# SCIENTIFIC SECTION

# An *in-vitro* investigation into the use of a single component self-etching primer adhesive system for orthodontic bonding: a pilot study

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*Objective*: This pilot study assessed force to debond (N); time, and site of bond failure of a single component self-etching primer (SEP) and adhesive system, Ideal 1 (GAC International Inc., USA) and compared it with the conventional acid etch and rinse regimen using 37% *o*-phosphoric acid solution and either Transbond<sup>TM</sup> XT (3M Unitek) or Ideal 1 adhesive.

Design: In vitro laboratory study

Setting: Bristol Dental Hospital, UK. Sept 2003-Sept 2004

*Material and Methods*: Nine groups of 20 premolars were bonded using metal orthodontic brackets using three protocols: (1) 37% *o*-phosphoric acid etch and Transbond<sup>TM</sup> XT adhesive; (2) 37% *o*-phosphoric acid and Ideal 1 adhesive; (3) Ideal 1 SEP and Ideal 1 adhesive. Force to debond and locus of bond failure were determined at three time intervals.

*Results*: Enamel pre-treatment prior to bonding, namely SEP versus conventional etching had no significant effect on the median force to debond with the Ideal 1 adhesive. Similarly, when the enamel was conventionally etched, the adhesive type, namely Ideal 1 or Transbond<sup>TM</sup> XT, had no significant effect on the measured force to debond. However, there appeared to be differences in the locus of bond failure: failure predominated at the enamel/adhesive interface for the Transbond<sup>TM</sup> XT conventional etch group and at adhesive/bracket interface for the Ideal 1 SEP and adhesive group and the Ideal 1 adhesive conventional etch group.

*Conclusion*: These results suggested that the complete Ideal 1 SEP and adhesive system might be successful *in vivo* leading therefore to a clinical trial. However, implications for clean up time are discussed and improvements to *in vitro* study designs are advised.

Key words: Brackets, bond strength, orthodontics, self-etching primers

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### Introduction

Modern contemporary orthodontics relies on the accurate placement of directly bonded attachments to the teeth in order to achieve the desired three-dimensional control of tooth movement. Even though the direct bonding of such attachments to enamel is now routine for most orthodontists, there is the ever-present desire to try to simplify the procedure without compromising reliability. It was Buonocore<sup>1</sup> who initially demonstrated the adhesion of acrylic filling materials to enamel, following acid etching with phosphoric acid,

Address for correspondence: Dr A. J. Ireland, Department of Child Dental Health, Bristol Dental Hospital, Lower Maudlin Street, Bristol BS1 2LY, UK. E-mail: tony.ireland@bristol.ac.uk © 2006 British Orthodontic Society and Newman<sup>2</sup> who suggested the technique might be used for orthodontic bonding. Since then, variables such as acid type, concentration, etch time and rinse time have been widely studied in order to simplify the process, reduce enamel loss and still create a reliable bond.<sup>3–7</sup> It is now generally recognized that enamel etching for 15 – 30 seconds with 37% *o*-phosphoric acid, followed by rinsing with copious amounts of water and then air drying until frosty white in appearance will produce the optimal bond of composite resin to enamel.<sup>5,8,9</sup> However, this conventional bonding process, consists of a number of time consuming stages namely; etching, rinsing, drying, priming and adhesive placement.

In an attempt to reduce the number of procedural steps when bonding to dentine and enamel the selfetching primers (SEPs) were developed.<sup>10</sup> These materials combine etching and priming into one stage for simultaneous use on enamel or dentine. SEPs are aqueous mixtures of acidic monomers and hydroxyethyl methacrylate (HEMA), the resultant methacrylated phosphoric acid ester being the active component of the SEP. It is this active molecule that etches and primes simultaneously. Unlike conventional acid etch methods; the SEP is not rinsed away after application. Instead, the calcium dissolved from the hydroxyapatite, forms a complex with the phosphate group and is then incorporated into the resin network during polymerisation.

The purported advantage of SEPs is that by combining etching and priming into a single procedure, enamel preparation for diacrylate bonding is streamlined, reducing clinical application time, improving cost effectiveness and improving comfort for the patient.

SEPs were originally developed for restorative use and as such these systems required higher bond strengths than those desirable for orthodontic purposes. They were also required to bond to hydrophilic dentine. There have been many in vitro studies to investigate bond strengths following their use in the restorative field<sup>11–13</sup> and more recently in orthodontics; initially using products such as Prompt-L-Pop (3M/UnitekESPE) designed for restorative dentistry.<sup>14–16</sup> To date there appears to be no consensus on the attainable shear bond strength following their use, with conflicting results even being reported by the same authors. Interestingly however, in response to concerns about possible enamel fracture at debond, the manufacturer of Prompt-L-Pop advised against using this product for orthodontic bonding.<sup>14–17</sup> It has subsequently been modified for orthodontic use and is marketed as Transbond<sup>TM</sup> Plus SEP (3M/Unitek, Dental Products Division, Monrovia, CA, USA). This material comes in a single-use foil package containing 3 blister pack compartments, which are pressed and folded to mix the components before application. Transbond<sup>TM</sup> SEP, like most of the SEPs on general release at the present time is a 2-component system that requires mixing in some way prior to use. In vitro experiments have shown there to be no significant difference in bond strength following the use of this SEP and a conventional 37% o-phosphoric acid etchant.<sup>18,19</sup> Indeed some laboratory based experiments have shown Transbond<sup>TM</sup> SEP to produce significantly greater shear bond strength than that achieved by etching with 37% o-phosphoric acid gel for 30 seconds.<sup>20,21</sup> Nonetheless if the ultimate aim of any adhesive system is to reduce the

number of clinical steps required during the bonding procedure, a true 1-component no-mix self-etching primer would be an advantage. The Ideal 1 adhesive system (GAC International Inc., Bohemia, NY, USA) is such a product and is supplied as a no-mix 1 component SEP solution along with Ideal 1 composite adhesive. To date only one other study has been performed investigating the same self-etching primer. In this in vitro study, the authors compared the shear bond strength of the Ideal 1 system with a 2-component self-etching primer system. Their findings were encouraging in that both systems produced similar bond strengths,<sup>22</sup> but human molars were used and bonded with central incisor brackets. Furthermore, the 2 component SEP was applied for 10 seconds longer than recommended by the manufacturer.

However, whilst Fox et al., (1994) highlighted the need for standardisation in laboratory bond strength studies,<sup>23</sup> another problem associated with such studies is that little or no attempt has been made to establish whether the studies are actually appropriately powered *i.e.* whether the sample sizes are sufficiently large to demonstrate a clinically and statistically significant difference should one exist.<sup>16-22</sup> This is essential if laboratory studies are to have any relevance to the clinical situation. The purpose of the present study was therefore fourfold: to undertake a pilot study to determine the force to debond (N) and locus of bond failure when bonding stainless steel orthodontic brackets with the complete Ideal 1 self-etching and adhesive system. This was then compared with the conventional acid etch and rinse regimen of 37% o-phosphoric acid solution and using either Transbond<sup>TM</sup>XT adhesive or the adhesive from the Ideal 1 system. The effect of time was also investigated on both force to debond and locus of bond failure. In addition, the results of this pilot study were intended to be helpful for future sample size calculations for other in vitro studies. This would not only help to improve the relevance of laboratory studies to the clinical situation but would also (in the event) help address some of the recent ethics approval changes. These relatively new arrangements now affecting the UK mean that studies *require* statistical input in order to demonstrate that they are adequately powered.

### **Material and Methods**

One hundred and eighty extracted human lower premolar teeth were collected and stored in distilled water at room temperature. A method of decontamination was not employed prior to placement in the distilled water. The criteria for tooth selection included premolars with intact buccal enamel, no cracks due to extraction forceps, teeth not subjected to any pre-treatment chemical agents and that were caries free. All teeth were visually inspected prior to preparation for any macroscopic evidence of fracture or infraction lines and were excluded if present. The distilled water was changed weekly and the teeth were stored in this way until the experiment commenced. The teeth were collected and the work undertaken in this project prior to the new COREC (Central Office for Research Ethics Committees) guidelines, which came into effect on 1st March 2004 (as a prelude to changes which came into effect as the result of the new European Clinical Trials Directive). Ethics committee approval for their use had therefore not been applied for and individual written consent was therefore not obtained from each patient who donated their teeth to the study.

Vacuum formed polythene moulds were made using a Drufomat thermopressure machine (Dreve, Germany) over a plaster of Paris block measuring  $15 \times 15 \times 35$  mm. Using these moulds each premolar tooth was embedded horizontally in self-curing acrylic, so that the buccal surface of the crown was proud of the block and parallel to it. The 180 teeth in their acrylic blocks were then randomly subdivided into 9 groups of 20 teeth and the base of each block was engraved with an experimental group reference code. The exposed enamel surface was then polished using a slow speed handpiece and slurry of pumice and water in a rubber cup.

0.022-inch lower premolar stainless steel orthodontic brackets (Omni, GAC International, Bohemia, NY, USA) were bonded to the teeth according to one of three protocols and the force to debond (N) and locus of bond failure were determined at three different time intervals, 10 minutes, 1 week and 6 months. All experimental procedures were performed by 1 operator (KH). The enamel preparation and materials were as follows:

## Group 1 - Conventional etch and Transbond<sup>TM</sup> XT adhesive

The enamel was etched with 37% *o*-phosphoric acid for 15 seconds followed by rinsing with copious amounts of water and then dried with oil free compressed air until frosty white in appearance. Transbond<sup>TM</sup> XT adhesive was then applied to the bracket base before positioning the bracket on the tooth. Transbond<sup>TM</sup> XT primer was not applied to the enamel surface. Firm pressure was applied to the bracket using a Mitchell's trimmer and any excess adhesive removed from around the margins using a probe.

#### Group 2 – Conventional etch and Ideal 1 adhesive

Enamel preparation and subsequent bonding in this group was identical to Group 1, the only difference being the adhesive used, namely Ideal 1 adhesive.

### Group 3 – Ideal 1 self-etching primer and Ideal 1 adhesive

Self-etching primer (Ideal 1 – GAC International, Bohemia, NY, USA) was applied to the enamel and rubbed gently for 20 seconds per tooth using the applicator provided and according to the manufacturer's instructions. A gentle 5 second blast of air, from an oil free triple syringe, was then applied to each tooth in order to thin the material. Ideal 1 adhesive was then applied to the bracket base, the bracket positioned on the tooth and any excess once again removed using a probe.

In the case of all groups, once the bracket was positioned on the tooth it was then light-cured for 20 seconds (10 seconds mesially and 10 seconds distally). using a halogen curing light (Optilux 501 curing lamp, Kerr, 21 Commerce Drive, Danbury, CT, USA). The efficiency of the lamp was tested after each curing cycle using the meter within the unit. The teeth from each group were then stored in separate beakers of distilled water in a water bath, at a constant temperature of  $37^{\circ}$ C until bond testing at one of three time periods, 10 minutes, 1 week or 6 months. The distilled water was changed weekly.

Shear bond testing to failure was performed using a custom-made jig in a Lloyd Universal testing machine (Series 2000R, Lloyd Instruments, Southampton, UK) and with a crosshead speed of 0.5mm/minute (Figure 1). The measurements recorded were force to debond and locus of bond failure. Locus of bond failure was recorded using the Adhesive Remnant Index (ARI)<sup>24</sup> following examination of the failure surfaces using a low power binocular microscope at x10 magnification. The ARI system was developed to grade the amount of adhesive remaining on the enamel surface following debond and thereby act as a means of helping define the mode of bond failure between the enamel, adhesive and bracket base. The amount of residual adhesive adhering to the enamel surface is scored by visual inspection and is allocated to one of four groups: 0 (where no adhesive is left on the tooth) to 3 (where all the adhesive left on the tooth, with a distinct impression of the bracket mesh.

### Results

The data were analysed using the Stata Release 7.0 (Stata Corp, TX USA) statistics package with a

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Figure 1 Lloyd 2000 series testing machine and the custom made testing jig

predetermined significance level of  $\alpha = 0.05$ . The median force to debond (N) and 95% confidence intervals of the medians were determined. Summary statistics are illustrated in Table 1.

When comparing firstly the two adhesives under test, and where the enamel was etched conventionally with 37% *o*-phosphoric acid, the median force to debond at each of the three time periods and with both adhesives were very similar (Figure 2). Except that is for Transbond<sup>TM</sup> XT at 1 week, where the median force to debond was lower (Figure 2).

When looking at the effect of enamel pre-treatment prior to bonding, namely SEP versus conventional etching and using the same adhesive, Ideal 1, it can be seen once again there is little difference in the median force to debond (Figure 2). Similarly, when the complete Ideal 1 system of SEP and adhesive is compared with Transbond<sup>TM</sup> XT and conventional etching, there is little observed difference in the median force to debond (Figure 2) and at each of the three time intervals except at one week.

For all the enamel pre-treatments and bonding material combinations under test, except that is for the 1-week results using the 37% *o*-phosphoric acid and Transbond<sup>TM</sup> XT adhesive, there appeared to be a trend for the median force to debond to increase with time.

Table 1	Summary statistics	for the test groups at the	e three time intervals	s for the various protocols
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Enamel treatment and adhesive	Obs	Mean (N)	Median (N)	SD (N)	Interquartile range (N)	95% Confidence Intervals of the Median (N)
37% o-phosphoric acid/ Transbond XT/ 10 mins	20	47.63	48.90	15.67	40.30 to 57.85	43.07 to 56.48
37% o-phosphoric acid/ Ideal 1 adhesive / 10 mins	20	49.49	52.85	15.53	41.10 to 57.00	43.25 to 55.38
Ideal 1 SEP and Ideal 1 adhesive/ 10 mins	20	50.93	47.50	14.29	43.05 to 57.55	43.49 to 56.54
37% o-phosphoric acid/ Transbond XT/ 1 week	20	38.01	32.27	22.67	22.92 to 44.28	24.57 to 39.86
37% o-phosphoric acid/ Ideal 1 adhesive / 1 week	20	54.06	55.40	14.60	45.15 to 59.85	45.65 to 58.39
Ideal 1 SEP and Ideal 1 adhesive /1 week	20	56.55	54.32	14.46	48.48 to 63.28	49.80 to 62.74
37% o-phosphoric acid/ Transbond XT/ 6 months	20	52.22	48.76	21.66	35.16 to 61.34	37.67 to 59.53
37% o-phosphoric acid/ Ideal 1 adhesive / 6 months		56.18	56.85	15.18	47.75 to 67.99	49.23 to 67.30
Ideal 1 SEP and Ideal 1 adhesive / 6 months	20	58.30	55.89	15.89	51.06 to 65.98	51.43 to 64.86

Key: Obs = observation

SEP = self-etch primer

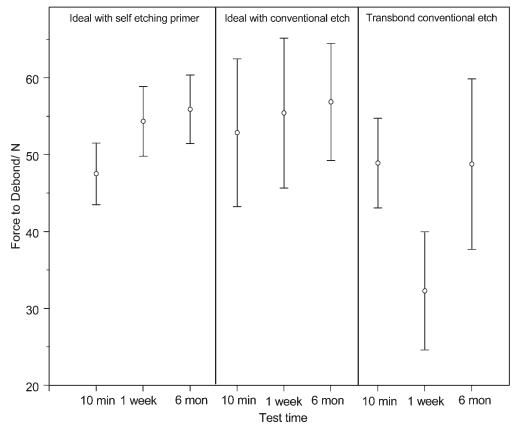


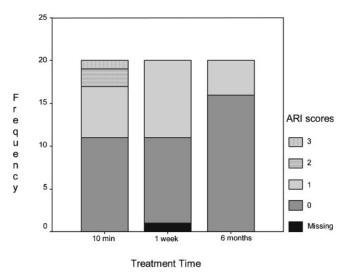
Figure 2 Median force to debond (N) and 95% confidence interval of the medians of the three main treatment groups and over the three time periods of 10 minutes, 1 week and 6 months

However, the increase in each case is probably not statistically significant in view of the overlap in the confidence intervals (Figure 2).

The effect of time on the ARI scores was analysed using the Kruskal-Wallis non-parametric one-way analysis of variance (Table 2). The results show that the ARI is unaffected by time in the case of each adhesive. However, the stacked bar charts (Figures 3, 4 and 5) show that for the Transbond<sup>TM</sup> XT conventional etch group, failure was predominantly interfacial at the enamel/adhesive interface. With the Ideal SEP and Ideal 1 adhesive group, and the conventional etch and Ideal 1 adhesive group, failure was predominantly interfacial at the adhesive/bracket interface. Perhaps somewhat alarmingly the 'missing' category represented teeth where the enamel fractured during testing and more of these were seen in the SEP group.

Table 2 Kruskal-Wallis Rank Sum Test for the Adhesive Remnant Ir	ndex scores for each treatment group over the three time periods
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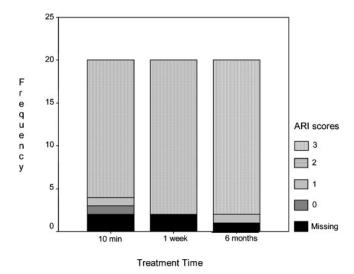
Treatment	Time	Observations	Observed Statistic	$P > X^2$
Conventional etch and Transbond XT	10 minutes	20	4.67	0.10
	1 week	20		
	6 months	20		
Ideal self- etching primer and adhesive	10 minutes	20	0.97	0.62
	1 week	20		
	6 months	20		
Conventional etch and Ideal adhesive	10 minutes	20	1.86	0.39
	1 week	20		
	6 months	20		



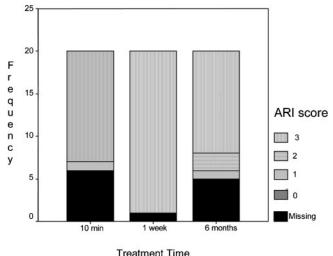
**Figure 3** ARI scores for the Transbond<sup>TM</sup> XT and conventional etch groups over the three time periods, 10 minutes, 1 week and 6 months

### **Discussion**

Currently used conventional *o*-phosphoric acid enamel preparation procedures have been shown to provide reliable and clinically acceptable bond strengths for direct bonding of orthodontic attachments time and again. However, the number of stages required during the bonding procedure and technique sensitivity to moisture of any kind has resulted in research and development to simplify the procedure without compromising the bond. The recent introduction and



**Figure 4** ARI scores for the Ideal adhesive and self-etching primer groups over the three time periods, 10 minutes, 1 week and 6 months



**Figure 5** ARI scores for the Ideal adhesive, pumice and conventional etch groups over the three time periods, 10 minutes, 1 week and 6 months

continual development of SEPs for orthodontic use aims to satisfy this requirement as they simplify and accelerate the clinical handling of adhesive systems by combining the etching step with primer application and as such reduce chairside time. In essence, the notion of eliminating the rinsing, drying and priming stages of the conventional bonding protocol, whilst maintaining acceptable bond strength and minimising enamel damage seems an attractive one. Many *in vitro* studies have investigated the bond strength of SEPs compared with the conventional etch and prime regimen and have found SEPs to perform as well, if not better.<sup>17–21</sup>

In order to fully evaluate each component of the Ideal 1 adhesive system under test, the effect of enamel pretreatment and adhesive were tested separately and then in combination, with the Transbond<sup>TM</sup> XT adhesive and conventional acid-etching specimens acting as the control. Looking firstly at the effect of enamel pretreatment it would seem there is little difference in the observed force to debond (N) between the SEP group and the conventional etch group certainly at both 1 week and 6 months (Figure 2). These results are in agreement with other in vitro investigations comparing SEPs designed for orthodontic use with conventional acid etch procedures.<sup>17–21</sup> The median force to debond at 10 minutes for the SEP was slightly lower than at the other two time periods when using the same Ideal 1 adhesive, although this difference may not be statistically significant as there is some overlap of the confidence intervals.

When considering the effect on force to debond of the two different adhesives tested, the conventional etch and

Ideal 1 adhesive combination provided a comparable if not slightly greater median force to debond than the Transbond<sup>TM</sup> XT adhesive and at all three time periods. The reason for this is unclear, although bracket/adhesive combination has been shown to have an effect on observed *in vitro* force to debond and it is possible that it may also be the case in this study.<sup>25,26</sup>

The present study ultimately aimed to compare the force to debond of a new adhesive system, Ideal 1 consisting of a one component SEP and light-cured adhesive, with Transbond<sup>TM</sup> XT and a conventional acid etch regimen. The findings would indicate that both systems provide a similar observed force to debond (Figure 2 and Table 1) and in both cases the median force to debond increased slightly with time (Table 1).

Analysis of the ARI scores using the Kruskal-Wallis one-way analysis of variance (Table 2) showed that within each of the three main treatment groups there was no statistically significant difference between the ARI scores at the three time periods under test. However, consideration of the raw data in the stacked bar charts (Figures 3, 4 and 5) shows there to be a significant difference in the locus of bond failure between the Transbond<sup>TM</sup> XT conventional etch specimens and the other two treatment groups namely the Ideal 1 SEP adhesive system group and the conventional etch and Ideal 1 adhesive group. This is despite the similar force to debond results. With the Ideal 1 system the majority of the ARI scores were 3, namely at the bracket/adhesive interface. Therefore the adhesive bond to the enamel and the cohesive strength of the adhesive were higher than the adhesive bond to the bracket base. The converse was true for the conventional etch Transbond<sup>TM</sup> XT group. Other in vitro investigations into the locus of bond failure when comparing the use of SEPs and conventional etching have not produced a consensus view. The majority of studies have shown bond failure to occur most frequently at the enamel/ adhesive interface, with less residual adhesive remaining on the enamel at debond than if prepared by the conventional acid etch and prime regimen.14,17,19,27-29 Other investigators have demonstrated that SEPs produce a similar locus of bond failure to conventional etching<sup>20,30,31</sup> Locus of bond failure is determined by a complex combination of contributory factors including the direction of applied force, enamel pre-treatment, the adhesive and the bracket type.<sup>32</sup> The reason for primarily adhesive/bracket interfacial bond failure when using the Ideal 1 SEP and adhesive system in the current experiment is unclear. Certainly the discrepancy between the Kruskal-Wallis analysis and the raw data as illustrated by the stacked bar charts might indicate there is a lack of statistical power. Therefore the correct

interpretation should be that there is perhaps a lack of evidence in the light of the current investigation as to the likely effect on the enamel in the clinical setting.

It would seem then from the observed force to debond results that the single component SEP system of Ideal 1 is comparable to the use of conventional acid etching and a light-cured composite bonding agent. However, for all the SEPs currently on sale, the manufacturer's instructions advise that the teeth are pumiced, rinsed and dried before application in order to remove any salivary pellicle that may inhibit the bonding process. For the conventional etching and rinsing regimen, current best evidence suggests that pumice prophylaxis is unnecessary.33,34 Therefore some of the potential time-saving with a SEP is negated by this necessity to pumice the enamel prior to use. Despite the evidence suggesting pumicing is not required prior to conventional etching, pumice prophylaxis was included for all groups in this study in an attempt to limit the number of variables.

In addition, the high number of adhesive/bracket interfacial failures seen with the SEP in this study would suggest that at debond more time must be spent cleaning the residual adhesive from the enamel surface. Of some concern were the large number of missing values (Figure 4 and 5) seen with the Ideal adhesive, both with the SEP system and particularly conventional etching. These missing values denote enamel fracture at debond. However, as always laboratory findings should be extrapolated to the clinical situation with some caution.

### Conclusion

Reducing the number of clinical steps during orthodontic bonding can benefit both the patient and clinician, however this will only be of real value if the bond strength over a course of treatment compares favourably with the conventional etch regimen and results in no increase in clean up time at debond. The results of this pilot study to investigate the *in vitro* performance of a single component self-etch primer system demonstrate that:

- The observed force to debond (N) was comparable to the conventional control.
- However, the amount of residual composite on the tooth surface at debond could mean that any time-savings at bond up would be lost at debond.
- For all the enamel pre-treatments and bonding material combinations under test, except the 1-week results using the 37% *o*-phosphoric acid and Transbond<sup>TM</sup> XT adhesive, there appeared to be a slight trend for the median force to debond to increase with time. The effect of time on the ARI scores show

that the ARI is unaffected by time in the case of each adhesive.

- *In vitro* studies, performed to give insight into how a material will behave in the clinical situation are only likely to be of value if study designs are improved and sample size calculations are applied in a similar way to clinical studies. This pilot study has highlighted the need for improved study design.
- These *in vitro* findings should be applied to the clinical situation with caution; work has been undertaken to determine the effectiveness of this SEP in the oral environment.

### Contributors

Dr K House was responsible for obtaining the specimens, experimentation and data collection; analysis; and drafting, critical revision, and final approval of the article. Dr M Sherriff was responsible for data interpretation and statistical analysis. Dr AJ Ireland was responsible for study design; logistic, administrative, and technical support and data interpretation; critical revision, and final approval of the article.

Dr AJ Ireland is the guarantor and as such accepts full responsibility for the conduct of the study, has access to the data and controlled the decision to publish.

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