FLUORIDE INTERPOLYMERIC RESIN

BACKGROUND OF THE INVENTION

This application is a continuation-in-part application of U.S. patent application Ser. No. 461,026 filed Jan. 26, 1983 now U.S. Pat. No. 4,515,910.

The present invention, which resulted from research conducted with the aid of funds granted by the National Institute of Health, relates to the art of dental health and, in particular, to interpolymeric resins useful in the treatment of teeth to prevent and/or inhibit dental decay.

In recent years, efforts in the area of preventive dental therapy have resulted in technology which provides a protective barrier for surfaces of teeth. This type of therapy, which generally includes a minimal removal of hard dental tissue cariously involved followed by restoration and/or sealing of the intact or acid-etched surface, has been shown to conserve health tooth tissue, reduce treatment time, and provide adequate protection against new caries.

Resins capable of setting (polymerizing and curing) in the oral environment play a primary role in effectuating such treatment. Depending on the nature of the desired results the resins employed in dental treatment should have specific characteristics such as good bonding properties, hardness, and non-degradation in the presence of water, etc. Since these preparations, which are variously characterized as sealant, restorative, and/or adhesive depending on the role they play in the particular treatment, must be capable of infiltrating an acid-etched surface and/or the porosity of carious tissue, the monomers must be highly fluid and have a strong affinity for mineral surfaces. Moreover, the resin must be able to solidify in thin dimensions under oral conditions.

In other dental and biomedical applications polymeric resins are used for constructing various removable and non-removable prosthetic devices and body-part replacements, and for various other purposes. Generally, depending on the desired results, the resins employed for these applications require little or no cross-linking and are not used as adhesives. In many applications in dentistry, prosthetic devices made from these materials interfere with good oral hygiene and, therefore, promote tooth decay and periodontal degradation. Materials for these applications can be formed and cured in situ, or they can be formed externally using an external source of energy such as light or heat. In this latter case, when the application of heat is utilized to effect curing an accelerating agent is not needed. Such materials are variously characterized as appliance resins, prosthetic resins, endodontic filling resins, resin cements, temporary restorative resins, veneering or utility resins, depending upon the role they play in dental or medical treatment. For example, U.S. Pat. No. 3,925,895 to Kliment, et al. describes an acrylic, hydrophilic root canal filling resin and U.S. Pat. No. 4,155,890 to Von Nostitz describes acrylic resins for both heat curing and accelerated curing in a patient's mouth to form prosthetic devices.

Dental resins are usually acrylic materials based on an ester of acrylic or methacrylic acid, typical monomers being methyl methacrylate or a diacrylate of 2,2-bis(p-hydroxyphenyl)-propane, known as BIS-(GMA) resins. The dental resin is normally used as a monomer or as a monomer/polymer mixture, i.e., an incompletely polymerized resin and polymerization is completed in situ when the resin has been placed in position on the dental tissue. Other types of clinically tolerated resins are known and used, e.g., in dentistry or orthopaedic surgery, all of which have polymerizable olefinic double bonds in the molecule. All such resins are available as monomers or monomer/polymer mixtures and include any necessary catalyst etc. so that, after the resin has been put in its final position, completion of polymerization occurs within a few minutes under ambient conditions.

U.S. Pat. No. 4,203,220 to Cranfield describes the use of a bifunctional bridging molecule for bonding dental resins, which are usually acrylic materials based on an ester of acrylic or methacrylic acid, to dental tissue. Specifically, this disclosure shows the use of alkylamino dihalotrazines which have a group that chemically reacts with the dental tissue and a reactive group that polymerizes with the dental resin.

U.S. Pat. No. 3,341,505 to Gander shows a film-forming composition resulting from polymerization of acrylic or methacrylic esters with certain acrylate or methacrylate amine containing monomers. The esters are of alkyl alcohols containing 1 to 12 carbon atoms, while the amine containing resins are typically reacted with acid ions such as fluoride, chloride, bromide, iodide and sulfate and organic sulfonates which are capable of being attached either directly or indirectly to form the amine salt. The resins can be used as a flexible water soluble film on the skin or as a cement composition for adhering dressings.

Further work in the dental area and, for that matter, in hard tissue technology in general has also provided methods of incorporating medicaments in sealants and/or restorations and/or adhesives such that the medicaments are released from the host composition over a period of time. In U.S. Pat. No. 3,969,499 to Lee Jr., et al. a polyurethane composition containing a fluoride ion is used as a dental tissue sealant which also serves as a topical fluoride treatment for teeth. The composition used in the Lee, Jr., et al. '499 disclosure is a polymeric reaction product of a hydroxy-terminated butadiene prepolymer and a polyisocyanate reactant, as well as an aromatic polyol in one embodiment, while the source of the fluoride ions by a diffusion/dissolution mechanism.

Similarly, in U.S. Pat. No. 3,625,916 to Newman a "decay-preventing" cement is disclosed which includes primarily an acrylic resin of polymethyl methacrylate and polyethyl methacrylate having an inorganic fluoride. Once again, fluoride is released by a diffusion/dissolution mechanism.

As a result of the teachings in the art in general relative to the mechanism of release of fluoride ions, dissolution of the anti-caries components in adhesive or restorative host resins has been regarded as a necessity to effect topical application of the anti-caries agent.

By the present invention, however, an improved sealant/adhesive/restorative resin has been provided which is readily wettable to the teeth, sets rapidly under oral conditions in a thin layer, and effects topical fluoride release without the necessity of dissolving components of the resin.

Furthermore, the mechanism for the amount of, and the time of fluoride ion release is highly controllable.

SUMMARY OF THE INVENTION

According to the present invention there is provided a highly effective fluoride releasing acrylic interpoly-