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Bisphenol A Release from Orthodontic Clear Aligners: An In-Vitro Study

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Abstract

Bisphenol A (BPA) is a widely used synthetic compound that has been identified as an endocrine disruptor. It has been linked to adverse health effects such as developmental defects, infertility in both men and women, cardiovascular disease, and obesity. There has been increased interest in BPA's effects on the developing fetus and data has revealed that doses below the presumed safe dose can produce harmful effects. Orthodontic clear aligner therapy is a popular treatment modality that involves the patient wearing sets of plastic aligners up to 22 hours per day for the duration of treatment. The BPA release from these aligners was rarely investigated. The objective of this study was to detect, quantify, and compare the amount of BPA released by 3 popular brands of orthodontic aligners in artificial saliva, artificial gastric fluid, and ethanol. Equal amounts of SmileDirectClub®, Invisalign®, and Essix Ace® aligners were placed in sterile glass vials and submerged in 5.5mL artificial saliva,

artificial gastric fluid, and ethanol. Samples were incubated at 37°C and 1 mL aliquots were removed at various time points. Samples were prepared and analyzed using high performance liquid chromatography tandem mass spectrometry. BPA was released from all three brands of aligners with great variability. Peak BPA concentrations were detected in artificial saliva; Smile Direct Club® produced 5.0 ng/mL after 20 days, Invisalign® released 3.5ng/mL after 24 hours, and Essix Ace® released 6.3ng/mL after 10 days of incubation in artificial saliva. There was no significant difference in BPA concentration between the 3 types of aligners in the 3 media. When comparing time points, there was a significant increase of BPA release in the first 24 hours after incubation compared to the baseline ($p<0.001$). There is potential BPA release from orthodontic aligners. There was no significant difference in the amount of BPA released between the three types of aligners at any time point. The majority of BPA release occurred during the first 24 hours.

Keywords
Orthodontics; clear aligner therapy; bisphenol A; estrogenicity