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DENTAL CREAM CONTAINING BENZALKONIUM HALIDE AND SULFA DRUG

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This invention relates to dental therapeutic preparations and to methods of using the same, and more particularly to a non-toxic, non-irrating cream preparation for the preservation of the sterility of exposed dental pulp.

While it is known that abnormal exfoliation time of both deciduous and permanent teeth is hastened by bacterial invasion of exposed dental pulp due to necrosis of the same, up to the present time only complicated and difficult means have been utilized for successfully arresting the progress of the invasion, and ultimate death of the pulp. The result has been that many teeth have been lost prematurely where the availability of simple treatment capable of being carried out in a dental office with standard equipment might have avoided expensive orthodontic treatment or artificial restorations as well as other pathological conditions whose etiology is premature loss of deciduous teeth.

The main object of the present invention is to provide a therapeutic preparation capable of easy application to exposed dental pulp for the prevention of premature loss of deciduous teeth, or for the restoration to normal function of vital permanent teeth having exposed pulps.

Another object is to provide a preparation which is non-toxic and non-irritating in character, and capable of exercising a detergent as well as a germicidal action.

Another object of the invention is to provide a preparation capable of destroying bacteria in exposed dental pulp and exerting a continuing germicidal action for this purpose thereby allowing the pulp to heal and permitting the insertion of a permanent restoration.

A further object is to provide an agent capable of maintaining sterility of exposed dental pulp and simultaneously exerting a mild stimulating action such as to encourage the formation of secondary dentin.

A still further object is to prevent disfiguration of the permanent dental arch by early loss of deciduous and permanent teeth resulting from traumatically or pathologically exposed pulps.

Numerous other advantages and objects of the invention will appear from the following specification.

By way of introduction, it may be pointed out that human teeth are composed of the core or

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dental pulp containing nerves and blood vessels, the dentin which encloses and protects the pulp, and the exterior enamel. Exposure of the pulp results in bacterial invasion followed by rapid necrosis of tooth structure, particularly deciduous or first teeth, the premature loss of which exerts an important effect upon the formation of the second or permanent teeth and of the dental arch. Premature loss of the deciduous molars results in drifting of the adjacent teeth and produces malformation of the dental arch capable of correction only by long and costly orthodontic treatment. The same condition is also met in the case of permanent teeth, and more particularly the six-year molars, which most often present this condition.

We have found that a relatively simple treatment of exposed dental pulp may stop its necrosis and, in some instances, actually encourage the formation of secondary dentin over the pulp area which has been exposed.

The invention is concerned with a preparation to be applied to the exposed pulp to sterilize the parts affected, and to exercise a detergent and antiseptic action capable of prolonging the life of the tooth.

Extensive clinical studies have demonstrated the efficacy, for accomplishing the above objects, of a preparation composed of a mixture of a sulfa drug, a germicidal detergent capable of synergistic action which the sulfa drug, rendering it more soluble, and a bland unguent base or carrier of a particular type.

The sulfa drug functions as a germicidal bacteriostatic agent to destroy the organisms which causes necrosis. Its action is multipled by the synergistic action of at least one of the ingredients with which it is used.

The term "sulfa" drug as used herein is intended to embrace not only the common "sulfa" drugs such as sulfanilamide, sulfathiazole, sulfapyridine, sulfadiazine and sulfamethylthiazol, but also their derivatives.

The germicidal detergent used is a member of the class of quaternary ammonium compounds having a low tissue toxicity and a phenol coefficient above unit. It acts in conjunction with the sulfa constituent to greatly amplify the germ-killing action of the preparation while exhibiting a low surface tension permitting close

and effective contact with mucous membrane. One member of this class of compounds which exhibits the desired characteristics is a compound known as "Zephiran chloride" and having the chemical name of alkyl dimethyl benzyl ammonium chloride. Important characteristics of this material are its germicidal stability and potency, its ability to affect bacterial organisms and fungi both antiseptically and germicidally, and its synergistic action with sulfa drugs. While the effectiveness of different materials of this class may vary, the properties of "Zephiran chloride" are typical, its tissure toxicity is low being only 0.48 whereas that of phenol is 4.0. Its phenol coefficient is, on the other hand, 579 as compared with the value of 1.0 for the phenol. Thus it exhibits to a marked degree the characteristics which we have found to be most desirable for the treatment of dental pulp according to the present invention.

By "low tissue toxicity" is meant toxicity low enough not to irritate delicate dental tissues which are among the most delicate in the body.

"Zephiran chloride" is soluble in acetone and alcohol, but it is also freely soluble in water forming a clear, colorless, almost odorless solution. Because of its effective action it is preferably used in highly diluted form, e. g., one part of "Zephiran chloride" with one thousand parts of water having been found to be highly satisfactory for the purposes of the present invention. The dilution is, however, subject to some variation.

The third and a necessary ingredient of the preparation is a bland unguent base or carrier and comprising an emulsion of the water-in-oil type. An example of a carrier of this type is a preparation known as aquaphor and described by its makers as "an inert grease base of Eucerite (alcohols and esters of the cholesterol groups with solid and liquid hydrocarbons)." This material is effective, and is preferred, because of its compatibility with the quaternary ammonium compounds especially when in contact with mucous membrane. It may also act as an emollient to allay irritation.

Other unguent carriers which might be used are water-in-oil emulsions of lanolin, lard, petrolatum and the like, but in any event it is essential that the emulsion have a surface tension such as to produce a wetting action on moist mucous membrane.

The preparation is compounded in known manner by combining from about ½ to 75% of the sulfa drug with from 15 to 25% of the "Zephiran chloride" in 1:1000 dilution, and then dispersing it in the carrier to make up a total of 100% by weight. The result is an unguent paste of low surface tension, capable of close adherence to mucous membrane and characterized by its low toxicity and by its ability to remain effective over substantial periods of time when in contact with dental pulp.

The percentages of ingredients are not extremely critical provided the toxicity is kept low, but it is essential that the preparation be stiff enough for ready application with a dental spoon but plastic enough to maintain close contact with the exposed areas to be treated.

The general method of application consists in removing the decayed portion of the tooth to be treated using a burr and hand instruments until the exposed pulp is cleared of debris. The cavity area should then be wiped and sterilized in the usual manner using some material compatible with the cream and in any event a non-caustic material of low tissue toxicity. The sulfa preparation is then gently wiped over the exposed area to substantially cover the same. This may be characterized as a "sulfa cap." A mixture of zinc oxide and eugenol or equivalent material is then placed over the sulfa cap for protective purposes, and a coating of zinc oxyphosphate cement or its equivalent applied. The tooth may then be given a ten-day rest period before placing the amalgam, or the amalgam may be placed at once with care to prevent too great a pressure shock to the pulp. The treatment after placing the preparation may conform to standard practice.

The sulfa cream remains in contact with the pulp and exerts a continuing germicidal, bacteriostatic effect resulting in a sterilizing action so that no further decay occurs and the tooth may continue its normal life as if no pulp had been exposed. Among three hundred and thirty-four clinical cases treated as indicated above, three hundred and twenty-three were successful, and no toxic effects on the patients were observed even though certain of the patients were known to be sensitive to sulfa drugs. In at least one case, a tooth treated as above showed, after a capped period of one year, that a heavy section of dentin had formed over the exposed pulp and under the capping material. In every case the treatment with proper cooperation on the part of the patient resulted in complete cessation of further pulpal involvement and such continued vitality of the teeth as might have been expected in a vital filled tooth having no pulp exposure.

It is evident from the above and that we have produced a combination of ingredients that are more effective under these conditions where no effective results have ever before been achieved. It is well to note that the cases selected were routine and as found in a general dental practice. The synergistic action of the quaternary ammonium compound and the sulfa drug, when aided by the unguent base, results in an unexpected and outstanding result long desired but never before achieved. It is, therefore, to be understood that while only a few examples from each class of ingredients have been named, these are exemplary only and the invention is to be construed as covering such equivalents as will be evident to those skilled in the art after reading the above specification.

Having thus described the invention, we claim:

1. A non-toxic non-irritating therapeutic cream for the treatment of exposed dental pulp comprising from about .5% to about 75% of a sulfa drug, from about .015% to about .025% of benzalkonium halide having low tissue toxicity and a phenol coefficient in excess of unity, said compound being capable of synergistic action with the sulfa drug, and a bland unguent carrier of the water-in-oil type for binding the sulfa drug and the ammonium compound together, and causing continuing germicidal and bacteriostatic action on the pulp to which the cream is applied.

2. A non-toxic non-irritating therapeutic cream for the treatment of exposed dental pulp, comprising from about one-half to about 75% of sulfanilamide, approximately .015% to .025% of alkyl dimethyl-benzyl ammonium chloride, and the remainder a bland unguent carrier emulsion of the water-in-oil type.

3. The method of treating exposed dental pulp to arrest decay therein which comprises applying to said exposed pulp a mixture of a bland unguent

carrier in the form of a water-in-oil emulsion, from about .5% to about 75% of a sulfa drug, and from about 0.15% to about .025% of a benzalkonium halide having low tissue toxicity and a phenol coefficient in excess of unity, and then sealing said mixture in contact with said pulp.

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