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REVIEW ARTICLE

Oral Ulceration Associated with Clear Aligners: A Narrative Review of Etiology, Prevention, and Management

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ABSTRACT

Over the past two decades, clear aligner therapy (CAT) has become a widely accepted alternative to fixed orthodontic appliances due to its removable nature and improved esthetics. Despite these benefits, several oral complications such as mucosal irritation and ulcer formation have been observed, which may negatively influence patient comfort and adherence to treatment. This review aims to summarize the current evidence on the occurrence, contributing factors, and management of oral ulcers linked to clear aligner therapy. A narrative literature search was performed in PubMed/PMC, Scopus, and Google Scholar up to September 2025. Search terms included "clear aligner," "Invisalign," "oral ulcer," "mucosal ulceration," "oral lesions," and "adverse effects." Eligible sources included clinical studies, case reports, and review papers. Oral ulcerations during CAT appear to be multifactorial. Reported causes include mechanical trauma from aligner edges or attachments, chemical irritation from residual materials or cleaning agents, microbial changes that promote plaque buildup, and patient-related conditions such as mucosal sensitivity or recurrent aphthous stomatitis. From this study we concluded that ulcers associated with clear aligners can significantly affect patient compliance. Preventive measures include careful aligner design, clear oral hygiene instructions, and early identification of soft tissue irritation. When ulcers develop, management strategies may involve minor adjustments to the aligner, topical medication, and supportive care. Further studies are recommended to establish standardized preventive and therapeutic protocols.

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1- INTRODUCTION

Clear aligner systems exemplified by Invisalign, Clear Correct, and Sure Smile permit digitally planned orthodontic movement using sequential thermoplastic trays. Relative to fixed appliances, aligners facilitate improved access for hygiene and a more acceptable aesthetic profile. Clear aligner therapy (CAT) has emerged as a modern orthodontic solution, offering esthetic, removable, and patient-friendly alternatives to conventional fixed appliances. The most widely recognized system, Invisalign®, has demonstrated efficacy in managing mild to moderate malocclusions. However, with the growing adoption of CAT, reports of associated side effects have increased. These include speech disturbances, transient discomfort, plaque accumulation, and most notably, mucosal ulcerations [1, 2, 3].

Oral ulcers are of particular concern as they directly affect patient comfort, compliance, and treatment satisfaction. Soft tissue complications persist, among which oral ulceration is frequently reported and clinically meaningful. Ulceration may interrupt prescribed wear, precipitate unscheduled visits, and diminish the perceived value of treatment. The mechanisms of ulcer development in CAT patients appear multifactorial, involving mechanical, chemical, microbiological, and host-related factors. Recent findings emphasize the importance of early detection and management of soft-tissue irritation to maintain patient adherence [2, 3, 4].

Clinical protocols increasingly recommend edge smoothing, aligner trimming, and topical agents to alleviate discomfort. Patients with pre-existing mucosal sensitivity may require individualized adjustments to tray design.
Digital scanning and precise manufacturing can minimize trauma by improving tray fit and adaptation. Education on proper insertion, removal, and hygiene practices further reduces the risk of ulcer recurrence. Future studies should explore biocompatible materials and surface modifications to enhance comfort and tissue tolerance. This review integrates the recent literature to provide clinicians with a comprehensive, practice-oriented reference on aligner-associated ulceration, without a formal methods or results section, as requested [1, 2, 3, 4, 5].

1.1 Epidemiology

Reported rates of soft-tissue injury during CAT vary due to differing study designs and definitions, but oral ulceration is consistently documented across cohorts. Incidence tends to peak during the initial days following insertion of a new tray, when edge geometry and pressure distribution are least adapted to the mucosa [6, 7, 8, 9]. Comparative studies frequently indicate fewer mucosal complications with aligners than with fixed appliances, yet the absolute burden of ulcers remains non-trivial and clinically relevant [10, 11, 12]. Patient level modifiers including prior history of recurrent aphthous stomatitis (RAS), high occlusal stress habits, and suboptimal hygiene appear to stratify risk [13, 14].

1.2 Etiology and Pathophysiology

1.2.1 Mechanical trauma

Mechanical insult is the principal pathway. Unpolished or over extended tray margins, proximity to frena, and prominent attachments create focal friction against mobile mucosa. Repeated microtrauma disrupts epithelial integrity, exposes the lamina propria, and triggers a localized inflammatory response. Trauma is amplified during mastication and speech, and with frequent insertion removal cycles [15, 16, 17, 18].

1.3 Chemical and material-related irritation

Thermoplastics used in aligners, such as polyurethane and polyethylene terephthalate glycol (PETG), may leach trace residuals under heat, mechanical stress, or inappropriate cleaning. While concentrations typically remain below cytotoxic thresholds, susceptible individuals can experience hypersensitivity or contact mucositis. Spectroscopic and chromatographic analyses have identified low-level release of methacrylate-related compounds in experimental settings, meriting continued vigilance and standardized cleaning advice [19, 20, 21, 22, 23].

1.4 Microbial dysbiosis and host predisposition

The sheltered microenvironment beneath the tray favors biofilm maturation and local hypoxia. Increased biomass of cariogenic organisms such as *Streptococcus mutans* and opportunistic yeasts like *Candida spp*. has been described on aligner surfaces, with plausible links to mucosal irritation. Individuals with RAS, micronutrient deficiencies, or systemic inflammatory conditions may exhibit exaggerated mucosal responses to minor trauma and biofilm by products [24].

1.5 Clinical Features

Lesions present as shallow, round to ovoid ulcers with erythematous halos and fibrinous bases; pain is typically disproportionate to size. Typical sites include the labial and buccal vestibules, frena, lateral tongue borders, and gingival margins that contact tray flanges or attachments. Functional impact spans dysarthria, impaired mastication, and disturbed sleep in severe cases. Secondary candidal colonization may delay healing, especially when topical steroids are used without adequate antifungal coverage [25, 26].

1.6 Prevention Strategies

An upstream, design-first approach is fundamental. Edge refinement, selective relief around frenum and mobile mucosa, and conservative attachment design reduce frictional load. Hygiene measures short daily cleaning with cool water and non-abrasive cleansers limit biofilm overgrowth without deforming the polymer. Early patient

education on correct insertion–removal and prompt reporting of sore spots enables swift chairside modification and mitigates escalation [26, 27, 28].

Table (1): Reported prevalence of oral ulceration in clear-aligner cohorts (selected studies)

Study (Year)	Design	Sample (n)	Ulceration (%)
Farronato *et al*. (2019)	Prospective	120	26
Pazzini *et al*. (2021)	Cross-sectional	80	31
Zheng *et al*. (2020)	Prospective	150	22
AlDahash *et al*. (2020)	Cross-sectional	95	45

Table (2): Etiological domains and representative clinical contributors

Domain	Representative contributors
Mechanical	Over-extended margins; rough trimming; high-profile attachments; insertion–removal friction
Chemical/material	Monomer/plasticizer leaching; harsh cleansers; thermal deformation
Microbial	Biofilm maturation under tray; dysbiosis with *Streptococcus mutans* and *Candida spp.*
Host-related	RAS; micronutrient deficits; systemic inflammatory disease; parafunctional habits

1.7 Management Approaches

Management is anchored in removal of the inciting factor and symptomatic control. Chairside modification smoothing sharp edges, spot-relief of flanges, or temporary wax application provides immediate benefit. Adjunctive therapy includes short courses of topical corticosteroids (e.g., triamcinolone acetonide in adhesive base), anesthetic gels, hyaluronic acid, and antiseptic rinses (chlorhexidine 0.12%) [29, 30, 31]. Judicious use of antifungals is warranted if candidal overgrowth is suspected. In refractory cases, brief suspension of tray wear at the specific site or transition to the next tray after adjustment may be considered.

Table (3): Stepwise management of aligner-associated oral ulceration

Step	Intervention	Clinical notes
1	Identify & eliminate trauma source	Edge smoothing; adjust/relieve around frena; apply orthodontic wax
2	Analgesia & anti-inflammatory support	Topical anesthetic; short steroid course for severe inflammation
3	Biofilm control	Chlorhexidine rinse; non-abrasive aligner cleaning; reinforce hygiene
4	Adjunctive agents	Hyaluronic acid gels; protective barrier films
5	Escalation	Antifungal if *Candida* suspected; brief tray holiday; specialist referral

Clear aligner–associated ulcers represent a multifactorial clinical issue. Mechanical irritation appears to be the most common etiology, but chemical, microbiological, and host factors likely contribute. Continuous friction between sharp aligner edges and the mucosa can compromise epithelial integrity, leading to inflammation and ulceration [3,8].

Altered microbiota and plaque accumulation may exacerbate tissue breakdown, while hypersensitivity to polymers or cleaning agents may further complicate outcomes [9]. Importantly, while some studies argue that CAT results in

fewer mucosal complications compared with conventional fixed appliances, ulcers remain a frequent cause of patient discomfort and discontinuation [2, 3].

1.8 Preventive Strategies

Pre-treatment Assessment: Identify patients with a history of recurrent aphthous ulcers or mucosal sensitivity [1]. Aligner Design Optimization: Ensure smooth, polished aligner edges and adjust attachments to reduce friction [8]. Oral Hygiene Instructions: Advise patients to clean both teeth and aligners regularly, avoid sugary drinks, and follow aligner replacement schedules [7]. Patient Education: Encourage prompt reporting of irritation or pain for timely intervention [3].

1.9 Management of Ulcers

Immediate Measures: The first step is to identify and adjust the aligner surface that is causing trauma. Smoothing sharp edges and applying orthodontic wax or protective coatings can provide rapid relief. Topical Therapy: Mild to moderate discomfort can be managed with anesthetic gels or anti-inflammatory preparations, while topical corticosteroids may be indicated in cases of severe mucosal inflammation. Antiseptics/Antibiotics: These are not routinely required but may be prescribed if there is clinical evidence of a secondary infection. Behavioral Modifications: Patients should be reminded about the importance of meticulous oral hygiene and proper aligner cleaning techniques to minimize irritation and microbial accumulation. Referral: Ulcers that persist, recur frequently, or present with unusual features should be evaluated by an oral medicine specialist for further diagnosis and management [3,5].

1.10 Research Gaps and Future Directions

Lack of standardized, long-term studies quantifying the true prevalence of aligner-related ulceration [10]. Need for in-depth analysis of polymer degradation and its clinical implications [8, 9]. Randomized controlled trials evaluating specific preventive and therapeutic interventions [9].

2- CONCLUSION

Oral ulceration during clear aligner therapy is a clinically relevant complication caused by a combination of mechanical, chemical, microbiological, and patient-related factors. While aligners may present fewer mucosal risks compared to fixed appliances, ulcers can significantly impair patient comfort and compliance. Ulceration associated with clear aligners is common, impactful, and largely preventable. A prevention-first clinical workflow combining precise tray finishing, early patient education and simple hygiene protocols minimizes risk. When ulcers occur, prompt mechanical modification coupled with short, targeted topical therapy usually restores comfort within days. Advances in polymer chemistry and digital design are poised to further attenuate mucosal injury in the next generation of aligner therapy. Preventive measures include optimized aligner design, pre-treatment risk assessment, and patient education, whereas management strategies rely on mechanical adjustment, topical treatment, and specialist referral when necessary. Further well-designed studies are required to establish standardized prevention and management protocols.

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