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A Randomized Controlled Trial to Investigate Brackets Bonded with a Hydrophilic Primer

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Abstract

Objective: To compare the clinical failure rates of brackets bonded using a prototype hydrophilic primer, designed to be insensitive to moisture, with brackets bonded with a conventional primer.
Design: Single centre randomised controlled clinical study. Thirty-three patients were bonded using a split mouth technique: randomly allocating the hydrophilic primer to one side of the mouth and a conventional primer to the other.
Setting: Hospital orthodontic department, Bradford, 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 6 months.
Results: Using survival analysis, there was an increased risk of bracket failure when bonded with the hydrophilic primer compared with the conventional primer (hazard ratio = 2·2, 95% confidence interval: 1·1 to 4·5, P = 0·01).
Conclusions: This hydrophilic primer cannot be recommended for routine clinical use.

Index Words: Hydrophilic Primer, Moisture Insensitive Primer, Orthodontic Bonding, Randomised Controlled Trial.

Introduction

Composite resin is at present the most effective and reliable adhesive available for bonding orthodontic attachments (Turner, 1996). It fulfils many of the requirements of an ideal bonding agent—biocompatible, adequate bond strength, long shelf life, good colour stability—but it is technique sensitive. Good technique is required to avoid moisture contamination, which is considered to be one of the commonest reasons for bond failure (Kinch *et al*., 1988; Wang and Lu, 1991).

A previous paper (Littlewood *et al*., 2000) reviewed the literature on bonding in the presence of moisture and reported an *in vitro* study of a hydrophilic primer used for orthodontic bonding. This prototype primer has been developed by 3M Unitek to overcome the problems of moisture contamination when bonding orthodontic attachments with composite resin.

The aim of the present study was to assess the clinical performance of brackets bonded with the new hydrophilic primer compared with brackets bonded with a conventional primer. The study, therefore, addressed the following null hypothesis: there is no difference in the clinical failure rate of brackets bonded with the hydrophilic primer compared to those bonded with a conventional primer.

Materials and methods

Subjects

The subjects were patients taken consecutively off the waiting list for orthodontic treatment at St Luke's Hospital, Bradford, UK. They were eligible for the study if they fulfilled the following inclusion criteria:

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

Ethical approval

This was obtained from the Bradford Local Research Committee (5th December 1995). Written patient and parental consent were obtained.

Assignment

A split mouth design was used, bonding one side of the mouth with the hydrophilic primer and the other side with the conventional primer. The sides were allocated randomly using random number tables. The side (right or left) to be used for the hydrophilic primer was sealed in pre-ordered individual envelopes, which were opened after the patient had been accepted onto the trial. The generator and executor of the randomization were separate individuals.

Interventions

Two types of primer were used for bonding the brackets:

(1) new hydrophilic primer supplied by 3M Unitek;
(2) conventional Transbond adhesive primer (unfilled compatible resin) to act as a control.

An Ortholux XT® (3M Unitek) visible light-curing unit was used for polymerization.

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Bonding procedure

All brackets were bonded by the same operator (SL) 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% phosphoric acid gel.
4. Thirty-second wash and 30-second dry using a 3-in-1 syringe.
5. Application of relevant primer to acid-etched enamel and air thin.
6. Adhesive precoated (APC®) bracket (3M Unitek) placed at long axis point on buccal surface of tooth.
7. Light polymerization: 30-second mesially and distally of each bracket.

Incisors, canines, and premolars were bonded. Molars were banded.

Blinding

The patient was not aware which primer was on which side of the mouth. As the consistency of the primers were different it was not possible to blind the operator to the type of primer used on each side of the mouth.

Data collection

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

(1) tooth where failure occurred;
(2) type of primer used;
(3) time since bonding.

Statistical analysis

To overcome the fact that not all brackets failed by the end of 6 months, a survival analysis was used. The first bracket to fail on each side was recorded and used in analyses. Kaplan–Meier estimates of survival curves were constructed and compared using the log rank test, stratifying by patient. In this way, the dependence of teeth within the same mouth was accounted for.

Sample size

To have adequate power (80%) to show a statistically significant difference ($P < 0{\cdot}05$) in proportions with at least one failed bracket after 6 months, the RCT needed 33 patients in each group using a log rank test ignoring the matching. This assumes a difference of 35 percentage points (45% versus 80%, hazard ratio = 3·6). As an approximate allowance for the effect of matching, an estimated 33 patients in total were required using a stratified log rank test for analysis.

Results

Profile of randomized controlled trial

Thirty-three patients fulfilled the inclusion criteria and were entered into the trial and a further four patients were excluded on the following grounds:

- one refused to give consent to take part in the study;
- one was an adult (over 18 years of age);
- two required functional appliance therapy.

The primers were randomly allocated to all 33 patients according to the split mouth design, with 266 brackets randomly allocated to each type of primer. In total 532 brackets were bonded. All 33 patients received the standard intervention as allocated and were followed up for the full 6 months (Figure 1).

Clinical bond failure rates

Table 1 shows the number of patients with at least one bracket failure, in addition to the overall percentage clinical failure rates.

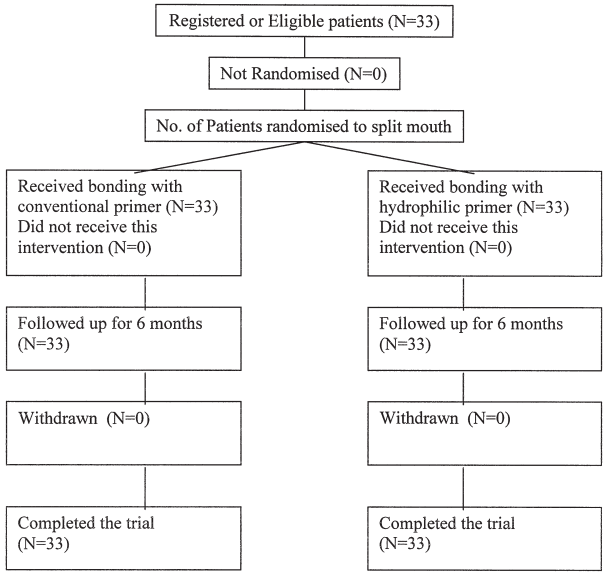

FIG. 1 Profile of randomized controlled trial.

TABLE 1 *Percentage clinical failure rates of bond of each primer*

	No. of patients with at least one failure	% Patients with at least one failure	Total no. of bonds	No. of bonds failed	Overall % failure rate of all bonds
Moisture insensitive	27	82	266	50	18·8
Conventional	15	45	266	18	6·8

Survival analysis

Figure 2 gives the Kaplan–Meier survival plots for both primers, based on the time to the first bracket failure.

Using time to first bracket failure for each primer, there was an increased risk of bracket failure when bonded with the hydrophilic primer (hazard ratio = 2·2, 95% confidence interval: 1·1 to 4·5, log rank test $P = 0{\cdot}01$).

Distribution of bond failure

Figure 3 shows that in all areas of the mouth, the failure rate was equal or greater for each tooth type when using the hydrophilic primer. Even in areas where moisture contamination is more likely, more posteriorly, the hydrophilic primer still produced more failures.

Discussion

Principle findings

The brackets bonded with the hydrophilic primer failed more frequently than those bonded with the conventional primer. The brackets bonded with the hydrophilic primer had double the risk of failure at any point over the subsequent 6 months than those bonded with the conventional primer (hazard ratio = 2·2).

Strengths and weaknesses of study

The purpose of using a prospective randomized approach in this study was to try and eliminate as much bias as possible, although weaknesses do exist. Unfortunately, the operator could not be blinded to the type of primer used,

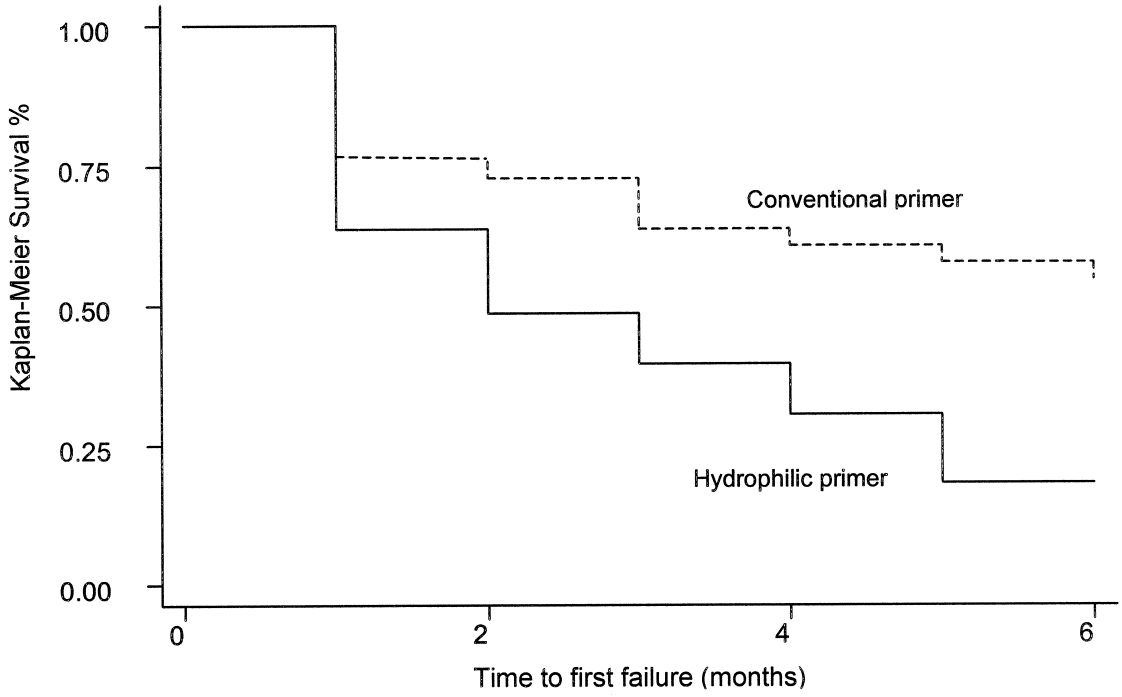

FIG. 2 Graph of survival plots for brackets bonded with each primer.

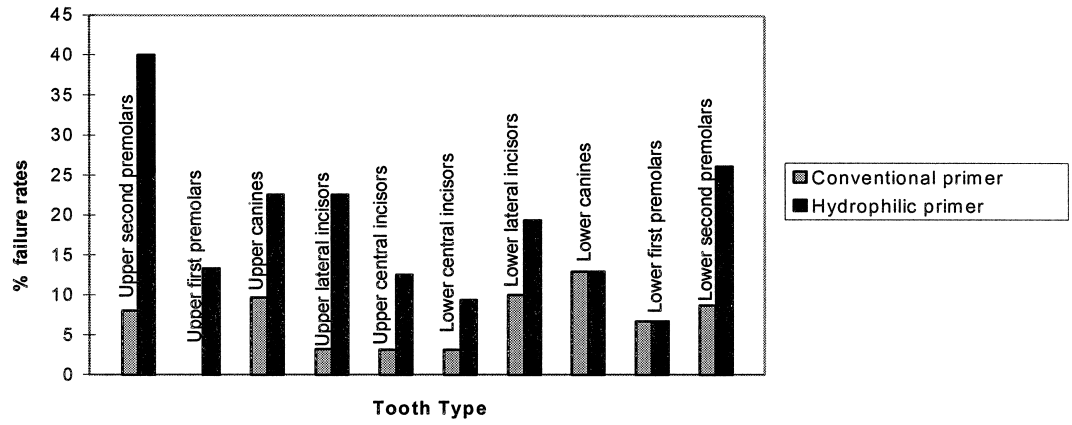

FIG. 3 Graph of percentage failure rate of each primer for each tooth type.

due to the difference in the consistency of the two primers. Secondly, although the primer was allocated randomly to each side of the mouth, this could incur a certain bias if one side of the mouth was more prone to failures than the other. This could have been overcome by randomly allocating to quadrants of the mouth.

Comparison with previous studies

It is difficult to make direct comparisons between studies due to the variety of techniques, materials, research designs and trial duration. Previous studies have shown failure rates of between 4–23 % (Cavina, 1977; Gorelick, 1977; Zachrisson, 1977; Zachrisson and Brobakken, 1978; Lovius *et al*., 1987; Kinch *et al*., 1988; O'Brien *et al*., 1989; Millett and Gordon, 1994). The APC brackets used in the study have composite based on Transbond adhesive. Hence, the research that bears the closest similarity to this study is a 5-year review of brackets bonded with Transbond, producing an overall failure rate of 6% (Millett *et al*., 1998). Certainly, the failure rate of the brackets bonded with the conventional primer (6·8% over 6 months) would appear to be comparable. This would imply therefore that the high failure rate of the hydrophilic primer (18·8%) is due to the product itself, rather than a reflection of the methodology.

Implications of the research

The clinical study clearly indicates that this new hydrophilic primer cannot be recommended for clinical use. It confirms the findings of a previous laboratory study (Littlewood *et al*., 2000).

In a review of orthodontic bonding in 1975 Reynolds proposed that a maximum bond strength of 60–80 kg/cm^3 (6–8 MPa) would be required for successful clinical bonding, but that adhesives with an *in vitro* bond strength of approximately 50 kg/cm^3 (5 MPa) would be sufficient. These figures have been quoted on many occasions since then. The findings of this prospective clinical trial, and the previous laboratory study (Littlewood *et al*., 2000) using the same materials and methods, allows these assumptions to be reassessed.

Brackets bonded with a conventional primer produced a clinical failure rate of 6·8 % over 6 months. The laboratory study using these materials produced a median bond strength of 8·71 MPa. However, it is the lower values of the bond strength distribution that govern the likelihood of clinical failure. The bond strength for a 5% chance of failure, a more appropriate level at which to assess bond strength, was 5·4 MPa. It is proposed, therefore, that the bond strength of a material with a 5% chance of failure should be at least 5·4 MPa. In future laboratory bond strength studies calculating the bond strength for a 5% chance of failure will allow comparison to this figure.

Future research

There is no doubt that a primer that allows bonding with composite in moist conditions would be useful, especially in areas where moisture control is difficult, such as lower second permanent molars and partially erupted teeth. It would appear that a primer with a different chemical composition to the one used here is required. 3M Unitek have developed a different version of this primer, which may warrant research.

Conclusions

Brackets bonded with this prototype hydrophilic primer had double the risk of failure over 6 months as those bonded using with the conventional primer. The hydrophilic primer cannot therefore be recommended for clinical use.

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