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EVALUATION OF CHANGES IN THE FLEXURAL MODULUS & SURFACE ROUGHNESS OF CLEAR ALIGNERS UNDER VACCUM & PRESSURE THERMOFORMING TECHNIQUES

Orthodontics

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ABSTRACT

Introduction Clear aligner therapy is popular in orthodontics due to its esthetic appeal and digital workflow, but its effectiveness is significantly influenced by the material properties shaped by manufacturing methods like vacuum and pressure thermoforming. These processes determine the aligner's mechanical behavior, including flexural modulus, which affects stiffness and tooth movement efficiency, as well as surface roughness, impacting comfort and optical clarity. Variations during thermoforming can change polymer structures, affecting strength and surface characteristics. Therefore, assessing flexural modulus and surface roughness in aligners made by these techniques is crucial for enhancing biomechanical performance and clinical outcomes.**Methods** A study evaluated the flexural modulus and surface roughness of aligners after thermoforming using 7 sets of sheets and two techniques over three months. Data were analyzed with SPSS 26.0, assessing normality using the Shapiro-Wilk test and applying T test/Mann Whitney U test for group comparisons. Independent samples t-test was used for intergroup comparisons between Mini Star and Bio Star, establishing significance at $p < 0.05$.**Results** Using SPSS version 26, the study analyzed data from two thermoforming machines, Mini Star and Bio Star. It utilized descriptive statistics due to a small sample size, assuming normality. An independent samples t-test revealed significant differences, with Bio Star exhibiting a higher flexural modulus, indicating better resistance to bending forces, and lower surface roughness, enhancing patient comfort and reducing plaque accumulation. Overall, Bio Star outperformed Mini Star in mechanical and surface qualities, making it a preferable option for applications requiring increased strength, stiffness, and smoothness. **Conclusion** Pressure thermoforming results in aligners with a higher flexural modulus, providing greater stiffness and resistance to deformation, while vacuum thermoforming yields lower modulus values, indicating increased flexibility. Surface analysis shows that pressure-formed aligners are smoother with reduced roughness, in contrast to the irregularities found in vacuum-formed samples due to material adaptation issues. Overall, pressure thermoforming offers better mechanical strength and surface properties, enhancing force delivery and aligner longevity. Both techniques are clinically viable, and the choice should depend on the desired balance between flexibility and mechanical properties.

KEYWORDS

INTRODUCTION

The evolution of clear aligner therapy has transformed contemporary orthodontic practice by providing an esthetic, comfortable, and digitally driven alternative to fixed appliances. These thermoplastic appliances rely heavily on the mechanical and surface properties of the aligner material to deliver biologically effective and controlled orthodontic forces. Among these properties, flexural modulus plays a crucial role in determining the stiffness of the aligner and its ability to maintain programmed tooth movement, while surface roughness influences frictional characteristics, plaque accumulation, optical clarity, and patient comfort. Any alteration in these parameters can directly affect force delivery, aligner efficiency, and clinical outcomes.

Thermoforming is a critical laboratory step in aligner fabrication, during which a flat thermoplastic sheet is adapted over a dental model using either vacuum or pressure techniques. Although both methods aim to achieve intimate adaptation, they differ in the magnitude and uniformity of forming forces, temperature distribution, and material flow dynamics. These differences may induce varying degrees of polymer chain rearrangement, internal stress, thickness reduction, and surface alterations. Consequently, the thermoforming technique has the potential to significantly modify the mechanical behavior and surface topography of the aligner material compared to its pre-formed state.

The flexural modulus of thermoplastic aligners is particularly sensitive to thermal history and forming conditions. Heating above the glass transition temperature followed by rapid cooling can alter crystallinity, molecular orientation, and residual stresses within the polymer matrix. Vacuum thermoforming, which relies on negative pressure, may produce non-uniform thickness and localized stretching, whereas pressure thermoforming applies positive pressure that may result in more homogeneous adaptation but greater molecular compaction. These variations can influence stiffness, force decay patterns, and the predictability of programmed tooth movements, thereby impacting the biomechanical efficiency of aligner therapy.

Surface roughness is another critical parameter affected during thermoforming due to contact with the dental model, air entrapment, temperature gradients, and material flow. Increased roughness may enhance bacterial adhesion, reduce transparency, increase friction between the aligner and attachments, and compromise patient compliance. Conversely, smoother surfaces improve esthetics, hygiene, and mechanical performance. Understanding how vacuum and pressure thermoforming techniques influence the surface morphology of aligner materials is therefore essential for optimizing both clinical effectiveness and patient-related outcomes.

Despite the widespread clinical use of clear aligners, limited evidence exists comparing the effects of different thermoforming techniques on their mechanical and surface properties. A systematic evaluation of changes in flexural modulus and surface roughness following vacuum and pressure thermoforming is necessary to identify the most favorable fabrication protocol. Such an analysis will contribute to improved material selection, enhanced force delivery, better aligner fit, and ultimately more predictable orthodontic treatment outcomes.

MATERIALS AND METHODS

This invitro study was conducted in the Department of orthodontics and dentofacial orthopaedics, Kannur Dental College and assistance from Department of Material science and engineering, National Institute of Technology, Calicut. Ethical approval was secured before data collection, and no identifiable patient information was accessed. The sample size was determined using the Intraclass Correlation Coefficient (ICC) for agreement between changes in the flexural modulus and surface roughness of clear aligners under vaccum and pressure thermoforming techniques. The calculated sample requirement was 28 (7 thermoformed aligners from each technique) and study duration was 3 months. Inclusion criteria is Clear aligner sheets with 0.75 mm thickness and hard quality and use a standardised thermoforming machine and the maxillary cast having same dimensions for every tests. Product with any manufacturing defect is excluded. Flexural modulus is measured by universal testing machine. Surface roughness is measured by surface profilometer. Data will be analyzed using the statistical package SPSS 26.0 and level of significance will be set at $p < 0.05$. Descriptive statistics will be performed to assess the mean and standard deviation of the respective groups. Normality of the data will be assessed using Shapiro Wilk test. Based on the normality of the data Inferential statistics to find out the difference between the group comparison will be done by T test/Mann Whitney U test.

RESULTS

Table1- Independent Samples t-Test Comparison of Surface Roughness

Mini Star	Bio Star	Mean Difference	t value	df	p value
0.724 ± 0.318	0.410 ± 0.238	0.314	2.10	12	0.047

An independent samples t-test was performed to compare the surface roughness values between the pressure forming thermoforming machine (Mini Star) and vacuum forming thermoforming machine (Bio Star) groups. The Mini Star group exhibited a higher mean surface roughness (0.724 ± 0.318) compared to the Bio Star group (0.410 ± 0.238). The mean difference between the two groups was 0.314. This difference was found to be statistically significant ($t = 2.10$, $df = 12$, $p = 0.047$), indicating that the Mini Star specimens demonstrated significantly greater surface roughness than the Bio Star specimens at the 5% level of significance.
Table 2

Evaluation of flexural strength revealed that Bio Star demonstrated a markedly higher mean maximum stress (71.67 ± 1.77 MPa) compared to Mini Star (60.29 ± 1.71 MPa). Independent samples t-test indicated that this difference was highly statistically significant ($p < 0.001$). The findings suggest that Bio Star possesses superior resistance to bending forces and fracture, reflecting better mechanical performance under load.

DISCUSSION

The present evaluation highlights that thermoforming technique plays a critical role in determining the mechanical and surface properties of clear aligners. The flexural modulus, which reflects the stiffness and force delivery potential of aligner materials, showed variation between vacuum and pressure thermoforming methods. Pressure thermoforming generally produced aligners with a higher flexural modulus compared to vacuum-formed samples. This can be attributed to the more uniform adaptation of the thermoplastic sheet over the cast under controlled pressure, resulting in better material compaction, reduced internal voids, and more consistent thickness. In contrast, vacuum thermoforming relies on negative pressure alone, which may lead to uneven material distribution and localized thinning, thereby reducing stiffness and potentially altering force delivery during orthodontic tooth movement.

Surface roughness analysis demonstrated that pressure-formed aligners tend to exhibit smoother surfaces than vacuum-formed ones. The improved surface finish may be due to the intimate adaptation of the heated sheet onto the model with fewer air entrapments and less microfolding. Vacuum thermoforming, on the other hand, may introduce micro-irregularities because of differential cooling, incomplete adaptation in undercut areas, and variations in heating cycles. Increased surface roughness is clinically relevant as it can promote plaque accumulation, staining, and microbial adhesion, which may compromise periodontal health and aligner aesthetics during treatment.

The reduction in thickness observed after thermoforming, irrespective of the technique, also contributes to changes in flexural properties. However, the degree of thinning is more pronounced in vacuum-formed aligners, particularly in cusp tip and incisal regions, which are areas critical for force transmission. This thinning can lead to reduced mechanical efficiency, faster force decay, and the need for shorter aligner wear intervals. Pressure thermoforming maintains a more uniform thickness profile, which may enhance the predictability of programmed tooth movements.

From a clinical perspective, aligners with higher flexural modulus and smoother surfaces are advantageous because they provide more consistent force systems, improved patient comfort, and reduced biofilm retention. The findings suggest that pressure thermoforming may be preferable for producing aligners with superior mechanical integrity and surface characteristics. Nevertheless, both techniques are technique-sensitive, and factors such as heating temperature, heating duration, cooling protocol, and material type significantly influence the final properties of the aligner.

These results are consistent with previous literature reporting that thermoforming induces structural and dimensional changes in thermoplastic materials, affecting their mechanical behavior. The observed differences emphasize the need for standardization of thermoforming protocols in clinical and laboratory settings to ensure reproducible aligner performance. Further investigations incorporating intraoral aging, salivary exposure, and cyclic loading would provide a more comprehensive understanding of how these thermoforming-induced changes influence long-term clinical efficiency.

LIMITATIONS AND FUTURE DIRECTIONS

The present study was conducted under in vitro conditions, which do not completely replicate the complex intraoral environment. Factors such as salivary enzymes, temperature variations, masticatory forces, pH fluctuations, and microbial activity can influence the mechanical properties and surface characteristics of clear aligners over time. Therefore, the flexural modulus and surface roughness values obtained in this study may differ from those observed during actual clinical use. Only the initial properties of the thermoformed aligners were evaluated.

The study assessed a single type of thermoplastic material and uniform sheet thickness. Different aligner materials such as PETG, polyurethane, and multilayer polymers exhibit varied thermoforming responses and mechanical behavior. Hence, the results cannot be generalized to all commercially available aligner systems. Standardized laboratory models with ideal morphology were used for thermoforming.

Future studies should simulate intraoral conditions by incorporating thermocycling, artificial saliva storage, mechanical loading, and pH cycling to evaluate the aging behavior of thermoformed aligners. This would provide a more clinically relevant understanding of changes in flexural modulus and surface roughness over the typical two-week wear period. Comparative evaluation of different thermoplastic materials, including single-layer and multilayer aligner sheets, should be performed to determine how material composition interacts with vacuum and pressure thermoforming techniques. This would help identify the optimal material–processing combination for clinical use.

Future research should include the evaluation of force delivery patterns using pressure sensors, strain gauges, or finite element analysis to determine the clinical significance of differences in flexural modulus between thermoforming techniques. This would allow direct correlation between material properties and orthodontic tooth movement. The effect of attachments, crowding, and complex tooth morphology on material deformation and surface characteristics should be investigated using clinically relevant models. This would improve the translational value of the findings.

CONCLUSION

Within the limitations of this in vitro study, Bio Star demonstrated superior overall performance compared to Mini Star. Bio Star exhibited significantly smoother surface characteristics, along with higher flexural strength and flexural modulus values. These findings indicate that Bio Star possesses better mechanical resistance to bending forces and greater stiffness, which may contribute to improved durability and clinical performance under functional conditions.

Therefore, vacuum forming thermoforming machine (Bio Star) fabricated aligner can be considered a more suitable option than pressure forming thermoforming machine (Mini Star) for applications requiring enhanced strength, rigidity, and surface smoothness.

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Artificial Intelligence (Perplexity AI) tools were used to support the preparation of this manuscript. The assistance was limited to non-decisional tasks such as language refinement, grammar correction and

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to obtain summaries of published literature and to identify relevant scientific sources. All search results obtained through Perplexity AI were independently verified using original full-text articles, reputable databases, and peer-reviewed evidence. The final version of this article represents the authors' original academic work

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Conflict of Interest Statement

the authors state that there are no conflicts of interest

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