

The omission of pumice prophylaxis on bracket failure rates after using self-etch primers: a randomised controlled clinical trial

Kaminii Thevadass,* Nor Nadia Zakaria† and Siti Adibah Othman†

Oral Health Programme, Ministry of Health Malaysia, Putrajaya, Malaysia*

Department of Paediatric Dentistry & Orthodontics, Faculty of Dentistry, Universiti Malaya, Kuala Lumpur, Malaysia†

Objectives: To investigate orthodontic bond failure rates and the associated effectiveness of pumice prophylaxis as a preparatory step before applying self-etching primers (SEP).

Methods: Twenty participants with an average age of 23.9 years $\pm$ 5.13, were included in the trial. A total of 320 teeth were randomly assigned, using block randomisation in a 1:1 ratio (block of four), to either pumiced ($n=160$) or non-pumiced ($n=160$) quadrants. After preparation using SEP, the teeth were bonded with stainless steel brackets and monitored for bracket failure until a one-month period in a 0.019" $\times$ 0.025" stainless steel arch wire.

Results: The Fisher's Exact Test and Chi-Square tests showed an overall bracket failure rate of 4.4%, with 1.8% in the pumiced and 2.5% in the non-pumiced group. The majority of bracket failures occurred on the 0.014" nickel titanium arch wire (71.4%) and an associated ARI score of one (57.1%). No significant difference was found in bracket failure rates between both groups related to the location, arch, ARI score or arch wire type ($P>0.05$).

Conclusions: Omitting pumice prophylaxis before applying SEP in orthodontic bonding does not lead to a higher bond failure rate, and factors like location, arch, ARI score, and arch wire type did not influence bracket failure in either group.

(Aust Orthod J 2024; 40: 130 - 138. DOI: 10.2478/aoj-2024-0027)

Received for publication: August, 2024

accepted: October, 2024.

Kaminii Thevadass: kaminiihevadass86@gmail.com; Nor Nadia Zakaria: nornadiazakaria@um.edu.my; Siti Adibah Othman: sitiadibah@um.edu.my

Introduction

Since their introduction in the early 1990s, self-etching primers (SEP) have proved to be a viable substitute for the conventional acid etch (CAE) bonding technique.¹⁻⁸ By combining etching and priming into a single step, SEP simplifies the bonding process which saves time and cost.² Additionally, SEP offers benefits such as reduced chair time, a lower risk of contamination, improved moisture control, and increased patient comfort.⁹ Several studies, which have compared the shear bond strengths (SBS) of orthodontic brackets affixed with SEP and CAE techniques, concluded that using a SEP provided

lower but clinically acceptable bond strength.^{1,10-12}

The lower bond strengths observed following SEP can be attributed to differences in the composition and concentration of its components, particularly the methacrylated phosphoric acid ester. Despite this, the bond failures between the two methods were reported to be similar.¹³

Effective orthodontic bonding relies on optimal enamel preparation, traditionally achieved by removing plaque, debris, and the acquired pellicle using a pumice slurry to enhance the effect of the acid etch and subsequent adhesive bonding. Interestingly, studies have shown that for conventional acid

etch systems, pumicing might not be essential.^{1,14} Lindauer (1997) proposed that good oral hygiene and thorough toothbrushing immediately before bonding could potentially provide a clean surface comparable to pumicing. While additional studies support the manufacturer's recommendation for pumicing before SEP application, these studies employed different SEP materials which produced outcomes suggesting variations in clinical effectiveness between the different SEP formulations.^{4,8} Therefore, there is a lack of clear evidence regarding the efficacy of omitting pumice prophylaxis in orthodontic bonding when using SEP.

Bond failure in orthodontic bonding is influenced by factors related to the position of the teeth (whether anterior or posterior, and upper or lower arch), the type of arch wire used, and the various phases of treatment. Mandall et al. (2006) reported that there was no statistically significant difference in patient discomfort, root resorption, nor treatment time between arch wire sequences.¹⁵ However, variations in arch wire sequences may affect bracket failure as most bond failures occur during the aligning phase.^{16–18}

Clinicians are becoming increasingly cautious in their daily practice and, if possible, would prefer to avoid an aerosol generating procedure particularly in light of the recent Coronavirus disease (COVID-19) pandemic. Omitting the process does not only reduce cross infection between clinicians, dental surgery assistants, and patients, but it could also shorten clinical time for orthodontic bonding procedures, making the overall process more cost-effective and safer. Therefore, the omission of pumicing prior to the use of SEP may prove to be advantageous related to clinical time, patient comfort, and infection control.

Therefore, the aim of the present study was to investigate the effectiveness of pumice prophylaxis prior to SEP application on orthodontic bond failure. A further investigation into the bond failures was conducted in relation to the tooth involved, arch wire used, and adhesive remnant.

Materials and methods

Trial design

This was a randomised clinical trial (1:1) with two-arm parallel groups at the Faculty of Dentistry,

Universiti Malaya and was undertaken from September 2018 to April 2021. The study protocol received ethical clearance from the Faculty of Dentistry Medical Ethics Committee, Universiti Malaya in July 2019 [DF CD1909/0057(P)] and was registered at the US National Institute of Health database (ClinicalTrials.gov) in October 2019 with the identifier number NCT04131855. The study was conducted, and its findings were documented following the guidelines outlined in the Consolidated Standards of Reporting Trials (CONSORT).¹⁹ Only patients who provided consent to participate in the study were recruited.

Participants

The inclusion criteria encompassed individuals undergoing orthodontic treatment using upper and lower fixed appliances, and who had good oral hygiene, balanced extractions in both arches, and right handedness. The exclusion criteria were teeth with enamel defects, buccal restorations that impeded the bonding process, bruxism, individuals presenting with a craniofacial deformity, a history of fixed appliance treatment and teeth necessitating a deferred bracket placement were also excluded from the study.

The power and sample size calculations were conducted by using G*Power Software Version 3.1.9.2 (Heinrich Heine Universität, Dusseldorf, Germany). The sample size was calculated at a power of 0.90, an α of 0.05 and a moderate effect size of 0.6. This was based on a previous randomised clinical trial study by Lill et al. in which the effects of pumice prophylaxis on bond failure rates with the self-etch primer was investigated.⁸ The estimated sample size for the present study was 266 teeth, but after assuming an attrition rate of 20%, this was increased to 320 teeth. This was equivalent to 20 patients (10 patients per group) with 16 orthodontic brackets placed on each patient.

Randomisation and blinding

A computer generated randomised numerical sequence (www.randomizer.org/) was created by an external party devoid of clinical participation within the study (NNZ).²⁰ The block randomisation technique with a 1:1 ratio was used with fixed block sizes of 4 (5 blocks). All 20 participants were

randomly assigned into one of two groups of ten subjects per group.

The allocation sequence was carried out by a second investigator (KT) and concealed. Participants were enrolled through a process involving the utilisation of sequentially numbered opaque, and sealed envelopes. To prevent tampering with the allocation sequence, the participant's name and date of birth were inscribed on the envelope. The envelopes containing allocation information were only opened once all participants in a given group had completed their baseline assessments prior to allocating the intervention. Each participant was assigned an envelope with an odd or even number. The split-mouth contra-lateral method was employed, in which individuals with odd-numbered envelopes had their maxillary right and mandibular left quadrants pumiced (Group 1), while those with even-numbered envelopes had their maxillary left and mandibular right quadrants pumiced (Group 2). To ensure participant blinding to the allocation, the occlusal surfaces of the teeth in the intervention quadrants were pumiced.

Intervention

As required, the extraction of four premolars was performed at least two weeks prior to the start of the study. Separators (3M™ AlastiK™ Separator Modules; 3M Unitek, Monrovia, USA) were placed, and molar bands were cemented on all first permanent molars on the subsequent visit. The patients were given standard oral hygiene instructions and required to brush their teeth immediately before the appointment. Bracket placement was commenced once oral hygiene was deemed to be satisfactory and without plaque on the bonding surfaces. The envelope containing each patient's details was opened, and the quadrants to be pumiced were determined.

The tooth surfaces in the control group were polished with a mixture of plain pumice and water for a three-second interval per tooth. This was carried out using a rubber cup attached to a slow-speed contra-angle handpiece. Following this, the enamel was rinsed and dried, and subsequently, each tooth surface was gently treated with SEP (Transbond™ Plus Self Etching Primer; 3M Unitek, Monrovia, USA) for a three-second duration. The surface of the enamel containing the SEP was lightly air-blown for two seconds per tooth using the 3-way syringe. The

stainless-steel brackets with an MBT prescription of 0.022" × 0.028" slot (Gemini® Series; 3M Unitek, Monrovia, USA) were bonded using resin adhesive (Transbond™ XT Light Cure Adhesive; 3M Unitek, Monrovia, USA). The brackets were then light-cured for 5 sec in each interspace using a light-emitting diode (LED) curing light (Planmeca Lumion Plus, Helsinki, Finland). To optimise moisture management and ensure uniform bonding, the teeth were bonded following a predetermined sequence of (1) Upper anterior teeth, (2) Lower anterior teeth, (3) Right upper premolars, (4) Right lower premolars, (5) Left upper premolars, 6) Left lower premolars.

The initial orthodontic arch wires were inserted following a check for occlusal interferences. The applied wires were either Nitinol Heat Activated arch wires or stainless-steel arch wires (3M Unitek, Monrovia, USA). The arch wire sequence was 0.014" nickel titanium (NiTi), 0.018" NiTi, 0.017" × 0.025" NiTi and 0.019 × 0.025" stainless-steel (SS) wires. Following the placement of the orthodontic brackets, the initial 0.014" NiTi arch wire was promptly inserted and secured using an elastomeric ligatures. The patients were recalled following a six-week interval to check for bond failures, and to change the arch wires for the continuation of standard orthodontic mechanics. Any bond failure during treatment was noted, and the bracket re-attached following the CAE technique using 37% phosphoric acid and priming.

Data collection

The study results were divided into primary and secondary outcomes. The primary outcome was the orthodontic bond failure rate using SEP between the pumiced and non-pumiced teeth. The secondary outcomes were: (1) The location of the bond failure (anterior or posterior), (2) The location of the bond failure (upper or lower), (3) The bond failure interface, and (4) The wire on which the failure most commonly occurred. For the purposes of the present study, the central and lateral incisors were classified as the anterior group, while the canine and premolars as the posterior group. The bond failure interface was assessed using the Adhesive Remnant Index (ARI) defined by 0 for no adhesive left on the tooth, 1 for less than half of the adhesive left on the tooth, 2 for more than half of the adhesive left on the tooth, and 3 for all the adhesives left on the tooth.

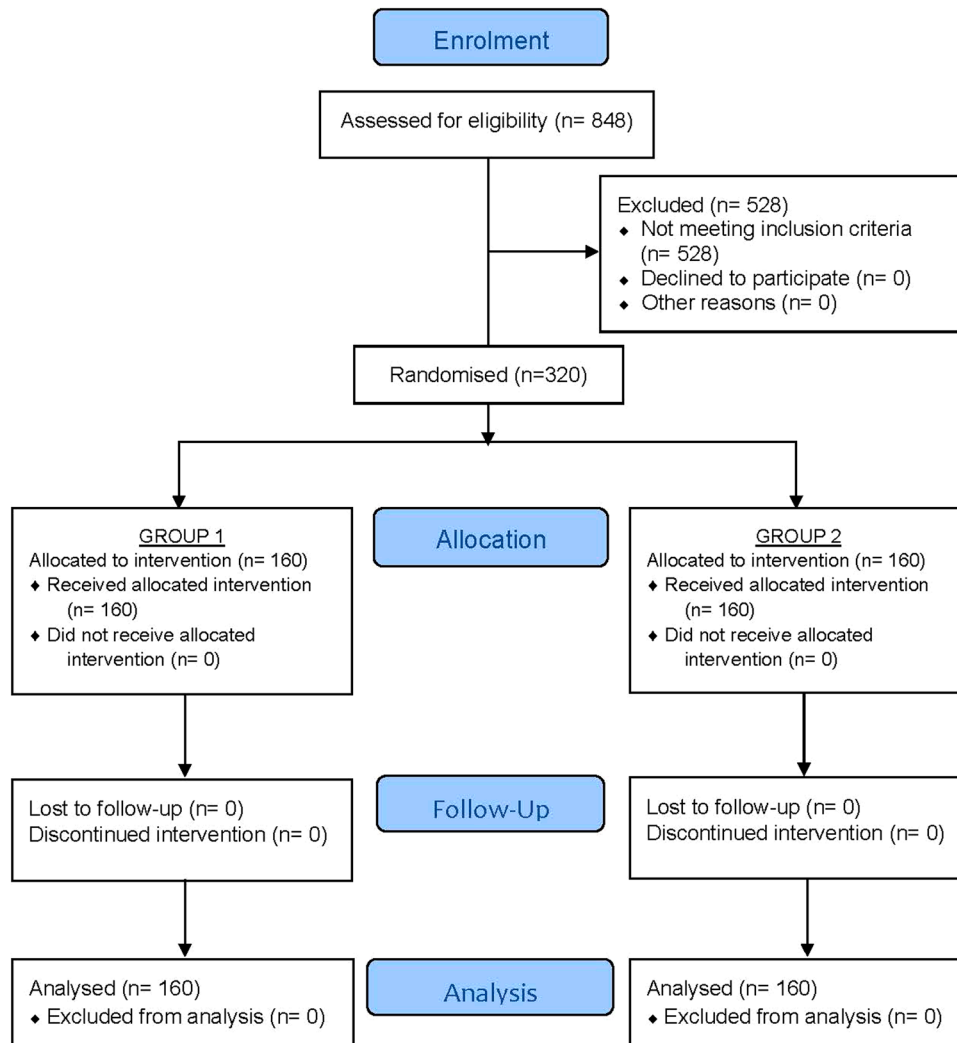


Figure 1. CONSORT flow diagram.

All bond failures were verified and recorded by KT. After confirmation, the tooth was removed from the study to prevent instances of duplication. Data collection was stopped after each patient had completed a minimum period of 4 weeks in the stainless-steel arch wire (0.019" × 0.025").

Statistical analysis

Data analysis was conducted using IBM Statistical Package for the Social Sciences version 26.0 (SPSS Inc., Chicago, USA). Cohen's kappa coefficient was used to measure the intra-rater reliability and inter-rater reliability of ARI scoring according to values interpreted by 0 (no agreement), 0.01–0.20 (none to slight), 0.21–0.40 (fair), 0.41–0.60 (moderate), 0.61–0.80 (substantial), and 0.81–1.00 (almost perfect

agreement). Inter-rater reliability was conducted between KT and an experienced orthodontist (NNZ) using ten prepared tooth samples with varying adhesive remnants. KT repeated the assessment two weeks later. Descriptive analysis was used to analyse the baseline patient characteristics. Mean age and gender between the randomised groups were compared using the Chi-square test. The Fisher's exact test determined the statistical significance ($p < 0.05$) between the bond failures for all the outcomes.

Results

Of the 53 patients screened for eligibility, twenty participants, consisting of eight males and twelve females, were recruited for the study. The mean age

Table I. Distribution of bond failures between pumiced and non-pumiced teeth

Group	Bond failure	Intact bonds	Total	Percentage (%)		<i>p</i> -value
				<i>n</i> =14	Total	
Pumice	6	154	160	42.9	3.8	0.393
No pumice	8	152	160	57.1	5	
Total	14	306	320	100	4.4	

for both groups was 23.9 years (± 5.13). Group 1 had a mean age of 26.8 years (± 5.13), while Group 2 had a mean age of 21.0 years (± 3.16). There were no statistically significant differences between the two groups according to age ($p = 0.400$) and gender ($p = 0.650$). All 20 patients completed the study, hence, a total of 320 teeth and orthodontic brackets were included for analysis (Figure 1). The intra-rater and inter-rater reliability for the ARI scores were 0.85 and 0.86, indicating almost perfect agreement.

The number of bond failures was 14 which was 4.4% of the total number of brackets. The results of the Chi Squared Test of Association (1 $\times$ 2) showed that there was a significant association between bond failure and intact brackets, $X^2(1, N = 320) = 2.66.45$, $p < 0.001$.

There was a total of six broken brackets in the pumiced quadrants which was 42.8% of all bond failures and eight in the non-pumiced quadrants which was 57.1% of all bond failures. The results of the Fisher's Exact Test (2 $\times$ 2) showed that there was no statistically significant association between the bond failures in the pumiced and non-pumiced quadrants ($p = 0.393$) (Table I).

There was a total of eight bond failures in the anterior teeth which was 57.1% of all bond failures and six in the posterior teeth which was 42.8% of all bond failures. The results of the Fisher's Exact Test (2 $\times$ 2) showed that there were no statistically significant bond failures associated with pumicing and the tooth groups ($p = 0.393$) (Table II). The distribution of bond failures according to tooth type are shown in Table III. Bond failure rates were highest in the upper and lower lateral incisors, as well as the lower premolars.

A total of five (35.7%) and nine (64.3%) bond failures were detected in the upper and lower arches, respectively. The results of the Fisher's Exact Test (2 $\times$ 2) showed that there was no statistically significant association between bond failures associated with pumicing and the upper or lower arch ($p = 0.238$) (Table IV).

There was one ARI score of 0 (28.6%), eight ARI scores of 1 (57.1%), and five ARI scores of 2 (21.4%). There were no bond failures with an ARI score of 3. The results of the Fisher's Exact Test (2 $\times$ 4) showed that there was no statistically significant association between bond failures associated with pumicing and the ARI score ($p = 0.576$) (Table V).

Table II. Distribution of bond failures between anterior and posterior teeth

Group	Location		Total	<i>p</i> -value
	Anterior, <i>n</i> (%)	Posterior, <i>n</i> (%)		
Pumice	3 (21.4)	3 (21.4)	6	0.393
No pumice	5 (35.7)	3 (21.4)	8	
Total	8 (57.1)	6 (42.8)	14	

Table III. Distribution of bond failures according to tooth type

Location	Upper, <i>n</i> (%)	Lower, <i>n</i> (%)	Total, <i>n</i> (%)
Central incisor	1 (7.1)	1 (7.1)	2 (14.2)
Lateral incisor	3 (21.4)	3 (21.4)	6 (42.9)
Canine	1 (7.1)	2 (14.3)	3 (21.4)
Premolar (1 st / 2 nd)	0 (0)	3 (21.4)	3 (21.4)
Total	5 (35.6)	9 (64.2)	14 (100)

Table IV. Distribution of bond failures between upper and lower arches

Group	Location		Total	<i>p</i> -value
	Upper, <i>n</i> (%)	Lower, <i>n</i> (%)		
Pumice	1 (7)	5 (35.7)	6	0.238
No pumice	4 (28.6)	4 (28.6)	8	
Total	5 (35.6)	9 (64.3)	14	

There were a total of six bond failures on the 0.014" NiTi arch wire which was 42.8% of all bond failures and eight on the 0.018" NiTi arch wire which was 57.1% of all bond failures. There were no bond failures on the 0.017"×0.025" NiTi and 0.019" × 0.025" SS arch wires. The results of Fisher's Exact Test (2×4) showed that there was no statistically significant association between bond failures associated with pumicing and arch wire type ($p = 0.594$) (Table VI).

Discussion

Throughout the present study, there were only 4.4% bond failures which was within the reported range of 2.4 to 11% determined by previous studies that utilised SEP prior to bonding.^{8,13,21–23} There were no significant differences between bond failures in the pumiced and non-pumiced quadrants. The findings of the present investigation contradicted those of two other studies, both of which found that the bond failure rates of brackets bonded with SEP significantly increased when pumice prophylaxis was omitted.^{4,8} Of note, the highest number of bond failures were located on the lower premolars followed by the maxillary and mandibular lateral incisors. This disagrees with previous studies that reported more bracket failures on the posterior teeth.^{16,17,24} The mandibular arch was found to have similar bond

failures as the maxillary arch which is inconsistent with other studies that indicated the mandibular arch had a higher risk.^{16,17,25,26} It was postulated that these failures might be due to the masticatory force from the maxillary cusps onto the lower brackets, moisture contamination during the bonding procedure in the mandibular arch and occlusal interference of the lower brackets. A prior study that supported a similar bonding outcome for both arches suggested that avoiding occlusal interference during bonding may enhance bonding success.²⁷

A higher rate of bracket failure in the anterior region has been observed.^{28,29} While no specific explanations have been provided, it has been suggested that habits like nail biting and pen chewing could be contributing factors. The higher rate of failure in the incisor brackets observed in the present study may be linked to either greater activation forces resulting from the anterior crowding or increased masticatory forces encountered when masticating. The inclusion criteria were a balanced extraction pattern in both arches and excluded teeth that required deferred bracket placement. This suggests that the malocclusion was moderately crowded and of average overbite.

The site where bonding failed reveals details about the strength of the bond between the adhesive and the tooth as well as the strength of the bond between the adhesive and the bracket base. The majority of the ARI scores were 1 and 2, in both pumiced and non-pumiced quadrants which is similar to reported literature.^{30,31} Past studies have regarded low ARI scores as advantageous, as they involve less adhesive removal from the tooth surface, resulting in a reduced risk of iatrogenic damage during enamel polishing.^{32,33} However, higher ARI scores are associated with higher bond strengths, as the point of failure is at the junction between the adhesive material and the bracket base which is desirable.^{34,35}

All of the bond failures occurred on the 0.014" NiTi or the 0.018" NiTi arch wires indicating that the

Table V. Distribution of ARI scores for the bond failures

Group	Adhesive Remnant Index (ARI) score				Total	<i>p</i> -value
	0 <i>n</i> (%)	1 <i>n</i> (%)	2 <i>n</i> (%)	3 <i>n</i> (%)		
Pumice	0	4 (28.6)	2 (14.3)	0	6	0.576
No pumice	1 (28.6)	4 (28.6)	3 (21.4)	0	8	

Table VI. Distribution of bond failures between archwires

Group	Archwires				Total	p-value
	0.014" NiTi n (%)	0.018" NiTi n (%)	0.017" × 0.025" NiTi n (%)	0.019" × 0.025" SS n (%)		
Pumice	4 (28.6)	2 (14.3)	0	0	6	0.594
No pumice	2 (14.3)	6 (42.8)	0	0	8	
Total	6 (42.8)	8 (57.1)	0	0	14	

majority of the failures occurred during the aligning phase. A recent study supported this finding, as nearly two-thirds of the bracket failures occurred during the first six months after bonding.¹⁶ Similarly, additional studies also supported the finding of bracket failures occurring during the first few months of treatment.^{17,18} The initial movements of alignment and de-rotation also placed more force on the bracket bases. The present study eliminated this confounding factor by excluding individuals with severe tooth displacement which requires any tooth to be managed at a later stage. Hence, breakages were attributed to patients needing time to adapt to their appliances.

It is generally accepted that SEPs are easier to use than conventional etching agents, as they do not require the use of separate etching and rinsing steps, which makes the bonding process more efficient and cost-effective. The SEP was found to produce time savings on an average of 24 seconds per tooth and a reduction of full arch bonding time of up to 8 minutes.^{10,36,37} It was however argued that the time savings did not include the time required for tooth surface preparation.^{10,38} According to Lill et al., the extra time required to pumice and rinse the teeth before SEP was over a minute.⁸ Hence, the need to pumice the teeth prior to applying the SEP reduces the time-saving advantage of SEP over CAE.

Pumice prophylaxis should also be considered in conjunction with infection control and aerosol generation, especially in light of the recent COVID-19 pandemic. A systematic review by Geng et al. found that pumice prophylaxis is an aerosol generating procedure (AGP) that poses a moderate risk to clinicians and patients.³⁹ Prophylaxis procedures produce contamination (splatter, droplets

and aerosol) in the presence of high-volume suction, with evidence showing that droplets take between 30 minutes and an hour to settle. AGP should hence be avoided or restricted whenever possible.⁴⁰ As a result, if there is no statistically significant difference in bond failure between pumicing and non-pumicing, it is recommended that the procedure may be omitted from the SEP step, particularly in patients presenting with good oral hygiene.

A limitation of the present study was that data collection in the final arch wire was limited to one month. A longer follow-up would allow assessment of the different stages of orthodontic fixed appliance mechanics, including space closure and finishing. The bonding protocols were carried out by a single operator in a single centre. Including multiple centres in future studies may improve the general nature of the results. It is recommended that further studies investigate clinical chairside time during bracket placement which includes the tooth surface preparation time.

Conclusion

The omission of pumice prophylaxis does not appear to have a detrimental impact on bond failure rates in a statistically or clinically significant way, indicating that the process can be safely omitted when using self-etching primers. The location of bond failures and the type of applied arch wires are not influenced by pumicing, as the majority of bond failures occurred at the interface between the enamel and adhesive.

Conflicts of interest

The authors declare that there is no conflict of interest.

Funding

This study received funding from the Universiti Malaya Dental Postgraduate Research Grant at the Faculty of Dentistry, (DPRG/15/19), as well as from the University Research Grant (GPF002E-2019).

Ethics approval

Permission was granted by the Medical Ethics Committee of the Faculty of Dentistry at Universiti Malaya, bearing the reference number DF CD1817/0060(P).

Corresponding author

Nor Nadia Zakaria, Department of Paediatric Dentistry & Orthodontics, Faculty of Dentistry, Universiti Malaya, 50603, Kuala Lumpur, Malaysia. Email: nornadiazakaria@um.edu.my.

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