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A Novel saliva ejector for effective orthodontic bonding: a laboratory investigation

Pichaporn Buranakunaporn[1], **Peerapong Santiwong**[2], Rochaya Chintavalakorn[2]

[1] *Residency Training Program in Orthodontics, Faculty of Dentistry, Mahidol University, Bangkok, Thailand*
[2] *Department of Orthodontics, Faculty of Dentistry, Mahidol University, Bangkok, Thailand*

Objective: To use computer-aided design and computer-aided manufacturing (CAD-CAM) to design a customized saliva ejector in order to investigate the performance of the new saliva ejector compared to the conventional saliva ejector with regards to shear bond strength, adhesive remnants, and bonding time.

Materials and Methods: Forty maxillary human premolars were mounted on acrylic dental models, with four teeth per side. Three-dimensional (3D) scans of the models were made using an intraoral scanner (iTero Element; Align Technologies, San Jose, Calif), then imported into an orthodontic software (OrthoAnalyzer; 3Shape, Copenhagen, Denmark) for bracket placement. The new saliva ejector was fabricated using ethylene-vinyl acetate (EVA) thermoplastic sheets. Orthodontic brackets were bonded on one side of the model using the new saliva ejector, and on the other side using the conventional saliva ejector. The effectiveness of the new saliva ejector was assessed by the duration of the bonding, shear bond strength, and adhesive remnant index (ARI).

Results: No statistically significant differences in shear bond strength were found between the new saliva ejector group (24.73 ± 9.93 MPa) with the conventional saliva ejector group (21.72 ± 1.45 MPa). Bonding time and ARI score did not differ significantly between the two groups either ($p > 0.05$).

Conclusion: The performance of the new saliva ejector was at least comparable to the conventional type with regard to shear bond strength, adhesive remnants, and bonding time.

Keywords: direct bonding, orthodontic bracket, saliva ejector, shear bond strength

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Introduction

The saliva ejector is used by orthodontists to drain intraoral fluids and debris from the oral cavity during the bonding of fixed appliances. The original saliva ejector consisted only of a narrow tube, but various designs with modifications to the tube and tip have emerged [1-2]. Even with the use of saliva ejectors, chairside dental assistance is usually indispensable in order to maintain a dry working field throughout the bonding procedure of orthodontic brackets.

From a survey carried out in 100 patients attending the Orthodontic Clinic at Mahidol University, Thailand, (Unpublished data). 34 respondents complained of pain from the saliva ejector tube during the orthodontic bonding procedure. From this group, 39% and 24% of respondents identified the pain to be from the floor of the mouth and the base of the tongue respectively. Interestingly, almost half of the respondents complained about the inattentiveness of the dental assistant, while another 44% reported discomfort and nausea

Corresponding author: Peerapong Santiwong
Department of Orthodontics, Faculty of Dentistry, Mahidol University
6 Yothi Road, Ratchathewi, Bangkok 10400, Thailand
Tel: +662 200 7849 Fax: +662 200 7849
E-mail: peerapong.san@mahidol.ac.th
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from the presence of fluids in their mouth. It appeared that the orthodontic bonding procedure would be better if the uncontrollable factor had been eliminated.

Several previous studies included systematic reviews found that the incidence of bracket bond failure within the first six months ranged from 0.6 to 9.6% [3-6], and other clinical studies discovered that the failure rate of brackets in the mandibular posterior region was significantly higher [7-8]. This could be due to the more directly applied occlusal forces on the posterior teeth, and moisture control being more difficult in these areas. The success of bracket bonding significantly depends on preventing contamination of the light-cured resin-based adhesives by any moisture, blood, or salivary fluids [9-10]. Even within a few seconds of exposure to these contaminants, etched enamel surfaces become completely obscured by organic substances, preventing micromechanical retention of the adhesives [11].

Therefore, to overcome this common barrier to effective bonding, a novel saliva ejector was developed by computer-aided design and computer-aided manufacturing (CAD-CAM). By using a biocompatible thermoplastic sheet made from ethylene-vinyl acetate (BIOPLAST® 2.0 mm, Scheu, Iserlohn, Germany), the saliva ejector was designed to cover all occlusal tooth surfaces and curvatures except the areas needed for bracket placement, while providing sufficient self-retention as well as patient comfort throughout the bonding procedure. The part used for saliva ejection was designed as a V-shaped tube resting on the floor of the oral cavity, where the middle part continues as a connecting tube to the aspirator system of the dental unit (Figure 1). As the device was modelled in three-dimensional (3D) software, occlusal contacts could be assessed to facilitate the saliva ejector design such that it would allow vertical control of the posterior bracket positions to be free from occlusal interferences to prevent bracket dislodgement. Besides functioning as a saliva ejector, this device was developed with the idea of eliminating the reliance on chairside dental assistance to aid in moisture control. Finally, the research has aim to test the performance of the new saliva ejector compared to the conventional type with regard to shear bond strength, adhesive remnants, and bonding time.

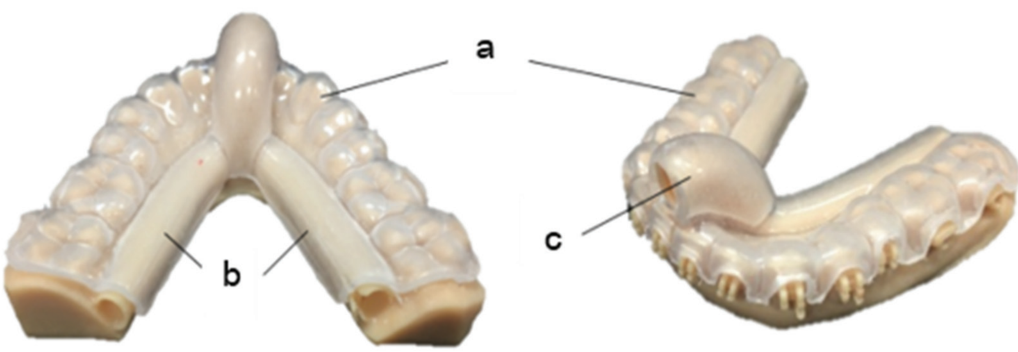

Figure 1 Design of the new saliva ejector consisting of three main parts: (a) PET-G thermoplastic sheet covering all tooth surfaces except the areas for bracket placement; (b) V-shaped tube for saliva ejection resting on the floor of the mouth; (c) Connecting tube to the suction system of the dental unit

Materials and Methods

Ethical exemption approval for this study was obtained from the Faculty of Dentistry/Faculty of Pharmacy, Mahidol University (COA.No.MU-DT/PY-IRB2021/026.2502).

1. Experimental set-up

This study was conducted at the Dental Simulation Centre of the Faculty of Dentistry, Mahidol University. A total of 40 human maxillary permanent first premolars extracted for orthodontic purposes were collected and stored in an aqueous solution of 0.1 w/v% thymol at room temperature. The buccal surface of each tooth was cleaned of tissue debris, and the teeth were selected according to the following criteria: intact buccal enamel, no caries or enamel defects, and not previously subjected to any chemical agents such as hydrogen peroxide.

The selected teeth were then fixed in an acrylic resin mandibular dental model, with four premolar teeth placed at the posterior tooth regions on each side of the arch (Figure 2a). All models were scanned with an intraoral scanner (iTero Element; Align Technologies, San Jose, CA) to generate a 3D model saved in Standard Tessellation Language (.STL) format. Each model was mounted in a phantom head attached to an automatic water pump controller machine that was programmed to generate water flow at a rate of 0.5 ml/min to replicate the average unstimulated salivary flow rate in adult humans [12] (Figure 2b).

Bracket positioning was done in an orthodontic 3D software (OrthoAnalyzer; 3Shape, Copenhagen, Denmark) before designing the saliva ejector in a 3D modelling software (Mimics version 7.0, CDI, Tokyo, Japan). The final model was printed by a 3D printer (Form 2; Formlabs, Somerville, MA) using dental model resin (Formlabs; Somerville, MA) and post-processed according to the manufacturer's instructions. Finally, the saliva ejector was fabricated from a 2.0 mm thermoplastic sheet (BIOPLAST® 2.0 mm, Scheu, Iserlohn, Germany) in a thermoforming machine (Biostar, Scheu-Dental GmbH, Iserlohn, Germany) according to the recommended settings.

Simple randomization was conducted on the experimental side by one of the academic staff (not involved in the study) using opaque, sealed envelopes containing label-cards with the word 'left' or 'right' to allocate the intervention side. Therefore, one side of four premolar teeth was designated as the control for bonding with a conventional saliva ejector while the other side was bonded with the new saliva ejector.

Figure 2 (a) Mandibular dental model with premolar tooth samples placed at the posterior regions; (b) Phantom head attached with water pump

All brackets were bonded by the same operator with one dental assistant who was responsible for moisture control only during bonding with the conventional saliva ejector. The moisture control involved suctioning the fluids after the acid etching procedure and whenever water appeared in the oral cavity of the phantom head.

2. Bonding procedure

The same bonding method was used to prepare the teeth for bonding with either the conventional or the new saliva ejector according to the manufacturer's instructions. After the dental model was mounted in the phantom head, each side was prepared and bonded separately. The teeth were first cleaned and polished for 5 seconds with a non-fluoridated, oil-free, pumice slurry using a rubber cup on a slow-speed handpiece, and rinsed with water before drying with an oil and moisture-free air spray for 20 seconds. The tooth surfaces were then etched with 34% phosphoric acid for 30 seconds followed by rinsing thoroughly with water for another 10 seconds. 0.022-in slot Roth-prescription brackets (American Orthodontics, Sheboygan, WI) were bonded to each premolar tooth with resin adhesive (BracePaste® color change, American Orthodontics, Sheboygan, WI) and light cured for 20 seconds.

Each bonding session started with using the new saliva ejector before changing to the conventional saliva ejector on the control side. The bonding time was measured for both groups by a digital stopwatch, and recorded in minutes. The bonding duration for each group of four teeth that were recorded started after the polishing step for enamel surface preparation until the completion of bonding (after light cured) by one operator.

3. Shear bond strength test

After all brackets were bonded, the specimens were stored in 37 ± 2°C distilled water for 24 hours. Shear bond strength tests were carried out on each sample immediately after removal from the water storage. A universal testing machine (Instron 5566, Instron Ltd., Buckinghamshire, England) was used with a crosshead speed of 1 mm/min to exert an occlusal-gingival load that produced a shear force at the bracket-tooth interface to dislodge the bracket. The test results were obtained in N (Newtons) and converted to pressure values in MPa (Megapascal), verified based on the measurement of the base of the bracket used.

4. Adhesive remnant index (ARI) evaluation

The enamel surface of each tooth sample after bracket debonding was observed by the naked eye under a UV light auxiliary illumination system to reveal the adhesive by fluorescence and scored using the ARI (Table 1).

Table 1 The scoring system of the adhesive remnant index (ARI) proposed by Årtun and Bergland [13].

Score	Description
0	No adhesive remaining on the tooth surface (bond fracture occurred at the resin/enamel interface)
1	Less than half of the adhesive remaining on the tooth surface
2	More than half of the adhesive remaining on the tooth surface
3	All the adhesive remaining on the tooth surface

5. Data analysis

The sample size was calculated (G*Power, Version 3.1.9.7) using t-tests, with the effect size = 0.914, α = 0.05, degree of freedom = 1, power = 80%, generating a total sample size of 40. Statistical analyses were performed by the Statistical Package for Social Sciences (SPSS for Windows, version 15.0; IBM Corp., Chicago, IL). A dependent paired t-test was used to analyze the differences in shear bond strength and duration of the bonding procedure. An intra-reliability test was performed by re-evaluating the ARI score in total samples after two weeks. Weighted kappa statistics were used to establish intra-examiner reliability values, and Wilcoxon signed-rank tests were used to assess the ARI scores between the samples bonded with the conventional and new saliva ejectors.

Results

The mean shear bond strength of brackets bonded using the new saliva ejector was 24.73 ± 9.93 MPa, while for the conventional saliva ejector was 21.72 ± 1.45 MPa. The difference in shear bond strength between these two groups was not statistically significant at $p > 0.05$ (Table 2).

The mean bonding time for the new and conventional groups was 8.13 ± 0.61 minutes and 8.54 ± 0.96 minutes respectively. The difference between the groups was also not statistically significant at $p > 0.05$ (Table 2).

With regard to the intra-reliability test, the weighted Kappa coefficient showed a high level of agreement value of 0.88. The table 3 showed the proportion of ARI scores for each type of saliva ejector, with the differences between the groups being statistically insignificant ($p > 0.05$).

Table 2 Shear bond strength and duration of bonding procedure for brackets bonded using the new and conventional saliva ejectors.

Saliva Ejector Type	N	Shear Bond Strength			Bonding Time		
		Mean (MPa)	S.D. (MPa)	*P*-value	Mean (minutes)	S.D. (minutes)	*P*-value
New	20	24.73	9.93	0.265	8.13	0.61	0.343
Conventional	20	21.72	1.45		8.54	0.96	

Table 3 The proportion of ARI scores for each type of saliva ejector

Saliva Ejector Type	ARI Score				*P*-value
	0	1	2	3	
New	15%	65%	15%	5%	0.248
Conventional	0%	75%	20%	5%	

Discussion

In our study, a novel saliva ejector for bonding orthodontic brackets was developed and its effectiveness was tested in vitro. From our laboratory study, no significant differences in shear bond strength, the duration for bonding, and ARI scores were detected between the new and conventional saliva ejectors.

BracePaste® color change is a medium viscosity, light-curable adhesive. Its main active components are Bis- EMA, Ethoxylated bisphenol A-dimethacrylate, and TD: Tetramethylene dimethacrylate, which the manufacturer claims comparable bond strength to Transbond XT™ as the Bis-GMA and Quartz Silica components are similar [14]. The advantage of color-changing adhesive is its purple chromatic indicators turns translucent upon curing for ease of cleanup, and enhanced placement of brackets. In addition, fluorescent additives of the color change adhesive under UV light will facilitate the discrimination between the enamel surface and remnants of the orthodontic adhesive, which is useful for the adhesive remnant index (ARI) evaluation [15].

The mean shear bond strength from the new saliva ejector group in our study was 24.73 MPa. Though the shear bond strength was not significantly different from the conventional ejector group, it was sufficient to withstand typical oral and orthodontic forces ranging from 5.9 to 7.8 [16]. Most previous studies which used Transbond XT resin adhesive for direct bonding reported lower shear bond strengths of 7.48 and 16.27 MPa [17-18]. A more recent study used the BracePaste® adhesive as in our study reported a mean shear bond strength of 22.56 N and 23.56 N for BracePaste® color change, which was comparable to our results (24.73 N) [14,19]. However, it is difficult to make relevant comparisons, because shear bond strength can be influenced by various factors, including bracket base design, etching protocol, bracket adhesive type, tooth condition, testing environment, loading mode, sample storage, and sample preparation [17-18, 20-25].

In this study, both the conventional and the new saliva ejector exhibited higher frequencies of score 1 for the ARI. Only 5% had an ARI score of 3. The low ARI scores, representing less adhesive remaining on the tooth surface after debonding, could be assumed desirable due to the reduced amount of adhesive needed to be removed [26-28]. In contrast, higher ARI scores of 2 and 3 could be unfavourable due to the increased need for prolonged adhesive removal, and great care is required to avoid damaging the enamel surface during debonding [29].

One distinct benefit of the new saliva ejector design is that the reliance on chairside assistance could be removed. Thus, it is our opinion that these can be taken as positive preliminary findings to serve as a guideline for more extensive research in vivo studies and development to improve the design, material, and performance of the new saliva ejector.

Conclusions

From our preliminary laboratory study, we can safely conclude that the performance of our newly developed saliva ejector was at least comparable to the conventional saliva ejector, in terms of shear bond strength, bonding time, and adhesive remnants. The new saliva ejector would also enable orthodontists to bond fixed appliances without relying on a chairside assistant.

Author contributions

Buranakunaporn P contributed to conducting the entire methodology of the study, analysis, and manuscript writing. Santiwong P and Chintavalakorn R contributed to the conception and design of the study, verifying the data interpretation, and revising the manuscript.

Conflict of interest

No potential conflict of interest was reported by the authors.

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