The Saudi Dental Journal (2023) 35, 953–959

King Saud University

The Saudi Dental Journal

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ORIGINAL ARTICLE

Comparison of mechanical properties and color stability of various vacuum-formed orthodontic retainers: An in vitro study

Aljazi H. Aldweesh [a,*], Nassr S. Al-Maflehi [b], Muhannad AlGhizzi [c], Eman AlShayea [a], Sahar F. Albarakati [a]

[a] *Division of Orthodontics, Department of Pediatric Dentistry and Orthodontics, College of Dentistry, King Saud University, Riyadh, Saudi Arabia*
[b] *Periodontics and Community Dentistry, College of Dentistry, King Saud University, Saudi Arabia*
[c] *College of Dentistry, King Saud University, Riyadh, Saudi Arabia*

Received 3 July 2023; revised 30 August 2023; accepted 4 September 2023
Available online 7 September 2023

KEYWORDS

Dental material;
Orthodontic retainers;
Retention;
VFR materials

Abstract *Background:* Vacuum-formed retainer (VFR) is the most used retainer due to its higher aesthetic properties and lower cost, their mechanical properties of are important in determining the stability and long-term use of appliances made out of them. Aim: This study aimed to evaluate and compare the flexural modulus, surface hardness, and color stability of three different VFR materials. Methods: Three different VFR materials, namely Duran, Keystone, and Zendura, of 1 mm thickness, were tested after thermoforming for flexural modulus, hardness, and color stability. They were formed over a stainless-steel model of 12 mm diameter and 6 mm height. Results: There were significant statistical differences ($p = 0.000$) in the flexural modulus and hardness of the three materials. Regarding color stability, Zendura exhibited significantly higher ΔE* values than Keystone and Duran ($p < 0.05$). Conclusions: Zendura had the highest flexural modulus and hardness compared with Duran and Keystone; however, it is more susceptible to color change compared to the other tested materials.

* Corresponding author at: 8357 al buhayrat-ar rahmaniyah, Riyadh 12343-3664, Saudi Arabia.
E-mail addresses: dr_aljazi@hotmail.com (A.H. Aldweesh), nassr.almaflehi@gmail.com (N.S. Al-Maflehi), Sakhrbds@gmail.com (M. AlGhizzi), e_shayea@hotmail.com (E. AlShayea), salbarakati@ksu.edu.sa (S.F. Albarakati).
Peer review under responsibility of King Saud University.

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1. Introduction

Retention following an orthodontic treatment is critical in preventing post-treatment relapse and maintaining the treatment result (Bratu et al., 2019). In practice, many types of orthodontic retaining materials such as bonded retainers, Hawley retainers, thermoplastic (vacuum-formed) retainers, and positioners (custom-made or prefabricated) are used with each one having its own advantages and disadvantages (Bratu et al., 2019).

https://doi.org/10.1016/j.sdentj.2023.09.004
1013-9052

Vacuum-formed retainer (VFR) is the most used retainer and is comparable to the traditional Hawley retainer due to its higher aesthetic properties, easier fabrication, minimal thickness, and lower cost (Moshkelgosha et al., 2016). It was first introduced by Ponitz in 1971 (Pointz, 1971) and is a colorless and transparent material formed of polyethylene polymers and polypropylene polymers, available in the market under the name of Essix C+, Essix ACE, Duran, and Tru-Train (Alassiry, 2019).

The mechanical properties of orthodontic retainers are important in determining the stability and long-term use of appliances made out of them (Moshkelgosha et al., 2016). The flexural modulus is defined as the tendency of a material to bend or is described in terms of flexural deformation, the ratio of stress to strain (Jawaid et al., 2018). While hardness is a measure of the resistance to permanent surface indentation or penetration (Albakry et al., 2003). Understanding those properties is essential to fabricate an accurate and optimal retainer, in addition to helping orthodontists who intend to use this technology (Al Noor and Al-Joubori, 2018).

In clinical settings, VFRs have unavoidable limitations such as fracture, short life span, unfavorable teeth settling, cracking, and discoloration (Lindauer and Shoff, 1998; Sheridan et al., 2001; Ahn et al., 2015).

Additionally, color stability and light transmittance are the other limitations of clear retainers, where aesthetic parameters might be compromised if any of these characteristics are affected (Agarwal at al., 2018). Many patients do not comply with the requirement of retainer removal while eating or drinking anything other than water; as a result of this behavior, the retainer loses its translucency and color stability (Agarwal at al., 2018). Effective cleaning and following the required instructions can help in maintaining the integrity of VFRs for longer periods (Virji, 2021).

Furthermore, hardness is governed by multiple factors such as proportional limit, strength, ductility, etc. Nevertheless, measuring the resistance to indentation is considered a measure of hardness, and it provides critical information characterizing the capabilities of the material being used, such as its structure, quality, and failure properties (Al Noor and Al-Joubori, 2018).

A study was conducted by Raja et al. to investigate the wear resistance of different VFRs, such as Essix C+, Essix ACE, Duran, and Tru-Train (Raja et al., 2014). The study concluded that Essix ACE, Duran, and Tru-Train exhibited lesser wear resistance compared with Essix C+ (Raja et al., 2014). Bratu et al. compared the wear resistance of VFR among four different manufacturers (Essix, Leone, Erkodent, and Bio-Art) but did not find any statistically significant differences between the VFRs of the four manufacturers (Bratu et al., 2019). Another study was conducted by Alexandropoulos et al. in which four types of thermoplastic materials with different thicknesses were tested for their chemical and mechanical characteristics. The authors of this study concluded that there were significant differences in the properties of these thermoplastic materials and that differences in their clinical behavior were therefore expected (Alexandropoulos et al., 2015).

To the best of our knowledge, no previous study compared the flexural modulus, hardness and color stability of Zendura, Duran and Keystone thermoplastic materials.

To address the mechanical properties and color stability concerns and also to improve the quality and longevity of VFRs, more studies need to be conducted. The aim of this study was to evaluate and compare the flexural modulus, surface hardness, and color stability of three different VFR materials, namely Zendura, Duran, and Keystone. The null hypothesis of this study was that there is no difference in flexural modulus, surface hardness, and color stability between the three tested VFR materials.

2. Materials and methods

The study was undertaken at the King Saud University Dental hospital, Riyadh, Kingdom of Saudi Arabia. The three retainer materials chosen were Zendura, Duran, and Keystone, each of which was of 1 mm thickness. The samples were divided into 3 groups, and each group consisted of 30 samples from each manufacturer except for color stability test the sample were 28 from each manufacturer (Table 1).

The samples were vacuum-formed according to manufacturer's instructions over a stainless-steel model of 12 mm diameter and 6 mm height (Fig. 1) using a Biostar vacuum forming machine (Scheu-Dental GmbH, Iserlohn, Germany).

2.1. Flexural modulus

The Instron machine (Instron Corp., MA, USA) was used to measure flexural modulus. A three-point bending test was performed at 8 mm distance between the supports. Specimens were loaded until they broke, at a cross-head speed of 1 mm/min (Elkholy et al., 2019).

The following equation was used to calculate the flexural strength in Megapascal (MPa). (Ryu et al., 2018):

$$\mathbf{E} = \frac{F1l^3}{4bh^3d}$$

where F1 is the (yield strength) highest load in the straight-line section of the load–deflection curve at 1 mm of deflection, d is the magnitude of the deflection at F1, l is the length between the supports, b is the width, and h is the height of the sample.

Table 1 Types of VFR retainers' materials used in the current study.

Brand	Manufacturer	Component	Thickness (mm)
Duran	Scheu Dental, Iserlohn, Germany	Polyethylene terephthalate glycol (PETG)	1
Zendura	Bay Materials LLC, Fremont, CA, USA	Polyurethane (PU)	1
Keystone	Keystone Industries, Gibbstown, NJ, US	Copolyster Polyethylene terephthalate	1

Fig. 1 The stainless-steel model that was used for the samples.

2.2. Hardness

Hardness was measured using the Innovatest hardness testing machine (Nova 130, Maastricht, the Netherlands) with Vickers indenter by application of a load of 9.8 N for 10 sec:

$$\boldsymbol{HV} = 1.854\frac{\mathbf{F}}{\boldsymbol{d}^2}$$

where F (force) = 9.8 N, and d is the average diameter of the indentations.

2.3. Color stability

As coffee, black tea, and wine have been reported to cause more severe stains than other beverages (Zafeiriadis et al., 2014), the present study used these liquids as staining agents, in addition to Coca Cola. The solutions were prepared according to the standard methods used in previous studies (Fernandes et al., 2014). Twenty-eight retainers from each manufacturer were randomly divided into 4 groups according to the 4 solutions. The aligners were immersed in each solution in a container and were stored in a water bath at 37 °C for 24 h and 7 days. The solutions were refreshed every day. The color changes were characterized according to the Commission Internationale de I'Eclairage L*a*b* color system (CIE L*a*b*). The following color parameters were measured; L* represents lightness (+bright, − dark), a* represents the red (+) to green (−) color scale, and b* indicates the yellow (+) to blue (−) color scale (Cörekçi et al., 2010). The LabScan XE spectrophotometer (HunterLab, Reston, VA) was used to measure the color parameters before staining (T0) and after periods of 24 h (T1) and 7 days (T2) of staining. An ultrasonic cleaner was used to wash the aligners for 5 min and dried with a tissue paper before the measurements. The investigator performing the measurements was blind to the group division of the aligners. The flat surface model was made using a flowable resin (Filtek Universal Restorative, 3 M ESPE, St. Paul, MN, USA), and an A3 Body Shade was used as the background reference and set behind the surface of each aligner (Inami et al., 2015). The measurements were performed by firmly contacting the optical sensor tip vertically to the flat surface of the aligner to simulate the tooth color. All measurements were conducted in the same room with standardized illumination. The following equation.

$$\Delta E^* = \left[(\Delta L^*)^2 + (\Delta a^*)^2 + (\Delta b^*)^2\right]^{1/2}$$

was used to measure the total color change (ΔE*) value, which represents the color difference before and after staining (Johnston, 2009). The obtained data were then converted to the NBS (National Bureau of Standards) system by following the equation NBS = ΔE* × 0.92 to relate the color changes to a clinical standard (Ryu et al., 2018).

2.4. Statistical analysis

2.4.1. Sample size determination

G* power programing was used to determine the required sample size for our study with three levels: material factor and measurement variables flexural modulus, hardness, and color stability, using the ANOVA statistical test. At significant level, $\alpha = 0.05$ and effect size ES = 0.3 with a power of 90% of the total sample size should be at least 90 and 30, respectively, for each material type. Focusing on the color change ΔE* at 24 h after immersion in solution (T0) and 7 days after immersion in solution (T1) independently as a cross-section study, the two-way ANOVA was used. In this case, at $\alpha = 0.05$ and effect size ES = 0.3 with a power of 95% of the total sample size should be at least 72, that is, 6 samples for each material and each solution.

2.4.2. Statistical analysis

Descriptive statistics frequency, mean, standard deviation, and 95% confidence intervals (95% CI) of the means are presented. One-way analysis of variance (ANOVA) was used to test the behavior of the material. This was followed by F-test to measure the statistical difference between the studied materials. The Tukey statistical test was used for multiple comparisons. The level of significance was set at $\alpha = 0.05$, and any statistical test *p*-value less than α was considered significant. For color stability, the ΔE* values of each group at T1 and T2 were analyzed using the two-way repeated measurements of ANOVA. Within subject analysis and one-way ANOVA followed by Tukey's multiple comparison tests were conducted to investigate the effects of each solution on the ΔE* values of the materials.

Normality and homogeneity of variance were tested for flexural modulus using the Shapiro–Wilk and Levene's test with p-values ($p > 0.586$) and ($p > 0.114$), respectively. For hardness, normality within material was tested using Shapiro–Wilk test ($p > 0.256$), which implies that normality was satisfied. For each material, Levene's test was used to test the homogeneity of variance ($p = 0.996$), which means that the assumption of quality of the variance was satisfied. Lastly, normality and homogeneity of the variance were tested for color stability. The Kolmogorov-Smirnov and Shapiro–Wilk tests showed normality were satisfied ($p > 0.05$) Also, the Levene's test showed that the equality of variances was satisfied ($p > 0.05$).

3. Results

3.1. Flexural modulus

One-way ANOVA showed that flexural modulus, mean ± SD (95% CI) of the materials, as follows: Duran 0.872 ± 0.08 M Pa (0.842–0.902), Keystone 0.562 ± 0.112 MPa (0.521–0.604), and Zendura 1.219 ± 0.115 MPa (1.176–1.262). However, ANOVA F-test showed there was significant statistical difference among the material's flexural modulus mean ($p = 0.000$). Tukey post hoc test showed that Keystone (0.562 MPa) had significantly the least mean of flexural modulus ($p = 0.000$), followed by Duran with (0.872 MPa), and lastly Zendura (1.219 MPa), which had the highest flexural modulus ($p = 0.000$) (Table 2).

3.2. Hardness

One-way ANOVA estimated the hardness, mean ± SD (95% CI) of the materials, as follows; Duran HV 10.804 ± 0.278 (10.7 00–10.908), Keystone HV 10.758 ± 0.287 (10.651–10.865), and Zendura HV 13.731 ± 0.311 (13.615–13.847). Furthermore, ANOVA F-test showed there was a significant difference among the mean hardness ($p = 0.000$) of the materials. Tukey as a multiple comparison test showed that there was no difference in hardness between Keystone and Duran ($p = 0.818$), while there was a statistical difference in hardness when compared to Zendura ($p = 0.000$). In summary, Zendura had the highest hardness among the materials followed by Duran and Keystone; moreover, the materials were not significantly different from each other in average hardness (Table 3, Fig. 2).

3.3. Color stability

The means and standard deviations of the ΔE* (color change) values are presented in (Table 4). Analysis of the ΔE* values with two-way ANOVA revealed no statistically significant differences in color changes among the different materials ($p > 0.05$) and the different staining solutions ($p > 0.05$); there was also no interaction effect ($p > 0.05$) at T1. However, at T2, there was significant interaction between material and solution ($p < 0.05$), significant differences in color changes among the different materials ($p < 0.05$) and the different staining solutions ($p < 0.05$). Zendura exhibited significantly higher ΔE* values than Keystone and Duran ($p < 0.05$), and there was no significant difference between Keystone and Duran (Table 4).

Fig. 3 depicts the effect of time and solution on the tested materials using NBS units, showing that all the 3 tested materials had trace to appreciable color changes at T1, while at T2, Zendura samples had the highest color change (Much) with coffee and the least with Coca Cola.

Furthermore, repeated measurement ANOVA followed by paired *t*-test showed that the color change values ΔE* increased significantly from T1 to T2 (p-value < 0.05) for all materials except for Duran for which there was no statistical difference in color change value at T1 and T2 (Table 5).

4. Discussion

One of the main challenges for orthodontists is the retention of treatment results and the selection of proper methods and materials for retention (Melrose and Millett, 1998; Ryokawa et al., 2006; Johnston and Littelewood, 2012, Moshkelgosha et al., 2016). To test the properties of VFR materials for clinical application, it should be tested after thermoforming (Ryu et al., 2018). In this study, 3 types of VFR materials were tested for hardness, color stability, and flexural modulus after thermoforming.

Regarding flexural modulus, a three-point test bending generally uses flat specimens, which has its own advantages and disadvantages when compared with 3D aligners used clinically. Although there is no direct clinical significance of the flat specimens when compared with those fabricated on dental casts, it is inexpensive, simple, and reduces the influencing factors, which allows the controlled evaluation of isolated factors influencing the force delivery of aligners (Elkholy et al., 2019). Using smaller specimens simulate local stress concentration on smaller aligners areas (Elkholy et al., 2019). The highest flexural modulus was for Zendura, followed by Duran and Keystone. This is in agreement with previous study as Zendura had the highest flexural modulus among the tested materials (Albilali et al., 2023).

The hardness of Zendura was also the highest, which too aligns with the findings of a previous study (Um and Ruyter, 1991), followed by Duran and Keystone.

Transparent appearance of VFR orthodontic retainers is due to the amorphous or partially crystalline polymers that allows light to pass through them (Ryu et al., 2018). Color change of VFR was associated with the absorption of pigmentation by the material when aligners where immersed in solutions. The color change depends on the solution used and the type of VFR material (Um and Ruyter, 1991; Kim and

Table 2 One-way ANOVA comparing the average of flexural strength between VFR materials.

Flexural Modulus									
Material	**N**	**Mean (MPa)**	**SD**	**P-value**	**95% Confidence Interval for Mean**		**MCT (Tukey)**		
					Lower Bound	**Upper Bound**	**Duran**	**Keystone**	**Zendura**
Duran	30	0.872	0.080	**0.000**	0.842	0.902	1		
Keystone	30	0.562	0.112		0.521	0.604	**0.000**	1	
Zendura	30	1.219	0.115		1.176	1.262	**0.000**	**0.000**	1

Table 3 One-way ANOVA comparing the average of Hardness between VFR materials.

Hardness									
Material	**N**	**Mean (HV)**	**SD**	**P-value**	**95% Confidence Interval for Mean**		**MCT (Tukey)**		
					Lower Bound	**Upper Bound**	**Duran**	**Keystone**	**Zendura**
Duran	30	10.804	0.278	**0.000**	10.700	10.908	1		
Keystone	30	10.758	0.287		10.651	10.865	0.818	1	
Zendura	30	13.731	0.311		13.615	13.847	**0.000**	**0.000**	1

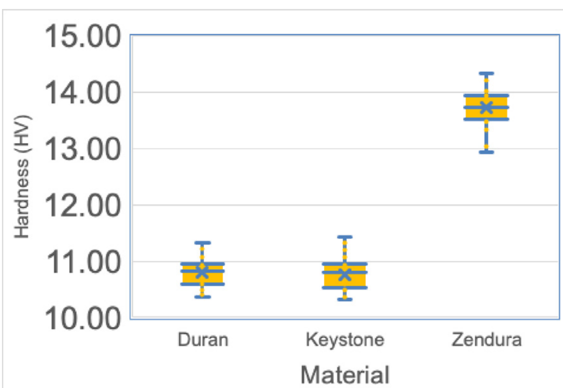

Fig. 2 Box plot showed the Hardness of each VFR material.

Lee, 2009; Erdemir et al., 2012; Fernandes et al., 2014; Liu et al., 2016). Different studies have evaluated the color changes of different aligner brands as well as different solutions (Liu et al., 2016; Daniele et al., 2020; Daniele et al., 2022). Most of the studies revealed that polymers tend to change after 7 days exposure, which is in agreement with our study (Liu et al., 2016; Daniele et al., 2020; Daniele et al., 2022). In our study, Zendura showed the most change in color at T2 and coffee and wine solutions. This might be because Zendura is a polyurethane (PU) polymer-based material, while the others are polyethylene terephthalate glycol (PETG) polymer-based material. This color change is in accordance with previous studies, which found that PU-based aligners had significant color changes and were more susceptible to pigment absorption; in addition, they do not provide adequate color stability when compared with PETG polymers (Kim and Lee, 2009; Fernandes et al., 2014; Liu et al., 2016). Furthermore, PU polymers contain the surface polar group "–NHCOO–," which makes them prone to the formation of hydrogen bonds that interact with hydrophilic pigments in solutions, thus facilitating pigment adsorption onto the material. In contrast, PETG polymers contain surface groups such as "–COO–" and "C–O–C" that are less polar than "–NHCOO–" (Liu et al., 2016).

Table 4 Two-way Anova compared color change (ΔE*) values of three types of aligners in each solution at each time point.

		Solution																
Time	Material	Coffee					Tea				Wine				Cola			
		N	Mean	SD	P-value	IC^	Mean	SD	P-value	IC	Mean	SD	P-value	IC	Mean	SD	P-value	IC
ΔE_T1	Duran	7	2.00	0.87	0,255	a	2.06	0.56	0.299	a	3.48	0.75	0.828	a	2.76	1.46	0.531	a
	Keystone	7	1.40	0.48		a	3.43	2.17		a	3.46	2.72		a	2.45	0.72		a
	Zendura	7	3.30	3.53		a	3.31	2.08		a	4.14	2.89		a	2.13	0.73		a
ΔE_T2	Duran	7	3.82	2.36	0.001	a	5.67	3.47	0.223	a	3.92	1.39	0.003	a	3.16	1.33	0.537	a
	Keystone	7	2.44	1.40		a	8.32	1.84		a	4.91	2.44		a	2.43	1.05		a
	Zendura	7	8.95	3.78		b	7.58	2.92		a	8.23	2.33		b	2.36	1.90		a

^IC, Intergroup comparison; SD, standard deviation. Different letters indicate a statistically significant difference between aligner types in each solution at each time point ($P < 0.05$).
*Intergroup comparison of colour differences regarding different aligner types according to the Tukey's multiple comparison test. Different letters indicate a statistically significant difference between aligner types in each solution at each time point ($P < 0.05$).

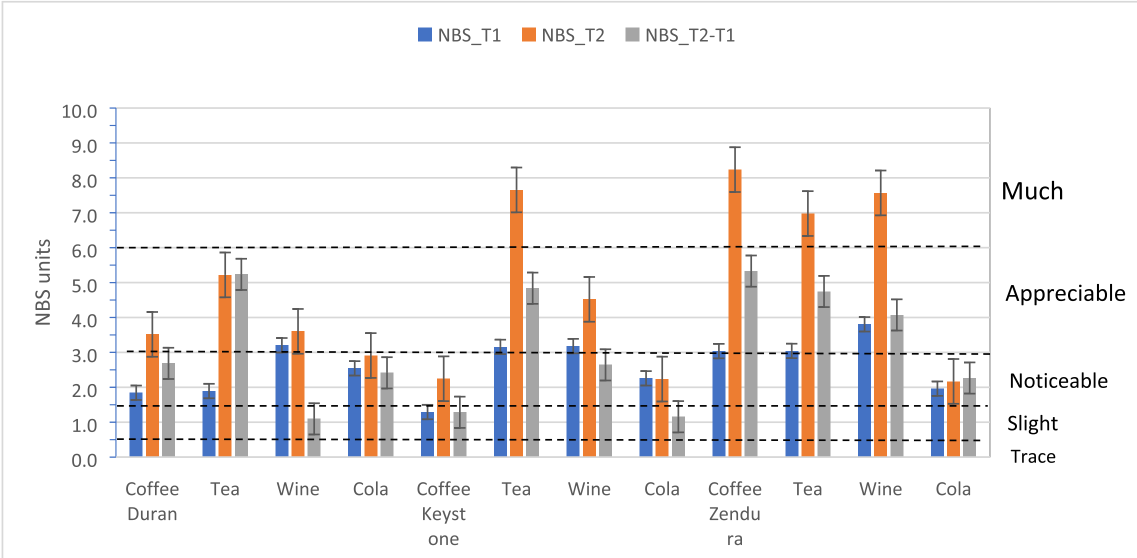

Fig. 3 Color Change using NBS units for each solution and VFR material.

Table 5 Repeated measurements followed by two-way anova compared colour change (ΔE*) values of different types of solutions in each material at each time point.

Material	Solution	N	ΔE_24H				ΔE_7days			
			Mean	SD	P-value	IC	Mean	SD	P-value	IC
Duran	**Coffee**	7	2.003	0.867	**0.027**	a	3.821	2.357	**0.237**	a
	Tea	7	2.057	0.558		ab	5.673	3.475		a
	Wine	7	3.483	0.752		b	3.917	1.392		a
	Cola	7	2.763	1.456		ab	3.163	1.332		a
Keystone	**Coffee**	7	1.403	0.480	**0.131**	a	2.441	1.404	**0.000**	a
	Tea	7	3.431	2.174		a	8.321	1.841		b
	Wine	7	3.456	2.716		a	4.913	2.436		a
	Cola	7	2.451	0.720		a	2.429	1.051		a
Zendura	**Coffee**	7	3.303	3.529	**0.539**	a	8.950	3.777	**0.001**	b
	Tea	7	3.307	2.085		a	7.584	2.922		b
	Wine	7	4.136	2.893		a	8.227	2.334		b
	Cola	7	2.133	0.732		a	2.357	1.899		a

All studies have their own limitations; in our study, only three different materials from three companies were compared, and materials of a single thickness of 1 mm were used. Future studies should consider comparing materials of different brands with different thicknesses. Also, the samples were prepared using a stainless-steel model, that is, teeth models were not used to fabricate the retainers, which might affect the results. Lastly, the study did not consider intraoral conditions such as salivation and temperature; therefore, more clinical trials are needed that would evaluate the effect of intraoral conditions and the repetitive use of the retainers on the studied properties.

5. Conclusions

Considering orthodontic patients use retainers for long periods, knowledge of the physical and mechanical properties of thermoplastic materials used for VFR fabrications is essential for the clinician to select the most durable and cost-effective material. The current study revealed a statistically significant difference in the hardness, flexural modulus, and color stability of different VFR materials. Zendura had the highest flexural modulus and hardness compared with Duran and Keystone, it showed significantly higher color change (ΔE*) values after 7 days immersed in staining solutions compared to Duran and Keystone.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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