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SCIENTIFIC SECTION

Long-term clinical evaluation of bracket failure with a self-etching primer: a randomized controlled trial

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Objective: A long-term comparison of the failure rates of orthodontic brackets bonded with either a self-etching primer (SEP) or conventional etch and primer (AE).

Design: Prospective randomized controlled clinical trial.

Setting: UK district general hospital with one operator, 2003–6.

Participants: Hospital waiting list patients needing fixed appliances (n=60).

Method: Experimental (SEP) group patients (n=30) received pre-adjusted edgewise brackets (n=438) bonded with Transbond Plus following manufacturer's instructions. Control (AE) group patients (n=30, brackets n=433) were bonded using a 15-second conventional etch and primer (Transbond XT). In both groups brackets were light-cured for 20 seconds. First-time bond failures were recorded with the time of failure. Bracket bonding time was recorded. All patients were followed to the end or discontinuation of treatment.

Results: Bracket failure rates: SEP=4.8%, AE=3.5%, P=0.793. Mean placement time per bracket (seconds): SEP=75.5 (±6.7; 95% CI=72.9, 78.0), AE=97.7 (±9.1; 95% CI=94.3, 101.2) P=0.000.

Conclusion: There was no difference in the failure rates of brackets bonded with either Transbond Plus SEP or conventional AE using Transbond XT paste. Bonding with SEP was significantly faster than using conventional AE.

Key words: Orthodontic bond failure rates, randomized controlled clinical trial, self-etching primer, Transbond Plus, bracket placement time

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Introduction

Self-etching primers have become increasingly popular for bonding orthodontic brackets as they combine etching and priming into one process. This eliminates the washing and drying stages, which are necessary after conventional etching, with potential benefits of reduced clinical time,[1] improved patient and operator acceptance, and less problematic moisture control.[2,3] In addition, enamel demineralization and resin tag penetration are reduced with self-etching primers,[4] which may reduce post-treatment decalcification, although this remains unproven clinically. In spite of increasing use of these materials their effectiveness remains unclear.

The few clinical trials published have failed to find agreement and have suffered from design inconsistencies[5] including a lack of subject randomization[6–8] power calculation[6–11] and failure to follow patients to the end of treatment.[6,7,9–12] Other studies have used selected and therefore non-representative subject samples and treatment mechanics[8] making comparisons with other reports difficult. The most frequently investigated material was Transbond Plus. Two authors reported lower failure rates using this than for AE,[9,11] two reported the reverse,[10,13] while another three found no difference.[8,1214] Two single stage products (One-Step,[7] Ideal 1[15]) produced unacceptably high bracket failure rates but in another study Prompt l Pop demonstrated failure rates of less than 1%.[6] There has been little agreement between studies regarding the factors which influence bracket failure. This reflects differences in study design, settings, populations, patient selection, treatment mechanics and materials used. A systematic review of previous randomized trials of conventional

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orthodontic adhesives reported bracket failure rates between 5 and 7%.[5]

Only one report recorded the clinical time for bracket placement with SEP and demonstrated a small but significant reduction (mean per bracket=24.9 s),[12] although this benefit may be slightly reduced as pumice prophylaxis is not necessary before conventional etching[16] but is required for self-etching primers.[17]

Laboratory investigations of shear bond strengths (SBS) have also produced inconclusive results, mainly finding lower SBS with SEP[18–20] or no difference in dry conditions.[21–23] The clinical relevance of such *in vitro* studies has however been questioned.[24]

The primary aim of this study was to compare bracket failure rates over the whole period of active treatment with SEP and AE. A secondary aim was to investigate the factors contributing towards bracket failure and to compare bracket placement times with each bonding technique.

Null hypothesis tested

That there is no difference in the failure rates of brackets bonded with SEP or AE during pre-adjusted edgewise appliance therapy.

Materials and method

Sample size calculation

The sample size for each group was estimated by the number of brackets required as this was the unit of measurement. For this whole-mouth study, it was calculated by postulating first-time bracket failure rates of 4% for AE and 10% for SEP, a difference considered to be clinically significant. The postulated value for AE was supported by the results of a systematic review of orthodontic adhesives[5] and of a previous clinical trial performed in our departments using Transbond.[25] For alpha=0.05 and power=0.85 using a two-sided continuity corrected chi square test (Elashoff JD, nQuery Advisor version 5.0, Los Angeles, CA, 2002) a sample size of 350 brackets and thus 25 patients per group was required, assuming an average of 16 brackets would be bonded per patient. To allow for clustering of bracket failures and for patient drop-outs we aimed to recruit over 30 patients to each group.

Subjects and clinicians

Treatment was carried out by one experienced consultant orthodontist. Participants were selected according to the following criteria.

Inclusion criteria

- patients requiring (with no previous history of) fixed appliance therapy.

Exclusion criteria

- orthognathic cases;
- teeth with facial restorations or congenital enamel defects;
- surgically exposed teeth and teeth where the bracket placement was delayed;
- patients with a craniofacial anomaly.

Study design. Ethical approval for the study was granted by Oldham Local Research Ethics Committee (reference 03/OL/45). All participants needed fixed appliance therapy and no attempt was made to match them for age, sex or malocclusion to ensure a representative sample. Patients were taken consecutively from the departmental treatment waiting list and consent was obtained. They were then randomized to either the control (AE) or experimental (SEP) group. This was achieved by the operator preparing opaque numbered sealed envelopes in blocks of 10 in advance, using random number tables. The operator enrolled participants and assigned them to their group using the sealed envelopes which blinded the operator and participant to the assignment before enrolment. Once the envelopes were opened the blinding to the operator was lost. Treatment was started within three months of the enrolment.

Clinical procedures used. All patients received Roth 0.022-inch stainless steel mini-twin brackets (A-Company, Ormco Europe, Amersfoort, Netherlands) after prophylaxis using a bristle brush with pumice and water slurry. All teeth were bonded apart from molars. AE group patients received a standard 15-second etch and light-cured hydrophobic primer (Transbond XT, 3M Unitek, Monrovia, CA, USA). Self-etching primer group patients were bonded using a self-etching primer according to the manufacturer's instructions (Transbond Plus – see below). In both groups Transbond XT paste was applied to the bracket bases before light-curing. All attachments were cured using an L.E.Demetron I curing light for 10 seconds mesially and distally (Demetron Research Corp, Danbury, CT, USA, producing light with a wavelength 450–70 nm and an intensity of 483 mW cm^{-2}). The same curing light was used throughout the study and its output was checked periodically.

Control group (AE) bonding technique

- Prophylaxis with pumice/water slurry and bristle brush at slow speed.
- Thorough wash and dry using oil-free compressed air from a 3-in-1 tip.
- Isolation of the bonding surface using a cheek retractor and saliva ejector.
- Etching the enamel surface for 15 seconds using 37% phosphoric acid gel.
- Thorough wash with water and air syringe for 5 seconds per tooth.
- Isolation of the bonding surface using cheek retractor, saliva ejector and cotton wool rolls.
- Dry with compressed oil-free air to produce a frosted enamel appearance.
- Application of a thin layer of Transbond XT unfilled resin to enamel surface.
- Application of Transbond XT paste to the bracket base.
- Firm seating of bracket and removal of excess paste with a Mitchell's trimmer.
- Composite set by applying curing light for 10 seconds mesially and 10 seconds distally to each bracket.
- Bonding was performed one side at a time to ensure good moisture control.

Experimental group (SEP) bonding technique

- Prophylaxis with pumice/water slurry and bristle brush at slow speed.
- Thorough wash and dry using compressed oil-free air from a 3-in-1 tip.
- Isolation of the bonding surface using a cheek retractor, saliva ejector and cotton wool rolls.
- Applying Transbond Plus SEP to enamel surface and rubbing for 3–5 seconds using the disposable applicator supplied with the system.
- Excess SEP removed by a short blast of compressed moisture-free air for 1–2 seconds to each tooth.
- Application of Transbond XT paste to the bracket base.
- Firm seating of bracket and removal of excess paste with a Mitchell's trimmer.
- Composite set by applying curing light for 10 seconds mesially and 10 seconds distally to each bracket.
- Bonding was performed one side at a time to ensure good moisture control.
- A fresh SEP unit was used for each arch bonded.

The time for bracket placement (excluding initial prophylaxis) was recorded for all patients using a stop watch.

Brackets were placed in their correct anatomical position on the tooth. As a result some produced a direct occlusal interference which may have increased the risk of bond failure.[26] In such cases a small quantity of glass ionomer cement (GIC) was placed on the occlusal surfaces of the mandibular molars to open the bite. Care was taken to ensure that this did not interfere with the brackets. The authors recorded the date of first-time bond failures during treatment and used the adhesive remnant index (ARI)[27] to record the amount of residual composite.

All patients received similar straight-wire mechanics and archwires to minimize the effect of different mechanics on bracket failure rates. Archwire sequences typically included initial 0.014 then 0.018×0.025-inch superelastic nickel titanium followed by 0.019×0.025-inch steel working wires. Occasionally 0.018 or 0.017×0.025-inch steel intermediate wires were used before the final archwires where bite opening was problematic. All patients were given verbal and written instructions about diet and care immediately after fitting the appliances. All patients were followed to the end or discontinuation of treatment.

Record taking. The following data were collected:

- the patient's gender and date of birth;
- the type of malocclusion assessed by the incisor relationship;
- the teeth included in the trial and date of attachment placement;
- date of first-time bond failures;
- ARI[27] for bond failures;
- date of completion or discontinuation of treatment.

Outcome. The first-time bracket failure for each tooth was recorded by date and tooth number.

Primary outcome was bracket adhesive failure rate and secondary outcomes were failure rates per subgroup (below) and bonding time per bracket. Where the patient was unaware of a bracket failure, the date was recorded as the date of the appointment when failure was first noted by the clinician. Subsequent failures for that same tooth were noted but not included in the study.

Statistical data analysis. Statistical data analysis was carried out using SPSS 13.0 software (SPSS Inc., Chicago, IL, USA). The bonding time per bracket was compared with the student *t*-test. Bracket failure rates were compared using chi square tests, both for each technique overall and for subgroup analysis (upper and lower arches, left and right sides, anterior [3–3] and posterior [4–5] segments).

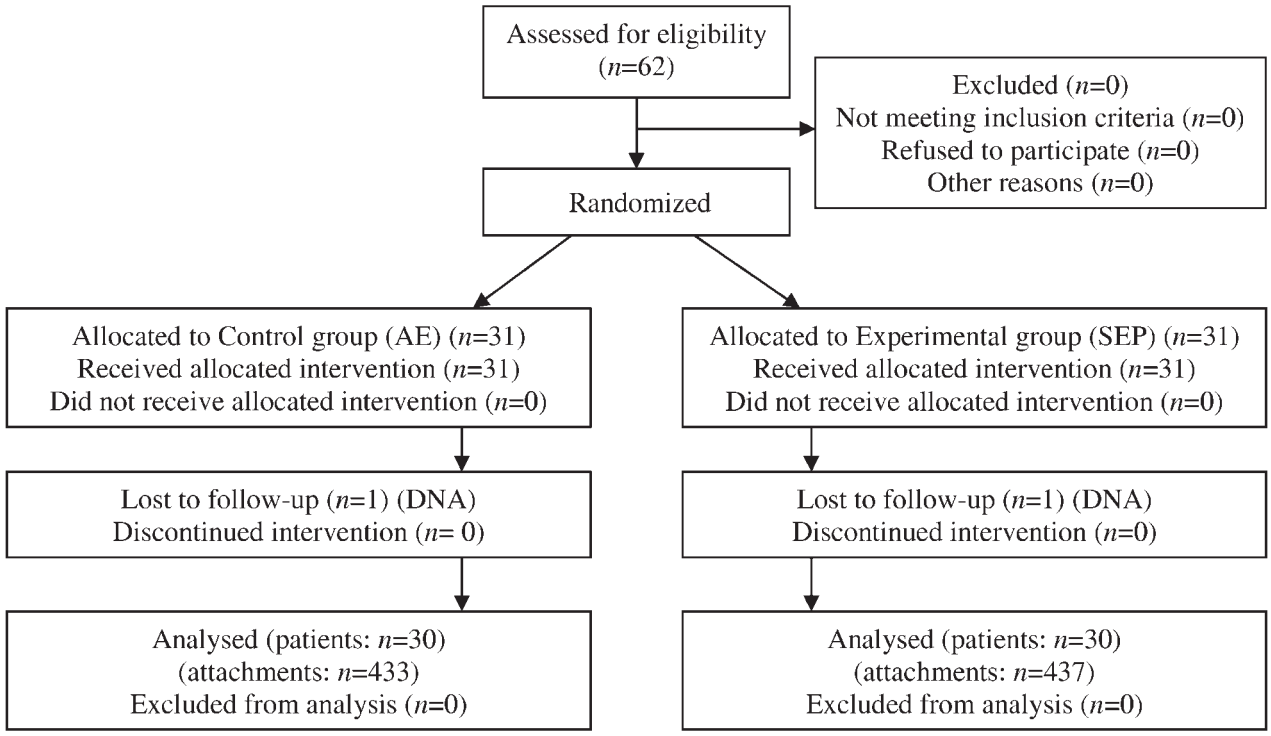

Figure 1 Consort diagram

A Kaplan–Meier survival analysis was used to compare bracket survival. The overall survival curve was assessed by bonding method, and a log-rank test was used to compare the two bonding methods.

Multiple linear regression analysis was used to investigate the influence upon bracket failure of patient variables: bonding method, patient age and sex.

Results

The patient flow chart for the trial is presented in Figure 1. During the trial 62 participants were enrolled (number refusing consent=0). One participant from each group failed to re-attend during treatment and was lost from the study. Data were obtained for the remaining 60 (30 from each group). Descriptions of the patient and tooth characteristics are presented in Tables 1 and 2. Patient age ranged from 11 years up to 36 years. The duration of follow up ranged from 5 to 37 months. A total of 871 brackets were placed, 438 were bonded with SEP and 433 with AE. There were no adverse events or side effects in either treatment group.

Primary outcome

Thirty-six bracket failures were observed, 21 (4.8%) for SEP and 15 (3.5%) for AE with the difference being not statistically significant (Table 3: X^2=0.069, *df*=1, *P*=0.753). The Kaplan–Meier analysis showed no statistically significant difference in bracket survival time between the two bonding techniques (log-rank test, *P*=0.219) (Figure 2).

Secondary outcomes

Overall, the bracket failure rates for maxillary (20 brackets, 3.4%) and mandibular (16 brackets, 4.0%) arches were not statistically significant (X^2=0.524, *df*=1, *P*=0.469). This was also the case when the two bonding techniques were analysed separately (AE: maxilla=10 brackets, 4.2%; mandible=5 brackets, 2.5%, X^2=0.007, *df*=1, *P*=0.935; SEP maxilla=10 brackets, 4.2%; mandible=11 brackets, 5.4%, X^2=0.603, *df*=1, *P*=0.438).

Similarly there was no difference in the overall bracket failure rates between anterior and posterior teeth (21, [3.6%]; 15, [5.2%] respectively, X^2=0.513, *df*=1, *P*=0.474), nor between left and right sides (14, [3.2%]; 22, [5.1%] respectively, X^2=2.431, *df*=1, *P*=0.119).

Multiple linear regression analysis did not find any significant correlation between bracket failure rate and treatment group, patient age or sex (Table 4).

The amount of residual composite after bracket failure was greater for the AE group (Table 2).

The bonding time per bracket with SEP was significantly lower (mean and SD=75.5±6.7 seconds; 95%

Table 1 Distribution of patient characteristics for each treatment group.

	Experimental group (SEP)	Control group (AE)
Patient characteristics	No. (%) of patients	No. (%) of patients
Total	30	30
Gender		
Males	14 (47)	9 (30)
Females	16 (53)	21 (70)
Malocclusion		
Class I	15 (50)	17 (57)
Class II div 1	10 (33)	6 (20)
Class lI div 2	2 (7)	1 (3)
Class lII	3 (10)	6 (20)
Age		
11–13	14 (47)	8 (27)
14–16	15 (50)	18 (60)
17+	1 (3)	4 (13)
Duration of follow-up (days)		
287–500	9 (30)	10 (33)
501–700	10 (33)	16 (53)
701–1022	10 (33)	3 (10)

CI=72.9, 78.5) than with AE (mean and SD=97.7±9.1 seconds; 95% CI=94.3, 101.2), P=0.000.

Discussion

The main finding of this study was that both bonding systems performed satisfactorily and there was no difference between them for bracket failure rate or survival time. This finding resulted in the confirmation of the null hypothesis. The bond failure rates for both groups were similar to those published previously in randomized controlled clinical trials,[5] and also to those from earlier studies carried out in our departments using Transbond adhesive.[25,28]

Table 2 Bracket distribution and failures.

	Experimental (SEP)	Control (AE)	Combined
	No (%)	No (%)	No (%)
Total brackets no.	438	433	871
Failed	21 (4.8)	15 (3.5)	36 (4.1)
Maxilla brackets no.	235	236	471
Failed	10 (4.2)	10 (4.2)	20 (4.2)
Mandible brackets no.	203	197	400
Failed	11 (5.4)	5 (2.5)	16 (4.0)
Anterior (3–3) no.	297	287	584
Failed	14 (4.7)	7 (2.4)	21 (3.6)
Posterior (4–5) no.	141	146	287
Failed	7 (5.0)	8 (5.5)	15 (5.2)
Left no.	220	216	436
Failed	11 (5.0)	3 (1.4)	14 (3.2)
Right no.	217	218	435
Failed	10 (4.6)	12 (5.3)	22 (5.1)
ARI score 0	6	0	
1	5	11	
2	3	3	
3	0	0	

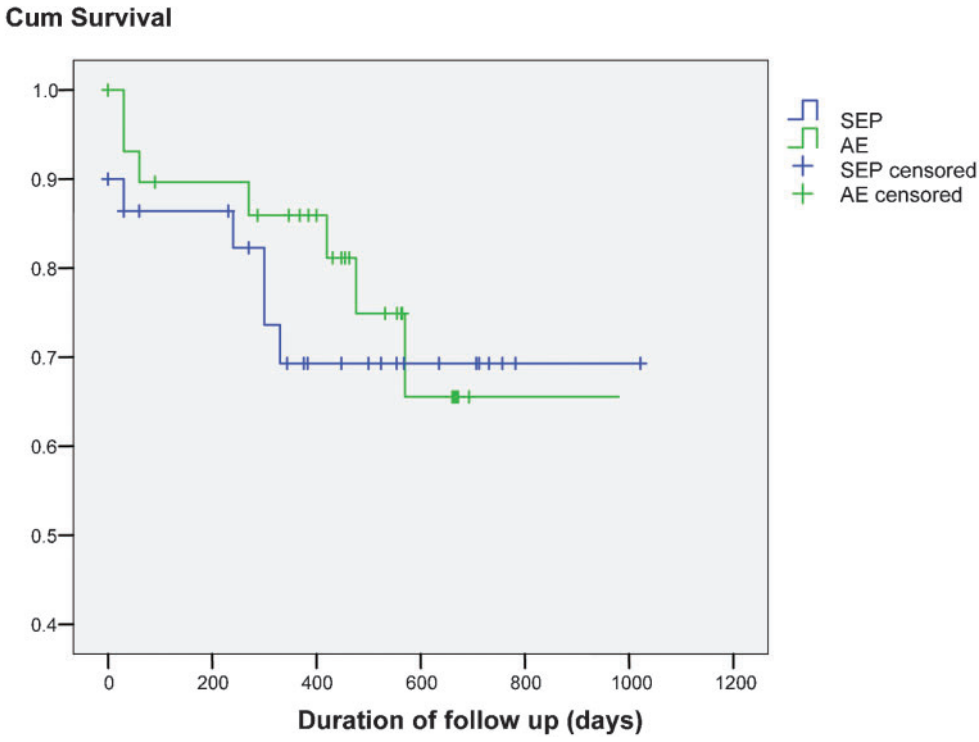

Figure 2 Kaplan–Meier analysis of bracket survival for both groups

Study design – strengths

Some studies evaluating orthodontic bonding materials have used a 'split-mouth' design where different quadrants are assigned as 'experimental' and 'control' in the same patient. This has the advantage that the patient acts as their own control reducing the influence of compliance. Unfortunately it is possible that one material may affect the performance of the other and that bracket bonding technique will be altered and will not conform to normal clinical practice. In view of this each patient was randomly allocated to one adhesive

Table 4 Association between bracket failure and patient level factors (multiple linear regression analysis: $n=60$, $F=0.331$, $P<0.05$ and adjusted $R^2=-0.035$).

		95% CI		
Variable	Coefficient	Lower	Upper	*P*
Treatment group	−0.031	−0.297	0.237	0.821
Age	−0.120	−0.040	0.015	0.374
Sex	0.033	−0.242	0.379	0.808

Table 3 Bracket failure analysis.

Failure rate between groups	Chi square (X^2)	Degrees of freedom (*df*)	Significance (*P*)
SEP versus AE	0.069	1	0.793
Upper versus lower (overall)	0.524	1	0.469
Anterior versus posterior (overall)	0.513	1	0.474
Left versus right (overall)	2.431	1	0.119
Bracket failures per patient	No. (%)	No. (%)	
0	17 (57)	19 (64)	
1	8 (27)	9 (30)	
2	3 (10)	1 (3)	
3	1 (3)	0 (0)	
4	1 (3)	1 (3)	

type only in this study. All but two participants completed the trial.

Study design – weaknesses

A weakness of the original study design was that the required sample size was calculated without allowing for clustering of bracket failures within patients. This was compensated for, however, by the increase in the actual sample size used. As the bracket failure rates were low and clustering was minimal (only three patients exhibited three or four failures, Table 3) cluster adjustment was not used for the bracket failure analysis.

Bracket failure rates

Comparing our results with those of other studies which investigated Transbond Plus, there is agreement with the studies of Aljubouri[12] and Manning *et al.*[14] but not with others,[8–10,13] although these were mostly of shorter duration (6 or 12 months). These results may have been different if patients had been followed to the end of treatment, as failure rates can increase with study duration.[5,14] Differences in bracket failure rates may also vary between different operators, with different patient samples and for treatment carried out in different settings.

Factors affecting bracket failure

Bracket failure rate was not influenced by any of the factors investigated. Thus bonding technique, patient age, sex or tooth location (maxilla versus mandible, left or right sides and anterior versus posterior tooth location) had no effect. This was not surprising as the number of failures was small, although statistical tests for subgroup analyses should be regarded with caution as these were not planned for in the original study design and are liable to be underpowered and therefore less reliable.

Residual composite

After bracket failure, more residual composite was seen with AE. This agrees with other reports confirming that AE commonly shows a combination of adhesive and cohesive failure while for SEP the main site of failure is at the enamel/adhesive interface, which is consistent with the shallower resin tag penetration and reduced enamel demineralization produced by SEP.[4]

Occlusal stress

As discussed above, brackets may be susceptible to failure from direct occlusal stress. To reduce the effect of this, all brackets were initially placed out of occlusion by the application of a posterior GIC biteplane when necessary. This is an effective clinical technique which requires minimal patient compliance and which may have contributed towards the low bracket failure rates in this study. Unfortunately most authors do not specify if attachments were placed out of occlusion or whether biteplanes were used making comparisons between studies problematic.[5]

Bracket bonding time

There was a significant reduction in the bracket placement time when SEP was used. This agrees with the findings of Aljubouri *et al.*,[12] and the mean bonding time per bracket for AE agrees with that found by Sunna and Rock.[29] Thus for a bond-up of 20 teeth this equates to a saving of over seven minutes. This may be clinically significant depending on the setting where treatment is carried out, although the benefit may be reduced by the need for pumice prophylaxis before using SEP. This is not required before AE if teeth are visually clean and stain-free (not all patients meet this standard). The time saved may also be slightly reduced if liquid etch is used as the rinsing stage is probably more rapid than for the gel etch used in this study.

External validity

The findings of this study have limited external validity and only apply to the bracket and adhesive types used, with reference to our patient inclusion criteria and to the types of patient typically treated in a district general hospital setting with treatment which is cost-free to the patient.

Clinical implications

The results of this study indicate that both conventional AE and Transbond Plus SEP provide a satisfactory clinical performance for bonding pre-adjusted edgewise brackets in conjunction with XT paste. Therefore the decision to use either system will be influenced by operator preference in our clinics.

Conclusions

- There was no difference in the failure rates or survival time of brackets bonded with Transbond XT paste using either Transbond Plus SEP or conventional etch and XT primer.
- Bracket placement time was significantly reduced with Transbond Plus SEP.

- Bracket failure was not influenced by tooth location, patient age or sex.

Contributors

Phil Banks was responsible for the study concept and design, administration, obtaining ethical approval, recruitment and treatment, drafting, critical revision and final approval of the article. Badri Thiruvenkatachari was responsible for data analysis, drafting, critical revision and final approval of the article. Jean Wright assisted with the study design. Phil Banks is the guarantor.

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