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# A Prospective Randomized Clinical Trial to Compare Pre-coated and Non-pre-coated Brackets

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## Abstract

*Objective:* To compare the clinical failure rate of pre-coated brackets and brackets bonded using Transbond XT light cure system

*Outcome measures:* (i) The clinical time required for bond up of upper and lower arches of both systems, (ii) bond failure rate for the first 6 months.

*Design:* Single centre randomized controlled clinical study. Thirty-three patients were bonded using a split mouth technique: randomly allocating the pre-coated brackets to upper left and lower right quadrants, and non-pre-coated brackets to the other quadrants.

*Setting:* Hospital Orthodontic Department, Basingstoke, Hampshire, UK.

*Subjects:* Orthodontic patients requiring fixed appliances.

*Main outcome measures:* The site and time to bond failure was recorded for each bracket that failed over the first 6 months. The time required to bond upper and lower arches was measured using a stopwatch for each patient.

*Results:* *t*-Test for the difference of mean time needed to apply both groups of brackets, no significant difference ( $P > 0.2$ ) was found. A chi-squared test for the difference in bracket failure between pre-coated (8.06%) and non-pre-coated (7.37%) showed no significant difference in bracket failure ( $P > 0.2$ ).

*Conclusions:* The clinical failure rate of pre-coated brackets is not significantly lower than conventional non-pre-coated brackets.

## Index words:

Pre-coated brackets, bond failure, bonding time

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## Introduction

Efficient treatment of malocclusions with fixed appliances is dependent on the bracket/adhesive system having adequate bond strength so that repair of appliances during treatment does not delay treatment progress. Furthermore, the clinical time that is required for placing fixed appliances should be as short as possible.

While bonding brackets to the teeth has been a long established procedure, a recent development has been adhesive pre-coated brackets (APC) (3M Unitek, PO Box 1, Bradford BD5 9UY) and the theoretical advantages of APC over non-APC systems are:

- A reduced chairside time
- An improved bond strength and clinical failure rate

(3M Unitek product literature, 1995).

Previous studies have compared the pre-coated brackets with other adhesive systems with respect to their bond failure rate. One study found that the failure rate of Mini Unitwin APC brackets was superior to similar brackets bonded with Unite, a no-mix chemically-cured composite.<sup>1</sup> In another clinical study, however, when APC brackets were compared with two other types of uncoated bracket the overall bond failure rate was 6.6%, with no significant differences in the bonding times or in failure rates using APC or Transbond.<sup>2</sup>

## Objectives of the current study

- To compare the clinical failure rate and clinical time taken to bond APC brackets and non-coated brackets.

The study therefore addressed the following null hypothesis:

- There is no difference between pre-coated and non-pre-coated brackets with respect to bond failure rate and clinical time to place brackets.

## Subjects, materials, and methods

### Subjects

The subjects were patients taken consecutively off the waiting list for orthodontic treatment at the North Hampshire Hospital, Basingstoke, UK. Patients and parents were given written information about the trial prior to being asked to take part. All subjects were treated by the same clinician (SP). They were eligible for the study if they fulfilled the following criteria:

- (1) required upper and lower arch fixed appliance therapy;
- (2) were under the age of 18 years at the start of treatment;
- (3) would give consent to the trial.

### Assignment

A split mouth technique was employed, bonding upper left and lower right with one group of brackets, and the other quadrants with the other group of brackets. As a result, all patients underwent placement of pre-coated brackets in two quadrants and non-precoated brackets in the remaining two quadrants. All teeth were bonded including first molars. The quadrants were allocated using random number tables. The quadrants to be bonded with the pre-coated brackets were sealed in pre-ordered envelopes, which were opened once the patient was accepted onto the trial. The generator (MW) and executor (SP) of the randomization were separate individuals.

### Interventions

One type of bracket was used: the Mclaughlin, Bennet, and Trevisi prescription full-sized twin brackets were used. These are available in standard non-precoated and pre-coated versions. In both the APC and non-coated brackets the light cured Transbond XT light-cured adhesive was the same.

Light curing was achieved using the Cromalux 100 blue halogen light-curing unit. Prior to each session the unit was tested for adequate light intensity via a light meter.

### Bonding procedure

All brackets were bonded by a single operator (SP) following this procedure:

1. Oil-free prophylaxis.
2. Thirty-second wash and 30-second dry using 3-in-1 syringe.
3. Thirty-second etch with 37 per cent phosphoric acid gel.
4. Thirty-second wash and 30-second dry using 3-in-1 syringe.
5. Stop-watch started.
6. Application of a moisture insensitive primer to the molars (according to manufacturer's instructions).
7. Application of pre-coated/non-precoated bracket placed at long axis point on buccal surface of tooth, positioned on the LA point of the tooth (Andrews 1976).<sup>3</sup>
8. Removal of excess adhesive.
9. Light polymerization: 10-seconds mesially and distally of each bracket.
10. Stop-watch stopped.

The time required for the bonding of the two quadrants was registered with a stopwatch. The time used for preparation of the teeth, etching, washing, and drying was not recorded as this was similar for both groups of brackets.

All patients were treated to a standard protocol. The aligning archwires used were 0.016-inch thermal nickel titanium archwires in the initial levelling and aligning stages, followed by the 0.018 × 0.025-inch thermal nickel titanium archwires. These were followed by 0.018 × 0.025-inch rectangular stainless steel archwires.

### Blinding

The patient was not aware which bracket system had been used on which side of the mouth. As the operator was adjacent to the operating assistant preparing the brackets it was not possible to blind the operator to the pre-coated or non-precoated brackets being used in each quadrant.

### Data collection

Each subject was monitored for 6 months. If a bond failed the following was recorded:

- (1) site of bond failure;
- (2) number of brackets failed;
- (3) date of bond failure.

Patients were seen at 6-weekly intervals, but were requested to attend as soon as possible once a bond failure had been detected.

#### Statistical analysis

Student *t*-test was used to compare the chairside time required to bond brackets. Failure rate of the pre-coated and non-precoated brackets was compared with a chi-squared test.

#### Sample size

To achieve a study with 90 per cent power of detecting a significant effect (12 per cent difference in proportions) with an alpha level of 0.05, we needed to enrol a minimum of 330 brackets for each group. As the average number of brackets per subject is 20 brackets in each group 33 patients were included in this study.

## Results

#### Profile of randomized controlled trial

Thirty-three patients fulfilled the inclusion criteria and all were entered into the trial. The pre-coated brackets were randomly allocated to all 33 patients with 372 pre-coated and 374 non-pre-coated brackets being allocated. In total, 746 brackets were bonded. All patients were followed up for 6 months.

#### Assessment of bond failure

Results of bond failure rates of both pre-coated and non-precoated brackets are illustrated in Table 1. The chi-squared analysis revealed that there was no difference between the groups.

More than 70% of the failures for both groups occurred in the first 3 months and 80% per cent of the bond failures in the non-pre-coated bracket group occurred in the first 3 months.

#### Assessment of bonding times

The mean time for bonding was 529 seconds (SD = 69.26) and 509 seconds (SD = 72.47) for the pre-coated and control brackets, respectively. The Student *t*-test revealed no significant differences ( $t = 109, P > 0.2$ ).

## Discussion

The results of this study revealed that there were no differences in either the clinical time required to place APC brackets or bond failure rate when compared to non-precoated brackets.

As a result we can suggest that there are no clinical advantages to the use of pre-coated brackets and we cannot support the claim for reduced failure rate when using APC brackets (3M Unitek product literature, 1995).

Kinch *et al.* found a less favourable survival rate of second and third time bond failures compared with first time bond failures.<sup>4</sup> In this population, 10 out of 33 patients had more than two bond failures during the observation period.

It could be suggested that this study is somewhat limited because we confined our data collection to the 6 months following bracket placement. However, most bond failures occur most commonly within the first 6 months of appliance therapy and, hence, the decision to limit our observation period.<sup>5</sup>

#### Evaluation of bond failure rates

The overall bond failure rate in both the pre-coated bracket group and the non-precoated bracket group was similar to other studies.<sup>6,7</sup> Other studies have shown failure rates between 4–23%.<sup>3,8–11</sup> It therefore appears that the failure rate of both of the bracket/adhesive systems that we tested is acceptable.

This finding does not support the claim for reduced failure rate using APC brackets (3M Unitek product literature, 1995).

**Table 1** Results of bond failure rates of pre-coated and non-precoated brackets

Failure	Precoated brackets	Non-precoated brackets	Total
Yes	30 (8.06%)	25 (6.68%)	55 (7.37%)
No	342 (91.94%)	349 (93.32%)	691 (92.63%)
Total	372	374	746
Chi square: $0.5 > P > 0.25$	0.508		

## Conclusion

- Neither the pre-coated nor the non pre-coated brackets evaluated were clinically superior in terms of bond failure rate in the first 6 months of fixed appliance treatment.
- The use of pre-coated brackets did not result in a significant reduction upon clinical bonding time.
- A small percentage of patients (31%) accounted for the majority of breakages (63%) but even when both bracket groups are compared there is no significant difference between the two groups

## Suggestions for further study

The development of an instrument for molar bond placement would be useful and is currently being developed by 3M Unitek.

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