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Particulate production during debond of fixed appliances: a laboratory investigation and randomised clinical trial assess the effect of using flash free ceramic brackets.

P Vig

Specialist Registrar in Orthodontics, Child Dental Health, Bristol Dental School, University of Bristol, Lower Maudlin Street Bristol, BS1 2LY, UK. paragh_vig@hotmail.co.uk

N E Atack

Consultant Orthodontist, Child Dental Health, Bristol Dental School, University of Bristol, Lower Maudlin Street Bristol, BS1 2LY, UK. nikki.atack@bristol.ac.uk

JR Sandy

Professor of Orthodontics, Child Dental Health, Bristol Dental School, University of Bristol, Lower Maudlin Street Bristol, BS1 2LY, UK. jonathan.sandy@bristol.ac.uk

M Sherriff

Visiting Professor, Child Dental Health, Bristol Dental School, University of Bristol, Lower Maudlin Street Bristol, BS1 2LY, UK. martyn.sherriff@brisol.ac.uk

AJ Ireland

Professor of Orthodontics, Child Dental Health, Bristol Dental School, University of Bristol, Lower Maudlin Street Bristol, BS1 2LY, UK. tony.ireland@bristol.ac.uk

Corresponding author:

Prof AJ Ireland, Child Dental Health, Bristol Dental School, University of Bristol, Lower Maudlin Street Bristol, BS1 2LY, UK. tel +441173429552, tony.ireland@bristol.ac.uk

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Particulate production during debond of fixed appliances: a laboratory investigation and randomised clinical trial assess the effect of using flash free ceramic brackets.

Abstract

Introduction: The aim of this laboratory and randomised clinical trial was to investigate particulate production at debond and enamel clean up following the use of flash free ceramic brackets and to compare them with non-flash free metal and ceramic brackets.

Methods:

In the laboratory study, brackets were bonded to bovine teeth. Following 24hours immersed in water the brackets were debonded, the adhesive remnant scores noted and the enamel cleaned up with rotary instruments. Four bracket/adhesive combinations and two different enamel pre-treatment regimens were tested including metal and ceramic brackets (conventional, APC and APC flash-free); conventional acid etch and self-etching primer. Quantitative (Mg m^{-3}) and qualitive analysis of particulate production was made in each case.

In the clinical trial, 18 patients treated using fixed appliances were recruited into this 3-arm parallel design RCT. They were randomly allocated to one of three groups, an experimental flash free ceramic bracket group, a non-flash free ceramic or metal bracket group. Eligibility criteria included patients undergoing non-extraction upper and lower fixed appliance therapy. At completion of treatment the brackets were debonded and the primary outcome measure was particulate concentration (Mg m^{-3}). Randomisation was by means of sealed envelopes. Data were analysed using quantile plots and linear mixed models (LMM). The effect of etch, bracket and stage of debond of clean up on particle composition was analysed using mixed effects regression.

Results: In the laboratory study the Clarity APC™ brackets produced the highest particulate concentration. Although statistically significantly higher than the metal and conventional ceramic brackets, this was not significantly higher than the ceramic flash free brackets. In the clinical study there was no statistically significant effect of bracket type on particulate concentration (p=0.29). This was despite three patients with APC Flash Free and one patient with conventional Clarity (with 1 bracket) having one or more ceramic brackets fracture at debond requiring removal. No adverse events reported.

Conclusions: Particulates in the inhalable, thoracic and respirable fractions were produced at enamel clean up with all bracket types. Although Clarity APC™ and Clarity APC Flash Free brackets produced the highest concentrations in the laboratory study, there was no difference between any of the brackets in the clinical trial.

Registration: The trial was not registered

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Introduction

At the completion of orthodontic treatment with fixed appliances, the removal of attachments and residual adhesive can lead to the production of visible clouds of dust, aerosols or splatter into the air around both the patient and operator. These particles are either produced directly by the agglomeration of multiple finer particles, or by the chemical reaction of different vapours produced during the clean-up process. Such airborne particulates are classified according to their mass median aerodynamic diameter (MMAD) in micrometres (µm), which is determined by their size, shape and density, not simply their geometric diameter. This is important, because particles with different geometric diameters may behave similarly in terms of how they move within an air stream.

Splatter particles usually range from 50 to 100 µm in MMAD, whereas aerosols comprise particles less than 50 µm in MMAD[1]. Of most importance are those particles less than 10 µm (PM_{10}) in MMAD, as these are most likely to be inhaled and deposited within the human respiratory system. Of these, the larger particles may reach the pharynx, trachea and perhaps the primary bronchi and will eventually be cleared by the mucociliary escalator. However, the smallest particles, less than 1 µm in aerodynamic diameter, will reach the terminal alveoli of the lungs, which is beyond the mucociliary escalator, meaning their clearance will be delayed until they can be cleared by alveolar macrophages[2]. This can have potentially harmful effects on respiratory health. Even smaller particles, referred to as ultrafines and less than 0.1 µm in size, might not only be deposited in the terminal alveoli, but translocate the alveolar walls into the pulmonary interstitium[3] or blood stream[4,5]. Studies on rats have demonstrated that ultrafine particles in the lungs elicit a greater inflammatory response than larger particles, per given mass[6].

Previous research, investigating the particulates released during orthodontic debond and enamel clean up, has reported that particles are produced within both the inhalable and respirable fractions[7,8,9] . They have been found to comprise various elements including: calcium, phosphorus, carbon, aluminium, iron, nickel, strontium, tungsten and silicon. The calcium and phosphorus were most likely from the enamel surface[10]. The aluminium and silicon were most likely from the polyalkenoate (glass-ionomer) cement and composite resin used to bond the molar bands and brackets to the teeth. The iron was thought to originate from the hand piece head and ball bearings[8], and the tungsten from the slow speed tungsten carbide burs used at enamel clean up[7].

When comparing metal versus ceramic bracket debonds *in vitro*, Johnston *et al*.[9]found more particulates were produced during the debond and clean-up following the use of metal brackets. However, if the ceramic brackets were fractured during debond and had to be removed using a high-speed diamond bur with a water coolant spray, more particulates were produced when compared to ceramic brackets that debonded without fracturing.

Since their introduction, ceramic brackets have undergone a number of refinements, including different bracket base designs and the addition of adhesive to the bracket base by the manufacturer, known as adhesive pre-coat (APC). Most recently, 3M Unitek have developed ceramic Clarity APC Flash free Adhesive brackets, where the adhesive is contained within a form-fitting fibre mat on the base of the bracket. When the APC flash free adhesive coated bracket is placed on the etched enamel surface, the non-woven fibre mat is compressed and the adhesive spreads out and conforms to the tooth surface. However, just as importantly, when the mat decompresses on removal of the seating force, any excess adhesive is pulled back towards the bracket base at the periphery. The result is a uniform and consistent contact between the bracket base and tooth surface with no flash to remove either at the time of placement, or at the time of bracket removal and enamel clean up following treatment. When removing ceramic brackets at the completion of treatment, manufacturers recommend that any excess adhesive (spew fillet) is removed prior to debonding the bracket, in order to make the process easier and with a reduced risk of enamel or ceramic bracket fracture[11]. With flash free brackets this stage can be omitted. Therefore, provided the ceramic bracket doesn't fracture at debond, the number of inhalable and respirable particles produced might be less than with more conventional ceramic brackets.

The aims of this research were therefore:

1. To investigate the relationship between bracket type (Metal vs Ceramic) and adhesive (non APC vs APC vs Flash free APC) on the particulates produced during both simulated and clinical debond and enamel clean up.

2. To investigate whether differences between enamel surface preparation regimes prior to bracket bonding influence residual adhesive quantity and subsequent particulate production during enamel clean up.

Hypotheses:

The null hypothesis (H_0) for this research was no difference between the particulate concentration produced at debond with any of the bracket types

Materials and Methods

The research project focused on debonding of brackets and subsequent enamel clean up and was divided into two parts:

1. A laboratory based investigation using bovine teeth, debonding four bracket types, and using two different enamel surface pre-treatment regimens.
2. A clinical trial on 18 patients using 3 different bracket types, following conventional acid etching of the enamel using 37% *o*-phosphoric acid.

Particulate concentration (Mg m^{-3}) was measured using a Personal Data Ram pDr-1200 real time monitor (Thermo Electron, USA). A Marple Cascade Impactor (Thermo Electron, USA) was used to collect respirable particulate fractions and to permit SEM and EDX analysis.

Laboratory simulated debond of fixed appliances

This part of the study comprised both a qualitative and a quantitative investigation into the particulate production during simulated debond and enamel clean up on bovine teeth, using four bracket/adhesive groups, namely:

1. Metal Bracket - Victory with separately applied Transbond XT adhesive (3M Unitek, USA)
2. Ceramic Bracket - Clarity with separately applied Transbond XT adhesive (3M Unitek,USA)
3. Ceramic Bracket - Clarity APC II/PLUS (adhesive pre-coated) (3M Unitek, USA)
4. Ceramic Bracket - Clarity APC Flash free (adhesive pre-coated) (3M Unitek, USA)

340 bovine mandibular incisors were sourced, disinfected with 1.0% chloramine-T trihydrate bacteriostatic/ bactericidal solution for one week, and thereafter stored in distilled water and refrigerated prior to use in accordance with ISO/TS 11405:2015. Just prior to use, 20 teeth at a time were set up in plaster of Paris using Perspex templates to simulate an upper

and lower dental arch, 2^{nd} premolar to 2^{nd} premolar tooth (Figure 1). A total of eight complete upper and lower arches were set up in this way.

For each of the four bracket/adhesive combinations two different enamel pre-treatment regimens were also tested:

1. Conventional acid etch (AE) regimen using 37% *o*-phosphoric acid**:**

- Teeth were not pumiced prior to etching, as is usual practice.
- The enamel was etched using 37% *o*-phosphoric acid for 30 seconds per tooth, followed by washing with water and then dried until frosty white in appearance using oil-free compressed air in a 3 in 1 syringe.
- A thin layer of Transbond XT primer was painted onto the etched tooth surface using a micro brush.

2. Self-Etching Primer (SEP) regimen using 3M Unitek Transbond Plus Self-Etching Primer:

- The enamel was pumiced using a slurry of pumice in water in a slow speed handpiece with a rubber polishing cup. It was then washed and dried using oil free compressed air.
- SEP was rubbed onto the enamel surface for 5 seconds per tooth following the manufacturer's recommended instructions.
- The tooth surfaces were then gently air dried for 10 seconds.

In all cases, except for the flash free brackets, once the bracket had been applied to the pre-treated enamel surface, the excess adhesive was removed using a Mitchell's trimmer where appropriate, and each bracket was light cured using a XL3000 halogen curing light (3M Unitek, St Paul, USA) for 10 seconds per interspace, totalling 20s per tooth. The light was tested during the bonding procedures using the inbuilt lux meter to ensure consistency in performance throughout the experimental period.

Following the bond up and prior to debond, the teeth in their plaster arches were submerged in water at 37^{o}C for 24 hours in order to try and replicate the oral environment.

The debonding protocol varied depending on the bracket type being investigated, namely:

<u>Metal Victory brackets:</u>

1. Debonded using debonding pliers.
2. Adhesive Remnant Index score (ARI) noted for each tooth.
3. Residual adhesive on the enamel surface removed with a spiral fluted tungsten carbide bur (Model 1172, Orthocare Ltd, UK) in a slow speed hand piece under dry conditions. A new bur was used for each arch.

<u>Conventional Clarity and Clarity APC II/PLUS brackets:</u>

1. Any excess adhesive around the bracket periphery was removed using a spiral fluted tungsten carbide bur (Model 1172, Orthocare Ltd, UK) in a slow speed hand piece under dry conditions.
2. Debonding was carried out in accordance with the manufacturer's instructions; using ceramic bracket debonding pliers (Unitek™ Self-ligating bracket debonding instrument, REF 804-170, 3M, USA) in order to collapse each bracket mesio-distally along the stress intensifying vertical notch in the ceramic bracket.
3. Adhesive Remnant Index score (ARI) was noted for each tooth.

4. Residual adhesive on the enamel surface was removed with a spiral fluted tungsten carbide bur in a slow speed hand piece under dry conditions. A new bur was used for each arch.
5. Any brackets that fractured during debond were removed using a diamond bur (Model 521M, Minerva Dental Ltd, UK) and high speed hand piece with water coolant, followed by removal of residual adhesive on the enamel surface using a spiral fluted tungsten carbide bur in a slow speed hand piece under dry conditions.

<u>Flash free brackets:</u>

1. Debonded according to the manufacturer's instructions using ceramic bracket debonding pliers to collapse each bracket.
2. Adhesive Remnant Index score (ARI) noted for each tooth.
3. Residual adhesive on the enamel surface was removed with a spiral fluted tungsten carbide bur in a slow speed hand piece under dry conditions. A new bur was used for each arch.
4. Any brackets that fractured during debond were removed using a diamond bur and high speed hand piece with water coolant, followed by removal of residual adhesive on the enamel surface using a spiral fluted tungsten carbide bur in a slow speed hand piece under dry conditions.

Air sampling using the Personal Data Ram particulate monitor (pDr-1200)

The pDr-1200 is a real time active air-sampling machine that is designed to measure the concentration of airborne particulate matter in Mg m^{-3}. The aerodynamic particle cut off point of the sampler can be determined by adjusting the flow rate of the attached air pump.

For each experiment the pump flow rate was set to 2.1 litres per minute, which correlates with an aerodynamic diameter cut off point of 5 µm, or fully respirable particles.

Each experiment was carried out in a well-ventilated single side surgery that had not been used for at least 12 hours prior to air sampling. Each air sampling run commenced by zeroing the pDr-1200 following the manufacturer's instructions, and the data recorder was set to record the concentration of particles every 15 seconds. The cyclone inlet of the pDr-1200 was then positioned at a distance of 30 cm from the bonded bovine teeth. This was done in order to simulate the typical distance the clinician's nose and mouth would be from the patient's mouth in the clinical situation. Prior to the removal of the brackets, the sampler was left to run for 2 minutes in order to sample the background air. The sampler was left to run until each part of the debond and subsequent enamel clean-up was completed and for at least 20 minutes. After which the green zeroing filter was reattached to the cyclone inlet for a further 2 minutes before switching off the pump. Therefore, although the total sampling observations in each case varied, sampling was for at least 22 minutes. Zeroing at the end of each sample run was carried out to prevent dust settling in and contaminating the sensing chamber of the air monitor.

A total of 9 individual sample runs were carried out using the pDr-1200 in order to test the effect of enamel preparation regime and bracket type on respirable particulate concentration. A summary of the laboratory experiments using the pDr-1200 is in Table I.

In order to be able to analyse specific aerodynamic particle sizes produced during both simulated and clinical debonds, the Marple Cascade Impactor was used (Figure 2). This enables particulates to be filtered and collected according to aerodynamic diameter for analysis using Scanning Electron Microscopy (SEM) and Energy Dispersive X-ray (EDX). For both the laboratory and clinical experiments the Marple Cascade Impactor was adapted so as to use 5 of its potential 8 stages. Stages 1-4 are the collection stages where mixed cellulose ester (MCE) 0.8 pm pore, 34 mm diameter filters were used. Stage 5 on the impactor contained the end collection filter, namely a PVC solid 5 mm pore, 34 mm diameter filter. Unlike the pDr-1200, the Marple Cascade Impactor is a compact personal air particulate sampler that can be worn on the lapel of the clinician during the sampling experiments. The inlet of the Marple Cascade Impactor was held at 30cm from the teeth being debonded, similar to the pDr-1200, in order to replicate the distance the operator would be from the brackets in the clinical situation. A total of 8 experiments were repeated using the Marple Cascade Impactor as summarised in Table II.

As with the pDr-1200, all experiments were carried out in a well-ventilated side surgery that hadn't been used for 12 hours. The Impactor was held at a distance of 30 cm from the bovine teeth. The pump was started and the air was sampled for 1 minute prior to debonding the appliance. The brackets were removed using the same debonding protocols used for the pDr-1200, which varied depending on the bracket type. The total sampling time was 22 minutes per experiment. A diamond bur and a fast handpiece with water coolant was used where ceramic brackets had fractured during the debonding stage (Table III). As with the pDr-1200 experiments, no HVE was used during the air sampling. Following each experiment, the filters from each sampling stage were removed and placed into individual air-tight plastic containers before being analysed using SEM and EDX.

Clinical study

The final part of the research involved a clinical study to evaluate particulate production and particle type at debond in the clinical setting. The 3 bracket types evaluated in the study were:

Metal Brackets:

1. Victory with Transbond XT adhesive (Control) (3M Unitek, USA)

Ceramic Brackets:

2. Clarity with Transbond XT adhesive (3M Unitek, USA)
3. Clarity APC Flash free (adhesive precoated) (3M Unitek, USA)

Ethical Approval

Ethical approval was gained following application to NRES Committee South Central-Hampshire B (REC reference 15/SC/0312) to carry out the service evaluation on 18 patients at the Orthodontic Department, Royal United Hospitals NHS Foundation Trust, Bath. As part of attaining this approval, patient and parent information, consent and assent forms were compiled. Local Research and Development approval was also granted. Additionally, all clinicians carrying out consent during patient recruitment had undergone Good Clinical Practice (GCP) training.

Participants, eligibility, settings and consent

A total of 18 patients were recruited to participate in the clinical study and who fulfilled the inclusion and exclusion criteria, namely:

1) Patients requiring fixed appliances without the removal of any permanent teeth
2) Patients with no medical contraindications to the use of fixed appliances
3) Patients who demonstrated a good standard of oral hygiene
4) Patients not requiring orthognathic surgery as a part of their treatment

Patients suitable for the study were approached during their orthodontic assessments and information leaflets were given regarding the purpose of the study. If the patients agreed to participate, a consent form was completed at the following appointment. For patients aged below 16 years of age, the patients completed an assent form and their parent/legal guardian completed a consent form. Using sealed envelopes with the numbers 1 to 18, which corresponded to the 3 treatment groups, patients were randomly allocated so that 6 patients each received either Victory, Clarity (Non-APC) or Clarity Flash free brackets for their upper arch teeth (upper right second premolar to upper left second premolar)(Figure 3). All patients had Victory metal brackets fitted in the lower arch. This was done to best replicate common practice when using ceramic brackets and to avoid damage to upper incisors if they should occlude with lower arch ceramic brackets. Additionally, on all four 1st molar teeth, orthodontic bands (3M Unitek, St Paul USA) were used and were cemented in place using glass polyalkenoate cement (Ketac Cem, 3M Unitek). Brackets were bonded as per the laboratory protocol, but in all cases using conventional 37% *o*-phosphoric acid etch (AE) enamel pre-treatment. There was an additional appointment prior to the bond up in order to place elastomeric separators between the first molars, to facilitate the placement of the molar bands during the bond up appointment.

Patients had their fixed appliances adjusted on average at 5-8 week intervals until their treatment was complete. If patients attended with a bracket(s) having been debonded partway through their treatment, this was replaced with an identical bracket.

At the visit prior to the patient being ready for their debond, consent was reconfirmed for participation in the study. Any second molar teeth that may have been bonded or banded during the treatment (e.g. for correction of cross bites or tooth alignment) were removed from the appliance at this visit and the cement was cleaned up on these teeth only, so that only 24 teeth were being sampled during the particulate collection day.

Sample Size calculation

Sample size calculations were not performed for either the laboratory or clinical study due to the mixed elemental nature of the particulates produced.

Blinding

It was not possible to blind either the patient or operator to the bracket/adhesive type

Debond Protocol for clinical study

Irrespective of the operator who carried out the orthodontic treatment, all patients in the study had their fixed appliances removed by the same clinician (PV) for standardisation. Each debond was performed in a well ventilated single surgery that had not been used for at least 12 hours previously.

Prior to bracket removal all auxiliary appliances were removed from the mouth, as was the orthodontic arch wire. Debonding of the brackets was carried out according to the manufacturer's instructions for the individual bracket type. The debond protocol was followed as for the laboratory study; with conventional debonding pliers being used for the metal brackets (Victory) and ceramic debonding pliers used for the ceramic brackets (APC II and Flash free). A tungsten-carbide bur and slow handpiece was used to remove the flash around each bracket on the Clarity APC II non-coated brackets, but this was not done for the Flash free or metal Victory brackets. Molar bands were removed using debanding pliers. The ARI scores on each tooth (except 1st molar teeth) were documented and the subsequent cement removed from the enamel using a tungsten-carbide bur and slow handpiece, as per normal clinical practice. If any ceramic brackets fractured, this was noted and the remaining fractured bracket was removed from the tooth using a diamond bur and fast handpiece with water coolant. HVE was used throughout the experiment, held at 30cm from the patients' mouth by the dental assistant, as per normal clinical practice. Wherever the water coolant and fast handpiece was used (in cases with fractured ceramic brackets), a salivary ejector was placed intraorally for patient comfort.

The first three patients in each group had their debond carried out whilst using quantitative air sampling via the pDr-1200 air monitor, and the remaining three had qualitative sampling using the Marple Cascade Impactor, and in this case the filters were subsequently analysed using the SEM and EDX analysis. In this latter qualitative part of the study 1 patient in the Clarity non APC (Clarity /Transbond XT) dropped out.

Results

The laboratory and clinical data were analysed using Stata Version 15, (Stata Corp, College Station, Texas, USA) with a predetermined significance level of $\alpha = 0.05$. Quantile plots were used to show ordered values against associated cumulative probabilities for particulate concentrations. ARI scores were analysed using spine plots. The data were analysed within the framework of linear mixed models (LMM) allowing for repeated measurements on the same patient. The effect of etch, bracket and stage on particle composition was analysed using mixed effects regression, and ordinal logistic regression was used for the ARI data. Where appropriate Šídák's method was used to adjust multiple comparisons.

Figure 4a. conventional etch and Figure 4b. self-etching primer are the quantile distribution plots for particulate concentration for the four bracket types at background, debond and enamel clean up in the laboratory experiment. The majority of the plots show an approximately normal distribution of particulates and there appears to be little difference between the samples at each stage of appliance removal, except for the Clarity APC II bracket at the enamel clean-up stage. In the laboratory particulate concentration tests two Clarity APC II brackets and one conventional Clarity bracket fractured at debond (Table I). The ceramic fragments in each case were removed using a diamond bur in a high-speed hand piece under water coolant spray.

LMM was used to investigate the effect of etch, bracket and stage of debond . However, this requires an assumption that the residuals are normally distributed, which was not always the case (Figure 4). A logarithmic transformation of the data resulted in normally distributed residuals and the results were analysed using mixed effects regression and Šídák's method to adjust multiple comparisons. All three main effects, etch type, bracket type and stage of debond were statistically significantly different ($p=0.001$). Conventional etch and SEP enamel pre-treatments were statistically significantly different (Table IV), with conventional etch associated with the higher particulate concentration. There was no statistically significant difference between the background particulate levels and those observed at debond (including any flash removal), but there was a statistically difference between these two stages and the number of particulates produced at enamel clean up (including the removal of any ceramic bracket remnants) (Table IV), with greater concentrations produced at enamel clean up. There was also no statistically significant difference in the particulate concentration produced between Victory™ and Clarity™ brackets, and no difference between Clarity APC™ and Clarity APC™ Flash Free brackets (Table IV). However, both pairs were statistically significantly different from each other. Clarity APC™ demonstrated the highest particulate concentration.

In the case of the clinical trial, the quantile plots (Figure 5) once again show there are extreme values for particulate concentration at the enamel clean up stage. A logarithmic transformation was required to produce normal residuals and LMM analysis allowed for clustered measurements on the same patient. There was found to be no statistically significant effect of bracket type on particulate concentration (p=0.29), but there was an effect of stage of debond, with the greatest concentration of particulates produced at enamel clean up (p=0.001). When looking at the mean concentrations however, the metal Victory brackets appeared to show the greatest concentration of particulates, with little difference between the conventional Clarity and the Clarity Flash free brackets.

As with the laboratory study there was no statistically significant difference between particulate concentration at background and debond (including any flash removal), but these were both significantly different from the concentration produced at enamel clean-up (Table V), which created the highest particulate concentration. In the clinical trial there was no statistically significant effect of bracket type on the concentration of particulates produced. This was despite three patients with APC Flash Free (2 patients with one bracket each and 1 patient with three brackets) and one patient with conventional Clarity (with 1 bracket) having one or more ceramic brackets fracture at debond, which then required a diamond bur in a high-speed hand piece to be used to remove the ceramic remnants.

Analysis of the laboratory ARI values showed there was no statistically significant effect of etch type (p=0.29) or bracket type (p=0.62) on the observed ARI at debond. The majority of the ARI scores were 3, *i.e*. all of the adhesive left on the tooth surface with a distinct impression of the bracket mesh[12]. Similarly, for the clinical trial there was no significant effect of bracket type on observed ARI (p=0.60) and the majority were 3.

As part of the clinical study, and in order to compare the results with the COSSH Workplace Exposure Limits (WEL), the potential particulate exposure (Mg m^{-3}) over an 8 hour period was calculated for all three brackets types tested, using the data from the pDr-1200 (Table V).

The qualitative data obtained using the Marple Cascade Impactor, in both the laboratory and clinical settings, were analysed using both SEM and EDX analysis. Although the particulate compositions varied to some extent, the most commonly occurring elements in all instances were calcium, phosphorus, silicon and aluminium. This was consistent for each of the bracket types tested and they were usually found on each of the four impactor filters. Other less commonly detected elements included iron, tungsten, sodium, chlorine, magnesium, zinc, manganese and zirconia.

Discussion

In the present study the MMAD cut off limit for the quantitative pdR-1200 was ≤ 5 µm and for the qualitative Marple Cascade Impactor the MMAD cut offs were 15 µm, 10.5 µm, 6.93 µm and ≤4.24 µm for filters 1 to 4. Particles were seen on each of the filters in each experiment and were therefore in the inhalable (may reach the nose and pharynx), thoracic (may reach beyond the larynx to the primary bronchi) and respirable fractions (the gaseous exchange regions of the lungs)[13]. This is consistent with previous studies on particulates produced during orthodontic debonds[7,8,9]. Such particles deposited in the upper respiratory tract are likely to be cleared by the ciliated epithelium (mucociliary clearance), whereas those depositing in the lower respiratory tract, where the epithelium is non-ciliated, are most likely to be cleared, and much more slowly, by alveolar macrophages[2]. It is for this reason that smaller particles deposited in the lower parts of the respiratory tract are potentially most hazardous to health.

The aims of the present study were to determine the effect of etch type, bracket type and stage of appliance removal on particulate production. In terms of the enamel pre-treatment, conventional 37% *o*-phosphoric acid etch versus SEP, there was a statistically significant difference in the particulate air concentration, with conventional etch producing a higher concentration of particulates at enamel clean up. However, what is interesting is that there was no such difference in the ARI scores, which were mainly 3, so that in all cases a large amount of residual adhesive had to be removed from the tooth surface at enamel clean up.

When considering the effect of bracket type, in the laboratory study there was no statistically significant difference between the metal Victory series bracket and the ceramic

Clarity bracket, but there was between these two and the Clarity APC bracket and the Clarity APC Flash Free bracket. The latter two brackets were not significantly different from each other, but both produced higher particulate concentrations than Victory and Clarity. This might be partially explained by the fracture of two Clarity APC brackets and one Clarity APC Flash Free bracket at laboratory debond, although one Clarity bracket also fractured at debond. It has been shown previously that if a fractured ceramic bracket has to be removed using a diamond bur in a high-speed handpiece, this can significantly increase the concentration of particulates sampled[9] . In the clinical investigation there was no statistically significant effect of bracket type between Victory, Clarity and Clarity APC Flash Free brackets, despite a single bracket fracturing in each of the two ceramic groups. As in the laboratory study, there was no statistically significant effect of ARI in particulate concentration, which in this case is perhaps not surprising as ARI might be expected to correlate with particulate concentration in the absence of ceramic bracket failure. However, when looking just at the mean particulate concentrations, that produced by the metal Victory brackets was higher than with either of the ceramic brackets, which supports the results of Johnston *et al*.[9].

When considering the stage of appliance removal in both the laboratory and the clinical parts of this study, there was no statistically significant difference in particulate concentration between background and debond. It should be remembered that in the case of the Clarity and Clarity APC brackets, a tungsten carbide bur in a slow speed handpiece was used around the periphery of each bracket base at the bond line, prior to removing the bracket from the tooth surface. This was done in order to remove any flash and to make bracket removal easier. As a result, it might have been expected that both the metal Victory and the Clarity APC Flash Free brackets might produce lower concentrations of particulates, but this was not the case. In both the laboratory and the clinic, the greatest concentration of particulates was produced at the enamel clean up phase, which is not surprising in view of most of the ARI scores being 3.

The potential particulate exposures over an 8 hour period were calculated and are illustrated in Table V. It can be seen that the time weighted average over 8 hours WEL for respirable dusts[14] of 4Mg m^{-3} was not exceeded with any of the bracket types over an 8 hour period. It should be remembered that all of these clinical experiments were carried out in the presence of HVE, as recommended by Johnston *et al.*[9] , and debonds are not usually performed one after the other continuously over an 8 hour period. As in the laboratory experiments, silica was found to be present frequently during the EDX analysis of the filters collected for three bracket types. If silica formed the entirety of the particulate fraction produced following debond and enamel clean up, the time weighted average over 8 hours WEL for silica[15] of 0.1 Mg m^{-3} would potentially have been exceeded with all bracket types if successive debonds were done over 8 hours. What is unknown is the precise fraction of the total that is comprised of silica, as the analysis of particulate composition was qualitative and not quantitative. Silica was just one of the elements detected, with the others including calcium and phosphorous, most likely from the enamel surface, as well as aluminium from the band cement and iron and tungsten from the handpiece and burs[7,8]. Although there are work place limits in place, a recent study has suggested that sampling studies often overestimate the concentration of particulates that will reach the lower respiratory tract, as penetration will be affected by breathing habits e.g. nose versus mouth breathing and breathing patterns, which in turn are affected by gender, age and activity[16] . As already mentioned, additional measures such as the use of a face mask or HVE have been recommended to reduce particulate inhalation during orthodontic debond[9] .

Limitations

It was not possible to blind the operator with respect to bracket type at debond in either the laboratory or clinical studies. In addition, although particulate concentration and likely site of deposition within the respiratory system could be determined, the identification of the particulates was, by its very nature, qualitative and elemental. Therefore, it was not possible to identify the concentration of particles with a specific composition.

Generalisability

Generalisability might be limited due to the single centre nature of the trial and because debond and enamel clean up in each case was performed by a single operator (PV).

Conclusions

The following conclusion can be reached as a result of this study:

1. Removal of fixed appliances at the end of treatment leads to the production of particulates in the inhalable, thoracic and respirable fractions and as such may penetrate the deeper parts of the respiratory tract
2. The use of conventional etch leads to a greater concentration of particulates at appliance removal than the use of SEP even though an ARI scores of 3 was seen in most cases
3. Enamel clean up is the stage at which most of the particulates are produced.

4. The use of Clarity APC Flash Free ceramic brackets has no effect on the concentration of particulates produced when compared to Clarity and Victory brackets in the clinical setting.
5. The use of Clarity APC Flash Free ceramic brackets does not lead to more particulates being produced at debond and enamel clean up in the clinical setting

Figures

Figure 1: Set up of bovine teeth in plaster of Paris.

Figure 2a: Marple Cascade Impactor fully assembled.

Figure 2b: Marple Cascade Impactor with inlet 30cm from teeth, and pump attached

Figure 3: CONSORT flow diagram

Figure 4a: Quantile distribution plots of particulate concentration (Mg m^{-3}) at background, debond and enamel clean up for each of the four bracket types and enamel pre-treatment using 37% *o*-phosphoric etch.

Figure 4b. Quantile distribution plots of particulate concentration (Mg m^{-3}) at background, debond and enamel clean-up for each of the four bracket types and enamel pre-treatment using the self-etching primer

Figure 5: Clinical trial quantile distribution plots of particulate concentration (Mg m^{-3}) at background, debond and enamel clean-up for each of the three bracket types

Tables

Table I: Summary of the quantitative laboratory experiments on particulate concentration at simulated debond and enamel clean up using the using the pDr-1200 (AE= acid etch, SEP= self-etching primer).

Table II: Summary of qualitative laboratory experiments using the Marple Cascade Impactor as simulated debond and enamel clean up (AE= acid etch, SEP= self-etching primer).

Table III Pairwise comparisons of predictive margins of particulate concentration (Mg m^{-3}) for etch type, appliance removal stage and bracket type in the laboratory study. Those groups sharing a letter are not significantly different at the 5% level.

Table IV Pairwise comparisons of predictive margins of particulate concentration (Mg m^{-3}) for appliance removal stage and bracket type in the clinical study. Those groups sharing a letter are not significantly different at the 5% level.

Table V The observed mean particulate concentration (Mg m^{-3}) produced at debond for each of the three bracket types in the clinical study, along with the potential particulate exposures over eight hours.

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