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In vitro comparison of the mechanical properties of single and triple layered clear aligner materials

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Aim: To compare between certain mechanical properties in TPU and PET-G aligner material in terms of tensile strength, hardness, and retention before and after simulated chewing and thermocycling.
Materials and methods: For this study, two types of thermoplastic aligner sheets were used: Memoflex from Aditek orthodontics, (single layered PETG sheets, 0.75 mm thick) and Zendura FLX, (triple layered TPU sheets, 0.76 mm thick). To prepare the samples, a disc shaped model was designed using Autodesk Meshmixer 3.3, then it was 3D printed.
Results: Compared to Zendura FLX aligners, Memoflex aligners had significantly larger median tensile strength, larger median retention force, larger median hardness before (p-value: <0.001) and after simulation.
Conclusion: PETG seems to have better mechanical properties when compared to TPU aligners. This can indicate it for use as long term appliances as retainers due to their assumed higher longevity and retentive forces.

Keywords: Tensile strength, Microhardness, Retention force

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Introduction

Thermoplastic clear aligners have acquired a major interest specially in adult orthodontics, particularly with the use of advanced technology in the treatment planning and fabrication. Clear aligners can offer an aesthetic and more convenient choice as an alternative to traditional fixed orthodontics.[1,2] Clear aligner therapy is identified by a stepwise correction of tooth malocclusion with crowding, and is highly accepted by most of the treatment population except for patients with allergic reactions.[3] Different materials and treatment approaches have been used since the usage of aligners by Kesling in 1945.[4, 5]

Technological developments in aligner materials and production techniques allowed the improvement of the force delivery, and better control of the teeth position in the three planes of space.[6] The thermo-plastic materials used by aligner manufacturers currently include polyethylene terephthalate glycol-modified (PETG), polypropylene, polycarbonate (PC), thermoplastic polyurethanes (TPU), ethylene vinyl acetate, etc..[7, 8]

The aligner performance is strongly influenced by the material construction. It is difficult to achieve certain tooth movements through using an aligner treatment only without using attachments. Attachments have been designed to apply force systems to teeth. Some beveled attachments increase retention significantly. However, it is still recognized that many parameters influence the biomechanical characteristics of aligners such as material properties, material thickness and amount of activation. Materials should be transparent, have a low degree of hardness, good elasticity, high resilience, and should be biocompatible and effective in terms of correcting tooth positions.[9] It is commonly said that softer materials provide less retention than more rigid materials, but no data have yet been published to prove this.[10]

Because the mechanical properties of the materials used to make clear aligners are critical for determining the efficacy of an orthodontic treatment based on these devices, technical data provided by material suppliers cannot always be used as a reference; instead, the materials must be experimentally assessed under the various conditions in which they are used. The mechanical characteristics of thermoplastic polymers can vary after thermoforming, indicating the need to evaluate them after this process.[11] Furthermore, aligners are exposed to a harsh environment in the oral cavity, which may result in significant degradation of their properties, reducing treatment efficacy.[12]

The numerical results from this study can be used to create guidelines for optimized future aligner therapy. Thus, orthodontists using aligner therapy will have a broader understanding of the two assigned materials in the study: Polyethylene Terephthalate Glycol (PETG) and Thermoplastic Polyurethane (TPU) aligner materials rather Memoflex ® and Zendura FLX ® in order. This study analyzes how these aligner materials are affected after thermocycling and chewing simulation to mimic the conditions inside patients' mouth during treatment. This will give them the chance to use materials wisely according to the needs of each case.

In a study conducted by Zhang et al[13] , it is stated that Polyethylene Terephthalate Glycol (Petg), Polycarbonate (PC) And Thermoplastic Polyurethane (TPU) are mostly used to modify the properties of aligners. Memoflex ® as PETG, a non-crystalline amorphous co-polymer of Polyethylene Terephthalate (PET), exhibits good mechanical properties, high fatigues resistance, dimensional stability, and solvent resistance. A Glygol Group (G) is added to the backbone of the copolymerizing agent that is a consisting of 31% mol 1,4-cyclohexylenedimethylene terephthalate (PCT) and 69 mol% PET. PETG has almost the same glass transition temperature (Tg), deformation behavior and optical properties as PET, but does not exhibit the straininduced crystallization behavior of PET at the production temperature. PC offers excellent mechanical strength, low water absorption, and transparency making this material very suitable for orthodontic applications. Its properties are very close to the one of Polymethyl Methacrylate (PMMA), but PC offers a higher mechanical strength and are usable in a wider temperature range. PCs also have a high transparency in visible light spectrum and provide a higher light transmission behavior than many kinds of Glasses.[13]

Finally, Zendura FLX ® is classified as a thermoplastic polyurethane (TPU). This thermoplastic is known for its exceptional versatility in technical applications. It exhibits remarkable resistance to abrasion and elasticity, along with a high shear strength and excellent transparency.[9, 14] TPU has a two-phase microstructure composed of hard and soft segments. The soft segments are often oriented perpendicular to the applied stresses and break into smaller pieces, enabling more deformation.[15]

This study aims to characterize and compare between certain mechanical properties in TPU and PET-G aligner material in terms of tensile strength, hardness, and retention before and after simulated chewing and thermocycling.

Significance of the study: The use of thermoplastic materials for orthodontic tooth movements requires a better understanding of the effect of the different material on torquing for selecting the optimal material.

Material and methods

For this study, two types of thermoplastic aligner sheets were used: Memoflex from Aditek orthodontics, Sao Paulo, Brasil (single layered PETG sheets, 0.75 mm thick) and Zendura FLX, from Bay Materials LLC, California, USA (triple layered TPU sheets, 0.76 mm thick).

To calculate the sample size, a highly cited paper published in 2020 investigating the mechanical properties of multiple thermoplastic polymers which are used in aligner manufacturing, including PET-G and TPU was used. The paper reported a difference in mean tensile strength of 13.08 MPa.[16] For the purposes of sample size estimation, we adopted this reported estimation. With an alpha cut-off of 0.05, an assumed standard deviation of 8 MPa, it's estimated that we need 9 study samples per group (n=9) to reach a statistical power of 90%. Sample size calculation was done using the R programming language for statistical computing version 4.2.1.[17] In our study we increased the number of samples to 11 to increase the power of the study.

A) Tensile strength testing

To prepare the samples, a disc shaped model was designed using Autodesk Meshmixer 3.3 (Meshmixer Inc, San Rafael, California, United States). The model was 10 mm high and the sample designs 1 mm high (**Error! Reference source not found.**A,B). The model was then 3D printed using a Form 3 printer and Formlabs Grey resin (Formlabs, Inc., Somerville, MA, USA) and used for thermoforming for aligner sheets, following manufacturers' guidelines, using a ministar-S (Scheu-Dental GmbH, Iserlohn, Germany). The sample shape and dimensions were designed following international ISO standard 527 for determination of tensile properties of plastics.[18-20] After thermoforming, a total of 22 samples for each material were trimmed off mechanically and divided into 2 groups with n=11. Group A, where the samples were stored for 24 hours in distilled water at 37ºC, and group B, where after storage, the samples were subjected to1000 thermocycles in distilled water, where they were immersed in 5ºC for 20 seconds then 55ºC for 20 seconds using Themoscientific THE1100 thermocycling machine (Life Technologies GmbH, Darmstadt, Germany). Afterwards, the samples were clamped to a universal testing machine (Shimadzu AG-X Plus, Shimadzu, Kyoto, Japan) and tested in tensile mode at cross-head speed 1 mm/min with load cell 1000N. The yield point was calculated by Trapezium-X software (Shimadzu, Kyoto, Japan) for all the samples.

B) Microhardness testing

For microhardness testing, samples were prepared using the same previous technique but with flat models (Figure 1A,B). Samples were divided into 2 groups with n=11, where group A was stored for 24 hours in distilled water at 37ºC, and group B received thermocyling as described before. Microhardness was then tested using a Vickers microhardness tester[20] (NEXUS400, Innovatest, Netherlands) under 100 gf load with dwell time 10 seconds. Afterwards, an image was taken using a microscopic lens at 20x magnification, and the Vickers hardness number (VHN) was calculated using the device software.

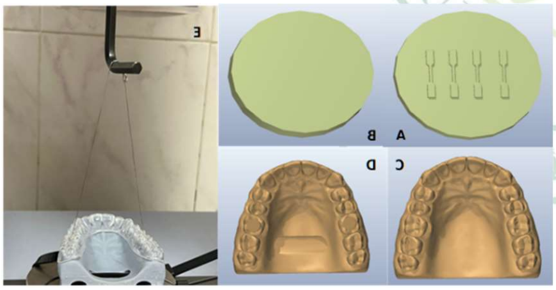

Figure 1: A,B: 3D models for thermoforming tensile and microhardness samples C,D: Retention test models with and without occlusal clearance. E: Mounted model and aligner for retention test.

C) Retention force testing

To test the retention force for the different materials, a full arch model was 3D printed, once as it is and once with a 4 mm deep, 8 mm diameter, cylindrical depression at the occlusal surface of the first molar (Figure 1C,D). The same arch was used to thermoform all aligners using the as is model. To standardize the thermoforming process, a guide was created to place the models in the exact position on the ministar machine, this way we could ensure that all aligners have similar thickness patterns. Afterwards, the aligners were trimmed and finished. The aligners were then divided into 2 groups (n= 11), where in group A, they were stored for 24 hours to allow any residual stress relaxation, and in group B, the aligners were placed into a chewing simulator where it received 11200 chewing cycles. After each 800 cycles, the aligners were subjected to 70 thermocycles as described before, then returned again to the chewing simulator. This process was repeated 14 times for each aligner. A chewing simulator CS-4.4 (SD Mechantronik GmbH, Germany) was used for this test. The aligners were then placed on the modified models, after a hole was created in their occlusal surfaces corresponding to the cylinderical depression. Through each hole, a stainless-steel ligature wire was passed and bonded to a composite disc that is smaller than the opening (2 mm thick with 5 mm diameter) so it doesn't cause any friction with the walls. The two wires were then tied together. The models and aligners were then clamped to the lower compartment of a universal testing machine (Shimadzu AG-X Plus, Shimadzu, Kyoto, Japan), and the wire was hooked to the upper compartment (Figure 1E). The aligner was then pulled off the model using cross-head speed 6 mm/min till it started to get dislodged. The maximum force was calculated using the software. For each aligner this process was repeated 5 times to take the average force.

The results were collected and tabulated, then check for normality using Shapiro-Wilk normality test. Afterwards, either t-test or Mann Whitney test was used for pairwise comparison according to data distribution. The statistical analysis was done using R programming language for statistical computing version 4.2.1.

Results

Error! Reference source not found. shows that, compared to Zendura FLX aligners, Memoflex aligners had significantly larger median tensile strength before (14.7 vs. 12.7; p-value: <0.001) and after simulation (Figure 2A; 14.4 vs. 12; p-value: <0.001). However, the mean percentage of tensile strength lost during simulation was comparable between Memoflex (1.1% drop) and Zendura FLX (Figure 2B; 3.5% drop; p-value: 0.18). It can also be seen that, compared to Zendura FLX, Memoflex had a significantly larger median retention force before (29.9 vs. 12.9; p-value: <0.001) and after thermocycling and chewing simulation (Figure 3A; 22.1 vs. 9.7; p-value: <0.001). Additionally, the percentage of retention force lost during simulation was comparable between Memoflex (-26.5%) and Zendura FLX (Figure 3B; -26.9%; p-value: 0.8176), indicating no significant difference. The results also show that, compared to Zendura FLX, Memoflex had a significantly larger median hardness before (9.8 vs. 8.1; p-value: <0.001) and after simulation (Figure 4A; 10.9 vs. 8.9; p-value: <0.001). However, the mean percentage of hardness gained during simulation was comparable between Memoflex (10.5% drop) and Zendura FLX (Figure 4B; 10% drop; p-value: 0.74).

Error! Reference source not found. shows that Zendura FLX showed a significant drop in its median tensile strength (12.7 to 12; p-value: 0.033), median retention force (12.9 to 9.7; p-value: <0.001), and a significant increase in its mean hardness (8.1 to 8.9; p-value: <0.001). We can also see that Memoflex sustained its tensile strength, with no significant difference before and after the simulation (p-value: 0.39). In contrast, the retention force showed a significant decrease (29.9 to 22.1; p-value: <0.001) and the hardness showed a significant increase (9.8 to 10.9; p-value: <0.001).

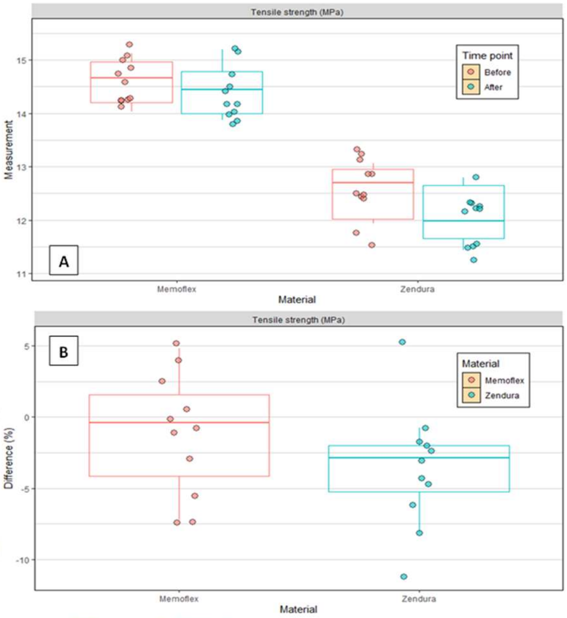

Figure 2: A: Tensile strength measurements before and after simulation per material, B: Difference (%) in tensile strength measurements before and after simulation per material.

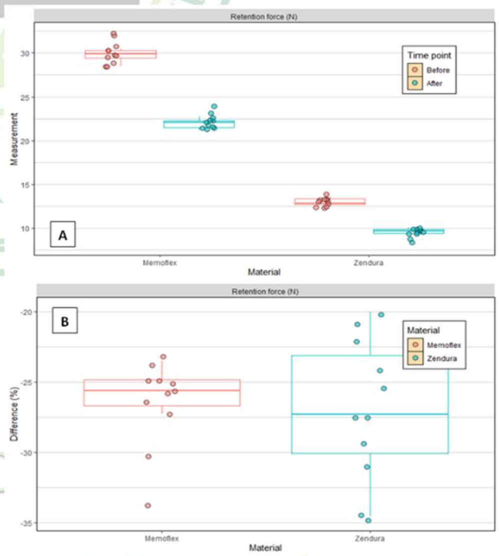

Figure 3: A: Retention force measurements before and after simulation per material, B: Difference (%) in retention force measurements before and after simulation per material.

Table 1: Comparing tensile strength, Retention force, and Microhardness of Memoflex and Zendura FLX

	Tensile strength (MPa)				Retention force (N)				Microhardness (VHN)			
Term	**Over-all**	**Memo-flex**	**Zendura FLX**	**p-value**	**Over-all**	**Memo-flex**	**Zendura FLX**	**p-value**	**Over-all**	**Memo-flex**	**Zendura FLX**	**p-value**
Before	**Med (IQR) 13.5 (1.9)**	**14.7 (0.8)**	**12.7 (0.9)**	**U: <0.001 *****	**Med (IQR) 21 (17)**	**29.9 (0.8)**	**12.9 (0.7)**	**U: <0.001 *****	**Med (IQR) 9.1 (1.6)**	**9.8 (0.3)**	**8.1 (0.5)**	**U: <0.001*****
After	**Med (IQR) 13.3 (2.4)**	**14.4 (0.8)**	**12 (1)**	**U: <0.001 *****	**Med (IQR) 15.6 (12.4)**	**22.1 (0.8)**	**9.7 (0.4)**	**U: <0.001 *****	**Med (IQR) 9.9 (2)**	**10.9 (0.3)**	**8.9 (0.3)**	**U: <0.001*****
Differ-ence	**Avg (SD) -0.3 (0.6)**	**-0.2 (0.6)**	**-0.5 (0.5)**	**t: 0.2623**	**Med (IQR) -5.6 (3.8)**	**-7.5 (0.9)**	**-3.7 (1.1)**	**U: <0.001 *****	**Avg (SD) 0.9 (0.3)**	**1 (0.3)**	**0.8 (0.3)**	**t: 0.0723**
Differ-ence (%)	**Avg (SD) -2.3 (4.3)**	**-1.1 (4.2)**	**-3.5 (4.3)**	**t: 0.1881**	**Avg (SD) -26.7 (4.1)**	**-26.5 (3.2)**	**-26.9 (5)**	**t: 0.8176**	**Avg (SD) 10.3 (3.5)**	**10.5 (2.9)**	**10 (4.2)**	**t: 0.7420**
α = 0.05. p < 0.05*, p < 0.01, p < 0.001*****												
P-values obtained from two-sample t-test (t) or Mann-Whitney test (U)												

Table 2: Comparing the study parameters of Zendura FLX and Memoflex aligners before and after the simulation

Zendura FLX Tensile strength (MPa)					**Memoflex Tensile strength (MPa)**				
Term	**Overall**	**Before**	**After**	**p-value**	**Term**	**Overall**	**Before**	**After**	**p-value**
Meas-urement	**Med (IQR) 12.4 (0.8)**	**12.7 (0.9)**	**12 (1)**	**U: 0.0336***	**Meas-urement**	**Avg (SD) 14.5 (0.4)**	**14.6 (0.4)**	**14.4 (0.5)**	**t: 0.3938**
Zendura FLX Retention force (N)					**Memoflex Retention force (N)**				
Term	**Overall**	**Before**	**After**	**p-value**	**Term**	**Overall**	**Before**	**After**	**p-value**
Meas-urement	**Med (IQR) 11.3 (3.2)**	**12.9 (0.7)**	**9.7 (0.4)**	**U: <0.001*****	**Meas-urement**	**Med (IQR) 26.1 (7.8)**	**29.9 (0.8)**	**22.1 (0.8)**	**U: <0.001*****
Zendura FLX Microhardness (VHN)					**Memoflex Microhardness (VHN)**				
Term	**Overall**	**Before**	**After**	**p-value**	**Term**	**Overall**	**Before**	**After**	**p-value**
Meas-urement	**Avg (SD) 8.5 (0.5)**	**8.1 (0.3)**	**8.9 (0.2)**	**t: <0.001*****	**Meas-urement**	**Med (IQR) 10.4 (1)**	**9.8 (0.3)**	**10.9 (0.3)**	**U: <0.001*****
α = 0.05. p < 0.05*, p < 0.01, p < 0.001*****									
P-values obtained from two-sample t-test (t) or Mann-Whitney test (U)									

Discussion

Triple layered TPU clear aligner sheets have been marketed as the more durable, more tolerated alternative to single layered aligner sheets. While this can be in part true, one can does not disregard the possibility of utilizing different aligner materials for different uses, whether different types of movement or retention. For this reason, a good comparison of mechanical properties as well as durability of the two types of materials is needed to aid the practitioner in selecting the material that suits the patient's exact need, maybe even by introducing a treatment combining and alternating the use of the two material to cope with the different movements, since each material can offer a different force amount and pattern as found by previous authors.[21]

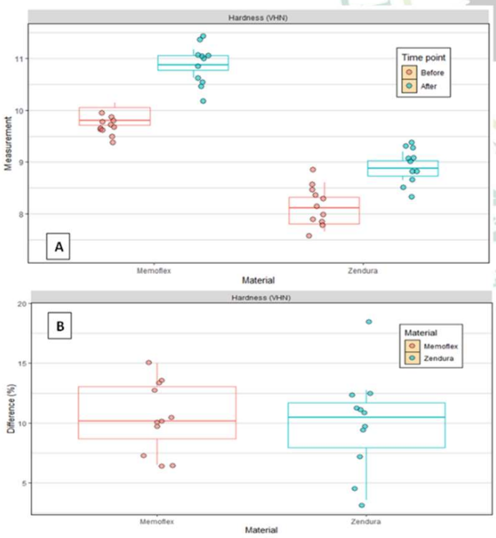

Figure 4: A: Hardness measurements before and after simulation per material, B: Difference (%) in hardness measurements before and after simulation per material.

Thermocycling has been utilized by many authors to assess clear aligners durability, and it is suggested that 500 cycles would simulate one week. Similarly chewing simulation was also used to assess the durability and serviceability of many dental appliance. It is suggested in literature that the chewing frequency for a day is usually between 800-1400 cycles. In our current study, since one aligner is usually used for 2 weeks, it was subjected to 1000 thermocycles, and 11200 chewing cycles to simulate the normal wearing period.[22] The aim here is to simulate the loading pattern as well as thermal fluctuations inside the patient's mouth to assess how they would affect the material.

High tensile strength is a desirable property in clear aligner sheets specially for the thermoforming process.[23] When comparing tensile yield strength of both materials, the PETG single layered groups (Memoflex) showed significantly higher tensile yield strength values at $P<0.001$, than the triple layered groups (Zendura FLX), with and without thermocycling. Where Memoflex showed tensile yield strength values of 14.7 and 14.4 MPa, and Zendura FLX showed tensile yield strength values of 12.7 and 12 MPa, for immediate and thermocycled samples respectively. This is in accordance with Tamburrino et al's results which showed significantly higher tensile strength values for Duran (like Memoflex, a single layered PETG material) when compared to Zendura FLX. When comparing the percentage of change in tensile yield strength values, there was no significant difference in the percentage of change between the two materials, where the percentage change ranged from 1.1% for Memoflex to 3.5% for Zendura FLX, where the change in both cases was a decrease in the yield strength values. Nevertheless, while the percentage of decrease was not significant, the numerical values of the yield tensile strength was significantly decreased only at $P<0.05$ after thermocycling for Zendura FLX, while it was non-significant for Memoflex groups. While at $P<0.01$ and $P<0.001$, there was no significant decrease in yield strength for both materials. This came in accordance with Tamburrino et al's results, who achieved higher tensile strength results with thermoformed PETG material (Duran) when compared to Zendura FLX (TPU), however, they used single layered Zendura A sheets not triple layered TPU Zendura FLX sheets like our study. They also recognized a decreased in the tensile strength values after aging and attributed it to water absorption, which had a plasticizer effect leading to decrease in material Tg.[16, 24] This can be an indication of a comparable stability in tensile strength with the intraoral thermal fluctuations.

Surface hardness is considered an important parameter to test any aligner material, as it has a direct effect on the material's susceptibility to crack initiation, resistance to scratching which could increase the surface roughness leading to discoloration and color instability as well as plaque and bacterial retention, due to the altered capability of crack initiation and propagation.[25] Surface hardness of clear aligners was measured using Vickers microhardness tester in several previous studies due to its suitability to be used on various materials including polymers.[26-28] As for the Vickers microhardness results, it showed a somehow similar behavior to tensile results, where the Vickers hardness number (VHN) was significantly lower for Zendura FLX when compared to Memoflex both immediate and after thermocycling. Similarly, the percentage of decrease in both materials showed no significant difference. However, the numerical comparison showed that thermocycling caused a significant increase in VHN in both materials at $P<0.001$. This is in accordance with the results from Kwong et al, and can be attributed to increased surface crystallization as reported by previous authors.[10] In 2024, Mei et al found no change in tensile strength, and a significant decrease in microhardness values of clear aligners after aging for 21 days, however, their samples were not subjected to thermocycling and were just stored at 37 degrees.[20]

Retention of clear aligners is a very important factor. It not only gives an indication about how fit the appliance is, the amount and accuracy of force delivery, it also gives an indication of the material's stiffness, and, when combining it with other variables like time and load, it can also give an indirect indication about the material's viscoelastic behaviour and stress relaxation rate, which is a very important factor to consider while choosing the clear aligner material. Looking at history, we can find several studies assessing retention of clear aligners. While those studies use different designs customized for the test, the main concept is the same; pulling technique and calculated the required force to dislodge the aligner.[29-31] Our current design is considered a modification or a variant to the previously used designs. Upon comparing the retentive forces on the other hand, Memoflex had significantly higher force levels at $P<0.001$ as compared to Zendura FLX, with and without thermocycling and chewing simulation. Both materials however, showed a significant decrease in retentive forces after thermocycling and chewing simulation at $P<0.001$. It is worth noting that thermoplastic materials possess viscoelastic properties, meaning that they fail to follow Hook's law after long term exposure to forces. This means that loading time has a big influence on the properties of the aligners. With time, the forces generated by the aligners start to decrease or decay as the aligner is undergoing permanent deformation[23]. This kind of behaviour also increases with increasing the temperature. This can all explain the decrease in retentive forces of aligners after exposure to chewing simulation and thermocycling. It is interesting to point out nonetheless, that the percentage of force decrease among both materials was not significantly different. In their study, Lijima et al also found a significant drop in force delivery by PETG and PU aligners after 2500 thermocycles, however the percentage decrease was much higher for PETG unlike our results which showed similar percentages. This can be due to the difference in composition and crystallization of their experimental PU material, as well the difference in the glass transitional temperature.[32] Kohda et al stated in their study the correlation between aligner hardness and force delivery. Where they stated that the higher hardness values denote more force delivery by the aligner.[33] It can also be seen in our study that the harder PETG material showed higher retentive forces.

This study has some limitations including the inability to simulate the effect of long-term immersion of the aligners inside the oral saliva as well as acid fluctuations that may also have an effect on the mechanical and surface properties of the aligners. It is also important to note that while fabricating thermoformed aligners, the aligner thickness is extremely variable between one case and another, as well as between one part and another in the same aligner. That difference as well as the difference in dental anatomy (tooth size and shape and presence of undercuts), beside the presence or absence of attachments, can have a great effect on aligner retention. From the current results we can conclude that PETG seems to have better mechanical properties when compared to TPU aligners. This can indicate it for use as long term appliances as retainers due to their assumed higher longevity and retentive forces. More studies are needed to further evaluate the efficiency of each material in force delivery with specific movements, and clinical serviceability of both materials.

Authors contribution

Conceptualization, M.A & Y.A.; methodology, M.A. & Y.A.; validation, Y.A.; investigations, M.A. & Y.A.; data curation, M.A..; writing—original draft preparation, M.A. & Y.A.; Writing—review and editing, M.A., Y.A., W.R. & K.M.; visualization, M.A., Y.A., W.R. & K.M.; supervision, Y.A., W.R. & K.M. All authors have read and agreed to the published version of the manuscript.

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Data availability

Data will be made available on request.

Ethics approval and consent to participate

This article does not contain any studies with human or animal subjects. Ethical committee approval is not required.

Competing Interests

The authors declare that they have no competing interests.

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