

# Monomer release from orthodontic retentions: An in vitro study

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**Introduction:** The adhesives used to bond orthodontic retentions are low-loaded composite resins with a resinous matrix containing bisphenol A diglycidyl ether dimethacrylate synthesized from bisphenol A (BPA), fluidizers such as triethylene glycol dimethacrylate (TEGDMA) and hydrophilic polymers such as hydroxyethylmethacrylate. BPA disrupts the endocrine balance, and TEGDMA has high risks for human health: eg, allergies and cytotoxicity. The aim of this study was to evaluate in vitro the release of monomers from orthodontic bonded retentions. **Methods:** A reproducible model of bonded retentions was carried out using calibrated molds. We analyzed the release of monomers by gas phase chromatography coupled with mass spectrometry. **Results:** This model allowed us to qualitatively and quantitatively evaluate the in-vitro release of monomers from orthodontic adhesives. The quantitative and qualitative analyses showed no BPA release above the 0.02 ppm detection limit. A greater release of TEGDMA was observed with Transbond LR (31.7 µg/mL) than with Transbond XT (13.12 µg/mL) (both, 3M Unitek, Monrovia, Calif). Other toxic components (iodobenzene, iodobiphenyl, triphenyl stibine, and so on) were also identified. **Conclusions:** Toxic and carcinogenic molecules not mentioned in the material safety data sheets were identified. (Am J Orthod Dentofacial Orthop 2018;153:248-54)

**B**onded systems occupy a prominent place in orthodontics, including fixed retainers that can remain in the mouth for several decades.

Fixed lingual retainers, which have been used in orthodontics since the 1970s,<sup>1</sup> are bonded to the anterior mandibular teeth to prevent relapse or secondary crowding of the incisors.<sup>2</sup> These retainers are composed of braided or metallic wires bonded to enamel with a restorative resin composite or flowable orthodontic adhesives.<sup>3,4</sup> Depending on the protocol, all 6 anterior teeth or only the canines are involved.<sup>4</sup>

The composite resins used in orthodontics consist of mineral fillers, resin matrix—generally bisphenol A diglycidyl ether dimethacrylate (Bis-GMA) synthesized from bisphenol A (BPA) and urethane—fluidifiers belonging

to the triethylene glycol family, catalysts (eg, camphroquinone), and various other additives. The self-etch bonding systems have introduced acid polymers and hydrophilic polymers such as hydroxyethyl-methacrylate.<sup>5</sup>

The increasing presence of polymers in the oral cavity has raised questions for several years about the safety of the components of the resinous matrix. Orthodontic adhesives induce cytotoxicity, disturbing cell metabolism and inducing cell death, even up to 2 years after polymerization<sup>6-15</sup> and may cause inflammatory response in test animals.<sup>16-19</sup> Eliades et al<sup>20</sup> indicated the absence of estrogenicity in orthodontic adhesive eluents. Gioka et al<sup>21</sup> noted that a moderate reduction in DNA synthesis was obtained by adhesive eluents, implying a minor cytostatic effect.

Among the leached compounds, BPA is the most studied. Qualified as an endocrine disruptor due to its ability to bind and activate the estrogen receptor in humans, its effects are proven in animals and suspected in humans.<sup>22-26</sup> In July 2012, the United States Food and Drug Administration<sup>27</sup> amended its regulations to disallow the use of BPA-based epoxy resins as coatings in packaging for infant formula.<sup>28</sup> The no observable adverse effect level is 5 mg per kg body weight per day of BPA in the United States.<sup>27</sup> In January 2015, the tolerable daily intake of BPA was reduced from 50 to 4 µg per kg body weight per day. BPA is banned for food contact in some European countries.<sup>29,30</sup>

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Other products less investigated than BPA but with potential toxicity, including some diluents such as triethylene glycol dimethacrylate (TEGDMA) and Bis-GMA, are released from restorative or bonding composites.<sup>22,23,31-37</sup>

A protocol for the bonding of orthodontic retention wires has been developed to investigate the possible release of monomers (BPA and TEGDMA in particular) and to quantify this release by expressing it per unit area of exposed bond using gas phase chromatography coupled with mass spectrometry.

## MATERIAL AND METHODS

To better simulate the quantity of adhesive applied to an orthodontic retainer, a sample of each composite (Transbond XT, Transbond LR; 3M Unitek, Monrovia, Calif) was prepared using calibrated molds by Mini-Mold Wire Bonder LG (diameter, 4 mm; height, 1.5 mm; G & H Wire Company, Franklin, Indiana). For each sample, 6 dots of composite representing the 6 anterior teeth were placed. The composition of the adhesives used is detailed in Table I.

Each dot was cured using a curing light (ScanWave Mini LED; Acteon; France) with a power of  $1500 \pm 10\%$  mW per square centimeter and a wavelength of radiant energy between 390 and 510 nm for 20 seconds.

In accordance with recommendations, the distance between the light and the composite was reduced to a minimum of 1 mm to prevent contact and therefore the mobilization of the Mini-Mold while remaining as close as possible to the bond.<sup>35</sup>

The total surface area of each adhesive dot was  $32.16 \text{ mm}^2$  according to the geometry calculation. Following the International Organization for Standardization (ISO) 10993-12:2012 standard for medical-device testing in biologic systems,<sup>38</sup> each cured sample was immediately immersed in 0.66 mL (surface area/volume ratio,  $3 \text{ cm}^2/\text{mL} \pm 10\%$ ) of Milli-Q water (Merck Millipore, Billerica, Mass) in a glass tube for 24 hours at  $37^\circ\text{C}$ .<sup>35,39</sup> The immersion liquid was then lyophilized, and 100  $\mu\text{L}$  of dichloromethane was added.

The composition of the eluates was analyzed using gas phase chromatography and mass spectrometry (TRACE Ultra Gas Chromatograph and ISQ Thermo; Thermo Finnigan Electron, Waltham, Mass). A capillary column 15 m in length with an internal diameter of 0.25 mm and a film thickness of 0.25  $\mu\text{m}$  was used with helium carrier gas at a flow rate of 1.5 mL per minute. The splitless mode was used to identify a maximum of molecules. The column temperature program was set as follows: initially,  $50^\circ\text{C}$  for 1 minute, increasing to  $300^\circ\text{C}$  at a rate of  $15^\circ\text{C}$  per minute. The injector temperature was  $230^\circ\text{C}$ , and the transfer line was  $250^\circ\text{C}$ . Mass spectra were obtained using

**Table I.** Composition of resins used

Product	Batch	Composition from chemical safety data sheet
Transbond LR	GF9RC	Silane treated quartz: 75%-85% (C.A.S. No. 100402-78-6) Triethylene glycol dimethacrylate (TEGDMA): 5%-15% (C.A.S. No. 109-16-0) Bisphenol A diglycidyl ether dimethacrylate (Bis-GMA): 5%-15% (C.A.S. No. 1565-94-2) Dichloromethylsilane reaction product with silica: <2% (C.A.S. No. 68611-44-9) N,N-dimethylbenzocaine: <0.3% (C.A.S. No. 10287-53-3) Diphenyliodonium hexafluorophosphate: <0.1% (C.A.S. No. 58109-40-3)
Transbond XT	N592900	Silane treated quartz: 70%-80% (C.A.S. No. 100402-78-6) Bisphenol A diglycidyl ether dimethacrylate (Bis-GMA): 10%-20% (C.A.S. No. 1565-94-2) Bisphenol A Bis(2-hydroxyethyl ether) dimethacrylate: 5%-10% (C.A.S. No. 24448-20-2) Silane treated silica: <2% (C.A.S. No. 68611-44-9) Diphényliodonium hexafluorophosphate: <0.2% (C.A.S. No. 58109-40-3)

electron impact ionization (70 eV, 150  $\mu\text{A}$ ,  $200^\circ\text{C}$ ). The compounds primarily sought were BPA, TEGDMA, and hydroxyethyl-methacrylate. Data were processed with the software Thermo Scientific Xcalibur (Thermo Fisher Scientific, Waltham, MA).

After identification of the released compounds, the molecules of interest were quantified. The exact concentration was calculated by comparison between the standard and the sample compound. To increase the sensitivity, the acquisition was performed by single ion monitoring.

## RESULTS

The Figure shows the chromatograms of each sample; peaks correspond to chemical compounds according to their retention time.

The identified chemical molecules in the tested samples are presented in Table II.

Both samples released iodobenzene, camphoric anhydride, iodobiphenyl, dimethyl benzocaine, TEGDMA, triphenyl stibine, and alkanes. Camphorquinone, lauric acid, and hydroxydiphenyl were only detected in Transbond XT. Butylhydroxytoluene was identified in Transbond LR (Table II).

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