ADAPT CONFIDENTIAL REPORT: PRIMABOND ADHESIVE

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INTRODUCTION

The use of adhesive bonding in general dental practice is increasing. The advantages of using enamel and dentine adhesives in direct composite restorative dentistry have been well documented. These include the ability to provide cavity sealing, a reduction in post-operative symptoms, a lesser risk of microleakage, of recurrent caries and of pulpal necrosis. All these advantages are well known, and are in addition to the claimed adhesive abilities of these products. As the use of composites continues to spread, the use of satisfactory adhesive bonding materials should also grow.

At the same time manufacturers are responding to dentists' demands for easier to apply systems, and a number of single bottle products are now available. Previously, adhesives capable of bonding to dentine as well as enamel were presented in two or more separate bottles, which needed to be mixed and applied in more than one stage. An example is Denthesive 2 by Kulzer.
PRESENTATION

PRIMABOND is a one bottle dental bonding agent that is claimed to adhere to Enamel, Dentine, and also Precious and Non-Precious metals and Porcelain. Tensile bond strengths are quoted in the literature, as well as the film thickness of 10-15 microns.

It is claimed to be compatible with all brands of composite resins, and this study was therefore designed to include a variety of popular brands.

The product also comes with a material safety data sheet, which was felt to be adequate.

Company data supplied quoted a Dentine Tensile strength of 10.1-12.4 MPa after 1hr. and an independent test by University of Paris of 11.2 Mpa also after 1hr.

The comparative material supplies data quoting 24 hr Dentine shear strength of 18MPa. The same product tested by PRIMABOND labs. generated a 24 hr strength of 4.6MPa. With such a disparity in results, ADAPT feels unable to make decisions on the relative merits of different adhesives by reference to data alone. Clinical success should be the final test.

Of interest was the warning to avoid direct pulp capping. Recent research is now indicating that in carefully selected instances, the use of a dentine adhesive can be beneficial to pulpal health. ADAPT is not able to to state the exact reasons for the contra-indication of this product.
STUDY FORMAT

ADAPT was requested to use clinically PRIMABOND one bottle adhesive manufactured by BJM laboratories Ltd., by the UK distributor METALOR. 8 dentally qualified members of ADAPT used PRIMABOND adhesive in general dental practices in the UK for a period of four months. They were asked to compare its handling characteristics together with any other clinical observations with another commercially available one bottle bond.

The PRIMABOND adhesive was to be used as directed in the Instructions For Use in alternate cases. So, one patient would receive one or more restorations in a single visit using PRIMABOND, and the next patient would receive the comparative adhesive.

In this way over 180 patients received over 350 direct restorations, of which at least 204 were made using PRIMABOND. The cavity types included Class I, II, III, IV, and V, under rubber dam and without rubber dam.

This study was limited to the use of the adhesive for enamel and dentine bonding.

A typical sequence would be isolation of the tooth, and preparation of the cavity with or without local anaesthesia.

The entire cavity would then be etched with 20% Phosphoric acid gel for 15 to 30 seconds. The cavity would then be spray washed carefully and quickly blow dried to remove gross moisture. A chalky appearance of the enamel and also a slightly damp dentine base was the desired result.

The PRIMABOND would then be applied with a brush, allowed to dry for a few seconds, and the excess blowed with a gentle air stream. Light curing for 20 seconds would then be done. A second coat, although optional, can then be applied. The direct composite of choice is then cured over this so creating the finished restoration.
RESULTS

During the test period over 180 patients received over 350 fillings, of which at least 204 were made with PRIMABOND.

The composites used were various, and included 3M Z100, CHARISMA(KULZER), COLTENE, BAYER PEKAFIL, DENTSPLY TPH, KERR HERCULITE and VOCO POLOFIL. This list is not exhaustive.

The restorations were made during a four month period and so would be of varying age at the time of preparing this report. It is NOT possible to comment on the durability of any of these restorations based on such a short time period.

However, members were able to report short term failures, and these amounted to 7 teeth, of which 2 had had PRIMABOND adhesive. Of interest were the other 5 failures. Of these none of the fillings were reported to be debonded. One tooth had a pulpitis due to accidental exposure, and one tooth was painful and the Class 1 filling remade. The reasons for the other 3 failures is not documented.

Of the 2 failures using PRIMABOND, 1 was a debond on a lower Class V molar tooth, possibly by saliva contamination, and the other failure was not detailed.

There were no reports of regular post operative sensitivity or complaints from either of the groups, neither the PRIMABOND group, nor the other product.

Handling of both products was liked by all ADAPT members. Various comments include 'easy to use', and 'did not pool.' One product had an odour, whereas the other (PRIMABOND) did not. This did not worry the dentists.

One member commented that the PRIMABOND film thickness appeared to the naked eye to be greater than another product (Tenure). However, he also notes that 'there was no observed loss of marginal integrity or loss of optical confluence.' The general feeling was that a one bottle system was to be preferred to other more complex products.
DISCUSSION

Within the limits of this study, ADAPT was able to use two contemporary one bottle products with success in clinical practice.

The low incidence of postoperative complaints and early failures is encouraging, although it is not possible to predict how any of these restorations will fair over extended time periods. Eventual failure may also occur despite proper bonding, as there are other factors that contribute to or cause filling failures.

It is also interesting to note that a variety of different composite fillings were used, and in all areas of the mouth. Both the test adhesive and the other brand were used in different types of location and cavity with equal facility.

Bearing in mind the importance of achieving an adequate seal under composite fillings, ADAPT's view is that a one bottle configuration is very convenient and is recommended for ease of use in widely differing locations.

It should be borne in mind that a single bottle does not equate with a single stage, and that the recommended techniques for successful enamel and dentine bonding be observed.

PRIMABOND one bottle adhesive was simple and convenient to use. Early postoperative problems were minimal.

HOWARD STEAN Founder and Chairman ADAPT