

Comparative Analysis of Mechanical and Thermal Properties of Different Thermoplastic Orthodontic Aligners Following Thermoforming and Simulated Intra-Oral Aging: An In-Vitro Study

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ABSTRACT:

This study aimed to evaluate and compare the mechanical and thermal properties of five commercially available orthodontic aligners made from polyethylene terephthalate glycol (PETG) and polyurethane (PU) following thermoforming and simulated intra-oral aging.

Materials and methods: In this experimental study, 100 samples of thermoformed polyethylene terephthalate glycol (PETG) and polyurethane (PU) aligners from five commercially available orthodontic aligners were divided into five groups and colour coded; Group - I: Invisalign, Group - II- V-clear, Group - III: Smile aligners, Group - IV: Illusion and Group - V: Dentcare. The experimental samples were subjected to aging in artificial saliva at 37°C for 2 weeks. The mechanical properties—including tensile strength, flexural modulus, compressive strength, and surface hardness—and thermal property (glass transition temperature) were evaluated and statistical analysis was performed using Student's *t*-test with a significance level set at $p \leq 0.05$.

Results: A statistically significant decrease in tensile strength was observed in Group II. Flexural modulus significantly increased in Groups II and IV, while compressive strength increased in Groups IV and V. Surface hardness significantly increased in Groups II, III, and V. A significant decrease in glass transition temperature was noted in Groups III and IV after aging.

Conclusion: Simulated intraoral aging and thermoforming significantly influences the mechanical and thermal properties of thermoplastic aligners, with variations depending on material composition.

KEYWORDS: Tensile strength, Flexural modulus, Compression strength, Surface hardness, Glass transition temperature, Thermoforming.

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INTRODUCTION

The advent of clear aligner therapy has significantly transformed orthodontic practice by offering enhanced esthetics, improved patient comfort, reduced chairside time, and better oral hygiene maintenance. These transparent, removable appliances are fabricated from thermoplastic materials and are designed to deliver controlled orthodontic forces for tooth movement.

The concept of aligner therapy dates back to 1945, when Dr. Harold Kesling introduced tooth positioning appliances. Subsequent advancements were made by Nahoum in 1964 with vacuum-

formed dental contour appliances, followed by Sheridan's Essix appliance in 1993. The introduction of digital workflows by Zia Chishti and Kelsey Wirth in 1997 (Invisalign system) revolutionized aligner therapy, enabling precise and efficient treatment planning. Overall, the development of aligners marks a major advancement in orthodontic treatment options, combining technology and convenience for better patient outcomes.

Modern aligners are primarily fabricated using thermoplastic polymers such as PET, PET-G, and polyurethane. These materials exhibit favorable

properties including transparency, elasticity, and biocompatibility. However, their mechanical and thermal properties may undergo alterations due to thermoforming and intraoral conditions such as temperature fluctuations, salivary enzymes, and masticatory forces. Studies by Dongyu Fang et.al.,² Roberta Condo et.al.,⁴ and Kazem Dalaie et.al.,³ found that there are mechanical and thermal properties changes of aligners observed when exposed to oral environment. Study conducted by Nitya K Olety et.al.,¹⁰ observed cytotoxicity of aligners during usage. Previous studies have demonstrated that exposure to the oral environment can significantly affect the structural and functional properties of aligners. Therefore, the present study aims to evaluate and compare the changes in mechanical and thermal properties of different commercially available aligners following simulated intraoral aging.

MATERIAL AND METHODOLOGY:

METHODS:

A total sample of 50 preformed aligners (length 120mm) were sectioned into 3 regions i.e., 1 anterior and 2 posteriors for standardised testing. The different aligner groups were coated with different colours and categorised into five groups:

- Group – I: Invisalign technology (PET-G) (blue)
- Group – II: V – clear aligners (PET-G) (black)
- Group – III: Smile aligners TPU (yellow)
- Group – IV: Illusion aligners (PET-G) (pink)
- Group – V: Dentcare aligners (PET-G) (orange)

Each group was subdivided into:

- Control subgroup (A): No aging
- Experimental subgroup (B): Aged in artificial saliva

Testing Methods:

- Tensile strength, flexural modulus, compressive strength: Universal testing machine
- Surface hardness: Vickers hardness tester
- Glass transition temperature: Differential scanning calorimetry (DSC)

Statistical analysis:

Student T test was used to investigate and perform comparison between the measurement methods. The data conformed to a normal distribution in all measurement areas. Mean value, Standard deviation, and Students T test was used to identify the relation between the two groups. The significant level of P value has set for 0.05.

METHODOLOGY:

For all control group aligners i.e., IA, IIA, IIIA, IVA, VA, the mechanical properties (tensile strength, flexion test, compression strength and surface hardness) and thermal properties (glass transition temperature) were measured. All sample group

aligners i.e., IB, IIB, IIIB, IVB, VB were immersed in artificial saliva at 37°C in incubator for 2 weeks, the mechanical and thermal properties were measured and compared among the control and sample group. Tensile strength, flexural modulus, compression strength are measured with universal testing machine. Surface hardness is measured with Vickers hardness tester. Glass transition temperature is measured with differential scanning calorimetry.



Fig :1 Invisalign



Fig :2 V-clear



Fig :4 illusion



Fig :5 Dentcare



Comparative Analysis of Mechanical and Thermal Properties of Different Thermoplastic Orthodontic Aligners Following Thermoforming and Simulated Intra-Oral Aging: An In-Vitro Study



RESULTS:

Simulated intraoral aging resulted in significant alterations in the properties of aligner materials:

- Tensile Strength: Significant reduction observed in Group II ($p \leq 0.05$).
- Flexural Modulus: Significant increase in Groups II and IV.
- Compressive Strength: Significant increase in Groups IV and V.
- Surface Hardness: Significant increase in Groups II, III, and V.
- Glass Transition Temperature: Significant decrease in Groups III and IV.

Table 1: Comparison of Tensile strength among all groups after exposure to oral environment.

	Group A Mean $\pm$ SD	Group B Mean $\pm$ SD	P value
Group - I	48.63 $\pm$ 5.76	35.91 $\pm$ 3.92	0.378
Group - II	49.35 $\pm$ 9.95	45.13 $\pm$ 6.06	0.002*
Group - III	43.91 $\pm$ 3.17	32.04 $\pm$ 3.62	0.926
Group - IV	48.08 $\pm$ 3.76	43.73 $\pm$ 3.07	0.452
Group - V	43.62 $\pm$ 3.03	33.97 $\pm$ 4.20	0.858

Student t-test; $p \leq 0.05$ considered statistically significant.

Graph 1: Comparison of tensile strength among all groups after exposure to oral environment. (unit: Mpa)

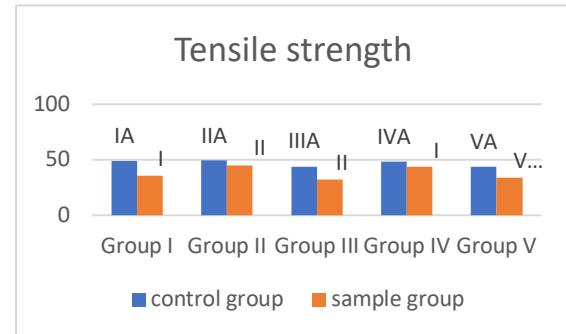


Table 2: Comparison of flexural modulus among all groups after exposure to oral environment.

	Group A Mean $\pm$ SD	Group B Mean $\pm$ SD	P value
Group - I	135.62 $\pm$ 17.67	240.38 $\pm$ 27.67	0.261
Group - II	164.70 $\pm$ 31.81	266.95 $\pm$ 47.13	0.002*
Group - III	114.25 $\pm$ 18.72	197.18 $\pm$ 26.78	0.624
Group - IV	155.33 $\pm$ 36.66	226.89 $\pm$ 26.43	0.000*
Group - V	127.43 $\pm$ 14.43	290.62 $\pm$ 26.79	0.347

Student t-test; $p \leq 0.05$ considered statistically significant.

Graph 2: Comparison of flexural modulus among all groups after exposure to oral environment. (unit: Mpa)

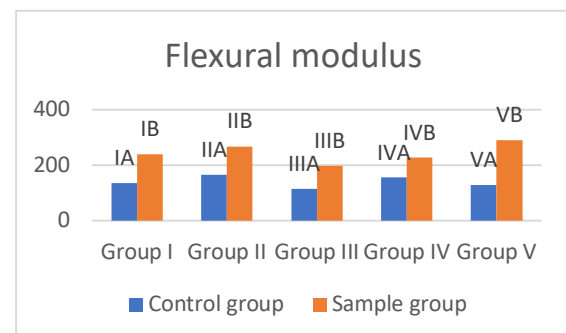


Table 3: Comparison of compression strength among all groups after exposure to oral environment.

	Group A Mean $\pm$ SD	Group B Mean $\pm$ SD	P value
Group - I	56.38 $\pm$ 7.06	71.36 $\pm$ 5.18	0.068
Group - II	54.61 $\pm$ 3.51	70.21 $\pm$ 5.13	0.186

Comparative Analysis of Mechanical and Thermal Properties of Different Thermoplastic Orthodontic Aligners Following Thermoforming and Simulated Intra-Oral Aging: An In-Vitro Study

Group - III	52.54±3.71	61.87±3.50	0.172
Group - IV	57.44±3.29	68.81±7.66	0.000*
Group - V	53.43±2.87	64.97±4.81	0.000*

Student t-test; $p \leq 0.05$ considered statistically significant.

Graph 3: Comparison of compression strength among all groups after exposure to oral environment. (unit: Mpa)

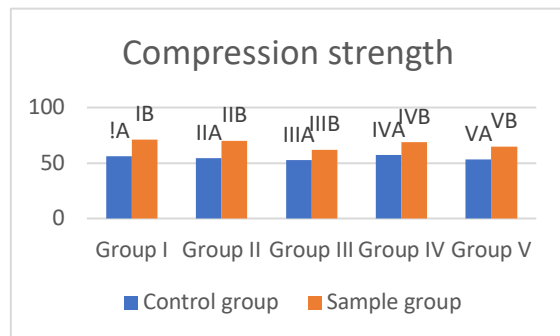


Table 4: Comparison of surface hardness among all groups after exposure to oral environment.

	Group A Mean ± SD	Group B Mean ± SD	P value
Group - I	6.69±0.60	7.52±0.52	0.377
Group - II	10.49±1.58	11.37±1.20	0.000*
Group - III	9.06±0.72	10.18±0.94	0.004*
Group - IV	7.94±0.50	9.61±0.59	0.987
Group - V	7.56±0.61	8.14±0.61	0.006*

Student t-test; $p \leq 0.05$ considered statistically significant.

Graph 4: Comparison of surface hardness among all groups after exposure to oral environment. (unit: N/mm²)

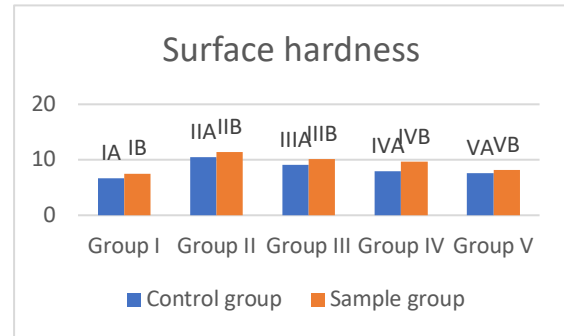
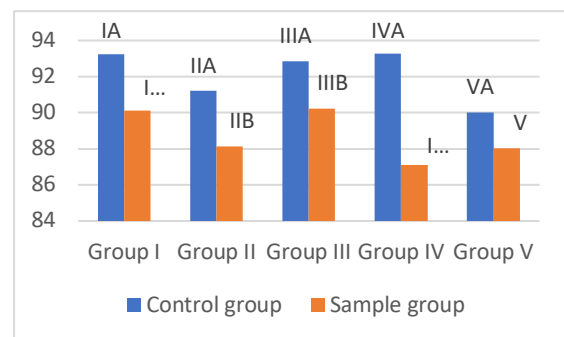


Table 5: Comparison of glass transition temperature among all groups after exposure to oral environment.

	Group A Mean ± SD	Group B Mean ± SD	P value
Group - I	93.23±0.02	90.13±0.02	0.638
Group - II	91.20±0.46	88.14±0.27	0.424
Group - III	92.84±0.47	90.22±0.14	0.005*
Group - IV	93.27±0.41	87.12±0.01	0.001*
Group - V	90.01±0.01	88.03±0.01	0.171

Student t-test; $p \leq 0.05$ considered statistically significant.

Graph 5: Comparison of glass transition temperature among all groups after exposure to oral environment. (unit: degrees)



DISCUSSION:

Thermoplastic materials used in aligner fabrication have evolved from single-layered polymers to advanced multilayered systems designed to optimize mechanical performance. While the soft layer imparts the property of elastic deformation allowing smooth seating of the aligner, the hard layer ensures strength and durability. The balance between

flexibility and rigidity is critical for effective force delivery and patient comfort.

Tensile Strength:

Tensile strength reflects the material's resistance to fracture under stress¹. The aligners should have high tensile strength.¹ Flexural modulus determines the feasibility of aligners in clinical application. Flexural modulus is directly proportional to the force of the thermoplastic materials and inversely proportional to their thickness. Therefore, it is reasonable to use thinner thermoplastic material for orthodontic treatment. Hardness is correlated with the amount of applied force. Changes in hardness can properly indicate the changes in applied force and consequently the efficiency of aligner therapy. Low hardness is ideal for the orthodontic treatment.³ Compressive strength is ability of material to resist the direct pressure of applied compression force. Aligners should have high compressive strength.⁶ Glass transition temperature is the point at which the glassy(rigid) state converts to a rubbery state as the increase in temperature. Temperature of oral environment can increase due to intake of hot drinks and it takes several minutes to return to its original temperature.³ Thus, altering the force application. In the present study the tensile strength before and after immersion in artificial saliva for 2 weeks there was statistically significant decrease in tensile strength after exposure to oral environment in group II.

Various studies states that the aligners should have high tensile strength for the desired tooth movement. With aging tensile strength is decreased. Materials with high tensile strength are less likely to fracture under load.

In-vivo study done by Dongyu Fang et.al²² on Invisalign aligners they found that there was no statistically significant change in tensile strength after exposure to oral environment for 2 weeks although there is a reduction in elastic modulus and acceleration in stress relaxation after clinical use. Creep strain of Invisalign aligners are stable after 2 weeks of clinical use, implying good material ductility to allow Invisalign aligner material to envelop the teeth and deliver designated force to move teeth. However, the aging effect of the oral environment on Invisalign material was not significant.

The materials tested in the present study exhibit significant reductions in tensile strength in group II after immersion in artificial saliva, whereas group I, III, IV and V showed no significant difference. The observed reduction in tensile strength in Group II suggests susceptibility to degradation under simulated oral conditions.

In-vitro study done by A. Boubakri et.al⁴⁴ on thermoplastic polyurethane (TPU) tensile strength of dried unaged, and aged TPU there was significant decrease in tensile strength after immersion in distilled water at a temperature of 70 C for up to 6

months this is due to the penetration of water molecules into the polymer structure, which decreases material resistance.

Both studies demonstrates that exposure to in-vitro environmental conditions (immersion in artificial saliva or distilled water) significantly affects tensile strength. The variability of results of study could be due to long duration of exposure at higher temperature compared to present study.

Benjamin A. Ihssen et.al²⁸ conducted an in-vitro study on tensile strength on PETG aligner films grouped them into control (group C) as received aligners, immersion in distilled water for 41hr 40min (group I) and thermocycled group (group T) the overall highest mean tensile strength was found in group T22, while lowest was retrieved from group I37. There was a statistically significant difference in tensile strength comparing groups of the same treatment that were tensile tested at different temperatures.

Due to its amorphous character, some authors state that PETG should only be affected by temperature-induced crystallization to a very small extent, i.e., it is less likely to undergo annealing. Nonetheless, it is likely that during immersion and thermocycling annealing takes place. This could be the reason for the observed highest ultimate tensile strength in groups T22 and T37 compared to the other groups tested at the same temperature. Extreme intraoral temperature changes may lead to even more accelerated physical aging of PETG aligner material. Food and drink consumption should be avoided during aligner wear to prevent alteration of the physical properties of the aligner material and to increase predictability of the resulting force systems. Annealing of aligners refers to a heat treatment process used to improve the mechanical properties and dimensional stability of clear dental aligners, such as those used in orthodontic treatments. The process involves heating the aligners to a specific temperature and then allowing them to cool down in a controlled manner. This can help to relieve internal stresses that may have been introduced during the manufacturing process and can also enhance the material properties of the aligners. Annealing can enhance the strength and durability of the aligners, making them more resistant to wear and tear during use.

Intraoral temperature (37°C) exposure resulted in lower tensile strength compared to room temperature (22°C) exposure suggesting impact of temperature on material properties. Thermocycling also improves the mechanical properties of the aligner material.

The LD30 material showed a reduced plastic capability and a greater elastic recovery, whereas the EX30 showed a greater residual deformation. Before aging, LD30 material was more rigid than the EX30 and both materials were inclined to become harder

with age and usage, changing their initial properties. Hence causing discomfort for the patient with usage. The higher degree of elasticity allows for better adaptation to the complexity of dental morphology, adhering perfectly to any surface and providing safety in terms of continuity of force expressed during the treatment as compared with that of an aligner built in a more rigid material.

In-vitro study done by Hiromi Ryokawa et.al⁵⁰ on 8 different thermoplastic materials - EVA (Bioplast), PE (Copyplast), PETG (Duran), PP (Hardcast), PC (Imprelon "S"), A+ (Essix A+), C+ (Essix C+) and PUR (Invisalign) they found that there was no significant differences were found in the elastic moduli of the simulated intraoral environment between PETG and A+ or between PP+ and C+, most likely because these materials have very similar molecular structures and no significant difference in tensile yield strength between PC and PUR, PETG+ and A+ or between PP and C+ after immersion in distilled water at a temperature of 37°C for 24hrs which correlates with group I, III, IV, V but does not correlate with group II as elastic modulus is directly proportional to tensile strength.

Materials with a high elastic modulus commonly have high tensile yield stress. PUR showed higher tensile yield stress in comparison with its elastic modulus. PC which that showed the same tensile yield stress level as PUR, showed the highest elastic modulus, PUR is a highly resilient material. Changes in temperature from 23⁰ C to 37 ⁰C will have little influence on their mechanical properties. Comparing the both studies materials that show less degradation over time in an oral environment are likely to have better longevity and durability, which is crucial for patient satisfaction and reducing the need for frequent replacements.

Flexural Modulus:

Flexural modulus determines the feasibility of the materials. The flexure modulus was directly proportional to the force of the thermoplastic materials and inversely proportional to their thickness. Thus, the flexure modulus was higher for thinner materials and lower for thicker materials.

The thickness of aligners before aging are group I: 0.75mm, group II: 0.36, group III: 1.0mm, group IV: 0.5mm and group V: 0.5mm. Flexural modulus, which indicates stiffness, increased in certain groups, suggesting enhanced rigidity after aging. In the present study, group II aligners has high flexural modulus compared to other groups before immersing in artificial saliva because the thickness of group II is less compared to other groups and after aging for 14 days the flexural modulus was highest in group V than other groups.

In in-vitro study done by Kazem Dalaie et.al¹⁹ on Duran and Erkodur aligners, they found that there was statistically significant decrease in flexural modulus after incubation in distilled water for 2 weeks which does not correlate with the present

study as thickness of aligners are not standardized and incubated in artificial saliva for 2 weeks. Thermoforming has a more dominant role to weaken the aligner materials in comparison to intraoral aging. Ryu et.al³¹ in their study stated that flexural modulus decreases with increasing material thickness

The materials used in the present study show a significant improvement in flexural modulus after immersion in artificial saliva, indicating that the exposure condition leads to a considerable increase in stiffness. While Duran aligners also show an increase in stiffness after aging, but not as pronounced as the present study. Erkodur aligners show almost no change in flexural modulus, indicating a very stable flexural property.

The compression strength before aging is highest in group IV and lowest in group III and after aging highest in group I and lowest in group V compared to other groups. High compression strength is advantageous to resist direct pressure of applied compressive force during tooth movement.

Surface Hardness:

Hardness is indicative of wear resistance. There is strong relation between the aligners and the amount of applied force by them. So, changes in hardness can properly indicate the changes in applied force and consequently the efficiency of aligner therapy. Vickers hardness was measured to compare the transfer of force and energy according to the type and thickness of the thermoplastic material, and it was found that the hardness affected the orthodontic force. The present study shows a uniform increase in surface hardness for all groups after immersion in artificial saliva. There was statistically significant increase in surface hardness after exposure to oral environment in group II, III and V.

In an in-vivo study done by Larine Ferreira Lira et.al¹³, on surface hardness on Invisalign®, there was decrease in surface hardness values with a statistically significant difference after exposure to oral environment for 14 days which does not correlate with the present study as they used Oliver-Pharr method was used to determine the surface hardness and oral environment conditions are different in both the studies. They stated that deterioration of the mechanical properties of the polymer can be due to the softening mechanism of the polyurethane.

In the present study, materials were immersed in artificial saliva which increases the surface hardness of the materials, indicating hardening effect which is beneficial indicating durability while in comparison to short term exposure to cleansers has minimal impact on surface hardness. In the previous study, there is significant reduction in surface hardness, suggesting that actual oral conditions might cause more wear due to factors such as pH, enzymatic activity.

Kohda et.al.⁴¹ in their study stated that there is a strong relation between the hardness of aligners and the amount of applied force by them. So, changes in hardness can properly indicate the changes in applied force and consequently the efficiency of aligner therapy. These studies suggest that immersion in in-vitro environments (artificial saliva vs distilled water) and duration (2 weeks vs 24 hours) impact surface hardness, the material type also plays a crucial role in determining the extent and nature of hardness changes.

In-vivo study done by Roberta Condo et.al.³² on Exceed 30 and Smart Track aligners, they found that there was significant increase in surface hardness after exposure to oral environment for 14±3 days, which does not correlate with group I, V but correlates with group II, III and IV of the present study. An in-vivo study done by Susan Schuster et.al.⁵² on Invisalign aligners, they found that there was statistically significant increase in surface hardness after exposure to oral environment for 2 weeks.

Changes in the Vickers hardness might be explained based on alteration in the crystallinity of the appliance under cold work produced by masticatory loads. This increase in hardness influences the mechanotherapy by acting as a stiffening mechanism, interfering with the force delivery by the appliances, requires further study. Both studies indicate that exposure to oral conditions (or simulated conditions) leads to an increase in surface hardness for dental materials, suggesting improved wear resistance and durability.

Glass Transition Temperature:

Glass transition temperature (T_g) is a critical thermal property representing the transition from a rigid (glassy) state to a flexible (rubbery) state. T_g had impact on dimensional stability, stiffness, toughness, mechanical and thermal properties. A reduction in T_g indicates increased molecular mobility, which may compromise dimensional stability and mechanical performance. A polymer will be hard and brittle below T_g and soft and deformable above T_g. It is affected by composition and crystallinity of the material. Polymers with higher T_g values tend to last longer because they are more resistant to creep deformation. At temperatures higher than T_g, Van der Waals interactions are weakened, allowing movement of polymer chains and subsequently solidify into new shapes when cooled.

In-vitro study done by Kazem Dalaie et.al.¹⁹ on Duran and Erkodur aligners they found that there was significant decrease in glass transition temperature after incubation in distilled water for 2 weeks which correlates with group III and IV but does not correlate with group I, II and V of the present study. They stated that attenuation of thermomechanical properties and the influential factor on the exerted force by aligners is their T_g and

not their crystal structure and glass transition temperature can be an appropriate representative of the efficiency of aligners.

Comparing the both studies aligners with smaller changes in T_g might retain their mechanical properties better over time. A significant drop in T_g after aging may indicate reduced mechanical properties, which can impact the aligner's performance and longevity.

In-vitro study done by A.Boubakri et.al.⁴⁴ on glass transition temperature and tensile strength on thermoplastic polyurethane (TPU) aging by immersion in distilled water until saturation causes decrease in T_g. They found that there was significant decrease after immersion in water for 6 months which correlates with group III and IV but does not correlate with group I, II and V of the present study. Overall, the findings of the present study indicate that exposure to simulated intraoral conditions can significantly influence the mechanical and thermal properties of aligner materials, although the extent of these changes is material-dependent. In the present study, variations in T_g were observed across different groups following aging. A reduction in T_g may indicate polymer plasticization and compromised mechanical performance. These findings are consistent with previous studies reporting decreased T_g following water immersion, attributed to increased polymer chain mobility. Materials with higher T_g values are generally more resistant to deformation and exhibit better long-term performance.

The findings of this study are consistent with previous research demonstrating that environmental exposure significantly influences the properties of thermoplastic aligners. Variations observed among different materials highlight the importance of material selection in clinical practice.

Clinical Significance

The present study provides clinically relevant insights into the selection of aligner materials with stable mechanical properties under intraoral conditions, thereby enhancing the predictability and efficiency of orthodontic treatment.

Limitations

The limitations of this study include a relatively small sample size and lack of standardization in aligner thickness. Additionally, the use of artificial saliva and controlled incubation does not fully replicate the dynamic intraoral environment, which involves variations in temperature, pH, occlusal forces, and exposure to cleansing agents.

Future Directions

Future research should focus on large-scale in vivo studies and comparative evaluation of thermoformed and three-dimensional (3D)-printed aligners to better understand their mechanical behaviour and clinical applicability.

CONCLUSION:

The following conclusions are formulated from the study:

The tensile strength before aging is highest in group II and lowest in group V and after aging highest in group II and lowest in group III compared to other groups. High tensile strength is advantageous as materials are less likely to fracture under load and will have desired tooth movement.

The flexural modulus before aging is highest in group II and lowest in group III and after aging highest in group V and lowest in group III compared to other groups. Low flexural modulus is advantageous for desired tooth movement. The compression strength before aging is highest in group IV and lowest in group III and after aging highest in group I and lowest in group V compared to other groups. High compression strength is advantageous to resist direct pressure of applied compressive force during tooth movement.

The surface hardness before aging is highest in group II and lowest in group I and after aging highest in group II and lowest in group I compared to other groups. High surface hardness is advantageous for effective tooth movement and will have wear resistance but initial they should have low surface hardness.

The glass transition temperature before aging is highest in group I and lowest in group V and after aging highest in group III and lowest in group IV compared to other groups. Material below T_g is hard and brittle and above T_g is soft and deformable affecting the mechanical properties. High T_g is advantageous for desired tooth movement.

- Thermoplastic aligners exhibit significant changes in mechanical and thermal properties following simulated intraoral aging.
- PET-G and TPU materials respond differently to aging conditions.
- Increased surface hardness and flexural modulus suggest enhanced stiffness, whereas decreased tensile strength and T_g may indicate material degradation.
- Selection of aligner material should consider its stability under intraoral conditions to ensure effective and predictable tooth movement.

An ideal aligner material should demonstrate high resilience, adequate elasticity, low hardness, resistance to deformation, excellent transparency, and biocompatibility. The clinician should consider these factors in deciding the duration of each aligner.

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