DOI: 10.4274/TurkJOrthod.2023.2022.176

TURKISH JOURNAL OF ORTHODONTICS

Original Article

Investigation of the Mechanical Properties of Thermoplastic Materials Influenced by Different Chemicals

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Cite this article as: : Asefi S, Nejatifard M, Kayyal S, Shahabi S. Investigation of the Mechanical Properties of Thermoplastic Materials Influenced by Different Chemicals. *Turk J Orthod.* 2024; 37(2): 91-97

Main Points

- Chemical solutions do not significantly affect the aligners performance or chemical composition.
- Orange juice and Cola should be avoided because of their cariogenic capability and not because of adverse effects on aligner performance.
- Chlorhexidine mouthwash can be used during clear aligner treatment without side effects.

ABSTRACT

Objective: The quality of orthodontic forces in aligners is mainly influenced by their mechanical properties. At present, there is insufficient information on how environmental factors affect the mechanical function of aligners, and studies have shown that patients do not pay enough attention to removing aligners while eating and drinking. Therefore, in this study, we investigated the effect of different chemicals on the mechanical properties of thermoplastic materials.

Methods: In this study, 175 thermoplastic samples from Easy-Vac gasket (3A Medes, Korea) were prepared, and their chemical composition, tensile strength, and hardness before and after exposure to solutions of orange juice, Cola, chlorhexidine mouthwash, and distilled water were measured. One-Way analysis of variance (ANOVA), Tamhane's test, and Tukey's test were used for statistical analysis.

Results: The tensile strength of the sheets increased with continuous exposure to orange juice and chlorhexidine mouthwash, and their hardness decreased with continuous exposure to carbonated beverages. There was no change in the chemical composition of the samples after exposure to different chemicals.

Conclusion: Although these changes are statistically significant, they do not have a significant effect on the result of aligner performance. Therefore, the only concern is the cariogenicity of orange juice and Cola during treatment with aligners and the administration of chlorhexidine mouthwash.

Keywords: Tensile strength, hardness, fourier transform infrared spectroscopy, clear aligner, chlorhexidine, solutions, dentistry, orthodontics

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Received: December 25, 2022 **Accepted:** April 27, 2023 **Publication Date:** June 30, 2024

INTRODUCTION

The appearance of orthodontic appliances plays a vital role in patient acceptance of treatment and satisfaction.[1,2] Many patients do not accept the metallic appearance of fixed orthodontic treatment and seek another alternative treatments to have a beautiful smile. Recent surveys have shown that only 33% of people who need orthodontic treatment are willing to undergo treatment using brackets.[3,4] Clear aligners are preferred by adults because of their aesthetics and comfort compared to fixed orthodontic treatment[5], as well as their mobility, convenience of hygiene, reduced chair time and longer intervals between visits to the orthodontists.[1,6]

Unlike traditional instruments, the quality of orthodontic forces in clear aligners is more influenced by the mechanical properties created during manufacturing.[7-9] Thermoplastic materials have a viscoelastic and changeable nature, making them prone to stress relaxation. Previous laboratory studies have shown a rapid decrease in these appliances' force productivity due to stress relaxation. Ideal properties of aligners include biocompatibility, translucency, good elasticity, strength, and stability in the oral environment.[10] Research has shown that the treatment outcome is strongly related to the physical properties of the aligners. Clear aligners with higher hardness, used for two weeks of activity time, have shown the best results in improving tooth alignment and smoothing.[11]

In addition to the initial mechanical properties, oral environmental conditions over time may affect the properties of materials, such as reduced force-bearing capacity and the effectiveness of treatment.[8,12] Despite the high level of precision during manufacture, the original shape and composition of the aligners in the mouth do not remain stable during use and change slowly. Although these materials are biocompatible, they are not inert. They are affected by various factors such as the consumption of food and coloring beverages, mouthwashes, organic and inorganic liquids, heat, moisture, long-term contact with salivary enzymes, inhaled gases, trauma from swallowing, speaking, and bruxism.[13,14]

Despite the significant impact of the physical properties of aligners on treatment success, there is currently insufficient information on how environmental factors affect the mechanical performance of aligners.[12,15] To prevent mechanical damage to the aligners, patients are advised to avoid eating and drinking while using the aligners. However, studies show that patients' compliance with removing orthodontic appliances is insufficient[16,17], which is often a concern for orthodontists.

There have been advanced developments in digital treatment planning by recent software and 3D printers, making clear aligner therapy easily accessible to clinicians and laboratories. The patent for this technology was originally held by Align technology, but today, it is available to others. Therefore, local laboratories can also use digital software and 3D printers to simulate treatment stages. However, they still need to use commercial thermoplastic materials to fabricate clear aligners. Previous studies have usually evaluated well-known aligners like Invisalign, whereas there is insufficient evidence about other commercial thermoplastic materials.[14,15,18,19] The manufacturer's information may be the only data available for clinicians or laboratories who want to use these thermoplastic materials as clear aligners.

To provide evidence to patients and orthodontists about clinical considerations and instructions for use, as well as inform manufacturers to improve the quality of their products and eliminate scientific shortcomings related to clear aligners, this study aimed to evaluate the mechanical properties and chemical composition of clear aligners after exposure to various chemical liquids *in vitro*. The null hypothesis was that there would be no change in the tensile strength, hardness, and chemical composition of aligners under different chemicals.

METHODS

According to the results of the study by Schuster et al.[20], considering $\alpha=0.05$ and $\beta=0.2$, an average standard deviation of 20 MPa, and an effect size of 0.46 using the One-Way ANOVA power analysis option of PASS 11 software (NCSS LLC, Utah, USA), the minimum sample size for each of the five study groups was estimated to be 13 samples for the tensile strength and hardness test and 5 samples for the Attenuated Total Reflectance- Fourier test Transform InfraRed (ATR-FTIR) test.

The research's executive protocol was reviewed and approved by the Institutional Research Ethics Committee, School of Dentistry-Tehran University of Medical Sciences (approval no.: IR.TUMS.DENTISTRY.REC.1398.089, date: 31.07.2019).

Thermoplastic sheets specifically for making aligners (Easy-Vac gasket, 3A Medes, Korea) with the same thickness were vacuum-formed in the laboratory using a vacuum form Easy-Vac machine (3A Medes, Korea) with a thickness of 0.75 mm on a glass plate with dimensions of 8×8 cm. In this experiment, five groups of 35 samples (each group included 15 samples in the form of an hourglass for the tensile strength test, 15 samples in the form of a square for the hardness test, and 5 samples in the form of a square for the ATR-FTIR test) were used.

Four of the five experimental groups were randomly placed in each of the following four vessels for 22 hours a day; 2 hours were considered for eating, drinking, or hygiene time over 14 days in an incubator at 37 °C (totaling 308 hours) to replicate conditions similar to oral conditions. The exposure time to chemical solutions may be longer than real conditions. Still, there is no consensus among experts on the exact exposure time since each patient has individual behavior in following the clinician's orders. Additionally, we wanted to detect influences under the most severe conditions, which may be identified by measurements

Container 1: Contains 100 mL of industrial orange juice (SunStar, Zarrin Jam Marina manufacturer, Kashan, Iran)

Container 2: Contains 100 mL Cola (Coca-Cola, Khoshgvar Company, Semnan, Iran)

Container 3: Contains 100 mL chlorhexidine mouthwash (chlorhexidine najo, Iran Najo company, Tehran, Iran)

Container 4: Contains 100 mL of distilled water (Zalal Teb Shimi Company, Karaj, Iran)

Container 5: Specimens were placed in a dry container and considered the control group.

The samples were removed from the solutions twice a day, washed under running water each time, and dried with a rapid flow of air. They were kept out of the solution for 1 hour and returned to the solution. This process simulated the removal of the aligners from the mouth while eating and performing health care.To measure the tensile strength, samples (75 mm long and 10 mm wide) were designed on both sides using SolidWorks software according to ISO 527-2-1BA and cut using a CO2 laser cutting machine (Figure 1), and 75 specimens were prepared. The specimens were randomly divided into five groups of 15.

After storage in each group's solution, the tensile force was applied to samples with the same thickness and hourglass shape at a constant speed of 5 mm/min while they were held at the same distance by the clamps of the universal testing machine (Zwick/Roell Z050, Germany). The samples torn in the middle area were considered acceptable, and the force applied to each sample was calculated in newtons. The increase in the length of each sample at the time of tearing was also calculated by measuring the length of each sample before and after tearing using a caliper with a reading accuracy of 0.01 mm. Samples that did not rupture in the middle region were excluded from the experiment and retested.

To evaluate the chemical composition, 25 samples were prepared in a square shape with dimensions of 1×1 cm and were randomly divided into five groups of five. After storing each group's solution, the groups were placed in an ATR-FTIR device (Nicolet 10, Thermo Scientific, USA) to study their chemical composition. In this device, the infrared light spectrum is irradiated on the specimens. Subsequently, this device calculates the absorption or emission spectrum of the infrared radiation that crosses through or reflects the specimens.

To measure microhardness, 75 samples were made in a square shape with dimensions of 1×1 cm and were randomly divided into five groups of 15. Fifteen samples from each group were subjected to the Vickers microhardness test (Bareisis, Germany). Each specimen was exposed to the diamond sink of the machine with an internal angle of 136°. Force was applied to each specimen at least three points, at a distance of 50 µm from each other and the edges of the specimen. The applied force was 10 mN, which was applied for 10 s, held for 1 s on the sample surface, and then removed for 10 s. The hardness of the sample was measured by calculating the diameters of the square impressions left on the sample under a microscope and reported with the Vickers hardness number (VHN). The mean numerical value obtained from the three indents was reported as the hardness number.[21] To reduce errors, all measurements were performed under the same conditions by a person blinded to the groups.

Statistical Analysis

Statistical analyses were performed using SPSS software version 22 (IBM, USA). A One-Way ANOVA test was used to evaluate the significant differences in the tensile strength and hardness test measurements. A significant level for p-value was considered to be 0.05. Levene's test was used to determine data normality.

Then, Tamhane's test was used to compare tensile strength between different study groups. Moreover, to measure the significant difference between the hardness tests groups pairwise, the Tukey Honest Significant Difference test was used because the data scatter was not significantly different from each other (p=0.31).

The ATR-FTIR test, which was used to evaluate the chemical composition, did not require specific statistical analysis because of the similar chemical composition of all samples.

RESULTS

The tensile strength comparisons between the groups distilled water, Cola, and dry groups, respectively are presented in Table 1 and Figure 2. One-Way ANOVA showed a significant difference in tensile strength between the groups (p=0.021). Chlorhexidine and orange juice have significantly higher tensile strength than the dry group (p<0.05), whereas this difference was insignificant in the other groups.

According to the FTIR results, which showed the number of molecular changes in the studied substance upon contact

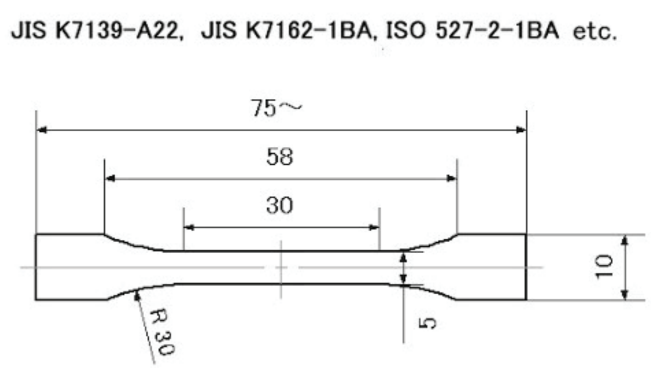

Figure 1. Standard shape of tensile strength specimens (measures are in mm scale)

with the mentioned chemicals, all groups showed the same peaks. The sum of the peaks indicates the characteristics of the following clauses:

OH (3380 cm^{-1}), NH (3313 cm^{-1}), aromatic C-H (3047, 1605, 1597, 812, 766 cm^{-1}), CH (2928, 2853, 1413, 915 cm^{-1}), C=O (1728, 1308 cm^{-1}), amide I (C=O of NCO, 1698 cm^{-1}), amide II (NH and C=O of NCO, 1518 cm^{-1}), C-O (1214, 1205 cm^{-1}), and C-O-C (1100-1060 cm^{-1}).

The total of these clauses indicates the urethane-based structure of the material under study. In fact, the observed molecular formula is a polyurethane thermoplastic material, which remained unchanged during contact with the mentioned materials.

The mean hardness was highest in the dry group, approximately 11.85 Newtons, followed by distilled water, orange juice, chlorhexidine, and Cola (Figure 3 and Table 2). One-Way ANOVA revealed a significant difference between the groups ($p<0.001$).

In the post hoc analysis, all groups were compared with the dry group. The Cola group showed a significant difference in hardness compared to the dry group ($p<0.001$), but this difference was not significant in the other groups.

DISCUSSION

Clear aligners should have certain physical characteristics to ensure clinical performance. Ideally, a thermoplastic aligner should have an acceptable tensile strength to apply the required force within the appropriate elastic range during the treatment period and high hardness to provide sufficient resistance against teeth and oral tissues, thereby preventing thinning and deformation.[19] As the aligner's hardness decreases, cracks may appear on the appliance surface, which can affect its performance during the treatment period.[22] Therefore, factors such as the manufacturing temperature of aligners[7,23], the temperature of foods or drinks consumed while using the appliance, and intraoral temperature can all affect the aligner's hardness.[2]

Despite the significant impact of the physical properties of aligners on treatment success, there is currently insufficient information on how environmental factors affect the mechanical performance of aligners.[12,15] Most existing studies have examined the effect of intraoral aging on the mechanical properties of aligners. Therefore, the findings of this study are novel and of great importance in the production of aligner sheets and recommendations for orthodontic treatment. In addition, it serves as a valuable guide for researchers to conduct more extensive studies in this field.

This study tested the accuracy of the tensile strength, hardness, and chemical composition of the Easy-Vac gasket thermoplastic

Table 1. Comparison of tensile strength of each experimental group by One-Way ANOVA test ($p<0.05$); Tamhane's test is used to compare groups pairwise

	Groups	Mean (n) ± Standard deviation
Tensile strength	Orange juice	$53.41^{\beta}\pm7.69$
	Cola	48.42 ± 6.35
	Chlorhexidine	$54.65^{\alpha}\pm7.46$
	Distilled water	51.96 ± 11.44
	Dry	$46.12^{\alpha,\beta}\pm4.56$

Symbols ($^{\alpha,\beta}$) shows significant difference between groups

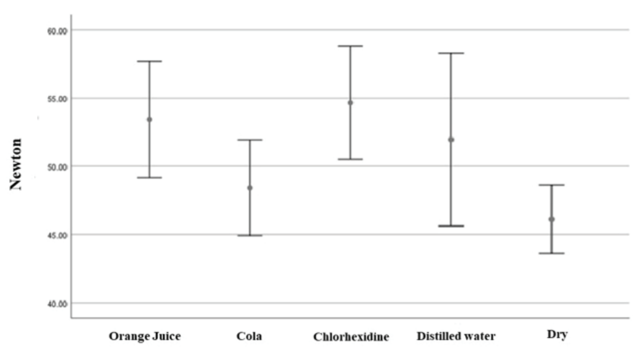

Figure 2. Tensile strength of each experimental group

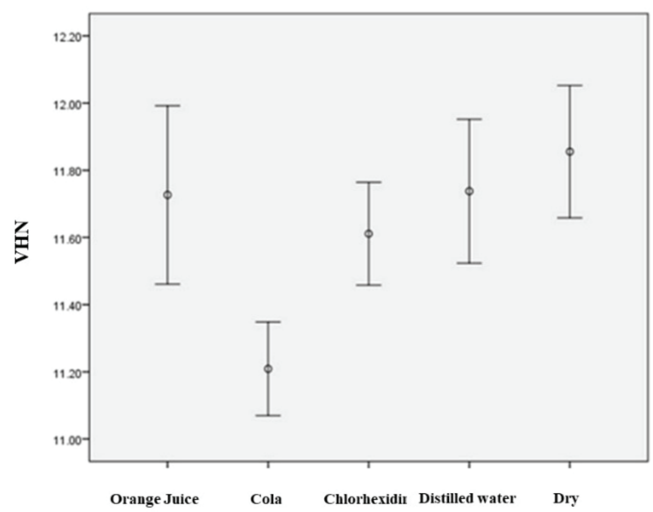

Figure 3. Hardness of each experimental group

Table 2. Comparison of hardness of each experimental group by One-Way ANOVA test ($p<0.05$); Tukey HSD test is used to compare groups pairwise

	Groups	Mean (VHN) ± Standard deviation
Hardness	Orange juice	11.72 ± 0.47
	Cola	$11.20^{\alpha}\pm0.25$
	Chlorhexidine	11.61 ± 0.27
	Distilled water	11.73 ± 0.38
	Dry	$11.85^{\alpha}\pm0.35$

Symbol ($^{\alpha}$) shows significant difference between groups
VHN, Vickers hardness number; HSD, Honest significant difference

sheet after exposure to carbonated beverages, orange juice, chlorhexidine mouthwash, and distilled water. The reason for not using artificial saliva as a group is the possibility of the effect of chemical compounds of artificial saliva on different properties of aligners because the composition of artificial saliva is not the same as that of natural saliva and can have harmful effects on the properties studied in this study. Additionally, dry specimens were considered a control group. After all, their mechanical properties are the most reliable data in the *in vitro* study. They can be used in future studies as basic information for clinical evaluation or study design. Simulation of the oral environment cannot be achieved reliably in an *in vitro* study design. It may come to mind that a group immersed in distilled water or artificial saliva should be considered a control group; however, the composition of these solutions is completely different from that of an oral fluid with enzymes, microorganisms, and fluctuations in temperature or PH. Thus, we considered dry specimens a reliable control group in the *in vitro* study design.

In this study, the tensile strength of specimens exposed to chlorhexidine mouthwash and orange juice increased, whereas that of samples exposed to Cola and distilled water did not change.

In the results of Ryokawa et al.'s[24] study, tensile yield stress decreased in all eight thermoplastic products under the *in vitro* condition. Factors affecting these properties include changes in temperature and saliva and intraoral aging. Gould et al.[25] examined the physical properties of mouth guards at 23 °C and 37 °C (mouth temperature). Hardness, water absorption, and tensile strength levels were examined according to mouthguard standards in five common market brands (Essix™ Resin, Erkoflex™, ProForm™-regular, Proform™-laminate, and PolyShok™). The results showed that the tensile strength decreased with increasing temperature. Temperature was the influencing factor on these properties. Ihssen[12] confirmed the Ryokawa[24] and Gould[25] test results for temperature change and intraoral aging on tensile strength.

These studies show that intraoral aging can decrease tensile strength in clear aligners, which contrasts with the results observed in the chlorhexidine and orange juice groups, where tensile strength increased. This study result is consistent with Ahn's[26] study, which revealed that intraoral aging increases the ultimate tensile strength of polyethylene terephthalate glycol (PETG) vacuum retainers. Although this increase was statistically significant, it is not enough to affect the performance of clear aligners; therefore, its impact can be ignored.

The results of the FTIR test showed that the structure of the studied thermoplastic material was based on polyurethane, and its molecular formula did not change after being placed in chemical solutions. Gerard Bradley et al.'s[14] study compared the effect of intraoral aging on the mechanical and chemical properties of Align Technology brand aligners used by the patient for 44 days with unused aligners from the same brand as control. The results showed no change in the chemical composition of the aligners before and after consumption. Other studies[17,27] have confirmed this result. Ahn[26] also implied that intraoral aging does not change the biochemical composition of PETG vacuum retainers. These studies are consistent with our study. This means that environmental factors do not affect the chemical composition of clear aligners, either *in vivo* or *in vitro*.

In our study, the hardness test results showed that the hardness of the samples exposed to carbonated beverages decreased, but the hardness of the samples in solutions of orange juice, chlorhexidine, and distilled water did not change. Condo' et al.[16] revealed that the crystal structure of aligners changes due to the heat of the mouth and the application of orthodontic forces, which increases the hardness and hyperplasticity after use. Gould et al.[25] showed that the degree of hardness decreased with increasing temperature from 23 °C to 37 °C (oral temperature). These results were also confirmed by Gerard Bradley et al.'s[14] study.

Although the hardness test results in our study in the carbonated beverage group were statistically significant, it is not enough to affect the performance of clear aligners, so their effect can be ignored. Chlorhexidine mouthwash and orange juice also did not affect the hardness of the aligner.

In summary, the results of our study showed that the tensile strength, hardness, and chemical composition of clear aligners could be influenced by different chemicals; however, these changes are negligible. The implications of future research are conspicuously felt. This report evaluated the tensile strength, ATR, and hardness. Future studies are needed to test other important characteristics such as flexural strength[28], fatigue[29], roughness[30], and color stability[31] to complete the knowledge about these thermoplastic materials.

Study Limitations

Our study has limitations, such as evaluating only one thermoplastic material, and being conducted under *in vitro* conditions. It is suggested to investigate other thermoplastic materials and different commercial products and design future studies to stimulate the oral environment or conduct studies *in vivo* conditions.

CONCLUSION

Beverages consumed by patients do not change the chemical composition of the thermoplastic sheets, but they do alter the tensile strength and hardness of the sheets. Although these changes are statistically significant, they are too negligible to cause problems in the treatment process. Therefore, the only concern is the cariogenicity of these drinks (orange juice and carbonated beverages) during treatment with aligners.

Chlorhexidine mouthwash is also safe during the treatment process.

Ethics

Ethics Committee Approval: The research's executive protocol was reviewed and approved by the Institutional Research Ethics Committee, School of Dentistry-Tehran University of Medical Sciences (approval no.: IR.TUMS.DENTISTRY.REC.1398.089, date: 31.07.2019).

Informed Consent: This study was designed as an experimental *in vitro* study, therefore informed consent is not involved for this study.

Author Contributions: Concept - S.A., S.S., Design - S.A., S.S., Supervision - S.A., Materials - S.K., Data Collection and/or Processing - S.K., Analysis and/or Interpretation - S.A., M.N., S.K., Writing - S.A., M.N., Critical Review - S.A.

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

Financial Disclosure: The authors declare that this study has received no financial support.

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