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Effects of aging on the tensile strength and surface condition of orthodontic aligners: a comparative study of five models

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Abstract

Background/Objective: The objective of this study is to determine the effect of aging on tensile strength and surface condition of orthodontic aligners on days 0, 1, 5, 7, 10, and 14.

Materials/Methods: The total sample of 80 aligners included five brands (Accusmile®, Angel®, GRAPHY®, Invisalign® and Suresmile®) were placed in a thermocycler to imitate the temperature variations of the oral cavity and accelerate aging for 50, 250, 350, 500, and 700 cycles. The mechanical tensile properties (Young's modulus E, yield strength YS, maximum elastic stress MES, Ultimate Tensile Strength UTS, and maximum stress MS) were measured by Universal Testing Machine at a rate of 5 mm of deformation per minute for 4 minutes. Microscopic observations were made under a voltage of 10 kV at magnifications times 50, 250, 500, 1000, and 2500 after cleaning with ethanol and ultrasound then metallization with gold.

Results: YS and MES of Angel® aligners are statistically reduced after five days of aging ($P = .003$). Aligners from the most rigid to the most flexible are (decreasing E): Accusmile® > GRAPHY® > Suresmile® > Invisalign® > Angel®. Surface conditions also deteriorated with aging (appearance of scratches, porosity, cracks, etc.). GRAPHY® aligners are more heterogeneous and weaker than others.

Limits: *In vitro* study

Conclusion: Mechanical properties of Accusmile®, GRAPHY®, Invisalign®, and Suresmile® were not affected by aging. YS and MES were reduced from day 5 for Angel® aligners. Surface conditions are also altered by aging.

Keywords: clear aligners; artificial aging; mechanical properties

INTRODUCTION

The growing demand from patients for an aesthetic orthodontic treatment combined with advances in Computer-Aided Design and Manufacturing (CAD/CAM) technologies have enabled the introduction of clear orthodontic aligners into our therapeutic options.(1) The latter therefore represents an invisible and comfortable alternative to classic orthodontic treatments using multiple brackets and whose effectiveness would be comparable for cases of mild to moderate malocclusion.(2,3)

Aligners provide numerous advantages including aesthetics, comfort, removability, good hygiene maintenance, and reduced treatment time.(4,5) However, they also come with disadvantages: patients must be highly compliant, they present difficulties in complex cases, they are costly, and recycling options are currently limited.(6–8)

The most commonly used materials for the manufacturing of orthodontic aligners are Thermoplastic Polyurethane (TPU) and especially Polyethylene Terephthalate Glycol (PET-G). These thermoplastic polymers are visco-elastic, meaning they deform under stress and return to their initial shape once the stress is removed. Major brands on the market use each their own material which are designed to meet criteria such as good mechanical, chemical, and optical stability unaltered by aging,(1,9–13) biocompatibility,(14) and comfort.

Since 1945 aligners and their materials have evolved to become even more efficient. Initially reserved for minor tooth movements, aligners have broadened their indications thanks to new materials introduced on the market and the use of auxiliaries and optimized attachments (3). The latest innovation in aligner technology is GRAPHY® (Seoul, Korea), the brand of aligners directly printed in shape memory material: Tera Harz TC-85.(8,15)

Despite these advances, only 50% of the predicted tooth movements are ultimately achieved (16). Some movements like the buccal version of the incisors, are successful in more than 80% of cases (7,17,18) whereas torque movements are less than 10% efficient (13). Factors influencing movement success include patient compliance, dental morphology and positioning (19), healthy periodontium, and the frequency of aligner insertion and removal(20). Material-related factors include the position of the gingival margin (21,22), the fitting (23), the thickness (13,19), and biomechanical characteristics. Stress relaxation due to the viscoelasticity of the material results in a 50% loss of force transmitted to the teeth within three hours (11). Additionally, exposure to the oral environment and temperature variations affect the mechanical properties of polymers (1,10,13,24).

The first aim of our study is to compare the effect of aging on the tensile strength of orthodontic aligners at different time intervals: unaged, 1 day, 5 days, 7 days, 10 days, and 14 days. Second aim is to compare the mechanical properties of the different materials.

MATERIALS AND METHODS

A sample of 80 aligners from 5 brands were included in this study:

- 18 aligners Invisalign®, Align Technology Inc®, San Jose, California USA
- 18 aligners Suresmile®, Dentsply Sirona Inc®, Charlotte, North Carolina USA
- 18 aligners Angel®, AngelAligner®, China
- 18 aligners Accusmile/Fas®, Forestadent Bernhard Foerster GmbH®, Pforzheim, Germany
- 8 aligners GRAPHY®, Graphy Inc., Seoul, Republic of Korea.

The characteristics of each are presented in *Table 1*. Each aligner was cut into 5 parts: the anterior and lateral parts (for tensile tests) and the second molars (for observations using a scanning electron microscope).

Aging of aligners

Thermocycling has been used to accelerate the aging of clear aligners. We followed the 2015 ISO/TS 11405 standard (25) which specifies that each cycle consists of 20 seconds in a cold bath and 20 seconds in a hot bath. Given the recommendation to change the aligners every 14 days, we monitored the aging of our samples for a maximum of 14 days. Our aging intervals of 1, 5, 7, 10, and 14 days corresponded to 50, 250, 350, 500, and 700 cycles respectively. Each aging group consisted of 3 Accusmile® aligners, 3 Angel® aligners, 1

GRAPHY® aligner, 3 Invisalign® aligners, and 3 Suresmile® aligners. Except groups J7 and J14 which included 2 GRAPHY® aligners (see *Table I*).

Tensile tests

Tensile strength is the maximum stress a material can endure before it becomes permanently deformed or breaks. The uniaxial traction tests were conducted using the Traction Dynamometer LRX Plus test bench from LLOYD Instruments® (Technical Engineering Hall of the Faculty of Odontology of Lorraine, Nancy, France). The cut sample was fixed between the 2 jaws of the machine, which applied a pulling force at a speed of 5mm per minute for 4 minutes using a 2kN force sensor at a constant and controlled temperature of 20°C.

The variables studied to determine the mechanical resistance of these materials are:

a- Young's modulus E (in GPa)

This modulus relates stress to strain when the material is stretched in the elastic phase. A higher modulus indicates a more rigid material that deforms minimally when transmitting significant forces (13). Conversely, a lower modulus signifies a more flexible material that deforms easily. The modulus is calculated experimentally from the stress versus strain graph.

$$\sigma = E\varepsilon \text{ so } E = \frac{\sigma}{\varepsilon}$$

b- Yield strength YS (in N) and maximum elastic stress MES (in MPa)

YS is the maximum force that can be applied to the material before it undergoes permanent deformation. This value is given by the LRX Plus® software.

Beyond this value, the material will enter plastic deformation and will not return to its initial shape. The maximum elastic stress corresponds to the force related to the section of the sample:

$$\sigma_{\text{max elastic}} = F_{\text{max elastic}} / S_{\text{sample}}$$

c- Ultimate Tensile Strength UTS (in N) and maximum stress MS (in MPa)

UTS determines the amount to which the sample is pulled before failure. The higher this value, the more robust the material. The lower it is, the more fragile the material. The maximum stress is calculated using the following formula:

$$\sigma_{\text{max}} = F_{\text{max}} / S_{\text{sample}}$$

Scanning Electron Microscopy (SEM) observations

a- Principles

SEM is a technique that allows the surface of conductive material to be visualized. It is based on the interaction of an incident electron beam with the sample. This can excite the atoms of the material which will ionize by ejecting a secondary electron (topographic analysis). When

the primary electron bounces off the nucleus of the atom, it is a back-scattered electron which communicates chemical contrast information.

b- Sample preparations

- Ethanol cleaning: removal of impurities and dehydration
- Ultrasound: remove residual impurities
- Drying
- Metallization with gold: to make the samples conductive.

c- Choice of constants

This study used the JEOL JSM-6010LA Analytical Scanning Electron Microscope from the Jean Lamour Institute, Campus Artem, Nancy, France. The observations were made under a voltage of 10kV at magnifications times 50 when the surface state was evaluated at systematic magnifications of 250, 500, 1000 and 2500.

Statistical analyzes

Statistical analyzes were carried out using the software Stata v13.0 (STACORP, USA).

All the parameters studied were quantitative, the comparison tests between the groups therefore consisted of applying ANOVA analyses with post-hoc Tukey tests after checking the normality of the distribution of values and the equality of variances between groups. Otherwise, non-parametric Kruskal-Wallis tests were applied. The level of significance is fixed at 5% and the beta risk at 20%.

RESULTS

The distribution of the aligners according to aging is presented in Table I. A total of 240 traction tests were carried out.

E (Table II)

No statistical differences were observed within each group between day 0 (D0) and the following days. However, there are significant differences between brands. At D0, the modulus of elasticity (E) of Accusmile® aligners (7.38 ± 1.83) is statistically different from that of Angel® aligners (3.4 ± 1.05) and Invisalign® aligners (3.81 ± 1.29). At D14, E of Accusmile® aligners (7.33 ± 1.93) is statistically higher than that of Angel® aligners (3.15 ± 0.39), Invisalign® (4.6 ± 9.84) and Suresmile® (4.63 ± 1.98) with $p < 0.0001$. In decreasing order of E: Accusmile® > GRAPHY® > Suresmile® > Invisalign® > Angel®. PET-G is approximately twice as rigid as Smart Track™, and Master Control S® multilayer materials.

YS and MES (Tables III and IV)

At D0, a statistically significant difference was demonstrated between the Accusmile® aligners (70.59 ± 18.8) and the Angel® aligners (52.9 ± 5.53) as well as between the Accusmile® aligners (70.59 ± 18.8) and Invisalign® aligners (51 ± 7.13). Accusmile® had the highest YS, while Angel® and Invisalign® had the lowest. No statistically significant differences were observed in the Accusmile®, GRAPHY®, Invisalign®, and Suresmile® groups between D0 and the following days, the p-values are 0.38, 0.93, 0.89, and 0.05 respectively. However, this mechanical parameter is affected by aging from the 5th day for Angel® aligners ($p=0.003$) decreasing from 52.9 ± 5.53 (D0) to 42.97 ± 6.87 (D14) (Fig. 1).

Similar observations were made regarding the maximum elastic stress (MES). This parameter is affected from the 5th day for Angel® aligners ($p=0.003$).

UTS and MS (Tables V and VI)

No statistically significant differences were observed within each group between D0 and the following days. However, significant differences were observed between the groups at different aging intervals. At D0, the maximum force necessary to break Accusmile® aligners (386.4 ± 56.58) is statistically higher than that of the other brands: Angel® (203 ± 27.22), GRAPHY® (170 ± 82.74), Invisalign® (259.5 ± 26.46) and Suresmile® (261.8 ± 54.5).

MEB

The surface conditions of Accusmile®, Angel®, Invisalign®, and Suresmile® aligners are relatively homogeneous at D0. However, some shallow scratches can be observed. By D14, we observed an abraded surface condition, with more significant scratches, porosities, tearing phenomena, and even cracks.

In contrast, the directly printed GRAPHY® aligners showed lines of material application corresponding to the printing technique, as well as deposits that appeared to flake off the surface. These deposits are heterogeneous and the same composition as the aligner. By D14, the deposits had disappeared, but we observed cracks crossing an entire cusp (fig. 2f).

DISCUSSION

A high modulus of elasticity (E) implies a stiffer material. Accusmile® aligners are approximately twice as stiffer than Angel® and Invisalign® aligners; before and after aging. In order of material stiffness, the most rigid to the most flexible: Accusmile® (PET-G) > GRAPHY® (Tera Harz TC-85) > Suresmile® (Essix ACE) > Invisalign® (Smart Track™) > Angel® (Master Control S®).

Other authors tried to determine the Young's modulus of aligner materials. Ihssen *et al.* tested PET-G samples after immersion in an aqueous solution or thermocycling, Fang *et al.* compared changes in mechanical properties of Invisalign® aligners before and after use and Alam *et al.* performed the meta-analysis of Young's moduli of Invisalign® aligners and PET-

G. All these studies reported E values significantly lower than those found in our study: from 1.85 to 2.05 GPa for PET-G,(12) and around 600 to 800 MPa for Smart Track™.(28,29)

This discrepancy can be explained by differences in material thickness, with our study using sections from 0.75 to 0.8mm, and 0.5mm in Ihssen *et al.*'s study. We considered that the thickness was constant regardless of the aligner area, and our samples were larger than those of other studies.

Another explanation for this difference could be an inaccuracy related to the traction machine. The traction must be purely linear and constant at a rate of 5mm per minute.

There is no statistically significant difference in the evolution of Young's moduli in our study. The same conclusion was found by Fang *et al.* They observed a downward trend between new and worn aligners. In our study, we noted an increasing trend until the 7th day and then a decreasing trend until the 14th day.

Regarding the elastic limit, Ihssen *et al.* found elastic limit values between 33 and 38 MPa. Accusmile® samples, made of PET-G, have values twice as high, and the Suresmile® samples, in slightly modified PET-G, have values 1.5 times higher (53.19 ± 8.37 MPa). The elastic limit is the only parameter for which a significant difference was demonstrated from the 5th day of aging for the Angel® aligners. This reduction in the elastic limit and thus in the maximum elastic stress implies a reduction in the forces transmitted to the teeth. If it is supposed that the deformation of the aligner passes into the plastic domain: in that case, it will not return to its initial shape, failing to deliver the expected forces at this stage of the treatment.

To our knowledge, no other study has investigated tensile mechanical properties in terms of stress.

Even though the mechanical properties of all brands except Angel® are not affected by aging, only 50% of the predicted tooth movements are ultimately achieved (26). This low success rate is mainly due to the phenomenon of stress relaxation in the polymers and mechanical and chemical wear in the mouth.

Regarding SEM observations, the same findings were made in the studies of Fang *et al.*, Schuster *et al.*, and Condo *et al.* on Invisalign® aligners (28,30,31). The presence of porosities, cracks, and fractures in the materials creates niches for oral bacterial infiltration and a gateway for the absorption of water and other elements present in saliva (32). SEM is a very powerful observation technique. However, the incident electron beam must be perpendicular to the sample surface. This is why our magnifications were only possible at the level of the cusps, potentially missing defects in other areas.

Advantages and limitations of the study

A wide range of brands of aligners was included in the study without limiting ourselves only to the most used brand, namely Invisalign® aligners. We will nevertheless note that certain brands did not respond to our request, particularly Smilers® (Biotech Dental®, France) and Spark® from ORMCO® (Glendora, USA), although widely represented on the market, were

also not included because our request for study invitation was rejected. GRAPHY® aligners, the latest innovation in the field, are less represented in our sample because the suppliers only offered 8 aligners. This reduced number may have prevented highlighting differences that nevertheless exist. Finally, monitoring at different time intervals allowed us to establish an evolution of the mechanical properties over time up to 14 days. Fang et al. also carried out monitoring over time but for 180 min to study stress relaxation.(11)

The thermocycling method used is a validated thermal aging technique but it nevertheless presents 2 major constraints: the absence of mechanical and chemical constraints. Indeed, thermocycling does not reflect the occlusion of patients nor the complexity of salivary composition. In the mouth, saliva is made up of enzymes, proteins, and bacteria and has a more acidic pH than thermocycler water. This configuration affects the chemical composition of thermoplastic polymers (13,24,27). Water causes degradation and hydrolysis of materials (12); this parameter was not considered in the study.

Future research

For future research, it would be interesting to include other brands like Spark® (Ormco, Glendora, US), Smilers® (Biotech Dental, France), Orthocaps® (Ortho Caps GmbH, Hamm, Germany) and expand the sample size of GRAPHY®. A larger sample could highlight a statistically significant reduction in mechanical properties, given the wide dispersion of the values found. This shape memory material could be more ductile at oral temperature applying light and constant forces, which could prevent the loss of strength linked to relaxation (33). Printed aligners might also be more mechanically resistant and more elastic than conventional aligners (34). According to our results, the Tera Harz TC-85 is more elastic than the Master Control S® (Angel®).

For Angel® aligners which lose their tensile strength significantly after 5 days, it would be wise to reduce their wear time to 7 or even 5 days, rather than 14 days. Aligners from other brands, that didn't show a significant difference, can be worn for 14 days. It is not the mechanical properties of the materials that determine the transition to a 7 or 10-day protocol but rather the type of movement desired. According to Al-Nadawi *et al.*, the 7-day protocol would be clinically acceptable except for complex posterior movements (35). Another study attained the same conclusion for the 10-day protocol, showing similar results without compromising the clinical efficacy (36). Stephens *et al.* found no difference in the accuracy of mandibular canine derotation between 7-day and 14-day protocols (37). Another study suggests that there is no benefit to increasing the wear time for mild to moderate malocclusions. The 7-day protocol would reduce treatment time (38), but the aligners will always be subject to the stress relaxation phenomenon which is maximal during the first hours of wear. The decrease in mechanical properties and poor occlusion achieved is linked to this phenomenon. Further clinical prospective studies are needed to determine the ideal time wear of each aligner's brand.

In this context, refinement is essential to compensate the material's weaknesses and achieve the clinical movement as close as possible to the movement planned by the ClinCheck®.

CONCLUSION

- The modulus of elasticity (E), ultimate tensile strength (UTS), and maximum stress (MS) were not affected by aging for the aligners included in our study: Accusmile®, Angel®, GRAPHY®, Invisalign®, and Suresmile®.
- The yield strength (YS) and maximum elastic stress (MES) are statistically significantly reduced from the 5th day of wear for Angel® aligners (in Master Control S)
- Accusmile® aligners are stiffer and more tensile-resistant than Angel®, Invisalign® and Suresmile®. GRAPHY® aligners are more resistant to elastic deformation than Angel®, Invisalign® and Suresmile®, which makes them more prone to breaking.
- SEM confirmed that surface defects worsen with aging. At day 0 Invisalign® aligners are the smoothest whereas GRAPHY® are the most heterogeneous. At day 14 fractures were observed only on GRAPHY® aligners.

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Figure 1. Experimental design of the study. Clear aligners were thermocycling to imitate the buccal aging then cut into several parts. Tensile tests and microscopic observations were carried out after

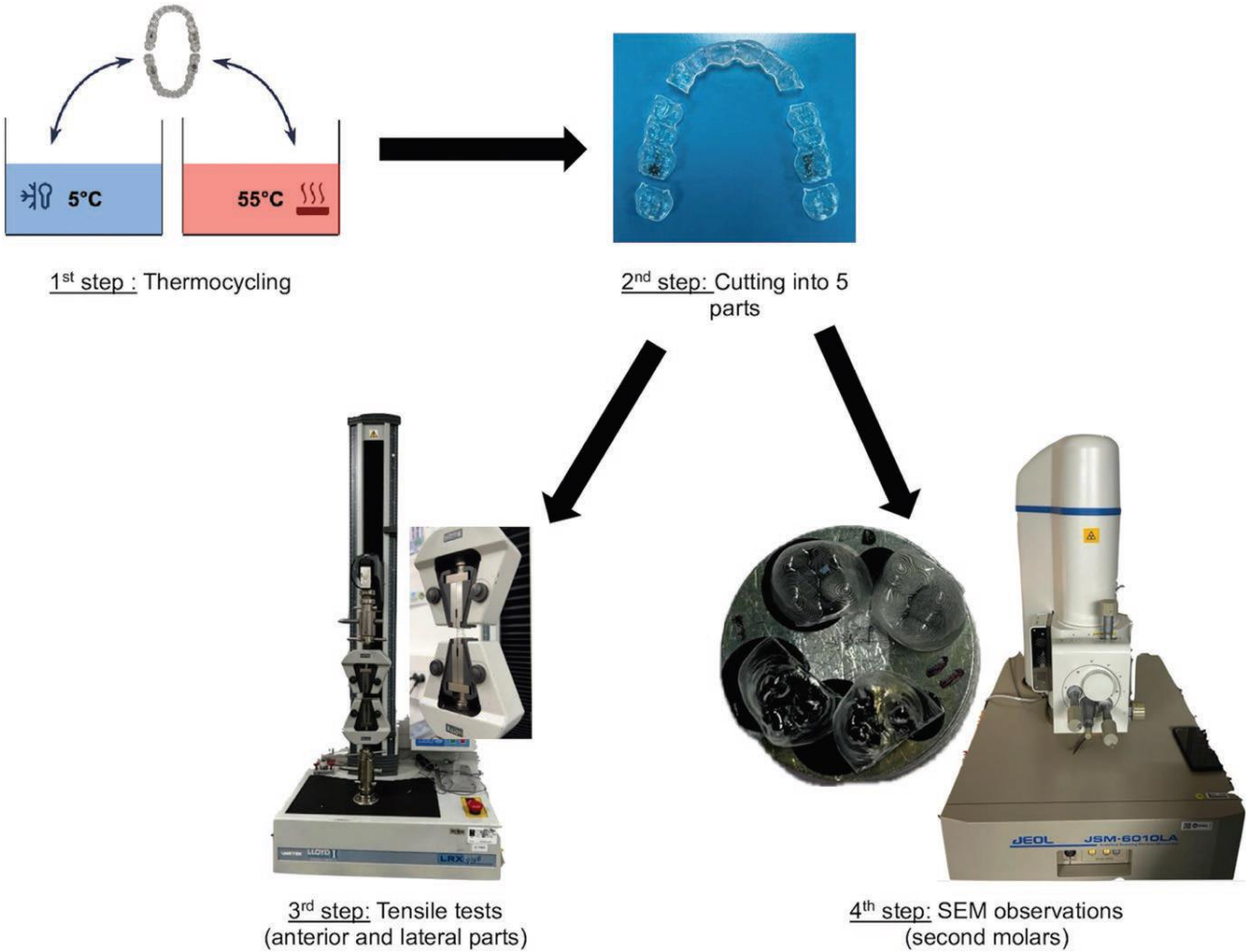


Figure 2. Young Modulus at Day 0 (Newton). This graph shows the values of E at day 0. Stars represent significant differences between groups ($P = .0001$).

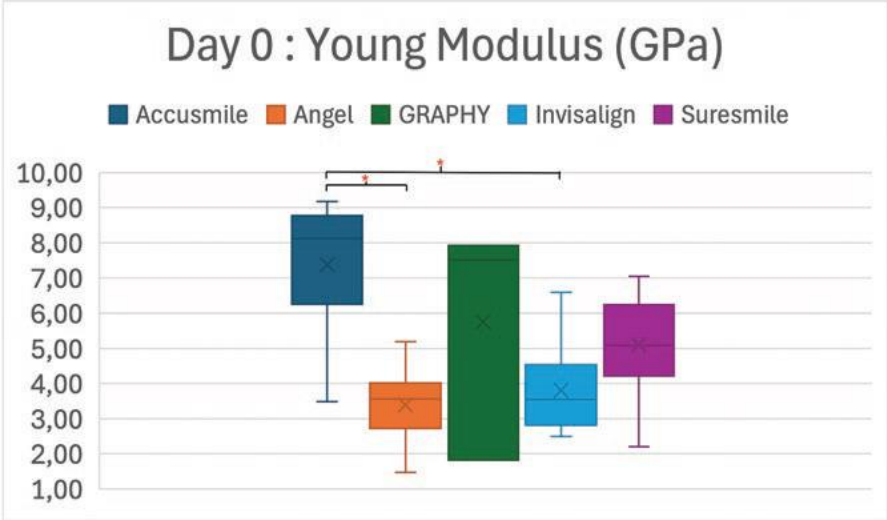


Figure 3. Young Modulus at Day 14 (Newton). This graph shows the values of E at day 14. Stars represent significant differences between groups ($P < .0001$).

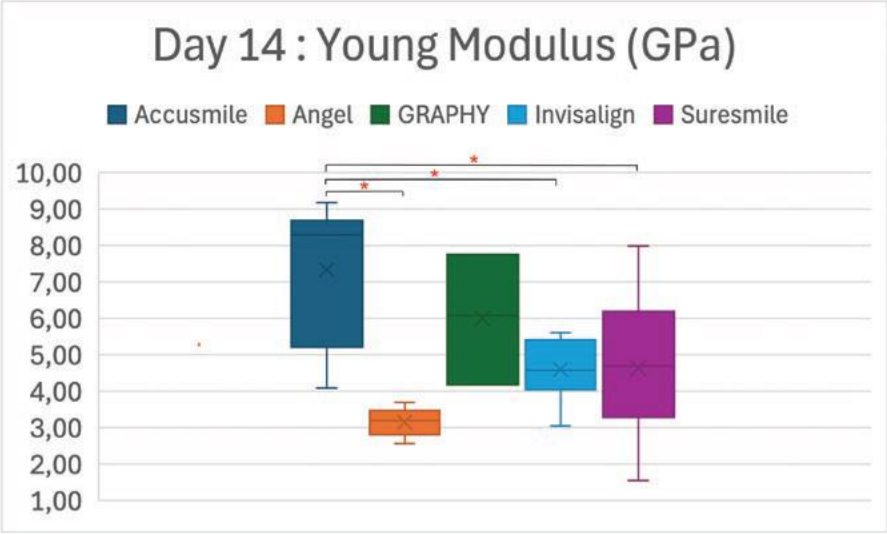


Figure 4. Yield Strength at Day 0 (Newton). This graph shows the values of YS at day 0. The Accusmile®'s YS is significantly higher than that of Invisalign® and Angel® ($P = .004$).

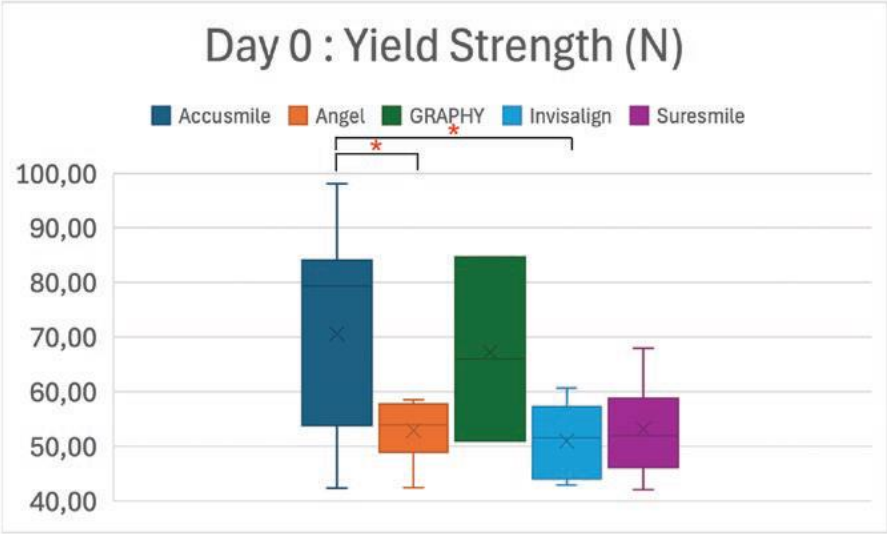


Figure 5. Angel®'s Yield Strength (N). This graph shows the values of Angel® YS from day 0 to day 14. This mechanical parameter is affected by aging from the fifth day for Angel® aligners ($P = .003$) decreasing from 52.9 ± 5.53 (D0) to 44 ± 4.27 (D5) and 42.97 ± 6.87 N (D14).

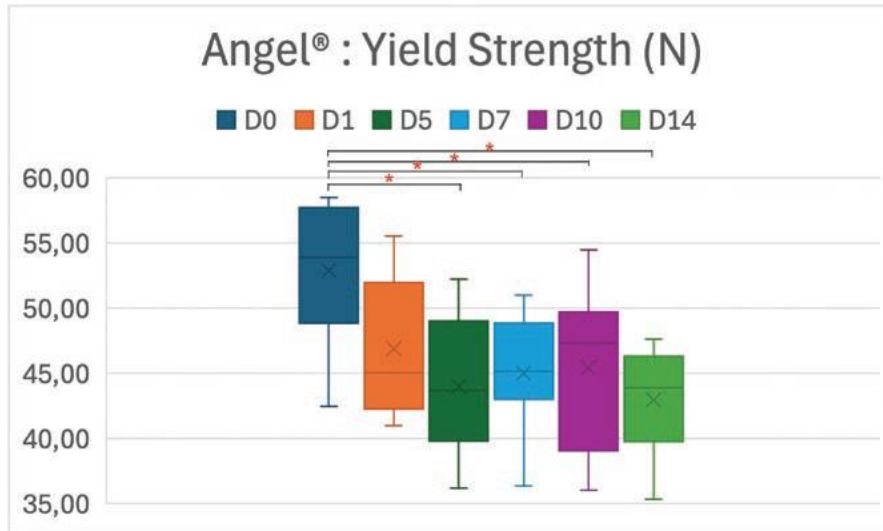


Figure 6. Ultimate tensile strength at Day 0 (N). This graph shows the UTS at day 0 of each group. Accusmile®'s UTS is significantly higher than UTS of other brands ($P < .0001$).

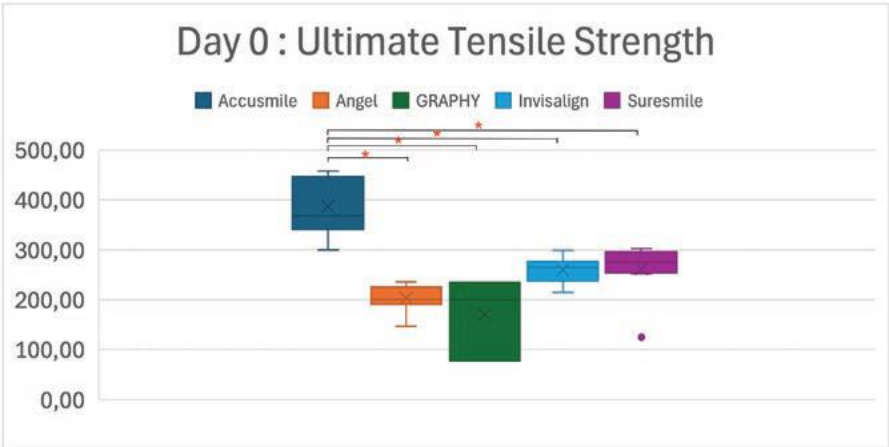
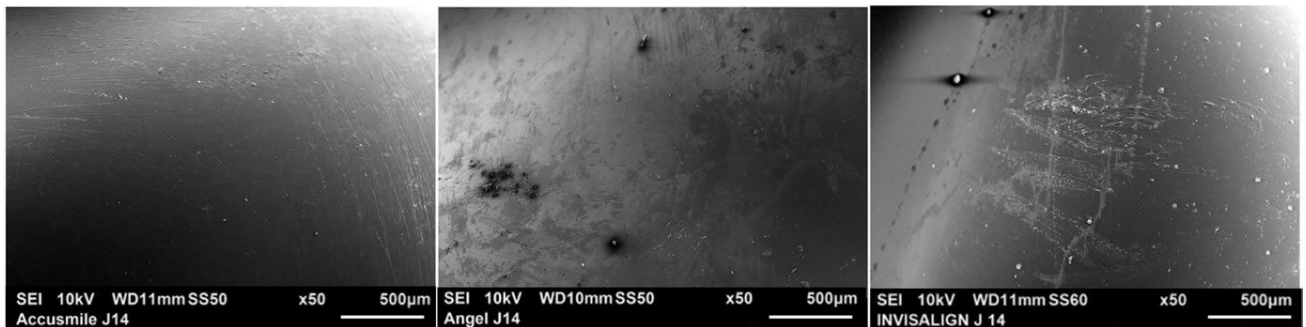


Figure 7. MEB observation at day 14 (×50). From left to right are represented the surface conditions of Accusmile®, Angel®, and Invisalign® clear aligners at day 14. We can observe scratches, porosities, scuffs, and stains.



Figures 8. MEB observation of GRAPHY®. (a) GRAPHY® at day 0: Lines of material application corresponding to the printing technique. (b) GRAPHY® at day 14: Cracks crossing a cusp.

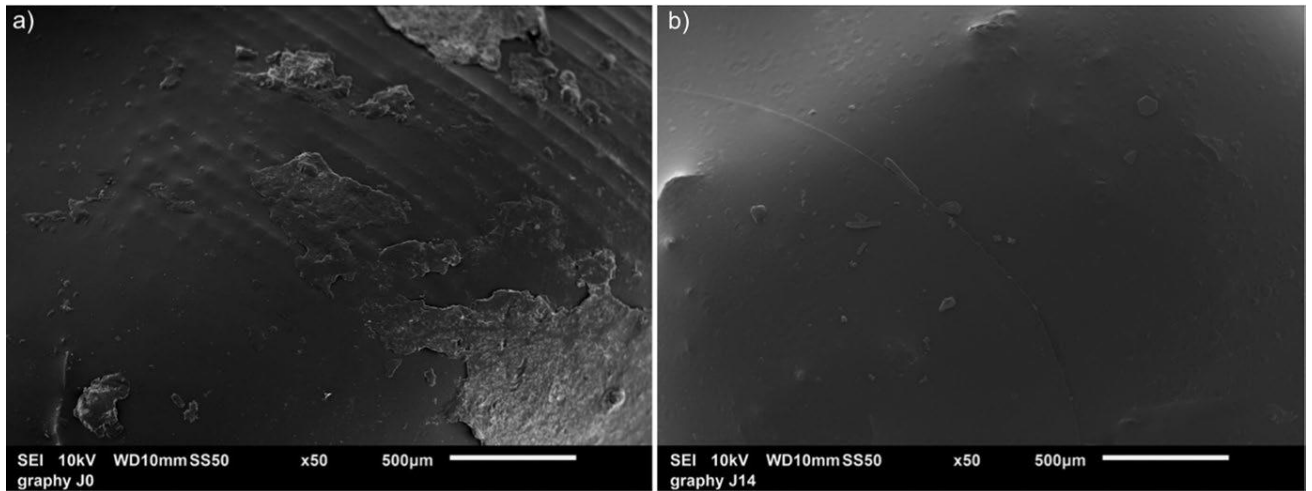


Figure 9. Invisalign® Young Modulus (Newton). This graph shows the values of E from day 0 to day 14. We noted an increasing trend until the 7th day and then a decreasing trend until the 14th day but not statistically significant.

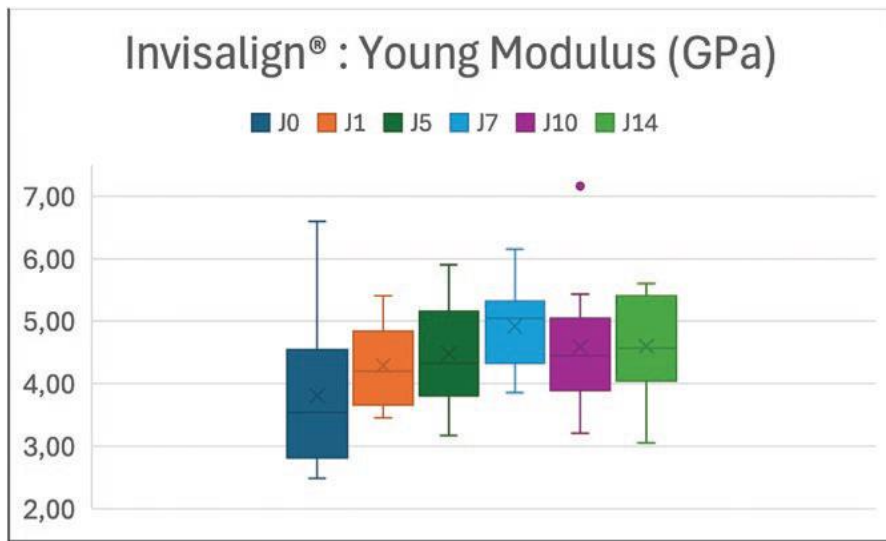


Table 1. Sample distribution characteristics

Model	Brand	Material	Thickness	D0	D1	D5	D7	D10	D14	Total
Accusmile®	Forestadent®	PET-G	0.8 mm	3	3	3	3	3	3	18
Angel®	AngelAlign®	Master Control S®	0.75 mm	3	3	3	3	3	3	18
GRAPHY®	Forestadent®	Tera Harz TC-85	0.75 mm	1	1	1	2	1	2	8
Invisalign®	Align®	Smart Track™	0.75 mm	3	3	3	3	3	3	18
Suresmile®	Dentsply Sirona®	Essix ACE®	0.8 mm	3	3	3	3	3	3	18