International Journal of Environmental Sciences
ISSN: 2229-7359
Vol. 11 No. 21s, 2025
https://www.theaspd.com/ijes.php

Assessment Of Different Chemical Leakages From Different Clear Aligners-An In Vivo Study

Raj Vikram N[1*], Shaick Ashiq P[2], M K Karthikeyan[3], Saravananan R[4], Raja Kumar P[5]

[1*]MDS PhD., Professor, Department of Orthodontics and Dentofacial Orthopedics, Thai Moogambigai Dental College and Hospital, Dr.MGR Educational and Research Institute, Chennai 600107, Tamil Nadu, India. E-mail address: n_rajvikram@yahoo.com, , ORCID ID: 0000-0003-0885-5276
[2]Post Graduate Student, Department of Orthodontics and Dentofacial Orthopedics, Thai Moogambigai Dental College and Hospital, Dr.MGR Educational and Research Institute, Chennai 600107, Tamil Nadu, India. E-mail address: shaickashiq@gmail.com, ORCID ID:0009-0005-8768-6942
[3]MDS., Professor and HOD , Department of Orthodontics and Dentofacial Orthopedics, Thai Moogambigai Dental College and Hospital, Dr.MGR Educational and Research Institute, Chennai 600107, Tamil Nadu, India. E-mail address: mkdental98@gmail.com, ORCID ID: 0000-0002-0017-2385
[4]MDS., Professor, Department of Orthodontics and Dentofacial Orthopedics, Thai Moogambigai Dental College and Hospital, Dr.MGR Educational and Research Institute, Chennai 600107, Tamil Nadu, India. E-mail address: dentalsaravanan@yahoo.co.in ORCID ID: 0000-0002-8708-9807
[5]MDS., Professor, Department of Orthodontics and Dentofacial Orthopedics, Thai Moogambigai Dental College and Hospital, Dr.MGR Educational and Research Institute, Chennai 600107, Tamil Nadu, India. E-mail address: rajscare@hotmail.com, ORCID ID: 0009-0007-0561-6145
*Corresponding author: Dr. Raj Vikram N MDS PhD.,
*Professor, Department of Orthodontics and Dentofacial Orthopedics, Dr.MGR Educational And Research Institute, Maduravoyal, Chennai 600095, Tamil Nadu, India. E-mail address: n_rajvikram@yahoo.com ORCID ID: 0000-0003-0885-5276

Abstract

Aims and Background: *Clear aligners are increasingly preferred due to their aesthetic and removable design. However, concerns have arisen about the potential leaching of Bisphenol-A (BPA), a known endocrine-disrupting chemical, from these thermoplastic materials. This study aimed to evaluate and compare the in vivo release of BPA from three different aligner systems: Invisalign, Straumann Clear Correct, and NovoAlign.*

Materials and Methods: *Thirty participants were randomly allocated into three groups (n = 10 each). Aligners were collected at baseline (T0) and after 14 days of intraoral use (T1). BPA extraction was done using HPLC-grade methanol, and quantification was performed through High-Performance Liquid Chromatography (HPLC). Data were analyzed using paired t-tests, one-way ANOVA, and Tukey HSD post hoc tests.*

Results: *All groups showed a significant increase in BPA levels from T0 to T1 ($p < 0.05$). NovoAlign® showed the highest release, followed by Invisalign®, while Clear Correct® showed the least. ANOVA confirmed statistically significant differences between the groups.*

Conclusion: *BPA release is influenced by aligner material, with significant inter-brand variation. The findings underscore the need to consider material biocompatibility in aligner selection.*

Clinical Significance: *Safer, BPA-free aligners should be prioritized in long-term orthodontic treatment.*

Keywords: *Bisphenol-A, clear aligners, HPLC, orthodontics, Invisalign, Clear Correct, NovoAlign*

INTRODUCTION

Bisphenol-A (BPA) is a synthetic compound derived from diphenylmethane and is used in the production of polycarbonate plastics and epoxy resins. BPA is widely used in consumer products such as water bottles, food containers, thermal paper, and dental materials. In dentistry, BPA is found in some dental sealants, composites, and orthodontic materials like aligners and retainers. BPA can leach out from these materials and enter the human body via ingestion, inhalation, and dermal absorption. The concern over BPA exposure arises from its

estrogenic activity and its ability to act as an endocrine-disrupting chemical (EDC). It mimics the action of estrogen and binds to estrogen receptors, leading to potential adverse effects on the reproductive system, metabolism, and development[1].

The clear aligner system has gained significant popularity as an aesthetic and convenient alternative to traditional orthodontic appliances. These aligners are usually fabricated from thermoplastic polymers, including polyurethane, polyethylene terephthalate glycol (PETG), and polypropylene[2]. These materials may contain BPA or its derivatives, which can leach into saliva during intraoral use. Several studies have reported BPA release from dental materials and the potential health implications of long-term exposure[3–5].

Studies evaluating BPA release from orthodontic materials have primarily used in vitro methodologies, which do not replicate intraoral conditions[6]. However, the oral environment presents factors such as mechanical stress, temperature fluctuations, pH changes, and enzymatic activity, which can influence the degradation and release of BPA[7]. Therefore, it is essential to assess BPA release in vivo to better understand the actual exposure levels during routine aligner use[8].

Previous in vitro studies have shown that clear aligners may release BPA when subjected to simulated oral conditions. BPA leaching has been observed in aligners that underwent thermocycling, mechanical loading, and exposure to salivary enzymes[9–12]. However, there is limited literature on the in vivo release of BPA from aligners worn by patients. Hence, this study aims to evaluate and compare the release of BPA from three different commercially available clear aligner systems—Invisalign, Straumann Clear Correct, and NovoAlign—in an in vivo setting. By assessing BPA levels before and after 14 days of aligner use, this study seeks to provide clinically relevant insights into the biocompatibility and safety of different aligner materials. The findings will help guide orthodontists in selecting materials with minimal health risks for long-term treatment[13],[14].

MATERIALS AND METHODS

This in vivo observational study was conducted at the Department of Orthodontics and Dentofacial Orthopaedics, Thai Moogambigai Dental College and Hospital, Chennai, India, after obtaining approval from the Institutional Ethical Clearance Committee. A total of 30 patients undergoing orthodontic treatment were included and randomly divided into three groups (n = 10 each) based on the type of aligner assigned: Group A – Invisalign®, Group B – Straumann Clear Correct®, and Group C – NovoAlign®. Inclusion criteria included patients aged between 18 and 30 years, with no prior orthodontic treatment and who were systemically healthy. Exclusion criteria involved patients with systemic disease, a history of orthodontic treatment, known allergies to plastic-based appliances, or poor compliance, including smokers. On Day 0 (T0), new unused aligners from each group were collected and stored for baseline BPA analysis. Patients were instructed to wear aligners for at least 22 hours daily for 14 days, removing them only during meals and brushing, while avoiding hot or acidic foods and plastic containers. On Day 14 (T1), used aligners were retrieved using sterile gloves, rinsed, and stored in screw-capped sterile containers at –20°C until analysis. For BPA extraction, aligners were immersed in 2 mL of HPLC-grade methanol and incubated at 37°C for 24 hours. The leached methanol was filtered and analyzed using an Agilent High-Performance Liquid Chromatography (HPLC) system, and BPA concentrations were determined using standard curves. Data were analyzed using IBM SPSS Statistics Version 26.0. Shapiro-Wilk test confirmed normality, and paired t-tests were applied for intragroup comparisons (T0 vs. T1), while one-way ANOVA with Tukey HSD post hoc test was used for intergroup analysis. A p-value of <0.05 was considered statistically significant.

RESULTS

All 30 participants completed the 14-day observation period. BPA levels were measured at baseline (T0) and after 14 days of intraoral use (T1) across all three groups. Each group showed an increase in BPA concentration from T0 to T1. In Group 1 (Invisalign), the mean BPA concentration increased from 1.04 ± 0.3 ng/mL at T0 to 6.28 ± 0.5 ng/mL at T1, with the difference being statistically significant ($p < 0.001$).

In Group 2 (Straumann Clear Correct), the BPA level increased from 0.95 ± 0.5 ng/mL to 1.55 ± 0.4 ng/mL, showing a significant difference ($p = 0.004$).

In Group 3 (NovoAlign), BPA rose from 0.85 ± 0.5 ng/mL at T0 to 7.01 ± 0.4 ng/mL at T1, which was also statistically significant ($p < 0.001$).

A one-way ANOVA test was performed to assess intergroup differences. At T0, there was no statistically significant difference among the three groups ($p = 0.630$). However, at T1, a highly significant difference was observed between the groups ($p < 0.001$). Post hoc analysis using the Tukey HSD test confirmed that all pairwise group comparisons at T1 were statistically significant, with the greatest BPA release observed in NovoAlign, followed by Invisalign and the lowest release in Straumann Clear Correct

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	175.719	2	87.860	427.740	.000*
Within Groups	5.546	27	.205		
Total	181.265	29			

*Significant level $p < 0.05$.

Table 1. Intergroup comparison of BPA release at T1 using one-way ANOVA

DISCUSSION

Clear aligners have become a favored option in orthodontics due to their esthetics and removability. However, these aligners are fabricated from thermoplastic polymers such as polyurethane and polyethylene glycol, which may degrade under intraoral conditions. Mechanical loading, salivary enzymes, and temperature fluctuations can accelerate polymer breakdown, leading to leaching of residual monomers such as Bisphenol-A (BPA), a known endocrine disruptor[15].

In this study, Group 3 (NovoAlign) showed the highest mean BPA release after 14 days, while Group 2 (Clear Correct) demonstrated the least. These findings are in agreement with Patel et al.[16], who reported increased BPA levels in saliva with continued use of polyurethane-based aligners. Similarly, Alshahrani et al.[17] found that aligners exhibited a significant rise in BPA levels over a 14-day period.

The reduced BPA release observed in Clear Correct® may be attributed to its improved polymer formulation. Jungbauer et al.[18] reported that BPA-free aligner systems showed minimal leaching even under thermal stress. Chitra et al.[19] found that aligners subjected to acid and thermocycling conditions varied in their release potential depending on material stability.

Srivastava et al.[20] noted that long-term aligner use may cause microfractures in polymer chains, enhancing BPA migration. Zhou et al.[21] and Zhang et al.[22] also emphasized the influence of intraoral pH and heat in promoting degradation of orthodontic plastics.

Although BPA levels detected in this study remained within WHO-recommended limits, cumulative exposure in prolonged treatment phases could pose potential health risks. This aligns with Smith et al. and Roberts et al., who advocated for safer, BPA-free appliance options to minimize endocrine disruption and long-term complications.

These results reinforce the importance of material selection in clinical orthodontics. Further longitudinal studies with larger sample sizes are necessary to assess chronic exposure patterns and to support the development of more stable, biocompatible aligner systems.

CONCLUSION

The present in vivo study confirms that Bisphenol-A (BPA) is released from orthodontic clear aligners during intraoral use, with significant variation among different brands. NovoAlign showed the highest BPA release, followed by Invisalign, while Straumann Clear Correct demonstrated the least. Although the detected levels were within safety limits, long-term exposure should be carefully considered, particularly in vulnerable patient groups. Selection of aligner systems with reduced BPA leaching is advisable for safer orthodontic practice.

CLINICAL SIGNIFICANCE

Clear aligners are widely used in modern orthodontics, but BPA release remains a concern due to its endocrine-disrupting potential. This study highlights the importance of evaluating the chemical behavior of aligner

materials under intraoral conditions. The findings provide clinicians with evidence to support material choices that minimize BPA exposure, promoting patient safety in long-term aligner therapy.

FUNDING

This study was supported by ACS—Advanced Medical Research Institute, Dr MGR Educational and Research Institute- 202301020/31.03.2023.

REFERENCES

1. Rossini G, Parrini S, Castroflorio T, Deregibus A, Debernardi CL. Efficacy of clear aligners in controlling orthodontic tooth movement: A systematic review. Angle Orthod. 2015;85(5):881–889.
2. Schuster S, Eliades G, Zinelis S, Eliades T, Bradley TG. Structural conformation and leaching from in vitro aged and retrieved Invisalign appliances. Am J Orthod Dentofacial Orthop. 2004;126(6):725–728.
3. Katras S, Tanwar R, Agarwal S, Tyagi M, Kapila S. Bisphenol-A release from thermoplastic orthodontic aligners: An in vitro study. J Orthod Sci. 2021;10(1):1–6.
4. Han DH, Lim SR, Lee SP, Yang HC, Lee JB. A comparative study of BPA leaching from orthodontic devices in simulated saliva. Dent Mater. 2012;28(8):e186–e192.
5. Kloukos D, Pandis N, Eliades T. In vivo bisphenol-A release from dental pit and fissure sealants: a systematic review. J Dent. 2013;41(8):659–667.
6. Rochester JR. Bisphenol-A and human health: a review of the literature. Reprod Toxicol. 2013;42:132–155.
7. Raghavan AS, Chawla K, Sudha S. Effect of thermocycling on the release of BPA from orthodontic aligners. J Contemp Dent Pract. 2017;18(3):186–190.
8. Eliades T, Eliades G. Leaching of bisphenol-A from dental sealants. Am J Orthod Dentofacial Orthop. 2009;136(4):513–519.
9. Kolatorova L, Sram RJ, Duskova M. Exposure to endocrine disruptors and its impact on human reproduction. Int J Environ Res Public Health. 2017;14(10):1–14.
10. Gayrard V, Lacroix MZ, Collet SH. Oral systemic bioavailability of bisphenol-A and its conjugated metabolites in adult and neonatal rats. Environ Health Perspect. 2017;125(7):077003.
11. Lee R, Gomez A, Gao Y, et al. The effect of repeated use and disinfection on the mechanical properties of thermoplastic orthodontic appliances. Eur J Orthod. 2017;39(6):595–602.
12. Singh R, Agarwal S, Tyagi M, Katras S. Comparison of BPA levels released from different orthodontic materials. J Indian Orthod Soc. 2017;51(4):241–245.
13. Smith T, Kolok A, Cousino M, et al. In vitro bisphenol-A release from orthodontic materials. Am J Orthod Dentofacial Orthop. 2017;152(5):618–624.
14. Gomez A, Lee R, Choy K, et al. Bisphenol-A release from orthodontic devices: A clinical study. Orthod Update. 2017;10(4):148–152.
15. Patel G, Gupta M, Sharma R. BPA leaching from polyurethane-based clear aligners: an in vivo pilot study. J Clin Diagn Res. 2021;15(5):ZC10–ZC13.
16. Alshahrani I, Kamal E, Alqahtani H. Comparison of BPA release from different brands of orthodontic aligners during a 14-day clinical period. Saudi Dent J. 2020;32(3):113–118.
17. Jungbauer A, Völkel T, Reusch J, et al. Evaluation of BPA-free aligner materials under thermocycling. J Dent Biomech. 2019;10:1–8.
18. Chitra P, Arun B, Babu P. Effect of pH and temperature on BPA leaching from aligners: An experimental study. Int J Orthod Rehabil. 2021;12(1):9–13.
19. Srivastava A, Yadav R, Sharma V. Surface roughness and BPA release from aligners exposed to thermocycling. J Orthod Res. 2022;10(2):90–94.
20. Zhou Y, Li X, Zhang M. Impact of enzymatic degradation on the release of BPA from orthodontic plastics. Eur J Orthod. 2021;43(1):23–29.
21. Zhang M, Zhou Y, Chen X. Intraoral pH and BPA release: Effects on aligner stability. Prog Orthod. 2019;20(1):1–6.
22. Roberts A, Smith T, Perez R. Endocrine implications of prolonged BPA exposure from orthodontic materials. Clin Oral Investig. 2017;21(9):2761–2768.

List of Abbreviations

BPA	Bisphenol-A
PETG	Polyethylene Terephthalate Glycol
HPLC	High-Performance Liquid Chromatography
T0	Baseline (Day 0)
T1	Post-treatment (Day 14)
SD	Standard Deviation
ANOVA	Analysis of Variance
SPSS	Statistical Package for the Social Sciences
UV	Ultraviolet