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EFFECT OF PH ON THE MECHANICAL PROPERTIES OF THERMOPLASTIC POLYURETHANES USED TO MANUFACTURE DENTAL ALIGNERS. IN VITRO STUDY

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ABSTRACT

The objective of this study was to evaluate in vitro the effect of pH on the mechanical properties of three different acetates brands used to manufacture dental aligners.

MATERIALS AND METHODS: 27 specimens of thermoformed acetates of the brands Zendura A., Dentsply Sirona and Valdi were incubated in artificial saliva at 37°C in a Shel-Lab 1510E incubator and immersed twice a day for 5 minutes in beverages with different pH levels to measure its elastic limit on days 0, 7 and 14.

STATISTICAL PROCESS CONTROL: Data analysis was performed using the Kolmorogov-Smirnov and Levene tests, and later with analysis of variance (ANOVA), multiple comparisons post -hoc with the Sheffe test and the Friedman statistical test for paired samples; all with a significance level of 0.05 using the IBM SPSS Statistics 26 statistical package.

RESULTS: The elastic limit measurements on days 7 and 14 indicate significant differences between the different pHs and are not consistent between the three brands of acetates. The Zendura A brand at neutral pH increased and then recovered to 99%, at acidic pH it decreased to 85% then 64%, and at alkaline pH it increased more than half, then returned to 105% of baseline. The Dentsply Sirona brand in neutral pH had a decrease and then recovered to 96%, in acidic pH it increased progressively to 113% and 118%, and in alkaline pH it decreased to 69% to later recover to 84%. The Valdi brand in all groups increased and at the end was recovered, in neutral pH to 92%, in acidic pH to 87%, and in alkaline pH to 80% with respect to the initial value.

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CONCLUSIONS: The mechanical properties of the aligners vary and may be affected depending on the pH to which they are subjected, having variability in their elastic limit. The specimens subjected to acidic and alkaline drinks had a greater decrease in their elastic limit when compared to those subjected to neutral pH. In general, it was possible to observe that the specimens increased their elastic limit on day 7 and then approached their initial value on day 14.

Keywords: Dental aligners, Elastic limit, pH effects, Thermoplastic polyurethanes.

INTRODUCTION

At present orthodontic treatments are required and accepted by a greater number of patients, the demand for an aesthetic, comfortable and functional treatment forces the orthodontist to know the physical, mechanical, and optical properties of the materials of choice for the treatments.

Polyester, polyurethane, and polypropylene are currently the predominant thermoplastic materials for the manufacture of invisible orthodontic appliances (Frick and Rochman 2004; Yu et al. 2022). Thermoplastic polyurethane is one of the most versatile materials due to its elastomeric properties, its ease of combining properties such as those of rubber, and the processability of thermoplastic polymers make it the material of choice in the industry (Lu and Macosko 2004). This material forms a large family of polymers that are used in a wide range of products such as foams, shoe soles, inflatables, coatings, biomaterials, clothing, among others (Boubakri et al. 2010).

Thermoplastic polymers melt and flow when heated above a certain temperature; two widely used polymers for aligners are Polyethylene Glycol Terephthalate (PET-G) and Thermoplastic Polyurethane (TPU) (Nanda et al. 2021).

Invisible aligners have become one of the preferred options for patients, but since they are made of thermoplastic materials, their physical and mechanical properties can be affected by the environment, temperature, pH salivary enzymes and fluids or foods that patients consume since they are exposed to the oral environment for approximately 14 days. These conditions can affect the properties of the material with which the aligners are made, and it is essential that the orthodontist knows the effects that thermoplastic materials can suffer, before, during and after their use in the oral environment in order to guarantee patients the effectiveness and success of treatment (Neto 2017).

The treatment indicates its continuous use for 22 hours a day with the instruction to remove them every time food is ingested, but patients may find it easy not to remove them when consuming food or drinks, and this can cause changes in the intraoral pH which could affect the properties of

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the aligners (Kesling 1945).

There is little information about the effects that daily exposure to different pH levels such as those of commonly consumed beverages might have on the mechanical properties of invisible aligners, due in part to the inaccessibility of raw materials protected by their patent (Fang et al. 2020).

According to the review of the literature, investigations have been found on the factors that affect dental materials, such is the case of elastomeric chains, where factors such as time have been investigated, when pre-stretching them, sterilization techniques, as well as environmental factors that modify or alter them (Kim et al. 2005). Fang et al. (2020) studied the changes in the mechanical properties of thermoplastic materials depending on the environmental conditions to which they are exposed, coinciding with other studies in which thermoplastic materials can undergo stress relaxation when absorbing water.

Ryu et al. (2018) focused their attention on the study of the effects of thermoforming on mechanical properties (before and after it), finding that in some cases the properties increase or decrease depending on the brand of thermoplastic material and that others may present a significant decrease. on bending forces after this process and exhibit permanent deformation.

Bradley et al. (2016) for their part investigated the modifications to the properties that Invisalign aligners present when exposed to humidity in the oral cavity. In their study they found changes in the mechanical properties, but not in the chemical composition. Although it has been found that thermoplastic materials can release nickel, zinc or aluminum after use, it has been concluded that the levels of these elements are not relevant due to their low levels of toxicity to health.

After reviewing the literature, it has been found that there are few studies focused on the alteration of the mechanical properties of the thermoplastic materials used in the manufacture of aligners that are caused by the oral environment and the factors to which it may be exposed during its daily use, such as the consumption of beverages with an acidic or alkaline pH during the time of their use, which is approximately 14 days and at least 22 hours a day.

The focus of this study will be to evaluate the effects on the mechanical property of the elastic limit of three brands of thermoformed acetates used to manufacture invisible aligners, caused by the different pH levels of common beverages consumed by patients. In this way it will be possible to evaluate whether the consumption of these beverages is detrimental to the success of orthodontic treatments with invisible aligners and provide better recommendations for their use. This will contribute to strengthening the scientific evidence on the materials available for the elaboration of this type of treatment.

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Therefore, the objective of this research is to carry out an in vitro study of the effect of drinks with acidic and alkaline pH on the mechanical properties of three commercial brands of thermoplastic polyurethane used to manufacture invisible aligners: Zendura A, Dentsply Sirona and Valdi.

MATERIALS AND METHODS

This research is experimental, in vitro, controlled, random, open, longitudinal and comparative.

Rectangular thermoplastic polyurethane acetates from Zendura A, Dentsply Sirona and Valdi were used. 27 specimens were obtained, and these were classified according to their brand in 3 groups made up of 9 specimens each.

The specimens of each brand were prepared in the form of test tubes according to the standard: EN ISO 527-2, type 5B specimen for tensile tests used for tensile tests, these measuring 50 mm long, 8 mm wide at their ends and in the narrow area 3 mm wide.

These were measured and cut with a water jet diamond blade and manually refined with a low speed bur. Each specimen was subjected to a thermoforming process and labeled by group for identification.

All the samples were organized in 3 Petri dishes with artificial saliva incubated at 37°C simulating the oral environment, for their subsequent immersion in drinks with different pH in periods of 5 minutes twice a day for a period of 14 days, time that approximately one dental aligner stays in the mouth.

The drinks that were used were: Gatorade (pH 3.5) and Essentia alkaline water (pH 9.7), after each process each test tube was washed with distilled water and submerged again in artificial saliva.

Throughout the experimental cycle, the pH of each of the solutions, including the artificial saliva, was measured using pH test strips to measure its acidity or alkalinity value.

The elastic limit of the specimens was measured on day 0, day 7 and day 14 using an MTS Alliance RT/30 universal testing machine, where they were held by the machine's jaws and stretched to their breaking point.

Once the experimentation process was finished, the data was analyzed with the Test Works 4.0 program.

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STATISTICAL PROCEDURE

An exploratory data analysis was carried out, obtaining the statistics of centrality and variation of the variable under study, which is the elastic limit of thermoplastic materials. Afterwards, the assumptions of normality and homogeneity of variances were checked using the Kolmorogov-Smirnov tests and the Levene test. Then an Anova of one factor was chosen, followed by post-hoc multiple comparisons with the Sheffe Test. In addition, the Friedman statistical test for paired samples was chosen.

All statistical tests were performed with an alpha value of 0.05 in the IBM SPSS STATICS 26 statistical package.

RESULTS

Day 0

When analyzing by groups, it was observed that at neutral pH, the Zendura A specimens reported an initial average force of 45.05 ± 0.35 MPa, while those of Dentsply presented a greater force of 24.43 ± 0.53 MPa, and the Valdi specimens registered 34.80 ± 0.14 MPa, which results in statistically significant differences (p: 0.001) (Table 1).

Table 1: Descriptive statistics of day 0 for Zendura A, Dentsply and Valdi with respect to their medium.

Brand	pH	Average	S.D.	Minimum	Maximum
Zendura A	Neutral	45.05	0.35	44.80	45.30
	Acidic	59.95	0.49	59.60	60.30
	Alkaline	34.05	0.21	33.90	34.20
Dentsply	Neutral	24.43	0.53	24.05	24.80
	Acidic	18.80	0.71	18.30	19.30
	Alkaline	24.05	0.07	24.00	24.10
Valdi	Neutral	34.80	0.14	34.70	34.90
	Acidic	30.75	0.64	30.30	31.20
	Alkaline	35.75	0.07	35.70	35.80

In the acid pH, the Zendura A specimens yielded a result of 59.95 ± 0.49 MPa, while the Dentsply specimens obtained an average of 18.80 ± 0.71 MPa, and the Valdi brand specimens showed 30.75 ± 0.64 MPa, which is statistically significant (p: 0.001) (Table 1).

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On the other hand, in the alkaline group, the Zendura A specimens reached an initial value of 34.05 ± 0.21 MPa, those of Dentsply 24.05 ± 0.07 MPa and those of the Valdi brand 35.75 ± 0.07 MPa, this being statistically significant (p: 0.001) (Table 1).

In this first measurement, the performance of Zendura A was better in the 3 groups, followed by the Valdi brand and finally the Dentsply brand.

Day 7

In the neutral group, the Zendura A specimens had an average of 54.05 ± 0.21 MPa, those from Dentsply reported 19.08 ± 0.17 MPa, and those from the Valdi brand measured 47.55 ± 0.35 MPa, in such a way that it is statistically significant (p: 0.001). (Table 2).

Table 2: Descriptive statistics of day 7 for Zendura A, Dentsply and Valdi with respect to their medium.

Brand	pH	Average	S.D.	Minimum	Maximum
Zendura A	Neutral	54.05	0.21	53.90	54.20
	Acidic	50.85	1.48	49.80	51.90
	Alkaline	52.30	0.57	51.90	52.70
Dentsply	Neutral	19.08	0.17	18.96	19.20
	Acidic	21.20	0.71	20.70	21.70
	Alkaline	16.55	0.21	16.40	16.70
Valdi	Neutral	47.55	0.35	47.30	47.80
	Acidic	41.05	0.35	40.80	41.30
	Alkaline	42.18	0.31	41.96	42.40

In the acidic environment, the Zendura A specimens indicated an average of 50.85 ± 1.48 MPa, while those of Dentsply presented 21.20 ± 0.71 MPa, and those of the Valdi group 41.05 ± 0.35 MPa, consequently, this result is statistically significant (p: 0.001) (Table 2).

In the alkaline pH, the Zendura A specimens reported an average of 52.30 ± 0.57 MPa, those of Dentsply 16.55 ± 0.21 MPa, and those of the Valdi brand indicated 42.18 ± 0.31 MPa, which is statistically significant (p: 0.001) (Table 2).

In the second measurement, the performance of Zendura A was again better in the 3 groups, followed by the Valdi brandand finally the Dentsply brand.

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Day 14

At neutral pH, the Zendura A specimens showed an average of 44.50 ± 0.71 MPa, the Dentsply specimens reached 23.45 ± 0.35 MPa and the Valdi specimens yielded 32.05 ± 0.21 MPa, this being statistically significant (p: 0.001) (Table 3).

Table 3: Descriptive statistics at day 14 for Zendura A, Dentsply and Valdi with respect to their medium.

Brand	pH	Average	S.D.	Minimum	Maximum
Zendura A	Neutral	44.50	0.71	44.00	45.00
	Acidic	38.75	1.20	37.90	39.60
	Alkaline	35.65	0.21	35.50	35.80
Dentsply	Neutral	23.45	0.35	23.20	23.70
	Acidic	22.15	1.48	21.10	23.20
	Alkaline	20.28	0.59	19.86	20.70
Valdi	Neutral	32.05	0.21	31.90	32.20
	Acidic	26.90	0.14	26.80	27.00
	Alkaline	28.50	0.57	28.10	28.90

In the acid group, the Zendura A test tubes registered an average of 38.75 ± 1.20 MPa, while those of Dentsply obtained 22.15 ± 1.28 MPa, and those of the Valdi brand expressed 26.90 ± 0.14 MPa, in such a way that this result is statistically significant. (p: 0.001) (Table 3).

In the alkaline medium, the Zendura A test tubes yielded an average strength of 35.65 ± 0.21 MPa, those of Dentsply reported 20.28 ± 0.59 MPa, and those of the Valdi brand showed 28.50 ± 0.57 MPa, which is why it is statistically significant (p: 0.001) (Table 3).

When analyzing the difference in the third measurement, the Zendura A brand was again the one that showed the best performance in the 3 types of pH, followed by the Valdi brand and lastly the Dentsply brand.

DISCUSSION

Few studies have evaluated the possible alterations that the acetates used in the manufacture of dental aligners may present in the mechanical property of the elastic limit against the multiple factors to which they are subjected within the oral cavity, such as the pH of the saliva and of commonly consumed beverages. The properties of thermoplastic polymers can change after thermoforming and, in addition, in the oral cavity the aligners are subjected to an environment

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that could result in a significant degradation of their properties, causing a negative result on the efficacy of the treatment (Tamburrino et al. al. 2020).

In the present study, results were obtained in which it is observed that the three brands of acetates for dental aligners had differences compared to the beginning of the experiment before being subjected to thermoforming, to the oral environment and to the pH levels to which they were exposed. Different values were presented in the three brands of acetates and no stable behavior was observed.

The results of the investigation coincide with what Hiromi Riowaka et al. (2006) present about the mechanical properties of thermoplastic materials that vary with respect to environmental factors and that their behavior is influenced by the molecular structure and its orientation, concluding that these were altered by the absorption of water and changes in temperature of 23°C to 37°C and that marked significant differences in the mechanical properties of the material.

Contrary to the conclusions of Ferriter et al. (1990) who point out on day 14 that alkaline pHs are more hostile to polyurethane chains, the results of this research show evidence that acetates suffer greater damage when exposed to acidic pH; In the measurements of the elastic limit of the samples of the Zendura A brand, it has been possible to observe a decrease on day 7 of 18% with respect to its initial value.

Similarly, there is disagreement with the results of the study by Ryu et al. (2018) who evaluated acetates to make aligners from 3 different brands and concluded that the Zendura A brand fell 13% compared to its initial value for day 7 at a neutral pH. In the results of this study, it was possible to find on day 7 that the elastic limit of the acetates of this brand had an increase of 19.7%.

Regarding what Fang et al. (2020) exposesin their research, a partial coincidence has been reached, since in their research on the changes in the properties of Invisalign aligners before and after 2 weeks of use in intraoral conditions, they found a trend in the decrease in the elastic limit in group 2 (which was analyzed two weeks after the experiment) of the elastic limit of 806 ± 19 MPa, which was lower than that of group 0 (week 0 group) (842 ± 63 MPa); In the results of the present work, a decrease in the elastic limit has been found on day 14 in the specimens of the Zendura A brand when subjected to a simulation of the oral environment and a considerable decrease in the elastic limit of 64% was observed when they were subjected to at acid pH, while in the Dentsply Sirona brand a partially stable behavior was observed in the 3 simulated conditions, which leads us to conclude that the environment and the factors to which the materials are exposed do alter their mechanical properties.

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The environment plays a key role in the properties of polymers, this is extremely important for biomedical applications such as orthodontics. These effects can arise from various factors such as temperature variation, solvents, or pH fluctuations (Huget, Patrick, and Nunez 1990).

CONCLUSIONS

Under the limitations of the research and after evaluating the results obtained, the following conclusions are established:

- The mechanical properties of the thermoformed acetates used for the manufacture of invisible aligners for orthodontics vary and may be affected depending on the pH to which they are subjected, having variability in their elastic limit.
- The specimens subjected to acidic and alkaline drinks had a greater decrease in their elastic limit when compared with those subjected to neutral pH.
- The specimens in general had an increase in their property on day 7, while on day 14 they returned to their initial value.

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