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Original Research Article

Unveiling the resilience of aligner materials: Comparative analysis of mechanical properties across thermoforming and saliva exposure

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Abstract

Background: Clear aligners have become a preferred choice in orthodontics, offering aesthetic and functional advantages over traditional fixed appliances. However, their clinical performance depends on the mechanical properties of the materials, which can degrade during thermoforming and intraoral exposure.
Objective: To evaluate and compare the mechanical properties of two aligner materials—CA PRO+ and ERKODUR AL—under three conditions: pre-thermoforming, post-thermoforming, and post-saliva exposure.
Materials and Methods: An in-vitro study was conducted using 96 samples, equally divided between CA PRO+ and ERKODUR AL. Samples were tested for tensile yield stress and elastic modulus before thermoforming, after thermoforming, and following seven days of saliva exposure at 37°C. Testing was performed using an INSTRON Universal Testing Machine per ASTM D638 standards. Statistical analysis included one-way ANOVA and Tukey's HSD for post-hoc comparisons.
Results: Both materials exhibited significant reductions in tensile yield stress and elastic modulus across the three conditions ($p < 0.05$). CA PRO+ showed a total tensile yield stress reduction of 15.9% (from 50.24 MPa pre-thermoforming to 42.25 MPa post-saliva exposure), while ERKODUR AL showed a similar decline of 15.9% (from 52.44 MPa to 44.05 MPa). The elastic modulus decreased by approximately 16% for both materials during the same period.
Conclusion: Thermoforming and intraoral simulation significantly degrade the mechanical properties of aligner materials, potentially impacting their clinical performance. Material selection and optimization of thermoforming processes are crucial to improving the durability and efficacy of aligners.

Keywords: Clear aligners, CA PRO+, ERKODUR AL, Thermoforming, Tensile yield stress, Elastic modulus, Artificial saliva, Orthodontic biomechanics, In-vitro study.

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1. Introduction

The advancement in orthodontic treatment has transformed patient care, with clear aligners gaining popularity as a comfortable and aesthetic alternative to traditional fixed appliances.[1-2] Clear aligners, initially introduced as tooth positioners by Dr Harold Kesling in 1945,[3] have evolved significantly due to advancements in materials and digital technology, including CAD/CAM systems.[4] A pivotal moment came in 1999 with the launch of Invisalign by Align Technology, which greatly improved treatment predictability and patient compliance.[5] These devices rely heavily on their mechanical properties, such as tensile yield stress and elastic modulus, to exert consistent orthodontic forces and achieve desired tooth movements.[6]

Modern patients increasingly prefer aligners due to their transparency, convenience and reduced soft tissue irritation. Additionally, these devices promote better oral hygiene, reduce periodontal risks, and allow greater dietary flexibility.[7] Despite these benefits, the success of aligner treatment is highly dependent on the mechanical integrity of the thermoplastic materials used. Thermoforming, a key step in aligner fabrication, involves heating thermoplastic sheets and molding them over dental models, ensuring a precise fit.[8] However, this process alters the material properties, often leading to a reduction in strength and stiffness.[9-10] Once placed intraorally, aligners face a dynamic environment characterized by salivary enzymes, temperature fluctuations, and masticatory forces, all of which can degrade their performance.[11-13] Studies have shown that saliva exposure

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can lead to stress relaxation, loss of mechanical integrity, and compromised orthodontic force application.[14-16]

Despite these challenges, aligners remain a preferred choice due to their superior aesthetics, minimal tissue irritation, and improved oral hygiene maintenance.[17-18] Research exploring the effects of thermoforming and intraoral exposure on aligner materials is essential to optimize their design and performance.[19-20] This study evaluates changes in the tensile yield stress and elastic modulus of two widely used aligner materials—CA PRO+ and ERKODUR AL—across three conditions: pre-thermoforming, post-thermoforming, and post-saliva exposure. The findings aim to guide clinicians in material selection and improve treatment predictability.[21-22]

2. Materials and Methods

This in-vitro study was conducted at NIMS Dental College, Jaipur, to simulate clinical conditions and evaluate the mechanical performance of aligner sheets. Ethical clearance was obtained from the Institutional review board (IEC/P-247/2023). The study employed two commercially available aligner materials: CA PRO+ (Scheu Dental, Germany) and ERKODUR AL (Erkodent, Germany).

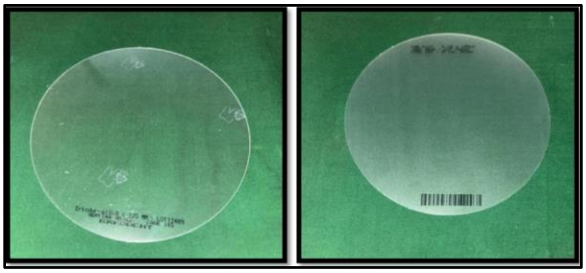


Figure 1: Aligner Sheets (Erkodur Al & Ca Pro respectively.

The mechanical properties of the samples were analyzed under three conditions: before thermoforming, after thermoforming, and after immersion in artificial saliva. Aligner sheets were cut into rectangular samples measuring 40 mm × 10 mm. For the post-thermoforming stage, the samples were molded using a Ministar S thermoforming machine at a temperature range of 160–220°C and a pressure of 4.5–6 bar.

Figure 2: Ministar thermoforming machine

Post-saliva exposure samples were immersed in Xerostat artificial saliva at 37°C for seven days to mimic oral conditions.

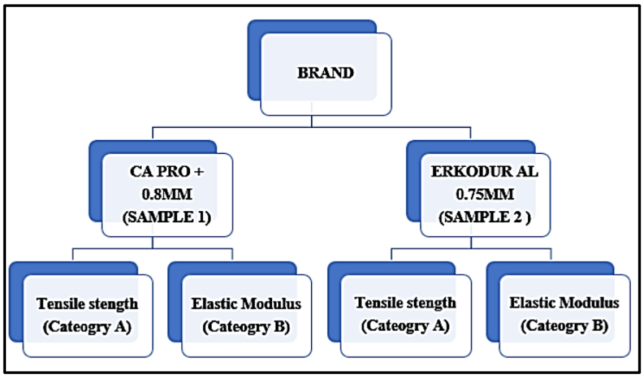
Figure 3: Xerostat artificial saliva

Mechanical properties were evaluated using an INSTRON 5967 Universal Testing Machine, following ASTM D638 standards. Tensile yield stress was calculated as the maximum load divided by the cross-sectional area, while elastic modulus was derived from the slope of the linear region of the stress-strain curve.

Figure 4: INSTRON universal testing machine

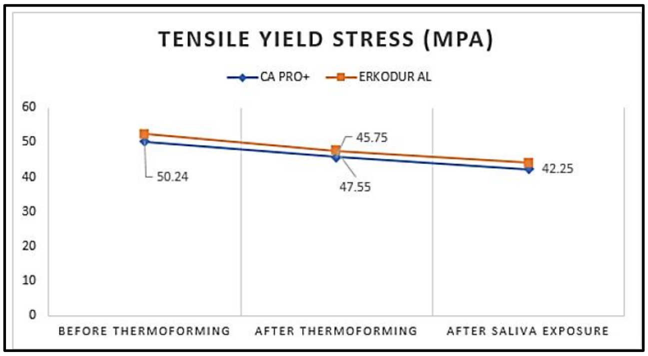
3. Sampling Technique

A total of 96 samples were analyzed in this study, divided equally between the two aligner materials (CA PRO+ and ERKODUR AL). Each material was further subdivided into three groups of 16 samples based on the evaluation stage: pre-thermoforming, post-thermoforming, and post-thermoforming with saliva exposure. This ensured a robust and statistically valid comparison of mechanical properties across the different conditions.



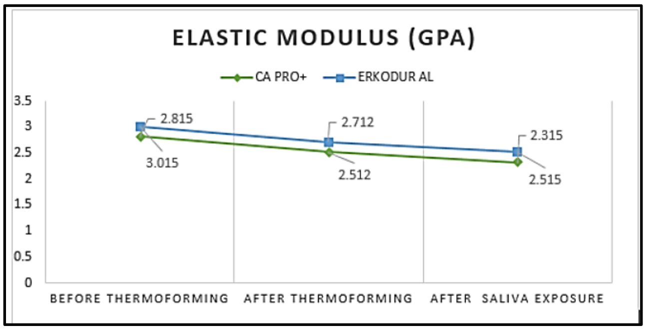
4. Results

The study revealed significant changes in the mechanical properties of both materials across the three conditions. Tensile yield stress decreased in both materials post-thermoforming and further declined after saliva exposure. For CA PRO+, tensile yield stress reduced from 50.24 MPa pre-thermoforming to 45.75 MPa post-thermoforming, and to 42.25 MPa post-saliva exposure, representing a total decline of 15.9%. ERKODUR AL demonstrated similar trends, with tensile yield stress dropping from 52.44 MPa pre-thermoforming to 47.55 MPa post-thermoforming, and to 44.05 MPa after saliva exposure, a total reduction of 15.9%.



Graph 1: Comparison of tensile yield stress before, After thermoforming and after post saliva exposure of both erkodur Al and Ca Pro +

Elastic modulus followed a comparable pattern. For CA PRO+, the elastic modulus declined from 2.815 GPa pre-thermoforming to 2.512 GPa post-thermoforming, and to 2.315 GPa post-saliva exposure. ERKODUR AL exhibited a decrease from 3.015 GPa pre-thermoforming to 2.712 GPa post-thermoforming, and to 2.515 GPa post-saliva exposure.



Graph 2: Comparison of Elastic Modulus Before, After Thermoforming and after post saliva exposure of both Erkodur Al and Ca Pro +

Both materials showed statistically significant reductions in tensile yield stress and elastic modulus ($p < 0.05$), indicating that thermoforming and saliva exposure adversely impact their mechanical performance. The findings suggest that aligners become less effective at maintaining force and resisting deformation over time.

5. Discussion

The results of this study demonstrate significant mechanical degradation in aligner materials following thermoforming and saliva exposure. CA PRO+ and ERKODUR AL showed substantial reductions in tensile yield stress and elastic modulus, aligning with findings from Tamburrino et al. (2020) and Dalaie et al. (2021), who reported similar material relaxations and structural transformations due to heating.[23-24] These changes compromise the aligner's ability to exert consistent forces during treatment.[25] Fang et al. (2013) also observed that thermal processing caused stress relaxation in aligners, reducing their capacity to maintain orthodontic forces.[26]

Conversely, Stardeni et al. (2024) found negligible changes in tensile strength after thermoforming, suggesting that specific materials like PET-G may exhibit resilience under thermal stress[27] Similarly, Matsuda et al. (2022) reported that increased material thickness improved mechanical stability post-thermoforming, a finding that contrasts with the results for CA PRO+ and ERKODUR AL in this study.[28]

The additional degradation observed post-saliva exposure is consistent with studies by Ihssen et al. (2019) and Lira et al. (2023), which highlighted the role of salivary enzymes and moisture in accelerating material fatigue and reducing stiffness[29-30] Bradley et al. (2015) further noted that saliva immersion leads to reduced elasticity and increased creep, similar to the reductions in elastic modulus observed here.[31] On the other hand, Sayahpour et al. (2024) found that multi-layer aligners exhibited better resistance to saliva-induced degradation, pointing to the potential benefits of advanced material designs.[32]

The clinical implications of these findings are significant. Degraded aligners may fail to maintain sufficient force levels, leading to prolonged treatment durations and suboptimal outcomes.[33] These results underscore the importance of selecting materials that resist degradation during thermoforming and intraoral exposure. Innovations in polymer chemistry and multi-layer aligner designs could mitigate these issues.[34-35] However, discrepancies in study results, such as those noted by Stardeni et al. (2024), highlight the need for standardized testing protocols to better understand material behavior under real-world conditions.[36-37] The thermoforming and saliva exposure pose challenges to aligner performance, material-specific characteristics and fabrication techniques play crucial roles in determining their durability and efficacy.[38-40]

6. Conclusion

Thermoforming and intraoral conditions significantly weakened the mechanical properties of aligner materials like CA PRO+ and ERKODUR AL. The process of thermoforming introduces internal stresses and uneven thinning, while exposure to saliva causes further degradation due to moisture absorption and enzymatic activity. These effects impair the aligners' ability to consistently deliver orthodontic forces, potentially prolonging treatment times. Future advancements should focus on developing materials that can better resist these stresses, coupled with improved manufacturing processes to enhance durability and clinical performance.

7. Source of Funding

None.

8. Conflict of Interest

None.

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