Particulate production during debonding of fixed appliances: Laboratory investigation and randomized clinical trial to assess the effect of using flash-free ceramic brackets

Paragh Vig, Nikki E. Atack, Jonathan R. Sandy, Martyn Sherriff, and Anthony J. Ireland
Bristol, UK

Introduction: The aim of this laboratory and randomized clinical trial was to investigate particulate production at debonding 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. After 24 hours of immersion in water, the brackets were debonded, the adhesive remnant scores noted, and the enamel cleaned with the use of rotary instruments. Four bracket-adhesive combinations and 2 different enamel pretreatment regimens were tested, including metal and ceramic brackets (conventional, adhesive precoat [APC], and APC flash-free) and conventional acid etch and self-etching primer. Quantitative (mg/m^3) and qualitative analysis of particulate production was made in each case. In the clinical trial, 18 patients treated with the use of fixed appliances were recruited into this 3-arm parallel-design randomized controlled trial. They were randomly allocated to 1 of 3 groups: experimental flash-free ceramic bracket or non–flash-free ceramic or metal bracket group. Eligibility criteria included patients undergoing nonextraction maxillary and mandibular fixed appliance therapy. At completion of treatment, the brackets were debonded, and the primary outcome measure was particulate concentration (mg/m^3). Randomization was by means of sealed envelopes. Data were analyzed with the use of quantile plots and linear mixed models. The effect of etch, bracket, and stage of debonding of clean-up on particle composition was analyzed with the use of mixed-effects regression. **Results:** In the laboratory study, the APC brackets produced the highest particulate concentration. Although statistically significantly higher than the metal and conventional ceramic brackets, it 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 3 patients with APC flash-free and 1 patient with conventional Clarity (with 1 bracket) having 1 or more ceramic bracket fracture at debonding 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 APC and 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. **Funding:** This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors. (Am J Orthod Dentofacial Orthop 2019;155:767-78)

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 patient and operator. These particles are produced either directly by the agglomeration of multiple finer particles or by the chemical reaction of different vapors produced during the clean-up process. Such airborne particulates are classified according to their mass median aerodynamic diameter (MMAD) in

Child Dental Health, Bristol Dental School, University of Bristol, Bristol, UK.
All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest, and none were reported.
Address correspondence to: Anthony J. Ireland, Child Dental Health, Bristol Dental School, University of Bristol, Lower Maudlin Street, Bristol, BS1 2LY, UK; e-mail, tony.ireland@bristol.ac.uk.
Submitted, November 2018; revised and accepted, February 2019.
0889-5406/$36.00

https://doi.org/10.1016/j.ajodo.2019.02.010

micrometers (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 <50 μm in MMAD.[1] Of most importance are those particles <10 μm (PM_{10}) in MMAD, because 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, <1 μm in MMAD, 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 <0.1 μm in size, not only may be deposited in the terminal alveoli, but also may 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 debonding and enamel clean-up, has reported that particles are produced within both inhalable and respirable fractions.[7-9] They have been found to comprise various elements including: calcium, phosphorus, carbon, aluminum, iron, nickel, strontium, tungsten, and silicon. The calcium and phosphorus were most likely from the enamel surface.[10] The aluminum 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 handpiece 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 debonding in vitro, Johnston et al[9] found that more particulates were produced during the debonding and clean-up after the use of metal brackets. However, if the ceramic brackets were fractured during debonding and had to be removed with the use of a high-speed diamond bur with a water coolant spray, more particulates were produced compared with 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 precoat (APC). Most recently, 3M Unitek (St Paul, Minn) have developed ceramic Clarity APC flash-free adhesive brackets, where the adhesive is contained within a form-fitting fiber mat on the base of the bracket. When the APC flash-free adhesive-coated bracket is placed on the etched enamel surface, the nonwoven fiber 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 toward 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 after treatment. When removing ceramic brackets at the completion of treatment, manufacturers recommend that any excess adhesive (spew fillet) is removed before debonding the bracket, to make the process easier and for reduced risk of enamel or ceramic bracket fracture.[11] With flash-free brackets this stage can be omitted. Therefore, provided the ceramic bracket does not fracture at debonding, the number of inhalable and respirable particles produced might be less than with more conventional ceramic brackets.

The aims of the present 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 debonding and enamel clean-up; and (2) to investigate whether differences between enamel surface preparation regimes before bracket bonding influence residual adhesive quantity and subsequent particulate production during enamel clean-up. The null hypothesis for this research was no difference between the particulate concentration produced at debonding with any of the bracket types.

MATERIAL AND METHODS

The research project focused on debonding of brackets and subsequent enamel clean-up and was divided into 2 parts: (1) a laboratory-based investigation with the use of bovine teeth, debonding 4 bracket types, and using 2 different enamel surface pretreatment regimens; and (2) a clinical trial on 18 patients with the use of 3 different bracket types, following conventional acid etching of the enamel with 37% *o*-phosphoric acid.

Particulate concentration (mg/m^3) was measured with the use of a personal DataRAM (pDR)-1200 real-time monitor (Thermo Fisher Scientific). A Marple Cascade Impactor (Thermo Fisher Scientific) was used to collect respirable particulate fractions and to permit scanning electron microscopic (SEM) and energy dispersive x-ray spectroscopic (EDX) analysis.

Fig 1. Set up of bovine teeth in plaster of Paris.

The laboratory-simulated debonding of fixed appliances comprised both a qualitative and a quantitative investigation into the particulate production during simulated debonding and enamel clean-up on bovine teeth with the use of 4 bracket/adhesive groups, namely: Victory metal brackets with separately applied Transbond XT adhesive (3M Unitek), Clarity ceramic brackets with separately applied Transbond XT adhesive (3M Unitek), Clarity APC II/Plus adhesive precoated ceramic brackets (3M Unitek), and Clarity APC Flash-Free adhesive precoated ceramic brackets (3M Unitek).

A total of 340 bovine mandibular incisors were obtained, disinfected with the use of 1.0% chloramine-T trihydrate bacteriostatic/bactericidal solution for 1 week, and thereafter stored in distilled water and refrigerated before use in accordance with ISO/TS 11405:2015. Just before use, 20 teeth at a time were set up in plaster of Paris with the use of Perspex templates to simulate an upper and lower dental arch from second premolar to second premolar (Fig 1). A total of 8 complete upper and lower arches were set up in this way.

For each of the 4 bracket/adhesive combinations 2 different enamel pretreatment regimens were also tested: (1) In a conventional acid etch (AE) regimen with the use of 37% *o*-phosphoric acid, teeth were not pumiced before etching, as is usual practice, the enamel was etched with the use of 37% *o*-phosphoric acid for 30 seconds per tooth, followed by washing with water, and then dried until frosty white in appearance with the use of oil-free compressed air in a 3-in-1 syringe, and a thin layer of Transbond XT primer was painted onto the etched tooth surface with the use of a microbrush; and (2) in a self-etching primer (SEP) regimen with the use of 3M Unitek Transbond Plus Self-Etching Primer, the enamel was pumiced with the use of a slurry of pumice in water in a slow-speed handpiece with a rubber polishing cup, it was then washed and dried with the use of oil-free compressed air, SEP was rubbed onto the enamel surface for 5 seconds per tooth following the manufacturer's recommended instructions, and 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 pretreated enamel surface, the excess adhesive was removed with the use of a Mitchell trimmer where appropriate, and each bracket was light cured with the use of a XL3000 halogen curing light (3M Unitek) for 10 seconds per interspace, totaling 20 seconds per tooth. The light was tested during the bonding procedures with the use of the built-in lux meter to ensure consistency in performance throughout the experimental period.

After the bond-up and before debonding, the teeth in their plaster arches were submerged in water at 37°C for 24 hours to replicate the oral environment.

The debonding protocol varied depending on the bracket type being investigated. The metal Victory brackets were debonded with the use of debonding pliers, the adhesive remnant index (ARI) was noted for each tooth, and residual adhesive on the enamel surface was removed with the use of a spiral fluted tungsten-carbide bur (Model 1172; Orthocare, U.K.) in a slow-speed handpiece under dry conditions, a new bur being used for each arch. For the Conventional Clarity and Clarity APC II/Plus brackets, any excess adhesive around the bracket periphery was removed with the use of a spiral fluted tungsten-carbide bur (Model 1172; Orthocare) in a slow-speed handpiece under dry conditions, debonding was carried out in accordance with the manufacturer's instructions with the use of ceramic bracket debonding pliers (Unitek self-ligating bracket debonding instrument 804-170) to collapse each bracket mesiodistally along the stress-intensifying vertical notch in the ceramic bracket, the ARI was noted for each tooth, residual adhesive on the enamel surface was removed with the use of a spiral fluted tungsten-carbide bur in a slow-speed handpiece under dry conditions, a new bur being used for each arch, and any brackets that fractured during debonding were removed with the use of a diamond bur (Model 521M; Minerva Dental, U.K.) and high-speed handpiece with water coolant, followed by removal of residual adhesive on

Table I. Summary of the quantitative laboratory experiments on particulate concentration at simulated debonding and enamel clean-up with the use of the pDR-1200

Experiment	*n*	*Bracket type*	*Enamel prep*	*Bracket fracture*	*High-speed handpiece used?*
1	20	Victory	AE	No	–
2	20	Clarity conventional	AE	Yes	Yes
3	20	Clarity APC II	AE	Yes	Yes
4	20	Clarity Flash-Free	AE	No	–
5	20	Victory	SEP	No	–
6	20	Clarity conventional	SEP	No	–
7	20	Clarity APC II	SEP	No	–
8	20	Clarity Flash-Free	SEP	No	–
9 (background)	20	–	–	–	–

the enamel surface with the use of a spiral fluted tungsten-carbide bur in a slow-speed handpiece under dry conditions. The flash-free brackets were debonded according to the manufacturer's instructions with the use of ceramic bracket debonding pliers to collapse each bracket, the ARI was noted for each tooth, residual adhesive on the enamel surface was removed with the use of a spiral fluted tungsten-carbide bur in a slow-speed handpiece under dry conditions, a new bur being used for each arch, and any brackets that fractured during debonding were removed with the use of a diamond bur and high-speed handpiece with water coolant, followed by removal of residual adhesive on the enamel surface with the use of a spiral fluted tungsten-carbide bur in a slow-speed handpiece under dry conditions.

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 cutoff 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 L/min, which correlates with an aerodynamic diameter cutoff 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 before air sampling. Each air sampling run commenced by zeroing the pDR-1200 according to 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 to simulate the typical distance that the clinician's nose and mouth would be from the patient's mouth in the clinical situation.[9] Before the removal of the brackets, the sampler was left to run for 2 minutes to sample the background air. The sampler was left to run until each part of the debonding and subsequent enamel clean-up was completed and for at least 20 minutes. Then 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 with the use of the pDR-1200 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 presented in Table I.

To be able to analyze specific aerodynamic particle sizes produced during both simulated and clinical debonding, the Marple Cascade Impactor was used (Fig 2). This enables particulates to be filtered and collected according to aerodynamic diameter for analysis with the use of SEM and EDX. For both laboratory and clinical experiments the Marple Cascade Impactor was adapted 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 30 cm from the teeth being debonded, similarly to the pDR-1200, to replicate the distance the operator would be from the brackets in the clinical situation. A total of 8 experiments were repeated with the use of the Marple Cascade Impactor, as summarized in Table II.

As with the pDR-1200, all experiments were carried out in a well ventilated side surgery that had not been used for 12 hours. The Impactor was held at a distance of 30 cm from the bovine teeth.[9] The pump was started and the air was sampled for 1 minute before debonding the appliance. The brackets were removed with the use

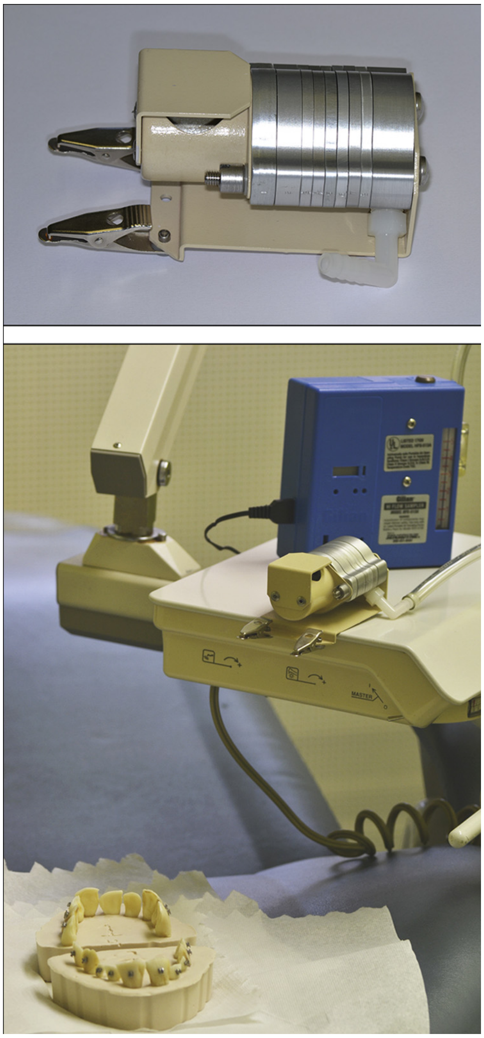

Fig 2. Marple Cascade Impactor. **A,** Fully assembled. **B,** With inlet 30 cm from teeth and pump attached.

of 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 high-volume evacuator (HVE) was used during the air sampling. After each experiment, the filters from each sampling stage were removed and placed into individual air-tight plastic containers before being analyzed with the use of SEM and EDX.

The final part of the research involved a clinical study to evaluate particulate production and particle type at debonding in the clinical setting. The 3 bracket types evaluated in the study were Victory metal brackets with Transbond XT adhesive (Control), Clarity ceramic brackets with Transbond XT adhesive, and Clarity APC Flash-Free (adhesive precoated) ceramic brackets.

Ethical approval

Ethical approval was obtained after application to National Research Ethics Service Committee South Central–Hampshire B (Research Ethics Committee reference 15/SC/0312) to carry out the service evaluation on 18 patients at the Orthodontic Department, Royal United Hospitals National Health Service Foundation Trust, Bath. As part of obtaining this approval, patient and parent information and consent and assent forms were compiled. Local research and development approval was also granted. In addition, all clinicians carrying out the consenting process during patient recruitment had undergone Good Clinical Practice 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: requiring fixed appliances without the removal of any permanent teeth, no medical contraindications to the use of fixed appliances, demonstrating a good standard of oral hygiene, and 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 younger than 16 years, the patients completed an assent form and their parent or 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; Fig 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. In addition, on all 4 first molars, orthodontic bands (3M Unitek) were used and cemented in place with the use of glass polyalkenoate cement (Ketac Cem; 3M Unitek). Brackets were bonded according to the laboratory protocol, but in all cases with the use of conventional 37% *o*-phosphoric acid etch (AE) enamel pretreatment. There was an additional appointment before the bond-up to place elastomeric separators between the first molars to facilitate the placement of the molar bands during the bond-up appointment.

Table II. Summary of qualitative laboratory experiments with the use of the Marple Cascade Impactor at simulated debonding and enamel clean-up

Experiment	*n*	*Bracket type*	*Enamel prep*	*Bracket fracture*	*High-speed handpiece used?*
10	20	Victory	AE	No	–
11	20	Clarity conventional	AE	Yes	Yes
12	20	Clarity APC II	AE	Yes	Yes
13	20	Clarity Flash-Free	AE	Yes	Yes
14	20	Victory	SEP	No	–
15	20	Clarity conventional	SEP	No	–
16	20	Clarity APC II	SEP	Yes	Yes
17	20	Clarity Flash-Free	SEP	Yes	Yes

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

Variable	*Margin*	*SE*	*Šidák group**
Etch			
Conventional	−3.35	0.051	
SEP	−3.60	0.052	
Removal stage			
Background	−4.06	0.095	A
Debonding (flash removal)	−3.97	0.062	A
Enamel clean-up	−2.95	0.052	
Bracket			
Victory	−3.61	0.071	A
Clarity	−3.75	0.074	A
Clarity APC II	−3.25	0.074	B
Clarity APC Flash-Free	−3.29	0.073	B

*Those groups sharing a letter are not significantly different at the 5% level.

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

At the visit before the patient being ready for their debonding, consent was reconfirmed for participation in the study. Any second molar teeth that may have been bonded or banded during the treatment (eg, for correction of crossbites 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 owing to the mixed elemental nature of the particulates produced. It was not possible to blind either the patient or the operator to the bracket and adhesive types.

Blinding

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

Before bracket removal, all auxiliary appliances were removed from the mouth, along with the orthodontic arch wire. Debonding of the brackets was carried out according to the manufacturer's instructions for the individual bracket type. The debonding 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 noncoated brackets; this was not done for the Flash-Free or metal Victory brackets. Molar bands were removed with the use of debanding pliers. The ARIs on each tooth (except first molars) were documented and the subsequent cement removed from the enamel with the use of a tungsten-carbide bur and slow handpiece per normal clinical practice. If any ceramic brackets fractured, this was noted and the remaining fractured bracket was removed from the tooth with the use of a diamond bur and fast handpiece with water coolant. HVE was used throughout the experiment, held at 30 cm from the patients' mouth by the dental assistant 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 3 patients in each group had their debonding carried out while using quantitative air sampling via the pDR-1200 air monitor, and the remaining 3 while using qualitative sampling via the Marple Cascade Impactor, for which the filters were subsequently analyzed by means of SEM and EDX. In this qualitative

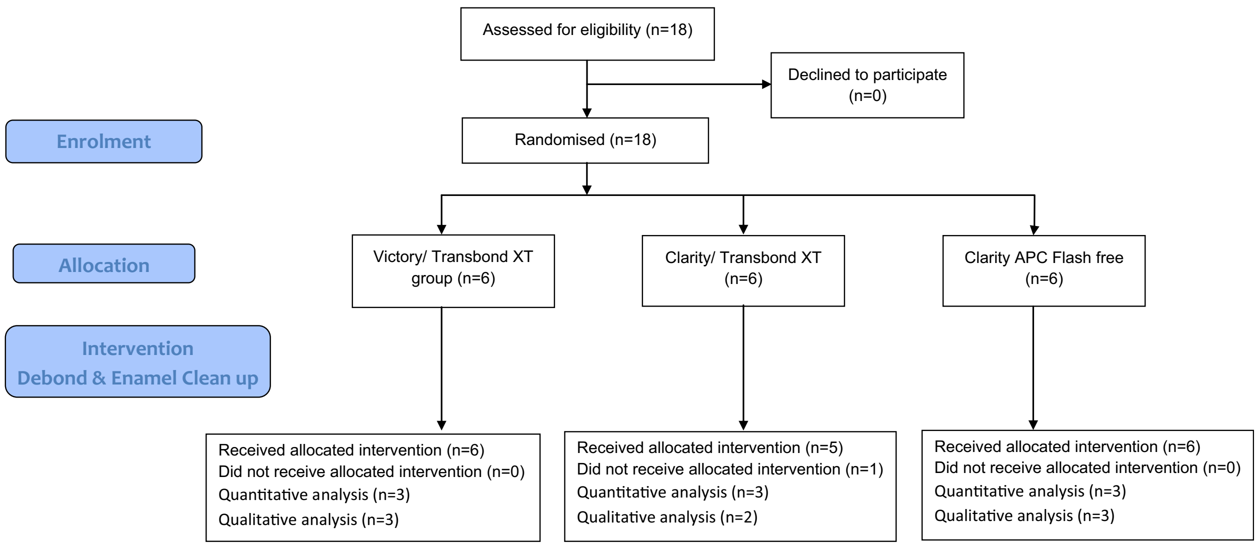

Fig 3. CONSORT flow diagram.

part of the study, 1 patient in the Clarity non-APC group dropped out.

Statistical analysis

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

RESULTS

Figure 4 shows the quantile distribution plots for particulate concentration for the 4 bracket types at background, debonding, and enamel clean-up in the laboratory experiments with the use of AE and SEP. 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, 2 Clarity APC II brackets and 1 conventional Clarity bracket fractured at debonding (Table I). The ceramic fragments in each case were removed with the use of a diamond bur in a high-speed handpiece under water coolant spray.

LMM was used to investigate the effects of etch, bracket, and stage of debonding. However, this requires an assumption that the residuals are normally distributed, which was not always the case (Fig 4). A logarithmic transformation of the data resulted in normally distributed residuals, and the results were analyzed with the use of mixed-effects regression and the Šídák method to adjust multiple comparisons. All 3 main effects—etch type, bracket type, and stage of debonding—were statistically significantly different ($P = 0.001$). AE and SEP enamel pretreatments were statistically significantly different (Table IV), with AE associated with higher particulate concentration. There was no statistically significant difference between the background particulate levels and those observed at debonding (including any flash removal), but there was a statistically difference between these 2 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 (Fig 5) once again show extreme values for particulate concentration at the enamel clean-up stage. A

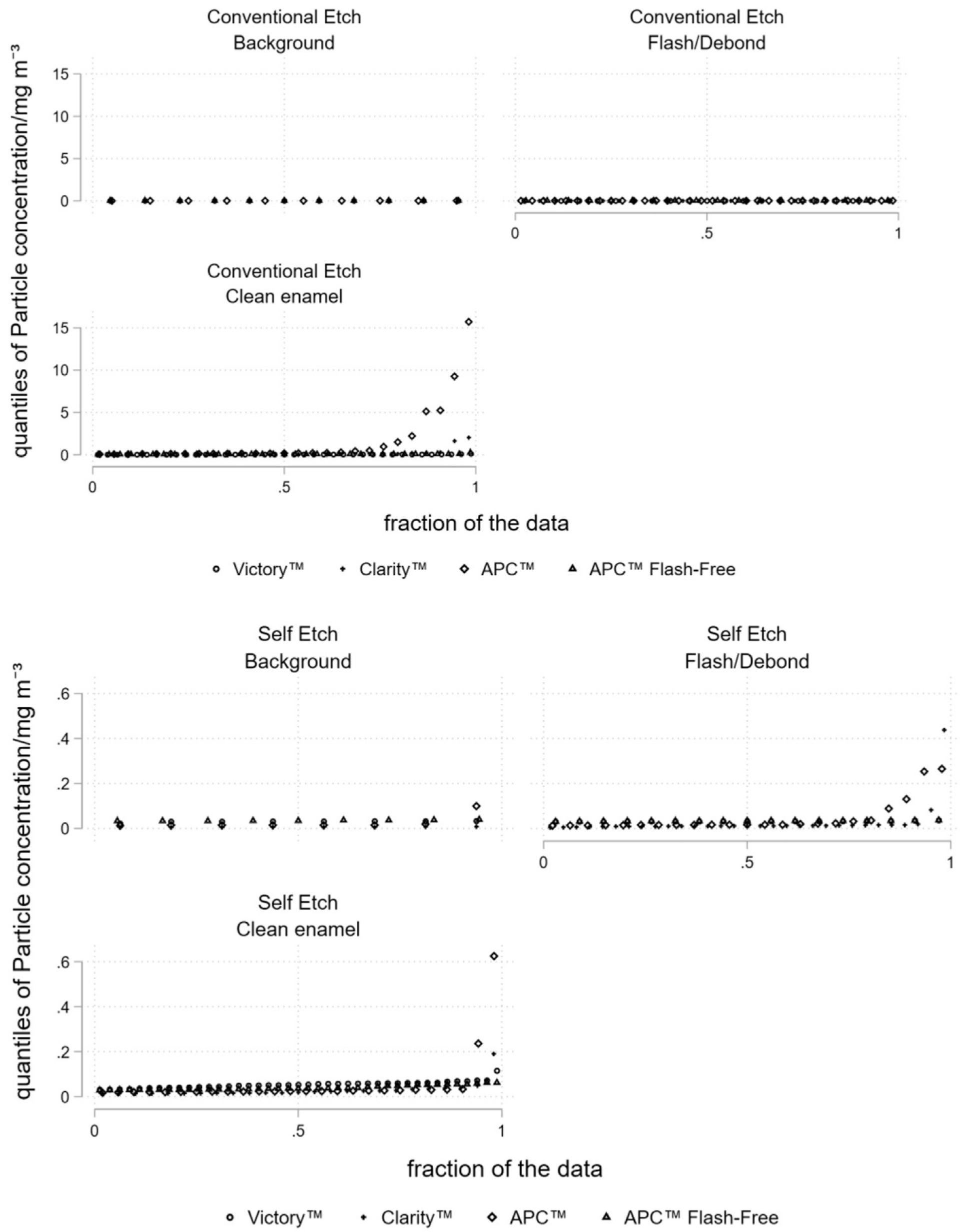

Fig 4. Quantile distribution plots of particulate concentration (mg/m^3) at background, debonding, and enamel clean-up for each of the 4 bracket types and enamel pretreatment. **A,** 37% *o*-phosphoric acid etch. **B,** Self-etching primer.

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 debonding, with the greatest concentration of particulates produced at enamel clean-up ($P = 0.001$). When looking at the mean concentrations, however, the Victory metal brackets appeared to show the greatest concentration of particulates, with little difference between the conventional Clarity and the Clarity Flash-Free ceramic brackets.

As with the laboratory study, there was no statistically significant difference between particulate concentration at background and debonding (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

Table IV. Pairwise comparisons of predictive margins of particulate concentration (mg/m^3) for appliance removal stage and bracket type in the clinical study

Variable	*Margin*	*SE*	*Šídák group**
Removal stage			
Background	−4.34	0.177	A
Debonding (flash removal)	−4.07	0.158	A
Enamel clean-up	−3.15	0.154	
Bracket			
Victory	−4.4	0.259	A
Clarity	−3.75	0.257	A
Clarity APC Flash free	−3.29	0.258	A

*Those groups sharing a letter are not significantly different at the 5% level.

statistically significant effect of bracket type on the concentration of particulates produced. This was despite 3 patients with APC Flash-Free (2 patients with 1 bracket each and 1 patient with 3 brackets) and 1 patient with conventional Clarity (with 1 bracket) having 1 or more ceramic brackets fracture at debonding, which then required a diamond bur in a high-speed handpiece to be used to remove the ceramic remnants.

Analysis of the laboratory ARIs showed that there was no statistically significant effect of etch type ($P = 0.29$) or bracket type ($P = 0.62$) on the observed ARI at debonding. The majority of the ARIs were 3 (Fig 6), ie, 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 (Fig 7).

As part of the clinical study, and to compare the results with the Control of Substances Hazardous to Health workplace exposure limits (WEL), the potential particulate exposure (mg/m^3) over an 8-hour period was calculated for all 3 bracket types tested with the data from the pDR-1200 (Table V).

The qualitative data obtained with the use of the Marple Cascade Impactor, in both the laboratory and clinical settings, were analyzed with the use of both SEM and EDX. Although the particulate compositions varied to some extent, the most commonly occurring elements in all instances were calcium, phosphorus, silicon, and aluminum. This was consistent for each of the bracket types tested and they were usually found on each of the 4 impactor filters. Other less commonly detected elements included iron, tungsten, sodium, chlorine, magnesium, zinc, manganese, and zirconia.

DISCUSSION

In the present study the MMAD cutoff limit for the quantitative pDR-1200 was ≤5 μm and for the qualitative Marple Cascade Impactor the MMAD cutoffs were 15 μm, 10.5 μm, 6.93 μm, and ≤4.24 μm for filters 1-4. 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 (may reach the gaseous exchange regions of the lungs).[13] This is consistent with previous studies on particulates produced during orthodontic debonding.[7-9] 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 nonciliated, 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. Regarding the enamel pretreatment—conventional 37% *o*-phosphoric AE versus SEP—there was a statistically significant difference in the particulate air concentration, with AE producing a higher concentration of particulates at enamel clean-up. However, what is interesting is that there was no such difference in the ARIs, 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 Victory metal bracket and the Clarity ceramic bracket, but there was between those 2 and the Clarity APC bracket and the Clarity APC Flash-Free bracket. The latter 2 brackets were not significantly different from each other, but both produced higher particulate concentrations than the Victory and Clarity brackets. This might be partially explained by the fracture of 2 Clarity APC brackets and 1 Clarity APC Flash-Free bracket at laboratory debonding, although 1 Clarity bracket also fractured at debonding. It has been shown previously that if a fractured ceramic bracket has to be removed with the use of 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 among Victory, Clarity, and Clarity APC Flash-Free brackets, despite a single bracket fracturing in each of the 2 ceramic groups. As in the laboratory study, there was no statistically significant effect of ARI on particulate concentration, which in this case is perhaps not surprising, because ARI might be expected

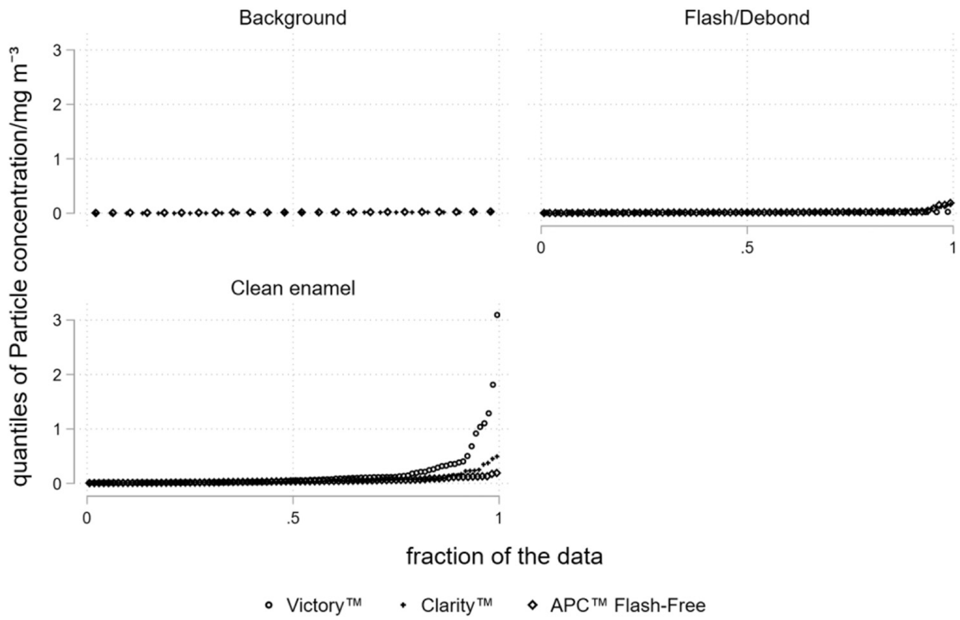

Fig 5. Clinical trial quantile distribution plots of particulate concentration (mg/m^3) at background, debonding, and enamel clean-up for each of the 3 bracket types.

Table V. The observed mean particulate concentration (mg/m^3) produced at debonding for each of the 3 bracket types in the clinical study, along with the potential particulate exposures over 8 hours

Bracket	*Patients*	*Observations*	*Mean conc (mg/m^3)*	*Mean time (s)*	*Mean conc/8 h (mg/m^3)*
Victory	3	256	0.158	3,840	1.185
Clarity	3	252	0.037	3,780	0.282
Clarity Flash-Free	3	246	0.031	3,690	0.242

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 Victory metal 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 debonding. 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 before removing the bracket from the tooth surface. This was done 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 ARIs being 3.

The potential particulate exposures over an 8-hour period were calculated and presented in Table V. It can be seen that the time-weighted average WEL over 8 hours for respirable dusts[14] of 4 mg/m^3 was not exceeded with any of the bracket types. 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 debondings 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 the 3 bracket types. If silica formed the entirety of the particulate fraction produced after debonding and enamel clean-up, the time-weighted average WEL over 8 hours for silica[15] of 0.1 mg/m^3 would potentially have been exceeded with all bracket types if successive debondings were done. What is unknown is the precise fraction of the total that is composed by silica, because the analysis of particulate composition

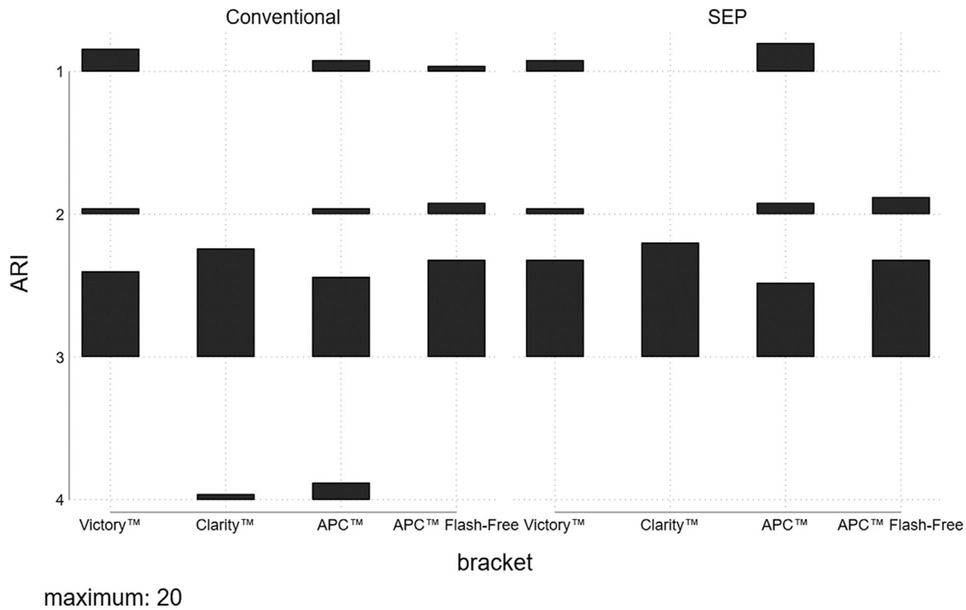

Fig 6. ARIs for each of the enamel preparation and adhesive bracket combinations in the laboratory experiment.

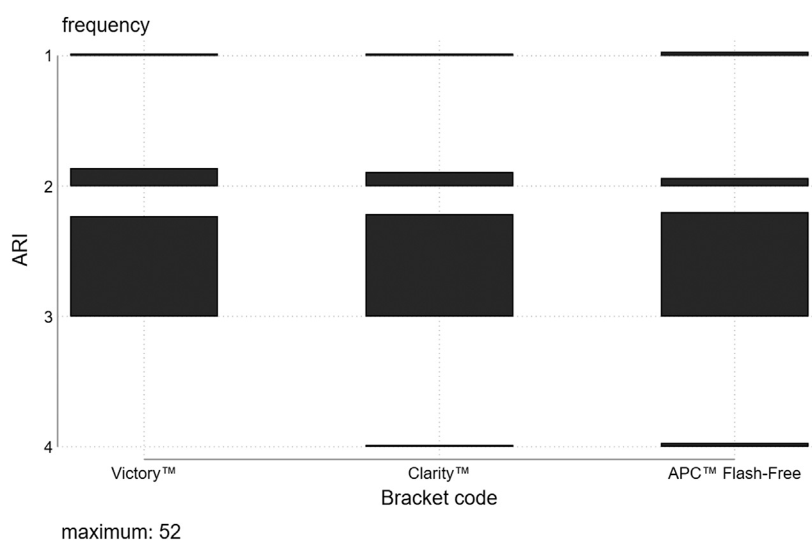

Fig 7. ARIs for each of the enamel preparation and adhesive bracket combinations in the clinical trial.

was qualitative and not quantitative. Silica was just one of the elements detected, with the others including calcium and phosphorus, most likely from the enamel surface, as well as aluminum from the band cement and iron and tungsten from the handpiece and burs.[7,8] Although there are workplace limits in place, a recent study has suggested that sampling studies often overestimate the concentration of particulates that will reach the lower respiratory tract, because penetration is affected by breathing habits, eg, 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 debonding.[9]

Limitations

It was not possible to blind the operator to bracket type at debonding in either the laboratory or the 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.

Generalizability might be limited by the single-center nature of the trial and because debonding and enamel clean-up in each case was performed by a single operator (P.V.).

CONCLUSIONS

The following conclusions 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 that may penetrate the deeper parts of the respiratory tract.
2. The use of AE leads to a greater concentration of particulates at appliance removal than the use of SEP even though an ARI 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 compared with 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 debonding and enamel clean-up in the clinical setting.

ACKNOWLEDGMENTS

The authors thank 3M Unitek for supplying the brackets and adhesives used in this study.

REFERENCES

1. Harrel SK, Molinari J. Aerosols and splatter in dentistry: a brief review of the literature and infection control implications. J Am Dent Assoc 2004;135:429-37.
2. Hext P, Rogers K, Paddle G, Evans M, Priston R, Tordoir W, Urbanus J. The Health effects of PM25 (including ultrafine particles). Concawe 1999;99/60: https://www.concawe.eu/wp-content/uploads/2017/01/2002-00226-01-e.pdf. Accessed March 18, 2019.
3. Ferin J, Oberdorster G, Penney D. Pulmonary retention of ultrafine and fine particles in rats. Am J Respir Cell Mol Biol 1992;6:535-42.
4. Seaton A, Godden D, Macnee W, Donaldson K. Particulate air pollution and acute health effects. Lancet 1995;345:176-8.
5. Seaton A. Particles in the air: the enigma of urban air pollution. J R Soc Med 1996;89:604-7.
6. Oberdörster G. Pulmonary effects of inhaled ultrafine particles. Int Arch Occup Environ Health 2000;74:1-8.
7. Ireland AJ, Moreno T, Price R. Airborne particles produced during enamel cleanup after removal of orthodontic appliances. Am J Orthod Dentofacial Orthop 2003;124:683-6.
8. Day CJ, Price R, Sandy JR, Ireland AJ. Inhalation of aerosols produced during the removal of fixed orthodontic appliances: a comparison of 4 enamel cleanup methods. Am J Orthod Dentofacial Orthop 2008;133:11-7.
9. Johnston NJ, Price R, Day CJ, Sandy JR, Ireland AJ. Quantitative and qualitative analysis of particulate production during simulated clinical orthodontic debonds. Den Mats 2009;25:1155-62.
10. Hosein I, Sherriff M, Ireland AJ. Enamel loss during bonding, debonding, and cleanup with use of a self-etching primer. Am J Orthod Dentofacial Orthop 2004;126:717-24.
11. 3M Unitek: Clarity Metal-Reinforced Ceramic Brackets. Available at: http://multimedia.3m.com/mws/media/1560420/clarity-metal-reinforced-ceramic-bracket-brochure.pdf. Accessed August 7, 2018.
12. Årtun J, Bergland S. Clinical trials with crystal growth conditioning as an alternative to acid-etch enamel pretreatment. Am J Orthod Dentofacial Orthop 1984;85:333-40.
13. International Standards Organisation. Air quality: particle size fraction definitions for health-related sampling. 2 BS EN 1993;481. https://www.iso.org/standard/14534.htm. Accessed March 18, 2019.
14. Approved Code of Practice (ACOP) to the Control of Substances Hazardous to Health Regulations 2002 (as amended). 6th ed. HSE; 2013. http://www.hse.gov.uk/pubns/books/l5.htm. Accessed March 18, 2019.
15. Workplace exposure limits containing the list of workplace exposure limits for use with the Control of Substances Hazardous to Health Regulations (as amended). HSE; 2011. https://books.hse.gov.uk/bookstore.asp?ACTION=BOOK&PRODUCTID=9780717664467. Accessed March 18, 2019.
16. Brown JS, Gordon T, Price O, Asgharian B. Thoracic and respirable particle definitions for human health risk assessment. Part Fibre Toxicol 2013;10:10-2.