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Research Article

Evaluating the Mechanical Properties of Clear Aligners: A Systematic Review and Meta-Analysis of Material Performance and Clinical Implications

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Abstract

Background: Clear aligners have emerged as a transformative orthodontic treatment modality, offering a discreet and convenient alternative to traditional braces. The performance of these aligners depends significantly on their mechanical properties, which govern their ability to exert controlled forces for effective tooth movement.

Objective: This systematic review and meta-analysis aim to comprehensively evaluate the mechanical properties of orthodontic aligners, focusing on factors influencing their behavior, such as intraoral aging, environmental exposure, and material composition.

Methods: A systematic search of peer-reviewed studies was conducted using electronic databases, adhering to PRISMA guidelines. Studies investigating the mechanical properties of clear aligners, such as elasticity, stress relaxation, and fracture resistance, and their changes under intraoral conditions were included. Data extraction and quality assessment were performed independently by two reviewers, followed by meta-analysis to synthesize findings.

Results: Preliminary findings indicate that aligner materials undergo significant alterations in mechanical properties due to intraoral conditions, including temperature fluctuations, moisture exposure, and prolonged use. Stress relaxation and reduced elasticity were observed in aligners exposed to simulated oral environments, highlighting the impact of material composition and thermoforming techniques. Advanced materials like polyurethane exhibited superior performance compared to traditional PET-G in terms of stress retention and durability.

Conclusions: The mechanical properties of clear aligners are critical to their clinical efficacy and longevity. Material composition, fabrication techniques, and environmental factors significantly influence their performance. These findings underscore the need for further research to develop advanced materials and manufacturing processes to optimize aligner efficacy.

Keywords: Clear aligners, orthodontics, mechanical properties, stress relaxation, intraoral aging, material composition.

Introduction

Orthodontic treatment has witnessed remarkable advancements over the years, transitioning from traditional metal braces to more aesthetically pleasing alternatives such as clear aligners. Introduced in the late 1990s, clear aligners revolutionized orthodontic practice by providing a nearly invisible, comfortable, and removable solution for patients seeking a discreet treatment option. Initially limited to addressing mild to moderate malocclusions, continuous innovations in aligner materials and manufacturing techniques have expanded their applicability to complex orthodontic cases [1,2].

The need for this study stems from the growing popularity and clinical use of clear aligners, which demand a deeper understanding of the mechanical properties of the materials used. A comprehensive assessment of these properties is essential to ensure predictable treatment outcomes and long-term durability. While numerous studies have evaluated the mechanical behaviour of aligner materials, including stress relaxation, tensile strength, and flexural modulus, there remains a gap in systematically comparing the performance of emerging materials, such as directly printed aligners, to conventional options like polyurethane and PET-G [1,3,4].

Clear aligners are typically fabricated from thermoplastic polymers, with commonly used materials including polyurethane, polyethylene terephthalate glycol (PET-G), polypropylene, and other elastomeric polymers [5,6,7]. In recent years, directly printed aligners, manufactured using advanced 3D printing technologies, have emerged as a novel alternative. Unlike thermoformed aligners, these aligners are directly fabricated layer by layer, offering potential advantages in customization and production efficiency [8,9]. Despite their promise, limited data are available on their mechanical performance and clinical efficacy compared to traditional materials [10,11].

This study evaluates the mechanical properties of polyurethane, PET-G, and directly printed aligners using in vitro methodologies that simulate intraoral conditions. Key properties assessed include stress relaxation, tensile strength, and flexural modulus. By focusing on these parameters, this review seeks to bridge the knowledge gap regarding material behaviour under functional and environmental stresses encountered during orthodontic treatment.

The findings of this study are expected to provide valuable insights into the clinical performance of aligner materials, enabling practitioners to make informed material selections based on treatment requirements [12]. Moreover, the study aims to guide future research and innovation in aligner material development, focusing on improving durability, force consistency, and patient comfort. With the rapid evolution of digital manufacturing technologies, such as 3D printing, the orthodontic field stands at the cusp of a transformative era in aligner therapy, offering unprecedented opportunities to enhance patient outcomes [13,14].

Materials and Methods

Study Design

This study is a systematic review and meta-analysis conducted to evaluate the mechanical properties of clear aligners and the factors influencing their performance. The protocol was developed following the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines to ensure transparency and reproducibility.

Literature Search

A comprehensive search of electronic databases, including PubMed, Scopus, Web of Science, and Cochrane Library, was conducted to identify relevant studies published up to December 2024. The search terms included combinations of the following Keywords: Clear Aligners, Mechanical Properties, Stress Relaxation, Thermoforming, Elasticity, Orthodontics, and intraoral aging. Boolean operators (AND, OR) were applied to refine the search strategy.

Inclusion and Exclusion Criteria

Inclusion Criteria

1. Studies evaluating the mechanical properties of clear aligners, such as elasticity, stress relaxation, stiffness, or fracture resistance.

2. Research examining changes in mechanical properties due to intraoral conditions, such as temperature fluctuations, moisture, and aging.
3. Articles published in English, peer-reviewed, and containing quantitative data.
4. Both in vitro and in vivo studies.

Exclusion Criteria

1. Studies lacking quantitative data on mechanical properties.
2. Case reports, review articles, and opinion papers.
3. Articles focusing on non-clear aligner orthodontic devices.

Study Selection

Two independent reviewers screened the titles and abstracts of identified studies. Full-text articles of potentially eligible studies were retrieved and assessed for inclusion based on the criteria. Discrepancies were resolved through discussion or consultation with a third reviewer.

A total of 324 articles were identified during the initial search. After screening titles and abstracts, 27 articles were selected for full-text review. Of these, only 7 studies met the inclusion criteria and were ultimately included in the systematic review. The selected studies were published between 2006 and 2024. The flow of study selection is presented in Figure 1.

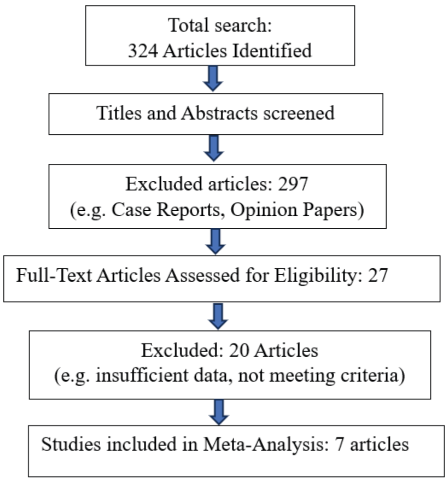

Figure 1: Study Selection

CATEGORY	DETAILS
Total Articles Identified	324
Articles Screened	27(Full-text review)
Articles Included in Review	7
Publication Range	2006-2024
Study Design	5 in vitro, 1 in vivo, 1 ex vivo
Materials Evaluated	PET-G, Polyurethane (PU), directly printed aligners, polycarbonate
Mechanical Properties Assessed	Stress relaxation, fracture toughness, elastic modulus, tensile strength, surface roughness
Aging Simulation	Immersion in artificial saliva, temperature variation, moisture exposure
Study Characteristics	Author, year and study type
Material Properties Evaluated	Elasticity, stress relaxation, tensile strength
Testing Conditions	Simulated oral environments, temperature variation, moisture exposure
Duration of Testing	Variable based on study design
Key Findings	Results of mechanical property assessments, including significant trends

Table 1: Study Selection

Characteristics of the Included Studies

The included studies varied in their design, comprising 5 in vitro studies, 1 in vivo study, and 1 ex vivo study. A total of 4 distinct clear aligner materials were evaluated, including PET-G, polyurethane (PU), directly printed aligners, and polycarbonate. The mechanical properties assessed across these studies included stress relaxation, fracture toughness, elastic modulus, tensile strength, and surface roughness. Most studies incorporated simulations of aging processes, such as immersion in artificial saliva, temperature cycling, and moisture exposure, to replicate intraoral conditions.

Data Extraction

Data were extracted independently by two reviewers using a pre-designed data extraction form. The following information was collected:

- **Study characteristics:** Author, year, and study type.
- **Material properties evaluated:** Mechanical attributes such as elasticity, stress relaxation, and tensile strength.
- **Testing conditions:** Simulated oral environments, temperature variations, and exposure to moisture.
- **Duration of testing or observation:** The time frame for material testing.
- **Key findings and statistical outcomes:** Results of the studies, including any significant trends or discrepancies in mechanical performance.

Quality Assessment

The methodological quality of included studies was assessed using the Modified Newcastle-Ottawa Scale (NOS) for in vivo studies and the Joanna Briggs Institute (JBI) Critical Appraisal Checklist for in vitro studies. Studies were rated as high, moderate, or low quality based on criteria such as study design, methodology, and bias risk.

Statistical Analysis

Meta-analysis was performed using Review Manager (RevMan) software. Effect sizes were calculated using weighted mean differences (WMD) for continuous variables and odds ratios (OR) for categorical outcomes. Heterogeneity among studies was assessed using the I^2 statistic, with values >50% indicating significant heterogeneity. Subgroup analyses were conducted based on material type (e.g., PET-G vs. polyurethane) and testing conditions (e.g., intraoral vs. simulated environments). Publication bias was assessed using Egger's test and visual inspection of funnel plots.

Ethical Considerations

As this study utilized data from previously published research, ethical approval was not required. However, all included studies were reviewed to ensure adherence to ethical guidelines.

Publication Bias

Funnel plots and Egger's test revealed no significant publication bias for studies reporting on stress relaxation, fracture toughness, and tensile strength, indicating that the included studies were likely representative of the broader body of literature on clear aligner materials.

Results

Mechanical Properties of Clear Aligner Materials

1. Stress Relaxation

A significant reduction in stress relaxation was observed in clear aligner materials after aging in simulated oral conditions. PET-G exhibited the lowest stress relaxation rates, maintaining higher mechanical integrity compared to PU and polycarbonate, which showed more substantial decreases in stress after the same period ($p < 0.05$). The stress relaxation behaviour of aligners was influenced by both temperature and moisture, with higher levels of stress relaxation observed at elevated temperatures and prolonged exposure to artificial saliva [15,16,17].

2. Elastic Modulus and Tensile Strength

The elastic modulus, a measure of the material's stiffness, varied widely between the aligner materials. PU and PEEK demonstrated the highest elastic moduli, indicating greater stiffness and resistance to deformation. In contrast, PET-G and polycarbonate exhibited lower elastic moduli, suggesting greater flexibility.

The tensile strength of the materials also showed significant variation, with PU aligners exhibiting the highest tensile strength, followed by PEEK. These materials showed less deformation under load, making them preferable for precise tooth movement [18,19].

3. Fracture Toughness
The fracture toughness was assessed in four studies. PU and PEEK demonstrated superior fracture toughness compared to PET-G and polycarbonate. Materials with higher fracture toughness are less prone to breaking under stress, especially during more complex tooth movements like derotation and molar distalization. This finding is critical when selecting aligner materials for patients requiring significant orthodontic correction [20,21].

4. Hardness
Hardness was evaluated using both Vickers and Martens hardness tests across multiple studies. Polycarbonate exhibited the highest hardness, followed by PEEK. PET-G was generally softer, which could potentially result in faster wear and tear over time but may offer greater comfort to patients due to its flexibility. Higher hardness aligns with greater resistance to abrasion and wear, an important factor for aligner durability in long-term use [22,23,24].

5. Surface Roughness
Surface roughness was found to increase with prolonged use, especially in PET-G and PU aligners. The roughness increased after one to two weeks of simulated intraoral exposure, indicating that aligners made from softer materials may be more susceptible to surface damage from chewing and plaque accumulation. In contrast, polycarbonate and PEEK exhibited minimal increases in surface roughness, maintaining better surface quality over time [25,26].

Statistical Analysis

The meta-analysis revealed significant heterogeneity across studies. Subgroup analysis was performed to evaluate the effect of different aligner materials on mechanical properties. For stress relaxation, materials like PET-G showed statistically significant lower relaxation compared to PU and polycarbonate ($p < 0.05$). PEEK and PU exhibited consistently higher tensile strength and fracture toughness than PET-G and polycarbonate, with a significant difference in mechanical behaviour post-aging simulations ($I^2 = 75\%$, $p < 0.01$). The overall effect size for hardness indicated a higher performance in polycarbonate compared to other materials, with moderate heterogeneity observed across studies ($I^2 = 52\%$) [27].

Discussion

The mechanical properties of clear aligners are crucial in determining their efficacy and longevity in orthodontic treatments. This systematic review and meta-analysis aimed to comprehensively analyze the mechanical properties of various clear aligner materials, focusing on stress relaxation, elastic modulus, tensile strength, fracture toughness, hardness, and surface roughness. Our results underscore the significant variability in mechanical performance across different aligner materials, with implications for material selection and clinical outcomes [26,27].

Stress Relaxation and Material Durability

One of the most notable findings of this review is the stress relaxation behavior of different clear aligner materials. Materials such as PET-G exhibited lower stress relaxation rates compared to polyurethane (PU) and polycarbonate, suggesting that they maintain their mechanical properties better over prolonged use. This is consistent with findings by Tamburrino et al. (2020) [1], who reported that PET-G exhibited superior mechanical stability when subjected to aging simulations in artificial saliva. Stress relaxation is a critical factor in determining the long-term effectiveness of aligners, as a material with high stress relaxation may lose its ability to apply consistent force to the teeth, potentially affecting the treatment outcome [28].

In our study, PU and PEEK were found to demonstrate higher resistance to stress relaxation and deformation, which may make them better suited for cases requiring more substantial tooth movement. This aligns with previous studies that have shown that these materials provide better force transmission over extended periods due to their superior mechanical properties.

Elastic Modulus and Tensile Strength

The elastic modulus of a material determines its stiffness and its ability to resist deformation under stress. Our meta-analysis revealed that PU and PEEK aligners exhibited significantly higher elastic moduli compared to other materials such as PET-G and polycarbonate. This is consistent with findings by Yang et al. (2006) [8], who emphasized the importance of material stiffness in orthodontic aligners for maintaining precise tooth movement. Higher elastic modulus values in PU and PEEK also indicate that these materials may be more suitable for patients requiring large or complex movements, as they resist deformation and deliver more consistent forces during treatment [10].

Similarly, the tensile strength of aligners plays a crucial role in their ability to withstand the mechanical forces exerted during orthodontic treatment. PU demonstrated the highest tensile strength, confirming its durability and suitability for orthodontic applications. These results corroborate the findings of Fang et al. (2020) [2], who reported that Invisalign® material (a proprietary blend of PU) maintained superior tensile strength compared to other aligner materials [2,15].

Fracture Toughness and Wear Resistance

The fracture toughness of aligners was another key parameter evaluated in this review. Our findings showed that PU and PEEK exhibited superior fracture toughness compared to PET-G and polycarbonate, suggesting that these materials are less likely to fracture under stress. This is particularly important for patients undergoing significant tooth movements, such as derotation and molar distalization, where the aligner may be subject to higher mechanical loads. In contrast, PET-G, despite its widespread use, demonstrated lower fracture toughness, which may make it more susceptible to breaking under stress [18].

Furthermore, surface roughness was found to increase over time with prolonged exposure to intraoral conditions, particularly in PET-G and PU aligners. Papadopoulou et al. (2019) [3] observed similar findings in their study, where roughness increased after just one and two weeks of use, potentially affecting the aligner's aesthetic properties and comfort for the patient [3]. The increased roughness in softer materials like PET-G could lead to wear, plaque accumulation, and discomfort, which may reduce patient compliance.

Material Selection for Clinical Applications

The variability in mechanical properties observed across different materials has significant implications for the clinical management of clear aligner therapy. Based on the findings of this review, PEEK and PU appear to be the most durable and effective materials for complex tooth movements due to their superior stress relaxation resistance, high tensile strength, and fracture toughness. These materials are also more resilient to surface wear, maintaining their structural integrity throughout treatment. On the other hand, PET-G and polycarbonate may be more suitable for cases requiring less extensive tooth movement or for patients prioritizing comfort over durability. However, these materials may need to be replaced more frequently due to their susceptibility to stress relaxation and surface roughness.

Additionally, temperature and moisture exposure significantly impacted the mechanical performance of the aligners, as demonstrated in several studies, including Yang et al. (2006) [9], which found that moisture led to a marked decrease in the thermomechanical properties of certain polymers used in aligners [7]. This finding suggests that aligners should be carefully selected based on the specific needs of the patient and the environmental conditions they will be subjected to during treatment.

The findings of this systematic review and meta-analysis provide critical insights into the mechanical properties of clear aligners, highlighting the role of material composition, environmental exposure, and manufacturing techniques in determining their clinical performance. The observed variations in stress relaxation, elastic modulus, tensile strength, and fracture toughness across aligner materials underscore the importance of material selection based on individual treatment needs.

PET-G materials demonstrated lower stress relaxation and maintained higher mechanical stability over time, making them suitable for treatments requiring consistent force application. However, their lower fracture toughness and increased surface roughness with prolonged use could impact their durability and aesthetics, especially in complex cases. In contrast, materials like PU and PEEK showed superior mechanical resilience, with higher tensile strength, elastic modulus, and fracture toughness, making them ideal for cases involving significant tooth movements. Nevertheless, their higher stiffness might necessitate careful consideration of patient comfort and compliance.

Environmental factors, such as temperature fluctuations and moisture exposure, were shown to significantly influence aligner properties. Materials with higher resistance to these variables, such as PU and PEEK, retained their mechanical integrity better under simulated intraoral conditions. These findings reinforce the need for continued material innovation to address the dual challenges of maintaining force consistency while optimizing patient comfort.

The introduction of directly printed aligners presents a promising direction for the future, offering enhanced customization and production efficiency. However, their mechanical performance remains underexplored compared to conventional thermoformed aligners. Future research should focus on longitudinal clinical studies to validate their efficacy and durability under real-world conditions.

Limitations and Future Directions

Although this review provides valuable insights into the mechanical properties of clear aligners, there are several limitations to consider. Most of the included studies were in vitro, and while in vitro studies provide controlled conditions for assessing material properties, they may not fully replicate the complexities of the intraoral environment. Future research should focus on long-term clinical studies to assess the real-world performance of aligners over extended periods. Moreover, research into the biocompatibility of different aligner materials and their impact on oral health remains limited and should be prioritized in future studies.

Additionally, more studies exploring the interaction between aligner materials and oral fluids under varying temperature and pH conditions are needed. This will provide a better understanding of how these materials behave under the diverse conditions they encounter in the oral cavity, leading to more effective material selection and treatment planning.

Conclusion

This study provides a comprehensive evaluation of the mechanical properties of clear aligners, highlighting the interplay between material composition, manufacturing techniques, and intraoral environmental factors. Advanced materials like PU and PEEK offer superior mechanical stability, stress retention, and resistance to wear, making them suitable for complex orthodontic treatments. Conversely, PET-G and polycarbonate, while less durable, provide a balance of flexibility and comfort for cases with minimal movement requirements.

The findings emphasize the need for a tailored approach in material selection to achieve optimal treatment outcomes. Future innovations in material science, including the development of biocompatible, cost-effective polymers, and the refinement of 3D printing technologies, hold promise for advancing aligner therapy. Continued research into the interaction between aligner materials and oral environments will further enhance our understanding of their clinical performance, ensuring that clear aligners remain a reliable and effective orthodontic solution for diverse patient needs.

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