

Original Article

Analysis, Comparison and Evaluation of the Microhardness and Elasticity of Thermoformed Polyurethane Sheets Used for Treatment with Aligners in Different Brands

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Abstract - The present *in vitro* study aimed to analyze the mechanical (flexural and Microhardness) and optical (color stability) properties of three commercial thermoformed polyurethane sheets used in orthodontics: Essix ACE,® Duran® and Taglus®. These properties, which are crucial for the clinical efficacy of aligners, were evaluated and compared to provide orthodontists with relevant information for selecting the most suitable material for each patient. The results revealed significant differences in mechanical properties between the three brands, suggesting that the choice of material may influence the effectiveness of the treatment. Duran® presented the highest flexural modulus, while Taglus® exhibited the highest Microhardness. Additionally, the color stability of the sheets was evaluated when immersed in different coloring substances, including red wine, orange juice and Fanta®. Red wine produced the greatest color alterations in the materials, a factor to consider for patients. In conclusion, the selection of material for aligner manufacturing should consider not only strength and durability, but also color stability, as well as other factors such as patient comfort. This study provides valuable information on the characteristics of different thermoformed polyurethane sheets, which can be useful for orthodontists to make more informed decisions when selecting the material to manufacture aligners.

Keywords - Aligners, Orthodontics, Thermoformed sheets, Properties, Stability.

1. Introduction

The aligner market has grown significantly due to the increasing demand for invisible and aesthetic orthodontic treatments. The tooth is gradually moved to its predetermined position by these highly aesthetic and efficient systems [1]. The creation of the aligners is based on the control of a specialized system that simulates the movement of the teeth using anatomical data from digital scans or Computed Tomography (CT) [2]. After that, an impression of the stereolithography model is made, which is then sent to a lab to record individual tooth movements [3].

Many orthodontists have begun producing clear aligners using Computer-Aided Design/Computer-Aided Manufacturing (CAD/CAM) technology in response to the growing demand for clear aligners among adult patients. To express desired tooth movement, dentists create clear aligners for dental models using various commercially available thermoplastic materials [4]. Different materials are used in the manufacturing process. The properties of the material, the thickness and the adaptability of the appliance to the teeth and/or brackets are factors that influence its

biomechanical effectiveness [5]. To get the teeth moving, they use both time and force [6]. The thickness of the leveler is determined by the dispenser, which can range from 0.50 to 1.5 mm [7]. Orthotics made of thicker material generate more force than those made of thinner material, so as the above characteristics change, the material's properties tend to change [8, 9]. The thickness is directly related to the amount of force generated. Manufacturers provide different materials and instructions, but the orthodontist must research the characteristics of the material to make a wise choice. Essix Ace is a polyethylene terephthalate copolymer produced by Dentsply Raintree Essix in York, Pennsylvania. Many different types of foils are available on the market to make aligners. Proaligner X has various thicknesses of 0.75 mm, 0.88 mm, and 1.0 mm [9, 10], with various thicknesses of 0.76 mm and 1.0 mm in the middle. Nowadays, orthodontic treatment with aligners is part of the main activities of dental health. Despite this reality, not many studies analyze the Microhardness and elasticity of thermoformed polyurethane sheets used for treatment with aligners. We will analyze these characteristics of 3 different brands, which are the most used in the market.



A proper advancement of orthodontic techniques needs to understanding the properties of thermoformed polyurethane sheets used to manufacture removable aligners for orthodontic treatment. Unlike fixed appliances, the orthodontic force exerted by thermoformed sheets differs from that of fixed orthodontics using metal devices.

This research will allow us to determine the Microhardness of thermoformed polyurethane sheets used in orthodontic treatment, allowing the clinician to use the materials in orthodontics with aligners to their maximum potential.

For the comparison analysis of the microhardness characteristics of Microhardness, an in vitro study was carried out. It was analyzed with the microdurometer, and the elasticity will be measured using the universal machine. With the results obtained, it will be possible to choose the polyurethane sheet that best adapts and responds to the mechanical requirements of each orthodontic treatment with aligners, ensuring the success of orthodontic treatments.

2. Related Jobs

Koenig N, et al. (2022) conducted research to compare the dimensional accuracy between aligners manufactured by direct 3D printing and those made by thermoforming. To do so, they used the Same Digital File (STL) to create three types of aligners: two thermoformed with Zendura FLX and Essix ACE materials, and one printed directly with TC-85DAP UV resin using a Tera Harz 3D printer. The results indicated that the aligners obtained by direct printing offered greater accuracy and fidelity to the original model compared to the thermoformed aligners [4].

Bucci R. and others (2019). He evaluated the uniformity of the thermoforming process regarding aligner thickness and changes in aligner thickness after 10 days of use in the mouth. 18 patients (average age 28.8 +/- 9.6 years, 5 males, 13 females) were evaluated simultaneously. Before intraoral exposure (T0), the thickness of different occlusal sites in a 3D model was assessed using specialized software (Geomagic Qualify 2013; 3D Systems, Rock Hill, SC, USA). After ten days of receiving the used aligners, the researchers concluded that the thermoforming technique is reliable for both active and passive aligner configurations, taking thickness variations into account. Furthermore, in a sample of healthy adults, the studied CAs exhibit significant thickness stability after intraoral physiological ageing [5].

Edelmann A, et al. (2020). They looked at the impact of the thickness of the digitally designed aligner on the thickness of the corresponding 3D printed aligner. Resins from a 3D format 3D printer, 3D 3D resins, Dental LT (N510 per group) and Grey V4 (N510 per group) were used to 3D print digitally designed aligners in 2 different thicknesses (0.500mm, 0.750mm, and 1,000mm). Stereolithography. A contrast spray was used to cover the Dental LT aligners, and an optical scanner was used to scan them. They concluded that producing clear aligners directly using 3D printing and workflow resulted in increased

thickness, which can have a negative impact on the clinical utility of aligners [8].

Dalaie et al. (2021) evaluated the thermomechanical properties of aligners made of polyethylene terephthalate glycol (PETG), specifically the Duran and Erkodur brands, after the thermoforming process and subsequent simulated ageing. Ninety-six samples were analyzed, divided into three groups: control (C), after thermoforming (T), and after thermoforming with ageing (TA). Thermoforming was carried out using 3D-printed molds, after a 24-hour immersion in distilled water at 37°C, and ageing consisted of 200 thermal cycles. A significant decrease in the flexural modulus (88% for Duran and 70% for Erkodur) and hardness (22% and 7.6%, respectively) was observed. Furthermore, the glass transition temperature (Tg) was reduced in both materials. Regarding the elastic modulus, Duran showed significant changes after ageing, while Erkodur's changes occurred after thermoforming, remaining stable thereafter. The viscous modulus and loss factor showed similar variation patterns: both increased after thermoforming, but did not change significantly after ageing. In summary, thermoforming considerably impacted the reduction of thermomechanical properties. This effect was accentuated with ageing, although Duran and Erkodur generally demonstrated good thermomechanical stability [11].

Golkani et al. (2022) analyzed how the mechanical properties of dental aligner foils changed after thermoforming using materials from three manufacturers and using three-point bending tests. They divided the samples into two groups: one non-thermoformed and the other thermoformed into cubes. They then measured the forces, thickness reduction, Young's modulus, and corrected forces after stretching. Essix®PLUSTM exhibited the highest initial force, followed by Duran Plus®, Essix ACE®, and Zendura®. After thermoforming, a significant reduction in thickness and strength was observed, especially in the lateral regions, and the Young's modulus decreased markedly in Essix®PLUSTM. They concluded that the three-point bending test was useful in evaluating the properties of thermoformed foils and that the thermoforming process significantly affected their mechanical behavior [12].

Shakir H, et al. (2018) conducted a study to evaluate the mechanical properties of three thermoplastic materials used to manufacture orthodontic aligners, focusing on hardness and elastic modulus. Hardness was measured using the Shore D test, following the ISO 7619-1:2010 standard and complying with the ASTM D2240-05 guidelines, using ten samples of each material. To determine the elastic modulus, tensile tests were performed using a universal machine, applying the ASTM D638-02a standard for sheets 1 mm or thicker and ASTM D882-02 for those less than 1 mm, with ten samples per material. The results indicated no significant differences in hardness between the three brands analyzed. However, regarding the elastic modulus, the 0.8 mm Leone material showed lower values than the 0.5 mm clear aligner

and the 1 mm Duran. In conclusion, although the three materials have similar hardness, the 1 mm Duran and the 0.5 mm transparent aligner show a significantly higher elastic modulus than the 0.8 mm Leone, with no appreciable differences between them [13].

Albertini et al. (2022) studied the stress relaxation of five different thermoplastic aligner materials subjected to continuous deflection for 14 days, evaluating their stiffness, stress-strain curve, and yield strength. Single- and double-layer samples were used; single-layer samples showed similar properties, while double-layer samples had significantly lower but similar stiffnesses. Over 15 days, F22 Evoflex and Erkoloc-Pro materials reached high stress levels, while Duran and Durasoft recorded the lowest values for both maximum and normalized stress.

All materials showed a rapid decrease in stress in the first few hours, followed by stabilization over time. F22 Evoflex stood out for maintaining the highest maximum stress and constant stress release over the 15 days of testing. It is concluded that further studies after in vivo ageing are needed to understand the real behavior of aligners during orthodontic treatment, although F22 Evoflex showed superior performance in maintaining stress [14].

Zinelis et al. (2022) evaluated how different 3D printing methods influence the mechanical properties of orthodontic aligners. A dental resin was used with five commercial 3D printer models. The aligners were prepared and analyzed according to ISO14577-1:2002 to measure Martens Hardness (HM), Indentation Modulus (EIT), and Creep Index (IT). Generalized linear regressions were used to compare results. Significant differences in mechanical properties were found between aligners produced by different printers, with better results for models with DLP technology compared to LCD ones. MIC showed greater hardness than PRO. The mechanical properties of aligners vary depending on the 3D printer used, which may affect their performance in orthodontic treatments [15].

Ryun J-H et al. (2021) performed a multiscale analysis to evaluate how thermoforming affects the physical and mechanical properties of thermoplastic materials used in Clear Orthodontic Aligners (TOAs). Samples with four types and thicknesses of thermoplastic materials were fabricated using thermal vacuum, and tests were performed on tensile, flexural, transparency, water absorption, solubility, and surface hardness. Data were analyzed using ANOVA and Student's t-tests. After thermoforming, transparency decreased for Duran and Essix A, but water absorption increased for all materials, solubility increased for some, and surface hardness increased for Duran and Essix A. The flexural modulus increased in 0.5 mm samples, but not at greater thicknesses. The elastic modulus also varied by material and thickness. It is concluded that it is essential to evaluate the physical and mechanical properties of thermoplastic materials after thermoforming to ensure their suitability for clinical applications [16].

Prashant Jindal and others (2019). The researchers used 3D printing and modeling techniques to analyse compressive mechanical characteristics and geometric inaccuracies between traditionally manufactured thermoformed Duran clear dental aligners and clear aligners made from Dental Long Term (LT) resin via 3D printing. In comparison to thermoformed aligners (4.41 percent), 3D printed cured clear dental aligners exhibited greater geometric accuracy, with an average relative difference in tooth height of 2.55 percent. For the height measurements of the teeth from all observers regarding both types of aligners, minimal standard deviations (0.03–0.09 mm) were noted.

Thermoformed aligners could endure a force of 105 N for a movement of 2.93 mm, whereas aligners made with 3D printing could handle a peak load of nearly 662 N. Thermoformed aligners experience plastic and irreversible deformation at larger displacements; 3D printed aligners show elastic deformation with reversibility at smaller displacements.

Conclusions: Given that 3D printed Dental LT resin clear dental aligners are geometrically superior and cure effectively, it is recommended that they are better suited for patient application. This creates a chance to decrease processing duration while guaranteeing that an aligner is more mechanically robust and flexible than comparable thermoformed clear dental aligners made from thermoplastic [17].

3. Materials and Methods

Research method: Deductive.

Research approach: Quantitative.

Type of research: Applied.

Research design: Experimental in vitro.

3.1. Population, Sample and Sampling

3.1.1. Population

We will work with a group of 6 slides because the design is experimental in vitro.

Inclusion Criteria

- Thermoplastic PET-G sheets
- Sheets from the same batch
- Essix Ace, Taglus and Proaligner brand films
- Blades without imperfections, wear or deformation
- Thicknesses established according to the availability of manufacturers
- Plates separated by an insulating sheet before the thermoforming process
- Pressure and temperature according to the thermoforming equipment
- Selected times to determine a standard deflection

Exclusion Criteria

- Other polymers are used to manufacture dental aligners.

3.2. Sampling

Sampling Type: Simple Random Probabilistic

$$n = \frac{2(Z_{\alpha} + Z_{\beta})^2 * S^2}{d^2}$$

It was determined using the statistical software Stata® v.

The formula goes or it does not, or explain the sampling.

3.2.1. Operational Definition

Microhardness of Thermoformed Sheets

Resistance offered by a material to the indentation of a diamond tip. Vickers

Elasticity of Thermoformed Sheets

The ability of a material to recover its original shape when the force that deformed it ceases.

Thermo Foil Markings

Foil brands that are available in the market.

Data Collection Techniques and Instruments

Technique: The in vitro technique will be used.

Equipment Description

A digital microhardness tester (SE-1000DT) will be used to measure Microhardness.

The universal materials testing machine (Zwick/ Roell ZmartPro, Zwick, Ulm, Germany) will be used to measure elasticity.

Validation: does not apply because the study is in vitro
Reliability: not applicable because the study is in vitro

Data Processing and Analysis Plan

4. Results

Table 1. Bending of the terformed sheets used for aligner treatment

Brand	N	Stocking Mpa	SD	Value p	95% confidence interval		Tukey		
					Inferior	Superior	Essix	Last	Taglus
Essix	20	76.4	8.39	< 0.001	72.5	80.4	---	---	---
Last	20	81.4	10.09		76.7	86.1	0.129	---	---
Taglus	20	71.1	4.47		69.0	73.2	0.101	<0.001*	---
*ANOVA (p<0.05)									

Table 1 shows the average values and standard deviations of the flexion of the thermoformed sheets used for treatment with aligners of the brand: Essix® 76.43 (8.39) Y; Taglus® 71.14 (4.47) Hv, and Duran® 81.41 (10.09) Hv. A statistically significant difference was found (p<0.05) when comparing the Duran® and Taglus® groups (p = 0.00). This can be physically visualized in Figure 1.

Table 2 shows the average values and standard deviations of the Microhardness of the thermoformed sheets used for treatment with the brand aligners are: Essix® 7.79 (0.11) Hv; Taglus® 8.96 (0.15) Hv, and Duran® 8.80 (0.08) Hv. A statistically significant difference was found (p<0.05) when comparing the Essix® and Duran® groups (p = 0.00), when comparing the Essix® and Taglus® groups (p = 0.00),

Procedure for Microhardness Testing

The aligner sample will be cut into 20 mm x 10 mm sections for microhardness analysis. Before attaching it to a glass slide, any adhesive film will be removed from its surface. The test will then be performed using a Micro Vickers Phase II 900-392B durometer. A load of 200 gf will be applied for 15 seconds, using 40x magnification to ensure proper visibility. After focusing, the lens will be replaced with the diamond indenter, and the test surface will be positioned perpendicular to apply the load. If the sample shifts, the evaluation will be repeated.

The indenter is then placed back on the 40x objective, and the left line is adjusted to touch the left end of the indentation. Once the right line is aligned, the value is set to zero and moved to the right end to obtain the first diagonal measurement. The eyepiece is rotated to an orthogonal position for the second diagonal, and the adjustment is repeated. Although Vickers hardness is typically reported in MPa or GPa, it is commonly expressed as a unitless integer. Finally, the diagonal length is entered, and the hardness is calculated based on the applied load and the average of both diagonals.

Procedure for Elasticity Testing

A standardized 3-point bending test setup integrated into a universal material testing machine (Zwick/Roell ZmartPro, Zwick, Ulm, Germany) will be used to examine the mechanical characteristics of aluminium sheets. The radius of curvature of the thrust matrix and the supports shall be 1 mm. The support points will be separated by 8, 16 and 24 mm. The displacements shall be chosen so that the visual examination of the material does not reveal plastic deformations or micro-cracks.

and finally when comparing Duran® and Taglus® (p = 0.00). This can be seen in Figure 2.

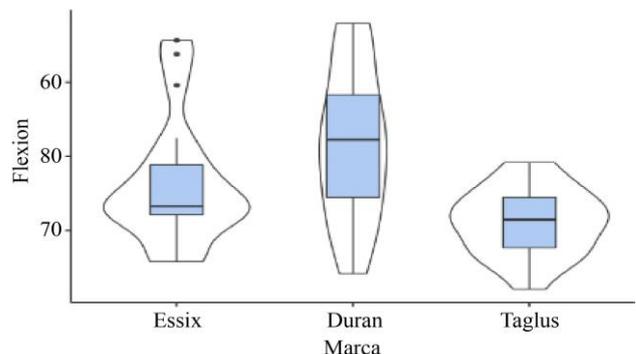


Fig. 1 Violin diagram showing the bending of each material

Table 2. Bending of the terformed sheets used for aligner treatment

Brand	N	Stocking Mpa	SD	Value P	95% confidence interval		Tukey		
					Inferior	Superior	Essix	Last	Taglus
Essix	20	7.79	0.11	< 0.001	7.74	7.84	---		
Last	20	8.79	0.08		8.76	8.83	< .001*	---	
Taglus	20	8.96	0.15		8.89	9.02	<.001*	<0.001*	---

*ANOVA (p<0.05)

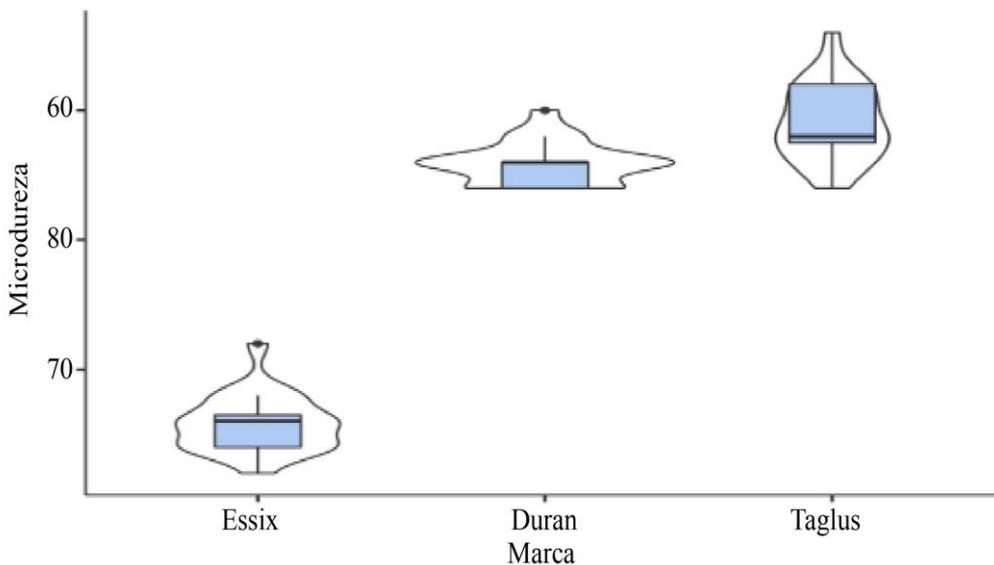


Fig. 2 Violin diagram showing the bending of each material

Table 3. Evaluation of the color stability of polyurethane thermoformed sheets (Essix ACE) used for treatment with aligners immersed in different coloring substances

Times	Solutions	Medium (ΔE)	D.S	Min.	Max.
Day 7	Distilled water	1,77	0,46	1,10	2,70
	Natural orange juice	5,65	1,02	4,70	7,70
	Artificial orange juice	5,53	1,02	3,40	6,90
	Fanta®	6,29	0,84	4,70	7,30
	Wine	8,59	1,28	6,90	10,70
Day 14	Distilled water	1,54	,50	,60	2,50
	Natural orange juice	6,90	1,60	5,00	9,80
	Artificial orange juice	6,32	1,86	4,20	9,00
	Fanta®	8,52	,81	7,10	9,70
	Wine	11,17	,93	9,70	13,00

Table 3 shows the data regarding the color stability of the Essix ACE terformed sheets, the highest values of the color difference were shown in the wine group at 7 days (8.59 ΔE) and 14 days (11.17 ΔE), followed by the Fanta® group at 7 days (6.29 ΔE) and 14 days (8.52 ΔE).

Table 4 shows the data regarding the color stability of the duran thermoformed sheets, for which the highest values of the color difference were shown in the wine group at 7 days (6.65 ΔE) and 14 days (7.40 ΔE), followed by the Fanta® group at 7 days (4.74 ΔE) and 14 days (5.78 ΔE).

Table 4. Evaluation of the color stability of duran polyurethane thermoformed sheets used for treatment with aligners immersed in different coloring substances

Times	Solutions	Medium (ΔE)	D.S	Min.	Max.
Day 7	Distilled water	,85	,40	,30	1,40
	Natural orange juice	4,58	1,82	1,60	8,60
	Artificial orange juice	4,47	,58	3,60	5,40
	Fanta®	4,74	,46	4,10	5,50
	Wine	6,65	1,89	4,30	9,90
Day 14	Distilled water	1,01	,60	,40	1,90
	Natural orange juice	5,79	2,32	1,60	9,70
	Artificial orange juice	5,61	,59	4,70	6,70
	Fanta®	5,78	,69	4,30	6,90
	Wine	7,40	,98	6,30	9,60

Table 5. Evaluation of the color stability of Taglus polyurethane terformed sheets used for treatment with aligners immersed in different coloring substances

Times	Solutions	Medium (ΔE)	D.S	Min.	Max.
Day 7	Distilled water	1,22	,57	,50	1,90
	Natural orange juice	5,12	,56	4,30	6,10
	Artificial orange juice	4,77	,89	2,70	6,00
	Fanta®	4,92	1,26	2,60	7,20
	Wine	4,87	,86	3,10	5,80
Day 14	Distilled water	1,26	,34	,80	1,80
	Natural orange juice	6,10	,45	5,40	6,80
	Artificial orange juice	6,01	,81	4,10	7,10
	Fanta®	6,11	1,01	4,80	7,90
	Wine	7,41	,62	6,10	8,30

Table 5 shows the data regarding the color stability of the Taglus thermoformed sheets, the highest values of the color difference were shown in the wine group at 7 days (4.87 ΔE) and 14 days (7.41 ΔE), followed by the Fanta® group at 7 days (4.92 ΔE) and 14 days (6.11 ΔE).

Table 6 shows the comparative data between the three different brands. In the Essix® brand groups, there is a statistically significant difference when comparing the 7 and 14 day times between the wine ($p < 0.00$) and Fanta®

($p < 0.00$) groups. In the Duran® brand, there is a statistically significant difference when comparing the 7 and 14-day times between the Fanta® ($p < 0.00$) and artificial orange juice ($p = 0.004$) group.

Finally, in the Taglus® brand groups, there is a statistically significant difference when comparing the 7 and 14-day times between the wine ($p < 0.00$), natural orange juice ($p = 0.001$), artificial orange juice ($p < 0.000$) and Fanta® ($p = 0.005$) groups.

Table 6. Comparison of the color stability of Essix ACE®, Taglus® and Duran® thermoformed polyurethane sheets immersed in different coloring substances

Times	Solutions	Day 7		Day 14		p
		Medium (ΔE)	D.S	Medium (ΔE)	D.S	
Essix®	Distilled water	1,77	,46	1,54	,50	,215
	Natural orange juice	5,65	1,02	6,90	1,60	,013
	Artificial orange juice	5,53	1,02	6,32	1,86	,183
	Fanta®	6,29	,84	8,52	,81	,000
	Wine	8,59	1,28	11,17	,93	,000
Last®	Distilled water	,85	,40	1,01	,60	,538
	Natural orange juice	4,58	1,82	5,79	2,32	,084
	Artificial orange juice	4,47	,58	5,61	,59	,004
	Fanta®	4,74	,46	5,78	,69	,000
	Wine	6,65	1,89	7,40	,98	,075
Taglus®	Distilled water	1,22	,57	1,26	,34	,751
	Natural orange juice	5,12	,56	6,10	,45	,001
	Artificial orange juice	4,77	,89	6,01	,81	,000
	Fanta®	4,92	1,26	6,11	1,01	,005
	Wine	4,87	,86	7,41	,62	,000

Table 7. Comparison of the color stability of Essix ACE® thermoformed polyurethane sheets at 7 and 14 days.

Times	Solutions	Natural orange juice	Artificial orange juice	Fanta®	Wine
Day 7	Distilled water	,005	,006	,000	,000
	Natural orange juice		,939	,290	,326
	Artificial orange juice			,326	,001
	Fanta®				,028
Day 14	Distilled water	,005	,017	,000	,000
	Natural orange juice		,701	,200	,001
	Artificial orange juice			,096	,000
	Fanta®				,040

Table 7 shows the results of the comparison of the thermoformed polyurethane sheets Essix Ace at 7 and 14 days, when comparing the groups of the Essix ACE® brand, a statistically significant difference was observed when comparing at 7 days between distilled water and the set of natural orange (p=0.005), distilled water and artificial orange juice (p=0.006). Distilled water and Fanta® (p<0.00), distilled water and wine (p<0.00), and finally

between artificial orange juice and wine (p = 0.001). At 14 days, a statistically significant difference was observed when comparing distilled water and natural orange juice (p=0.005), distilled water and artificial orange juice (p=0.017), distilled water and Fanta® (p<0.00), distilled water and wine (p<0.00), natural orange juice and wine (p=0.001), artificial orange juice and wine (p=0.00) and finally between Fanta® and wine (p=0.040).

Table 8 shows the results of the comparison of the thermoformed polyurethane sheets Essix Ace at 7 and 14 days, when comparing the groups of the Taglus® brand, a statistically significant difference was observed when comparing at 7 days between distilled water and natural orange juice (p=0.001), distilled water and artificial orange juice (p=0.004). Distilled water and Fanta® (p<0.00), distilled water and wine (p<0.00), and finally between

artificial orange juice and wine (p = 0.001). At 14 days, a statistically significant difference was observed when comparing distilled water and natural orange juice (p=0.002), distilled water and artificial orange juice (p=0.003), distilled water and Fanta® (p=0.001), distilled water and wine (p<0.00), natural orange juice and wine (p=0.009), artificial orange juice and wine (p=0.06) and finally between Fanta® and wine (p=0.024).

Table 8. Comparison of the color stability of Taglus® thermoformed polyurethane sheets at 7 and 14 days

Times	Solutions	Natural orange juice	Artificial orange juice	Fanta®	Wine
Day 7	Distilled water	,001	,004	,000	,000
	Natural orange juice		,765	,629	,018
	Artificial orange juice			,434	,008
	Fanta®				,060
Day 14	Distilled water	,002	,003	,001	,000
	Natural orange juice		,902	,736	,009
	Artificial orange juice			,645	,006
	Fanta®				,024

Table 9. Comparison of the color stability of Duran® thermoformed polyurethane sheets at 7 and 14 days.

Times	Solutions	Natural orange juice	Artificial orange juice	Fanta®	Wine
Day 7	Distilled water	,000	,000	,000	,000
	Natural orange juice		,519	,596	,741
	Artificial orange juice			,908	,753
	Fanta®				,842
Day 14	Distilled water	,001	,001	,001	,000
	Natural orange juice		,976	,951	,011
	Artificial orange juice			,976	,012
	Fanta®				,013

Table 9 compares color stability for the thermoformed polyurethane sheets of the Duran® brand. A statistically significant difference was observed when comparing at 7 days between distilled water and natural orange juice (p=0.00), distilled water and artificial orange juice (p=0.00), and distilled water and Fanta® (p=0.00). Distilled water and wine (p=0.00), and finally between artificial orange juice and wine (p=0.00). At 14 days, a statistically significant difference was observed when comparing distilled water and natural orange juice (p=0.001), distilled water and artificial orange juice (p=0.001), distilled water and Fanta® (p=0.001), distilled water and wine (p<0.00), natural orange juice and wine (p=0.011), artificial orange juice and wine (p=0.012) and finally between Fanta® and wine (p=0.013).

5. Discussion

The present study aimed to evaluate and compare the mechanical and optical properties of three brands of thermoformed sheets used to manufacture orthodontic aligners: Essix, Duran and Taglus. The flexural modulus, Microhardness, and color stability of these materials were specifically analyzed, crucial factors influencing the clinical efficacy of aligners. The results revealed significant differences between the brands studied, which could have important implications for clinical practice in orthodontics.

5.1. Bending

Bending, it is important to know that the values of the flexural modulus could vary depending on the methodologies applied in each study, such as the bearing

distance in the three-point bending tests and the temperature conditions for thermoforming. In the study it was shown that Duran had a higher flexural modulus (81.4 MPa) when compared to Essix and Tagus. The study by Aldweesh et al. (18) evaluated 3 brands (Keystone, Duran and Zendura), with the highest flexion being Zendura's. However, this study did not include Essix and Tagus; the value obtained for Duran is useful for comparing with other studies and substantiating the results. In the study by Dalaie et al. (11), where they evaluate the dynamic thermal and mechanical properties of aligners after thermoforming and ageing, they focused on the variation of the modulus of elasticity, where they highlight that it is a material with significant flexibility that can change with use and ageing. In the study, Duran and Tagus stand out as materials with a high flexural modulus.

Duran is superior in rigidity, which can be interpreted as a material of greater durability and efficacy in orthodontic treatments. Although less rigid than Duran and Tagus, Essix is still a viable option with good flexibility. The standard deviation of 8.39 indicates moderate variability, suggesting a reasonable consistency in its behavior under load. Taglus with a flexural modulus of 71.1 MPa and the lowest standard deviation of 4.47 shows that it is the least rigid of the three. Its lower standard deviation indicates a greater consistency in its performance, which can be beneficial in applications where more controlled flexibility is required however it can be limited in constant and prolonged forces.

5.2. Microhardness

Microhardness, in this study, the microhardness property of three materials used to manufacture clear aligners (Essix, Duran, and Tagus) was evaluated. Duran in our study was 8.79 Hv with a standard deviation of 0.08; this value is lower than that reported by Aldweesh et al (18), where a 10,804 Hv was found. The difference in microhardness values may be due to variations in the experimental and methodological conditions of the test and the conditions of the materials. The thermoforming and ageing process can significantly affect the microhardness properties of materials used for aligners, in the study by Dalaie et al. [11] A significant reduction in Duran's microhardness results was observed after thermoforming, suggesting that these processes may weaken the material's structure. Our study did not perform a specific assessment of the impact of thermoforming and ageing. Still, the observed difference in Duran's microhardness values between studies suggests that these factors should be carefully considered in future research.

5.3. Color Stability

Color stability, in terms of color stability, in the study by Venkatasubramanian et al. (19), turmeric caused the

largest color change, followed by saffron and Kashmiri red chilli. On the other hand, in our brand comparison study, red wine produced the most significant color changes, followed by Fanta®. Interestingly, despite the differences in the substances tested and exposure times, both studies agree that aligner materials are prone to staining. However, the magnitude of colour changes varied significantly between studies. For example, in the study by Venkatasubramanian et al.(19), the most dramatic color changes were observed with substances such as turmeric, which were not tested in the other study. This suggests that foods and spices typical of certain cultures can have a significant impact on the color stability of aligners.

Aldweesh et al.(18) found that Zendura showed the greatest susceptibility to color change, especially after 7 days of immersion, while the study without a specific author indicated that Essix ACE® was generally more susceptible than Duran® and Taglus®. Daniele et al.(20) used red wine, coffee, nicotine and artificial saliva in five types of aligners where red wine produces the most significant color changes in the materials analyzed, Daniele et al.(20) found that PETG-based materials (such as Erkodur and Essix Plastic) generally showed less color change than polyurethane (PU)-based materials such as Zendura and Invisalign. This was attributed to differences in the chemical structure of the materials. This study showed significant differences between the brands. Essix ACE® generally showed greater color changes than Duran® and Taglus®, especially with wine and Fanta®.

6. Conclusion

Among the conclusions of the work presented in the document, we can list:

- Selecting the right material for aligners should consider the flexion modulus and other factors such as patient comfort, ease of fabrication, and color stability, especially in aligners where aesthetics and durability are crucial.
- Duran is the thermoformed sheet with the highest flexural modulus, making it ideal for cases requiring high rigidity and durability.
- In the property of Microhardness, statistically significant differences ($p < 0.05$) were found between the three brands evaluated. Tagus showed significantly higher Microhardness than Essix.
- It is important to consider color stability in selecting and handling orthodontic aligner materials. Understanding how different substances affect the color of aligners can help orthodontists provide better advice to their patients and potentially influence the development of more stain-resistant materials in the future.

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