THREE PART DENTAL BONDING COMPOSITIONS AND METHODS OF USE

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a divisional of Ser. No. 11/360,978 filed on Feb. 23, 2006, now U.S. Pat. No. 7,452,925, which priority to of U.S. Provisional Patent Application No. 60/656,498, filed on Feb. 25, 2005, the entire contents of both of which are incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates to dental etching solutions, reactive monomeric based adhesive compositions, packaged pharmaceuticals that contain the etch solution and adhesive composition and methods for their use. More specifically, the present invention relates to a superior three step, three part process, whereby an etch solution is applied to a tooth and subsequently causes the dentin to become receptive to adhesive compositions. After the reaction has occurred, a second preparative solution is applied followed by an adhesive composition that is applied to the tooth and the tooth is readied for a restorative material.

BACKGROUND OF THE INVENTION

The use of biomaterials as restorative materials, in both the dental and medical fields is growing and the requirements for such materials are often times difficult to achieve. Restorative materials such as amalgam or resin composites are often used to repair dental tissues and bones.

For example, there has been considerable research devoted to the improvement of the adhesion of resins to hard tissues such as dentin or enamel. The adhesives are typically applied to the hard tissue after a pretreatment or etch of the tissue with an acidic solution. Various resin composites are available and generally suffer one or more disadvantages in providing a satisfactory bond between the tissue and the restorative material. Some of adhesive materials are designed to achieve higher bond strengths between tissue layers or the treated tissue and a restorative material, to improve physical properties, or the esthetics of the restored target substrate. Other desired properties of such adhesive composites are directed to their use and include ease in preparation and formulation for use under relatively humid conditions.

Typically an etch solution is utilized to remove the smear layer and demineralize the surface of the dental tissue. The etch solution can alter wettability or chemical reactivity of the pretreated dentin, prior to applying a bonding adhesive agent which is generally a polymerizable monomer. Polymerization of the bonding agent facilitates the bonding agent to adhere to the dentin. The interaction(s) between the bonding agent and the treated substrate is not entirely understood and is believed to be related to chemical, mechanical, interfacial diffusion or a combination of all three physical processes. Polymerization of most bonding adhesives provide an approximately 5-micron thick hybrid layer that is formed of part resin and part dentin. The depth and effectiveness of the penetration of the bonding agent is an important and often critical aspect to the adhesion between the bonding agent and substrate. This hybrid layer is believed to contain little or no apatite and the adhesion to dentin is believed to occur through collagen with the bonding agent.

Even though there has been continued research in the area of etching solutions and bonding agents, the techniques and/or products currently available for pretreating the dental or bone tissue or adhering a restorative material to the bone or dental tissue have limitations. For example, the bonding agents should effectively seal the dentin tubules to prevent postoperative sensitivity and protect the pulp. Additionally, the bonds should last the lifetime of the restorative correction and be durable under a variety of conditions.

Therefore, a need exists for new compositions, solutions and methods that overcome one or more of the disadvantages of currently available products.

BRIEF SUMMARY OF THE INVENTION

The present invention provides a unique unexpectedly simple and easy to use bone, i.e., tooth, etch solution or in an alternative embodiment, a gel etchant, a second preparative solution, and a curable adhesive bonding composition, packaged products containing one or more of the compositions, and methods to use the compositions of the invention. The systems of the present invention can be self-cured or can be treated with light energy to facilitate curing.

The present invention provides distinct advantages over presently known etching/bonding systems. For example, the present etching solution is not required to be rinsed off, removed and/or dried prior to the application of a bonding composition. Most commercially available bonding systems require that the etch solution is rinsed off and the substrate dried prior to the application of the bonding resin. Alternatively, currently available bonding systems include both an etch solution and the bonding resin as a one component application. Often times, the one component application systems do not bond well to the bone substrate because the etch solution interferes with the ability of the bonding resin to adhere to the substrate.

In one embodiment, the present invention provides a three part bonding system capable of adhering a composite material to bone. In one aspect, the bone is a tooth and more specifically, the substrate is dentin, enamel, amalgam, metal, porcelain or plastic.

In one aspect the present invention provide compositions and methods for adhering a material to a dental substrate. This is accomplished by applying to a dental substrate an effective amount of a dental etching solution, where etch solution includes an inorganic acid, present in an amount of from about 1 to about 10 parts by weight; an organic acid, present in amount from about 0.1 to about 10 parts by weight; a solvent present in an amount from about 0 to about 65 parts by weight; an ethylenically unsaturated functional monomer, present in an amount from about 0.1 to about 10 parts by weight and water, present in an amount from about 0 to about 50 parts by weight, all components in an amount to equal a total of 100 parts by weight.

Alternatively, in place of the etch solution, a gel etchant can be used that includes a gelling agent, an inorganic acid, an organic acid, a surfactant, with the remainder being water. The gelling agent is present in an amount of from about 5 parts to about 40 parts by weight. The inorganic acid is present in an amount of from about 1 to about 10 parts by weight. The organic acid is present in amount from about 0.01 to about 20 parts by weight. The surfactant is present in an amount from about 0.01 to about 10 parts by weight and the water is present in an amount to equal a total of 100 parts by weight of all components.

In another aspect, the gel etchant can include a gelling agent, an inorganic acid, an organic acid, a solvent and water. The gelling agent is present in an amount of from about parts to about 40 parts by weight. The inorganic acid is present in an