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Comparison of leaching from different thermoformed aligner systems-An In-vitro study

By

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ABSTRACT

BACKGROUND AND OBJECTIVES

Clear aligners have gained immense acceptance in recent years due to their graceful appeal and comfort compared to traditional braces. They offer a cautious way to straighten teeth without the visibility of metal brackets and wires. This makes them particularly attractive to adults who may feel self-conscious about wearing braces. Clear aligner therapy has been a part of orthodontic practice for decades. Clear aligners work by gradually shifting teeth into their proper positions using a series of custom-made, removable trays. Each tray is worn for a specified amount of time, typically about two weeks, before moving on to the next tray in the series. This process continues until the desired results are achieved. Clear aligners are also superior in that they are removable, custom-made in sequence on patient-specific malocclusion setups, and capable of gradually guiding teeth into their determined positions. Knowledge of Bis phenol A(BPA) released into the oral cavity by different thermoplasticised aligner materials is unclear. Comparison of amount of BPA released into oral cavity by popular thermoformed aligner materials is ambiguous

METHODOLOGY: An invitro study was conducted on aligner materials from different manufactures (Zendura, Biolon, Duran) were allocated into 3groups. which were thermoformed using Ministar thermoforming machine (Scheu SN 26282). Four samples of 5x5mm thermoformed aligner materials were cut from each group and immersed in artificial saliva, samples were tested after 1hr, 24hrs, 3rd day and 14th day by high performance liquid chromatography (HPLC) and amount of BPA released at different time intervals were analysed. The results were then statistically analysed using inferential statistics (Friedman chi square, Kruskal Wallis and Mann Whitney test)

RESULTS: The mean difference in area and concentration among three groups was significant at one hour and one day time interval and the comparison between groups showed that Zendura leached highest amount of BPA followed by Biolon and Duran at one hour and one day time intervals. The amount of BPA leached was insignificant on day three and day fourteen among three groups. However, all materials initially released concentrations of BPA that exceeded the tolerable daily intake (TDI) level, which is set at 4µgm/kg bw/day. Biolon and Duran, ceased leaching BPA after a certain period (in this case, by day fourteen), indicating a decrease in the release of BPA over time. This could suggest that these materials are less prone to continuous leaching of BPA compared to Zendura. Zendura continued to leach concentrations of BPA that exceeded the TDI even on day fourteen, suggesting that this material has a more persistent or higher rate of BPA release compared to the other materials tested.

CONCLUSION: Leaching from Zendura was higher followed by Biolon and Duran, the higher amounts of leaching from Zendura could be attributed to its polyurethane composition, which might have properties that make it more prone to BPA release compared to polyethylene terephthalate glycol used in Biolon and Duran. This information underscores the importance of understanding the potential risks associated with materials containing BPA and the need for alternatives or improved manufacturing processes to mitigate such risks.

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