

EVALUATION OF BIOCOMPATIBILITY OF ORTHODONTIC RETAINERS

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ABSTRACT

It is in the clinician's interest to select the least hazardous devices and materials among the many offered by manufacturers. The polymer chosen is important; some polymers have been reported to be hazardous, and these are quite often used in direct contact with human tissues. Long-term studies testing the biocompatibility of these material (acrylic and bioplastic sheet) are not available. The aim of the study is to analyse the leachable monomers, polymers and dilatational products from retainer materials. **Materials and Methods:** Using the oxidation reduction reaction taking place in the presence of two different concentrations of potassium permanganate and distilled water separately, three different samples of different companies were tested. The sequence of colour change from purple to red to brown to yellow to clear was used to determine the amount of leaching. This is the result of a stoichiometric relation between the oxidizing agent and the reducing sample. Colour changes were observed through naked eyes over a period of 24 h. Photographs were taken at 15 min, 8 h and 24 h using D-SLR1000 Canon camera. Photos were evaluated separately. **Result:** Using oxidation reduction reaction colour changes were observed visually and the amount of colour change and leaching showed heat cure>cold cure>bioplastic sheet. **Conclusion:** The release of BPA and the leaching of monomers, such as Bis-GMA and TEGDMA, is a well-demonstrated phenomenon in oral conditions, which requires special clinical handling and further research.

KEYWORDS: Orthodontic retainers, biocompatibility, polymer.

INTRODUCTION

Polymer-based biomaterials are widely used in dentistry. In orthodontic treatment, polymer-based materials are used both as base-plate materials and as adhesives for brackets.^[1] Incomplete polymerization of dental resins is the cause of residual monomers within the material (Ruyter and Oysaed, 1982; Vallittu et al., 1998). These unreacted monomers are free small molecules present within the polymer matrix. As such, they may leach out of the material both from the surface layer and, over longer time perspectives, from inside of the material through diffusion. Several reports are available on monomers leaching from orthodontic adhesives (Baker et al., 1988; Eliades et al., 1995; Gioka et al., 2005), whereas information is scarce within the case of orthodontic base-plate materials (Stafford and Brooks, 1985; Rose et al., 2000).^[1]

In 1980s, vacuum formed clear thermoplastic sheets fitting tightly over the teeth were introduced into orthodontics as "retainers". It quickly became apparent that if the teeth were slightly reset before forming, a tooth moving device would result; hence the name "aligner" was used.^[2] Soon it was apparent that it could be used for far more than just minor movements. Today it is on the verge of bringing about a paradigm shift from unesthetic brackets and archwires to invisible orthodontic treatment.^[2]

Polymers are the base or matrix substance for many plastics and devices (like adhesives, retainers, elastomeric chemicals, elastic ligation rings) used in orthodontics, many of which are placed in direct contact with human soft tissues, often for years Bisphenol-A (BPA) is an industrial chemical used to manufacture

polycarbonate and numerous plastic materials.^[3] Recent studies have shown that it can leach out from certain products. Low level of BPA have also been found to cause biological effects. Mode of action appears to mimic that of female hormone oestrogen. BPA therefore belongs to group of chemicals termed “**Hormone Disrupters**” or “**Endocrine Disrupters**”.

There is growing international concern about man made endocrine disrupting chemicals causing:

- 1) Disruption of development of offspring in the womb.^[4]
- 2) Decline in sperm count.^[4]
- 3) Increased rates of hormone related cancers, such as cancer of breast, testes and prostate.
- 4) Birth defects and other hormones related effects such as early puberty in girls.^[4]

Many manufactures do not disclose the ingredients or the procedure used in the manufacturing of their products. Hence, there is need to devise a simple yet effective test to detect and measure the amount of hazardous by-products released from routinely used orthodontic materials.

AIMS AND OBJECTIVE

The aim of the study is to analyse the leachable monomers, polymers and dilatational products from retainer materials. (Fig 1)

Group I- Heat cure acrylic.

Group II – cold cure acrylic.

Group III – Bio plastic sheets.



Fig 1: Samples containing retainers of heat cure acrylic, cold cure acrylic and thermoplastic sheet.

MATERIAL AND METHODS

This is a simple test which can be performed by the clinician or an assistant in the clinic itself using easily available material.

Preparation of disclosing solution: Three different types of disclosing solution used were.

- 1) 1.6 mg potassium permanganate $KMnO_4$ (99%) added to 1 litre of distilled water.
- 2) 3.2 mg potassium permanganate $KMnO_4$ (99%) which was added to 1 litre of distilled water. The solution was stored in closed container for at least an hour before use.
- 3) Distilled water, separately.

After mixing, the solution is stored in a closed container for 24 hours. The adhesives and restorative materials to be tested were cured. After curing, the foils were cooled and reduced to particles by using a coffee grinder and weighted to samples of 1 g each. The particles were then

immersed in 20 mL the permanganate solution in 25-cc capped test tubes.

The reaction proceeds in two ways, according to the pH of the solution. In a neutral environment, the Mn ions are reduced to manganese oxides that give the solution a brownish tint. By adding a few drops of an acid, such as phosphoric, sulfuric, or hydrochloric (muriatic) to pH 1-2, the colour further changes to clear as the manganese is reduced to colourless salts (Fig 2).

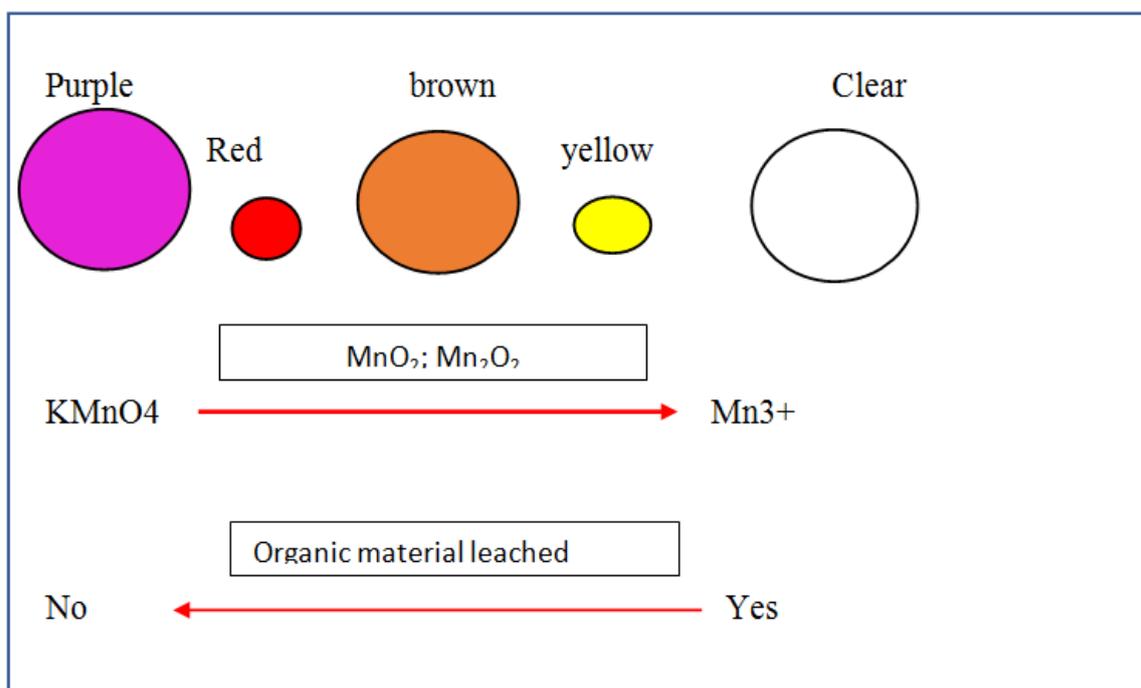


Fig 2: Colour transitions occurring during the reduction of potassium permanganate as it oxidizes the leached ingredients.

Alternatively, if a reacted solution obtained in a neutral environment is acidified, it will have either a shade of purple (unreacted permanganate) or become clear. The latter indicates a total consumption of the Mn ions, i.e., an excess of leached (and oxidized) ingredients. Due to the resiliency of the rubber-like material of the retainer, grinding did not result in particles fine enough to expose a large surface area. The samples were then cooled.

All sheets of retainers were powdered into fine particles using straight handpiece with stainless steel round bur 1 mm in diameter. 1 g of each powdered sheet was added to 5ml of the reagent in capped and marked test tubes and photographed. All the samples of group I, group II, group III of 1 gm each were weighted and immersed in 5ml of potassium permanganate and distilled water solution separately taken in 10 cc capped test tube and they are numbered from 0 to 6 which contain different testing samples.

0-Control group

1-Heat cure acrylic (Trevlon)

2-Heat cure acrylic (DPI)

3-Cold cure (Trevlon)

4-Cold cure (DPI)

5-Bio Plastic sheet (Denmark)

6-Bio plastic sheet (Bio art)

Using Nikon DSLR Camera, the samples were photographed for colour change using different time intervals.

a) After 15 minutes (Fig 3, Fig 4, Fig 5)

b) After 8 hours (Fig 6, Fig 7, Fig 8)

c) After 24 hours (Fig 9, Fig 10, Fig 11)

RESULTS

Each fresh sample was subjected to test on 5 different days, the results were tabulated and statistically evaluated keeping in mind that faster the discoloration time, the greater the amount of leached product present.

After 15 min colour changes were observed visually in three different solutions.

Two different solutions of potassium permanganate in concentration of (1.6 mg & 3.2 mg) showed colour changes and there was no colour change in distilled water solution.

After 15 min test tubes containing heat cure acrylic shows more colour change compared to test tubes containing cold cure acrylic and bio plastic sheet which indicates more amount of polymer leaching by heat cure acrylic.

While differing in speed, some oxidation-reduction reaction took place in all cases, as shown by the discoloration of all the samples except the control. In a neutral environment, the reaction is slow and the discoloration more difficult to assess due to the suspended particles of manganese oxides; therefore, an acid environment was preferred. In an acid environment, the reaction is faster and the shades vary between clear and purple.

Amount of colour change and leaching – heat cure > cold cure > bio plastic sheet.

After 15 min



Fig 3: 3.2 mg pf potassium permanganate.

After 8 hours



Fig 6: 3.2 mg potassium permanganate.



Fig 4: Distilled Water.



Fig 7: Distilled Water.



Fig 5: 1.6 mg of potassium permanganate.



Fig 8: 1.6 mg potassium permanganate.

After 24 hours



Fig 9: 3.2 mg of potassium permanganate.



Fig 10: Distilled Water.



Fig 11: 1.6 mg of potassium permanganate.

DISCUSSION

In this study, an oxidation reduction reaction using KMnO_4 takes place. In a neutral environment, the permanganate in the presence of polymers is reduced to manganese (IV) oxide (MnO_2) and manganese (III) oxide (Mn_2O_3) which precipitate and give the liquid a yellow-brown colour, manganese is further transformed into a nearly colourless salt (Mn^{2+}). The amount of polymer in the solution determines the degree of progress of reaction; the sequence of colour is from

purple to red to brown to yellow to clear. This is the result of a stoichiometric relation between the oxidizing agent and the reducing sample.

In this study, we made three readings differing in concentration of reagent in order to check if we could increase the rate of the reaction for clinical usage and still get consistent results. Diluted solution did show faster results, because it had lesser concentration of KMnO_4 , hence it requires lesser amount of leaching products to complete the reaction and hence shows faster changes in colour. The results were almost like those obtained using concentrated reagent but occurred at a faster rate. This study only provided an approximation of the degree to which a polymer leached oxidizable, organic matter. Although the latter may not always be harmful, as a general rule the less leaching, the safer the product is considered. By showing the relative degree of leaching, the method allows the manufacturer to optimize his product, the clinician and the researcher to select the least harmful and the researcher to follow the progress of the leaching in time. According to Matasa, because the relative molecular mass of the polymer is increased and therefore the crosslinked network gets denser the larger molecules become entangled and are kept within the polymer's structure thus reduced amount of leaching.^[5] Thermoplastic overlay orthodontic appliances are generally recommended to be used for 2 weeks in each stage. During this period, temperature fluctuations in the oral cavity can change the properties of these materials.^[6] It was reported by *Waked et al.*^[7] that aging induced various dimensional changes in mouthguard materials, which have similar compositions to those of thermoplastic overlay orthodontic materials, counting on the materials and processing techniques.

The shortcoming of this method is that it gives only comparative results based only on visual estimates; the precise amount of polymer leaching can't be evaluated. There is a requirement for a way more accurate but simple method for evaluation of polymer leaching from clear aligner sheets, especially considering its increasing demand.

CONCLUSION

This is a simple in vitro observational study to evaluate the amount of potentially harmful polymer, monomer and dilatational products leached from various orthodontic products.

The decision to use material in the mouth is one that is based on balance between risk and benefit. Ultimately, the practitioner must determine whether the benefit to the patient outweigh the risk in his or her own mind.

The release of BPA and therefore the leaching of monomers, like Bis-GMA and TEGDMA, may be a well-demonstrated phenomenon in oral conditions, which needs special clinical handling and further research.

REFERENCES

1. Kopperud H, Kleven I, Wellendorf H. Identification and quantification of leachable substances from polymer based orthodontic base plate material. *Eur J Orthod*, 2011; 33: 26-31.
2. Ansari SA, Chaudhari AR, Patil CB, Pullori SR. Simple method of testing polymer leaching from thermoplastic sheets used for clear aligner. *APOS Trends Orthod*, 2014; 4: 66-9.
3. Hassan, R.; Aslam Khan, M.U.; Abdullah, A.M.; Abd Razak, S.I. A Review on Current Trends of Polymers in Orthodontics: BPA-Free and Smart Materials. *Polymers*, 2021; 13: 1409.
4. Kloukos D, Pandis N, Eliades T. Bisphenol-A and residual monomer leaching from orthodontic adhesive resins and polycarbonate brackets: A systematic review. *Am J Orthod Dentofacial Orthop*, 2013; 143: 104-12.
5. Matasa CG. Screening Orthodontic Polymer for Leaching. *World J Orthod*, 2003; 4: 157-161.
6. Schuster S, Eliades G, Zinelis S, Eliades T, Bradley TG. Structural conformation and leaching from in vitro aged and retrieved Invisalign appliances. *Am J Orthod Dentofacial Orthop*, 2004; 126: 725-8.
7. Waked EJ, Lee TK, Caputo AA. Effects of aging on the dimensional stability of custom-made mouthguards. *Quintessence Int*, 2002; 33: 700-5.
8. Koty M, Wiltshire W. An investigation into bisphenol-A leaching from orthodontic materials. *Angle Orthod*, 2014; 84: 516-520.
9. Hosseinzadeh T, Shahroudi A S, Eraghihazadeh Z, Aghajani F. Comparison of residual monomer loss from cold-cure orthodontic acrylic resins processed by different polymerization techniques. *J Orthod*, 2014; 41: 30-37.
10. Pelourde C, Bationo R, Boileau MJ, Parros JC, a and Fabienne Jordanac. Monomer release from orthodontic retentions: An in vitro study. *Am J Orthod Dentofacial Orthop*, 2018; 153: 248-54.
11. Proffit WR. Contemporary orthodontic appliances. In: Proffit WR, Fields HW, Sarver DM, editors. *Contemporary Orthodontics*. 4th ed. St. Louis, MO: Mosby Elsevier, 2007; 402-4.
12. Soderholm KJ, Mariotti A. BIS-GMA-based resins in dentistry: are they safe? *J Am Dent Assoc*, 1999; 130: 201-9.
13. Nazir, S.; Khan, M.U.A.; Al-Arjan, W.S.; Abd Razak, S.I.; Javed, A.; Kadir, M.R.A. Nanocomposite Hydrogels for Melanoma Skin Cancer care and Treatment: In-vitro drug delivery, drug release kinetics and anti-Cancer activities. *Arab. J. Chem*, 2021; 14: 103120. [CrossRef]
14. Soderholm KJ, Mariotti A. BIS-GMA-based resins in dentistry: are they safe? *J Am Dent Assoc*, 1999; 130: 201-9.
15. Hume WR, Hood AM. Cytotoxicity comparison between composite resins containing di-, tri-, or tetra-ethyleneglycol dimethacrylate [abstract]. *J Dent Res*, 1991; 70: 423.
16. Athas WE, Gutzke GE, Kubinski GE, Kubinski H. In vitro studies of the carcinogenic potential of orthodontic bonding materials. *Eco toxicol Environ Safety*, 1979; 3: 401-10.
17. Nah WH, Park MJ, Gye MC. Effects of early prepubertal exposure to bisphenol A on the onset of puberty, ovarian weights, and estrous cycle in female mice. *Clin Exp Reprod Med*, 2011; 38: 75-81.
18. Gerzina TM, Hume WR. Diffusion of monomers from bonding resin-resin composite combinations through dentine in vitro. *J Dent*, 1996; 24: 125-8.
19. Eliades T, Hiskia A, Eliades G, Athanasiou AE. Assessment of bisphenol-A release from orthodontic adhesives. *Am J Orthod Dentofacial Orthop*, 2007; 131: 72-5.
20. Hanks CT, Strawn SE, Wataha JC, Craig RG. Cytotoxic effects of resin components on cultured mammalian fibroblasts. *J Dent Res*, 1991; 70: 1450-5.
21. Kanerva L, Estlander T, Jolanki R. Allergic contact dermatitis from dental composite resins due to aromatic epoxy acrylates and aliphatic acrylates. *Contact Dermatitis*, 1989; 20: 201-11.
22. Hougaard KS, Hannerz H, Feveile H, Bonde JP. Increased incidence of infertility treatment among women working in the plastics industry. *Reprod Toxicol*, 2009; 27: 186-9.