The Effect of Thermoforming on Aligner Thickness: A Systematic Review

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Abstract

The aim of this systematic review is to search any relevant literature on any changes in aligner thickness after thermoforming process.

This Review was registered at PROSPERO no. CRD42022371213. A systematic search was performed through five databases and hand-searching of the reference lists of the included studies. Reporting is based on the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) guidelines. Risk of bias assessment was based on the Cochrane Risk of Bias Tool.

A total of 245 eligible studies were identified but only five studies were included for quality assessments. Aligners in the studies were made from three different materials (PETG, PU, and SmartTrack). The thickness values were compared by arch, tooth and location points. The analysis between upper and lower aligners fabricated from SmartTrack showed a significant difference in the molar lingual region when comparing upper (0.631 mm) and lower aligners (0.563 mm). Significant differences by tooth were also detected between first molar–incisors and first molar–canine. However, no significant difference was found between incisors and canines. All three different materials reported higher thickness values on cusp tips compared to gingival region.

Aligner thickness was only 44% - 92% with respect to the original material thickness. Inhomogeneity of thickness was detected to be higher at the posterior region, particularly on molar cusp tips, and lower toward the anterior region.

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Introduction

Aligners have become the orthodontic appliance of choice for adults and teenagers who value esthetic, comfort and hygiene. The optical properties of aligner materials made them “invisible” compared to braces but both appliances effectively guide teeth into the targeted position.[1] Aligners are alternative treatment modalities to correct mild to moderate malocclusion.[2] They are removable, so they do not hamper oral hygiene activities and can be removed during meals. Therefore, reducing the risk of enamel demineralization, caries or periodontal diseases.[3]

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Aligners are plastic shells which fit over the buccal, lingual/palatal, and occlusal surfaces of the teeth. They are worn for a minimum of 22 hours per day and are changed to further steps of orthodontic movement on a 2-weekly basis.[4] A full treatment consists of a set of appliances with sequential movement stages, until the teeth are in the aligned positions. Each aligner is designed to move a tooth or small group of teeth about 0.2–0.5mm based on the software set-up.[5]

Thermoplastic materials are used by manufacturers for aligner fabrications. The most used materials are polyurethane (PU) and polyethylene terephthalate glycol (PETG) because they have excellent mechanical and optical properties.[6] These materials are available in foil sheets with a variety of thicknesses ranging from 0.5 - 1.0 mm. The material sheets are thermoformed onto series of dental model set-up to produce well-fitted aligners. Thermoforming processes are performed strictly according to manufacturers’ recommendations regarding pressure, heating, and cooling time.[7]

The ideal aligner should be precisely fit and retentive in order to exert force to induce orthodontic tooth movement.[8] The magnitude of force relates to the mechanical properties of material, the thickness of the material and the activation set-ups. Selection of material thicknesses and set-up increments are pivotal to avoid overloading of teeth and periodontal tissues. Therefore, any changes in the aforementioned factors will cause changes in the force application system and the effectiveness of treatment.[5,6,9]

Many studies have reported the effect of thermoforming on the properties of aligner materials. Thermoforming processes are also confirmed to cause reduction of thickness. Thus, the changes will directly affect the orthodontic biomechanics.[5–7,10–15] The aim of this systematic review is to search any relevant literature in order to synthesize the available evidence on any changes in aligner thickness after thermoforming process.

Materials and methods

A study protocol was registered at PROSPERO (International Prospective Register of Systematic Reviews) no. CRD42022371213.

On October 10 until 25, 2022, a systematic search in the medical literature published in English with no date restriction was performed to identify articles relevant to the review's question. We search several databases (PubMed, Cochrane Library, Embase, Scopus, ProQuest) with a search string: ((clear aligner appliance) OR (thermoplastic aligner) OR (aligner) OR (Invisalign)) AND ((material) OR (properties) OR (character*) OR (behavi?r)) AND (thermoform*). Hand-searching of the reference lists of the included studies was also conducted. Title and abstract screening were performed to select articles for full text retrieval. The exclusion criteria are articles with incomplete information or meeting/congress report.

The eligibility criteria were determined according to the Population, Intervention, Comparison, Outcome, and Study design (PICOS) scheme. "Population" is any type of aligner material and thickness. "Intervention" is the thermoforming process by any type of thermoforming machine; any method of thickness measurement. "Comparison" is any pre-formed aligner material and thickness. "Outcome" is any change in thickness due to thermoforming process. "Study Design" is any in vitro/laboratory study reporting the effect of thermoforming on clear aligner thickness. Eligibility assessment was performed independently by three reviewers. Disagreements were resolved through discussions among authors.

Data synthesis was performed by one reviewer in pre-piloted forms which comprise details of sample size, comparator, intervention and method, outcome, result and conclusion. The reviewer was not blinded to author's identity or study origin and all information obtained was confirmed by a second author.

The risk of bias was assessed using the Cochrane Risk of Bias Tool (RoB 2) in accordance with the Cochrane Handbook for Systematic Reviews of Interventions.[16] The assessment was implemented by one author and was calibrated by the second and third author. Robvis Tool for visualizing risk-of-bias assessments was used to report the risk of bias domains. The tool creates "traffic light" plots of the domain-level judgments for each individual result.[17] (Figure 1).

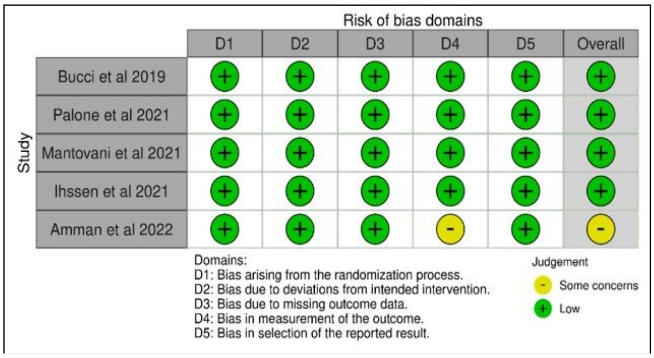

Figure 1. Risk of Bias Traffic Plot.

Results

A total of 245 potentially eligible studies were identified. After excluding 42 duplicates and 9 records other than English, 194 records were left. Initial screening for the titles and abstracts excluded 179 studies because they were not eligible. The remaining 15 studies were sought for retrieval and followed full-text assessment. Ten studies were excluded (eight studies thermoformed specimens instead of aligners; two studies assessed specimen thickness instead of aligner thickness). Five studies were included for quality assessments. [10–14] Apart from analyzing thickness changes, two studies also evaluated the gaps formed between aligner and model[11,14]; one study evaluated the thickness changes after 10 days of intraoral exposure.[10] The PRISMA flow diagram of the literature selection process is presented in Figure 2. A summary of systematic review characteristics is presented in Table 1. The included studies were published from 2019 to 2022 and reviewed changes of three different aligner materials (PETG, PU, SmartTrack) with foil thickness 0,75 mm, 0.8 mm, 0.55 mm after thermoforming process.

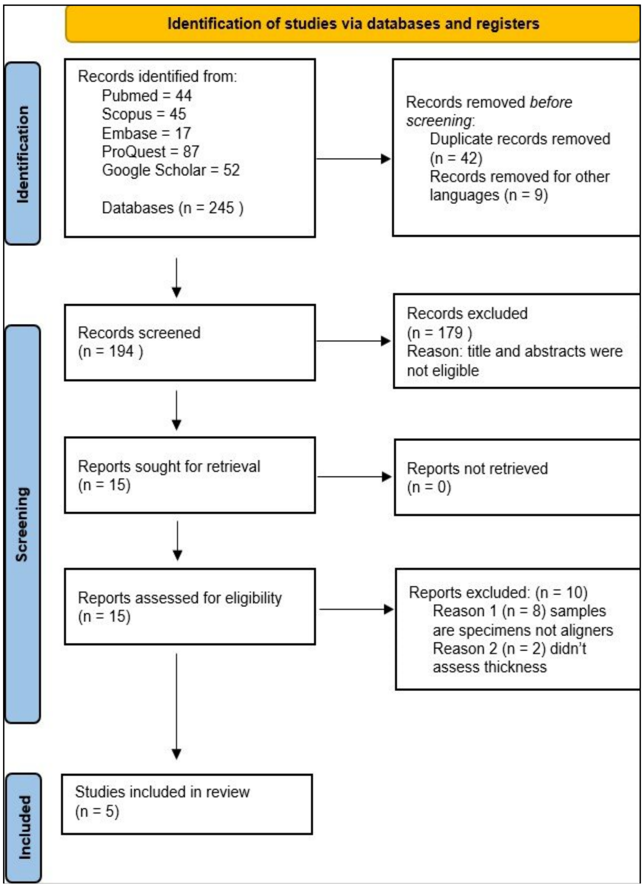

Figure 2. PRISMA Flow Diagram.

Five studies were assessed using a new version of Cochrane Risk of Bias 2 tool.[16] (Figure 1). Five domains comprised of bias arising from randomization process, bias due to deviations from intended intervention, bias due to missing outcome data, bias in measurement of the outcome, bias in selection of the reported result. Experimental conditions of the five studies were comparable between groups. Losses or non-inclusion of samples were not reported. One study did not clearly state the reference points of measurement, so there are some concerns in measurement of the outcome domain.

Thickness values by arch. The analysis between upper and lower aligners fabricated from SmartTrack showed that there was a significant difference only in the molar lingual region when comparing upper (0.631 mm) and lower aligners (0.563 mm) (mean difference = 0.067 mm; 95% CI, 0.008-0.126 mm; *P*=.038).[12] (Table 2).

Thickness values by tooth type. The aligner thickness after thermoforming process by tooth type was measured on incisors, canines, premolars and first molars. SmartTrack aligner thickness on the incisives were reduced within ranges 0.582 - 0.639 mm compared to the original 0.75 mm SmartTrack. The thickness reduction on canines ranges from 0.569 - 0.644 mm and on first molars ranges from 0.566 - 0.634 mm. Statistically no significant differences were found among SmartTrack aligner thickness on the incisors, canines and molars.[12]

PETG aligner thickness was reduced due to not only the thermoforming process but also the base height of study model. This study used 0.5 mm PETG material with two different study model bases, high and normal. PETG aligners thermoformed on high base model were measured on incisors (0.311 mm), canines (0.315 mm), premolars (0.309 mm) and first molars (0.316 mm). On the normal base models, the results were slightly higher: incisors (0.330 mm), canine (0.315 mm), premolars (0.320 mm), first molars (0.324 mm).[13]

PETG aligner thickness was not affected by modification shape of the aligners, like attachments or divots. The thickness of passive (P) and active (A) aligners (with attachments or divots) was measured and compared to the original 0.75 mm PETG. The average thickness of P ranged from 0.38 ± 0.08 mm to 0.69 ± 0.04mm, while the average thickness of A ranged from 0.42 ± 0.09 mm to 0.68 ± 0.04mm.[10]

Six commercial aligner manufacturers which used PETG 0.75 - 0.8 mm, PU 0.75 mm and SmartTrack 0.75 mm analyzed the thickness by tooth type. The results were 0.512 mm on incisors, 0.520 mm on canines and 0.590 mm on first molars. Statistical analysis showed significant differences between first molar–incisors and first molar–canine. However, no significant difference was found between incisors and canines.[11] (Table 3).

Thickness values by location. Data of

SmartTrack material showed that there was a significant difference in the molar region when comparing occlusal cusp tips (0.634 mm) and gingival-lingual margin (0.566 mm; mean difference = 0.068 mm; 95% CI, 0.009-0.126 mm; *P*=.024).[12] The measurement of PETG aligners showed that thickness values were smallest at facial surfaces and highest at incisal faces. Thickness values were also higher at cusp tips compared to the fissures. The study results of PETG, PU and SmartTrack material reported similar findings which showed a significant difference when comparing cusp tips (0.522 - 0.663 mm) and vestibular gingival edge (0.500-0.548) (*P*=.001).[11] (Table 4).

Aligner Thickness Distribution. Thermoforming temperatures were reported to influence the thickness distribution of thicker material (0.75 mm) compared to thinner material (0.55 mm). At lower to higher thermoforming temperature (112°C – 200°C), the thinner material produced an aligner with fairly even thickness. However, the 0.75 mm aligners showed noticeable differences when exposed to rising process temperatures.[14] All studies showed inhomogeneity in aligner thickness;[10–14] throughout the occlusal surface[10]; greater thickness at the posterior occlusal surface decreasing toward anterior regions[11]; thinner at the gingival region.[11–14]

Overall, aligner thickness after thermoforming ranges from 0.565 mm – 0.639 mm out of the 0.03 inches or 0.762 mm SmartTrack material (74% - 83%).[12] PETG 0.75 mm thickness decreased from 0.38 mm – 0.69 mm (55% - 92%),[10] the mean thickness reduction of 58.8% was reported by Amman et al.[14] PETG 0.5 mm thickness decreased from 0.222 mm – 0.427 mm (44% – 85%),[13] the mean thickness reduction of 0.55 mm PETG was 60.7%.[14]

Discussion

The aligner material foil is exposed to heat and then pressed onto a set-up model to mold an aligner. During the fabrication process, the temperature is set higher than the glass transition temperature of the thermoplastic material so that it can easily deform.[15] Therefore, the thermoforming process should follow the manufacturers' recommendations and be based on the type of thermoplastic material. A good thermoforming process is a key to accurate fit which leads to effective orthodontic force system.[18]

A study by Amman et al, evaluated four selected temperatures for the thermoforming processes of 0.55 mm and 0.75 mm PETG foils. The result indicated the 0.55 mm thermoformed aligner thickness distribution was fairly even across the temperature range from 112 – 200°C. Unlike the 0.75 mm aligner which showed noticeable differences when exposed to higher temperatures.[14] Although lower temperature will produce a more homogenous aligner, the accuracy of fit can only be achieved with thermoforming in higher temperatures because at higher temperatures the gap volume between aligner and model decreases.[18]

After thermoforming process, Ryu et al observed changes in the material's mechanical properties. The amorphous structure changed to the crystalline form which accounts for a decrease in force and elastic modulus, and transparency, but an increase in water absorption.[15] Based on the studies appraised in the present review, the thermoforming process was reported to overall decrease aligner thickness.[10–14] The thermoforming process stretches the plastic foil on the cast model, leading to reduction from its original thickness.

Thickness values by arch were assessed by Mantovani et al. with SmartTrack material. The unused aligner samples of 10 upper arches and 10 lower arches were collected from Invisalign patients. There was no significant difference between the upper or lower arch except in the molar lingual region (*P*=.038). The lingual region of the upper molar (0.631 mm) which was thicker than the lingual region of the lower molar (0.563 mm) may be clarified by the higher complexity of upper molar anatomy so the material foil was stretched thinner on the gingival lines compared to the occlusal sites.[12]

The dental anatomy showed impact to aligner thickness values after thermoforming. Differences in aligner thickness values were found among incisors, canines, premolars and first molars. Aligners were thicker on the cusp tips compared to fissures, thicker on occlusal surfaces compared to facial surfaces, but thinnest on the gingival region.[10–13] The greater thickness at the posterior region decreased toward the anterior region. Overall analysis showed inhomogeneity of aligner thickness, except for F22 aligner which statistically showed no significant differences between canine-incisors, canine-first molar and incisor – first molar.[11] SmartTrack aligners by Invisalign were reported to have only small differences among teeth.[12]

F22 and SmartTrack are both commercial aligners. F22 aligners are made from a polyurethane-based material.[11] SmartTrack is made from multilayer aromatic thermoplastic polyurethane.[11,12] The exact content of those materials and thermoforming processes are not disclosed to public. Polyurethane (PU) is an extremely versatile polymer with excellent mechanical, elastomeric and adhesion properties. Moreover, it has good chemical and abrasion resistance. Due to the material's flexibility, PU changes its shape when subjected to load, but is able to recover its original shape when the load is removed. The material also exhibits high tear resistance and a wide range of resiliency.[19] Therefore, the low inhomogeneity of PU based aligners is the result of its wide range of resiliency, flexibility and simplicity of processing. However, PU is physically not transparent, easily absorbs water and not stiff enough to exert orthodontic force. To overcome the weaknesses, PU are combined with other durable materials such as PETG. PETG is transparent, ductile, exhibits hardness, stiffness and good strength, thus dimensionally stable.[6,19]

Aligner thickness contributes to the amount of force exerted onto the teeth. The thinner the aligner the less force it produces. The present review found that aligner thickness was reduced to 44% - 92% with respect to the original material. On that account, characterization of aligners should be evaluated after thermoforming process. Since the aligner thickness distribution was not homogeneous, in order to control the tooth movement, additional attachments and divots must be added to the targeted teeth or the anchorage unit.[5] The thinner gingival region could cause uncontrolled buccolingual inclination of molars.[12] To enhance stiffness on the thinner gingival region, aligner edge can be extended. A wider gingival part will also increase aligner retention.[20]

The greater thickness in the occlusal surfaces, especially cusp tips explained the open posterior contact that developed at the finishing stage of treatment. Occlusal forces will intrude the posterior teeth by biting down on the thick occlusal surface of the aligner However, the bite-block effect is beneficial for open bite cases.[11]

The evidence of the five studies in the present review was based on small sample size. One study collected samples of upper and lower arches,[12] the other four collected upper arches only.[10,11,13,14] The malocclusion status of samples was not clearly defined. The thermoforming process setting was not possible to be controlled due to private manufacturing policy of commercial aligners.[11] Thus, heating and cooling temperatures are mostly unknown.

The method of measurements in all five studies were done digitally with softwares to gain optimal accuracy. The selection of reference points is similar in four studies, but not clearly explained in one study. The reason might be that the latter study was only focusing on the aligner thickness distribution and gap volume. In general, all interventions were similar and carefully conducted.

Further research should include more variety of thickness and material composition and proper sample size in order to reveal other effects of thermoforming that might influence clinical application.

Conclusions

Based on the available evidence, the following conclusions were made:

The thermoforming process will produce an aligner thickness of only 44% - 92% with respect to the original material. The thickness distribution of three different materials included in the review (PETG, PU and SmartTrack) was not homogeneous.

The greater thickness was detected at the posterior region, particularly on molar cusp tips, decreasing toward the anterior region.

Material foil was stretched thinner on the gingival lines compared to the occlusal sites.

Declaration of Interest

The authors report no conflict of interest.

Author Year of Publication (Study Design)	Sample	Comparison	Intervention and Method	Outcome	Result	Conclusion
Bucci et al[10] 2019 (in Vitro)	PETG 0.75mm Passive aligner (P) without attachment (n = 18) Active aligner (A) with attachment (n = 18)	material foil vs aligner thickness	Thermoforming 220°C. The thickness was measured with software.	Thickness changes and inhomogeneity	The thermoforming process showed good reproducibility for both aligner configurations (passive and active).	Considering the thickness changes, the thermoforming process is reliable both with active and passive aligner configurations.
Palone et al[11] 2021 (in Vitro)	Airnival PETG 0.75mm (n = 1) ALL IN PETG 0.80mm (n = 1) Arc Angel PETG 0.75mm (n = 1) F22 Polyurethane 0.75mm (n = 1) Invisalign SmartTrack 0.75mm (n = 1) Nuvola PETG 0.75mm (n = 1)	material foil vs aligner thickness	All aligners were produced by respective manufacturers. Aligners + models were scanned with micro-CT. Thickness was measured with software.	Thickness changes and inhomogeneity	Tooth type, dental region, and aligner type affected both the gap width and aligner thickness. The aligner thickness remained moderately stable across the arch only in the F22.	All thermoformed samples displayed smaller aligner thickness and gap width at anterior teeth and both gingival and coronal centers than at posterior teeth and occlusal surfaces.
Mantovani et al[12] 2021 (in Vitro)	Invisalign SmartTrack 0.75mm (n = 20)	material foil vs aligner thickness	Unused aligners were collected from patients. Physical resin models were obtained from STL files of Clincheck software. Aligners + models were scanned with micro-CT. Thickness was measured with software.	Thickness changes and inhomogeneity	No significant differences in the aligner thickness of different regions and thickness homogeneity for the molar region when the data were stratified by tooth.	Invisalign aligner thickness is characterized by small differences. The only significant difference was revealed in the molar region where thickness of the gingival–lingual edge is significantly thinner than that measured at the occlusal aspect.
Ihssen et al[13] 2021 (in Vitro)	PETG 0.5mm Narrow (N) base height (n = 10) High (H) base height (n = 10)	material foil vs aligner thickness of narrow base model height and high base model height	Thermoforming 220°C. Aligners were scanned with micro-CT. The thickness was measured with software.	Thickness changes and inhomogeneity	Significant differences in thickness values were observed among tooth types between both groups. Whereas thickness values were comparable at cusp tips and occlusal / incisal / cervical measurement locations, facial and palatal surfaces were significantly thicker in group N compared to group H.	The base height of 3D-printed models impacts on local thickness values of thermoformed aligners. The clinician should consider potential implication on exerted forces at the different tooth types, and at facial as well as palatal surfaces.
Ammann et al[14] 2022 (in Vitro)	PETG 0.55mm (n = 4) PETG 0.75mm (n = 4)	material foil vs two types of aligner thicknesses	Thermoforming with 4 different temperatures. Aligners + models were scanned with micro-CT. Thickness was measured with software.	Thickness changes and inhomogeneity	The aligners show a better fit when the foils were processed at higher temperatures. Thermal processing reduced the average thickness of the aligners to 60% with respect to the planar starting foil. These thickness distributions demonstrated that the aligners were generally thicker on the occlusal surfaces of molars and premolars but thinner around the incisors and buccal as well as on oral surfaces.	Hard x-ray tomography with micrometer resolution is a powerful technique employed to localize the gaps between aligners and teeth, and it also enables film thickness measurements after thermoforming.

Table 1. A Summary of Systematic Review Characteristics.

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