



Original Article

Comparative Assessment of Dimensional Accuracy and Fit of Aligners Manufactured by Direct Printing and Thermoforming: An *in vitro* Study

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Main Points

- Direct-printed aligners made with TA-28 resin showed superior dimensional accuracy compared to thermoformed polyurethane (PU) and polyethylene terephthalate glycol-modified (PET-G) aligners.
- Direct-printed aligners showed significantly lower deviations at all nine bilateral anatomical landmarks assessed.
- PU-based thermoformed aligners exhibited smaller deviations at all nine landmarks than PET-G.
- The elimination of intermediate fabrication steps in direct printing contributes to improved dimensional accuracy and clinical fit.

ABSTRACT

Objective: The objective of the study was to compare the accuracy and fit of direct-printed and thermoformed aligners.

Methods: The *in vitro* study included a pre-treatment scan as a reference model. Thirteen successive treatment stages were digitally planned and exported as Standard Tessellation Language (STL) files. Based on the treatment plan, 39 aligners were manufactured for three groups: Group 1, direct-printed aligners with TA-28 resin; Group 2, thermoformed polyurethane (PU) aligners; and Group 3, thermoformed polyethylene terephthalate glycol-modified (PET-G) aligners. All aligners were subsequently scanned, and the resulting STL files were superimposed on the baseline models. The dimensional accuracy and fit of the aligners were evaluated. The groups were compared using the Kruskal-Wallis test, followed by Dunn-Bonferroni post-hoc comparisons, with significance set at $p \leq 0.05$. Intra-rater and inter-rater reliability were evaluated via intraclass correlation coefficients.

Results: Group 1 exhibited greater dimensional accuracy, as evidenced by the lowest mean deviation compared with Groups 2 and 3 ($p < 0.001$). Pairwise comparisons indicated significant differences between Group 1 and Group 2 and between Group 1 and Group 3 ($p < 0.001$); however, no significant difference was found between Groups 2 and 3 ($p = 0.489$). Landmark-based deviation analysis indicated that Group 1 demonstrated the least deviation across all nine evaluated anatomical landmarks ($p < 0.001$). Group 3 showed slightly greater deviations than Group 2 for most landmarks.

Conclusion: Direct-printed aligners fabricated using TA-28 resin exhibited significantly higher dimensional accuracy and a better fit than thermoformed aligners manufactured from PU and PET-G.

Keywords: Computer-aided design, dimensional accuracy, orthodontic appliances, three-dimensional printing, polymers

INTRODUCTION

Clear aligner therapy has gained popularity among patients due to its aesthetic appeal.¹ It also offers enhanced comfort for patients due to the seamless fit, hence diminishing the probability of soft tissue irritation and facilitating easier oral hygiene maintenance compared with conventional braces.^{2,3} The advancements in computer-aided design and manufacturing (CAD/CAM) have fueled this increasing demand for aligners.⁴ Traditionally, clear aligners were fabricated

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through a thermoforming process, where thermoplastic sheets were vacuum-formed over digitally planned and 3D-printed dental models.⁵ Various aligner sheets, software, printers, and thermoforming machines are available on the market, each with distinct specifications and characteristics. Thermoformed aligner treatment fundamentally relies on the properties of the plastic sheets used, the thermoforming process, and the precision of dental model printing.⁶ Previous research has shown that the thermoforming process itself can cause alterations in the physical and mechanical properties of the aligners.^{7,8} In response to these issues, direct-printed aligners have emerged as a notable technological advancement in aligner orthodontics. These aligners are manufactured using additive 3D printing techniques, such as digital light processing (DLP) or stereolithography, directly from digital models without the intermediary step of model printing and thermoforming.⁹ By eliminating these additional fabrication stages, direct-printed aligners theoretically offer higher dimensional accuracy, improved adaptation to the dentition, and more predictable force delivery.¹⁰ Furthermore, they reduce waste and time in the production workflow, making them particularly attractive for in-house aligner systems.¹¹

Since the advent of direct-printed resins and aligners, various studies have compared their properties, such as thickness, force profile, and other mechanical properties, with those of thermoformed aligners.¹²⁻¹⁴ Among the various properties, the dimensional accuracy of the aligners that are manufactured from the 3D model and the fit of the aligner are important characteristics, which affect their effectiveness in moving teeth.⁶ The dimensional accuracy of the aligner can be evaluated by one of three methods: optical scanning-based measurements, micro-computed tomography, and computer-coordinate machines.¹⁵ Investigations by Jindal et al.¹⁶ and Spangler et al.¹⁷ compared the dimensional accuracy of thermoformed aligners with direct-printed aligners. Both studies found that directly printed aligners were more accurate. However, they used Dental LT material (Formlabs, Somerville, MA, USA) as

the direct-printed aligner resin. Recently, Graphy introduced direct-printed shape memory aligners for clinical use. Initially, TC-85 (Tera Harz, Graphy Inc, Seoul, South Korea) was available; an improved resin, TA-28 (Tera Harz, Graphy Inc, Seoul, South Korea), has now been introduced. TA-28 has improved flexural strength, flexural modulus, and superior chemical stability compared to the TC-85.^{18,19} Although TA-28 and TC-85 possess several shared components and physical characteristics, there may be variations in the biomechanical qualities and performance of the aligners that need to be assessed.¹⁸ Koenig et al.¹⁵ compared the dimensional accuracy of direct-printed aligners manufactured using TC-85 with thermoformed aligners. However, there is limited evidence regarding the performance of TA-28 material. The primary objective of the present study was to compare the accuracy and fit of direct-printed aligners fabricated using TA-28 resin with those of thermoformed aligners.

METHODS

The study commenced following approval from the Saveetha Dental College Institutional Human Ethical Committee (approval number: SRB/SDC/ORTHO-2307/25/091, date: February, 2025). This *in vitro* observational study used a pretreatment upper-arch scan in Standard Tessellation Language (STL) format from a patient with 3.5 mm anterior crowding as a reference digital model. This file was used to plan sequential tooth movements and evaluate aligner fit and trueness in the presence of mild crowding and intact anatomy. The STL file of the arch was exported to OrthoAnalyzer (3Shape, Denmark) for planning the tooth movements. Apart from the pre-treatment model, 12 models at different stages of planning were exported as individual STL files. Three groups of aligners were fabricated on each of the 13 baseline models (n=13). The study workflow has been illustrated in Figure 1.

The sample size was calculated based on a previous study¹⁵ using G*Power software (version 3.1, University of Dusseldorf, Dusseldorf, Germany). Based on a calculated effect size (f)

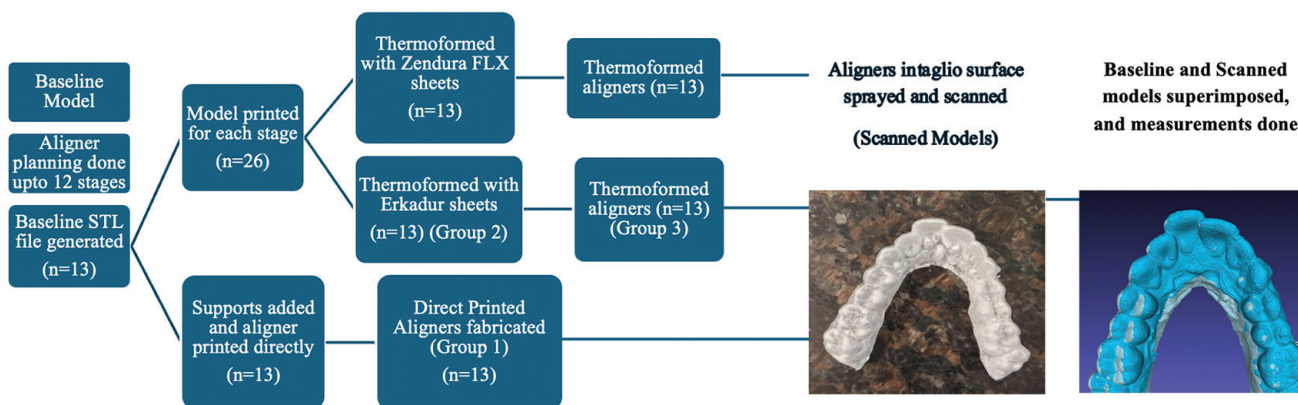


Figure 1. Study workflow. STL, Standard Tessellation Language.

of 0.46, a significance level (α) of 0.05, and a power ($1-\beta$) of 0.90 for a one-way analysis of variance across three groups, a sample size of 13 aligners per group was required. A total of 13 models, comprising one pre-treatment stage and 12 sequential planning stages, were used to fabricate aligners. A total of 39 aligners were included in the study across three groups as follows:

Group 1: Direct-printed aligners using TA-28 resin (Tera Harz™, TA-28, Graphy Inc, Seoul, Korea); (n=13).

Group 2: Thermoformed aligners using triple-layer polyurethane (PU) sheets (Zendura FLX™, Bay Materials LLC, Fremont, CA, USA); 0.75 mm thickness; (n=13).

Group 3: Thermoformed aligners using polyethylene terephthalate glycol-modified (PET-G) sheets (Erkodur™, Erkodent Erich Kopp GmbH, Pfalzgrafenweiler, Germany); 0.75 mm thickness; (n=13).

For direct-printed aligners, additional setup and slicing were performed for each STL model using Graphy Aligner Design Studio software (Graphy Inc., Seoul, South Korea), and the models were printed with the Graphy GP-200 DLP printer (Graphy Inc., Seoul, South Korea), specifically calibrated for TA-28 resin. All aligners were printed with a uniform thickness of 0.75 mm and a gingival coverage of 1 mm. After printing, the aligners were cured under a nitrogen atmosphere using Cure M (Graphy Inc., Seoul, Korea). Excess resin and supports were carefully removed and polished.

For thermoformed aligners, the STL files of the models were exported to NextDent™ design software, where they were optimized for model printing, and then printed using a DLP 3D printer (NextDent™ 5100, version 1.1, 3D Systems Inc., the Netherlands) with NextDent® Model 2.0 resin (3D Systems Inc., the Netherlands). All models were printed with a layer

thickness of 50 μ m, oriented horizontally to ensure surface uniformity. Each model was post-cured in accordance with the manufacturer's guidelines using the LC-3DPrint Box (NextDent, 3D Systems Inc., Netherlands). Based on the group assignment, the respective aligner sheets were thermoformed over the models using a Biostar® pressure thermoforming unit (Scheu Dental, Germany). The sheets were heated and vacuum-formed over the printed models following a cooling protocol as advised by the respective manufacturers. The aligners were trimmed 1 mm above the gingival margin using rotary discs to simulate clinical finishing.

Assessment of Dimensional Accuracy

Aligners from all three groups were prepared for scanning by spraying their intaglio surfaces with CAD/CAM scan spray (Easy Scan, Alphadent, Korea), which rendered the aligners opaque. The aligners were then scanned using the 3Shape Trios 3™ intraoral scanner (3Shape, Denmark), producing high-resolution STL files.

The baseline models and the models obtained after scanning the aligners (scanned models) were imported into MeshLab software (version 2023.12, Italian National Research Council, Rome, Italy) for superimposition to assess the overall deviation between the models. The baseline and scanned models were superimposed using point-based gluing. The overall accuracy was recorded as root-mean-square (RMS) values. The measurements were performed in triplicate, and the mean was used for the final statistical analysis. The RMS value reflected the accuracy (trueness) of the aligners.

The fit of the aligner was evaluated by measuring the distance between the scanned and baseline models at nine designated points (Figure 2). These landmarks were selected to ensure a thorough distribution of points across anterior, posterior, occlusal, and gingival regions, thereby facilitating a multi-

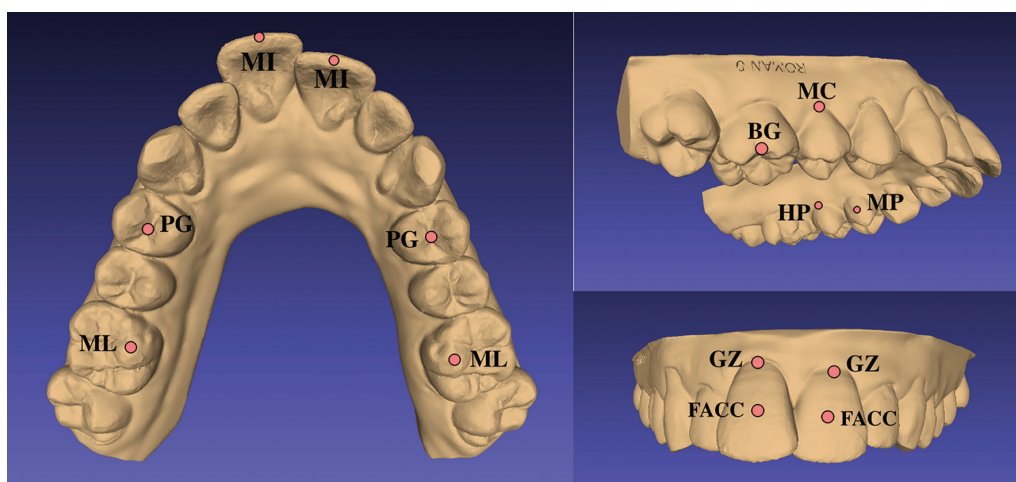


Figure 2. Nine bilateral landmarks used in the study. MI, point on the mid-incisal edge of the central incisors; PG, mid-point on the central groove of the first pre bicuspid; ML, mesio-lingual cusp tips of the first molars; FACC, the point of the facial axis of the central incisor that separates the gingival and occlusal halves; MP, mid-point on the palatal surface of the first bicuspid; BG, a point on the buccal groove of the first molars; GZ, gingival zenith of the central incisor; HP, highest point on the palate-gingival margin of the second bicuspid; MC, highest point on the bucco-gingival margin of the second bicuspid; SD, standard deviation.

surface evaluation of the aligner’s anatomical fit. Each deviation value (in mm) was recorded separately for the left and right sides, and the mean of two sides was used for statistical analysis. The methodology and landmarks for deviation analysis were adapted from the protocol described by Koenig et al.¹⁵

Statistical Analysis

Descriptive statistics (mean and standard deviation) were calculated for all parameters. Normality of the data was assessed using the Shapiro-Wilk test. The overall accuracy (RMS value) and deviation values at each landmark among the three groups were compared using the Kruskal-Wallis test, followed by intergroup comparisons using the Dunn-Bonferroni post-hoc test. To assess reliability, all measurements from 10 randomly selected samples were repeated after 3 weeks by the same operator. Two additional operators repeated the measurements after 3 weeks. Intra- and inter-rater reliabilities for both overall and landmark-based deviation values were assessed using the intraclass correlation coefficient (ICC). Statistical significance was set at a p-value less than or equal to 0.05.

RESULTS

The reliability of measurements was high, with intra-rater ICC values ranging from 0.820 to 0.932 for all parameters.

The inter-rater ICC values ranged from 0.75 to 0.81, indicating good agreement across all parameters.

Based on the Shapiro-Wilk test, the data were not normally distributed; therefore, a non-parametric test was performed. The overall mean deviation, expressed as RMS values, was lowest in Group 1 (0.2169±0.0312 mm), followed by Group 2 (0.3046±0.031 mm) and Group 3 (0.3292±0.024 mm). Pairwise comparisons revealed significant differences between Group 1 and Group 2 (p<0.001) and between Group 1 and Group 3 (p<0.001); the difference between Groups 2 and 3 was not significant (p=0.489) (Table 1).

The deviation values at the nine anatomical landmarks were consistently the smallest relative to the baseline models for Group 1. The differences among the three groups were statistically significant at all landmarks (p<0.001) (Table 2). However, pairwise comparisons of the landmark-based deviations revealed that across all nine landmarks, the deviation in Group 1 was significantly lower than in Groups 2 and 3 (p<0.001). When Group 2 and Group 3 were compared, significant differences were observed at most landmarks, with Group 3 exhibiting slightly greater deviation than Group 2 (Figure 3).

Table 1. Comparison of the root mean square (RMS) values between the groups

Parameter assessed	Groups (mean ± standard deviation) ⁺			p-value
	Group 1	Group 2	Group 3	
RMS value	0.2169±0.0312	0.3292±0.024	0.3046±0.031	<0.001*
Inter-group comparison[^]				
	Group 1-Group 3	Group 1-Group 2	Group 2-Group 3	
Adjusted p-value	<0.001*	<0.001*	0.489	

⁺Kruskal-Wallis test.
[^]Pairwise comparison using Dunn-Bonferroni test.
 *Indicates statistical significance (p<0.05).
 RMS, root-mean-square.

Table 2. Comparison of the mean deviation values at each landmark between the groups

Landmarks	Deviation values Mean ± standard deviation (SD) ⁺			p-value
	Group 1	Group 2	Group 3	
MI	0.1995±0.0035	0.218±0.0033	0.2347±0.0034	<0.001*
PG	0.1894±0.001	0.1923±0.001	0.2148±0.0012	<0.001*
ML	0.4261±0.0008	0.4695±0.0011	0.5042±0.0011	<0.001*
FACC	0.4705±0.0005	0.5005±0.0005	0.5081±0.0008	<0.001*
MP	0.286±0.0032	0.3109±0.0038	0.329±0.0035	<0.001*
BG	0.4542±0.003	0.4921±0.0038	0.5208±0.0058	<0.001*
GZ	0.2475±0.0145	0.3043±0.0401	0.3954±0.0537	<0.001*
HP	0.15±0.0019	0.1577±0.0027	0.1671±0.0039	<0.001*
MC	0.3497±0.0032	0.3755±0.0039	0.4009±0.0035	<0.001*

Table 2. Continued

Landmarks	Deviation values Mean ± standard deviation (SD) [†]			p-value
	Group 1	Group 2	Group 3	
Pairwise comparison (Adj. p-values)[^]				
	Group 1-Group 3	Group 1-Group 2	Group 2- Group 3	
MI	<0.001*	0.011*	0.011*	
PG	<0.001*	0.015*	0.009*	
ML	<0.001*	0.01*	0.01*	
FACC	<0.001*	0.003*	0.01*	
MP	<0.001*	0.004*	0.011*	
BG	<0.001*	0.004*	0.004*	
GZ	<0.001*	0.028*	0.013*	
HP	<0.001*	0.013*	0.011*	
MC	<0.001*	0.011*	0.004*	

[†]Kruskal-Wallis test.

[^]Pairwise comparison using Dunn-Bonferroni test.

*Indicates statistical significance (p<0.05).

MI, point on the mid-incisal edge of the central incisors; PG, mid-point on the central groove of the first pre bicuspid; ML, mesio-lingual cusp tips of the first molars; FACC, the point of the facial axis of the central incisor that separates the gingival and occlusal halves; MP, mid-point on the palatal surface of the first bicuspid; BG, a point on the buccal groove of the first molars; GZ, gingival zenith of the central incisor; HP, highest point on the palate-gingival margin of the second bicuspid; MC, highest point on the bucco-gingival margin of the second bicuspid.

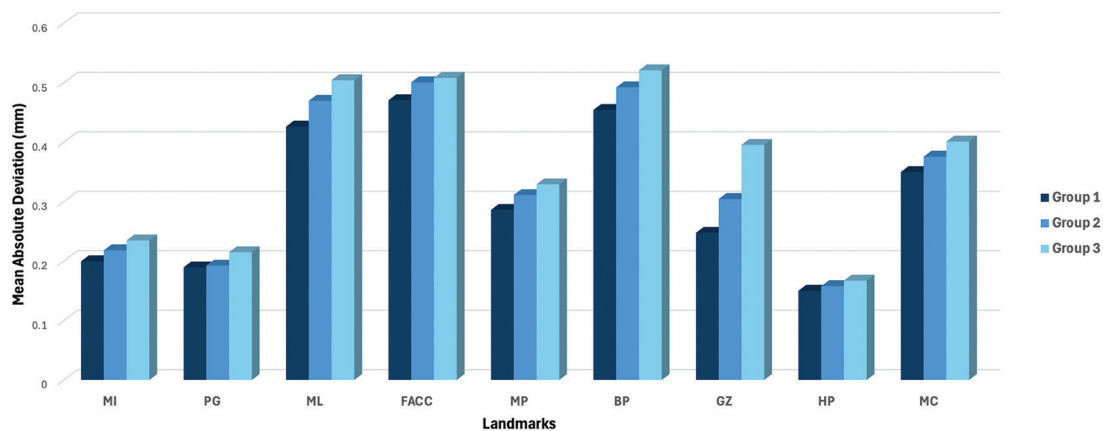


Figure 3. Graph depicting the comparison of the mean deviation of the aligners across Groups 1-3 in the nine landmarks assessed.

MI, point on the mid-incisal edge of the central incisors; PG, mid-point on the central groove of the first pre bicuspid; ML, mesio-lingual cusp tips of the first molars; FACC, the point of the facial axis of the central incisor that separates the gingival and occlusal halves; MP, mid-point on the palatal surface of the first bicuspid; GZ, gingival zenith of the central incisor; HP, highest point on the palate-gingival margin of the second bicuspid; MC, highest point on the bucco-gingival margin of the second bicuspid.

DISCUSSION

The present study used MeshLab software to assess the accuracy of aligners by applying point-based gluing for superimposition. MeshLab is utilized for processing STL files and superimposition; it is free, open-source software.²⁰ Koenig et al.¹⁵ and Spangler et al.¹⁷ utilized Geomagic Control X software (3D Systems, Morrisville, NC, USA) and MeshMixer (Autodesk, San Rafael, CA, USA) to process and assess deviations across the samples. The best fit alignment used in Geomagic software utilized the rugae area as a landmark for superimposition and was found to be more accurate than using landmarks on teeth for model alignment.²¹ The use of this software provides comprehensive three-dimensional analysis but requires careful consideration of scanning spray thickness, which accounts for approximately 0.01899 mm and 0.0803 mm and potential alignment errors due to the type of superimposition.¹⁵ Jindal et al.¹⁶ employed direct measurement of tooth heights by multiple observers, while Cole et al.²² used engineering software to measure distances at specific reference points. Differences in the measurement protocol could introduce errors and may account for variations in the reported outcomes and the slight deviations observed in the present study. The study protocol and methodology closely followed those of Koenig et al.¹⁵ to ensure comparability with the newer direct-printed aligner material TA-28, which was not included in their original investigation.

The result of this study indicated that direct-printed aligners exhibited greater dimensional accuracy and better fit than thermoformed aligners. The overall deviation of the aligners (RMS value) from the baseline STL models was smallest for direct-printed aligners (Group 1), and this difference was significant compared with thermoformed aligners. Previous studies have found that about 0.15-0.25 mm of space between the tooth and aligner is acceptable.¹⁷ However, in this study, thermoformed aligners showed deviations of more than 0.25 mm, unlike the direct-printed aligners. The study also assessed deviations from the baseline models at nine specific bilateral landmarks to evaluate aligner fit. The landmarks were selected to represent all surfaces of the aligners. Aligners produced by direct printing showed the lowest deviations at all nine reference points evaluated in this study; their deviation values were significantly lower than those of aligners produced by thermoforming.

Koenig et al.¹⁵ reported RMS values of 0.188 ± 0.074 mm for Zendura FLX™, 0.209 ± 0.094 mm for Essix ACE™, and 0.140 ± 0.020 mm for direct-printed aligners manufactured using Tera Harz™ TC-85DAP resin. The present study's RMS values were slightly higher than theirs; however, the direct-printed aligners showed significantly better overall trueness than thermoformed alternatives. They also observed the lowest deviations at all nine assessed landmarks, with statistically significant differences at six of the nine bilateral landmarks

compared with thermoformed aligners. Another study by Jindal et al.¹⁶ compared geometrical and mechanical properties of thermoformed Duran aligners with 3D-printed aligners fabricated using Dental LT Clear resin. Their geometric analysis revealed that 3D-printed aligners were more accurate, with an average absolute difference of 0.21 mm compared with 0.37 mm for thermoformed aligners, which supports the present study's findings of superior dimensional accuracy with direct printing. Similarly, Spangler et al.¹⁷ compared Dental LT clear resin with vacuum-formed aligners (Invisacryl Ultra, Thermal Forming Material, Great Lakes Dental Technologies, Tonawanda, NY) and found that the direct-printed aligners exhibited better trueness than the vacuum-formed aligners. However, Cole et al.²² reported conflicting results when evaluating 3D-printed retainers fabricated with Dental LT Clear resin. In their study, vacuum-formed retainers exhibited the smallest deviation from reference models (0.10-0.20 mm), whereas 3D-printed retainers exhibited the largest deviation (0.10-0.40 mm). The differences between the findings between Cole et al.²² and other studies may be due to differences in resin materials and post-curing protocols. They acknowledged that all retainers, including the 3D-printed ones, yielded measurements within the 0.50 mm threshold generally considered clinically acceptable for orthodontic appliances. For direct-printed aligners, resin selection is critical. The present study and the study by Koenig et al.¹⁵ used Tera Harz resins (TA 28 and TC-85 DAP, respectively), which were specifically formulated for aligner printing, and demonstrated superior dimensional accuracy. In contrast, Jindal et al.¹⁶ and Cole et al.²² used Dental LT Clear resin, which was originally intended for hard splints and retainers. This variability highlights the necessity of using resins specifically designed for aligner applications, rather than materials intended for other dental uses.

Among thermoformed materials, the present study found that PU-based aligners (Zendura FLX) were more accurate than PET-G aligners (Erkodur); however, the differences were not statistically significant. This aligns with the findings of Koenig et al.,¹⁵ who reported lower RMS values and more consistent performance with Zendura FLX compared to Essix ACE. The favourable performance of PU materials may be attributed to their superior thermoforming characteristics and adaptability.²³

Strengths of the study include using the same intraoral scanner for all groups. The present study set the thickness of both thermoformed and direct-printed aligners to 0.75 mm. However, previous studies have suggested that although thickness can be controlled in direct 3D printing, the 3D printing workflow did not accurately replicate the designed thicknesses, and this discrepancy may have an impact on the fit of the aligner.²⁴ The study by Shirey et al.¹³ found that thermoformed aligners measured thinner after thermoforming, while direct-printed aligners measured thicker. Direct printing of aligners often resulted in an increase in wall thickness of approximately 0.2 mm.²⁴

Study Limitations

Although the the present study used uniform thickness for all groups, the thickness of the manufactured aligners was not confirmed post-fabrication, and their relationship with dimensional accuracy and fit was not assessed. This limitation should be investigated in future research. The dimensional accuracy and the properties of the aligners can vary with changes in materials used, printing technology, printing orientation, post-processing techniques, and the software used for assessment.^{25,26} Hence, the present study sheds light on only one aspect of these collective factors. Moreover, dimensional accuracy alone is not a sufficient indicator of the aligner's performance. Consequently, more clinical studies using standardized manufacturing processes must be conducted to evaluate the clinical predictability and translation of tooth movements between direct-printed and thermoformed aligners, in order to validate the results of *in vitro* studies. Furthermore, given advances in direct-printed aligner systems, a comparison of the various resins available on the market could facilitate informed clinical decision-making. Direct-printed aligners provide a more accurate alternative to thermoformed aligners, minimizing the manufacturing steps and reducing the need to discard millions of unrecyclable dental models, which adds to the environmental burden.²⁷

CONCLUSION

In this *in vitro* study, direct-printed aligners fabricated using TA-28 resin demonstrated significantly greater dimensional accuracy and improved fit compared with thermoformed aligners made from PU (Zendura FLX) and PET-G (Erkodur). Direct-printed aligners demonstrated significantly reduced deviations across all nine anatomical landmarks assessed. Among thermoformed materials, PU-based aligners showed marginally better accuracy than PET-G aligners. The enhanced dimensional accuracy and consistent fit demonstrated by directly printed aligners suggest potential advantages for clinical orthodontic practice.

Ethics

Ethics Committee Approval: The study was approval from the Saveetha Dental College Institutional Human Ethical Committee (approval number: SRB/SDC/ORTHO-2307/25/091, date: February, 2025).

Informed Consent: Written consent was obtained from the patient for using digital model in the study.

Footnotes

Author Contributions: Concept - S.N.; Design - N.F., S.N.; Data Collection and/or Processing - N.F.; Analysis and/or Interpretation - N.F., S.N.; Literature Search - N.F., S.N.; Writing - N.F., S.N.

Conflict of Interest: The authors do not have any conflict of interest to disclose.

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