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Chemical leaching and microplastics from clear aligner materials: Current evidence and future perspectives

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Abstract
Clear aligners have revolutionized orthodontic therapy by providing a more aesthetic and comfortable alternative to fixed appliances. However, increasing concerns have emerged regarding their biocompatibility and potential health risks associated with chemical leaching and microplastic release. This review explores the composition, degradation behavior, and biological implications of commonly used thermoplastic materials such as polyethylene terephthalate glycol (PETG), polyurethane, and polycarbonate. Evidence from *in vitro* and systematic reviews indicates that while most aligners comply with international safety standards, variable levels of bisphenol A (BPA), urethane dimethacrylate (UDMA), and other additives can leach into the oral environment, particularly during initial wear periods. The release of these compounds and microplastic particles poses possible cytotoxic, estrogenic, and systemic risks, including endocrine disruption and microbiome alterations. Despite advancements in manufacturing, data from human studies remain limited, and the long-term biological impact of chronic exposure remains unclear. Future research should prioritize standardized testing protocols, robust clinical trials, and the development of safer, sustainable biomaterials for aligner fabrication.

Keywords: Clear aligners, chemical leaching, microplastics, bisphenol A

1. Introduction
In recent years, clear aligners have rapidly emerged as a highly preferred treatment modality among orthodontic patients, transforming the landscape of orthodontic care. Unlike traditional fixed mechanotherapy, clear aligners offer a more discreet and comfortable alternative that aligns with the growing demand for aesthetic and lifestyle-friendly options. The increasing popularity of aligners can be attributed to several factors, especially the social and psychological considerations of patients - particularly adults and young professionals. A survey conducted by Vásquez *et al* in 2021 [1] evaluated the reasons influencing the preferences of prospective patients for a certain type of orthodontic appliance over another and concluded that the convenience of reduced chairside time, improved quality of life, and fewer emergency visits compared to conventional appliances, in addition to being an esthetic alternative, have strengthened the appeal of clear aligners.
In another cross-sectional survey conducted by Alansari *et al* in 2019 [2], among the 199 adults who participated, the adults' perspective reflected that more innovative and discreet treatment modalities, such as clear aligners (86.9%) and lingual brackets (84.9%), were a preferred method, and a second survey conducted among 194 youth participants in 2020 [3] concluded that same.
With the growing adoption of clear aligners, attention has increasingly shifted to their potential drawbacks. While they offer undeniable advantages in terms of aesthetics and convenience, their widespread use has also brought concerns regarding material degradation, chemical leaching, and the release of microplastics. These byproducts may pose risks not only to oral health but also to systemic health, underscoring the need for critical evaluation of their long-term safety.

Composition of clear aligners

Originally developed for the management of simple cases, the perpetual progress in material science and technology has broadened its spectrum of patients to include individuals of all age groups and to include more and more complex cases. These appliances are primarily fabricated from thermoplastic polymers such as polyethylene terephthalate glycol (PETG), polyurethane, and other modified plastics [4].

The material composition used in clear aligner fabrication plays a key role in determining their clinical performance. This composition is further shaped by the manufacturing technique, which generally falls into two main categories: the traditional vacuum thermoforming of thermoplastic sheets over physical models, and the more recent approach of direct 3D printing that eliminates the need for intermediary models. Currently, thermoforming remains the most widely used method in both commercial production and in-house aligner manufacturing.

These plastics are susceptible to environmental and mechanical influences that can break them down into smaller fragments, also called microplastics. Microplastics are broadly classified into two categories: Primary microplastics- those that are deliberately incorporated into certain products, such as toothpaste, face washes, cosmetics, and industrial abrasives, and secondary microplastics- those that are generated through the physical, chemical, or biological breakdown of larger plastic materials during use or after being released into the environment. Over the past decade, they have been recognized as emerging pollutants, drawing significant scientific interest due to their widespread occurrence and potential toxic effects. Microplastics that could be released from aligners started raising significant concerns regarding potential health implications, emphasizing the critical importance of comprehending and addressing this issue within the realm of orthodontic care. Studies indicate that these minuscule plastic particles can lead to adverse health effects upon ingestion or inhalation, potentially causing systemic inflammation and health risks.

Hence, the dynamic nature of the oral cavity necessitates a few prerequisites for an aligner material, as discussed below, to curb its aging/degradation:

Aligners are frequently exposed to saliva and its various enzymes and occasionally to changes in temperatures and environment due to the consumption of food and beverages. This may influence the mechanical and chemical properties of it. Certain polyesters such as polycarbonates and polyamides may exhibit irreversible hydrolysis that may lead to the eventual degradation of their polymer structure, followed by proteinaceous biofilm apposition in areas of salivary stagnation, leading to calcification, which in turn affects the reactivity and mechanical properties of aligners or leaching of residual monomers, additives, and other chemical byproducts [5]The release of such substances into the oral cavity raises important concerns regarding patient safety, as they may have cytotoxic or inflammatory effects, even at low concentrations; hence, the polymers used for their fabrication should be resistant to such phenomena.

Aligners are also subjected to intermittent forces associated with normal functions such as speech and mastication and parafunctional activities. Hence, the material used should be durable and wear-resistant so that clinical performance is not compromised [4]. In addition to this, Bisphenol A (BPA), a commonly utilized synthetic organic compound known for its ability to disrupt endocrine function due to its estrogen-mimicking properties, may also be present in aligner materials. It is a key component in manufacturing polycarbonate plastics and epoxy resins, which are used in producing food storage containers, children's toys, and other dental materials [6, 7]. The main route of BPA exposure in humans is believed to be through consuming food contaminated with BPA that has leached from containers and dental materials.

Oral and Systemic Implications of Clear Aligner Materials

While clear aligners are generally considered biocompatible and less detrimental to periodontal health compared to fixed appliances, their design and material composition can influence oral and systemic health.

Favero *et al*. [8] found that aligners with a vestibular rim (extending beyond the gingiva) are less likely to cause periodontal inflammation compared to juxta-gingival designs, which may promote plaque accumulation and mechanical irritation. Lo *et al*. [9] showed that most aligner materials (PETG, TPU, PET) maintain adequate cell viability (>70%) *in vitro*, though thermoformed PETG may exhibit increased cytotoxicity over time. Additionally, Feng *et al*. [10] highlighted broader environmental health concerns, noting that micro and nano-plastics—which may originate from degraded plastic products, including aligners—can accumulate in human tissues and potentially disrupt multiple organ systems (Fig 1), though direct clinical evidence in humans remains limited.

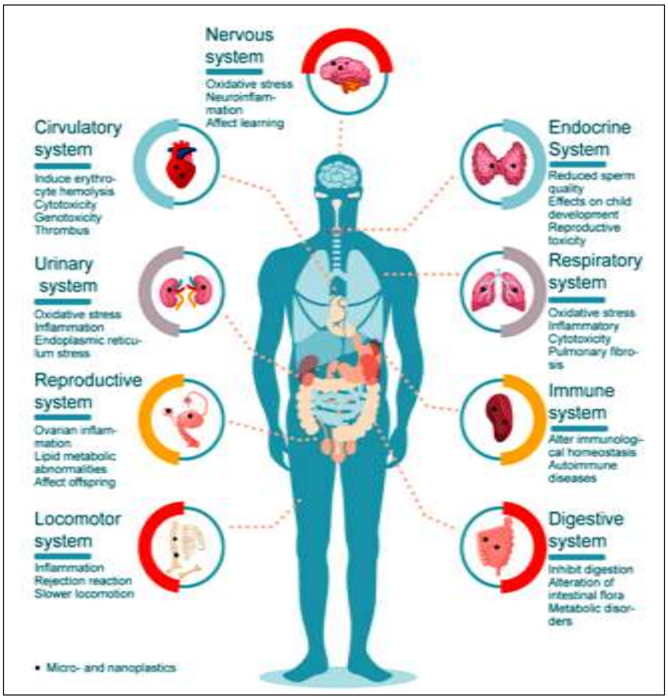

Fig 1: Potential health risks of micro- and nano-plastics to nine human organ systems.

Health Implications

The problems caused by the use of clear aligners can be broadly divided into two categories. First is the accumulation of non-biodegradable plastic appliances, which may indirectly enter the human body, while the second and more serious is the direct ingestion of microplastics. The degradation of aligners in the oral cavity can potentially cause a range of side effects, from mild irritation to more severe systemic health concerns. Although the composition of clear aligner material has seen significant improvements in recent years, concerns remain about the potential for leaching other bisphenol A derivatives or additives under certain environmental conditions.

Fackelmann & Sommer [11] and Fournier *et al*. [12] highlight that plastic-derived micro- and nano-plastics, and chemicals such as those potentially leached from aligner materials, can disrupt gut microbiota and intestinal homeostasis. Fackelmann & Sommer describe how ingested plastics act as physical stressors and chemical carriers, altering microbial diversity and metabolic function, leading to dysbiosis that affects host immunity and nutrient processing. Similarly, Fournier *et al*. emphasize that microplastics serve as vectors for pollutants, antibiotics, and pathogens, which may impair the gut barrier, disturb microbial communities, and promote antimicrobial resistance.

BPA is recognized as an endocrine disruptor; it has been shown to bind to estrogen receptors and exhibit estrogen-like effects in laboratory experiments. Additionally, BPA can function as an anti-estrogen by competing with natural 17β estradiol, thereby inhibiting the estrogenic response. It can also directly attach to androgen receptors and may act as an anti-androgen, obstructing natural androgen activity [13]. BPA interacts with thyroid receptors, exerting both stimulating and inhibiting effects on thyroid function. Beyond disrupting hormonal actions, BPA is associated with an increased risk of cancer, diabetes, heart disease, and hyperactivity in children [14]. It can also lead to infertility in both males and females [15, 16].

Research has indicated that BPA reduces sperm count in workers at facilities where BPA is used. It can trigger early puberty, encourage the growth of hormone-dependent tumors, affect metabolic disorders like polycystic ovarian syndrome, disrupt blood sugar control, and increase insulin resistance in individuals with type 2 diabetes [17, 18]. The Environmental Protection Agency initially set a safety standard for BPA at 50 µg/kg BW/day in 1988, which the Food and Drug Administration adopted as a reference dose. This level remained unchanged until 2015, when the tolerable daily intake of BPA was lowered to 4 µg/kg BW/day. Evidence suggests that BPA may exhibit non-monotonic dose-responses, meaning that even low doses (in the nanomolar range) could have harmful effects, despite being considered safe. Furthermore, the activity level falls within a range that is below the detection limit of most analytical methods.

Evidence from in-vitro studies

In 2021, an in-vitro study by Katras *et al* [19] concluded that even though it was below adult toxic levels, clear aligners released BPA, especially in the first 24 hours. In 2023, a spectroscopic study conducted by Quinzi *et al* [20] on orthodontic aligners, highlighted for the first time, the detachment of microplastics from commercial clear aligners due to mechanical friction. In all groups, most of these particles were greater than or equal to 20 µm and could likely be excreted from the gastrointestinal tract. Regarding cell metabolic activity, Martina *et al*. [21] reported a slight cytotoxic activity of aligners' material eluates on human gingival fibroblasts, whereas Eliades *et al*. [22] found no evidence of cytotoxicity on human gingival fibroblasts with Invisalign precursor material.

Other studies, such as the one by Aseel *et al*. [23] examined aligner eluates for their toxic and estrogenic effects on human gingival fibroblasts and breast cancer cell lines. Their findings indicated that while most tested aligner materials released detectable levels of substances, the cytotoxicity was generally low. However, some materials demonstrated mild estrogenic activity. Ozkan *et al*. [24] assessed six commercial aligner brands using the MTT assay on human gingival fibroblasts. Results showed material-dependent differences in cytotoxicity. The study concluded that although most aligners were within ISO safety standards, Zendura and Duran should be used with caution due to higher variability and potential cytotoxic effects. A study by Willi *et al* [25], quantitatively assessed the degree of conversion and the water-leaching targeted compound from 3-D printed aligners and concluded that although efficiently polymerized and BPA-free, the great variability in the amount of UDMA monomer leached from the examined samples may raise concerns about potential health hazards after repeated intraoral exposure, which is indicated for this class of materials.

Evidence from systematic reviews

Across multiple systematic reviews, evidence remains mixed regarding the extent of chemical leaching, cytotoxicity, and estrogenic effects of aligner polymers. Evidence by Iliadi *et al*. [26] highlighted inconsistencies between *in vitro* and clinical data, showing no estrogenic or cytotoxic effects in laboratory studies, yet reporting increased bisphenol-A (BPA) levels in saliva in a clinical trial. The overall certainty of evidence was low to medium, underscoring the need for further clinical validation. Similarly, Yazdi *et al*. [27] found that while *in vitro* studies generally showed negligible or very low BPA release, the single clinical trial reported high salivary BPA concentrations. Adverse effects such as soft-tissue irritation, mucosal lesions, and systemic complaints were also documented, making the overall safety profile uncertain.

Expanding the scope, Francisco *et al*. [28] reviewed 3D-printed orthodontic resins and concluded that current data are insufficient to confirm cytotoxicity or systemic toxicity, though potential risks such as estrogenicity and reproductive toxicity were reported in some experimental settings. The authors stressed the lack of robust human studies and highlighted the implications for young patients, who represent a large proportion of aligner users. Lorusso *et al*. [29] specifically addressed printed aligners and found that cytotoxicity was highly dependent on resin type and post-curing protocols. While some studies reported no cytotoxic effects, others indicated mild toxicity, emphasizing the importance of standardized manufacturing protocols and the need for clinical studies.

Material-based comparisons by Ravuri *et al*. [30] suggested that commonly used thermoplastics such as PET-G, polypropylene, polycarbonate, thermoplastic polyurethane, and EVA are generally biocompatible, with PET-G and EVA showing the least tissue irritation. However, long-term data remain scarce. More recently, Ferreira *et al*. [31] concluded that clear aligners are overall safe, though some materials exhibited moderate cytotoxicity and concerns about chemical leaching persist. Reported side effects were generally mild (mucosal irritation, inflammation, hypersensitivity), but the potential for chronic exposure effects requires further study.

Emerging trends and future considerations

Current research on the health impacts of micro- and nanoplastics on humans remains in its infancy, with major knowledge gaps persisting in quantifying its concentrations in food, estimating human exposure levels, understanding their absorption and translocation within the body, and elucidating their mechanisms of toxicity. To address these challenges, future research must prioritize the standardization of detection methods and the establishment of quality control systems to enable reliable exposure assessments. There is also a critical need to develop advanced *in vitro* models and innovative imaging techniques to better study its accumulation and transfer. Furthermore, dose-response studies using standardized models and long-term epidemiological research are essential to evaluate the toxicity and chronic health effects, particularly in vulnerable populations. Ultimately, tackling the complex issue of microplastics demands interdisciplinary collaboration and technological innovation within a One Health framework.

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Not available

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