

Leaching from Thermoplastic Sheets-A Quantitative Assessment

Afraz Walele¹, Sunilkumar P.², Abhay Chaudhari³, Chandrashekhargouda Patil⁴, Prashant Yaragambalimath⁵, Ranjeet Survase⁵

ABSTRACT

Introduction: With the increasing popularity of clear aligners, newer materials are introduced in the form of thermoplastic sheets which are polyurethane polymers possessing superior mechanical properties. They are highly abrasion resistant and elastic with high shear strength and transparency. However, biocompatibility of these materials with human soft tissues is still under research. Aim of the study was to quantitatively assess the organic compounds leached out from the thermoplastic sheets using “high-performance liquid chromatography”

Material and methods: Thermoplastic sheets from five manufacturers CA, Scheu, Germany; Ultradent, US; 3A Medes, Korea; Avac R, Jaypee, Kerala; EVA, Endent Pvt. Ltd., Delhi; were collected and investigated. All samples selected were 2mm thick and 2x4cm in dimension. These pieces were cut out from the excess material left after manufacturing the aligners. Each sample was powdered using liquid nitrogen prior to elution. Elution was performed with ethanol (75%) + water (25%) in a shaker incubator at 35.5°C for 7days. The extract medium obtained is then subjected to High Performance Liquid Chromatography which provides a precise quantification of the leachables from the thermoplastic sheets thereby determining the biocompatibility of the samples.

Results: The biocompatibility of the samples will be better known in terms of concentration of the released organics compounds from each sample using liquid chromatography. The test performed showed ULTRADENT with the greatest amount of leaching whereas JAYPEE, kerala with the least leaching potential among the five samples studied.

Conclusion: The sample with the highest concentration of the leached out compounds will be least biocompatible. Thus, the compatability factor in descending order was found in jaypee followed by CA, Scheu, Germany, 3A Medes, Korea, EVA, Endent Pvt. Ltd., Delhi, and the least compatible was Ultradent, USA.

Keywords: high-performance liquid chromatography, thermoplastic sheets, leaching.

oral tissues as well. As a result of this, there is an increasing concern about the biocompatibility of these materials with the tissues. Although there is limited research data available on this topic, few previous studies performed on these materials to determine their tendency to leach out organic compounds, have suggested positive results for leaching. However, none of the previous studies have been able to successfully quantify the amount of leaching from these thermoplastic sheets. Plus there is wide variety of thermoplastic sheets that are available in the market to choose from, everyday newer brands and materials are emerging. The companies' confidentiality policies make the exact content unknown to the users, thus raising questions. Hence there is a need for a more precise and specific method which can be done to find the least leaching and thus most biocompatible product out of the options available.

The aim of this study was to quantitatively assess the organic compounds leached out from the thermoplastic sheets using “high-performance liquid chromatography”.

The objectives of this study were to help obtain a quantitative measure to which a polymer leaches oxidisable, organic matter; thus giving a relative comparison between the various options available to clinicians.

Another objective was to allow 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.

MATERIAL AND METHODS

The sample collection for this particular study was done with the help of over 20 different dental laboratories using these thermoplastic sheets. For the purpose of convenience, five commonly used brands were shortlisted. These were; CA, Scheu, Germany; Jaypee, Kerala, India; Ultradent, US; 3A Medes, Korea; EVA Endent Pvt. Ltd. New Delhi, India. Medium consistency sheets which were 2mm in thickness were selected. Each sample was cut into 2cms X 2cms pieces to maintain uniformity of size between the samples (Fig-1). Each of the pieces cut were obtained from the remnant excess material after the manufacturing process of the aligners, as

INTRODUCTION

The use of “retainers” in orthodontics started in the 1980s, in the form of thermoplastic vacuum formed sheets fitting tightly over the teeth. The name “aligner “ came into use as it became clear over time that these retainers can be used as tooth moving devices if the teeth were reset slightly before forming. The extent of its use for more than just minor movements was realized soon.¹ The use of these aligners has almost brought about a shift in the paradigm from unesthetic brackets and arch wires to invisible orthodontics.

As these materials have found abundant increase in their usage over the recent past, there has been a simultaneous increase in the duration of contact of these materials with the

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How to cite this article: Afraz Walele, Sunilkumar P., Abhay Chaudhari, Chandrashekhargouda Patil, Prashant Yaragambalimath, Ranjeet Survase. Leaching from thermoplastic sheets-a quantitative assessment. International Journal of Contemporary Medical Research 2016;3(5):1518-1521.

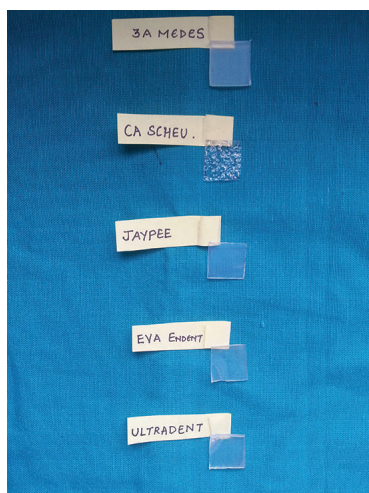


Figure-1: 2cms X 2cms pieces of samples of thermoplastic sheets

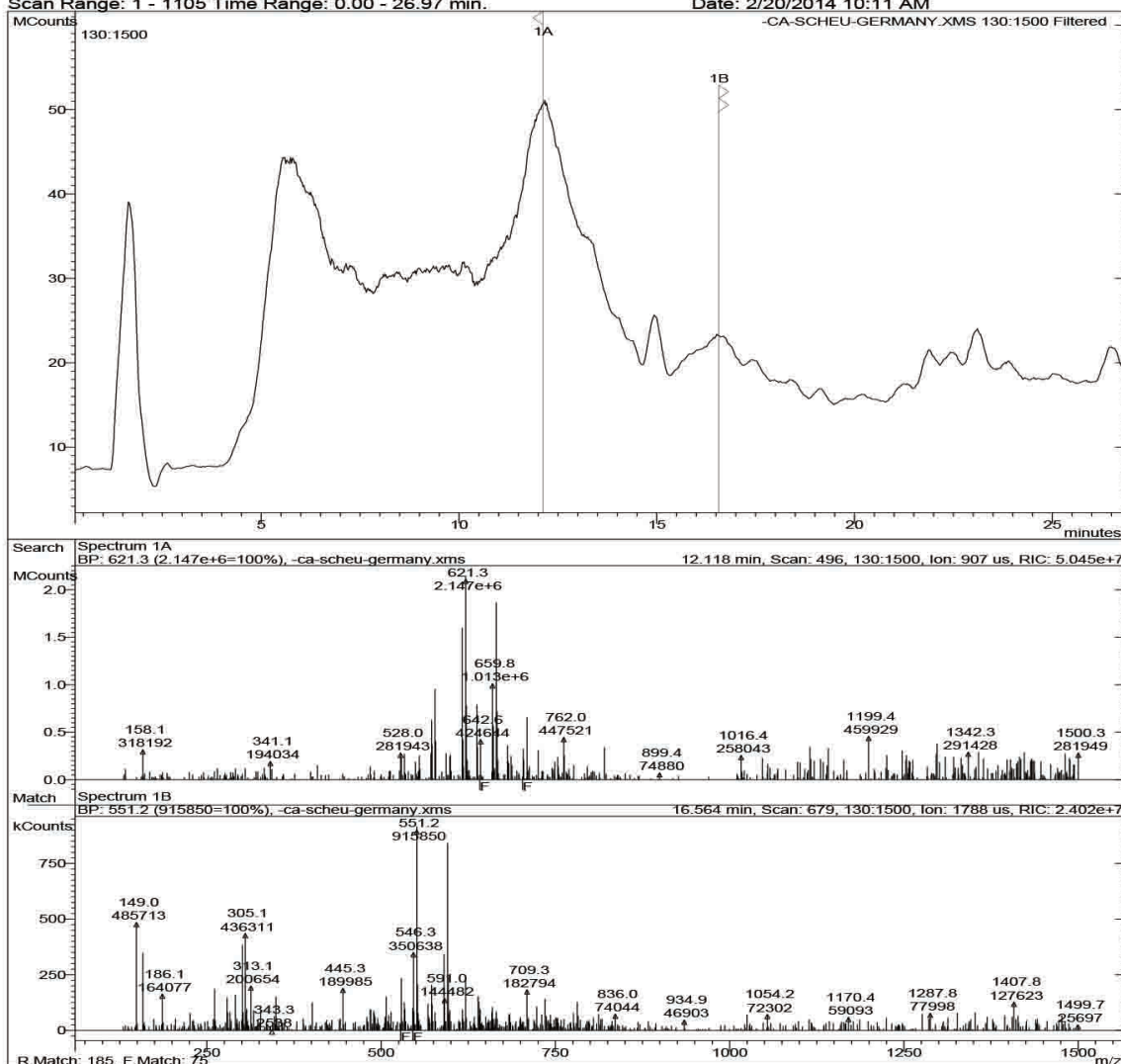


Figure-2: Powdered samples in solvent (75% ethanol + 25% water)

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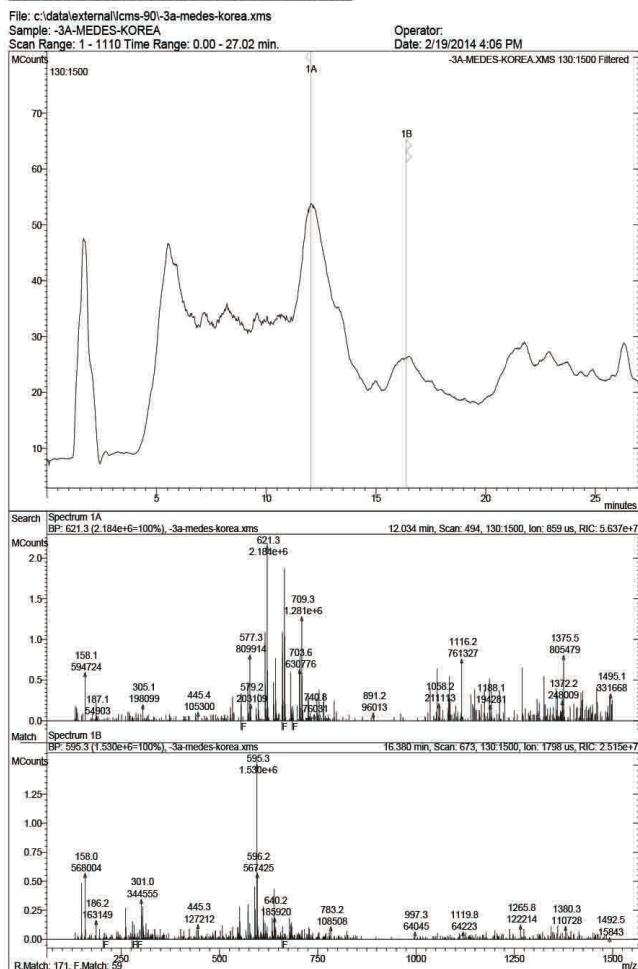


Graph-1: CA Scheu(Germany)

a result of which, every sample had already undergone one customary heating and cooling cycle before delivery. Each of the samples was powdered using liquid nitrogen as the powdered form will have a greater surface area exposed

to the solvent in separate test tubes (Fig. 2) prior to elution. Elution in this case, is the process of separating the organic compounds from the material using a solvent. Elution is carried out using 75%(v/v) ethanol - 25% water immersion

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Graph-2: 3A Medes (Korea)

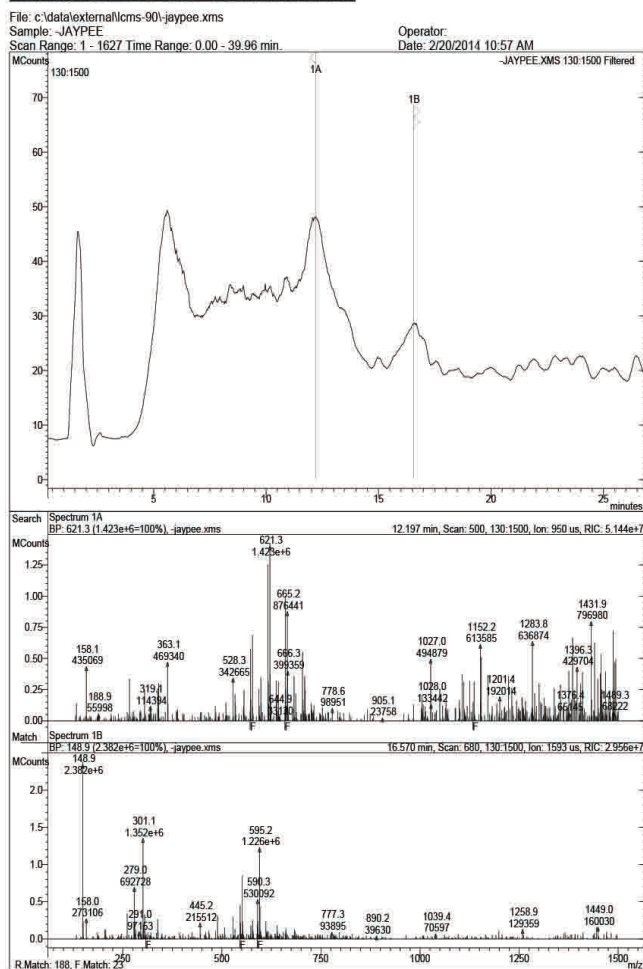
medium for 1 week at 23°C in a shaker incubator to simulate accelerated aging as proposed previously.²

This is done in order to obtain the extract containing the leached out organic compounds from the thermoplastic sheets. This extract is then subjected to high performance liquid chromatography (HPLC)³ using the ProStar / Dynamax system. Approximately 10 mL of the samples was extracted with 10 mL HPLC-grade dichloromethane, and the extract was dried over anhydrous sodium sulfate at 350°C under a pressure of 15.0 psi. the nebulizer gas used was nitrogen under a nebulizer pressure of 30.0 psi. A PB-5 column of 30 m in length was used with the carrier gas at a flow rate of 30 cm/msec. The column program was 5 minutes at 40°C, 140°C intermediate temperatures, at a rate of 5°C per minute, 290°C final temperature at 10°C per minute, and 20 minutes holding time.

RESULTS

All the products that were tested leached, but the amount varied from one product to another. The results were consistent on repeated testing over a number of days. The Figs. (1-5) show the graphical records depicting the amount of leaching by each of the products; The amount of methyl methacrylate leaching from the polymethyl methacrylate-based thermoplastic material CA Scheu(Germany) – 51 MCounts (Graph:1), 3A Medes (Korea) – 54 MCounts

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Graph-3: Avac R, Jaypee (Kerala, India)

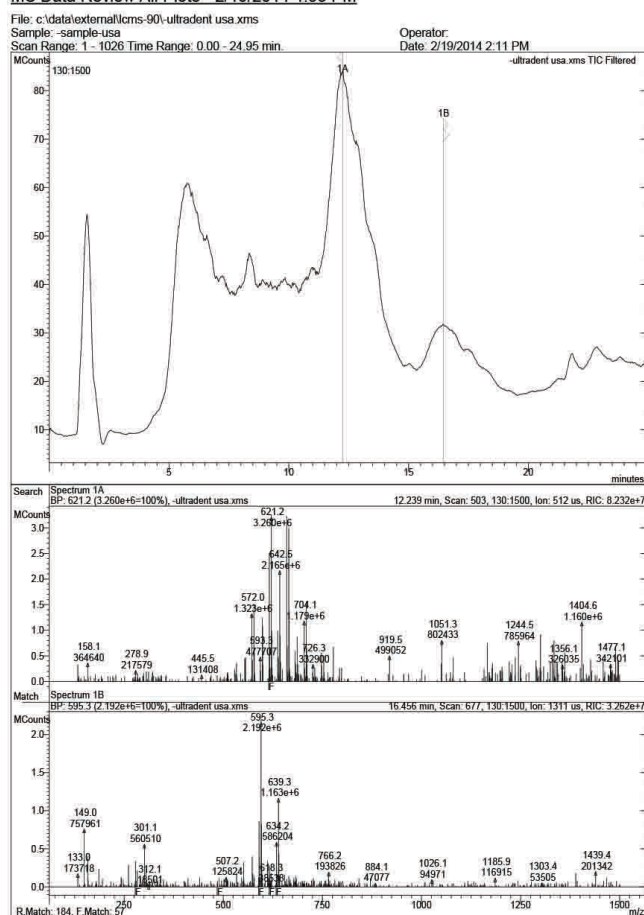
(Graph: 2), Avac R, Jaypee (Kerala, India) –48 MCounts (Graph: 3) Ultradent (USA) – 82 MCounts (Graph:4), EVA, Endent Pvt. Ltd. (Delhi, India) – 63 MCounts (Graph:5), respectively.

DISCUSSION

Polymer leaching is a common finding in all the previous studies performed. However the rate of leaching of the polymer differed considerably. However various factors could be the reason for this differential rate of polymer leaching. According to the study previously performed by Matasa,^{4,5} the amount of polymer leaching is reduced with increase in the molecular weight of the polymer. This is because the increased molecular weight and density of the crosslinked network cause the larger molecules to get entangled and remain within the polymer structure thus causing lesser amount of leaching.

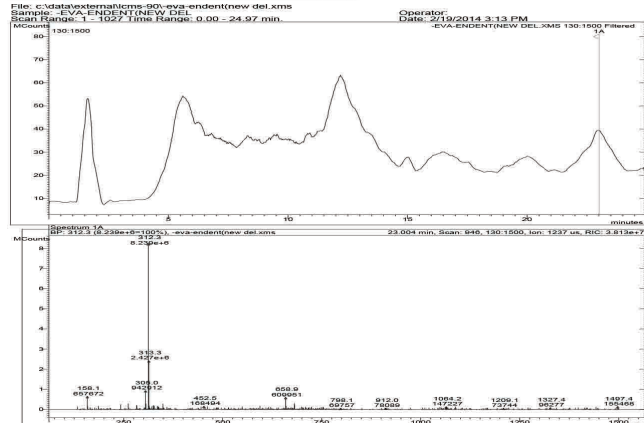
Leaching from thermoplastic sheets generally results in the release of monomers such as bisphenol A (BPA). The implications of BPA related from dental biomaterials were first reported in a study that assessed dental sealants. BPA is known to cause skin allergies,⁶ adverse effects on the reproductive systems of animals,⁷ cell death via necrosis,⁸ and high hemolytic activity.⁹ The role of BPA as a potent endocrine disruptor with a weak estrogenic effect is well known. Terhune et al¹⁰ in their study have suggested

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Graph-4: Ultradent (USA)

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Graph-5: EVA, Endent Pvt.Ltd (Delhi, India)

clinicians against the prolonged contact of thermoplastic materials with the patient's gingiva, mucosa or skin.

This study will only provide a quantitative measure to which a polymer leached oxidizable, organic matter. While the latter may not always be harmful, as a general rule the less leaching, the safer the product is considered. Also, the amount of leaching quantified may not show significant clinical alterations in patients subjected to these materials during treatment rather a relative comparison between the various options available to clinicians. The results of this study show the amount of leaching in a comparative manner that helps in the optimization of the product by the manufacturer, the ease

of selection of the least harmful product for the clinician and the researcher and also enhances the ability of the researcher to study the progress of leaching in time.

The shortcomings of this study are that it is very elaborate, expensive and requires specific machinery and trained personnel to perform the test.

CONCLUSION

Within the limitations of this in vitro study, it was found that the amounts of leaching varied with the Ultradent (USA) with the greatest amount of leaching followed by EVA, Endent Pvt. Ltd (Delhi, India), 3A Medes (Korea), CA Scheu (Germany) whereas Avac R, Jaypee (Kerala, India) with the least leaching potential among the five samples studied.

These results help in concluding that Avac R, Jaypee (Kerala, India) is relatively superior in terms of its biocompatibility with the oral tissues as compared to the other materials tested. Also, though the overall amount of leaching from each product may not be clinically significant, as a general guideline, the safety of the product is inversely proportional to the amount of leaching.

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Source of Support: Nil; **Conflict of Interest:** None

Submitted: 23-03-2016; **Published online:** 30-04-2016