Original Research Paper

University J Dent Scie 2025; Vol. 11, Issue 2

Comparative Evaluation of Tensile Strength in Orthodontic Aligners Exposed to Common Disinfectants: An In-vitro Study

Abstract:

Aim: This in-vitro study aimed to evaluate and compare the tensile strength of three commercially available orthodontic aligner materials—Duran Plus, Erkodur-AL, and Zendura FLX—after exposure to commonly used disinfectants, thereby simulating real-world oral hygiene practices.

Materials and Methods: Seventy-two aligner specimens were fabricated using thermoforming over standardized 3D-printed maxillary models from three thermoplastic materials: Duran Plus, Erkodur-AL, and Zendura FLX (n=24 per material). Each material group was further divided into four disinfectant exposure groups—Povidone-Iodine (1%), Chlorhexidine Gluconate (0.02%), Hydrogen Peroxide (5%), and Cetylpyridinium Chloride (0.6%)—with exposure durations of 1 day and 7 days. Specimens were immersed in disinfectants for 15 minutes, three times daily, and stored in artificial saliva between cycles. Tensile strength testing was conducted using a Universal Testing Machine, and results were analyzed using one-way ANOVA with Tukey's post hoc test ($p \leq 0.05$).

Results: Zendura FLX consistently exhibited the highest tensile strength across all disinfectant groups, followed by Duran Plus and Erkodur-AL. While short-term (1-day) exposure showed no statistically significant difference within materials across disinfectants, prolonged exposure (7 days) led to a noticeable decline in tensile strength, especially in Erkodur-AL. Statistically significant differences were observed between materials ($p < 0.001$), with Zendura FLX demonstrating superior mechanical stability.

Conclusion: Zendura FLX retained significantly higher tensile strength following both short-term and extended disinfectant exposure, suggesting its superior durability among tested materials. Although disinfectant type did not significantly affect the tensile strength within the same material, prolonged exposure contributed to mechanical degradation. These findings underscore the importance of material selection and aligner maintenance protocols in optimizing clinical outcomes in clear aligner therapy.

Key-words: Aligners, Tensile strength, Disinfectants.

Introduction:

The advent of clear orthodontic aligners has revolutionized the field of orthodontics by providing aesthetically pleasing, removable alternatives to traditional fixed appliances. These aligners are fabricated from thermoplastic polymers, and their clinical performance relies heavily on mechanical properties, particularly tensile strength.

Patients are advised to maintain oral hygiene using various chemical agents, many of which may interact with the aligner material. Commonly used disinfectants include povidone-iodine, chlorhexidine gluconate, hydrogen peroxide, and cetylpyridinium chloride. These substances can potentially alter the tensile strength of the aligners, compromising treatment efficacy.

This in-vitro study aims to evaluate the tensile strength of different aligner materials after exposure to these disinfectants to simulate real-world oral hygiene practices.

Access this article online	
Website: www.ujds.in	Quick Response Code
DOI: https://doi.org/10.21276/ujds.2025.v11.i2.4	

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Received : 14 June, 2025, **Published :** 30 June, 2025

How to cite this article: Navin Gokul E, Monis Raza, Prashant Kumar Shahi, Ridhi Kothari Tyagi, Achint Juneja, & Nivedita Sharma. (2025). Comparative Evaluation of Tensile Strength in Orthodontic Aligners Exposed to Common Disinfectants: An In-Vitro Study. UNIVERSITY JOURNAL OF DENTAL SCIENCES, 11(2).

Hence the aim of the study was to compare the tensile strength of orthodontic aligners made from different materials such as Duran, Erkodur and zendura when exposed to commonly used mouthwash solutions: povidone-iodine, chlorhexidine, hydrogen peroxide and cetylpyridinium chloride.

Materials And Method:

Study Design:

This study was designed as a controlled in-vitro experimental investigation aimed at evaluating the effect of different disinfectant agents on the tensile strength of orthodontic aligners fabricated from three distinct thermoplastic materials. The methodology was structured to simulate realistic exposure scenarios encountered during the routine cleaning of aligners while maintaining standardized laboratory conditions for mechanical testing.

Materials:

A total of 72 orthodontic aligner specimens were fabricated from three commercially available aligner materials:

Duran Plus (Scheu-Dental GmbH, Germany)

Erkodur-AL (Erkodent Erich Kopp GmbH, Germany)

Zendura FLX (Bay Materials LLC, USA)

These materials were selected due to their widespread clinical usage and distinct polymer compositions. Each material group included 24 samples, resulting in a total of 72 samples.

Aligner Fabrication Procedure:

Maxillary dental arch models extending from the first premolar to the second molar were digitally designed and 3D printed using a stereo lithography (SLA) printer to ensure uniformity in dimensions and morphology. The aligner materials were thermoformed over these 3D models using a pressure-molding thermoforming machine (Ministar, Scheu-Dental GmbH, Germany) at a standardized pressure of 4 bar and material-specific heating parameters.

After thermoforming, each aligner was carefully trimmed and finished to replicate clinical contours and avoid variability in sample dimensions. All samples were inspected under magnification for defects and dimensional inconsistencies. A digital caliper was used to confirm uniform thickness across the samples.

Artificial Saliva Preparation:

For interim storage, an artificial saliva solution was prepared containing the following components: sodium carboxymethylcellulose, xylitol, potassium chloride, calcium chloride, potassium thiocyanate, potassium phosphate, and distilled deionized water. The solution was maintained at a constant temperature of 37°C throughout the experimental period to simulate intraoral conditions.

Disinfectant Solutions:

The aligner samples were exposed to four commonly used disinfectant solutions:

Povidone-Iodine (1%)

Chlorhexidine Gluconate (0.02%)

Hydrogen Peroxide (5%)

Cetylpyridinium Chloride (0.6%)

Each disinfectant group was further divided into two subgroups based on the exposure duration: 1 day and 7 days. Every subgroup contained three samples from each material (n = 3), resulting in 6 subgroups per disinfectant and 24 samples per disinfectant group.

Exposure Protocol:

Each aligner sample was immersed in 15 mL of the assigned disinfectant solution for 15 minutes, three times daily (morning, afternoon, and evening). After each immersion, samples were thoroughly rinsed with distilled water for 30 seconds and stored in artificial saliva between treatments. For the 1-day exposure groups, this regimen was followed for one day, while for the 7-day exposure groups, the protocol was continued daily for seven consecutive days.

Tensile Strength Testing:

Upon completion of the exposure period, all samples were subjected to tensile strength testing using a Universal Testing Machine (Asian Test Equipments Pvt. Ltd., India). Each sample was mounted between two custom-fabricated grips, ensuring parallel alignment and a consistent gauge length of 25 mm. The tensile load was applied at a crosshead speed of 5 mm/min until the sample failed. The maximum force (in Newtons) required to cause failure was recorded for each specimen.

To reduce variability, each test was repeated twice for every sample, and the mean of the two readings was considered for statistical analysis. Environmental conditions during testing were standardized (room temperature: 23 ± 2°C, relative humidity: 50 ± 5%).

Data Collection and Statistical Analysis:

Tensile strength values were recorded and tabulated for each aligner material across all disinfectant groups and exposure durations. Descriptive statistics (mean and standard deviation) were computed.

Inferential statistical analysis was conducted using IBM SPSS Statistics Version 23. A one-way Analysis of Variance (ANOVA) was used to determine statistically significant differences among groups. Post hoc pairwise comparisons were performed using Tukey's HSD test. A p-value ≤ 0.05 was considered statistically significant for all analyses.

Figures:

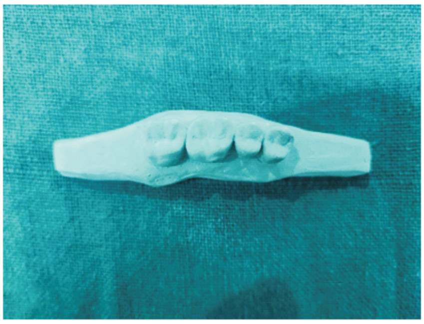
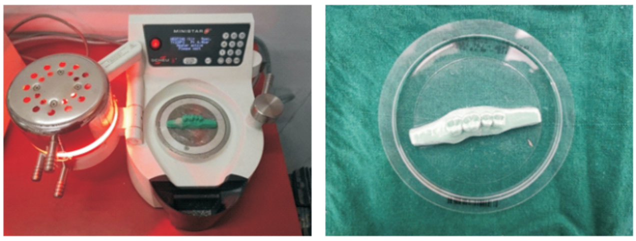


Figure 1: 3D-printed model used for aligner fabrication



(a) (b)

Figure 2: Thermoforming process using Ministar thermoforming machine

(a) Thermoforming in progress

(b) Adapted aligner sheet on model

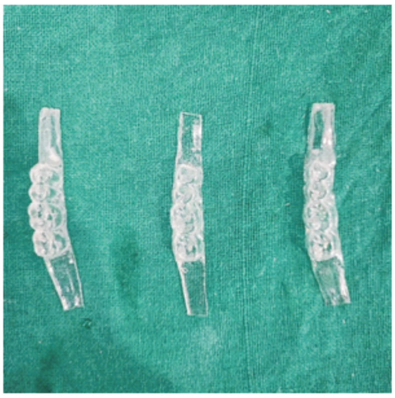
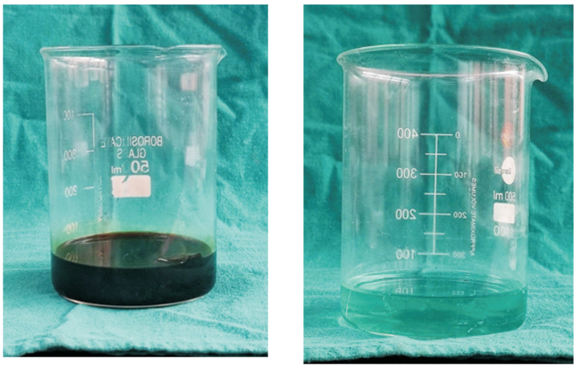


Figure 3: Fabricated aligner samples

(a) Duran Plus

(b) Erkodur-AL

(c) Zendura FLX



(a) (b)

(c) (d)

Figure 4: Immersion of aligners in disinfectant solutions

(a) Povidone-Iodine

(b) Chlorhexidine Gluconate

(c) Hydrogen Peroxide

(d) Cetylpyridinium Chloride

Statisticial Analysis:

Statistical analysis was performed using IBM SPSS Statistics for Windows, Version 23.0 (IBM Corp., Armonk, NY, USA). Descriptive statistics, including mean and standard deviation, were computed for the tensile strength values of each group.

To assess differences in tensile strength across the various disinfectant agents, aligner materials, and exposure durations, a one-way Analysis of Variance (ANOVA) was employed. The assumptions of normality and homogeneity of variances were verified using the Shapiro–Wilk test and Levene's test, respectively.

In cases where significant differences were detected by ANOVA ($p \leq 0.05$), Tukey's Honestly Significant Difference

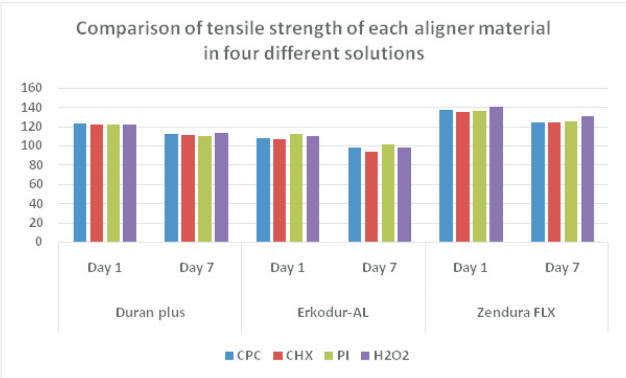
(HSD) post hoc test was conducted to perform pairwise comparisons between group means.

The level of statistical significance was set at $p \leq 0.05$ for all analyses.

Results:

Table 1: Comparison of tensile strength of each aligner material in four different solutions

Material	Interval	CPC		CHX		PI		H_2O_2		p-value
		Mean	SD	Mean	SD	Mean	SD	Mean	SD	
Duran plus	Day 1	123.0	2.7	121.9	2.7	122.1	2.0	121.8	3.5	0.892
	Day 7	111.9	8.4	111.1	3.3	109.8	5.4	112.8	3.3	0.844
Erkodur-AL	Day 1	107.9	6.8	106.9	3.5	112.1	6.7	110.1	6.3	0.532
	Day 7	97.6	7.4	93.2	4.7	101.3	6.2	97.5	7.3	0.306
Zendura FLX	Day 1	136.7	4.3	134.6	9.2	135.9	3.5	140.0	1.4	0.459
	Day 7	124.2	3.0	124.3	5.3	124.7	4.6	130.4	4.0	0.100



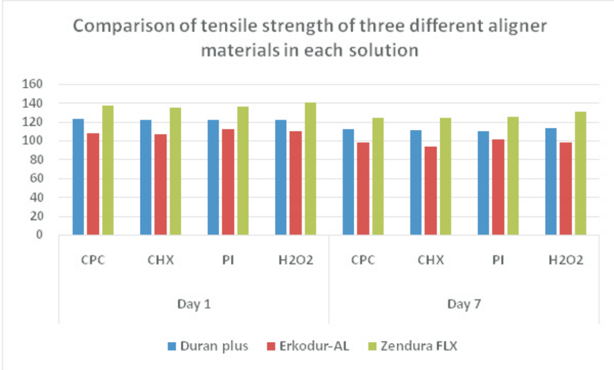
One-way ANOVA test

This table compares the tensile strength of each aligner material in four different solutions. The difference in the tensile strength of Duran plus material between four solutions on day 1 and day 7 was non-significant. Similarly, the difference in the tensile strength of Erkodur-AL material between four solutions on day 1 and day 7 was non-significant. Also, the difference in the tensile strength of Zendura FLX material between four solutions on day 1 and day 7 was non-significant.

Table 2: Comparison of tensile strength of three different aligner materials in each solution

Solution	Duran plus		Erkodur-AL		Zendura FLX		p-value
	Mean	SD	Mean	SD	Mean	SD	
Day 1							
CPC	123.0	2.7	107.9	6.8	136.7	4.3	<0.001*
CHX	121.9	2.7	106.9	3.5	134.6	9.2	<0.001*
PI	122.1	2.0	112.1	6.7	135.9	3.5	<0.001*
H_2O_2	121.8	3.5	110.1	6.3	140.0	1.4	<0.001*
Day 7							
CPC	111.9	8.4	97.6	7.4	124.2	3.0	<0.001*
CHX	111.1	3.3	93.2	4.7	124.3	5.3	<0.001*
PI	109.8	5.4	101.3	6.2	124.7	4.6	<0.001*
H_2O_2	112.8	3.3	97.5	7.3	130.4	4.0	<0.001*

One-way ANOVA test; * indicates a significant difference at $p \leq 0.05$



This table compares the tensile strength of three different aligner materials in each solution. On day 1 as well as day 7, the highest tensile strength was seen in Zendura FLX material and the lowest in the Erkudor Al material. On day 1, the difference in the tensile strength of three different aligner materials in each solution was statistically significant. On day 7, the difference in the tensile strength of three different aligner materials in each solution was statistically significant.

Table 3: Pairwise comparison of tensile strength of three different aligner materials in each solution

Pairwise comparison	Duran plus vs Erkodur-AL	Duran plus vs Zendura FLX	Erkudor-AL vs Zebdura FLX
Day 1			
CPC	0.001*	0.002*	<0.001*
CHX	0.004*	0.013*	<0.001*
PI	0.011*	0.001*	<0.001*
H_2O_2	0.002*	<0.001*	<0.001*
Day 7			
CPC	0.014*	0.033*	<0.001*
CHX	<0.001*	0.001*	<0.001*
PI	0.070	0.002*	<0.001*
H_2O_2	0.001*	<0.001*	<0.001*

Post hoc Tukey test; * indicates a significant difference at $p \leq 0.05$

This table presents the pairwise comparison of the tensile strength of three different aligner materials in each solution. On day 1, the tensile strength of Zendura FLX material in each solution was significantly greater than the other two materials, and the tensile strength of Erkudor-AL material was significantly lower than the other two materials. On day 7, the tensile strength of Zendura FLX material in each solution was significantly greater than the other two materials, and the tensile strength of Erkudor-AL material was significantly lower than the other two materials except in Povidone Iodine solution where the tensile strength between Duran plus and Erkudor-AL did not differ significantly.

Discussion:

The current study aimed to evaluate and compare the tensile strength of three orthodontic aligner materials—Duran Plus, Erkodur-AL, and Zendura FLX—when exposed to four commonly used disinfectants: povidone-iodine (PI), chlorhexidine gluconate (CHX), hydrogen peroxide (H_2O_2), and cetylpyridinium chloride (CPC). The findings provide valuable insights into the material properties and durability of aligners under clinical conditions.

Impact of disinfectants on Tensile Strength

Day 1 Results:

Across all aligner materials, exposure to the various disinfectants resulted in differences in tensile strength. However, the differences observed within the same material when exposed to different solutions were not statistically significant. This suggests that short-term exposure to these solutions does not drastically affect the structural integrity of the aligners.

- Duran Plus: The tensile strength values ranged between 121.8 N and 123.0 N, showing minimal variation across the solutions. The highest tensile strength was noted in CPC, while the lowest was in H_2O_2.
- Erkodur-AL: This material exhibited the lowest tensile strength among the three materials, with values ranging from 106.9 N to 112.1 N. Exposure to Povidone Iodine showed slightly higher tensile strength compared to other solutions.
- Zendura FLX: This material demonstrated the highest tensile strength, ranging from 134.6 N to 140.0 N, with H_2O_2 showing the maximum value.

Day 7 Results:

Prolonged exposure (7 days) revealed a notable reduction in tensile strength for all materials. Despite this, the differences in tensile strength between solutions for the same material remained statistically non-significant.

- Duran Plus: Tensile strength decreased significantly over 7 days, with values ranging between 109.8 N and 112.8 N. This reduction reflects potential material degradation over time.
- Erkodur-AL: The tensile strength values further declined, ranging from 93.2 N to 101.3 N. This material showed the greatest susceptibility to tensile strength loss, particularly in CHX and CPC solutions.
- Zendura FLX: Despite a decrease in tensile strength, Zendura FLX consistently outperformed the other materials, with values ranging from 124.2 N to 130.4 N.

The H_2O_2 solution resulted in the highest tensile strength after prolonged exposure.

Comparison of Materials Across Solutions:

The comparison of tensile strength among the three aligner materials for each solution demonstrated statistically significant differences both on Day 1 and Day 7 ($p < 0.001$).

Pairwise comparisons further elucidated these differences:

1. Duran Plus vs. Erkodur-AL: Duran Plus consistently showed higher tensile strength than Erkodur-AL across all solutions. The differences were statistically significant except for Povidone Iodine solution on Day 7.
2. Duran Plus vs. Zendura FLX: Zendura FLX exhibited superior tensile strength compared to Duran Plus. The differences were statistically significant in all solutions.
3. Erkodur-AL vs. Zendura FLX: Zendura FLX significantly outperformed Erkodur-AL across all solutions, with substantial differences noted in both Day 1 and Day 7 results.

These findings align with previous research demonstrating that thermoplastic aligner materials undergo degradation over time due to water absorption.[4] This phenomenon occurs as water molecules penetrate the polymer matrix, increasing molecular mobility and leading to stress relaxation. As water molecules integrate into the material's structure, they disrupt intermolecular bonds, resulting in changes to the material's mechanical properties, such as reduced tensile strength. This degradation is more pronounced in materials without protective layers or barriers to water penetration, further emphasizing the critical role of material composition in aligner durability.

Water absorption in polymers is well-explained by Fick's law of diffusion[4], a principle that describes how molecules diffuse through materials. Initially, water molecules enter the polymer matrix rapidly, as the concentration gradient between the surrounding environment and the polymer's interior is at its highest. Over time, this rate slows as the material absorbs water and approaches saturation equilibrium, where no further diffusion occurs.

In the context of aligner materials, the observed degradation in tensile strength corresponds with the stages of water absorption. Prolonged immersion in liquids allows the materials to reach saturation, beyond which mechanical properties stabilize. The rate at which this occurs and the degree of mechanical degradation depend on the polymer's intrinsic properties, including its chemical composition, crystallinity, and surface features.

- Zendura FLX: Among the materials studied, Zendura FLX displayed exceptional resistance to water-induced degradation. This resistance is likely due to its waterproof layer, which acts as a barrier to water penetration. The waterproof layer significantly reduces the rate of water absorption, preserving the material's tensile strength even after prolonged exposure to liquids. This feature makes Zendura FLX particularly suitable for patients who regularly clean their aligners with mouthwashes or other solutions.
- Duran Plus and Erkodur-AL: These aligners, composed of polyethylene terephthalate glycol (PETG) and similar polymers, exhibited notable strength degradation attributed to their water absorption properties. PETG is known for its high chemical resistance; however, its susceptibility to water absorption compromises its mechanical integrity over time. The absorbed water disrupts the polymer chains, increasing flexibility but decreasing overall tensile strength. Erkodur-AL showed greater susceptibility compared to Duran Plus, suggesting differences in their polymer structures and manufacturing processes.

The strength degradation seen in this study is consistent with other research examining the long-term behavior of polymers in moist environments. Water absorption not only affects mechanical properties but also reduces the polymer's glass transition temperature (Tg), further enhancing molecular mobility.[16] This increased mobility contributes to stress relaxation within the material, resulting in a flattened stress-strain curve and reduced resistance to tensile forces.

Understanding the impact of water absorption on aligner materials underscores the importance of selecting polymers that balance mechanical strength, flexibility, and resistance to environmental factors. For aligner wearers, these findings highlight the need for proper maintenance practices, such as limiting prolonged exposure to liquids and storing aligners in appropriate conditions.

Clinical Implications:

The findings highlight key considerations for clinicians and patients:

1. Material Selection: Among the three materials, Zendura FLX demonstrated the highest tensile strength under all conditions, suggesting it is the most resilient and durable option for orthodontic aligners, particularly for patients who frequently use disinfectant.
2. Effect of Prolonged Exposure: While short-term exposure to disinfectants had minimal impact, prolonged exposure (7 days) resulted in a measurable decline in tensile strength. This highlights the potential for material degradation over time with regular use of mouthwashes.
3. Disinfectant Selection: Although the type of disinfectants did not result in statistically significant differences in tensile strength within the same material, variations in the degree of reduction suggest that some solutions (e.g., H_2O_2) may be less aggressive than others (e.g., CHX) over extended periods.
4. Maintenance of Aligners: Patients should be advised to minimize prolonged or frequent exposure of their aligners to disinfectant to preserve their mechanical properties. Regular rinsing with distilled water and storing in artificial saliva may help mitigate tensile strength loss.

Limitations of the Study:

1. In Vitro Design: This study was conducted under controlled laboratory conditions, which may not fully replicate the oral environment, including variations in pH, temperature, and microbial activity.
2. Exposure Protocol: The immersion protocol may not accurately reflect real-world usage patterns, where aligners are typically exposed to saliva and disinfectant intermittently.
3. Sample Size: A larger sample size might provide greater statistical power and reduce variability in results.

Future Directions:

To build on these findings, future research should:

1. Investigate the combined effects of additional factors such as thermal cycling, pH fluctuations, and microbial colonization on aligner tensile strength.
2. Conduct clinical studies to validate the in-vitro findings and assess long-term aligner performance in patients.
3. Explore alternative aligner materials and coatings that may enhance resistance to tensile strength degradation.

Conclusion:

The study demonstrates that Zendura FLX exhibits superior tensile strength compared to Duran Plus and Erkodur-AL, both in short-term and prolonged exposures to commonly used disinfectants. While disinfectants type does not significantly affect tensile strength within the same material, prolonged exposure reduces material durability. These findings underscore the importance of material selection and proper aligner maintenance in orthodontic practice.

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