RESEARCH PAPER

Assessment of Mechanical Attributes in Two Types of Clear Aligner Materials Through In Vitro Methods

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Received: 04th June, 2026; Revised: 25th June, 2026; Accepted: 11th July, 2026; Available Online: 20th July, 2026

ABSTRACT

Introduction: The use of clear aligners is considered now as a popular substitute for conventional fixed appliances. These appliances are made from many materials, thermoplastic resin polyethylene terephthalate glycol and polyurethane derivatives which are the two common materials used. Aligners offer benefits such as improved aesthetics, comfort, and hygiene. However, these materials are subjected to degradation from the oral environment and non-compliant patient behavior. Extensive research focuses on biomechanics while mechanical characteristics and comparative studies about integrity of different aligner materials are crucial now to decide which material will be chosen for each case. **Aim:** The purpose of this study was to assess and contrast the mechanical characteristics of two transparent aligner materials, Material I (polyethylene terephthalate glycol) and Material II (polyurethane polyethylene glycol polycarbonate), including flexural strength, flexural modulus, and hardness. **Materials and Methods:** An in vitro study was conducted on specimens of Material I [Polyethylene terephthalate glycol (PETG)] and Material II [Polyurethane polyethylene glycol polycarbonate (PU/PC)]. A Vickers hardness test and a three-point bending test (flexural strength and modulus) were used to assess mechanical parameters. Statistical analysis employed a two-way ANOVA for and Student's -test for mechanical properties. Results: For every mechanical property evaluated, including flexural strength, flexural modulus, and hardness, Material I's mean values were statistically considerably higher than Material II's. **Conclusion:** Material I [Polyethylene terephthalate glycol (PETG)] offers superior mechanical rigidity (higher strength, modulus, and hardness). Clinical decision-making must weigh the importance of long-term mechanical durability. Further research involving longer follow-up periods is recommended to fully understand them in vivo performance and material preference.

Keywords: Aligner, flexural strength, hardness test.
How to cite this article: Shehata Y.M.K, Elnagar W.E.R and Diab M.E, Assessment of Mechanical Attributes in Two Types of Clear Aligner Materials Through In Vitro Methods. 2026;16(72s): 351-358. DOI: 10.25258/ijddt.16.72s.39
Source of support: None
Conflict of interest: None

INTRODUCTION:

Clear aligner therapy (CAT) has emerged as a fundamental aspect of contemporary aesthetic orthodontics, providing a favored and visually appealing alternative to traditional fixed appliances. This approach offers numerous benefits, including enhanced appearance, user-friendliness, ease of removal, and improved oral hygiene (1,2). CAT employs a series of customized clear plastic trays, with its origins tracing back to Harold D. Kesling's tooth positioners from 1945, and has been notably advanced by the digital, CAD/CAM-driven processes introduced by Invisalign (Align Technology) in 1998 (3,4). This digital methodology encompasses virtual treatment planning, 3D printing of staged models, and thermoforming of the aligners, often integrating additional components like attachments to optimize force application (3),(5).

The thermoplastic polymers used in aligner fabrication must possess material properties that generate precise and controlled forces for effective tooth movement. These aligner materials are viscoelastic, demonstrating a time-dependent response between stress and strain that does not conform to Hooke's law (3),(6). This characteristic allows the aligner to deform upon insertion and exert a biological force. A significant challenge in this context is stress relaxation, which refers to the gradual decrease in force delivery under sustained strain (3). Research has shown a significant exponential decline in force within the initial hours of use, a crucial consideration for treatment planning (7,8).

The conventional thermoforming process, which involves molding polymer sheets onto models, has been found to modify the original physical properties of the material, leading to reduced transparency,

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thickness, and hardness (9-11). Aligners are constantly subjected to temperature fluctuations, saliva, and functional stresses, which can result in material changes such as hygroscopic expansion and alterations in mechanical properties (3,12). Polyurethane-based materials, like SmartTrack™, exhibit advantages in elasticity but are often more prone to pigment absorption compared to polycarboxylate and polyethylene terephthalate glycol-based materials (10),(13).
Ongoing advancements aim to address the limitations associated with traditional materials and manufacturing processes. The future of aligner production is leaning towards direct 3D printing, which eliminates the error-prone thermoforming step. This method, including the development of 3D Printed In-House aligners, holds promise for improved geometric precision, reduced cumulative errors, lower costs, and enhanced sustainability (14-16). Nonetheless, achieving the desired aligner thickness and fully removing post-polymerization toxicity from printed resins remain significant challenges (17-19).
Research into shape memory polymers, which can return to a predetermined shape when subjected to thermal stimulation, presents the potential for a single aligner to replace multiple successive trays. This innovation simplifies treatment and decreases plastic waste (20,21). Additionally, bioactive aligner materials infused with ions such as fluoride and calcium are being developed to encourage remineralization and prevent demineralization of tooth structures during treatment (22-24).
Given the critical importance of material properties in determining clinical success and the notable gap in comparative studies within the existing literature, there is a clear need for comprehensive investigations into various aligner material characteristics. This study aims to perform a comparative in vitro analysis of the mechanical resistance properties of two distinct orthodontic clear aligner materials: polyethylene terephthalate glycol and polyurethane polyethylene glycol polycarbonate. The results will provide valuable insights into the material trade-offs, aiding in informed clinical decision-making.

METHODS

Research Design:

This study was an in vitro analysis involving 40 clear aligner specimens aimed at assessing the mechanical properties of two different orthodontic aligner materials. Approval from the Research Ethics Committee (REC) of the Faculty of Dentistry at Suez Canal University was not required for this study, assigned the code 532/2022, as it did not involve human participants or experimental animals.

****Sample Size Calculation:***

The power analysis conducted was for an analysis of variance with two fixed effects, specifically the factor of Aligner type, which included two levels. The effect sizes were determined to be f = 0.86 and 1.18 for a power of 80%, based on the findings of Liu et al. (2016). The study included 10 samples from each subgroup, resulting in a total of 40 samples. The sample size was calculated using IBM® SPSS® Sample Power® Release 3.0.1 (Liu et al., 2016).

****Sample Grouping:***

The specimens were categorized into two primary groups based on the type of material:
- *Group 1:* Polyethylene terephthalate glycol (PETG)
- *Group 2:* Polyurethane polyethylene glycol polycarbonate (PU/PC)

Each primary group was further subdivided into two experimental subgroups:
- *Subgroups 1A and 2A:For hardness assessment utilizing the Vickers test.
- *Subgroups 1B and 2BFor flexural strength testing using a Universal Testing Machine.

Study Procedure:

The mechanical properties of the materials were evaluated through a three-point bending test to measure flexural strength and a Vickers hardness test. For each of the subgroups 1A, 1B, 2A, and 2B, ten samples were prepared from both materials: Polyethylene terephthalate glycol and Polyurethane polyethylene glycol polycarbonate.

A. Three-Point Bending Test for Flexural Strength

1. **Sample Preparation:** Ten samples from each material group were cut to standardized dimensions of 12 mm x 4 mm.
2. **Apparatus and Protocol:** The tests were conducted using an Instron Model 3345 Universal Testing Machine (see Figures 1 & 2) in accordance with ISO 178 standards.
 - A bar-shaped specimen was positioned on two supports (refer to Figure 3).
 - A vertical force was applied at the midpoint of the specimen, situated between the two supports (illustrated in Figure 4).
 - Both the applied force and the resulting deformation were recorded to calculate the flexural strength and flexural modulus (shown in Figure 5).

Figure (1): Instron model 3345 Universal testing machines.

Figure (2): force applied vertically to the top of the specimen midway between two supports at cross head speed 1mm/min.

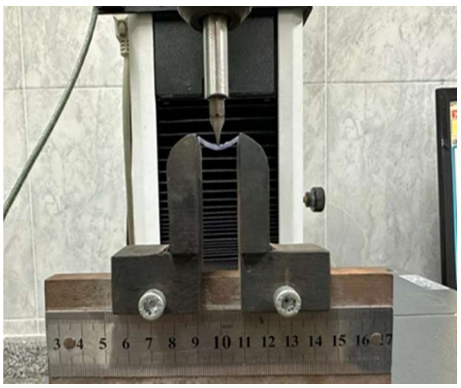

Figure (3): bar shaped plastic specimen is placed between two supports.

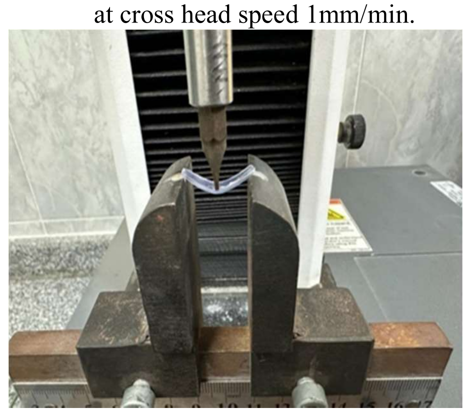

Figure (4): Application of vertical force midway between two supports.

Figures (5): Showing steps of specimen deformation before measuring flexural strength and flexural modulus.

Evaluation Method
Data Acquisition: Data were collected and analyzed using BlueHill Universal software (Instron, England).
Flexural Stress Calculation: The flexural stress (Q) was determined using the following formula:

$$Q=3FL/2bd2$$

Where: Q is the flexural stresses in MPa, F is the load (force) in Newton.

B. Vickers Hardness Test

1. **Sample Preparation:** Ten samples from each material group were cut to dimensions of 12 mm x 4 mm.
2. **Apparatus and Protocol:** The hardness assessment was conducted using a Wilson hardness tester, Model TUKON 1102 (Germany) (see Figure 6).
 - A load of 100 grams was applied gradually to the diamond indenter without any impact, pressing the indenter into the test specimen (illustrated in Figure 7).
 - The indenter was maintained in position for 10 seconds (depicted in Figure 8).

- After the load was released, the two diagonal impressions were measured with a micrometer, and the average was calculated.

Figure (6): Wilson hardness tester model TUKON 1102 Germany.

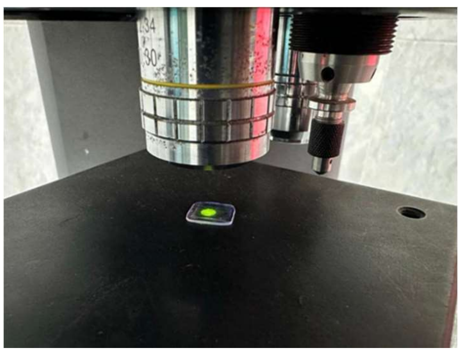

Figure (7): Showing Vicker's test, applying 100-gm load is applied smoothly without impact, forcing the indenter into the test specimen.

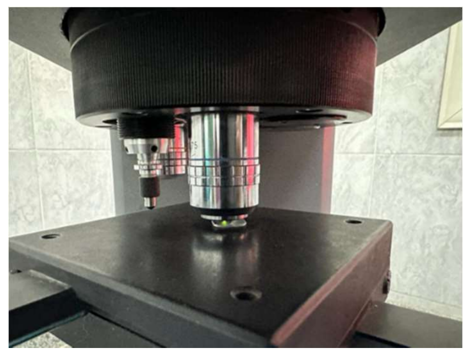

Figure (8): Showing applying force to the test specimen using hardness tester for 10 seconds.

Evaluation method:

1. **Hardness Calculation:** The Vickers hardness was calculated using the formula:

HV=1854.4L/d2

Where the load L is in gf and the average diagonal d is in um (this produces hardness number units of gf/um2. In practice the numbers are reported without indication of the units).

2. Statistical Analysis

Bonferroni's post -hoc test was used for pair wise comparisons when ANOVA test is significant.

Mechanical Properties (Flexural Strength and Hardness): The **Student's -test** was used to compare the mechanical properties between the two material groups.

The significance level was set at $P \leq 0.05$. Statistical analysis was performed with IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp.

RESULTS:

Table (1) presents a comparison of the flexural strengths (MPa) between the two types of materials. The results indicate that Material I exhibits a significantly higher flexural strength than Material II, with a statistically significant and clinically substantial difference that is highly relevant for dental restorative applications (see Figure 9).

Flexural strength refers to a material's ability to withstand bending forces, which is crucial in dentistry for restorations that experience occlusal loading and bending stresses. Material I (45.7 ± 2.8 MPa) demonstrates more than double the flexural strength of Material II (20.6 ± 3.2 MPa), suggesting that Material II is more susceptible to fracture under functional loads.

The p-value of < 0.001 indicates a statistically significant difference in flexural strength between the two materials, implying that the observed difference is highly unlikely to result from random sampling error at the 5% significance level. The effect size of d=8.344 reflects an extremely large difference between the materials; in most biomedical contexts, an effect size of approximately d=0.8 is considered significant, indicating that these two materials exhibit markedly different mechanical behaviors.

In clinical practice, materials with higher flexural strength are preferred in areas subjected to stress to minimize the risk of fractures, chipping, and long-term failure of restorations. Due to its considerably lower flexural strength, Material II may not be suitable as a standalone restorative option in high-stress areas and could be limited to low-stress applications (such as small non-load-bearing repairs or liners) or require reinforcement with stronger materials. In contrast, Material I is better suited for situations where bending forces are anticipated.

I. Flexural strength (MPa)

Table (1). Mean, standard deviation (SD) values and results of Student's t-test for comparison between flexural strengths (MPa) of the two material types

Material I		Material II		*P*-value	*Effect size (d)*
Mean	**SD**	**Mean**	**SD**		
45.7	2.8	20.6	3.2	<0.001*	8.344

*: Significant at P ≤ 0.05

II. Flexural modulus I. Flexural Modulus (MPa)*

Table (2) illustrates a statistically significant difference in flexural modulus between the two dental materials, with Material I demonstrating greater stiffness compared to Material II. This comparison, analyzed using Student's t-test, emphasizes the potential benefits of Material I for load-bearing dental restorations. In the field of dentistry, flexural modulus quantifies a material's resistance to bending under applied stress, which is essential for restorations that must withstand occlusal forces (see Figure 10).

Material I shows a mean flexural modulus of 1075.9 MPa (SD 86.2), significantly surpassing Material II's value of 456.8 MPa (SD 60), with a p-value of < 0.001 indicating a high level of significance. The effect size (Cohen's d = 8.339) reveals an exceptionally large practical difference, with the distributions of the two materials barely overlapping—over 99.9% of the samples of Material I outperform those of Material II. These findings are consistent with the typical ranges for resin composites (611–1783 MPa) and bioactive flowable materials, suggesting that Material I is well-suited for high-stress applications, such as posterior fillings. (MPa)

Table (2). Mean, standard deviation (SD) values and results of Student's t-test for comparison between flexural modulus (MPa) of the two material types

Material I		Material II		*P*-value	*Effect size (d)*
Mean	**SD**	**Mean**	**SD**		
1075.9	86.2	456.8	60	<0.001*	8.339

*: Significant at P ≤ 0.05

III. Hardness (VHN)

Table (3) provides data on the Vickers hardness number (VHN) for two dental materials, indicating that Material I has a higher hardness compared to Material II. A Student's t-test reveals a highly significant difference (P < 0.001), corroborated by a large Cohen's d effect size of 10.242, which signifies a meaningful practical difference between the two materials (see Figure 11).

Material I has a mean hardness of 12.1 VHN (SD 0.5), surpassing Material II's hardness of 8.3 VHN (SD 0.1). The low standard deviations suggest a high level of consistency within each material group. The t-test p-value of less than 0.001 rejects the null hypothesis of equal hardness, establishing the result as statistically significant at P ≤ 0.05. Furthermore, Cohen's d of 10.242 exceeds the conventional thresholds for a large effect (>0.8), indicating that the mean difference is greater than 10 pooled standard deviations.

Table (3). Mean, standard deviation (SD) values and results of Student's t-test for comparison between hardness (VHN) of the two material types

Material I		Material II		*P*-value	*Effect size (d)*
Mean	SD	Mean	SD		
12.1	0.5	8.3	0.1	<0.001*	10.242

*: Significant at P ≤ 0.05

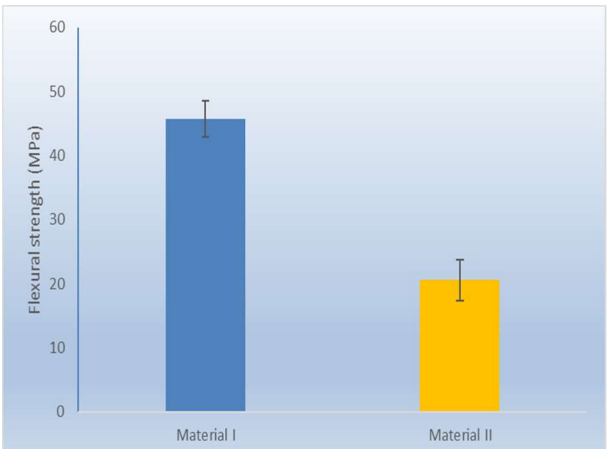

Figure (9): Mean and standard deviation values for flexural strengths of the two material types.

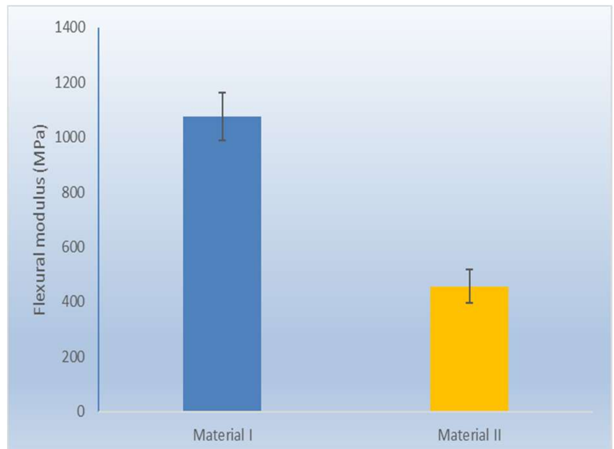

Figure (10): Mean and standard deviation values for flexural modulus of the two material types

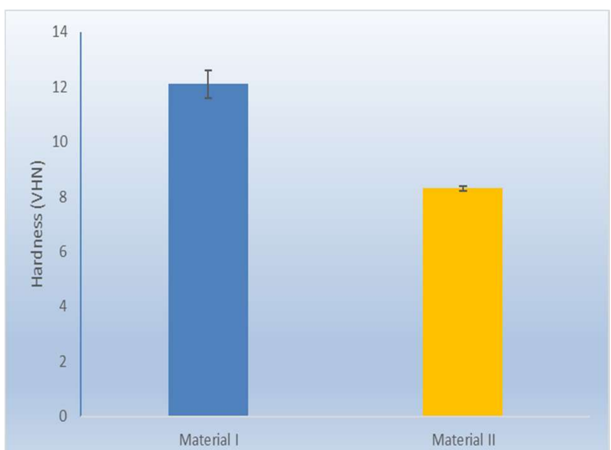

Figure (11): Mean and standard deviation values for hardness of the two material types.

DISCUSSION

The growing demand for aesthetic orthodontic options has led to a notable shift towards clear aligner therapy (CAT), making the material properties of these devices a crucial area of research [3],[25]. Aligner materials, which are generally thermoplastic resin polymers such as polyvinyl chloride, PET, PETG, and polyurethane, are constantly exposed to the challenging conditions of the oral environment, including heat, humidity, and continuous forces [26]. Consequently, the clinical effectiveness of CAT relies heavily on the materials' ability to withstand mechanical degradation and maintain aesthetic integrity against staining [15],[27]. To determine which material performs better, the present study compared the mechanical characteristics (flexural strength, modulus, and hardness) of Material I (polyethylene terephthalate glycol, PETG) and Material II (polyurethane polyethylene glycol polycarbonate, PU/PC).

Mechanical Properties: Flexural Strength and Hardness

The mechanical testing results consistently indicated that Material I (PETG) had statistically significant higher mean values for flexural strength, flexural modulus, and hardness when compared to Material II (PU/PC).

Flexural Strength and Modulus: The notably higher flexural strength and modulus of Material I suggest that it is a stiffer material, capable of better resisting deformation and fracture under bending forces. This aligns with the findings of Dalaie et al. [10] and Albilali et al. [28], which highlighted the stiffness of PETG materials such as Duran. Conversely, while Material II has lower stiffness, it may offer a more continuous and lighter orthodontic force due to its increased flexibility, which is often viewed as biologically beneficial [29].

Hardness: The significantly higher Vickers hardness (VHN) of Material I (PETG) indicates a superior ability to resist surface indentation and wear compared to Material II (PU/PC). This contrasts with the findings of Alexandropoulos et al. [30], who linked high hardness with thermoplastic polyurethane (INV) devices. Nevertheless, other studies have indicated that materials like PETG (Duran Plus) exhibit high VHN values, consistent with our findings for Material I [28]. While the reduction in hardness noted in other studies following thermoforming or intraoral aging [10],[11] was not the primary focus of this research, it highlights that the initial material properties (as measured in this study) may deteriorate over time during clinical use.

CONCLUSION

According to the laboratory results, Material I (PETG) exhibited superior mechanical properties, including increased flexural strength, modulus, and hardness, indicating enhanced initial resistance to deformation and surface wear. Choosing between these materials in a clinical context involves a compromise: while PETG provides mechanical rigidity, further clinical studies are needed to link these in vitro results to actual clinical performance, especially concerning long-term force delivery and resistance to degradation in the challenging oral environment.

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