micro-computed tomography for thickness and gap width.	Tooth type, dental region, and aligner type significantly affected gap width and thickness; F22 aligners remained moderately stable across the arch.	Insights into the variability in aligner performance can improve treatment planning.
Nucera R et al.	2022	Differences in clear aligner therapies with/without attachments	To evaluate the influence of attachments on orthodontic movements	Literature review across eight electronic databases focusing on the effectiveness of attachments in orthodontic treatment.	Attachments improve effectiveness for various movements, but evidence on some movements is lacking; further studies are needed.	Understanding attachment configurations can optimize orthodontic treatment outcomes.
Koenig A et al.	2022	Dimensional accuracy of thermoformed vs. direct-printed aligners	To compare accuracy between different aligner manufacturing methods	Three types of aligners (thermoformed Zendura FLXTM and Essix ACETM; direct-printed TeraHarzTM) were manufactured and scanned to measure discrepancies from a reference	Direct-printed aligners showed greater trueness and precision compared to thermoformed aligners.	Enhancing dimensional accuracy can lead to improved treatment outcomes in orthodontics.

				STL file.		
Chen S et al.	2023	Force decay of invisible aligners under simulated conditions	To assess force decay with varying labial movements in a simulated oral environment	Aligners were immersed in artificial saliva and subjected to labial movement of 0.1 mm, 0.2 mm, and 0.3 mm over 7 days; thin-film pressure sensors measured force changes.	Larger labial movements resulted in greater force decay, which increased with immersion time in artificial saliva.	Awareness of force decay dynamics can inform aligner wear schedules and treatment planning.

Future Prospects: Ongoing advancements in orthodontic materials and techniques present several exciting avenues for future research and clinical practice regarding aligners. Key prospects include the development of new thermoplastic substances with superior characteristics—such as enhanced strength, reduced wear, and improved biocompatibility—that could significantly elevate the performance of clear aligners, along with the exploration of biodegradable or bioactive materials to promote sustainability in orthodontics. Continued refinement of thermoforming processes and the investigation of alternative methods like 3D printing could enhance the precision and adaptability of aligner fabrication.[46]Longitudinal studies assessing the durability and efficacy of aligners over extended periods will provide valuable insights into the longevity and effectiveness of various materials and techniques.[47]Additionally, developing patient-centric designs through personalized treatment plans can boost satisfaction and outcomes, facilitated by cutting-edge imaging and modeling technologies.[48]The integration of digital workflows, including artificial intelligence and machine learning, has the potential to revolutionize treatment planning by optimizing aligner design and movement protocols.[49]Establishing standardized protocols for material selection and aligner thickness based on empirical evidence can empower orthodontists to make informed decisions and enhance treatment results.[50] Furthermore, innovations like smart aligners equipped with sensors to monitor wear and compliance could significantly improve patient adherence to treatment regimens.[51]

Finally, further investigation into the biomechanics of tooth movement with various aligner configurations and materials will enable orthodontists to refine strategies, ensuring predictable and efficient outcomes.[52] By embracing these prospects, the field of orthodontics can continue to evolve, enhancing the effectiveness and appeal of clear aligner therapy for a broader range of patients.[53] Future studies should continue to explore these factors and their long-term impacts on treatment effectiveness; ensuring aligner designs are tailored to meet patient-specific needs.[54]

CONCLUSION

This study identified significant variations in aligner thickness attributable to vacuum and pressure thermoforming techniques, with PU aligners demonstrating greater thickness than PET-G aligners. These findings pave the way for further advancements in aligner production, benefiting both practitioners and patients alike. These findings underscore the importance of thermoforming methods in determining aligner performance, as even minor thickness differences can affect treatment effectiveness and patient comfort. The pressure thermoforming technique produced aligners with superior consistency and precision, enhancing the accuracy and predictability of tooth movements. Careful selection of thermoforming techniques and materials is essential for optimizing treatment outcomes. Future research should focus on the long-term effects of thickness variations on clinical efficacy and patient satisfaction. A deeper understanding of these factors will enable orthodontic practitioners to make more informed decisions, ultimately improving the quality of clear aligner therapy and enriching patient experiences.

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