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Original Research Article

Assessing biomechanical aging of aligners produced by different thermoformed machine using 3d scanner -An invivo study

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ABSTRACT

Introduction: Clear aligner therapy(CAT) ses a variety of appliances with different applications to different malocclusion therapies and differing modes of action and construction methods. While clear aligner therapy seems very easy to use, but any kind of aligner system needs to go through a rigorous laboratory process to get the desired results. With the help of CAT Therapy products, a variety of malocclusions have been effectively treated. Clear aligners are still frequently made using the thermoforming process, despite the range of 3D Printed clear aligner systems that are currently on the market. However, orthodontists need to be aware of the materials' post-process mechanical and chemical properties because the thermoforming process significantly affects the aligners' mechanical and chemical properties. Thus, the goal of my research is to compare the adaptation and marginal thickness of aligners produced using various thermoforming machines both before and after intraoral exposure.

Aim: Aim of this study is to compare the thickness, adaptability, and marginal fit of orthodontic aligners made by various thermoformed machines.

Materials and M ethods: The sample size was determined using G power software, which showed that the sample size of six patients divided into four groups had a 95% power of statistical testing. 3 consecutive patients, three women(mean age ± SD 26.0 ± 10.2 years) and three men(mean age ± SD 26.0 ± 9.0 years) per group made up the study sample,

Statistical analysis: The statistical analysis used was paired t-tests for comparison between the groups. A one-way ANOVA test was used to calculate the mean difference among the four groups. The p-value <0.05 shows that it was statistically significant.

Results: Both the thermoforming machines can used to fabricate aligners that are equally good in terms of thickness considering the manufacturing recommendation. However, Aligner fabricated using Ministar thermoforming machine(Group A) with 1 mm thickness sheets shows that Mild changes thickness throughout the aligners in incisor and canine and molar regions and Druformat with shows uniformly distributed(group B) thickness in incisor, canine and molar region. between intra group comparison group shows mild changes after intraoral exposure. but the values within clinical tolerance level.

Conclusion: Two distinct thermoforming machines were used to fabricate the passive aligners, and the overall dimensional accuracy at each of the teeth was within clinical tolerances. However, location-specific deviations that may affect clinical utility may not always be represented by the overall deviations.

1. Introduction

Orthodontic aligners have become a popular treatment modality due to their aesthetic appeal and convenience.

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While clear aligner therapy seems very easy to use, any kind of aligner system needs to go through a rigorous laboratory process to get the desired results. However, the longevity and effectiveness of aligners can be influenced by various factors, including the thermoforming process used for their fabrication.[1] This in vivo study aims to assess the biomechanical aging of aligners produced by different thermoformed machines using a 3D scanner. By comparing aligners produced by different thermoforming machines, this research seeks to provide insights into the impact of manufacturing processes on aligner performance and durability.

The findings of this in vivo study will provide valuable insights into the biomechanical aging of aligners produced by different thermoformed machines. By elucidating the impact of manufacturing processes on aligner performance, this research has the potential to inform clinical practice and guide advancements in aligner fabrication technology.

Thermoforming units can be used to make counter bites, sports mouthguards, bleaching trays, and transparent aligners, among other thing.[2]The Ministar thermoforming machine and the Druformat thermoforming machines were taken for this study, both of which are readily available on the market. According to the manufacturers, the efficiency of the machines was quite impressive.

2. Aim

The aim of this study is to compare the biomechanical aging behaviours like Surface wear profile, dimensional changes of orthodontic aligners made by various thermoformed machines over different time periods from day 1 to day 10 in intraoral environment.

3. Materials and Methods

The sample size was determined using G power software, which showed that the sample size of six patients divided into four groups had a 95% power of statistical testing. Five patients, three women(mean age ± SD 26.0 ± 10.2 years) and two men(mean age ± SD 26.0 ± 9.0 years) per group made up the study sample. Patients who reported to Adhiparasakthi Dental College and Hospital provided study samples. Each patient received an explanation of the study protocol, which included the fact that they were not part of the active phase of treatment, that the patients who volunteered were part of the study, and that their informed consent was obtained.

3.1. Inclusion criteria

Subjects over the age of 18, with natural dentition except for the third molars, good oral hygiene, and no signs of periodontal disease. Mild crowding - 0.5-3mm ,Class I and II molar relationship less than 30° rotation of tooth Subjects who are in good health and have no medical or psychological issues.

3.2. Exclusion criteria

Medications used to treat neurological diseases(such as anti depressants) Patients suffering from orofacial or temporomandibular pain, temporomandibular disorder,Patient who are suffering from bruxism Symptoms of active carious lesions.Patient who has undergone previous orthodontic care History of polyethylene terephthalate glycol - modified(PET -G) *polyurethane, polyether* resin allergy.

The study sample was chosen based on inclusion and exclusion criteria, and random allocation was done without bias. To avoid operational errors and discrepancies, all procedures and lab-related operations are performed by the principal investigator and a well-trained assistant.

3.3. Study materials

The aligners used in this study were made of *polyethylene terephthalate glycol copolyester*(PET-G) Duran® SCHEU-DENTAL transparent aligner material,(1.0-mm thick) and were all produced with a thermoforming machine (Ministar of Scheu Dental, Iserlohn, Germany, Drufomat thermoforming machine) using the vacuum thermoforming process at a temperature of 220 °C and 2.5 bar(36 psi) pressure. The models used as molds for thermoforming the aligners were created using a 3D printing machine (UNIZ NBEE Desktop 3D Printer). Each aligner was manually cut and trimmed along the gingival margins, and the edges were manually refined to ensure the best comfort for the patients and to avoid negative influences that could arise from an automatic cutting process.

The aligners were produced by using Ministar(Group A) (Figure 1) and Druformat (Group B) (Figure 2) thermoforming machine. Followed by the fabrication process the aligners were scanned initially using ATOMS industrial scanner(Figure 3) at day 0(T_0). Then aligners were delivered to both the groups and instructed wear the aligner for 22 hours maximum.[1] The patients of both groups were recalled at day 10 and the retrieved aligners were scanned. The Surface profile changes of orthodontic aligners of both the groups were analysed using Geomagic control X software(Figure 4) and values were tabulated and subjected to statistical analysis(Figure 5).Thermoforming machine (Figures 1 and 2).

3.4. Study design

Each patient was individually scanned using an intraoral scanner(densply sirona) by principal investigator. Following the scanning, all digital impressions were imported into Maestro 3D Dental Studio software, where a virtual three-dimensional model was created.

(https://www.maestro3d/dental.studio.aspx?id=en-US).

Figure 1: Ministar thermoforming machine

Figure 2: Drufomat thermoforming machine

After creating a virtual model, the next step is to create a 3D printing file, which is known as slicing. After the so ftware(https://www.uniz.com/software) has finished slicing the model, it has sent it directly to the printer. UNIZ NBEE Desktop 3D Printer used to print the virtual models.

The thermoplastic sheet was then inserted into the tension ring of the thermoforming machine(Ministar of Scheu Dental, Iserlohn, Germany), and the 3D-printed model was placed on the Ministar platform. For the thermoforming process, the temperature was set to 220 degrees Celsius and the pressure to 2.5 bar (36 psi)

Figure 3: *Polyethylene terephthalate glycol copolyester* (PET –G) Duran® Scheu-Dental transparent material (0.75 mm and 1.00 mm)

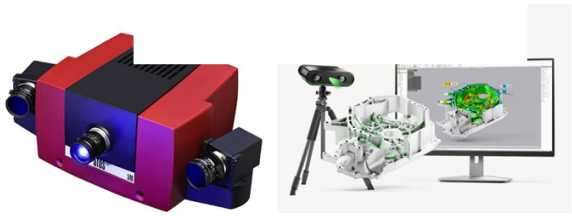


Figure 4: Atoms compact scan portable 3D Scanner and geomagic control X metrology software

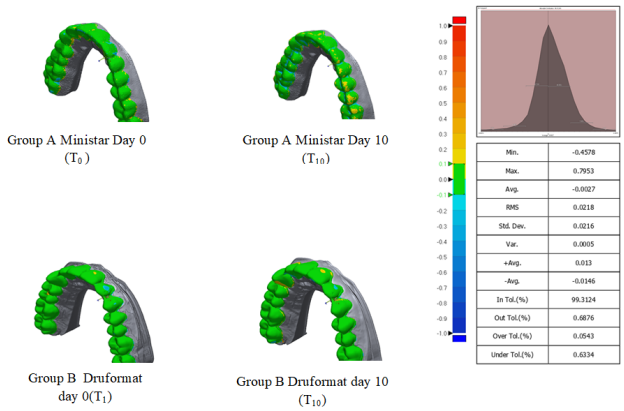


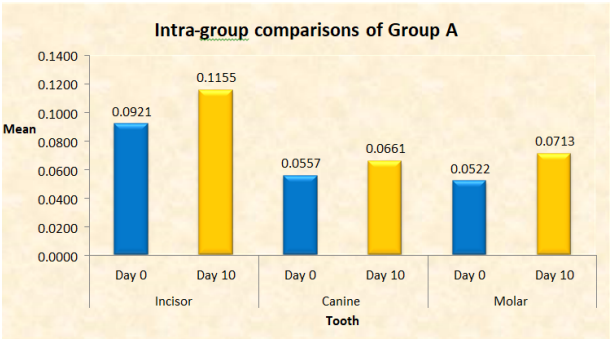
Figure 5: Analysed model from geomagic control X metrology software

pressure.The thermoformed untrimmed Passive aligner sheets were removed from the Ministar.

The Duran® sheets were then placed in the Drufomat thermoforming machine, the temperature was set to 220 degrees Celsius, and the pressure was set to 2.5 bar(36 psi). After the retrival of untrimmed aligner sheets from the machine, the final step is to finishing.low-speed grinding tools used to perform detailed trimming of the aligners. It is vital to avoid creating any sharp or jagged edges that could irritate the patient's mouth or damage the surrounding tissues.

Once trimmed, their internal surface of the Passive aligner(P aligner) is spray coated with a CAD/CAM spray(Yeti Dental, GmbH, Engen, Germany) white translucent matter to visualize the aligner from the resin model in 3D scanner.[3] Prior to insertion,(T_0) P aligner the was individually scanned using a ATOS Compact Scan Portable 3D Scanner with the resin model, followed by the P aligner without the resin model, to measure the marginal gap between the aligner and the resin model. After scanning, the models were, thoroughly cleaned and cold sterilized before inserting the patient. The insertion of the P aligners was overseen by a principal investigator. Proper instruction and guidance were given to the patient regarding aligner wear time and its maintenance. With regard to the same a designed Performa was made and patient was instructed to make an entry regarding their wear time of aligner.

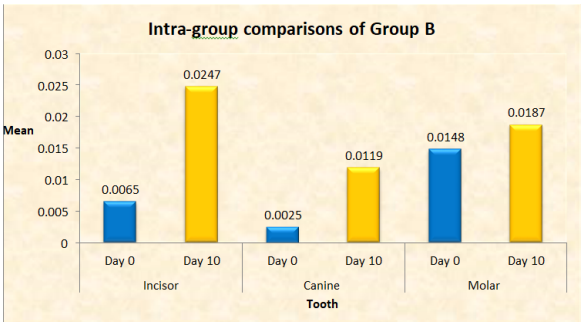
4. Results



Graph 1: Intra-group comparisons of group A

5. Discussion

The present clinical prospective study was to investigate and evaluate the efficacy of aligner manufactured by different thermoforming equipment's with regard to aging changes. The recent studies concentrating only on the analysis of three-dimensional(3D) printed aligners, But the most popular technique for creating aligners is thermoforming so the fit of thermoformed aligners is determined by the



Graph 2: Intra-group comparisons of group B

manufacturing procedures, as well as the elastic modulus of the materials utilized.[4] With regard to the modification of nominal aligner thickness by thermoforming procedures which could affect the orthodontic forces transmitted.[5]

In this study we have used Duran thermoforming sheets for this investigation. Studies also proven that Statistically, Duran sheets(Figure 3) provide best efficacy in aligner fabrication. These sheets of Duran are composed of PETG, which is a transparent, amorphous copolymer of polyethylene terephthalate(PET) that has good optical, fatigue, mechanical, and dimensional stability characteristics.[6] It is distinguished by having good manufacturability and minimal hygroscopic Changes.[7] When Kwon et al., evaluated the force delivery characteristics of thermoplastic orthodontic materials, they discovered that the forces provided by thin materials of the same brand were higher than those delivered by thick materials.[3] So, to assess the aging of the thicker material have been selected for this study. The thermoplastic materials used to fabricate aligners are structurally made of partially crystalline or amorphous polymers, which allow visible light to pass through and give a transparent appearance.[8] Owing to the transparent nature of the p aligners utilized in this investigation, an opacifying liquid had to be applied to each P aligner.

An Opacifying liquid had been used to increase the scanning accuracy. It creating an opaque surface that allows light to bounce off the object uniformly. Contrasting spray thickness was measured by Nickolas Koeniget al., in 2022; it ranged from 0.01899 mm to 0.0803 mm. It is evident that the spray affected the readings even if the study was unable to pinpoint the exact effect of the spray on aligner thickness.[9] When compared side by side, the average positive deviations had greater magnitudes of values than the average negative deviations,[10] According to Marian C. McCarty et al's., 2020 report, this discrepancy could be caused by the aligners' residual supports and the application of opacifying spray. Despite the possibility for positive biases from these sources, the aligners were generally found to be within a tolerance range that is considered clinically appropriate.[11]

Table 1: Intra-group comparisons of group A

Tooth	Time	Mean	SD	Mean difference	95% Confidence Interval of the Difference		P value
					LCL	UCL	
Incisor	Day 0	0.0921	0.0065	0.0234	-0.1165	0.0698	0.524 NS
	Day 10	0.1155	0.0754				
Canine	Day 0	0.0557	0.0134	0.0104	-0.0275	0.0068	0.168 NS
	Day 10	0.0661	0.0092				
Molar	Day 0	0.0522	0.0155	0.0191	-0.0666	0.0284	0.326 NS
	Day 10	0.0713	0.0402				

Statistical analysis: paired t test. S: statistically significant if P<0.05.

Table 2: Intra-group comparisons of group B.

Tooth	Time	Mean	SD	Mean difference	95% Confidence Interval of the Difference		P value
					LCL	UCL	
Incisor	Day 0	0.0065	0.0034	0.0182	-0.0400	0.0036	0.082 NS
	Day 10	0.0247	0.0146				
Canine	Day 0	0.0025	0.0012	0.0094	-0.0170	-0.0017	0.027 S
	Day 10	0.0119	0.0068				
Molar	Day 0	0.0148	0.002	0.0039	-0.0112	0.0032	0.199 NS
	Day 10	0.0187	0.0047				

Statistical Analysis: Paired t test. S: Statistically significant if P<0.05.

Table 3: Inter-group comparison between group A and group B.

Tooth	Time	Group A		Group B		Mean difference	P value
		Mean	SD	Mean	SD		
Incisor	Day 0	0.0921	0.0065	0.0065	0.0034	0.0856	0.000 S
	Day 10	0.1155	0.0754	0.0247	0.0146	0.0908	0.029 S
Canine	Day 0	0.0557	0.0134	0.0025	0.0012	0.0532	0.000 S
	Day 10	0.0661	0.0092	0.0119	0.0068	0.0542	0.000 S
Molar	Day 0	0.0522	0.0155	0.0148	0.002	0.0374	0.001 S
	Day 10	0.0713	0.0402	0.0187	0.0047	0.0526	0.020 S

Statistical analysis: independent sample t test. S: statistically significant if P<0.05.

The thermoforming process reduces the thickness of the sheet, creating aligners from 0.125 mm up to 0.30 mm thinner than the original thermoforming sheet thickness. The reduction of thickness is not uniform and varies at different locations. [12] Thickness as well volumetric changes of the aligner will be changed due to its hygroscopic nature of the polymers. These properties of the aligners will affect the effective tooth movement and ultimately lowers standards of the aligner treatment. Aligners have been used in clinical applications where stepped teeth have been moved by approximately 0.25 to 0.33 mm. Here, it was shown that activation of the device every 2 weeks was effective for orthodontic tooth movement. [13] Prolonged use of the aligner will lose its integrity ultimately lowers the effective tooth movements. [14] In this study the Passive Aligners were fabricated using with two different thermoforming machine and biomechanical aging of aligners were analysed before and after intraoral exposure.

Geomagic software used to assess the volumetric changes after using ATOMS industrial scanner. Geomagic software packages consistently showed maximum accuracy in measuring the amount of tooth movement in the maxillary arch compared to the reference standard. [15]

Both the thermoforming machines can used to fabricate aligners that are equally good in terms of thickness considering the manufacturing recommendation. However, Aligner fabricated using Ministar thermoforming machine(Group A) with 1 mm thickness sheets shows that Mild changes thickness throughout the aligners in incisor and canine and molar regions (Table 1) and Druformat(Table 2) with shows uniformly distributed(group B) thickness in incisor, canine and molar region between intra group comparison group(Table 3) shows mild changes after intraoral exposure but the values within clinical tolerance level.

6. Conclusion

The Passive Aligners fabricated using with two different thermoforming machine and the total dimensional accuracy at each of the teeth was within the clinical tolerances. The overall deviations, however, might not always represent location-specific deviations that could have an impact on clinical utility. The overall changes are within the clinical tolerance level. In terms of Biomechanical aging, these values are suggesting change of an aligner, within 10 days, prolonged use of aligner will lose its integrity, so that, it will not produce efficient tooth movement.

The information's about the thermoforming process could be useful to clinicians, who have the intention to establish their staging procedure for clear aligner therapy with good efficiency and without overtaxing the periodontal ligament.

7. Limitation

This study was done in passive aligners with normal occlusion, to validate this finding the study has to be done in larger population with severe malocclusion by varying thickness of sheets.

8. Source of Funding

None.

9. Conflict of Interest

None.

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