

CONFIDENTIAL

CLINICAL EVALUATION OF PRIMA BOND

BY THE PREP PANEL

F J T BURKE & R J CRISP

RESTORATIVE DENTISTRY

UNIVERSITY DENTAL HOSPITAL OF MANCHESTER

HIGHER CAMBRIDGE STREET

MANCHESTER M15 6FH

INTRODUCTION

Product :Prima Bond

Description: Direct Composite Bonding Agent

Manufacturer: B J M laboratories Ltd

12 Hassadna Street

Industrial Park

Or-Yehuda 60200

Israel

Sponsor: The Scientific Metal Company

104-105 Saffron Hill

London

EC1N 8HB

Telephone 0171 831 1956

INSTRUCTIONS TO EVALUATORS

Explanatory letters, questionnaires and a Prima Bond kit were distributed to evaluators on 17 January 1996. The practitioners were asked to complete their evaluation by 16 March 1996 and to return the completed questionnaires as soon as possible after that date. The questionnaire is reproduced in Appendix 1.

THE EVALUATORS

Eleven practitioners were selected at random from the PREP panel, 10 of the panel were male. The average time since graduation was 19 years, with a range of 3 to 31 years.

BACKGROUND INFORMATION

REPLIES TO SECTION 1

The response to the questionnaire was 100%, with the respondents indicating that the number of anterior composites placed in a typical week was as follows;

<u>Number of Restorations</u>	<u>Number of Respondents</u>
<10	1
10-15	5
16-20	2
>20	3

Respondents indicated that they used a dentine bonding agent in an average of 71% of cases (range 10-100%)

The proportion of cavities in which the anterior composites were placed was as follows:

In the restoration of:

	<u>Mean</u>	<u>Range</u>
Class III	48%	20-80%
Class IV	14%	5-25%
Class V	38%	15-75%

The restorations placed in non-retentive, non-carious, abrasion/erosion Class V cavities comprised 67% (with a range of 0-100%) of the total.

The number of posterior composites placed in a typical week was as follows:

<u>Number of Restorations</u>	<u>Number of Respondents</u>
<5	7

5-10

2

>10

2

Of these a dentine bonding agent was used for 92% (with a range of 10-100%)

Respondents used a range of dentine bonding agents ; Scotchbond (4), Liner Bond 2(3), and single users of High Q Bond, Prisma, Optibond and Bisco Onestep.

Reasons given for the use of these materials were primarily 'ease of use' and 'good clinical results', with 'manufacturers' reputation' and the bonding agent 'coming as part of the composite kit' also being given.

The respondents were asked to state the approximate mean start to finish time for commencement of etching to placement of the restorative for a Class V restoration, using the current dentine bonding system. The result was a mean of 3.3 minutes (with a range of 1-7.5 minutes)

Respondents rated the ease of use of their current dentine bonding agent as follows:

Excellent

Poor

5

Mean 4.0

1

The price of the current dentine bonding agent was known by 55%(n=6) of the respondents.

The choice of adhesive was made in the following order of priority:

1. Performance
- 2 = Reported ease of use
- 2 = Speaker's comments
- 4 = Manufacturer's reputation

4= Part of another kit

6= Price

7= Other

82% of the respondents(n=9) used a dentine bonding agent to treat root hypersensitivity and 100% (n=11) felt that a dentine bonding agent which requires a minimal number of stages (1or 2) would be useful.

EVALUATION OF PRIMA BOND

a. EVALUATION OF THE KIT AND MATERIAL AFTER FAMILIARISTION-

REPLIES TO SECTION 11

The respondents rated the presentation of the kit as follows:

<u>Excellent</u>	<u>Poor</u>
5 Mean 4.2	1

Suggestions to improve the presentation of the kit were:

- * Include brushes in kit
- * Include etchant in kit

82% (n=9) of the respondents stated that the Prima Bond liquid handled in the anticipated way, the remaining two respondents found the liquid to be less viscous than anticipated.

73% (n=8) of the respondents experienced no problems in using the bottle, the remaining three reporting leaks, especially if the closed bottle was left on its side.

The clarity of the instruction leaflet was rated as follows:

<u>Very clear</u>	<u>Not clear</u>
5 Mean 4.5	1

Three respondents suggested that the leaflet should be laminated.

b. EVALUATION OF PRIMA BOND IN CLINICAL USE-REPLIES TO SECTION III

Number of restorations placed

A total of 756 restorations were placed during the evaluation as follows:

Anterior	Class V	224
	Class III	252
	Class IV	96
Posterior	Class I	101
	Class II	83

The approximate mean start-to-finish time from commencement of etching to placement of restorative for a class V restoration using Prima bond was 2.2 minutes (with a range of 1-4.5 minutes)

91% (n=10) of the respondents found the Prima bond liquid easy to dispense and apply and when asked to give a rating for the system in clinical use for dentine/enamel bonding the result was as follows:

<u>Good</u>	<u>Unsatisfactory</u>
5 Mean 4.3	1

When asked for comments relating to the Prima Bond system when used for dentine/enamel bonding to composite one evaluator found the liquid 'a little thick-it did not evaporate'. However, three commented that the liquid pooled in cavities. One evaluator would have liked confirmation that it can be air thinned without detriment to the bond.

When the evaluators were asked for their opinion as to whether the Prima bond system had performed satisfactorily the result was as follows:

Yes	No
5	1
Mean 4.5	

91%(n=10) of the evaluators stated that to their knowledge none of their patients displayed post-operative sensitivity. The remaining evaluator estimated that 15% of cases did display post-operative sensitivity, but the evaluator did not know how many had sensitivity before treatment and 'most' disappeared following treatment.

Prima Bond was also used for other applications by 55%(n=6) of the evaluators. These applications were:

Metal adhesive	3 cases
Porcelain repair	2 cases
Porcelain composite veneers	8 cases
Treatment of	
Sensitive cementum	7 cases
Dentine seal prior to	
amalgam placement	65 cases
Dentine bonded crowns	1 case

When asked to compare Prima Bond with the material normally used 55% (n=6) commented that it was easier to use and 45% (n=5) found it quicker. Other comments were :

"similar but less stages" (2)

“good value”

“better shade but more post-op sensitivity”

When asked if there was anything the evaluators disliked about Prima Bond three evaluators(27%) mentioned the bottle leaking and three (27%) the ‘pooling’ of the material in cavities. One evaluator mentioned the film thickness which caused difficulty with matrix placement after curing.

When the panel was asked if they would purchase Prima Bond if available at a cost of £50 plus VAT ,82%(n=9) said they would and if priced 20% more than equivalent materials 36% (n=4) evaluators would still purchase Prima Bond

CONCLUSIONS

The Prima Bond system has been subjected to an extensive evaluation in clinical practice by eleven members of the PREP panel during the placement of 756 restorations. Based on this assessment the main criticisms to emerge are:

- a) Instructions: would be better if laminated for surgery use.
- b) Bottle: Attention to propensity to leak. The other comment made was the difficulty of telling how much liquid is left in the opaque bottle but this applies to all manufactures of light cured bonding materials.

Overall the material received very good ratings.

The rating for the Prima Bond system in clinical use was 4.3 (on a linear scale of 5 good-1 unsatisfactory) in comparison to 4.0 for the rating for the material used prior to the study. The mean timing for the etching to placement of a Class V restoration improved from 3.3 minutes prior to the study to 2.2 minutes with Prima Bond, an improvement of 33%. The generally good ratings are reflected in the high number (9- 82%) who would purchase the

material if priced at ~~50~~ plus VAT and also that 36%(n=4) would still purchase Prima
bond if 20% more than equivalent materials.