J. Dent. Ass. S. Afr. Vol. 28, No. 8, pp 460-466

A Clinical and Laboratory Evaluation of a New Composite Restorative Material

M. Friedman and D.H. Retief

Dental Research Unit of the University of the Witwatersrand and the South African Medical Research Council, Johannesburg.

SUMMARY

A new composite restorative material has recently been introduced for the conservative treatment of cervical erosion and hypoplastic enamel surfaces. This material was subjected to clinical evaluation and some of its physical properties determined. Excellent aesthetic results were achieved and satisfactory retention of the restorations obtained. The adaptation of the restorative material to conditioned enamel surfaces was very good but poor to etched cementum and dentine. These observations were confirmed by dye penetration studies. A mean tensile bond strength of 112,2 kg cm^{-2} was obtained on etched enamel surfaces but much lower figures recorded on etched cementum and dentine. The effect of the cleanser on enamel, dentine and cementum was determined by means of scanning electron microscopy.

OPSOMMING

'n Nuwe saamgestelde herstelmateriaal is onlangs beskikbaar gestel vir die konserverende behandeling van servikale erosie en hipoplastiese glasuuroppervlakke. Hierdie materiaal is klinies ondersoek en sekere fisiese eienskappe is bepaal. Uitstekende estese en bevredigende retensie van herstellings is verkry. Die aanpassing van die herstelmateriaal aan suurbehandelde glasuuroppervlakke was uiters goed; maar die aanpassing aan geëtste sementum en dentien was swak. Hierdie bevindings is bevestig deur kleurstof-deurdringingsstudies. 'n Gemiddelde trekbindsterkte van 112,2 kg cm^{-2} is verkry op glasuuroppervlakke; maar heelwat laer lesings is vir geëtste sementum en dentien aangeteken. Die effek van die reinigingsmiddel op glasuur, dentien en sementum is deur middel van skandeerelektronmikroskopie bepaal.

INTRODUCTION

The satisfactory restoration of cervical erosion with its frequently associated hypersensitivity is a perplexing problem. The conventional treatment of these lesions is the placement of Class V restorations. In severe cases of cervical erosion, pulpal exposure during cavity preparation is not uncommon. Dental lesions in endemic fluorosis (mottled enamel) or hypoplastic enamel surfaces are unsightly particularly in the anterior part of the mouth. Likewise the treatment of these conditions usually involves radical removal of tooth structure and the fitting of full crowns.

The recent introduction of a new composite restorative material* has made the conservative treatment without cavity preparation of these lesions possible. The basic resin system of Enamelite consists of the reaction product of diglycidyl ether of bisphenol A and methacrylic acid, a molecule originally synthesized by Bowen (1962). It is diluted with a small amount of an aliphatic diacrylate. The catalyst is benzoyl peroxide and a tertiary amine accelerator is employed. The filler is a microfibre pretreated with a silane coupling agent and the filler-resin ratio is lower than that of the commercial composite restorative materials. A cleanser, consisting of a 50 per cent phosphoric acid, is used to condition the tooth surface prior to the application of the restorative material (Lee, 1973).

The purpose of this investigation was to subject Enamelite to clinical testing and to evaluate some of its physical properties such as its tensile adhesive bond strength and marginal adaptation to tooth structure. In addition the effect of the cleanser on enamel, dentine and cementum was determined by means of scanning electron microscopy.

*"Enamelite", Lee Pharmaceuticals, South El Monte, California, U.S.A.

MATERIALS AND METHODS

1. Clinical evaluation.

Patients presenting with marked cervical erosion or hypoplastic enamel surfaces were selected for this study. The teeth to be treated were isolated with rubber dam followed by prophylaxis with pumice. After drying, the cleanser was applied to the affected area with a cotton pellet for two minutes. The etching was extended well onto adjacent sound enamel to ensure subsequent adequate bonding of the restorative material. The tooth was washed thoroughly with water and the etched enamel should present with a dull appearance after drying.

The Enamelite was activated according to the manufacturer's instructions and mixed with the second component on a glass slab. Various shades can readily be obtained by varying the ratios of the basic mix or by the incorporation of a tinting agent. The etched surface was finally dried by the application of a drying agent* and the mixed Enamelite applied to the affected area. The material is thixotropic and will not flow over the tooth surface unless stimulated with the applicator or a camel hair brush. This enables the operator to obtain smooth margins with a minimum of excess material. The material has a working time of approximately one minute. Final finishing of the restoration was done at least 10 minutes after the material had set. Excess material was removed with a fine-pointed diamond and the restoration polished with Dedeco Tan midget discs**. The margins of the resorations were carefully checked with a sharp explorer.

2. Laboratory investigations.

a. Adhesion to tooth structure.

The tensile disruptive force required to break a prepared bond was used as a measure of adhesive strength. The adhesion of Enamelite to human enamel and dentine and bovine cementum was determined. The technique used in this investigation was developed by Hanke (1966) and modified by Phillips, Swartz and Rhodes (1970).

The human and bovine teeth were ground on a polishing machine to prepare a flat surface of enamel, dentine and cementum respectively. The teeth were mounted in a mould with self curing acrylic resin to expose the flattened areas. Final polishing of the tooth surfaces was done on wet, 600 grit silicon carbide paper on the polishing machine. The exposed tooth surfaces were etched with the cleanser for two minutes, washed thoroughly and dried with Prep-Dry immediately prior to the preparation of the experimental bonds.

Split ring matrices with an inside diameter of 6 mm were prepared with a polyether rubber impression compound in a special mould. A split ring matrix was placed on the etched tooth surface and a close fitting metal band slipped around the matrix to maintain the contour and hence the inside diameter of the split ring. The Enamelite was mixed, the ring matrix filled with a portion of the restorative material and the remainder placed in an undercut recess in a brass ball bearing. The bearing was carefully aligned on the matrix and the restorative material allowed to set for 15 minutes at room temperature. The metal bond and split rubber matrix were removed and the prepared specimens stored in water at 37°C for one week prior to testing.

The prepared specimens were mounted in a test jig consisting of a series of joints assembled to produce a universal joint (Hanke, 1966; Phillips *et al* 1970). The test jig was designed to allow proper alignment of the specimen in the testing machine and to eliminate as nearly as possible all forces other than tensile during the application of load. An Instron Table Model 1026 tensile testing machine was used to determine the bond strength. A loading speed of 0,05 cm min was applied and the force required to break an experimental bond automatically recorded.

b. Adaptation to tooth structure and marginal leakage.

Freshly extracted, sound human maxillary anterior teeth were used in this part of the study. The teeth were lightly cleaned with pumice, washed well in water and dried. The necks of the teeth were etched with the cleanser for two minutes ensuring that the etch extended beyond the area to be covered with Enamelite. The teeth were washed thoroughly in running water to remove excess phosphoric acid and dried. Enamelite was applied to the etched enamel and cementum surfaces. In some teeth buccal Class V cavities were cut extending into dentine. The material was allowed to set and the teeth ground along their long axes to expose the interfaces between the restorative material and enamel, dentine and cementum. The cut surfaces were polished on 600 grit silicon carbide paper and the teeth air dried. The specimens were mounted on aluminium stubs and coated with silver in a high vacuum evaporator. The specimens were viewed in a Cambridge S4 Stereoscan operated at 10 kV and the beam/specimen angle varied to obtain the best surface projection.

Marginal leakage at the various interfaces was studied by means of a fluorescent dye. The composite restorative material was placed on the etched surfaces as previously described and allowed to set. The whole tooth surface, with the exception of a small area surrounding the restoration, was coated with several applications of nail varnish. This treatment exluded the penetration of the dye at any other points of entry except at the restoration/tooth structure interfaces. The teeth were placed in a

* Prep-Dry, Lee Pharmaceuticals
** Dedeco, 647 Washington Avenue, Brooklyn, New York

solution containing one tablet of Blak-Ray red fluorescent dye* in 25 cm^3 water at 37°C for one week. This dye was successfully used by Holliger (1967) to demonstrate marginal leakage. Very thin ground sections of these teeth were prepared through the restoration and underlying tooth structure and examined by transmitted ultraviolet radiation.

c. Effect of cleanser on tooth structure.

The cleanser was applied to clean enamel and cementum surfaces for two minutes. To study the effect of the cleanser on dentine, the labial surfaces of maxillary central incisors were ground on a polishing machine on 600 grit silicon carbide paper until the underlying dentine was exposed. The dentine surfaces were etched in a similar way. Specimens of unetched and etched enamel, cementum and dentine surfaces were prepared for examination in the scanning electron microscope as previously described.

RESULTS

1. Clinical evaluation.

To date some 150 restorations have been placed. Of these at least 50 have been in the mouth for longer than a year. Two of the restorations became dislodged and three had to be removed because of persistent sensitivity of the restored teeth. Excellent aesthetic results were obtained. The successful restoration of cervical erosion (fig 1) is demonstrated (fig 2). One patient presented with gross cervical erosion involving practically all her teeth (fig 3). The satisfactory result obtained after conservative treatment with Enamelite is shown (fig 4). The patients were recalled at regular intervals for examination. Chipping of the margins of the restorations on cementum surfaces was observed in a few cases but undetectable on enamel surfaces.

2. Laboratory investigations

a. Adhesion to tooth structure

The tensile bond strengths of Enamelite to etched human enamel and dentine and etched bovine cementum are given in table 1.

Table 1: *Tensile bond strength of Enamelite to etched human enamel, dentine and bovine cementum*

Surface	Number of specimens n	Mean bond strength kg cm^{-2}	± S.D. kg cm^{-2}
Enamel	10	112,2	30,0
Dentine	10	2,81	5,71
Cementum	10	4,62	4,40

*Ultra-Violet Products, Inc., San Gabriel, California

The adhesion of Enamelite to etched enamel was excellent and the mean tensile bond strenth of 112,2 kg cm^{-2} obtained was the highest ever recorded in our laboratory for a wide range of restorative materials under similar experimental conditions. Except for two experimental bonds which failed within the material, failure occurred at the Enamelite/enamel interface.

The adhesion to etched dentine was poor and a mean bond strength of only 2,81 kg cm^{-2} was obtained. Five of the experimental bonds failed during exposure to water at 37° C.

Similarly, poor results were obtained for the adhesion of Enamelite to etched cementum. Four of the specimens failed during assembly in the test jig prior to the application of any force. A mean bond strength of 4,62 kg cm^{-2} was recorded.

b. Adaptation to tooth structure and marginal leakage

Scanning electron microscopy revealed that the adaptation of the restorative material to etched enamel was good (fig 5). Intimate interfacial contact was established between the Enamelite and enamel. The adaptation to dentine (fig 6) and cementum (fig 7) was poor. These observations were confirmed by the dye penetration study. The fluorescent dye did not penetrate at the enamel/Enamelite interface (fig 8) but seepage of the dye occurred along the restoration/cementum interface and extended along the margins of the restoration into dentine (fig 9).

c. Effects of cleanser on tooth structure

An unconditioned enamel surface has a relatively smooth, featureless appearance (fig 10). Surface treatment with the cleanser for two minutes produced the characteristic "prism end" structure and demonstrated the preferential etching action of the phosphoric acid solution (fig 11).

Unetched polished dentine surfaces showed no characteristic features apart from scratches produced by the 600 grit silicon carbide paper (fig 12). The cleanser removed the superficial dentine and exposed the underlying dentinal tubules (fig 13).

Unetched cementum has a featureless surface topography (fig 14). No demonstrable changes were produced by the application of the cleanser.

DISCUSSION

The clinical studies revealed that severe cervical erosion can be successfully treated with Enamelite without resorting to operative procedures. Only two of the 150 restorations became dislodged. Similar results were obtained in a clinical study carried out by Ibsen (1972). Drilling was only resorted to when decay was present in the eroded area.

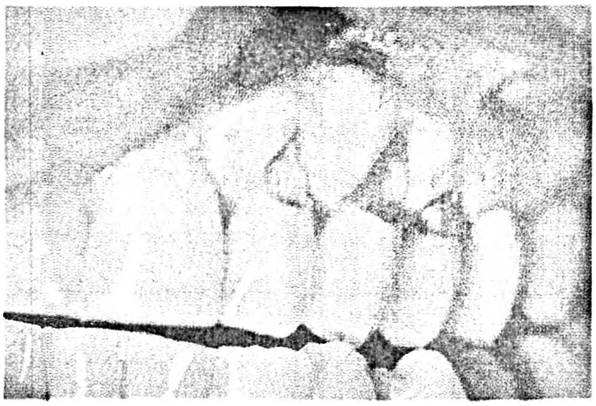

Fig 1. Cervical erosion before treatment.

Fig 2. Cervical erosion after treatment with Enamelite.

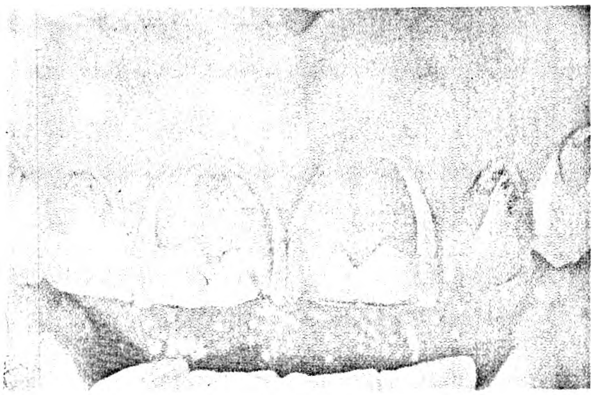

Fig 3. Severe cervical erosion before treatment.

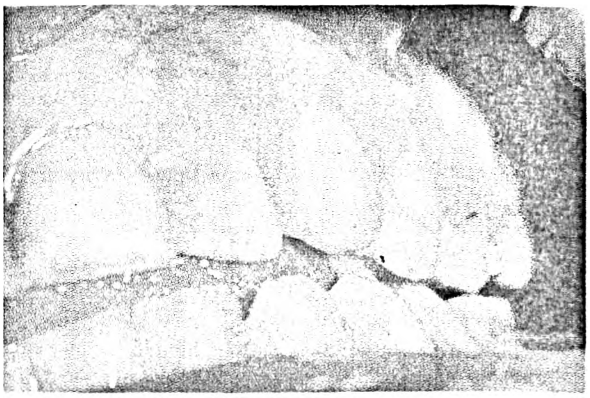

Fig 4. Cervical erosion after treatment with Enamelite.

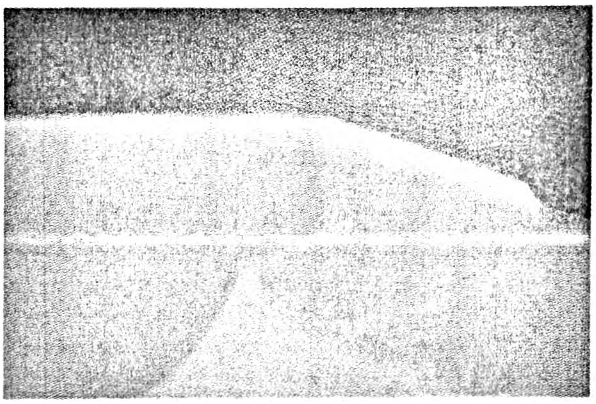

Fig 8. Absence of dye penetration at Enamelite/etched enamel interface. x 25

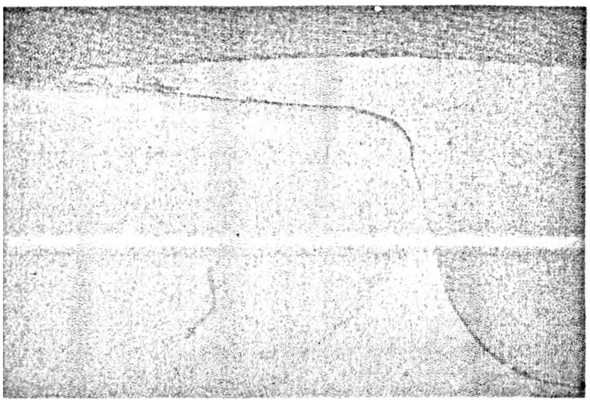

Fig 9. Dye penetration along Enamelite and cementum and dentine interfaces. x 25

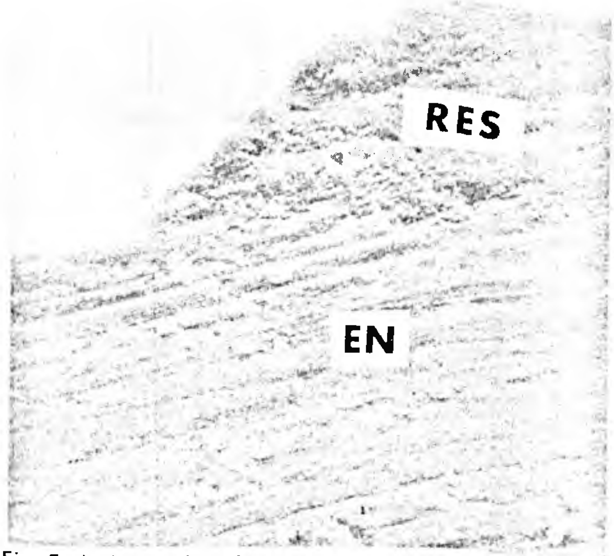

Fig 5. Intimate interfacial contact between Enamelite (RES) and etched enamel (EN). SEM x 1000

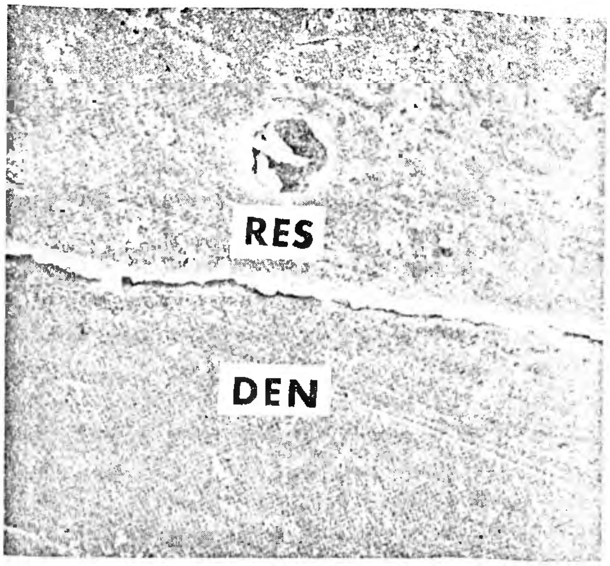

Fig 6. Poor adaptation of Enamelite to etched dentine (DEN). SEM x 200.

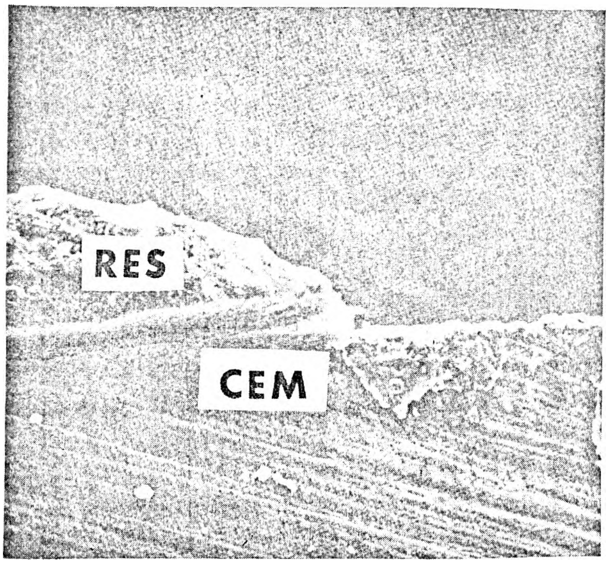

Fig 7. Poor adaptation of Enamelite to etched cementum (CEM). SEM x 200

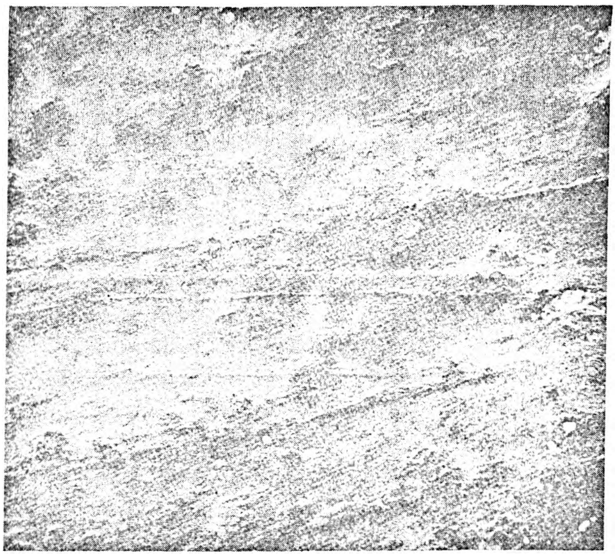

Fig 10. Featureless surface appearance of unetched enamel surface. SEM x 1000

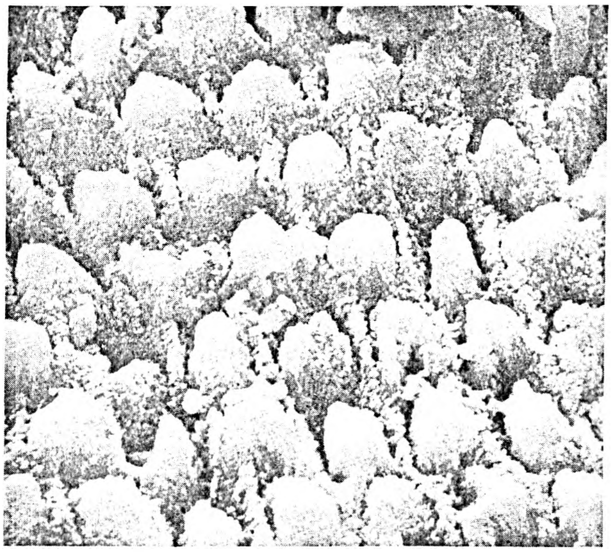

Fig 11. Characteristic prism end structure of ename surface conditioned with the cleanser. SEM x 2000

Fig 12. Polished, unconditioned dentine surface. SEM x 1000

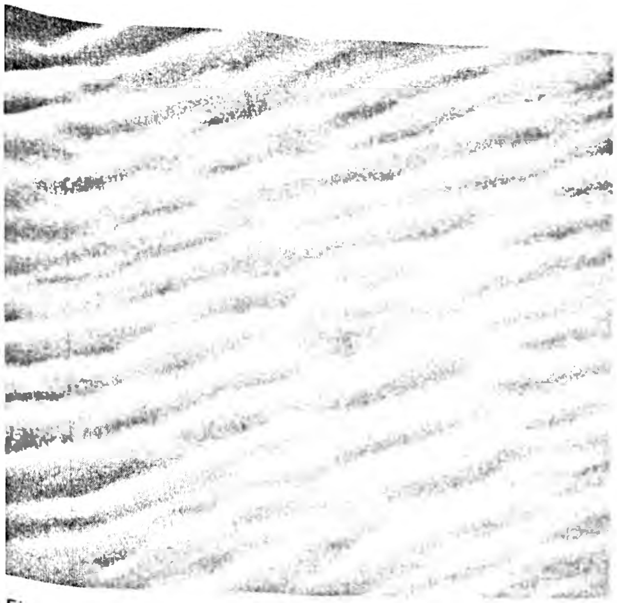

Fig 13. Polished dentine surface etched with cleanser. SEM x 1000

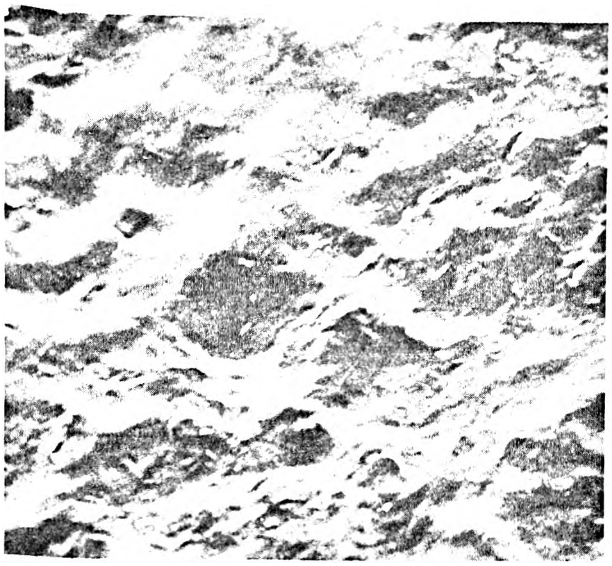

Fig 14. Featureless surface topography of unetched cementum. SEM x 2000

Chipping of the restorative material overlying cementum was occasionally observed. This is not surprising because of the poor adaptation and adhesion of Enamelite to etched cementum. Similar microleakage was observed with other composite restorative materials under equivalent experimental conditions in our laboratory (Valcke, 1971; Rea, 1972).

The hypersensitivity often associated with cervical erosion was greatly reduced by sealing the exposed areas. The cleanser apparently has no detrimental effect on the pulp. Goto and Jordan (1972) showed that a 50 per cent phosphoric acid solution applied to Class V cavities in dog teeth did not produce harmful effects in the pulps of the experimental teeth. In a study involving over 100 monkey teeth, it was found that the restorative material itself elicited a mild pulpal response (Retief, Cleaton-Jones and Austin, 1973). This response was only slightly more severe than that elicited by the zinc oxide eugenol control. It is recommended, however, that a lining be used for excessively deep lesions.

Excellent aesthetic results were obtained and after one year no colour changes were observed in the restorations. At recall, in no case has the erosion been noted to proceed beyond the restored margins.

The adhesion of Enamelite to etched enamel was excellent but poor to conditioned dentine and cementum. The application of the cleanser and the subsequent placement of the restorative material should therefore be extended well on to sound enamel. The phosphoric acid pretreatment increases the surface energy of enamel from 25 dyne cm^{-1} to about 50 dyne cm^{-1} (Lee Pharmaceuticals Research Report RR72-111). This increase in surface energy should result in increased wettability of the conditioned enamel surface and improved flow and penetration of the restorative material into the etched enamel surface. The penetration of other resinous materials into conditioned enamel surfaces has been described previously (Gwinnet and Matsui, 1967; Gwinnet and Ripa, 1973; Retief, 1973). The excellent adaptation of Enamelite to etched enamel and the absence of dye penetration at the restoration/enamel interface indicated that adequate penetration of the polymerising resin occurred into the etched enamel surfaces.

Bovine teeth were used to determine the adhesion of Enamelite to cementum. A large enough polished cementum surface could not be obtained on human teeth.

ACKNOWLEDGEMENTS

The authors wish to thank Lee Pharmaceuticals who made the material available for this study and generously financed the production of the colour plate. Thanks are also due to the staff of the Electron Microscope Unit of the University of the Witwatersrand and the technical staff of the Dental Research Unit.

REFERENCES

Bowen, R.L. (1962) Dental Filling material comprising vinyl silane treated fused silica and binder consisting of the reaction product of bis phenol and glycidyl acrylate. *U.S. Patent* No. 3,066, 112.

Goto, G. & Jordan, R.E. (1972) The pulpal effects of 50 per cent phosphoric acid. *Journal of the Canadian Dental Society,* **38,** 248.

Gwinnett, A.J. & Matsui, A. (1967) A study of enamel adhesives. The physical relationship between enamel and adhesive. *Archives of Oral Biology,* **12,** 1615-1620.

Gwinnett, A.J. & Ripa, L.W. (1973) Penetration of pit and fissure sealants into conditioned human enamel in vivo. *Archives of Oral Biology,* **18,** 435-439.

Hanke, G. (1968) Screening test methods and their application in measuring adhesion of selected dental resins. Thesis, Indiana University School of Dentistry.

Holliger, H.H. (1967) Penetration of restorative margins. A fluorescent dye study. *Dental Radiography and Photography,* **40,** 9-14.

Ibsen, R.L. (1972) Non-operative treatment for gingival erosion. *Dental Survey,* March, 22-24.

Lee, H. (1973) Personal communication.

Phillips, R.W., Swartz, M.L. & Rhodes, B. (1970) An evaluation of a carboxylate adhesive cement. *Journal of the American Dental Association,* **81,** 1353-1359.

Rea, M. (1972) Marginal leakage of a new restorative material — TD 71. *Diastema,* **3,** 11-13.

Retief, D.H. (1973) The effect of conditioning the enamel surface with phosphoric acid. *Journal of Dental Research,* **52,** 333-341.

Retief, D.H., Cleaton-Jones, P.E. & Austin, J.C. (1973) Unpublished work.

Valcke, C.F. (1971) Observations on a composite resin filling material. *Journal of the Dental Association of South Africa,* **26,** 120-133.